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From: Clark, Aaron
To: Anderson, Narin
Subject: RE: 1:1 Aaron & Narin (Comments From 10-Apr-2025 Discussion)
Date: Monday, April 14, 2025 2:19:52 PM
Attachments: image001.png

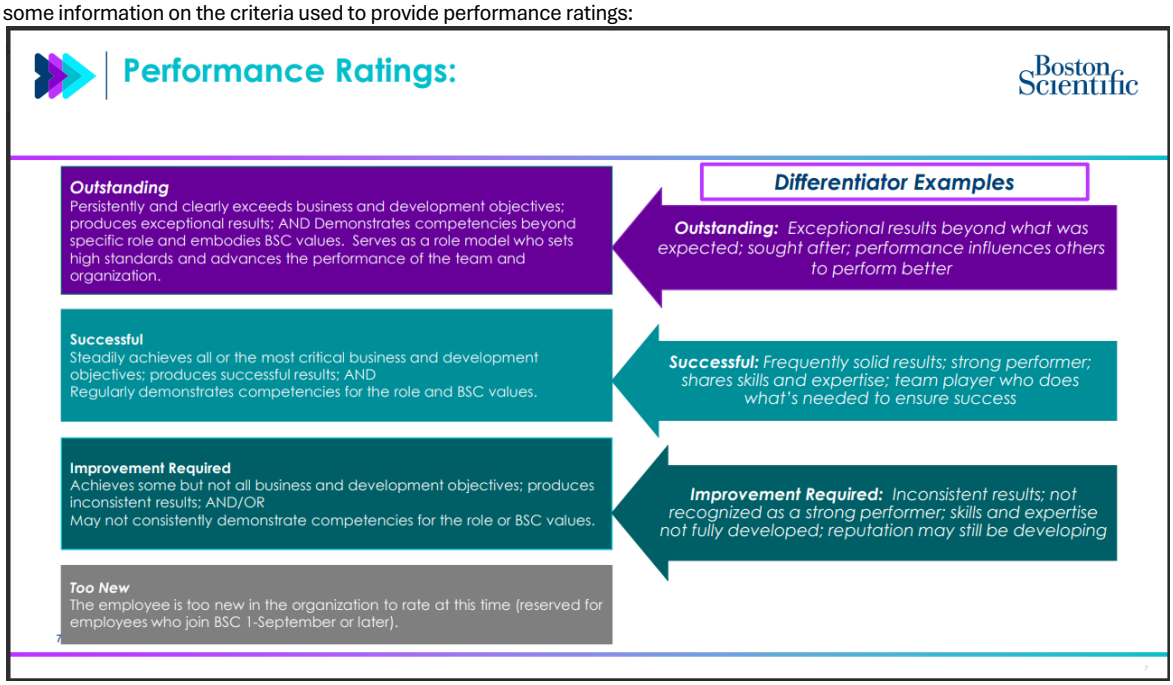
Hi Narin,

I appreciate the open, honest, and difficult discussion during our 1:1 last Thursday (April 10, 2025). It's understandable that you are frustrated with the "Improvement Required" performance rating you received for 2024. We need to continue having open conversations to ensure alignment and work together to strengthen the performance areas that led to this rating.

During our discussion, you expressed dissatisfaction with the rating and questioned how your long workdays, including nights and weekends, to meet workstream deliverables and project business goals under a pressurized schedule could result in an "Improvement Required" rating. While it's true that there was pressure on the project schedule and the goals were met due to your hard work, which is commendable, the focus of our performance feedback discussions has never been about the amount of work or effort you put into your deliverables.

The discussions have centered on your performance in terms of **how** you manage your packaging workstream activities and the resulting negative impact on the project team and coworkers. Your performance has been below the expected level for a P-5 Level Engineer in the areas of collaboration, planning, communication, and deliverable execution. In your 2024 year-end performance review document, I included examples of these areas for improvement and provided feedback gathered from peers to give you added context and examples. I encourage you to review this feedback for a better understanding and interpretation of the issues raised throughout the year.

Here is some information on the criteria used to provide performance ratings:



We are committed to supporting you through this corrective action process. This includes providing you with the necessary resources, training, and guidance to help you improve in the identified areas. Our goal is to ensure you have the tools and support needed to succeed and meet the expectations of your role. Your growth and success are important to our team.

Regards,
Aaron

-----Original Appointment-----
From: Clark, Aaron
Sent: Monday, November 18, 2024 4:48 PM
To: Clark, Aaron; Anderson, Narin
Subject: 1:1 Aaron & Narin
When: Thursday, April 10, 2025 1:30 PM-2:00 PM (UTC-06:00) Central Time (US & Canada).
Where: MAP ConRm MPL3-2 Curie C2-112 (VC)

Moved meeting to today and booked room in MG since we're onsite.

Adding additional 1:1 time slot to make recurrence weekly. We can adjust as appropriate.

Thanks,
Aaron

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Meeting Transcript: Aaron (Manager) & Narin (Direct Report)

Date: April 10, 2025 **Start Time:** 01:20 **Location:** MAP ConRm MPL3-2 Curie C2-112

Project Updates

Aaron (01:20): Hi. How's it going today?

Narin (01:38): Fine.

Aaron (01:38): How's the tube flaring going?

Narin (01:38): Fine.

Aaron (01:38): Are you making progress?

Narin (01:41): Yes.

Aaron (01:43 - 02:07): I went in there this morning and got a little tutorial on the setup there, because I just wanted to see what it entailed. Sure. And we'll just... It produces a pretty good tube. Pretty nice flared part. It's just that it's... There's definitely a kind of an art to it, as far as the process. I don't know what your thought is there, what you're thinking.

Narin (02:20 - 03:02): Yeah, it's generally pretty consistent. Yesterday before I went home I had set up a small experiment where I had three different temperature settings and then I flared them. That O-ring, that is meant to have a consistent placement or insertion. And then I think to help maintain consistency, it's just a matter of having a single operator versus multiple operators due to the differences in strength of each person. So I've been doing it. I've already told Tom from R&D that since the quantities are small, we probably wouldn't need his time, that Kirk and I can do it.

Narin (03:02 - 03:35): But I think if I can, I'm just going to finish it up myself to help maintain consistency. From the units that I did set up yesterday, I determined one of the three temperatures that worked best. It produced pretty consistent flare ID. It comes out at about 0.20, which is about 15 thousandths more than our ID. And then the flare length is about a millimeter to two millimeter, which is what we want. So I think that should meet GOWI's expectations.

Aaron (03:37 - 03:39): And these are the TL tubes, right?

Narin (03:39): That's right.

Aaron (03:43 - 03:47): Yeah, that's unfortunate. So what's your throughput on those?

Narin (03:47 - 03:57): It goes pretty fast, maybe about a couple of seconds per unit, both ends. Not a couple of seconds, maybe five seconds, both ends. A couple of seconds for one end.

Aaron (03:57 - 04:00): So a few hundred should...

Narin (04:00 - 04:02): Should only be about a few hours.

Aaron (04:05 - 04:14): I guess that's good that you guys can use them. Are you gonna just use those on, I'm assuming, builds that aren't packaging related?

Narin (04:14 - 04:15): That's right. That's the intent.

Aaron (04:16 - 04:31): Okay. And you'll just use the same rationale that you guys already have in place? That's right. So it doesn't really, other than building additional units, it doesn't incorporate any additional rationale or risk, really?

Narin (04:31): No.

Aaron (04:32 - 04:34): Okay. That's good.

Narin (04:39 - 04:48): Do you have specific questions or comments that you would like to make? Otherwise, I can just give you a brief update on where I stand this week.

Speaker 1 (04:49 - 04:59): Actually, from a project standpoint, is there anything pressing, really?

Narin (05:00): No,

Aaron (05:02 - 05:09): I don't need an in-depth update this time. I just wanted to talk. We haven't talked. Really so kind of want to do this talk about just us interactions and stuff.

Speaker 1 (05:14 - 05:17): Yeah, you know, I've been sensing tension and whatnot.

Narin (05:19 - 05:26): I'm focused on work. That's where I'm at. So yeah, that's what I'm I'm pretty focused on work.

Aaron (05:28 - 05:38): No, I told that and that's obviously what it should be so but I just also want to keep have an open dialogue with you because I just want to make sure that we're on the same page.

Narin (05:39 - 05:42): Are we not on the same page on project-wise?

Aaron (05:42 - 05:49): No, I just want to- I'm not saying we're not, I just want to make sure that we're- Okay, I think we are.

Narin (05:49 - 05:57): Yeah, I've updated you consistently on what's going on in the projects and, you know, feel free to send me an email if there's something-

Aaron (05:57 - 06:12): Have you had any thoughts about 25. Any initiatives or development type goals that you want to go after or anything like that?

Narin (06:14 - 06:22): Just executing to the projects that I'm allocated to supporting. So that's what I'm working on. Yeah. Yeah.

Aaron (06:25): How are things going?

Narin (06:26 - 07:12): Going well. I think the design freeze was a big hurdle, so I'm glad that that is over with. And I had my one-on-one with Orla this morning. I was just telling her that with that hurdle behind us, I think it's just a matter of execution. So in that regards, I've been in discussion with Patrick and Kirk getting the shippers sent from the DCs so that we can have them available for our sorting operations here. I've got a meeting set up to meet with Kirk and Patrick and Amy and Mike to just walk through the sequence of events that will happen when we get the units from DV.

Narin (07:14 - 08:13): So that will happen in about a week or two, which is well before we'll receive units from the sterilizers, so that's going well. The other stuff I have ongoing are just following up on some feedback from spec maps that we need to update because I committed to addressing some

of the feedback that was provided during the last round of review. So yeah, I think that's it. Probably the biggest thing that's on the topic discussion this week was some bomb issues related to alignment of the change controls between Boston Scientific and Hematech. So we had a meeting with Hematech this morning with a walkthrough indicating that for projects that are in development, they don't require an AI form, but once it's commercial, they do need that.

Narin (08:14 - 09:14): And I think there was a bit of misunderstanding in the group here, but I think that helped to clarify that. And then I've also got follow-up meeting with a larger group just for internal BSE set up for Monday or Tuesday of next week. And I've got the SFMD guys who will be part of the call. So we're just going to talk through maybe some questions that Patrick still has outstanding on this issue to make sure that we're all on the same page. But generally, I think we're good on that front. Yeah, I think probably the biggest thing was there's a slight misalignment in our bomb structure between Boston Scientific and Hemotech, but everybody recognizes that that is fine since they're controlled separately anyway, so it's just that bridging document that Patrick was able to identify that is the link that will allow us to make sure that what we need to happen will actually be reflected at Hemotech's end.

Narin (09:19 - 09:43): And then for the localized thermal protection project, I told Keith I was going to get back to him on his final ask, which was to come up with additional supporting information on how the project would be a benefit to the business. That is still on my to-do list. I'll probably get that done tomorrow.

Aaron (09:52 - 10:18): How about, um... Yeah, because that would be, you know, that was one of the biggest asks, or not biggest asks, but one of the asks was just how can this be applied?

Narin (10:18 - 10:19): Yeah.

Aaron (10:21 - 10:45): You know with the exploratory project is it worth so I guess I know then when you pitched the um the prototyping and things like that. Is it worth pulling your group together and having a little bit of brainstorming on just to refine the concept that you're going to go after to help streamline that if needed?

Narin (10:45 - 11:02): Yeah. I've informed both Amit and Kurt that if they have any ideas for that, to just move forward with it. But I think it's a good idea to just regroup and see if we can flesh that out some more. So yeah, I'll take that on.

Aaron (11:03 - 11:15): Just because I was thinking it was, you know, when we talked last, it was, you were looking at using those temp dots, and then in the discussion you were like, we could possibly use those data logger.

Narin (11:16 - 11:17): Data logger,

Aaron (11:17 - 11:18): Yeah. Pyro buttons?

Narin (11:18 - 11:19): Yeah, that's right, same.

Aaron (11:20 - 11:26): And so, you know, just things like that might be like, all right, how can we fish that out, so.

Narin (11:26): Yeah, I think that's a good idea.

Aaron (11:44 - 11:49): Oh, I know you mentioned Mitt Kirk. Yeah. Or not. Yeah,

Narin (11:49): Mitt

Aaron (11:49 - 11:53): and Kirk. Might be worth having a brain discussion.

Narin (11:53 - 11:54): That's a good idea. Yeah.

Aaron (11:55 - 12:44): Um, I can go ahead and say that too if you want to. Okay. Um... Just throwing it out there. I don't know. It's just more of a... Just bouncing your idea. Okay. Okay, so prototype refinement. And then just the whole, the topic of, you know, activities for Brittany. You know, what are your thoughts there?

Narin (12:45 - 13:31): Well, your ask for me was to get her engaged with this prototype. I don't think it'll take that much, but we can use her for our DV stuff that's happening for Ranger as well. So I'll involve her as much as I can, because my plan is to actually develop maybe about 30 to 40 prototypes. We'll need to get the components together and then we'll actually need to maybe put a protocol together so she can probably do that and then just monitor the progress of the end result over time. Yeah, we'll definitely involve her with that, but I don't think it will take like 50% of her total time.

Aaron (13:33 - 13:43): Is there something we can have like? Is there a piece of that we can just give her broader ownership of?

Narin (13:44 - 13:45): What are you thinking?

Aaron (13:46 - 13:56): I'm just speaking out loud. I don't know. Like, just something that we can... So between now and... May 19th. Yeah. That's your start date.

Aaron (13:57 - 14:04): Where do you think, also on May 19th, where do you think we'll be with procurement of stuff?

Narin (14:04 - 14:32): It depends on when Keith will get Heather's permission to get some budget for funding because we need design work from a designer to help put that concept together. So if it happens before Brittany arrives, then we should just move forward and not hold off on it. But if it happens after Brittany arrives, then we can hand that off to her. And she can... Yep. Yep. Yeah. Yeah.

Aaron (14:50 - 15:05): And try to make it a positive experience for her. Because she's expressed, she has expressed some desire to get to like, look at new, something new. On our co-op, she just spent the time in the lab,

Narin (15:05 - 15:06): Right?

Aaron (15:07 - 15:08): Just doing test cams and stuff.

Narin (15:08 - 15:27): She'll enjoy this, and it'll also make use of her experiences from last time. Yeah, so for engagement, it will really depend on when the budget will be available for us to charge. It's not much, it's only like a few thousand dollars, but we do need to charge it somehow.

Aaron (15:47 - 15:54): Protocol. Are you envisioning having yourself already do the protocol or do you think that's something we can help have her be involved in?

Narin (15:54 - 16:39): Brittany can drive the protocol. It's not that challenging and I think it'll be a good experience for her to take ownership of that. Yeah, like I said, we can definitely use it for DV stuff, but I don't know to what extent. I'm not sure. Maybe help coordinating. Yeah, I'm not sure on that part yet. Just making sure that parts gets to where they need to get at certain parts of the schedule.

Aaron (16:49 - 16:55): I guess, sorry, I meant like what are you envisioning for like a test setup? Like what are you thinking?

Narin (16:56 - 17:13): Just when the parts arrive in Maple Grove, DA might need help with sorting and repackaging some of the units into smaller shippers. And then just making sure that those shippers get to Arden Hills on a specific date and when they come out of aging, et cetera.

Aaron (17:14 - 17:15): Are you referring to?

Narin (17:16 - 17:17): DV for Ranger.

Aaron (17:17 - 17:21): Oh, I was still, I was talking to Explorer. Oh, okay. Sorry.

Narin (17:21): Yeah.

Aaron (17:23 - 17:27): Okay. So you were saying she could help with, Ranger DV as well part of it.

Narin (17:27 - 17:28): As well part of

Aaron (17:28 - 17:42): it. Okay. Okay. Yeah, I guess I was thinking more on from the exploratory side of the test. Like your concept, testing your concept, what are you envisioning? As far as is it just putting it in an oven or is it some sort of...

Narin (17:42 - 18:21): Yeah, that's what I had communicated in our last meeting with Keith was putting... So we'd 3D print the parts and then we would put the units together. So the phase change material will need to be melted. So that will need to happen in a lab. She'll probably need to use a syringe to actually inject it into the wall, like one of the walls. We'll need to put the aerogel into it. We'll need to cut down the vacuum insulated panel. So all of those need to be put together, and that will be a little bit involved.

Narin (18:21 - 18:26): So it's not like a walk in the park. That will take a bit of practice.

Aaron (18:26 - 18:29): How big is this? What are you envisioning?

Narin (18:30 - 18:53): It depends on how small the supplier can make that micro vacuum insulated panels. So right now I think the largest one was about four inch in length. So I'm asking them to see if they can make it even smaller than that. They say it seems like they can, but it requires a bit more time for them to put it together.

Aaron (18:53): And

Narin (18:53): That's a flat panel?

Narin (18:54 - 19:04): It's a sheet that we can roll into a shape that will be inserted into one of the walls of that container.

Aaron (19:05 - 19:07): The container you're going to print or something?

Narin (19:08): Yeah, the container that we're printing.

Aaron (19:09): So that

Narin (19:09 - 19:19): container will contain three concentric walls. And each wall will incorporate a certain component of that whole technology.

Aaron (19:22 - 19:25): What about the bottom of it and top of it?

Narin (19:26 - 20:12): That will be, yeah, that's part of the thing that I'm trying to flesh out is it really depends on how small the supplier can make that vacuum insulator panel. Because ideally, that's what we want as well. The whole thing should be enclosed such that there's no air gap. Otherwise, there would be leakage through the system, and that's what we don't want. So it really depends. So I think that is a follow-up discussion I need to have with a supplier to see how small they can make it. And then what we'll do is we'll design that chamber in such a way that it will be able to incorporate that in that panel.

Narin (20:13 - 20:34): So the size of that panel will actually be the thing that dictates the overall size of the chamber. Because I think from an aerogel standpoint, we can just cut it down to shape based on what I've seen of what's on the market. It's the vacuum insulated panel that will drive the whole size.

Aaron (20:39 - 20:47): Interesting. So then that, the phase change material, you decided to make it liquid, put it in a syringe, and inject it.

Narin (20:47): That's right.

Aaron (20:54 - 21:07): Sounds cool. Now it's exciting to see like that kind of starting to come to fruition, right?

Narin (21:07): Yeah.

Aaron (21:09 - 21:17): So that's it. You can see the theory, and you can see the potential actual prototype is kind of cool.

Narin (21:40 - 21:44): Yeah, those are really all my updates. Do you have any other comments or questions on

Aaron (21:44 - 21:57): work? Not really the project stuff specifically, right? It's more just how you're doing.

Narin (21:58 - 21:59): I'm doing fine.

Aaron (21:59 - 22:15): I mean, just in terms of, you know, last year was a, you know, it was a major bumpy road there for six months and I just want to make sure you're doing all right. you know, curious of how your dynamic on your team is going, if everything's...

Narin (22:16 - 22:17): Seems to be going fine.

Aaron (22:18 - 22:21): Seeing things are going all right. Make sure you're all right.

Narin (22:21 - 22:26): I think I'm fine, yeah.

Aaron (22:26 - 22:51): I hope so. I'm just saying it feels like, I just sense there's some anger and frustration, which is totally understandable, right? But I'm just, I don't want that anger and frustration channel for me. I feel like it is turned to me, but I feel like I'm not... I shouldn't be necessarily taking the brunt of that.

Narin (22:51 - 22:56): What makes you say that? I mean, what makes you say that I'm channeling it to you?

Aaron (22:56 - 23:07): I just, I just, I just feel that, you know, that just the, you know, in staff meeting, right? You just sit and you just face away. There's no, there's no...

Narin (23:08 - 23:11): I'm looking at the content that you're presenting.

Aaron (23:11 - 23:15): Okay, that's fair. But I'm just saying that's how I perceive it.

Narin (23:18 - 23:27): You know, if the way that I conduct myself impacts work, I think that is what we need to talk about. But if it's not work-related, I think we should...

Narin (23:28 - 23:39): Well, this is work, right? No, I'm just saying that if the way that I conduct myself in the office isn't conducive to work, I mean, please let me know and I'll address it.

Aaron (23:40 - 23:48): Well, that's what I'm telling you. Standoffish feel and non-engagement feel, and that's what I want to make sure.

Narin (23:48 - 23:55): Am I not answering all of the questions that you've asked me? I thought I am, so...

Aaron (24:07 - 24:13): I didn't do anything to you, Darn. I am not your enemy.

Narin (24:17 - 24:18): I didn't say you're my enemy.

Aaron (24:18 - 24:28): I know, but it's that tension, right? I'm trying to help. We need to be on the same page in order for me to help. OK? OK. It's a two-way street.

Aaron (24:30 - 25:09): We need to work together. That's all I got to say. We have to be in this together, right? We had feedback from last year that resulted in a not good it was not the best feedback, right? And if I missed something, we've, like, maybe that should be the question. Is there something that you, that I could be doing better to help you? or that you feel like I could be doing better to help re-engage or anything like that?

Narin (25:09 - 25:17): Are you sure you want to ask me that type of question? I mean, you want me to be honest with you? How I feel?

Aaron (25:17 - 25:51): Well, I just want to know, like... I'm just wanting... to let you know, or I want to be on the same page, that I'm not against you. Okay. When we did, throughout the last, you know, we had discussions on performance and feedback, right? I was just relaying feedback that I was gathering from other individuals and compiling feedback. Okay? It was not coming from me. I'm making observations based on everything that I'm being brought into and told.

Narin (26:00 - 26:13): Okay. Yeah, and that was the driving factor for my performance rating without taking into account the consideration for the output of the overall deliverables of the program.

Aaron (26:14 - 26:16): That was not fully the case.

Narin (26:17 - 26:18): Really?

Aaron (26:18 - 26:19): Yes.

Narin (26:19 - 26:23): Okay. From my perspective,

Aaron (26:23 - 26:25): that's what I feel. Have I ever said you were not putting in...

Narin (26:27 - 26:31): It's not about putting in the effort, it's about being able to deliver for the project.

Aaron (26:31 - 26:38): Yes. That, yes. You were able to deliver and you did, right? Yeah. At some expense.

Narin (26:41 - 26:42): What expense are you referring to?

Aaron (26:44 - 26:48): I'm just saying the amount of time and whatnot that was put in.

Narin (26:48 - 26:59): So you're telling me that you recognized that I was able to pull off and deliver for the project. Is that what you're saying or not saying?

Aaron (27:02 - 27:03): Did you meet your design priest?

Narin (27:05 - 27:28): More than me, design freeze. That design freeze happened one quarter before I was committed. And in addition to that, it also accelerated launch timelines. So yes, I feel like I more than did contribute that because my work had a direct impact on everyone else's ability to do their work.

Aaron (27:28 - 27:30): But it also had an impact on the team.

Narin (27:33 - 27:35): What are you saying? Clarify for me what you're referring to.

Aaron (27:35 - 27:52): The amount of, I'm just saying, the amount of discussions, the amount of feedback that I was getting, right? There was feedback from the team in general around the fact of just needing to get involved in patching Workstream, or the feedback...

Narin (27:52 - 28:41): What new product development project doesn't go into all these challenges that we need to talk through as a team? I think that there might be a discrepancy in the expectations there. All of the projects that I've been involved with, and they're not minor projects, they're all very high visibility projects. In each and every one of my projects, we always encounter obstacles and we work through them as a team. So the experiences that I endured for Ranger, it's For me, it's a typical set of challenges. I think there's probably recognition by the team that, yes, I did struggle because it was a new product line, and I told you multiple times that I needed time to get acclimated to the project.

Narin (28:43 - 29:19): And in my one-on-one meeting with Orla, I don't think she, well before she didn't really understand what that statement that I just made until I explained to her that it's not a

matter of just reading technical reports and DV reports, it's about understanding it to the degree where you're able to connect all the dots. That's what I'm referring to. And things like this, I mean, even though the product is leveraged, it takes time to really understand the nuances and be able to connect all the dots. And it's taken me that long to get to this stage.

Narin (29:20 - 29:54): But now that I'm here, I feel like I've already mastered, my understanding is far superior than it was a year ago. And I think what I don't really like is the fact that my entire rating was based on peer feedback without consideration for the deliverables. That's what I don't appreciate. To be objective, I think as a manager, you should take into account not only the challenges, but the fact that you're able to deliver.

Narin (29:54 - 30:31): Because at the end of the day, that's what the whole team on the project is being judged on, is what we're able to deliver. But in my case, that wasn't taken into account at all. It was all based on peer feedback. And to be honest with you, I remember, I vividly remember that when I had, you know, there was a lot of stuff that I was dealing with. Everything that you said to me in our one-on-one, I remember all of those. And there's a difference between just criticism and constructive criticism.

Narin (30:32 - 30:59): I don't know what your perspective is, but I vividly remember all of our discussions. And while it was tough for me, I still clearly remember them. That I don't meet the standards of a principal engineer, that the feedback that I get from the team is a bad reflection of you?

Aaron (30:59 - 31:58): There was elements of that coming my way. I was not the... Saying that you don't meet the standards of a principal engineer is a very broad statement. There's elements of that. You mentioned that to me multiple times. There's elements of that that was raised during the interactions and the feedback, right? Interactions around planning, right? There was feedback early on in project planning that, hey, I was pulled in in August by the team. Basically saying, hey, I need you to follow up with ARN because We are not getting a straightforward or a clear path or a clear understanding on the packaging work stream.

Aaron (31:58 - 32:36): We don't understand the timing or where it's at or if there's a clear plan. The communication from that aspect was not clear to the team. When the team is coming asking for questions that they're not getting a clear understanding or can find out where things are at, what that clear plan is, that is the execution phase or the planning phase that I'm referring to when I'm saying that we should be able to explain and have a clear laid out path for your work stream to be able to tell your team members, hey, here's what we're doing, this is our plan.

Aaron (32:43 - 32:54): That's one example. So when I was pulled in, And I had asked you for a plan, but there was never a plan.

Narin (32:55 - 32:56): How can you say that?

Aaron (32:56 - 33:13): That was clearly conveyable, right? I was approached by multiple individuals saying, hey, we can't find anything. We don't know where the team, there's nothing in the team site, right? So we asked. You uploaded your stuff to the teams, but it hasn't been touched since.

Narin (33:15 - 33:55): It's because I'm working on them on my network drive and I asked Orla how critical it was for me to upload it there. The problem is just making sure that I'm working on one location of the drive and I just was worried about having other non-work related issues like the performance review being mistakenly uploaded onto the team site. So that was where my hesitation came from. And then regarding the project timeline, I'm in every one of those core team meetings. It's a matter of priorities. At that stage in August, I was trying to finalize the design.

Aaron (33:55 - 34:36): It's not even timeline I'm referring to. It's the overall strategy. Being able to clearly communicate the strategy and plan and to articulate what you're going to be going after, right? Conducting the pre-DV or the concept assessment testing, right? Back in July, when we did the concept, you did an initial feasibility study. There was observations that clips were popping, right? We had a discussion and said, hey, I would recommend doing some small studies to start getting some feel or getting a read to make sure that this stuff is clear, right? A couple months later, nothing. You didn't do the small studies.

Aaron (34:37 - 34:43): And I've been asked why. You just said, I prefer I don't want to do small studies because I don't work like that. I wanted to have captured all the data.

Narin (34:43 - 34:57): That is not true. I told you that you have to factor in multiple parameters in there. You just can't just isolate a particular design problem just to a certain variable. There are a lot of multiple. I understand that.

Aaron (34:57 - 35:14): But what I'm saying is just in terms of that specific concepts like deliverable. It was about, at the time, just reducing lowering the concern or risk that you saw, right? You saw a clip pop, and you're like, oh, maybe we should do something to just double check that we're not having an issue.

Narin (35:15 - 35:42): And I did follow up on that. I did do follow-up experiments on that. So I didn't let it go. When it was brought to my attention, I did address them. But you keep raising up the same point, despite me trying to explain and give you the proper context of a particular situation. It's like, whatever I explain, it just I don't know, I don't know what the thing is. That's what frustrates me.

Aaron (35:42 - 35:55): I'm looking for a way to communicate with you better. I want to get on the same page.

Narin (35:55 - 35:57): Am I not giving you the information that you need for work?

Aaron (35:57 - 36:10): No, that's not what I'm saying. I'm just saying, I want to, I want, I am not against you. And I don't feel like you feel that way.

Narin (36:13 - 36:25): You know why I feel that way? It's because when you offered Mitch to help me when I was in a really tough bind in November, December, I really appreciated that. I thanked you for the help that you gave me. And I was really sincere about that. Then you turn around and it seems like when you responded to Keith, it seemed the tone of it was so resentful of the fact that you need to offer extra help for me as a principal engineer. That really stuck with me vividly.

Aaron (36:43 - 37:22): And if that bug knew that at that point, we should have had a discussion on that. Because there was no intention of trying to rub you that way. Whether you did it or not, it did. I was answering a clear ask from Keith. Keith came to me and said, why do we have to bring extra

resources on this when you show me to use a half of the head? That was his ask. So I had to reply back and just let them know what the scenario was. It was a clear ask from Keith.

Aaron (37:27 - 37:45): And along this whole way, I've been, it hasn't been just me You say you hate this, I hate this, man.

Aaron (37:56 - 37:57): You've been here 25 years, dude.

Narin (38:04): And?

Aaron (38:05 - 38:06): I'm just saying, you've been here 25 years, and...

Narin (38:13 - 38:17): What? I'm not able to advance? No. Like other people?

Aaron (38:17 - 38:18): No.

Narin (38:18 - 38:20): Not accomplished as much as they have?

Aaron (38:20 - 38:20): No.

Narin (38:21 - 38:22): Been here too long?

Aaron (38:22 - 38:24): No, that's not where I was going.

Narin (38:24 - 38:26): Okay. Well, what point are you trying to make?

Aaron (38:26 - 38:33): It's just, we've been here, I've been here 20 years. We've been here a long time.

Narin (38:33): Yeah.

Aaron (38:34): That's all I'm saying.

Narin (38:45 - 38:54): Yeah, what bugs me is that my rating was driven primarily by feedback. That bugs me a lot.

Aaron (38:55 - 39:16): And that's fair, but they are. We had, this year was the biggest year that I can recall, unless you recall another one, where PI pushed for feedback and gathered an absolute ton of feedback. This was the most feedback that I can ever recall we've gotten.

Narin (39:24 - 40:26): From a manager perspective, if I were the manager, I would judge people more fairly, not just based solely reliant on peer feedback. And I think you need to take proper context of a given situation. You have to, I don't know, the way that you and I think, we're just different. At this stage, the project is in a good state. We pulled off what needed to be pulled off. Yeah, it accelerated timeline, so I think that's the outcome that we should just focus on. Orla mentions to me that there's a likelihood that the project may actually launch by the end of the year, but that is unofficial.

Narin (40:30 - 40:49): It's unofficial, but that's what we're striving for from a team perspective. Yeah, if I'm not up to par, you have an issue, just let me know and I will address it.

Aaron (40:51 - 41:26): I want that to work both ways. I'm learning in this role too, Aaron. So I need to gather feedback from you, too. We need to have an open dialogue and open communication. So if there's something I'm doing, thank you for your honesty. I really appreciate that.

Narin (41:27 - 41:32): The damage for me has already been done. That rating, it's done.

Aaron (41:32 - 41:34): That rating was not done.

Narin (41:40 - 41:42): Yeah, it was from feedback from my peers.

Aaron (41:52 - 42:01): No, I got you. You said it multiple times. Yeah, the company got a lot of feedback, and that was what drove the rating.

Aaron (42:06 - 42:10): It wasn't just feedback either, Narin. It was the involvement, too.

Narin (42:13 - 42:14): Involvement of what?

Aaron (42:14 - 42:30): Well, like myself. I got pulled in back in July and August. Which resulted, since August, we've been having regular meetings and discussions.

Narin (42:32 - 43:19): But in those discussions, have you ever thought that, you know, Constructive criticism for me is being able to identify an issue, helping the person that you're trying to help find a solution to it. When you're engaging with me, you said you were involved since June, July of last year. I feel like my team was really who worked hand-in-hand with me trying to solve various problems. In that PIP plan that you put together, I think it's mainly as a platform for me to just give you more regular updates. I still encountered the various issues that I did.

Narin (43:19 - 43:58): I still endured all the stress. Those problems, I still had to figure it out. And during shutdown and Christmas, I was the one who was dealing with them. So even if you're involved, How did it make my life easier? Because I look back at it and it didn't. It just put me under a lot more stress than, yeah, it just put me under a lot more stress. The PIP plan didn't do anything to help me out when I was in a bind. It didn't help me find solutions faster or easier. It just put me under more stress.

Narin (43:58 - 44:04): My focus was on delivering for the project. Getting the deliverables completed, But all of these extra...

Aaron (44:04 - 45:19): That wasn't the intent for the PIP. It wasn't the deliverables of the project. It was the other stuff, the soft skills around the team engagement, the people engagement, the project planning, the coordination, the collaboration. That was what that PIP is for and what most of our discussion is being driven from. Not the deliverables. I know you can do the deliverables. It's the feedback that we got and the way that questions are answered that we have to continuously follow up on, right? The most recent example was with Ryan, when there was a response with that graphic information that included data that was not relevant to what you were trying to communicate or what the question was being asked.

Aaron (45:25 - 45:30): That resulted in multiple meetings, multiple back and forths, multiple communications.

Narin (45:30 - 45:32): What project doesn't go through that?

Aaron (45:32 - 45:41): I'm talking about the way that data was presented before it was sent out.

Narin (45:41 - 45:50): What's the point of a team? I thought the point of a team is to help each other out, right? So if you see some sort of a negative, that's the whole thing, is we try to make each other better, yet what you do is you just focus on my,

Aaron (45:53): You

Narin (45:53 - 45:56): magnify all my missteps and mistakes. That's it.

Aaron (45:56 - 46:13): That is what I'm saying. That's the feedback that I get. It wasn't me that calls it out. People see that and they're like, hey, why is this happening? So then I have to circle back and try to understand. It's not me picking at you.

Aaron (46:31 - 46:58): It's not. In the way this has happened, in the way that some of that is presented, in the way people are seeing that and perceiving the ability or inability to communicate, I'm getting feedback. And quite frankly, I had a team request that you weren't on their team.

Narin (47:01 - 47:02): Mind ranger.

Aaron (47:02 - 47:22): No. Like, so that's where I'm trying to say it. It's not me picking on you. It's I'm being pointed out things or observations, and that's where I'm having to come in and say, okay, how can we address this?

Aaron (47:28 - 47:35): So we need to get on the page with, I want you to embrace me trying to help. Yeah, I'm learning along the way. But we need to work together.

Aaron (48:10 - 48:12): Does that make any more clarity or sense?

Narin (48:13 - 48:20): I understand that. Yeah. Do you have any other comments?

Aaron (48:59 - 49:33): So with that, we just need to keep having an open dialogue and working through, right? I've seen much improvement in terms of the engagement with the team, the awareness, like I've seen it in your tech team, right? Your open communication, your talking, engaging, right? It's just we need to keep working on the ability of articulating and getting that message across.

Narin (49:37): Okay.

Aaron (49:57 - 49:59): Yeah, maybe that.

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From: Anderson, Narin
To: Harris, LaDeja
Subject: RE: New Evidence in Formal Complaint - Narin Anderson
Date: Friday, April 18, 2025 10:19:00 PM

Hi LaDeja,

Thank you for meeting with me today. I appreciate you clarifying the company policy regarding recording meetings, and I sincerely apologize for not being aware of this policy beforehand. As I mentioned, I recorded the April 10th meeting solely to accurately recall the discussion after receiving significantly different written minutes from Aaron. My intention was never malicious, only to ensure clarity given previous instances when my recollections and those documented officially differed substantially.

I completely accept responsibility for this oversight and have already discontinued recording. Additionally, please be informed that I canceled the previously scheduled (April 17th) informal discussion with my sub-team, as I reflected on it further and concluded that it might not be appropriate since you were conducting your own investigation. I also didn't want to place my team members in an uncomfortable position. I was simply trying to fill some gaps in my understanding of the conditions behind the feedback that led to me being placed on a PIP in the first place which was unexpected.

My goal throughout this process remains transparency, professional integrity, and fairness. Thank you again for your attention to these matters.

Respectfully,

-Narin

From: Anderson, Narin
Sent: Thursday, April 17, 2025 11:45 PM
To: Harris, LaDeja <ladeja.harris@bsci.com>
Subject: New Evidence in Formal Complaint - Narin Anderson

LaDeja,

Earlier this week, I received the minutes from Aaron Clark for my 1:1 meeting last week on

April 10th, 2025. Further to my formal complaint, I am requesting the following material be scoped into your ongoing investigation:

- Aaron Clark's meeting minutes from our April 10, 2025, 1:1 meeting.
- A full transcript of the same meeting.
- A detailed analysis highlighting critical discrepancies between the minutes and the transcript.

The analysis demonstrates that Aaron omitted key elements of the conversation and fabricated content that was never discussed. This includes misrepresenting my concerns, the meeting's tone, claims of support offered, and the omission of his statement regarding a team's request that I not be included on their projects. An mp3 recording of the meeting is also available if needed.

I believe this new evidence strongly supports my claims of biased treatment and a flawed performance evaluation process. I request your prompt review of this material.

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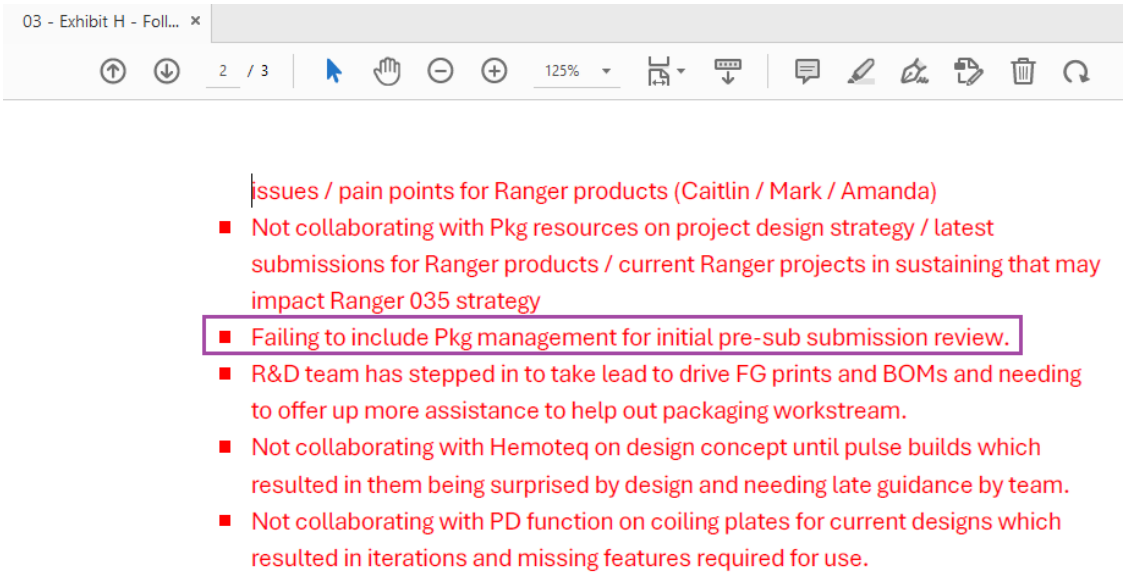
From: Anderson, Narin
To: Harris, LaDeja
Subject: Addendum: Performance Improvement Documentation — Incident Regarding FDA Pre-Sub Consultation
Date: Sunday, April 20, 2025 1:42:00 PM
Attachments: 04.6 - Addendum 2025-04-20_FDA Pre-Submission Incidet - Narin Anderson.pdf
02 - BSC PI Pkg NPD - Complaint_Revised 2025-04-20.pdf
image001.png

Dear LaDeja,

Further to my previous submissions, please include the following documented incident into your ongoing investigation as it provides critical evidence of a pre-existing pattern of significant factual misrepresentation by my manager, Aaron Clark, that adversely impacted my performance evaluation.

This incident relates to the FDA Pre-Sub submission for the Ranger 035 program and provides a clear timeline of consultation and subsequent omission in Aaron's reporting. The FDA Pre-Sub submission process is an event of critical significance since all functional teams—including Packaging—must be fully aligned prior to submission to the FDA.

This incident relates to a claim in my Performance Improvement Plan that I failed to consult with Packaging Management prior to an FDA Pre-Submission.



Here is a concise, factual timeline that establishes the contradiction clearly and conclusively:

Timeline with Supporting Documentation:

- August 28, 2024 [9:30 AM CST]: Team finalizes content for the FDA Pre-Sub submission.
- August 28, 2024 [12:48 PM CST]: I sent a meeting invitation to Aaron for a meeting scheduled September 3, 2024, to discuss the FDA Pre-Sub submission content and ensure alignment across functions. (Documented on Page 31 of my formal complaint.)
- September 3, 2024: The meeting occurred as scheduled, where I briefed Aaron on the

submission content.

- November 8, 2024: After Keith questioned me about Packaging Management's involvement, I proactively sent Aaron a message to clarify the timeline and his inclusion. (Documented on Page 30 of my formal complaint.)
- November 18, 2024: Aaron sends meeting minutes (cc Keith) stating, "Failing to include Packaging management for initial pre-sub submission review," despite previously being briefed and invited to the meeting (Documented in "03 - Exhibit H - Follow up - Performance Improvement Discussion," page 2.)

Supporting Evidence:

Calendar invites and meeting records attached (pages 30–31, and 56 of formal complaint).

Significance:

This incident demonstrates:

- A clear pattern of Aaron misrepresenting facts prior to the previously documented April 10th incident.
- Willful omission of material information (critical FDA consultation) to support a negative narrative in official performance documentation.
- His communication of inaccurate information up the management chain (to Keith).
- A direct connection between this misrepresentation and my negative performance documentation.
- The underlying email and calendar records demonstrate that I took steps to include Aaron prior to the FDA Pre-Sub submission, and that Aaron's later statements to the contrary directly contributed to my negative performance documentation and PIP process.

I believe this further supports my claim that Aaron's management practices were not only biased but also systematically misrepresentative as my consultation with him was later mischaracterized as never occurring, and that official records were knowingly constructed in a way that unjustly damaged my role and reputation.

This instance aligns with the broader pattern revealed by the recorded April 10, 2025, transcript and other documentation already provided. This further substantiates my claim that the negative performance narrative authored by Aaron is demonstrably inaccurate and unfair, and represents an ongoing practice, rather than isolated occurrences.

This evidence further substantiates my claims of biased treatment, and a fundamentally flawed performance evaluation process rooted in factual inaccuracies. I request this addendum be formally reviewed and incorporated into your ongoing analysis.

Respectfully,

Narin Anderson
Principal Engineer

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From:	Ward, Monica (Employee Relations)
To:	Anderson, Narin
Subject:	RE: Request for Reconsideration of Performance Review and Investigation into Potential Bias in Packaging Engineering
Date:	Monday, April 14, 2025 8:20:49 AM

Hello Narin,

Thank you for reaching out. I understand that you are currently working with another Employee Relations team member, LaDeja Harris, who is reviewing your concerns. She will continue to partner with you and review the concerns you have shared.

Thank you,

Monica Ward | Employee Relations | P: 763-494-2037 or C: 952-679-0133

From: Anderson, Narin <Narin.Anderson@bsci.com>
Sent: Friday, April 11, 2025 12:21 AM
To: Ward, Monica (Employee Relations) <Monica.Ward@bsci.com>
Subject: Request for Reconsideration of Performance Review and Investigation into Potential Bias in Packaging Engineering

Dear Monica,

My name is Narin Anderson, and I have been a committed and dedicated employee of Boston Scientific for 25 years, currently serving as a Principal Packaging Engineer. I am writing to express serious concerns regarding my recent performance review and the potential for bias in the evaluation and promotion processes within the Packaging Engineering department in Minnesota.

Performance Review Concerns:

1. ***Biased and Inconsistent Evaluation Process***
   My recent performance review, which resulted in an "Improvement Required" rating—the lowest in my 25-year tenure—relied heavily on subjective peer feedback, nor adequately reflect the actual outcomes of my projects. This was neither transparent nor balanced.

   My manager, Aaron Clark, expanded the peer feedback pool from six individuals I nominated to twelve, without disclosure or consideration of their familiarity nor directly knowledge of my work. This raises serious concerns about the objectivity of the evaluation. The reliance on this feedback, without clear weighting or

interpretation, further erodes the credibility of the process. My explanations regarding the challenges faced during the project, including onboarding into a new product line and compressed project timelines, were not adequately considered. Additionally, Aaron's repeated comments that negative feedback about me reflected poorly on him raise concerns that my rating may have been influenced by his personal image rather than my actual performance.

2. ***Overlooked Achievements***
   The performance review failed to acknowledge several major accomplishments. For example:
   - As the Packaging Core Team member for the Ranger 035 PDP program, I led the Packaging Design and Development workstreams making critical contributions to the Ranger 035 Design Freeze. This required me to work 14-16 hours daily for 3.5 months, forfeit 40 hours of earned vacation in 2024, and restart critical design work a week before Christmas due to a last-minute team decision. My efforts enabled cross-functional peers to build test units and obtain critical data, ultimately leading to a successful Design Freeze on March 20, 2025, and accelerating multiple market launches.
   - I filed a patent for my work on the Localized Thermal Protection TDP
   - I also contributed significantly to the TheraSphere GBM HFA program through active team participation, guidance, DV protocol creation, test unit builds and execution, among others.
   - These accomplishments were not considered in my evaluation.

3. ***Mischaracterized Collaboration***
   Feedback citing insufficient collaboration ignored early team decisions to limit engagement with Hemoteq AG. When gaps were identified, I took swift action to address them, yet the review highlighted isolated incidents while disregarding ongoing improvements.

<u>Concerns of Racial and Age Discrimination</u>

What troubles me most is the growing concern that racial and age-based bias may have influenced both my performance evaluation and the lack of advancement opportunities. As the only Asian Principal Packaging Engineer in our Minnesota facility, I have observed a troubling pattern in promotional decisions: several of my Caucasian colleagues with comparable or lesser experience and achievements have advanced to similar or higher roles within a fraction of the time it has taken me to reach my current position. These

disparities suggest potential bias in both evaluation and advancement decisions, warranting a formal investigation.

- I received one promotion in all of my 25 year tenure (moving from Senior Engineer to Principal Engineer after 18 years). In contrast more than eight Caucasian colleagues I have worked directly with advanced to similar or higher roles within 6–8 years.
- I was not considered for an interview for the Mgr I PI Pkg NPD role, which was awarded to Aaron without a transparent selection process despite my qualifications.

Impact on My Career and Well-being

The biased treatment and flawed review process have:

- Damaged my professional reputation and career progression.
- Caused significant emotional distress.
- Limited my compensation and advancement eligibility.

Requests for Resolution

I respectfully request the following actions to address these concerns:

1. ***Re-evaluation of My Performance Review***: I request a reconsideration of this review, taking into account a more balanced evaluation of objective results and contributions.
2. ***Review of Compensation Decisions***: Alignment with my demonstrated impact and the company's performance.
3. ***Investigation into Promotion Processes***:
    - An investigation into the selection process for recent management promotions, including criteria used, and the specific qualifications sought for the role.
    - Consideration of potential race and age discrimination factors in these decisions.

I respectfully request a review of my performance evaluation, focusing on the objectivity and transparency of the process. Additionally, I urge you to investigate the selection criteria and decision-making behind recent promotions within the Packaging Engineering department, ensuring that fairness is upheld.

I have dedicated 25 years to Boston Scientific, consistently delivering high-impact work and upholding the company's values. I remain hopeful that leadership will take these concerns seriously and lead by example, ensuring Boston Scientific uphold its commitment to fairness and integrity.

Please let me know the next steps in addressing these concerns.

Sincerely,

Narin Anderson

Narin Anderson
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From: Calderon, Esmeralda
To: Anderson, Narin
Subject: Follow Up 4/25/25
Date: Friday, April 25, 2025 6:26:20 PM
Attachments: image001.png
image002.png

Hi Narin,

I have taken the time to have reviewed your concerns about the rating. As mentioned on our call today, the rating is considered final and the year end rating supported the decision. I encourage you to take the time review the resources and focus on the future. It's important to regularly discuss management expectations, goals, action items, and project updates during your one-on-one meetings.

Resources

- Advance My Career - Home – A lot of what we had discussed is on this page and I've linked the below details that you can explore.
  - CPM Resources for Employees
  - Individual Development Planning Tools
  - Employee Pathways

Tips for Effective Communication For Feedback & Receiving Feedback

1. **Prepare in Advance**: Define your goals and gather relevant information.
2. **Active Listening**: Focus on the conversation and reflect on what your manager says.
3. **Open-Ended Questions**: Encourage dialogue with questions that require more than a yes/no answer.
4. **Be Clear and Concise**: Stay on topic and use specific examples.
5. **Positivity**: Approach the conversation with a positive mindset and express appreciation.

Again, I recommend keeping communications with the management team open, positive, proactive, and future-focused.

In partnership,

Esmeralda Calderon
People Partner II – N. America
Boston Scientific
Advancing science for life™

One Connect HR **https://bsciprod.service-now.com/esc** ← *Click here to visit OneConnect HR, your streamlined and enhanced one-stop shop for HR services!*

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Narin Anderson

Principal Packaging Engineer

763.337.3786	narinanderson@gmail.com	Shakopee, MN

Summary

Results-driven professional with a proven track record of leading complex medical device packaging projects and cross-functional teams. Expertise in developing innovative packaging solutions, managing stakeholder relationships, and driving continuous improvement initiatives. Skilled in navigating ambiguous situations, resolving conflicts, and ensuring compliance with industry regulations. Demonstrated ability to balance technical expertise with strategic thinking to deliver high-impact results in fast-paced environments.

Experience

Boston Scientific Corporation, Maple Grove, MN

Principal Packaging Engineer, New Product Development, Aug 2018 - Current

- Managed and orchestrated the activities of complex packaging engineering projects for new Drug Eluting Stent Platforms and Drug Coated Balloons medical devices with multiple stakeholders and external partners, meeting critical project deliverables and timelines while still complying with complex performance and regulatory requirements.
- Built, developed, and maintained strong relationships with internal stakeholders, suppliers and other external partners, ensuring alignment and driving project success.
- Led the development of tactile coatings and localized thermal protection technology development programs & drove innovative packaging design initiatives, enhancing product presentation, competitive differentiation, and brand recognition.

Senior Packaging Engineer, New Product Development, Nov 2008 - Aug 2018

- Redesigned the product packaging for Innova™ Stent Delivery System and ELUVIA™ Drug Eluting stent platforms helping the organization establish best in class status for their respective product category.
- Spearheaded the design and development of flexible temperature controlled soft bags that enabled room temperature storage of drug coated medical devices for Sales Rep Assigned Inventory (SRAI) increasing annual revenue for the business by several million.
- Pioneered the application and adoption of advanced materials (soft touch coatings, phase change material, temperature indicators) and novel user-centric packaging design concepts across multiple medical device product lines that helped establish the modern look and feel of future products and setting new standards for the business.

Senior Research & Development Engineer, June 2000 - November 2008

- Co-developed & patented thin membrane fabrication process for FilterWire™ that increased efficiency by 40%.
- Investigated electrostatic spray coating process to enhance material transfer efficiency and coating uniformity.

Graseby Medical, Arden Hills, MN

Advanced Operations Engineer, September 1996 – September 1998

Narin Anderson

Principal Packaging Engineer

- Managed international component suppliers, ensuring compliance with product specifications and resolving complex supply chain issues.

HB Fuller, Oakdale, MN
Chemist, March 1994 – August 1996

- Developed a range of industrial coatings, serving major automotive OEMs with innovative and high-performance products.
- Conducted comprehensive tests for product certifications, adhering to stringent automotive and military specifications.

Education

Master of Mfg. Systems, University of St. Thomas, Mpls, MN, 2005

Bachelor of Chemistry, University of Minnesota, Mpls, MN, 1994

Bachelor of Chem. Engineering, University of Minnesota, Mpls, MN, 1994

Key Skills

- Strategic Planning & Execution
- Cross-functional Team Leadership
- User Experience Enhancement
- Data Analysis & Optimization
- Creative Problem Solving
- Relationship Management

Patents

Provisional Patent – "Localized Thermal Protection of Medical Devices"

Provisional Patent – "Providing Interactive Instructions For Medical Apparatus"

U.S. Patent No. 7,691,431 - "System and Method For Spray Coating Multiple Medical Devices Using A Rotary Atomizer"

U.S. Patent No. 7,163,549 - "Filter Membrane Manufacturing Process"

Achievements

Led the development of industry-defining medical device packaging, resulting in enhanced brand presence and customer engagement.

Successfully managed complex projects and teams, significantly improving product development cycles and operational efficiencies.

Adept at introducing novel packaging designs, contributing to the successful launch of Innova and Eluvia.

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2024 – Year-End Performance Feedback – Narin Anderson
Performance Rating: **Improvement Required**

Manager Comments:
Entering 2024, Narin was assigned to support the Ranger 035 PDP project for the year in addition to supporting the Cryoablation NPD program in Q1/Q2 and the Localized Thermal Protection Exploratory project in the second half of the year. As Q1 ended, the Cryoablation project was cancelled, allowing Narin opportunity to solely focus on Ranger 035 for NPD and lead the exploratory project, which is his passion.

Throughout the year, Narin made some valuable contributions to the organization, particularly in the exploratory domain, showcasing the PI NPD Pkg department to upper management with creative initiatives. His innovative solutions such as the multilayered phase change material for localized thermal protection exploratory for temperature sensitive devices and Chatbot Artificial Intelligence (AI) ideation, were instrumental in achieving initial exploratory packaging R&D goals and resulted in multiple successful intellectual property patent disclosure filings for:

- Localized Thermal Protection
- Providing Interactive Instructions for Medical Apparatus

Narin's passion for exploratory work was evident in his phenomenal presentations and discussions on the Localized Thermal Protection concept and packaging technology advancement to the PI divisional leadership. This effort gained PI divisional leadership support to continue exploratory efforts into 2025.

Additionally, when the Ranger 035 project faced a manufacturing challenge with difficulties loading the device strain relief into the carrier tube, Narin pushed the team to work with the carrier tube vendor to incorporate a "flare" design, effectively reducing the forces required for product builders to insert the device into the carrier tube.

As the year progressed, the Ranger 035 packaging workstream began struggling to meet deadlines, impacting project timelines and team productivity, which led to increased scrutiny and pressure from upper management. When the project schedule began to be expedited and compressed by the business mid-year (end of Q2), peer performance feedback expressed frustration and concern that the packaging workstream deliverables and status were not clearly understood or available for team review in the project teams shared folders, indicating workstream planning and execution was not being performed to a level necessary to successfully satisfy the project schedule. Consequently, Narin's performance came under scrutiny, revealing deficiencies not typically expected of a Principal Engineer, necessitating management involvement in workstream deliverables and meetings to understand the issues. Additional resources were needed, and management had to increase involvement to track progress and assist in restoring faith in Packaging's ability to deliver. A typical PDP project with minimal packaging design development like Ranger 035 is assigned 0.5FTE allocation, so given that Narin was already 0.5FTE and additional help was required highlighted the need for Narin's coaching and management involvement which raised concerns.

Feedback from peers, team members, and managers identified both strengths and areas for improvement. They appreciated Narin's strengths in innovative ideas and hard work, but noted that attention to detail, responsiveness, clarity in communication, and adherence to deadlines needs improvement. Additionally, strong ownership of packaging decisions, knowledge of PDP process, and feeling empowered to push back as a Principal Engineer on cross-functional PDP teams are areas needing to be addressed as he works towards increasing his functional expertise.

Areas of strengths:

- **Creativity and Innovation**: Narin showcases the PI NPD PKG department to upper management with his creative and out-of-the-box initiatives. His innovative solutions, such as the multilayered phase change material, have resulted in successful patent approvals and tangible outcomes that benefit the entire

packaging department. Narin does not stop trying and often comes up with alternative solutions when initial concepts do not come to fruition.

- **Hard Work and Dedication**: When Narin's project objectives were in jeopardy of missing deadlines or causing delays as a result of self-inflicted consequence, Narin took accountability and ownership of the workstream mishaps. This highlighted that when motivated and engaged, Narin is hardworking and willing to work nights, weekends, and holidays to resolve issues. His commitment to his work is evident in his willingness to put in extra effort to achieve project objectives.

Opportunities for improvement:

- **Initial Concept Development**: During initial concept development activities prior to Concept Select, minimal feasibility studies were performed on the intended design. Given the existing nature of the design and components, more studies could have been conducted to provide hoop assembly condition and device removal force data post-conditioning and prior to the Concept Select milestone. This would have helped in early discovery of the design risks due to tight fitment into the sterile barrier, carrier tube clip securement, device removal forces relative to spec and environmental conditioning impact. During initial pre-DV testing, units returned from conditioning (sterilization, thermal, and distribution) with observed bending / kinking at the strain relief due to the coiled assembly fitting too tightly into the header bag. This resulted in a late-stage redesign of the coiled assemblies to reduce the coiled assembly diameter and allow better fitment into the sterile barrier. Fitment into the header bag was identified as one of the primary initial risks to the project packaging workstream, and any issues or feasibility should have been assessed during the Concept Select phase, not at pre-DV.
- **Engagement**: It has sometimes appeared that Narin was less engaged compared to others on the team based on feedback that Narin appears to rush through updates and presentations and quick to leave meetings or discussions. He goes so quickly that it seems the team doesn't have ample time to really think about what is being presented.
- **Deliverables**: Weekly published core team meeting minutes track action items status and showed packaging deliverables with dates repeatedly pushed.
- **Communication with Sustaining Engineering & Past Project Engineers**: The scope of the Ranger 035 project was to utilize as much technology as possible from the packaging design of the commercially released Ranger product and align with existing commercial Ranger product initiatives. Narin focused on Ranger 018 design and components. However, he did not reach out the Sustaining Engineering team for collaboration until November. At that point, it was realized that Ranger 018 packaging was undergoing MDR conversion, and the initially leveraged components were MDD and being replaced. This resulted in a late-stage shift in component strategy requiring alignment and planning with the project core team and Hemoteq. This highlighted the importance of dialogue and partnership between NPD and SE and the need for engagement in the early stages in NPD projects to allow proper planning and scoping when utilizing commercialized products as the baseline.
- **Attention to Detail**: Greater attention to detail would help prevent mistakes that lead to redo loops. Throughout the project, there were instances of re-do's; for example, the initial packaging tolerance stack-up did not include the loading tool device component, resulting in the initial purchase order of carrier tubes intended for design verification being too short and failing tolerance stack-up for device fitment. This oversight led to additional print updates, new purchase orders, strain on the relationship with the component vendor, and required multiple additional meetings with DA, R&D, Ops, and Management to agree on path forward strategy to support critical product development builds.
- **Design Approach**: Narin tends to take a very serial, iterative approach to designing, focusing on one aspect at a time before moving on to the next. While this is not necessarily a bad thing, he did not allot sufficient time for this mode of working in the Ranger 035 packaging workstream. Consequently, his 135cm & 75cm

coiling plates deliverable ended up causing strain on his time, resulting in insufficient hours in the day to complete development, and requiring him to work through holidays and weekends at the end of the year. If Narin had done more upfront planning to understand the intricacies, involved Operations functionally, and identified the activities required to develop a coiling plate earlier in the year, and conducted more upfront testing to confirm hoop assembly design concept, some delays and stress could have been avoided. It seemed that he did not have a sense of urgency on his deliverables until his workstream was on the verge of causing delays.

As we move into 2025, I need to see Narin demonstrate an increased focus on project workstream planning and execution, and setting clear direction for product development teams. Enhancing communication skills is essential for effectively conveying ideas and collaborating with teams and peers, and is crucial for providing a quality of work that meets business standards. Narin should work towards improving his functional expertise to increase the effectiveness of his role. Employees with functional expertise can provide guidance with confidence and contribute toward effective change. As a Principal Engineer for New Product Development programs, the business expects the engineer to perform with minimal guidance in the functional workstream.

As the Principal lead for the PI NPD Pkg exploratory area, I look for Narin to lean in and lead the team in gathering ideation on how we can move forward in exploratory initiatives. Additionally, Narin should continue to lead the Localized Thermal Protection exploratory activities and devise a way to generate "proof of concept" data in this area. There has been great work done to get to this point, and I'm proud to watch Narin navigate and express passion as he explores new ideas.

While there are areas that need improvement, I believe in Narin's potential to succeed. With focused effort and support, he can overcome these challenges and strive to excel in his craft. As a long-standing Principal Engineer with Boston Scientific, Narin understands business expectations and has taken feedback seriously. He is humble and hardworking. During project pressures, he did not hesitate to work long hours, including nights, weekends, and holidays to accomplish his project objectives. Narin embraced his performance feedback received in 2024 and has shown a willingness to address development areas. He has maintained a professional demeanor and is improving in assertiveness, team engagement, and communication, which has started to garner positive feedback since the start of 2025. Despite these efforts, it was not enough to offset the observed performance issues in 2024; thus resulting in an Improvement Required performance rating, necessitating a Performance Improvement Plan in 2025 to drive improvements. Receiving feedback on areas of improvement is not easy, and I appreciate Narin's openness and willingness to discuss the feedback. I'll do my best to help support and assist him with challenges, and our open communication will be key. Narin's hard work and efforts are appreciated, and I look forward to seeing him make progress in the coming year.

Peer Feedback: (9/12 responses)

Things done well over the last year:

- Narin is a gem. He showcases the entire PI NPD PKG department to top management with his incredibly creative and out of the box initiatives. I am very proud and our PI NPD PKG group should also be very proud of the work he has been doing outside his regular project work. The initiatives Narin undertakes are not easy to achieve, yet he often materializes his out of the box concepts into tangible outcomes and into physical samples. His solutions have benefited the entire packaging department in many ways before and we will continue to enjoy some of his creative solutions in many other products/packaging in years to come.
- Narin is an incredibly humble and hardworking person. His ideas have a high rate of failure, yet he does not stop trying and often comes up with alternative solutions when the initial concept does not pan out. For examples, As soon as we learned that the thickness of the phase change material was not optimum, Narin not only proposed a multilayered phase change material which would reduce the need of excessive material but also successfully got a patent approved for this new concept. Doing all this in addition to his project work is incredibly impressive. I am always very proud of the work Narin does and interested in collaborating with him on his creative solutions.
- I believe Narin has been an effective communicator over the past year. In meetings he very clearly states intention, and then clearly describes the path forward that he is planning to take. This is very beneficial as it leaves no question about what exactly is being done. As things change, he will take the initiative to reach out and explain changes from the original plan that was developed. One example of this was in the Pre-DV packaging work for the Ranger 035 project. Originally, Narin agreed to oversee all packaging and management of that part of the project. A well organized and communicated plan was developed, and work began without incident. After a couple of weeks, Narin realized that his schedule was too full to support this work in an effective manner and so he reached out to me to explain the situation. We then worked together to develop a new path forward that was compatible with everyone's schedules. Narin's clear communication of plan changes and concerns minimized the impact of this shift on the broader project.
- Narin has come a long way over the year in establishing a sense of urgency. Ranger 035's key driver is timeline. If we could do something 3 months faster, the business would want us to do everything we could to make it happen. I think recently Narin has internalized that urgency and is now working with the team to address issues as quickly as possible.
- I have had the opportunity to work closely with Narin over the past year on the Ranger 035 project. While I have been responsible for developing the EDS package for the device items, Narin has focused on the EDS package for the device packaging items. Throughout this project, Narin has demonstrated quick and innovative thinking, especially when tasks needed to be addressed urgently. One notable example was prior to the Pulse Builds at HTQ, where last-minute drawing updates were critical for the builds to proceed. Narin stepped up and delivered the necessary updates promptly, ensuring the project stayed on track.
- While there have been instances where additional prompting was required to complete tasks, I've observed that once Narin focuses on a task, he is highly capable and ensures it is completed effectively.
- Narin has shown great adaptability throughout the project. He has been able to pivot between tasks, especially during high-pressure periods like the lead-up to the Pulse Builds, where multiple priorities demanded immediate attention. His ability to handle these demands efficiently has been a valuable asset to the project.
- Narin assisted the TheraSphere GBM team select a label stock for the acrylic box to be used in the next phase of the FRONTIER clinical trial. He provided a well written memo outlining the data to be leveraged in addition to supplemental lab data he collected to justify the label stock selection.
- Narin's actual pkg design work (flared CT design, coil plate prototype designs) have been solid for R035. Also, Narin's communications with the team (written and verbal updates) were excellent (clear, concise, timely).

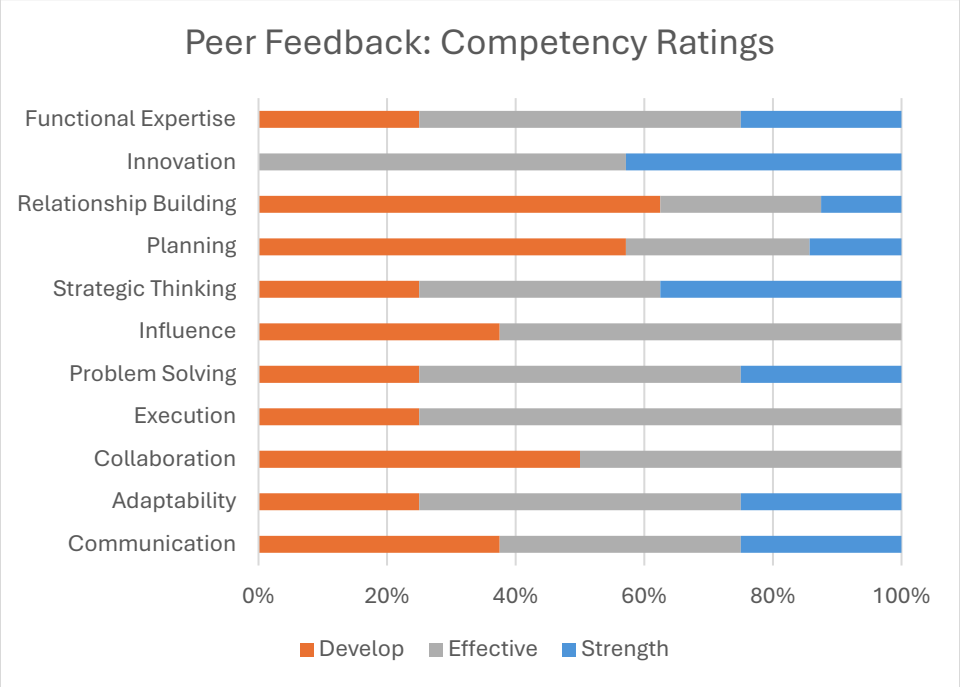
- Narin is a hard worker. Over the past month I have often seen him working nights and weekends to resolve issues that have arisen. I appreciate the time and effort he is putting in to keep the project on track. I know he is also planning to put in some time over the holidays, which is greatly appreciated.
- I appreciate Narin's frequent email updates and IMs about hot issues. He has been doing a good job of keeping relevant folks in the loop and providing status updates.
- Narin did a great job of coming up with a solution for our hub fitment issue in the carrier tube. The rollover flare solution seems like it will fit our needs perfectly, and has the added bonus of making it easy to see which end of the carrier tube the hub should go into. I also appreciate that this solution is leveraged from another product, which removes some risk around unexpected issues.
- Narin has done a considerable amount of work over the last number of weeks to try to get the DWGs and Coiling plate sorted. He has put together detailed communication and slides to capture the information. He has demonstrated a willingness to learn from feedback and address areas of concern. He is a good guy and genuinely wants to do a good job.

Things that could improve or enhance:

- Narin's strengths maybe hidden sometimes because he may seem as someone who does not speak up. People who don't know him may not be able to really understand how intelligent he is as an engineer. But when he does speak, he is effective, concise and to the point always and very effective in relaying his thoughts that matters. I do not see that as a problem but rather a virtue as someone who communicates effectively only when needed. Narin is effective at what he does great, because he is ultra focused on difficult and unexplored ideas and solutions.
- I think one main area of improvement that Narin could focus on is in his attention to detail. On a couple of occasions over the course of this year, it seems that small oversights were made that had significant impacts on the packaging portion of the Ranger 035 project. To name just the latest, the first ~150 units for Pre-DV testing returned from sterilization and conditioning with kinks at the manifold due to the packaging configuration. This was an issue that probably should have been caught earlier. After investigation, it seems that the coil diameter used differed from that of Ranger 018 and a redesign of the coiling plate is now being completed. This redesign is going to cause some downstream timeline impacts in the coming weeks. Small oversights like this have happened on a couple of occasions.
- My biggest piece of feedback is for Narin to focus on the big picture and understand the "requirements" of the packaging work on Ranger035. Through the entire year I'm not convinced that Narin really understands the project's mantra of "Keep everything identical to Ranger if possible, and if not possible, change as little as possible." This mantra has driven essentially every single design consideration for the Ranger035 team, from design requirements, to manufacturing processes, to wording on labeling and marketing materials.
- I've faced some challenges working with Narin this year, particularly regarding his commitment and effort on the Ranger 035 project. Narin has sometimes needed additional prompting to complete tasks, which has occasionally caused delays. I've considered that he may have faced challenges balancing other projects, but it has sometimes appeared that he was less engaged compared to others on the team. For example, opportunities to take ownership of specific tasks—such as ensuring that packaging part numbers were correct in the checklists before the HTQ Pulse Builds—were missed. On multiple occasions, team members had to step in to ensure the work was completed or take on tasks to keep the team moving forward. I believe that taking more initiative and proactively identifying what needs to be done would demonstrate stronger leadership and improve the team dynamic.
- There is significant potential in Narin, and I believe he is a highly capable engineer. However, communication has been an area for improvement. I've found myself having to frequently follow up or chase for updates to ensure packaging tasks were completed. Additionally, greater attention to detail would go a long way—there have been several occasions where corrections were needed because the work wasn't done accurately the first time.

- Overall, I enjoy working with Narin, but there are some key areas where I would like to see improvement in the new year. The Ranger 035 project is highly demanding, with tight timelines, and having someone with drive, determination, and attention to detail is crucial for success.
- The TheraSphere GBM team approached Narin in November about selecting an over label and label stock for use with our updated tubing set design. There have been several instances where Narin has pushed out meetings/timeline. I appreciate Narin communicating that he is busier than normal with other projects and that he needs additional time. In the future, please don't hesitate to let the team know if there is anything we can help with (additional information, resources, etc.) to keep moving forward with the activity.
- Via more conservative, up-front planning, Narin would have greatly benefited by allowing himself ample time for several iterations / potential customer failures of the coil plate design / prototypes to avoid team delays. This amount of work appeared to be significantly underestimated.
- One thing Narin could improve on would be thinking about the big picture and understanding how his work feeds into the entire project timeline. It seems that Narin takes a very serial, iterative approach to designing things, focusing on one aspect at a time to adjust and tweak before moving onto the next. This is not necessarily a bad thing, but he did not allot an appropriate amount of time for this mode of working and his coiling plate deliverable ended up being the cause of project delays at the end of the year. If Narin were to either start working on these things earlier (and do more testing to ensure the right plate had been made, rather than finding out from the outside company) or to try to do more parallel path work and make changes to multiple aspects of the design at a time, I think this could have been avoided. It seemed that he did not have a sense of urgency on his deliverables until his workstream was actively causing delays.
- Narin could improve on leveraging things from existing products. From the beginning, on the coiling plate, the team had asked Narin to take a look at the Ranger 018 and Ranger Radial designs and make tweaks to fit our different length carrier tube. Instead, he proceeded to design something from scratch which ultimately did not end up working. He was asked to look into using Ranger 018 and Ranger Radial designs several times, and was even sent the files to look at via email so that he would not have to do much digging. But went down his own path without looking much into it. Ultimately, when his design failed to meet the requirements, the team went back to the Ranger 018 design, made a few tweaks, and was able to come up with something that we think will work for us. It is understandable that Narin does not have knowledge of what predicate products have done, but he was sent all of the relevant information and also was asked to reach out to packaging engineers who had supported those projects for input. Yet, he insisted on only pursuing his design.
- I think that if Narin had stood back at the beginning of the project and understood what the ask was and engaged with other Packaging Engineers earlier to understand how Ranger 035 fitted in relative to R018, he would have avoided a lot of rework and effort that he has faced over the last number of weeks.
- I believe not fully understanding the brief and with compressed timelines, Narin possibly underestimated the amount of work required and the starting point which resulted in delays in getting a functioning Coiling Plate. Narin is a capable packaging engineer and should trust his ability. I think sometimes defaults to taking direction but does not lean in and own his workstream. It might be an idea to share his plan / proposal with Manager or Pkging peer to make sure that he is comfortable with the design and then own it.
- He could improve outcomes by making better use of project support resources to offload time consuming tasks. He seems to be putting in a lot of time to complete tasks when he has taken on more than can be handled which leads to a misinterpretation of time management as he works to complete tasks for other functions. Another recommendation for improvement is strive for a proactive approach and develop a great relationship like he did with the CAVU group on his thermal project. When timing became tight on a component order or a vendor is slow to respond it can make pivoting difficult and increases frustration or possibly leads to additional miscommunications.

Competency Ratings (Peer Feedback): Something to <u>Develop</u> / Is <u>Effective</u> at / Is <u>Strong</u> at



Context provided for competency responses:

- I put develop for relationship building. However, I believe it takes two people to build relationship. If you want to build a relationship with Narin, you need to know him before he opens to you. That is very normal and I believe Narin is a high performer because he is always focused on what is most important.
- Adaptability - There have been several times that Narin has been asked to make a change or meet a new requirement. In my experience, it can take 2 or 3 requests before I think Narin understands the request and acts on it.
- Collaboration - None of his work was on the shared Teams directory, which makes it difficult to get information when he's not available. He also tends to work alone for days or weeks at a time without touching base with the rest of the team. This has led to several mix-ups this year that otherwise could've been avoided.
- Problem Solving - Narin has come up with several solutions this year for various issues. However, the solutions frequently don't address the actual issue at hand. I have personally felt like he has needed guidance and asks for input from team members who don't know packaging intricacies rather than utilizing the packaging group's expertise.
- Relationship Building - As several tasks have devolved over the year, Narin has become defensive about the work he has done rather than proactive about creating new solutions. Recently Narin sent an email explaining how his coiling plate design works well and in the email he essentially stated that the technicians hadn't been following the correct procedures. Several people on the email immediately recognized his statement as essentially throwing other team members under the bus.
- Functional Expertise - For a principal Packaging Engineer, Narin does not seem to know the histories of the packaging for any relevant products. That in itself is not a problem. However, he also seems to have not reached out to learn that missing information during the year. For several weeks if not months, Narin hadn't looked at the reference Ranger018 drawings and didn't know the details of what the project is trying to leverage.

- I believe that by improving his communication skills and fostering greater collaboration with the team, Narin could make significant progress. Additionally, planning his work more effectively, thinking ahead to identify potential issues, and addressing them early in the project—or as soon as they arise—would greatly benefit the team's momentum. While some delays are inevitable, many can be avoided by prioritizing proactive thinking, thorough planning, and clear communication. This approach would help the team move forward more efficiently and minimize setbacks.
- Communication: Narin does a good job of communicating updates to the team. He maintains a professional demeanor, even under stress. The only reason I did not put this as a strength is that it often feels that he is trying to rush through things as fast as possible and be done with his updates. Sometimes he goes so quickly that it seems the team doesn't have ample time to really think about what he is presenting.
- Adaptability: Narin has been very fixed on his coiling plate design from the get go. When other suggestions have come up, he has been resistant to look into them and move away from his initial ideas. I see this as part of the reason things have been moving so slowly.
- Collaboration: Narin was asked to dig into what predicate products had done for the coiling plate, and to my knowledge did not. Coming into this with little balloon catheter experience, if he had reached out and gotten feedback from other packaging engineers, it could have greatly helped the project and likely sped things up. While he does a good job of reaching out to Ranger 035 team members for feedback on designs, going outside the project for some packaging expertise would have been very helpful.
- Execution: Generally, Narin executes on what he says he is going to do and provides good updates while doing so. It is just a matter of ensuring he truly understands the needs and the plan so that what is executed is correct.
- Problem Solving: Narin seems to have a good head for engineering, but he gets very hung up on his own ideas and seems unwilling to move away from them until absolutely necessary. To me, this is what hurts his problem solving skills. On the recent coiling plate issue, he did not offer any solutions, and instead continued to dig into how his original design could be made to work.
- Influence: Narin does a good job getting his points across and influencing decisions.
- Strategic Thinking: Narin could improve his strategic thinking by looking more into how we can leverage things from other projects to work more efficiently. A ground-up approach is not always the best way when under timeline pressure.
- Planning: Narin could improve his planning by thinking more about the big picture and how his workstream feeds into the overall project timeline.
- Relationship Building: Narin seems to work well with others generally, but got defensive and started pointing fingers at others when his design came into question. This was not a good way to maintain relationships with the team.
- Innovation: Narin has good innovative ideas on how to do things differently. He is good at thinking outside the box.
- Functional Expertise: For his level, Narin does not seem to always grasp the requirements of the project and the constraints we are working under. He requires close monitoring to ensure things are getting done correctly. It is understandable that he would not come in knowing everything about balloon catheter packaging, but he also has not seemed to have reached out to others who have worked on similar projects to try to understand more about it.
- Communication/ Collaboration / Relationship Building-These are all quite connected competencies - I think Narin would gain hugely from having better collaboration with his Packaging Peers. He appeared to be reluctant to reach out to them to discuss scope of work and starting point. There is a wealth of knowledge within his own group that he did not tap into and if he had he may have had a better understanding of what

needed to be done and how long it would take. I think he has taken this feedback on board already and has begun to engage more and bring others into the discussion.

- When a few tasks require extra scope and timelines get tight on projects it is easy to miss the big picture and become mired in details. Narin is very good at most of the competency skills, but when falling behind on a few tasks it becomes difficult to recover without some help. Accepting to handle all Ranger 035 Pre-DV builds was a nice gesture, but it required a lot of his time, my time and our coop resulting in an extra 20-30 hours of tasks weekly that we could not support. The inability to catch up which may have caused a cascading effect for other tasks.

Miscellaneous Feedback:

- I truly believe, Narin should be recognized for the number of Patents he comes up with and his innovative approach that is quite frankly very unique than anyone else I have seen in the entire PKG department.
- In February/March 2024 the team realized that we would need a "new" coiling plate design because our carrier tube is a different length than Ranger and the catheter manifold is a different shape than Ranger.
- This feedback is truly meant as constructive feedback on ways to improve work performance. On a personal level, Narin seems to be a great person and this feedback shouldn't be interpreted as feedback about him as a person. Instead, this is feedback in the context of how a Principal Packaging Engineer could further help the project team and what level of competency is expected at that career level.
- I have enjoyed working with Narin the past year and the team appreciates his help on the TheraSphere GBM project!
- I appreciate Narin’s level of consistent professionalism even when he was under significant team pressure to meet timelines.
- I think Narin is a good guy, works hard, and maintains a professional demeanor at all times.
- It would be nice if he would work more collaboratively with other packaging engineers and gain their insight to ensure his work is meeting requirements.
- Narin is a good guy and has shown a willingness to address development areas.
- Narin can easily handle of the competencies needed to do his job well and has been doing it for quite some time, he just can’t do everyone else’s too and needs to say “no” more often and push back.

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From: Anderson, Narin
To: Clark, Aaron
Subject: RE: 1:1 Narin / Aaron
Date: Wednesday, March 5, 2025 9:24:00 AM

In addition, I also led the Localized Thermal Protection TDP project that culminated in a Patent Filing. That is one of two patents that I filed for the year and the only two patents filed under PI NPD group. Finally, what little time I had, I supported the Therasphere GBM HFA workstreams when they need time, feedback, and guidance. This is the totality of the contributions I made to the organization this past year.

From: Anderson, Narin
Sent: Wednesday, March 5, 2025 8:00 AM
To: Clark, Aaron <Aaron.Clark@bsci.com>
Subject: RE: 1:1 Narin / Aaron

I'm struggling with deep resentment. Here is my perspective of the situation. I spent a lot of time finalizing the previous coil layout design to get it ready in November due to the compressed project timeline. It took a lot of effort to get all the supporting workstreams in place to get to that point. In mid-December, I stood alone in that room defending the design while both you and Keith were silent. I was unsuccessful at defending the design and the team insisted on a new design due to misperception by the team that an observed kink was the result of a flawed concept correlated with the bend. After building so many units, I had never encountered that situation before so I rushed to work long hours getting to the root cause of the observation that Gary pointed and later concluded it was due to mishandling of the unit using the wrong sealing equipment. That design passed multiple reviews without question and no one had ever pointed out that a manifold in a bend configuration was unacceptable. It's water under the bridge now.

That December meeting necessitated a redesign where I had to sacrifice significant vacation hours that I could not recuperate and working through the holidays, 7-days a week through weekends for the past several months to make up for the shortened timeline. I had to start the whole process again from scratch a couple of weeks before Christmas. All of this is compounded with a 'Needs Improvement' rating with no raise and a token bonus given the company's stellar performance and other employees receiving 150% bonus. Throughout all of that I was still able to help the team successfully completed a Subject Matter Expert review with other technical experts, completed essential coiling plate designs, and allowed the team to initiate Design Verification builds on schedule that will culminate in a Design Freeze in several weeks.

From: Clark, Aaron <Aaron.Clark@bsci.com>
Sent: Wednesday, March 5, 2025 7:17 AM
To: Anderson, Narin <Narin.Anderson@bsci.com>
Subject: RE: 1:1 Narin / Aaron

Hi Narin,

Thank you for being open about how you are feeling. I understand that receiving and processing feedback can be challenging, and it's completely okay to take the necessary time to reflect. Please keep in mind that feedback is intended to help us grow. If we aren't told, we won't know, and negative feedback is not a sign that you aren't appreciated. You are appreciated and have done amazing work over the years.

Please know that I am here to support you. If there's anything specific you'd like to discuss, please don't hesitate to reach out. We can reschedule our 1:1 for the end of the week when you feel more ready.

Take care, and I'm here if you need anything.

Best Regards,
Aaron

-----Original Appointment-----
From: Anderson, Narin <Narin.Anderson@bsci.com>
Sent: Tuesday, March 4, 2025 4:36 PM
To: Clark, Aaron
Subject: Declined: 1:1 Narin / Aaron
When: Wednesday, March 5, 2025 11:00 AM-11:45 AM (UTC-06:00) Central Time (US & Canada).
Where: Microsoft Teams Meeting

I'm starting to digest my review rating. I need to cancel this week's 1:1 meeting as I'm just not in the mood for it.

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From: Anderson, Narin
To: Clark, Aaron
Subject: RE: Ranger 035 Additional Support / Resources
Date: Tuesday, December 17, 2024 7:56:00 PM

I can endure a lot of hardships for the teams that I am on and will go to great lengths to make up for the shortfall in my contributions.

I don't enjoy going through all the design iterations, spending evenings, and even all night at times shifting between the designer in India and Arden Hills and weekends trying to come up with an efficient and effective solutions under a tight timeline nor do I enjoy impacting the lives of the invisible people behind me you've never met nor heard of in order to pull off my deliverables. To help me out of a bind they have had to reshuffle their priorities, come in during the evenings and weekends. I never take their help lightly. All our work is dependent on the whole team but at the end of the day, we are all people who make mistakes. Even if I do not make mistakes I still rely on their output which is what is visible to you.

Reading your message to Keith below disappoints me greatly. As I am not the kind of person who puts up a fake smile in front of others, I know I will not be able to put up a smile even if I try. You should celebrate the holiday with the rest of the team without me. I will not be attending the team lunch tomorrow.

It is hard enough to deal with the situation I am in on the project so I prefer to spend the time on my work to rectify the situation I am now under.

Thank you for your motivation and support during a challenging and difficult time.

From: Clark, Aaron <Aaron.Clark@bsci.com>
Sent: Tuesday, December 17, 2024 5:01 PM
To: Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>
Cc: Anderson, Narin <Narin.Anderson@bsci.com>
Subject: RE: Ranger 035 Additional Support / Resources

Hi Keith,

You are correct in understanding that typically for a project like Ranger 035, where the design is highly leveraged from a predicate product, we would allocate 0.5FTE max since the project requires minimal development of "new" elements of the packaging system (new hoop assembly). In the case of Ranger 035, we have allocated Narin at 0.5FTE and Kirk at 0.25FTE with the understanding there would be up and down involvement throughout the year. With

Ranger 035 being Narin's only NPD project, he has actually been able to provide primary focus on that program and allocate the majority of his time to that project with minimal allocation to the exploratory program.

Over the course of the year, I have received feedback expressing some concern from various individuals that the packaging workstream was not being driven at a level expected from a Principal Engineer; therefore I have been engaging with Narin and the team since August. Although there has been an increased effort in order to improve performance and meet the teams expectations, I am still seeing some frustration by the team since the Packaging Workstream now has critical path elements linked to the success of meeting timelines for upcoming pre-DV, pulse builds, and ultimately DV builds.

Unfortunately we are in a scenario where a series of compounding misses and delays in deliverables has put the workstream on critical path and unfortunately in the "limelight" and gating elements of the project.

A few of the compounding elements were:

- Team not set up with assigned build coordinator so Narin took on responsibility to coordinate procurement for all components, builds in final packaging assembly, and coordinating shipping of units out for conditioning for both packaging and device development units. → There should have been some better foresight in this workstream to understand that project teams typically allocate an assigned build coordinator since this alone can be a full time job. Narin started needing to pull in Kirk as well as the Pkg Co-op Luke for a ton of support which was beyond their initial scope of allocated activity.
- Series of compounding "misses" in design development/feasibility assessments leading to last minute scramble to conduct feasibility assessments to flush out packaging risks → It was identified back in July that there were studies needed for device securement/removal from hoop and carrier tube assembly inspections post sterilization and distribution conditioning; these studies are still pending and the Tech Team is asking for this data to eliminate risk going into design freeze.
- Component prints and assembly print documents have been delayed and now need to be at a "final" state in order to procure parts for DV and allow Hemoteq to conduct appropriate process qualifications for DV.
- Many coiling plate iterations as a result of lack of communication and collaboration with Hemoteq and other BSC engineers with coiling plate development experience.

Due to these compounding elements, the workstreams and deliverables necessary for Design Freeze and Design Verification have not been progressing as needed. In an effort to help the Ranger 035 project team be successful, I therefore needed to pull in additional engineering resources to help pick up project deliverables needing attention not because of Narin being

overloaded over the course of the project but as a result of compounding workstream misses and delays that now require more work than a single person can handle in the amount of time allowed to complete.

I held a meeting on Monday (16-Dec) with Mitch, Kirk, and Narin to walk through the Ranger 035 workstreams and started clarifying where Kirk and Mitch can be better utilized. It was clear that Kirk was not being utilized to his strengths that would benefit Narin with relation to print development and CNs and that Mitch was able to pick up some workstreams. Attached to this email are the notes from that meeting.

Fortunately, there have been some device development delays that have provided a very small window for our workstream to catch up but we cannot afford any more issues.

Let me know if you have any additional questions and we can discuss further.

-Aaron

From: Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>
Sent: Tuesday, December 17, 2024 8:29 AM
To: Anderson, Narin <Narin.Anderson@bsci.com>; Clark, Aaron <Aaron.Clark@bsci.com>
Subject: RE: Ranger 035 Additional Support / Resources

Aaron,

Still looking for a response on this…

From: Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>
Sent: Friday, December 13, 2024 6:20 PM
To: Anderson, Narin <Narin.Anderson@bsci.com>; Clark, Aaron <Aaron.Clark@bsci.com>
Subject: Re: Ranger 035 Additional Support / Resources

Thanks for pulling this together Aaron. I have to raise the question as to why we need additional resources on a project that appeared to be fairly straightforward at the onset: develop new carrier tube, leverage other existing components. Typically, we assign .5FTE to NPD projects that require the development of multiple components, so I'm struggling to understand why Narin's allocation isn't sufficient to accomplish the task at hand.

-Keith

From: Anderson, Narin <Narin.Anderson@bsci.com>

Sent: Friday, December 13, 2024 3:35:35 PM
To: Clark, Aaron <Aaron.Clark@bsci.com>
Cc: Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>
Subject: RE: Ranger 035 Additional Support / Resources

That makes sense. I appreciate the additional support at this point. Thank you for offering it.

From: Clark, Aaron <Aaron.Clark@bsci.com>
Sent: Friday, December 13, 2024 3:30 PM
To: Anderson, Narin <Narin.Anderson@bsci.com>
Cc: Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>
Subject: Ranger 035 Additional Support / Resources
Importance: High

Hi Narin,

Given the amount of deliverables currently in process for the Ranger 035 project and the time crunch being put on the team, I would like to pull in additional resources in an effort to help divide the workload needed to support the various efforts and help ensure we can meet the project goals effectively. As there are multiple "critical path" items at the moment, your time is getting spread so "thin" that there's just not enough time in a day in order to appropriately keep everything moving on Ranger 035 as well as your exploratory project and other day-to-day activities.

I pulled together a quick list of Ranger 035 workstreams needing attention at the moment:

- **Carrier Tubes**
  - Open items with vendor selection / capabilities for rolled tubes / print dimensions
  - Open items with quotes / Purchase Orders / delivery process to Galway
- **Pre-DV**
  - Support for builds / component procurement / testing
- **Coiling Plates**
  - Need 2 plates created
  - Modified designs needed for both 75cm & 135cm coils
  - Need collaboration with designers / R&D / Regulatory / Hemoteq / ect… to ensure next designs provided to HTQ are "final" for DV
- **Assembly Print**
- **FG Print**
- **BOM reviews and development with team**
- **Feasibility Studies**
  - 3 Experiments currently in process → will need to conduct additional studies to

confirm “new” hoop assembly designs
    - Need to understand → Device removal from hoop / tube securement in clips / strain- relief “straightness” post conditioning
- **DV Readiness Activities**
    - DV Planning
    - Protocols
    - DV component prints and procurement
- **UMD Kit Assessment**
- **Tolerance Analysis**
- **Design Freeze Activities:**
    - Print package at appropriate level
    - Design Matrix inputs → Ensure all DRs / Test Methods / EDOs / conditioning matrix / Business Requirements / ect….are scrubbed and accurate to “final” state
    - Create and present slide decks for SME updates / Design Update “Frost” Review / Design Freeze slides

I’m sure there are other activities as well; however just with this list, there is plenty of work for additional resources since Kirk is starting to also get spread “thin” as well as Luke’s co-op is ending.

With Mitch just joining our group and hasn’t had a project kick-off yet, let’s pull him in to get him involved and help you and Kirk out where he can. It will be a good opportunity for him to start working on some NPD deliverables as well as be able to provide input to design and component reviews.

We’re coming up on vacations starting the end of next week; however I will schedule a meeting for Monday (Dec. 16th) for you, me, Kirk, and Mitch to discuss the various workstreams and determine what makes sense for the workstreams.

Thanks for all your continued hard work and dedication and I’m confident more support with be beneficial to meeting the project challenge effectively.

-Aaron

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Exhibit J	Executive Summary for Valuation of Two Key Patents
Exhibit K	Patent Valuation #1 – QR Code Speech Based Multi-Language IFU Chatbot
Exhibit L	Patent Valuation #2 - Localized Thermal Protection of Medical Devices

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From: Clark, Aaron
To: Anderson, Narin
Cc: Robertson, Keith (he/him/his)
Subject: Follow up - Performance Improvement Discussion (15-Nov)
Date: Monday, November 18, 2024 2:26:40 PM
Importance: High

Hi Narin,

I wanted to follow up on our recent performance improvement discussion held last Friday (15-Nov). As discussed, there has been an increase in feedback that unfortunately has highlighted some areas of deficiency of what's expected and performance is trending towards a "needs improvement" rating. As it's not easy to hear undesirable feedback, I truly appreciate your willingness to listen and openly discuss the feedback and work towards setting specific goals and action steps to help improve in the identified areas.

To recap, the key points we discussed were:

- **Performance Deficiencies & Examples:**
  - **Project Dates and Dependencies**
    - Expected completion dates communicated to team for component and assembly prints development continue to be missed; Regular core team meeting minutes provided from Orla show deliverable dates that keep being pushed.
    - Compounding deliverable delays ultimately putting Packaging workstream on critical path for project success; As a result, packaging workstream is pushed into running as "reactive" instead of "proactive" which is opening up more risk for mistakes.
  - **Mistakes / Redo's**
    - Coiling plate development is on 8th iteration; it's understood iterations are expected, but there were misses early on with regards to leaning on predicate hoop assemblies and coiling plates as a starting point as well as pulling in appropriate PD, Packaging Engineers, and Hemoteq for commercial Ranger for guidance.
    - Print development and attention to detail; Carrier Tube Assembly print re-do's for views being incorrect and not at level needed for Hemoteq use
    - Carrier Tube component print mistakes; Plan communicated from team was to only have 1-end "rounded" but when print came through it had both ends rounded which caused re-do loop for print/quote/PO
    - Multple PO requests / pullbacks as a result of incorrect quotes or print changes.
    - Vendor selection and confirmation on capabilities for components/delivery to Mfg site; spent much of carrier tube development working with a vendor that was never intended to be used by Galway for manufacturing; resulted in late changes to vendor strategy.
  - **Not Guiding Packaging Function as Principal Pkg Lead**
    - Haven't efficiently utilized Pkg resources to collaborate on predicate designs /

back
the
o Aaron
e 1:1

See addendum

See feedback contexts - explained the situation to Aaron in multiple 1:1 meetings

issues / pain points for Ranger products (Caitlin / Mark / Amanda)
- Not collaborating with Pkg resources on project design strategy / latest submissions for Ranger products / current Ranger projects in sustaining that may impact Ranger 035 strategy
- Failing to include Pkg management for initial pre-sub submission review.
- R&D team has stepped in to take lead to drive FG prints and BOMs and needing to offer up more assistance to help out packaging workstream.
- Not collaborating with Hemoteq on design concept until pulse builds which resulted in them being surprised by design and needing late guidance by team.
- Not collaborating with PD function on coiling plates for current designs which resulted in iterations and missing features required for use.

- **Actions / Next Steps to show improvement:**
  - Schedule Regular 1:1's to start mending relationships, communicate workstream status, and understand clear expectations for project and team.
    - Aaron – Increase occurrence to weekly vs. current bi-weekly
    - Orla Sugrue (Ranger 035 Project Manager)
    - Amy Sandberg (Ranger 035 Tech Lead)
    - Mike Harris (Ranger 035 R&D Functional Core Team Member)
  - Start a weekly communication for status and deliverables intended to complete for each week.
  - Generate a Project Plan / Status Update
  - Execute Feasibility studies Needed for Design Review in December to demonstrate DV risk has been mitigated:
    - Device Securement & Removal from carrier tube
    - Carrier Tube Assembly Condition – Confirm Hoop assembly will not experience carrier tube clips dislodging
  - Review the PI NPD Packaging "Work Breakdown Structure" document to use as guide/checklist for functional deliverables.
  - Proactively engage team to understand clear DV strategy, intended process, and ownership of each deliverable (i.e. Protocols, Reports, Build Requests, Sterilization, Unit Coordination)

Our next follow-up meeting is scheduled for Friday (22-Nov). During this meeting, we will review your progress, address any challenges you may be facing, and make any necessary adjustments to the plan.

Please feel free to reach out if you have any questions or need further assistance before our next meeting.

Thank you for your commitment to improving your performance.

Regards,
Aaron

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Topics	Feedback	My Comments (Narin Anderson)
Functional Expertise	- Lack of knowledge about packaging histories of relevant products - Not fully grasping project requirements and constraints	• Thoroughly reviewed the Bill of Materials (BOM) structure of relevant products, including extensive research on the Ranger Radial design. • Proactively conducted comparative analyses to ensure a comprehensive understanding of the packaging requirements, which guided initial design solutions • Worked closely with DA to provide input for Design Matrix development that defines performance requirements for Ranger 035 • Constantly managed project complexities by balancing immediate project needs with long-term requirements prioritizing efforts and limited resources.
Problem Solving	- Solutions not always addressing the actual issue at hand - Difficulty in moving away from original ideas when they don't work	• Devised plan for label stock updates that considered both immediate needs (Pulse build) and future requirements (MDR) and adapted with evolving circumstances and constraints • Strongly believed in initial design solutions and stood up for myself and my work even when my own management team didn’t support me and when it was hard to stand against the crowd • However, I adjusted and adapted my plans in order to execute necessary changes and comply with the team’s last minute decision and the implications that came along with that decision.
Engagement	- Appearing less engaged compared to others on the team - Needing additional prompting to complete tasks	• Actively sought feedback and engaged with team members through regular Core Team and Tech Team meetings when I had important updates to share or required team input. • Where information gaps were identified, I took the initiative to address collaboration gaps and proactively updated my team and stakeholders with new information and downstream implications for workstreams and activities.
Relationship Building	- Becoming defensive when designs are questioned - Difficulty in building relationships with team members	• When the team suggested that operator error in the assembly and packaging of a unit was a result of the manifold being in a bend configuration, I worked through the weekend to prove that root cause was operator error of using the wrong coiling plate with the wrong sealing equipment. I respectfully shared this with the team and tried sincerely to convey my belief in the integrity of the design itself because I had personally built hundreds of units with no issue before. Some members of the team incorrectly assumed that I tried to portray the operator in a negative light when that was never my intention. • When I initially learned about negative feedback related to my performance, I immediately took steps to become more effective in terms of the way I interacted with my team, becoming more vocal as needed, scheduling more frequent 1:1 meetings with relevant functions, and sincerely trying to be more personable with my team.

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Advancing science for life™

PI NPD
Packaging Strategy 2023

Vision Initiatives Opportunities

Introduction

Minnesota PI NPD Packaging



Keith Robertson
Manager II
11yrs @ BSC



Aaron Clark
Prin. Engineer
17yrs @ BSC



Narin Anderson
Prin. Engineer
22yrs @ BSC



Amit Rauniyar
Sr. Engineer
14yrs @ BSC



Mark Harding
Sr. Engineer
6yrs @ BSC



Caitlin Peterson
Sr. Engineer
6yrs @ BSC



Britteny Schalk
Engineer II
5yrs @ BSC



Kirk Krona
Sr. Pkg Spec
8yrs @ BSC

Our Vision - PI NPD Packaging

Boston Scientific makes high-quality medical products.

Channels and enhances marketing message

Appealing – aesthetics, informative, organized

Look and feel

"Modern, clean packaging that complement the quality of Boston Scientific Products and resonate with end users for simplicity and ease of use."

Stakeholders – end users, buying organizations

Simple, easy to use, sustainable

*** Help grow market share by continued enhancement of PI brand recognition ***

Key User Experiences

We Implement Our Vision by Designing For Key User Experiences (similar to Apple Corp.)

What are the 3-5 most important things that people will want to do with the product so that we can do them really, really well?

What key user experiences should we focus on?:

- ❑ Wide carton opening for easy product access ***[Usability]***
- ❑ Smaller footprint ***[Sustainability]***
- ❑ Enhanced Visual Appeal w/ More Modern Feel ***[Aesthetics]***

  - ➢ ELUVIA Packaging Pkg Vision: "A simple, clean, premium package which emphasizes sustained drug elution, stent length, and stent flexibility."

  - ➢ SAVAL Packaging Pkg Vision: "A simple, clean, premium package which emphasizes sustained drug elution, stent size, and stent strength for the leg."

Pkg Attribute Differentiation

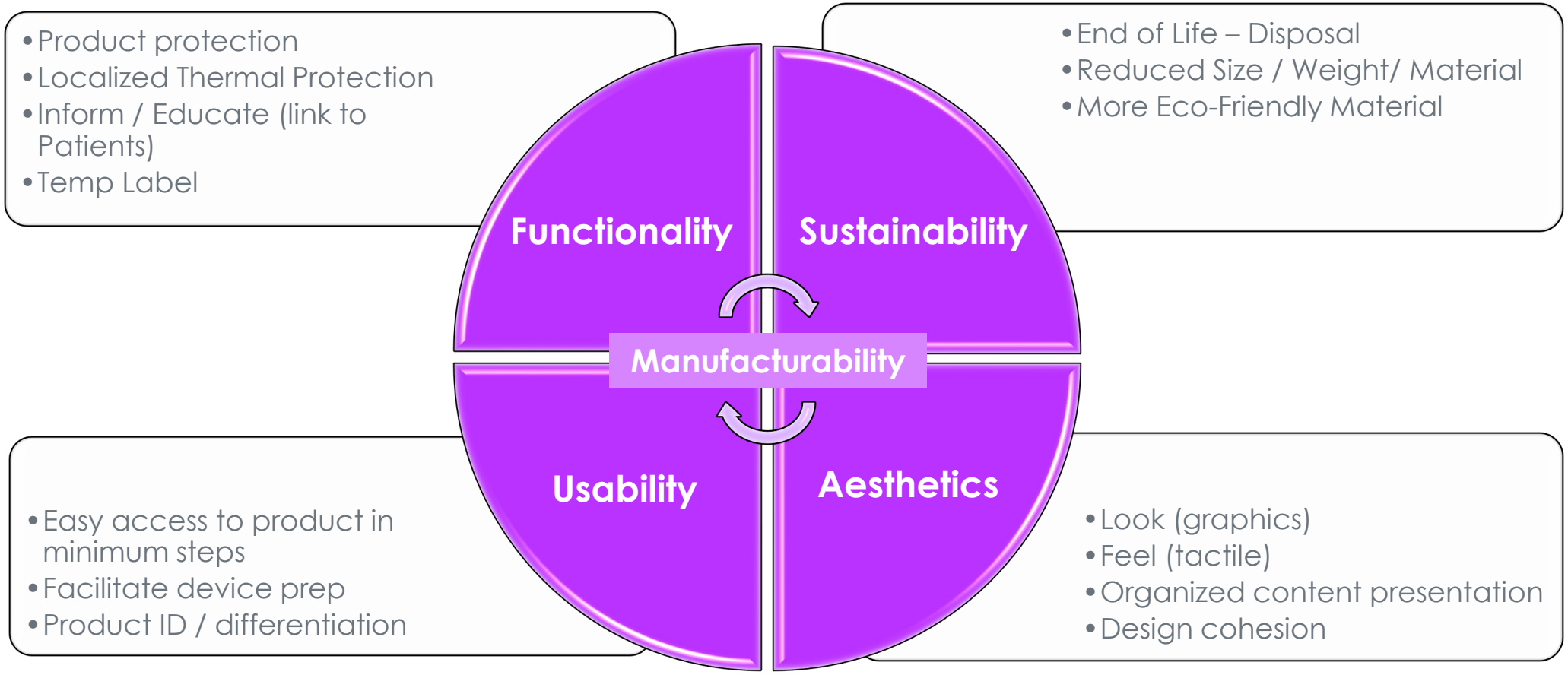
Basic	Premium
Master Brand Tab – BSC Blue	Master Brand Tab - Premium Colors
• Aqueous	▪ Enhanced Soft Touch ▪ Synthetic ▪ Pearlescent ▪ Reticulation ▪ Chrome Silver ▪ Soft Touch

Vs.

PKG that aids device use
Functional Enhancement
User Enhancement

More **Suppliers** **Fewer**

Packaging Strategy – Core Capabilities



Pop Quiz Time



Aesthetics
Tactile Finish

NOW | LATER

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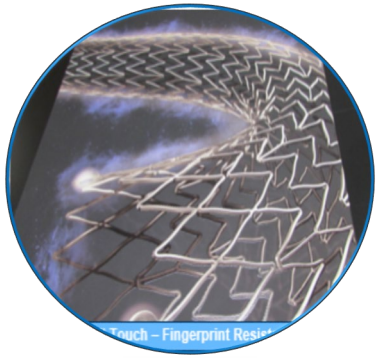
Synthetic



Pearlescent

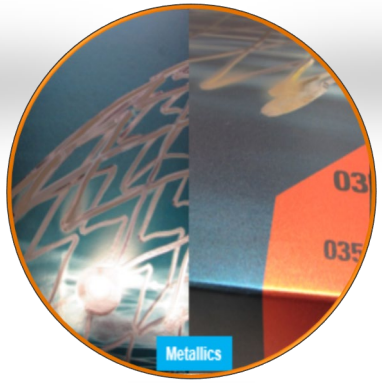


Soft Touch (Fingerprint Resistant)





Sand Texture



Metallic

- Aqueous

- Aqueous
- Soft Touch

- Soft Touch – Fingerprint Resistant
- Synthetic
- Pearlescent
- Reticulation
- Chrome Silver

- Novel Tactile Coatings that complement design or device performance
- Tactile Coating Evaluation via Technology Investment Proposal (TIP) ~ $70K + 2 Co-Ops + 1Yr
- Result – Increased design options from two to six

Core Competencies – Tactile Coatings

Raised UV

Metallic (Chrome Silver)

Soft Touch (Finger-Print Resistant)



SAVAL Commercial

Master Brand Tab



Aesthetics
Cohesive Design

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Legacy Galil Design





Single Needles & MTS PKG

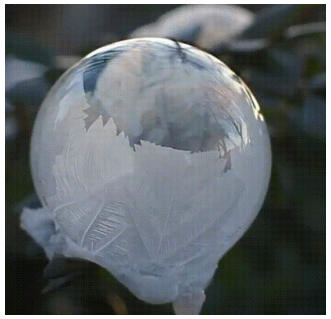


UWS PKG



Prostate Kits





BSC Design



Single Needles

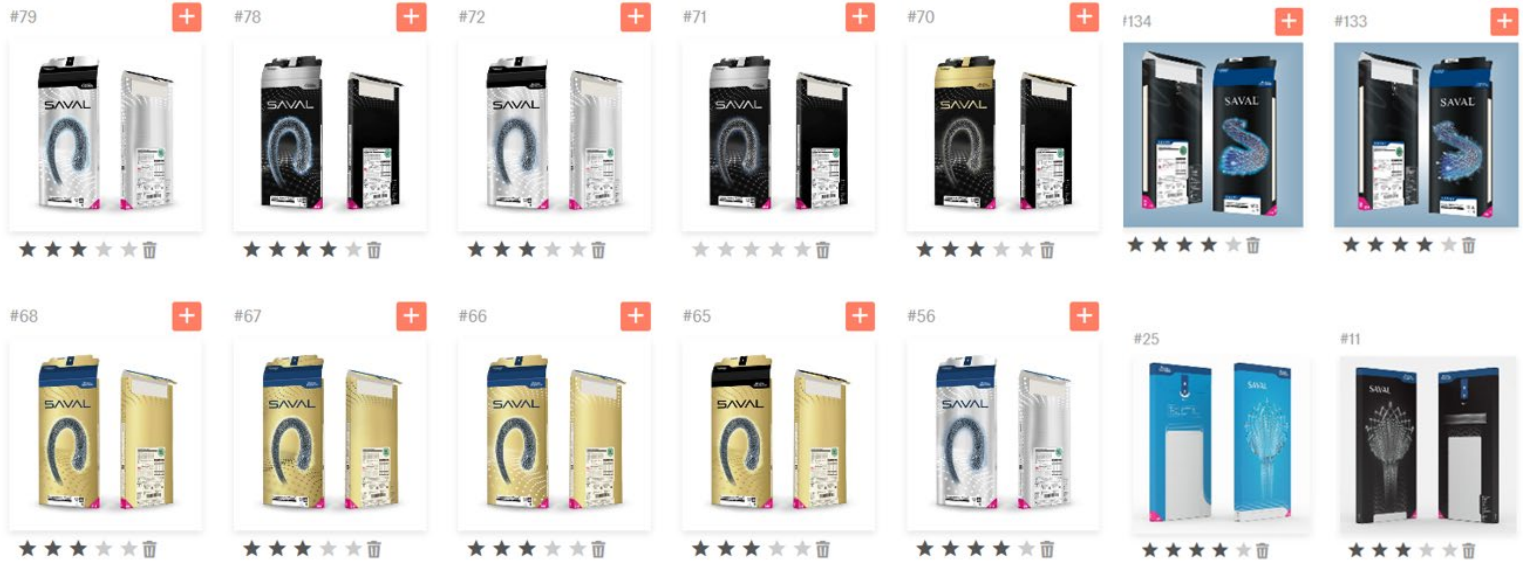


Cohesive – PKG Compliments Device Performance

Products	Footprint Reduction
Prostate Procedure Kits	9%
Warming Set	40%
Single Needles – Long	40%
Single Needles/MTS - Small	53%

Crowd Sourcing – Cheaper, Faster, High Quality





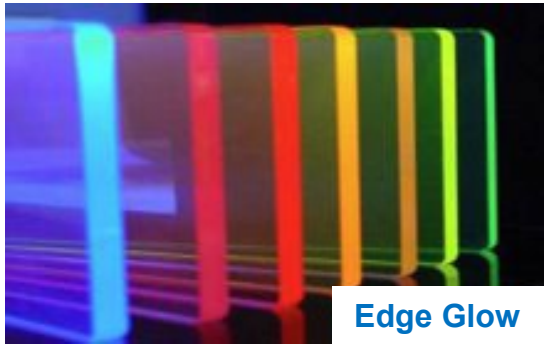
New Approach

- Innovate cheap/fast ways to filter potential design solutions
- Crowd Sourcing Talent – Graphic designs ~ $3,500, two-weeks
- Resulting in 50-100 high quality concepts
- Pioneered in two projects

Aesthetics
Delight Our Customers

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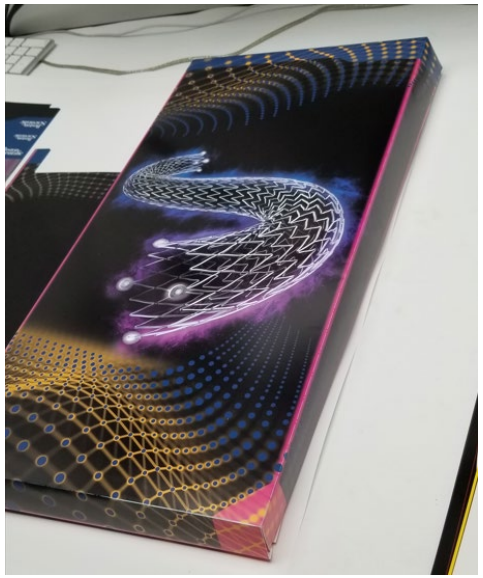
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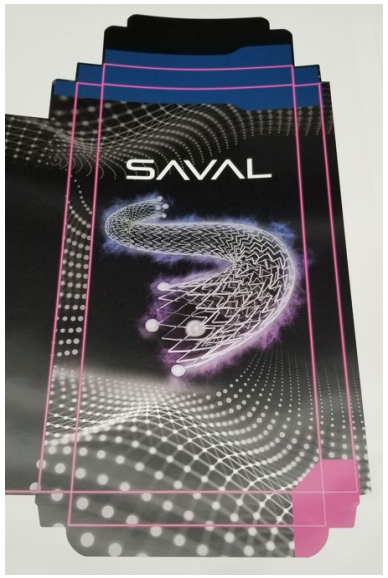

Edge Glow



Future Considerations

- Edge Glow / Low Light Coatings that alters appearance
- Multi-Functional Structural Designs (New ICEFlex Carton)







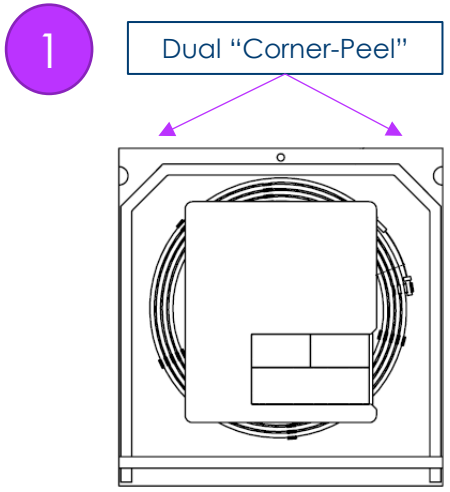
- Dual purpose (primary + return kit)
- Intuitive User Interface requiring no training
  - ✓ Strap to carry heavy device
  - ✓ Pockets to organize literature components
  - ✓ Seal (1–Mfr) / Unseal (2-User)/ Reseal (3-User)

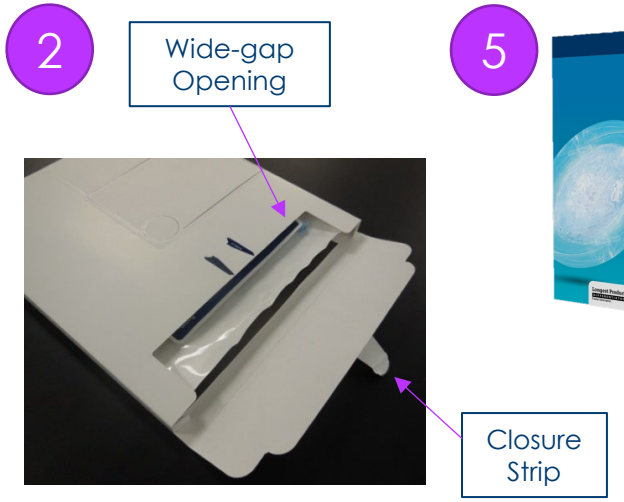
Usability
VOC Design Features

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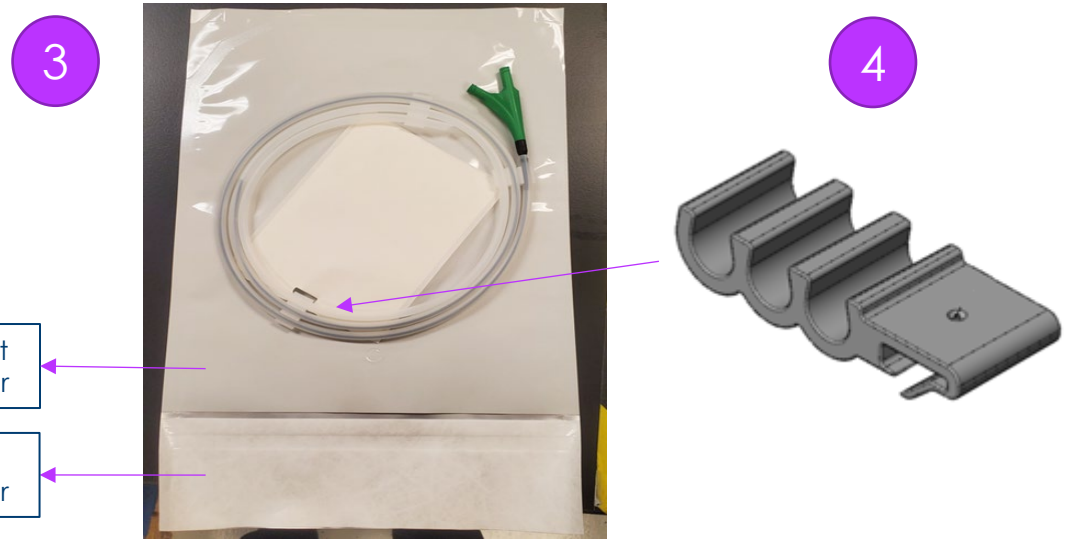
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1. Dual-Corner Peel Pouch Opening
2. Carton Opening Feature
   - "One-Step" Opening
   - "Wide-Gap" for product loading, presentation, and access
3. Dual-Chamber Pouch Design
   - Separates device from desiccant and end-user
4. Compliance Chart Clip
5. Product Differentiation/Selection









Eye Tracking Technology

From Hardware Generated to Software Calculated



32 Lab Techs

Packaging Usability Benefits

- Assess how design and formatting of pkg/lbl impacts identification & selection
- Product size most important to end user
- End users spend most time locating product size
- Understanding importance of color, font size, and shelf location



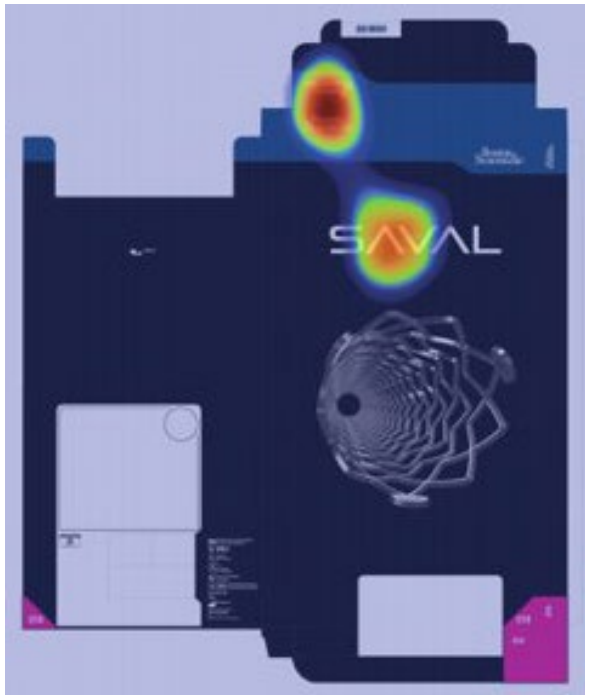


Image Upload

Usability Enhancements

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FEATURES

Tear-off Implant Card - user receives 4-color printed premium look card

Internal Pocket - easy access to IFU improves organization of literature

BENEFITS

Improved visibility – card and IFU pocket promotes product information that satisfies consumer expectations

Internal securement - Strategic placement of Implant card and IFU

CLIENTS

Intuitive

Designed for everyone

Simple

Easy to use

Unique

USERS



Internal Pocket

Implant Card



Sustainability

NOW | LATER

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Corporate Social Responsibility Council Governance

- Metrics Generation
- Increased Communication/Education
- Designing for Sustainability
- Sourcing Strategies
- Exploring Regulations/Request for Information

3 NPD Case Studies (2018-2021) submitted

3,007 kg CO2 emission savings

7, 830 lbs. of material saved





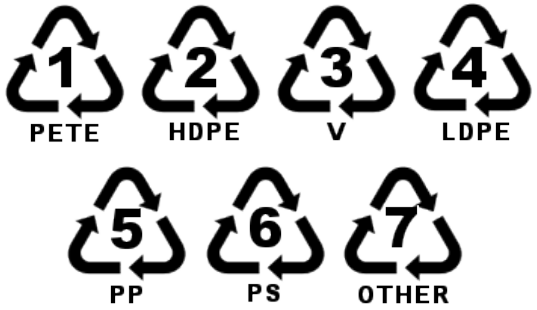


Sustainability

NOW | LATER

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More prominent End of Life – How to Discard/Recycle









ReMagine Paperboard

- Contains up to 30% post-consumer recycled fiber



Stone Paper

- More resistant, composed of recycled materials, no water

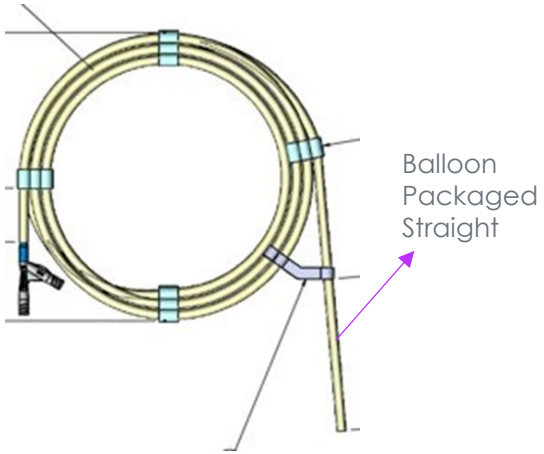


Functionality
Products Enhanced Through Pkg
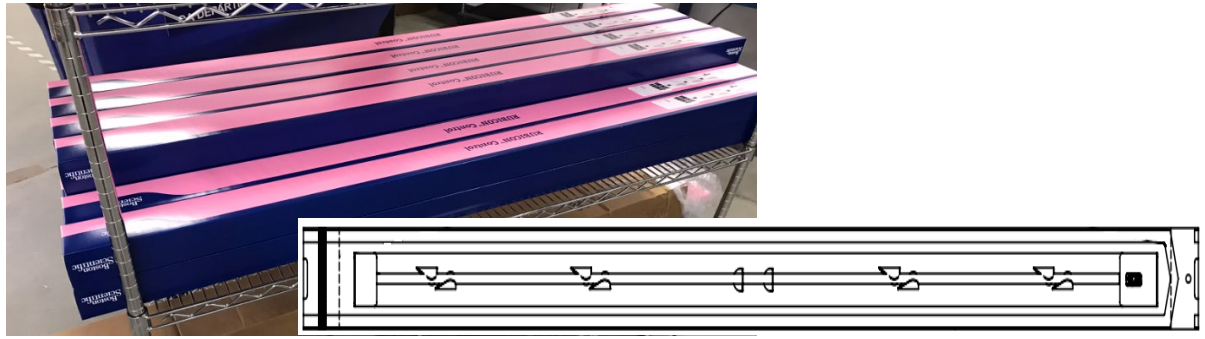
NOW | LATER

Boston Scientific

Ranger 200 cm Balloon Twist:
- Hoop modifications to mitigate Balloon twist



Rubicon Control:
- Elongated package to maintain device performance



Everest Dual Chamber Pouch Design:
- Pkg Provides moisture and oxygen barrier





Functionality
Electronic Medical Equipment (EME)

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Boston Scientific

- Many packaging needs and possible solutions:
  - Needs: new consoles, accessories and components, return/repair consoles, field replaceable units, SRAI/trunk stock
  - Solutions: wooden crates, corrugated crates/shippers, plastic crates/shippers, metal cases
- Complex packaging design and testing
  - Console construction, geometry, size, and weight
  - System and subsystem sensitivities
  - Understanding shock and vibration is crucial to protect product
  - Reusable packaging
- These are resource-intensive projects

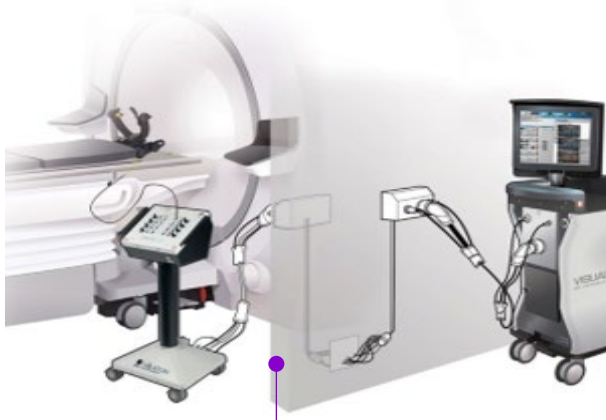
Cryo Ablation EME



ICEfx™



Visual-ICE™


Visual-ICE™ MRI


Interior PKG


Corrugated Crate


Wooden Crate


Polypropylene Shipper


ICEfx SRAI - Suitcase

Functionality

Electronic Medical Equipment (EME)

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Boston Scientific

Objective: Provide guidance and consistency around the design and development of Electronic Medical Equipment in alignment with the BSC Design Control System

Phase 1	Phase 2	Phase 3
Define DRs driven by **IEC 60601-1** Standard applicable for EME PKG	Define User, Business and Regulatory Needs & DRs Create **Design Trace Matrix Template** for EME PKG	**Provide guidance** on DV Testing. Complete **KSD and DV SOP** for EME PKG

Advantages:

- Consistency across all BSC EME
- Faster Development Time
- Speed to Market

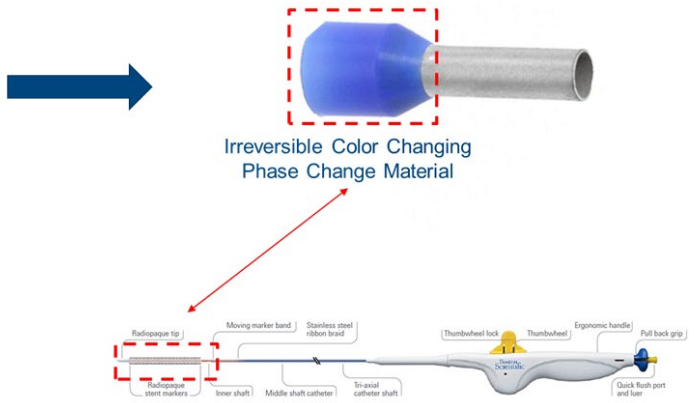
Functionality
Innovative Designs

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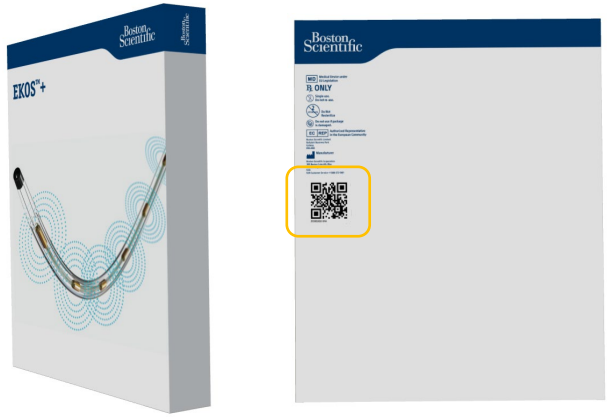
Boston Scientific

Localized Thermal Protection



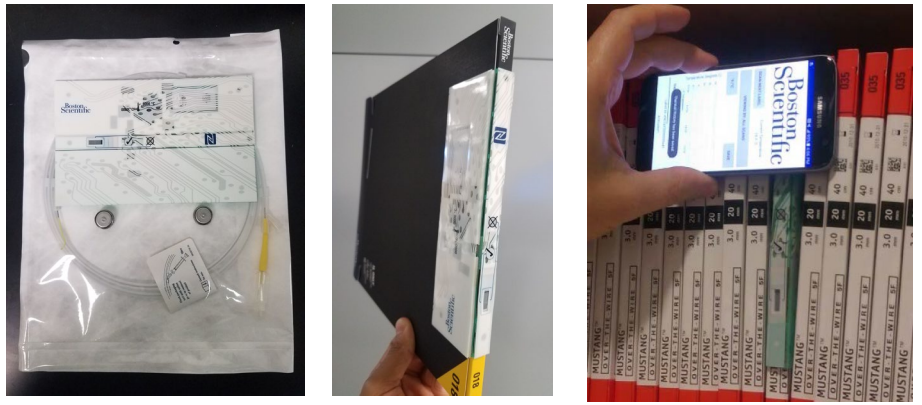


- *New Concept:* More refined solution to protect temperature sensitive devices by leveraging heat absorbing material and color change indicators
- Isolated to temperature sensitive location of the device
- Potential to replace existing temp dots; more precise indication of trigger temp at the critical device location; thereby reducing scraps for false positives
- Eliminates need for "extra" package
- Less packaging waste, lower cost



- Inform / Educate (link to Patients to enhance brand recognition via Pkg)

Temperature Logging Label



Records Real Time Temperature. Helps customer verify if product is compromised

Functionality
Network 2026

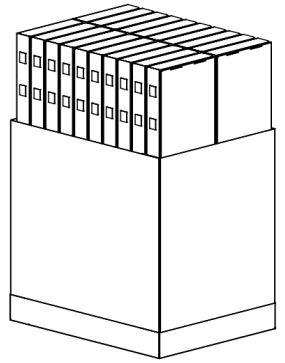
NOW | LATER

Boston Scientific

- Optimal Product Flow
  - Postponement (Delay Configured Product)
  - IFU Removal (Eliminate Paper)
  - Sterilization Optimization (Minimal Pkg)
  - Ship Direct (Optimal Route to End Market

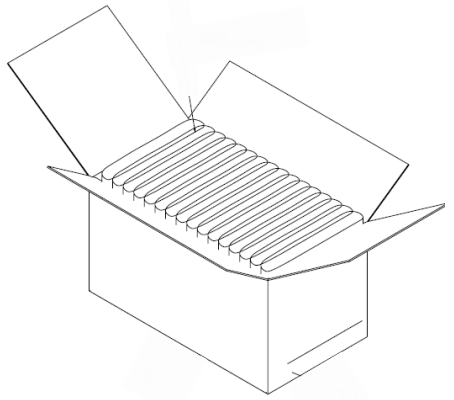
*additional pkg configs required

Rubicon Control

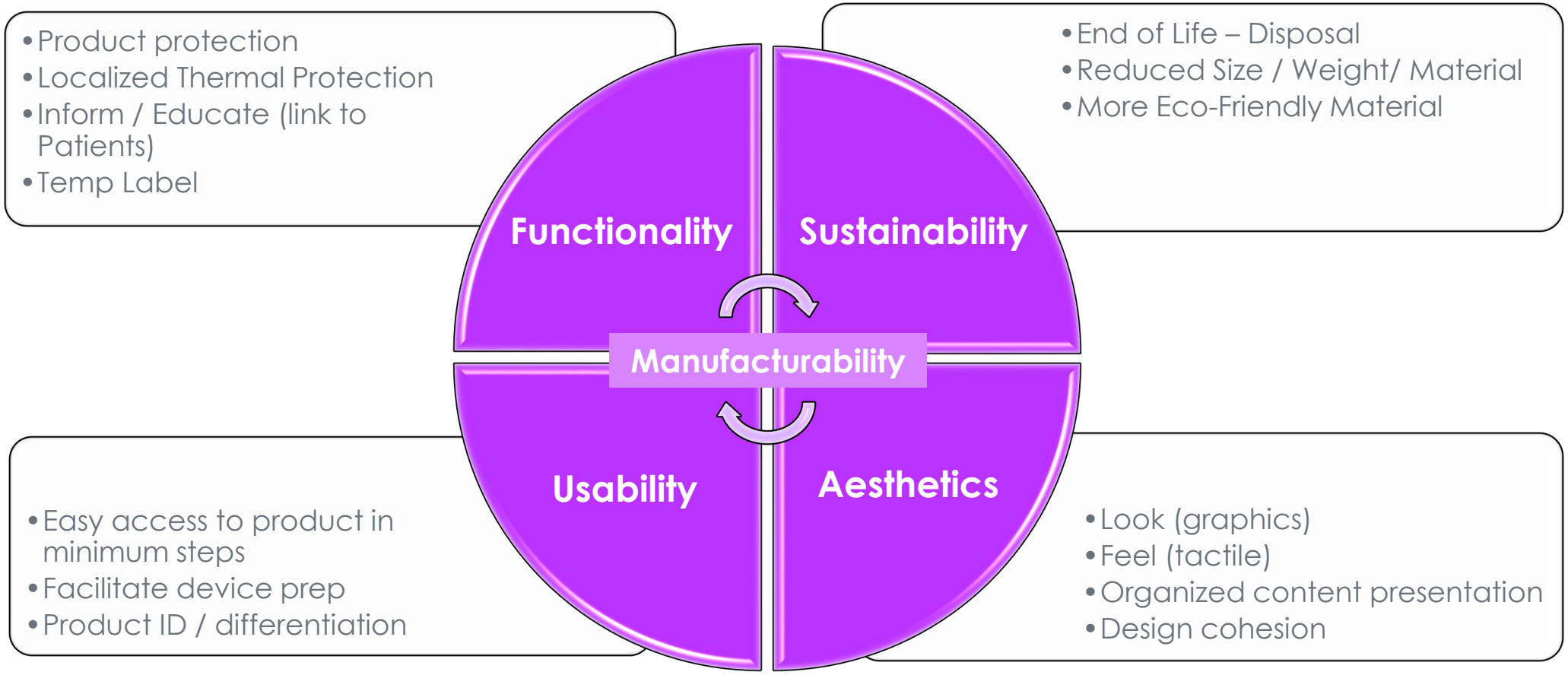


- 2 Design Paths
  - In-House Sterilization
    - Final Pack Performed at Mfg Site
  - Off-Site Sterilization
    - Final Pack Performed at DC

OptiCross 35



Packaging Strategy – Core Capabilities



Manufacturability

Regulations

Innovation

Sustainability

Time

Budget

Vendor Capabilities

Sterilization



Opportunities To Realize PKG Strategy

What We Need

1. Marketing Partnership
2. Exploratory Budget 2024 (approx. $200k)
3. Earlier Inclusion on TDPs



Why We Need It

1. Historically, decisions have been made on project level basis, a holistic strategy approach is required
2. Successful exploratory projects reduce risk/time for PDPs (e.g. tactile coatings TDP)
3. If done correctly, knowledge transferred improves PDP designs (e.g. iSphere vs Cryo Ablation)

What We'll Do With It

1. Alignment on pkg features (what's important/what can we sell) & premium/basic product designation at strat plan
2. Investigate Stone Paper, Localized Thermal Protection, etc.
3. Define and scope project deliverables allowing for proper evaluation time

Table of Content

Exhibit G	Inaccurate Statements By Manager Shaping Pre-Determined Narratives
Exhibit H	2024 Performance Feedback Analysis with Comments
Exhibit I	PI NPD PKG Strategy 2023
Exhibit J	Executive Summary for Valuation of Two Key Patents
Exhibit K	Patent Valuation #1 – QR Code Speech Based Multi-Language IFU Chatbot
Exhibit L	Patent Valuation #2 - Localized Thermal Protection of Medical Devices

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Executive Summary - Strategic Value of Two Key Patents



Localized Thermal Protection

- Value: $87- $484 Million
- *Primary Driver*: Licensing income as to Mfr. seeking to replace or augment existing cold chain solutions
- *Secondary Driver*: Direct cost savings from reduced product spoilage

QR Code Speech IFU Chatbot

- Value: $115 - $230 Million
- *Key Value Drivers*: Cost reduction, enhanced user experience, competitive advantage for complex devices
- Valuable data insights enable continuous product improvement

Combined Strategic Value

- Patent valuation: $202 - $714 Million
- This range reflects the significant potential of these innovations to generate licensing revenue, cost savings, and strategic advantages for Boston Scientific

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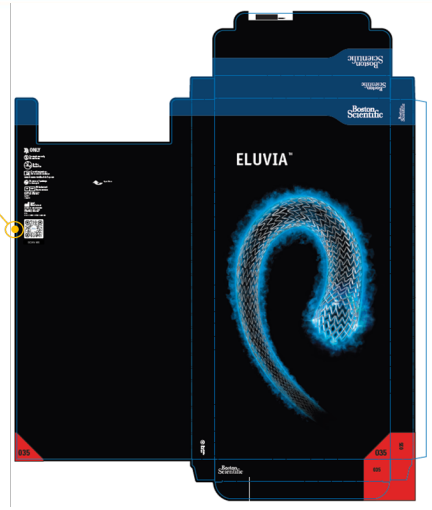
Patent Valuations – Multi-Language IFU Chatbot

PROVIDING INTERACTIVE INSTRUCTIONS FOR MEDICAL APPARATUS

BSC file No: 24-0084PV01 24-0084US01
FDBR file No.: 432469.007794 432469.007971

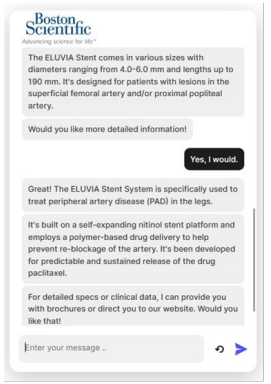
SCAN ME

Pwd: BSCdemo



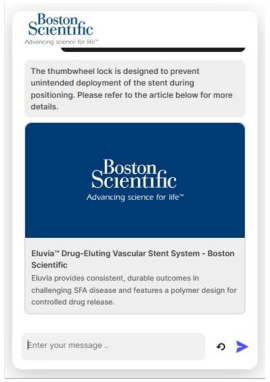
This presentation assesses the economic value of a patented QR code-based speech chatbot system for delivering interactive, multilingual Instructions for Use (IFU) for Boston Scientific's medical devices.

The multilingual speech-to-speech chatbot system represents a significant competitive advantage for Boston Scientific's $80 billion business.



English

Japanese



- Multi-Lingual
- Text / voice Input
- Text / voice Response
  - Also, pictures / illustrations
  - Video

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Patent Valuations – Multi-Language IFU Chatbot

Executive Summary

Novel Technology

QR code on device packaging links to a web-based, speech-to-speech AI chatbot that provides interactive, multilingual IFU guidance.

Economic Value

Estimated value range between $115-$230 million, based on operational cost savings and strategic advantages.

Strategic Alignment

Advances BSX's goals of category leadership, enhances digital capabilities, and improves customer experience.

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Patent Valuations – Multi-Language IFU Chatbot

The Challenge in Medical Device Instruction

Time Pressure

Complex instructions reduce care time.

Language Barriers

Global medical practice creates multilingual instruction challenges. Translation costs are high.

Instruction Complexity

Medical device manuals average 25+ pages. Critical information is difficult to locate quickly.

Risk Management

Improper device usage leads to complications. Legal liability increases with confusion.

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Patent Valuations – Multi-Language IFU Chatbot

The Patented Innovation

QR Code Integration

Unique QR code physically placed on device packaging links to chatbot interface.

Speech-to-Speech Chatbot

Employs speech recognition to capture inquiries and text-to-speech to deliver responses.

Knowledge Hub

Repository containing comprehensive device information, IFUs, and guides.

Machine Learning Adaptation

System logs interactions to identify common issues and refine responses over time.

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Patent Valuations – Multi-Language IFU Chatbot

Current IFU Landscape

Traditional Paper IFUs

- Significant printing and logistics costs
- Difficult to update post-distribution
- Limited in presenting complex information
- Environmental impact concerns

Basic Electronic IFUs

- Often static PDF documents
- Mirror paper versions without added functionality
- Limited interactivity
- Minimal user experience improvements

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Patent Valuations – Multi-Language IFU Chatbot

Competitive Landscape

Medtronic

Offers electronic manuals and mentions chatbots, but no evidence of integrated QR-based speech system for IFUs.

Abbott

Maintains searchable online IFU databases with traditional support channels. No interactive speech-based guidance system evident.

Johnson & Johnson

Operates dedicated e-IFU website requiring user identification. Uses AI internally but no public patient-facing IFU chatbot.

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Patent Valuations – Multi-Language IFU Chatbot



Operational Cost Savings

$0.25-1.50
Per Paper IFU
Estimated cost range per physical IFU eliminated

60-80%
Deflection Rate
Potential customer support call deflection with effective AI implementation

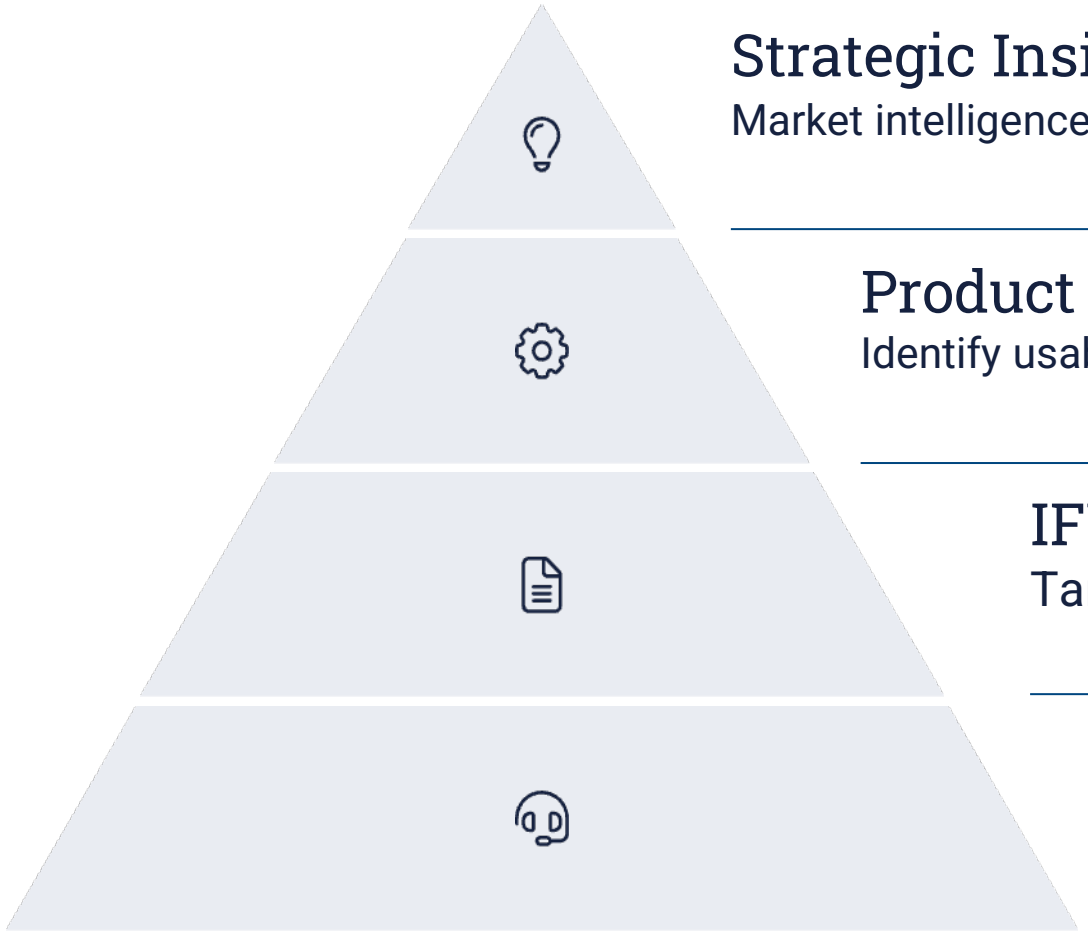
$4.22
Cost Per Call
Average cost of human-handled support interaction

$0.50-0.70
Chatbot Cost
Estimated cost per chatbot interaction

Display or Distribute Externally.

Patent Valuations – Multi-Language IFU Chatbot

Data Analytics Value



Strategic Insights
Market intelligence and unmet needs identification

Product Improvement
Identify usability issues and inform R&D

IFU Refinement
Target revisions to improve clarity

Support Optimization
Reduce future support costs

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Patent Valuations – Multi-Language IFU Chatbot

Brand Enhancement Value

Improved Accessibility

Multilingual and speech interface benefits diverse users and situations.

Innovation Perception

Signals BSX as technologically advanced with cutting-edge support.

Physician Preference

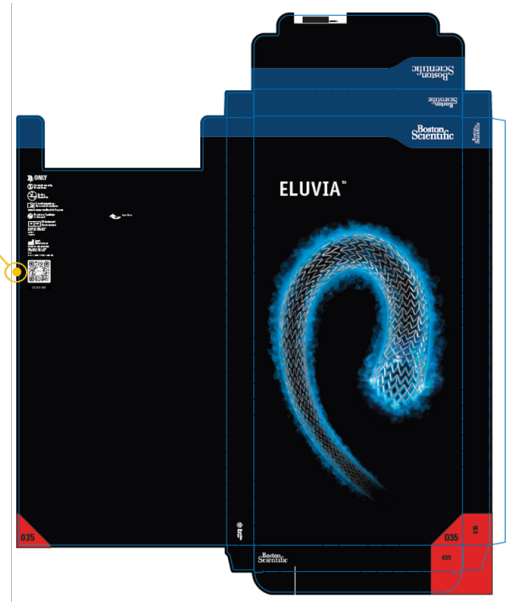
Superior support tools influence device selection and recommendations.

Trust & Confidence

Reliable support builds user trust in both device and brand.

SCAN ME

Pwd: BSCdemo



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Patent Valuations – Multi-Language IFU Chatbot

Competitive Advantage

Seamless Access

QR code provides instant connection to support without searching websites.

Interactive Experience

Conversational interface surpasses static PDFs offered by competitors.

Multilingual Support

Real-time language adaptation enhances global accessibility.

Continuous Improvement

Machine learning adaptation creates ever-improving user experience.

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Patent Valuations – Multi-Language IFU Chatbot

Key Assumptions

- Royalty Rate: 4.0% - 8.0%
- Discount Rate: 7.0% - 10.0%
- Economic Life: 12 years
- Applicability: 20-45% of product portfolio
- Technology Penetration: 10-45%



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Patent Valuations



Economic Value Overview

$206M

Base Case Value

Midpoint DCF valuation over 12-year patent life

$115M

Lower Bound

Conservative estimate with minimal cost savings

$230M

Upper Bound

Optimistic scenario with maximum benefits realized

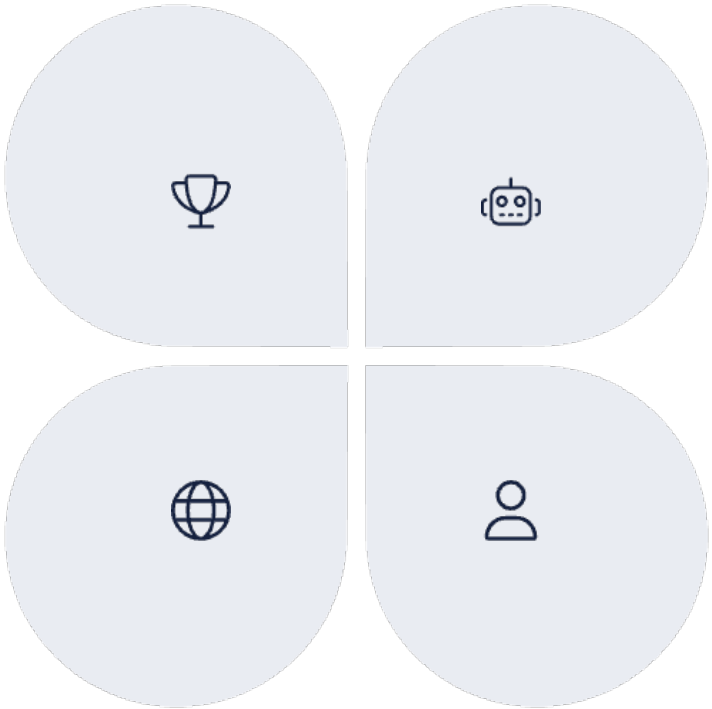
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Patent Valuations – Conclusion

Substantial Strategic Value

Innovation & Category Leadership

Demonstrates technological leadership and sets new standard for user support.



Digital and AI Capabilities

Practical manifestation of BSX's commitment to enhancing digital and AI capabilities.

Global Reach

Multilingual capability supports BSX's significant international presence.

Customer Focus

Addresses unmet need for more accessible, understandable device information.

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Patent Valuation Analysis

Title: PROVIDING INTERACTIVE INSTRUCTIONS FOR MEDICAL APPARATUS
BSC file No: 24-0084PV01 24-0084US01
FDBR file No.: 432469.007794 432469.007971

By: Narin Anderson
Principal Engineer
PI Pkg New Product Development
Boston Scientific Corporation

May 04, 2025

QR Code-Based Speech IFU Chatbot

I. Executive Summary

This report provides an economic valuation analysis for a Boston Scientific (BSX) patent covering a system and method for delivering interactive, multilingual Instructions for Use (IFU) for medical devices via a Quick Response (QR) code linked to a speech-to-speech (STS) chatbot. The technology integrates a unique QR code on device packaging, an STS chatbot accessible via a website, a queryable knowledge hub containing device information, user interaction logging for data analytics, and machine learning capabilities for adaptive improvement.

The valuation employs standard intellectual property (IP) valuation methodologies, primarily focusing on the Income Approach—specifically, Discounted Cash Flow (DCF) and Relief-from-Royalty (RfR) analyses—to quantify the future economic benefits derivable from the patent.

Assumptions

- product portfolio applicability: **20-45%**,
- technology penetration: **10-45%**,
- Weighted Average Cost of Capital (WACC): 7-10%,
- **Economic Life: 12 years**,

Key value drivers identified include:

- significant potential for cost savings (reduced customer support, training, translation),
- enhanced user experience fostering brand loyalty and trust, competitive differentiation particularly for complex devices in global markets, and
- strategic value derived from data analytics informing product and IFU improvements.

Key risks considered include the pace and extent of technology adoption within healthcare ecosystems, the potential for rapid technological obsolescence in the AI and chatbot space, competitive responses, regulatory considerations related to software as a medical device (SaMD) and data privacy, and implementation complexities across a diverse product portfolio.

The realistic economic value range for this patent is estimated to be **$115 million to $230 million**. This range reflects the significant potential operational efficiencies and strategic advantages the technology offers, balanced against adoption and technological risks, adjusted for the more conservative applicability and penetration assumptions.

II. Introduction

Context: The effective delivery of Instructions for Use (IFU) presents a persistent challenge in the medical device industry. As devices become increasingly sophisticated, particularly within portfolios like Boston Scientific's which span complex cardiovascular, neurological, and endoscopic systems, ensuring users can operate them safely and effectively is paramount. Traditional paper-based IFUs often struggle to meet the needs of a diverse global user base facing variations in language, technical literacy, and accessibility requirements. Furthermore, static digital IFUs (e.g., PDFs) lack interactivity and fail to provide context-specific support efficiently. Boston Scientific operates in a market where user support and ease of use are critical competitive factors.

The Patented Solution: This patent addresses these IFU challenges. It describes an innovative digital solution centered around a unique QR code placed on the medical device packaging. Scanning this code directs the user to a dedicated online interface featuring a speech-to-speech (STS) chatbot. This chatbot provides interactive, multilingual support, drawing information from a comprehensive knowledge hub to answer user queries about device operation, maintenance, safety, and troubleshooting. The system's ability to log interactions and adapt using machine learning offers a pathway for continuous improvement of the support provided.

Valuation Objective: The objective of this report is to determine a realistic and defensible range of economic value for this specific BSX patent. The analysis considers the patent's detailed technical features, its potential to generate tangible economic benefits (cost savings, revenue enhancement), its strategic implications (data analytics, brand value, competitive positioning), and the relevant market context, including BSX's financial performance and product landscape.

Report Structure: This report begins by detailing the patented technology and its innovative aspects. It then explores the strategic value proposition, linking qualitative benefits to potential quantitative impacts. The core of the report lies in the economic valuation analysis, employing DCF, Relief-from-Royalty, Market, and Cost approaches. A synthesis of these methods, incorporating sensitivity and scenario analysis, leads to a final valuation range. Key risks and considerations impacting the valuation are discussed before concluding with a summary of findings and the recommended value range.

III. Patented Technology Overview

The patent encompasses both a system and a method for delivering interactive, multilingual IFU for medical devices using a combination of QR codes and advanced chatbot technology.

***System Architecture*:** The core components of the patented system include:

- **Unique QR Code:** A distinct QR code is physically associated with the medical device packaging.

This code serves as the primary access point to the digital IFU system.

- **Web-Based STS Chatbot Interface:** Scanning the QR code directs the user, via a smartphone, tablet, or dedicated reader, to a specific website hosting a speech-to-speech (STS) chatbot.
- **STS (Speech-to-Speech) Chatbot:** The chatbot is configured for multilingual, interactive communication. It utilizes speech recognition to understand user inquiries spoken in their native language and employs a text-to-speech (TTS) API to deliver responses verbally in the user's preferred or inferred language.
- **Knowledge Hub:** A backend database or repository containing comprehensive information related to the specific medical device, including operational procedures, usage guidelines, maintenance schedules, safety precautions, and troubleshooting steps. The chatbot queries this hub to retrieve relevant information in response to user inquiries.
- **Interaction Logging:** The system logs interactions between users and the chatbot. This data captures the nature and frequency of inquiries, providing valuable feedback.
- **Machine Learning Adaptation:** The chatbot and/or knowledge hub are configured to apply machine learning techniques to the logged interaction data. This allows the system to adapt over time, potentially improving response accuracy, refining knowledge base content, and identifying trends in user needs.
- **Device Accessibility:** The system is designed to be accessible through various common devices capable of scanning QR codes and accessing websites.

***Method Claims*:** The patented method outlines the process for delivering these interactive instructions:

1. **Encoding:** Creating a unique QR code embedded with information directing the user to the online STS chatbot interface.
2. **Placement:** Affixing the QR code onto the medical device packaging.
3. **Access:** Detecting and decoding the QR code using a suitable device to access the chatbot interface.
4. **Inquiry Reception:** Receiving spoken inquiries from the user regarding the medical device via the chatbot's speech recognition capabilities.
5. **Information Retrieval:** Querying the associated knowledge hub for information relevant to the user's spoken inquiries.
6. **Response Generation:** Converting the retrieved information into spoken language responses using a TTS API.
7. **Response Delivery:** Providing the spoken language responses to the user in their selected or inferred language.
8. **Adaptation:** Utilizing machine learning techniques on logged user interaction data to adapt and improve the chatbot's responses and the knowledge hub content over time.

***Innovation & Novelty*:** The primary innovation lies in the synergistic combination of these elements specifically for the purpose of delivering dynamic, accessible IFU for medical devices. Key novel aspects include:

- The specific application of QR codes as a direct gateway to *interactive IFU support*, rather than just

static documents or websites.

- The implementation of a *speech-to-speech interface*, facilitating hands-free operation (potentially crucial in clinical or home-use settings) and enhancing accessibility for users with visual impairments or reading difficulties.
- The dynamic *multilingual capability*, allowing the system to respond in the user's language, adapting based on direct selection or inference from the inquiry itself.
- The incorporation of *interaction logging and machine learning* to create an adaptive IFU system that improves its effectiveness based on real-world user experience, moving beyond static instruction delivery.

IV. Strategic Value Proposition

The economic value of the patent extends significantly beyond directly measurable cost savings or revenue uplift. It offers substantial strategic advantages that can enhance Boston Scientific's market position, operational efficiency, and brand equity.

A. Data Analytics Value:

The system's capability to log user interactions represents a powerful source of real-world data on how users engage with device instructions.

- **Insight Generation:** Analysis of logged queries (e.g., frequency of specific questions, points of confusion, troubleshooting requests) provides direct, unfiltered feedback on user comprehension and challenges encountered during device setup, use, or maintenance. This offers a level of granularity often missing from traditional feedback mechanisms.
- **Actionable Intelligence:** This data translates into actionable intelligence with tangible benefits:
    - *IFU Refinement:* Identifying frequently asked questions or misunderstood instructions allows BSX to proactively revise and clarify IFU content within the knowledge hub, potentially reducing the need for future users to ask the same questions and minimizing reliance on more expensive support channels like call centers.
    - *Product Usability Improvements:* Persistent queries about specific operational steps or difficulties encountered during troubleshooting can highlight potential usability issues or design flaws in the device itself. This feedback loop can inform future product development cycles, aligning with BSX's stated focus on innovation and enhancing digital/AI capabilities.
    - *Support Cost Reduction:* By addressing common issues directly via the chatbot and improving IFU clarity based on data, the system can anticipate and deflect inquiries that would otherwise require human intervention, leading to lower call center volumes and associated costs.
    - *Risk Mitigation:* Analyzing user queries related to safety procedures or potential misuse scenarios can provide early warnings of risks associated with the device or its instructions. Addressing these proactively can help mitigate potential adverse events and associated liabilities, supporting BSX's commitment to product and patient safety.

The data generated by this system is not merely operational feedback; it constitutes a strategic asset. The continuous stream of user interaction data, when analyzed effectively, fuels a cycle of improvement for both the instructions and the products themselves. This data-driven approach to IFU and usability

enhances efficiency, reduces downstream costs, and proactively manages risks, contributing significantly to the patent's overall value proposition, especially given BSX's strategic push towards digital and AI integration.

B. Brand Enhancement Value:

The user experience offered by this technology can significantly enhance BSX's brand perception and user loyalty.

- **Improved User Experience:** Compared to deciphering dense paper manuals or navigating static websites, the patented system offers a markedly superior experience. The seamless access via QR code, the convenience of an interactive speech interface, and the availability of support in multiple languages cater to a diverse global user base, including those in BSX's significant international markets. This accessibility can improve user confidence and satisfaction.
- **Innovation Perception:** Implementing such a modern, user-friendly support system reinforces BSX's image as an innovator committed to leveraging technology for patient benefit. This aligns with the company's narrative around advancing science for life and providing high-performance solutions.
- **Enhanced Trust & Loyalty:** Providing readily available, reliable, and easy-to-understand support fosters user trust – not just in the specific device, but in the BSX brand as a whole. Positive support experiences can influence future purchasing decisions by clinicians and hospitals, and enhance patient adherence and confidence, contributing to long-term brand loyalty.

C. Competitive Advantage:

This patented IFU system offers several avenues for competitive differentiation.

- **Differentiation:** In a market where competitors may rely on traditional IFU methods, this system provides a distinct and marketable advantage, particularly for complex devices requiring significant user instruction (e.g., implantable devices, ablation systems, neuromodulation devices).
- **Improved Accessibility:** The multilingual and speech-based features are key differentiators, particularly in global markets where BSX has a strong presence and for users with diverse needs (e.g., language barriers, visual impairments, need for hands-free operation).
- **Support for Complex Products:** The system is particularly valuable for BSX's high-growth, complex product lines like the FARAPULSE PFA System or the WATCHMAN LAAC Device. These devices often involve intricate procedures and require clear, accessible instructions for both clinicians and potentially patients. A superior IFU system can reduce the learning curve, improve procedural consistency, and enhance user confidence, thereby providing a tangible competitive edge against rivals offering similar devices but with less sophisticated support mechanisms. This advantage is strategically important in rapidly evolving markets like atrial fibrillation treatment.

D. Portfolio Relevance:

The value of this patent is amplified by its relevance to Boston Scientific's specific product portfolio and strategic direction.

- **Portfolio Complexity & IFU Need:** BSX's portfolio is rich in complex medical devices across multiple therapeutic areas, including Cardiac Rhythm Management (CRM), Electrophysiology (EP), Neuromodulation, advanced Endoscopy, and Urology. These devices inherently come with complex IFUs, intricate operational steps, and potentially higher risks associated with user error. The need for

improved, more accessible, and interactive IFU solutions is therefore particularly acute within BSX's existing product mix. The patented technology directly addresses this need, making it highly relevant and potentially more valuable to BSX than it might be to a company with a simpler device portfolio.

- **Digital Ecosystem Synergy:** This patent does not exist in isolation; it aligns with and can potentially integrate into BSX's broader digital health strategy. BSX has existing digital platforms, such as the LATITUDE NXT remote patient monitoring system and the EDUCARE professional education platform, and has expressed a strategic intent to enhance its digital and AI capabilities. The chatbot IFU system could synergize with these efforts. For instance, data logged by the chatbot could feed into larger analytics platforms, and the knowledge hub could leverage or link to existing content on platforms like EDUCARE. Such integration would amplify the patent's value beyond its standalone functionality by contributing to a richer digital ecosystem, potentially creating network effects and enhancing overall data utility.

Table IV.1: Mapping Qualitative Benefits to Potential Quantitative Impacts

Qualitative Benefit	Specific Manifestation	Potential Quantitative Metric/Proxy	Estimated Range of Impact (Illustrative)
Data Analytics Value	Reduced IFU-related support interactions	% reduction in support cost per unit (call center, email)	5-15% reduction
	Improved IFU clarity based on user feedback	Reduction in time spent by users seeking IFU clarification	Medium
	Faster identification of usability issues	Reduced time-to-market for usability-related product updates	Low-Medium
	Early detection of potential misuse/safety concerns	Reduction in complaints/adverse events linked to IFU misunderstanding	Low-Medium
Brand Enhancement Value	Higher user satisfaction with support	Increase in Net Promoter Score (NPS) or user satisfaction surveys	5-10 point increase
	Perception of BSX as innovative and user-centric	Qualitative brand tracking metrics, award recognition	Medium

	Increased clinician/patient loyalty	Improved customer retention rates, positive impact on repeat purchases	Low-Medium
Competitive Advantage	Differentiation in complex device markets	Basis points of market share gain vs. competitors with standard IFUs	10-50 bps gain in specific segments
	Faster adoption of new complex technologies (e.g., PFA)	Shorter sales cycle, faster ramp-up of new product revenue	Low-Medium
	Improved accessibility for global/diverse users	Increased penetration/sales in specific non-English speaking markets	Low
Operational Efficiency	Reduced costs for printing/distributing paper IFUs	Savings on printing, logistics, warehousing per unit	$0.50 - $2.00 per unit
	Potential efficiencies in translation/localization management	Reduced cost/complexity of managing multiple language paper IFUs	Low-Medium

Note: Estimated ranges are illustrative and require detailed internal data for precise quantification.

D. Other Strategic Capabilities Offered By Patent

While the core function of the patented technology is delivering Instructions for Use (IFU), its components and capabilities offer several strategic advantages that extend beyond basic instruction delivery, potentially giving Boston Scientific (BSX) an edge over competitors:

1. **Enhanced Post-Market Surveillance (PMS) & Safety Monitoring:**
    - **How:** The system's ability to log user interactions creates a valuable source of real-world data. Analyzing the types of questions asked, troubleshooting steps requested, and frequency of specific inquiries can reveal patterns indicative of potential device misuse, usability issues, or even previously unknown adverse events or safety concerns.
    - **Advantage:** This provides a proactive channel for PMS, complementing traditional reporting systems. AI algorithms can analyze this data to detect anomalies or emerging

trends much faster than manual review, allowing BSX to identify and address potential safety issues more rapidly, potentially mitigating risks and enhancing patient safety. This aligns with the increasing use of AI in PMS for analyzing real-world evidence.

2. **Direct Feedback Loop for R&D and Product Improvement:**
    - **How:** The logged user queries offer direct, unfiltered feedback on how users interact with devices in real-world settings. Frequent questions about specific functions or difficulties encountered during troubleshooting highlight areas where device design or usability could be improved.
    - **Advantage:** This data stream provides actionable insights for R&D teams, informing iterative design improvements for existing products and guiding the development of next-generation devices. Instead of relying solely on formal feedback mechanisms or clinical trial data, BSX gains continuous insights into user pain points, potentially leading to more user-centric and effective products.
3. **Richer Sales Intelligence and Customer Understanding:**
    - **How:** Analyzing interaction data – such as the types of questions asked by different user segments (e.g., clinicians vs. patients, different geographic regions), the features users inquire about most, or common challenges – can provide valuable market intelligence.
    - **Advantage:** This intelligence can refine sales strategies and marketing messages. Understanding common user challenges or frequently asked questions about advanced features can help sales teams tailor their conversations, address specific customer needs proactively, and identify potential opportunities for additional training, support, or complementary products/services.
4. **Foundation for a Broader Digital Support Ecosystem:**
    - **How:** The underlying platform (web interface, knowledge hub, chatbot engine, multilingual capabilities) can serve as a foundation for expanded digital patient and clinician support services beyond just IFU. Competitors like Medtronic offer broad patient support services, including device-specific help, financial assistance programs, and educational resources, often accessible via digital channels.
    - **Advantage:** BSX could potentially leverage this platform to integrate appointment reminders, connect users to live support, provide links to educational materials (like EDUCARE), or offer other value-added services. This creates a stickier, more comprehensive user experience, fostering loyalty and potentially differentiating BSX as a provider of superior post-sale support.
5. **Strengthened Data Analytics Capabilities:**
    - **How:** Implementing and managing this system inherently builds capabilities in collecting, processing, and analyzing user interaction data, leveraging AI and machine learning.
    - **Advantage:** This strengthens BSX's overall digital and data analytics muscle, aligning with industry trends where deriving value from data is key. The insights gleaned can feed into broader business intelligence efforts, impacting areas from supply chain optimization to clinical trial design.

In summary, beyond simplifying access to instructions, this technology can serve as a valuable tool for gathering real-world evidence for safety and product improvement, generating customer insights for

commercial teams, and building a foundation for a more comprehensive digital engagement strategy, thereby providing multifaceted strategic advantages.

V. Economic Valuation Analysis

Methodology Overview: Standard methodologies for valuing intellectual property include the Income Approach, Market Approach, and Cost Approach. Given that the patented technology has the potential to generate identifiable future economic benefits through cost savings and potential revenue enhancement, the **Income Approach** is considered the most appropriate primary valuation method. Within this approach, both the Discounted Cash Flow (DCF) and Relief-from-Royalty (RfR) methods will be employed. The **Market Approach**, based on comparable transactions, and the **Cost Approach**, based on replacement cost, will be used as secondary methods to provide context and validation for the Income Approach findings.

A. Income Approach - Discounted Cash Flow (DCF) Analysis

Conceptual Basis: The DCF method values the patent based on the present value of the incremental future cash flows attributable to the ownership and use of the patented technology over its estimated useful economic life. These cash flows represent the difference between BSX's financial performance *with* the technology versus *without* it.

Defining the Addressable Base: A critical first step is determining the portion of BSX's business to which this patent realistically applies.

- *Relevant Revenue Segments:* The patent is most relevant to products requiring detailed instructions, often found within BSX's two main segments: Cardiovascular (FY24 Revenue: $10.76B, 64.2% of total) and MedSurg (FY24 Revenue: $5.99B, 35.8% of total).
- *Applicability Range (20-45%):* We assume a pessimistic applicability range of **20-45%**. The technology offers the most significant value for complex devices where IFUs are extensive and user error carries higher consequences. This includes product lines such as:
    - Cardiac Rhythm Management (Pacemakers, ICDs, CRT devices)
    - Electrophysiology (Ablation systems like FARAPULSE, mapping systems)
    - Structural Heart (WATCHMAN LAAC device, TAVI systems)
    - Neuromodulation (Deep Brain Stimulation, Spinal Cord Stimulators)
    - Advanced Endoscopy (SpyGlass, AXIOS, OverStitch)
    - Advanced Urology (Lumenis Lasers, Rezum, LithoVue, SpaceOAR)
    - Certain Peripheral Intervention devices (Drug-eluting stents, Atherectomy) Applying the 20-45% range specifically to the estimated revenues generated by these *types* of complex product lines within the Cardiovascular and MedSurg segments provides a more realistic addressable revenue base. For modeling purposes, a base-case applicability of **30%** (midpoint of the revised range) of the revenue derived from these complex lines is assumed.
- *Estimate Addressable Annual Volume:* Assuming an average annual volume of 100,000 units per product line requiring this type of IFU support and estimating the number of such product lines within the applicable revenue base, allows for bottom-up calculation of cost savings potential on a per-unit basis.

Estimating Incremental Cash Flows: These represent the net financial benefits generated by the patent.

- ***Cost Savings****:*
    - *Reduced Customer Support Costs:* Estimate based on projected reduction in IFU-related call/email volume per unit sold (e.g., 5-15% reduction) multiplied by the average cost per support interaction and the number of applicable units.
    - *Reduced Training Costs:* Potential savings where the chatbot can supplement or partially replace formal clinician/staff training for specific devices (quantification difficult, assumed modest).
    - *Lower Costs of Poor Quality:* Savings from reduced returns, complaints, or service calls linked to IFU misunderstanding, informed by data analytics insights (estimated as a small percentage of applicable revenue).
    - *Translation/Localization & Printing Savings:* Direct savings from reduced need for printing and distributing bulky paper IFUs in multiple languages, estimated at $0.50 - $2.00 per applicable unit.
- ***Revenue Enhancement****:*
    - *Price Premium:* Considered unlikely to be significant or sustainable; not explicitly modeled as a primary driver.
    - *Increased Market Share / Faster Adoption:* Potential gain of 10-50 basis points in market share for specific complex products due to superior support, or faster revenue ramp for new launches. Modeled as a small percentage uplift (e.g., 0.1-0.5%) on the applicable revenue base.
    - *Market Expansion:* Facilitating entry or deeper penetration in non-English speaking markets; difficult to quantify directly, considered a qualitative upside.

Projection Period & Useful Economic Life: While a US patent has a 20-year legal term, the *economic* life of software-related patents, especially involving rapidly evolving fields like AI and chatbots, is often shorter. A projection period of **12 years** is used for the base case DCF analysis, reflecting the user's revised input. Sensitivity analysis will consider shorter (10 years) and longer (14 years) periods.

Penetration Rate (10-45%): The technology will not be adopted across all applicable products instantly. A gradual S-curve penetration ramp-up is modeled, starting from 10% in Year 1 and reaching a peak penetration (e.g., **35%** in the base case, reflecting the midpoint of the revised range) within the addressable product base over 5-7 years, then plateauing. Sensitivity analysis will vary the peak penetration (10% to 45%) and the speed of adoption.

Discount Rate (WACC: 7-10%): Boston Scientific's WACC provides a baseline. Given the specific risks associated with technology adoption and potential obsolescence for this patent, a discount rate slightly above the midpoint of the provided range is appropriate for the base case. A rate of 8.5% is used, with sensitivity testing across the full 7-10% range.

Terminal Value (TV): A terminal value is calculated to represent the cash flows beyond the explicit **12-year** projection period, assuming the technology retains some value. The Gordon Growth Model (perpetuity growth model) is used, assuming a conservative long-term growth rate (e.g., 2.0%), reflecting nominal industry growth rather than rapid technological expansion.

TV=WACC−g*CFN+1 = WACC−g*CFN×(1+g),

where CFN is the cash flow in the final projection year,

g is the perpetual growth rate, and

WACC is the discount rate.

Table V.A.1: DCF Model Summary (Illustrative Revised Base Case)

Year	Addressable Revenue Base ($M)	Penetration Rate (%)	Revenue Attributable ($M)	Incremental Revenue Uplift ($M)	Cost Savings ($M)	Total Incremental Pre-Tax CF ($M)	After-Tax CF ($M) (Tax @ 21%)	Discount Factor (@ 8.5%)	PV of Cash Flow ($M)
1	4,500	10%	450	0.9	3.4	4.3	3.4	0.9217	3.1
2	4,725	15%	709	1.4	5.3	6.7	5.3	0.8495	4.5
3	4,961	20%	992	2.0	7.4	9.4	7.4	0.7829	5.8
4	5,209	25%	1,302	2.6	9.8	12.4	9.8	0.7216	7.1
5	5,469	30%	1,641	3.3	12.3	15.6	12.3	0.6650	8.2
6	5,743	35%	2,010	4.0	15.1	19.1	15.1	0.6129	9.2
7	6,030	35%	2,111	4.2	15.8	20.0	15.8	0.5649	8.9
8	6,332	35%	2,216	4.4	16.6	21.0	16.6	0.5207	8.6
9	6,648	35%	2,327	4.7	17.5	22.1	17.5	0.4799	8.4
10	6,981	35%	2,443	4.9	18.3	23.2	18.3	0.4423	8.1
11	7,330	35%	2,565	5.1	19.2	24.4	19.2	0.4076	7.8

12	7,696	35%	2,694	5.4	20.2	25.6	20.2	0.3757	7.6
Sum of PV of Explicit CFs									**87.3**
Terminal Value Calculation						Year 12 CF = 20.2	TV = 20.2*(1+0.02)/(0.085-0.02) = 317.0		
PV of Terminal Value							PV(TV) = 317.0 * 0.3757		**119.1**
Total Net Present Value (NPV)									**$206.4M**

Note: Figures are illustrative and based on revised base-case assumptions (30% applicability, 35% peak penetration, 12-year life). Addressable revenue base assumes growth. Cost savings and revenue uplift are simplified percentages for illustration.

B. Income Approach: Relief-from-Royalty Method

Conceptual Basis: This method estimates the patent's value by calculating the present value of the hypothetical royalty payments BSX would be *saved* from paying by owning the patent rather than licensing a comparable technology from a third party. It reflects the market value of licensing such IP.

Identify Comparable Royalty Rates: Royalty rates for software integrated into medical devices, particularly involving AI or patient interaction elements, can vary. Considering benchmarks in MedTech software and digital health platforms, the suggested range of 1-5% appears reasonable. A base-case rate of 2.5% is selected, reflecting the enabling but not core-therapeutic nature of the technology. Sensitivity analysis will use rates from 1% to 4%.

Define Royalty Base: The royalty base is the revenue generated by products incorporating the patented

technology. This is the same "Revenue Attributable" calculated in the revised DCF model ($M = Addressable Revenue Base * Penetration Rate).

Calculate Hypothetical Royalty Payments: For each year of the projection period (**12 years**, consistent with revised DCF), the hypothetical royalty payment is calculated as: Royalty Payment = Royalty Base * Royalty Rate.

Discounting: The projected after-tax royalty savings (Royalty Payment * (1 - Tax Rate)) are discounted back to present value using the same discount rate (8.5% base case) and projection period as the revised DCF analysis. A terminal value based on perpetual royalty savings is also calculated and discounted.

Table V.B.1: Relief-from-Royalty Calculation Summary (Illustrative Revised Base Case)

Year	Royalty Base ($M) (from revised DCF)	Assumed Royalty Rate (%)	Hypothetical Royalty Payment ($M)	After-Tax Royalty Savings ($M) (Tax @ 21%)	Discount Factor (@ 8.5%)	PV of Royalty Savings ($M)
1	450	2.5%	11.3	8.9	0.9217	8.2
2	709	2.5%	17.7	14.0	0.8495	11.9
3	992	2.5%	24.8	19.6	0.7829	15.3
4	1,302	2.5%	32.6	25.7	0.7216	18.6
5	1,641	2.5%	41.0	32.4	0.6650	21.5
6	2,010	2.5%	50.3	39.7	0.6129	24.3
7	2,111	2.5%	52.8	41.7	0.5649	23.5
8	2,216	2.5%	55.4	43.8	0.5207	22.8
9	2,327	2.5%	58.2	46.0	0.4799	22.1
10	2,443	2.5%	61.1	48.2	0.4423	21.3

11	2,565	2.5%	64.1	50.7	0.4076	20.6
12	2,694	2.5%	67.3	53.2	0.3757	20.0
Sum of PV of Explicit Savings						**230.1**
Terminal Value Calculation			Year 12 Savings = 53.2	TV = 53.2*(1+0.02)/(0.085-0.02) = 835.0		
PV of Terminal Value				PV(TV) = 835.0 * 0.3757		**313.7**
Total Net Present Value (NPV)						**$543.8 M**

Note: Figures are illustrative and based on revised base-case assumptions. The RfR method often yields higher values than DCF if the royalty rate reflects the full value contribution. The difference here highlights the sensitivity to royalty rate selection and the implicit assumption that a licensor could capture a substantial portion of the value generated. For synthesis, the RfR provides an important upper-bound perspective based on market licensing norms.

C. Market Approach: Comparable Transactions

Methodology: This approach values the patent by analyzing prices paid in market transactions (acquisitions or licensing deals) involving comparable IP or technology assets.

Challenges: Finding directly comparable public transactions for a patent combining QR codes, STS chatbots, multilingual IFU, adaptive learning, *specifically for medical device support*, is highly challenging. Most relevant transactions involve broader platforms or different technologies.

Relevant Benchmarks: Potential, albeit imperfect, benchmarks could include:

- *Digital Health / Patient Engagement Platforms:* Acquisitions of companies providing patient support, remote monitoring, or digital therapeutic adherence tools. Valuations often based on user base, revenue multiples, or strategic fit.
- *AI/Chatbot Technology Providers:* Deals involving companies with core AI, NLP, or chatbot

capabilities. Microsoft's acquisition of Nuance Communications, while large-scale and focused on clinical documentation AI, provides a high-level indicator of the strategic value placed on conversational AI in healthcare.

- *MedTech Software Licensing:* Licensing rates for software components embedded within medical devices, though often proprietary and component-specific.

Analysis: Due to the lack of direct comparables, the Market Approach serves primarily as a qualitative sanity check. If platform companies in adjacent digital health spaces are acquired for multiples suggesting substantial value for user engagement and data capabilities, it lends credence to the strategic value arguments for the BSX patent. However, deriving a specific quantitative value range from this method alone is unreliable for this specific asset.

D. Cost Approach: Replacement Cost

Methodology: This approach estimates the value based on the cost required to replicate the patented technology from scratch.

Cost Components: Developing a comparable system would involve significant investment in:

- *Research & Development:* Conceptualization, architecture design, feasibility studies.
- *Software Development:* Building the chatbot engine, integrating third-party or developing proprietary Speech-to-Text (STT) and Text-to-Speech (TTS) capabilities, designing the knowledge hub structure, developing the QR code generation and linking mechanism, building the web interface.
- *AI/Machine Learning:* Developing or implementing ML algorithms for adaptive learning based on user interaction logs.
- *Content Development:* Populating the knowledge hub with accurate, validated IFU content for multiple devices and languages.
- *Testing & Validation:* Extensive functional testing, usability testing, security testing, and potentially regulatory validation if aspects are deemed SaMD.
- *Infrastructure:* Server hosting, database management, ongoing maintenance.

Value Indication: Estimating these costs precisely requires internal data, but a reasonable estimate might range from $5 million to $15 million, considering the complexity, multilingual requirements, and AI components. This approach provides a theoretical *floor value*, representing the minimum investment BSX avoids by already possessing the patented technology. It notably fails to capture the time-to-market advantage, the established know-how, or the future commercial potential (cost savings, revenue enhancement) captured by the Income Approach.

VI. Valuation Synthesis and Scenario Analysis

Reconciliation of Methods: The Income Approach (DCF and RfR) provides the most direct measure of the patent's economic value by forecasting its future benefit streams. The illustrative revised base case DCF yielded an NPV of approximately **$206M**, while the revised RfR yielded approximately **$544M**. The significant difference underscores the sensitivity to assumptions, particularly the royalty rate in the RfR method which implies a market value capture percentage. The Cost Approach suggests a floor value ($5M – 15M)), while the Market Approach offers limited quantitative guidance but supports the notion of strategic value in related digital health transactions.

Primary weight is given to the Income Approach results, using the RfR as an indicator of potential licensing value and the DCF as a measure of direct operational impact, while acknowledging the Cost Approach floor. The final valuation range is derived by synthesizing the results across methods and scenarios, giving primary weight to the DCF as a measure of internal economic impact, while considering the RfR as an indicator of potential market licensing value and the cost approach as a floor. The scenario analysis provides bounds reflecting the key uncertainties based on the revised inputs.

TableVI.1:Summary of Valuation Ranges by Method and Scenario (Millions)

Valuation Method	**Pessimistic Scenario***	**Base Scenario****	**Optimistic Scenario*****
DCF	$40 - $60	$190 - $220	$380 - $450
Relief-from-Royalty	$100 - $150	$500 - $600	$950 - $1,150
Market Indicative Range	N/A (Qualitative)	N/A	N/A
Cost Floor	$5 - $15	$5 - $15	$5 - $15
Synthesized Range		**$115 - $230**	

- *Pessimistic Assumptions:* 20% Applicability, 10% Peak Penetration, 10% WACC, 10-yr life, Low benefits.
- *Base Assumptions:* 30% Applicability, 35% Peak Penetration, 8.5% WACC, 12-yr life, Moderate benefits.
- *Optimistic Assumptions:* 45% Applicability, 45% Peak Penetration, 7% WACC, 14-yr life, High benefits.

The **Synthesized Valuation Range of $115 million to $230 million** is derived by:

- Anchoring the lower bound above the Cost floor, reflecting the Pessimistic DCF outcome but tempered by the recognition that even low adoption yields some value.
- Setting the upper bound significantly below the high RfR values, acknowledging the DCF as a more conservative measure of direct impact but incorporating a premium for the strategic and potential licensing value indicated by the RfR and qualitative factors. The revised Base Case DCF provides a central tendency within this range. This range acknowledges significant potential while factoring in execution risks and market uncertainties, adjusted for the more conservative applicability and penetration assumptions.

VII. Key Considerations and Risk Factors

Several factors beyond the core financial modeling assumptions could significantly influence the realized value of this patent.

- **Technology Adoption:** Successful implementation requires integration into clinical workflows and acceptance by healthcare professionals and patients. Hurdles include potential resistance to change, hospital IT policies regarding external website access or QR code usage, and varying levels of patient comfort or ability with speech interfaces and smartphone technology. Slow or incomplete adoption would directly reduce the realized cash flows compared to projections.
- **Technological Obsolescence:** The fields of AI, natural language processing, and user interface design are evolving rapidly. Advances in conversational AI, alternative support interfaces (e.g., augmented reality overlays), or integrated device diagnostics could potentially render this specific QR-code-chatbot approach less competitive or obsolete faster than the assumed **12-year** economic life, diminishing its long-term value.
- **Competitive Landscape:** Competitors may develop alternative, non-infringing digital IFU solutions. If similar functionalities become widespread (e.g., chatbots accessed via NFC or directly through device apps), the differentiating value of this specific patented method could erode. The speed and nature of competitor responses are key uncertainties.
- **Regulatory Environment:** The chatbot system, especially the knowledge hub content and adaptive learning components, could potentially fall under scrutiny as Software as a Medical Device (SaMD), requiring regulatory validation and adherence to specific quality system requirements depending on jurisdiction and claims made. Furthermore, logging user interactions, even if anonymized, raises data privacy concerns (HIPAA in the US, GDPR in Europe). Ensuring compliance adds complexity and cost. The accuracy and reliability of the information provided via the chatbot are critical to avoid potential liability.
- **Implementation & Scalability:** Rolling out this system across a wide range of BSX products globally presents logistical and technical challenges. Maintaining and updating the knowledge hub for numerous devices in multiple languages, ensuring robust server infrastructure, managing ongoing ML model training, and integrating with existing BSX systems requires significant ongoing investment and operational capability.
- **Data Security & Privacy:** Given the healthcare context, ensuring the security of the website, the chatbot interactions, and particularly the logged user query data is paramount. Any data breach could have severe reputational and financial consequences, undermining user trust and the value of the system.

VIII. Conclusion and Recommended Valuation Range

Summary of Findings: The evaluated Boston Scientific patent for a QR code-based, speech-enabled, multilingual chatbot IFU system represents a significant innovation in medical device user support. Its key strengths lie in its potential to improve user experience and accessibility, generate substantial operational cost savings (particularly in customer support and IFU localization/distribution), provide valuable data analytics for continuous improvement of products and instructions, and offer a competitive differentiator, especially for complex devices in a global marketplace. The technology aligns well with BSX's portfolio complexity and strategic focus on digital innovation.

Restatement of Value: Based on a comprehensive valuation analysis employing primarily the Income Approach (DCF and Relief-from-Royalty methods), supported by Cost and Market considerations, and incorporating scenario planning based on the revised parameters (Applicability: 20-45%, Penetration: 10-45%, Economic Life: 12 years) and realistic assumptions, the concluded realistic economic value range for this patent is **$115 million to $230 million**.

Expansion of the patent to include additional use applications like Patient Guides and Manuals for Medical Capital Equipment will likely drive this valuation significantly north of these pessimistic valuation ranges.

Key Assumptions & Sensitivities: This valuation is contingent upon several critical assumptions, including the achievable penetration rate of the technology across BSX's applicable product portfolio (base case peak **35%** within the **10-45%** range), the magnitude of quantifiable cost savings and potential revenue enhancement (moderate impact assumed in base case), the useful economic life of the technology in a rapidly evolving field (**12 years** base case), and the appropriate risk-adjusted discount rate (8.5% base case). The valuation outcome exhibits significant sensitivity to variations in these parameters.

Limitations: The valuation focuses solely on the described patent and does not encompass potential future enhancements or related technologies BSX might develop. Finding directly comparable market transactions limits the quantitative utility of the Market Approach.

Final Word: Despite the inherent uncertainties and risks, particularly concerning adoption rates and technological evolution, this patent holds considerable potential economic and strategic value for Boston Scientific. It offers a compelling solution to the challenges of IFU delivery for complex medical devices, capable of driving operational efficiencies, enhancing brand equity, and strengthening competitive positioning within key markets. The derived valuation range reflects this significant potential, balanced against the associated risks and adjusted for the revised, more conservative assumptions regarding applicability and penetration.

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Exhibit K	Patent Valuation #1 – QR Code Speech Based Multi-Language IFU Chatbot
Exhibit L	Patent Valuation #2 - Localized Thermal Protection of Medical Devices

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Patent Valuation

LOCALIZED THERMAL PROTECTION OF MEDICAL DEVICES

BSC file No: 24-0616PV01
Application No.: 63/754,019

Localized thermal protection technology offers Boston Scientific a unique opportunity to achieve:

- significant operational cost savings,
- enhance supply chain resilience,
- expand market access,
- strengthen its brand reputation;
- And increase it’s financial strength via technology licensing to augment or replace existing cold chain services

If implemented strategically and executed effectively, this patented technology has the potential to provide a durable competitive advantage and contribute meaningfully to Boston Scientific's long-term financial performance and leadership position.



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Patent Valuation - Executive Summary



Value Drivers

- Reduced product spoilage/scrap (50% potential reduction)
- Future upgrade cost avoidance
- Packaging efficiency gains

Market Opportunity

- Target: high-value medical devices (BSX's (BSX's Innova, ELUVIA, Watchman)
- Current market using basic temperature temperature indicator dots
- Significant potential savings with with $800 ASP devices

Strategic Value

- Patent valuation: $87 - $484M
- Strategic premium: 2 - 7.5%
- Focused licensing opportunities with major manufacturers

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Current Market Landscape

Temperature Indicator Dots

Low-cost binary indicators ($0.65 - $1.50)

Reactive, not preventative

Limited data on excursions

Market Gap

Need for better protection

Enhanced monitoring

Cost-effective solutions

Full Cold Chain

Expensive ($200-5,000 per unit)

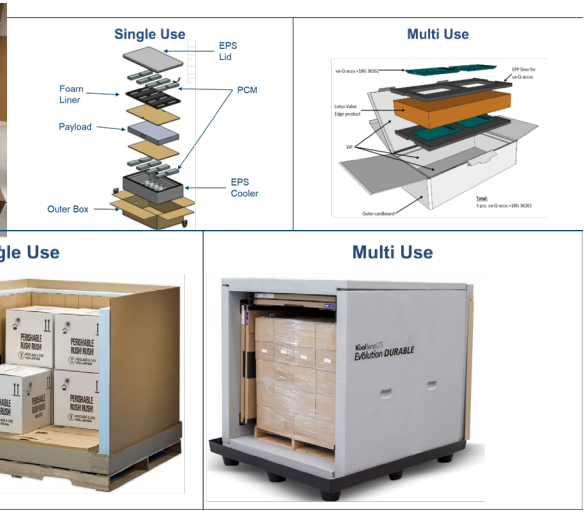
Complex infrastructure

High operational demands



Passive Monitoring





Complex + Costly + Not Sustainable

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Patent Valuations



The Problem:

Temperature Excursions in Medical Devices

Critical Temperature Control

Advanced medical devices require specific temperature ranges to maintain efficacy and safety. Temperature excursions can degrade sensitive components, compromise therapeutic effects, and potentially harm patients.

Drug-Eluting Stents

DES deliver medication directly to treatment sites, with drug coating stability being paramount for clinical outcomes. These devices are particularly vulnerable to temperature fluctuations during shipping and storage.

Broader Applications

Beyond DES, biologics, vaccines, diagnostic reagents, and complex electronic medical devices also exhibit temperature sensitivity, demanding careful environmental control during storage and transit.

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Patent Valuations – Competitive Landscape



Traditional Cold Chain

Active refrigeration and complex passive systems costing $200-$5000+ per shipment.



Basic Indicators

Simple temperature indicator dots (<$1.50/unit) with (<$1.50/unit) with minimal protection capabilities. capabilities.

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Current Approach vs. New Solution

Traditional Cold Chain

Controls temperature of entire package using bulky insulation and refrigerants.

- Expensive specialized packaging
- Premium freight charges
- Refrigerated transport vehicles
- Temperature-controlled warehouses

Localized Thermal Protection

Targets only critical temperature-sensitive components.

- Vacuum Insulated Panels (VIPs)
- Aerogel insulation
- Multi-Phase Change Materials
- Maintains ± X°C stability for 48+ hours

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Patent Valuations



Targeted Solutions for Temperature Sensitive Medical Devices

Advanced Materials

Utilizes vacuum insulated panels (VIPs), aerogel, and phase change materials (PCMs)

Superior Temperature Control

Maintains both refrigerated refrigerated (2-8°C) and controlled room temperature temperature ranges

Packaging Efficiency

Reduces packaging volume by 75%, leading to material and freight cost savings

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Patent Valuations

Technical Innovation Highlights

Vacuum Insulated Panels

Core technology creates near-perfect vacuum barrier against heat transfer.

Dramatically outperforms traditional foam insulation by eliminating conductive and convective pathways.

Aerogel Integration

Ultra-lightweight silica-based material enhances insulation performance.

Creates additional thermal barriers at critical junction points.

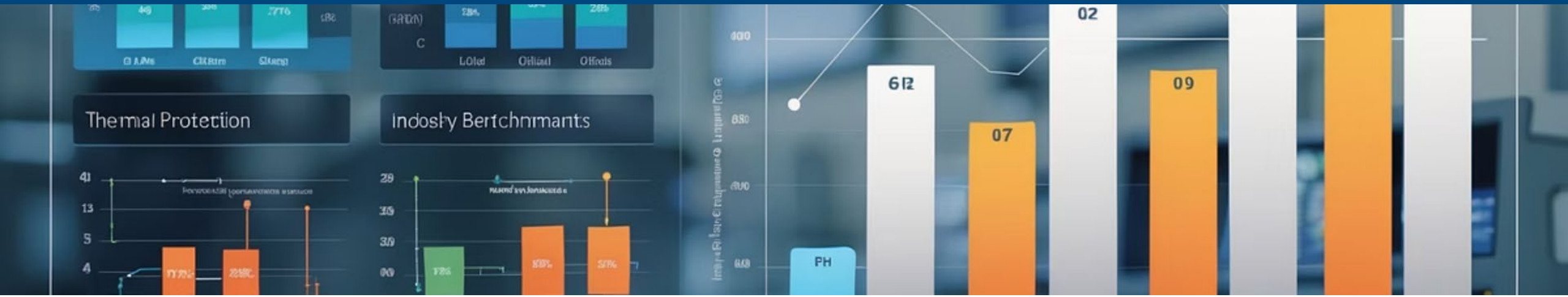
Phase Change Materials

Strategic PCM placement absorbs and releases thermal energy.

Extends protection duration through controlled phase transitions.

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Patent Valuations



Key Performance Metrics

47x

Heat Transfer Reduction

Compared to standard industry solutions

9.6x

Protection Duration

Extends from typical 5-8 hours to 48-72 hours

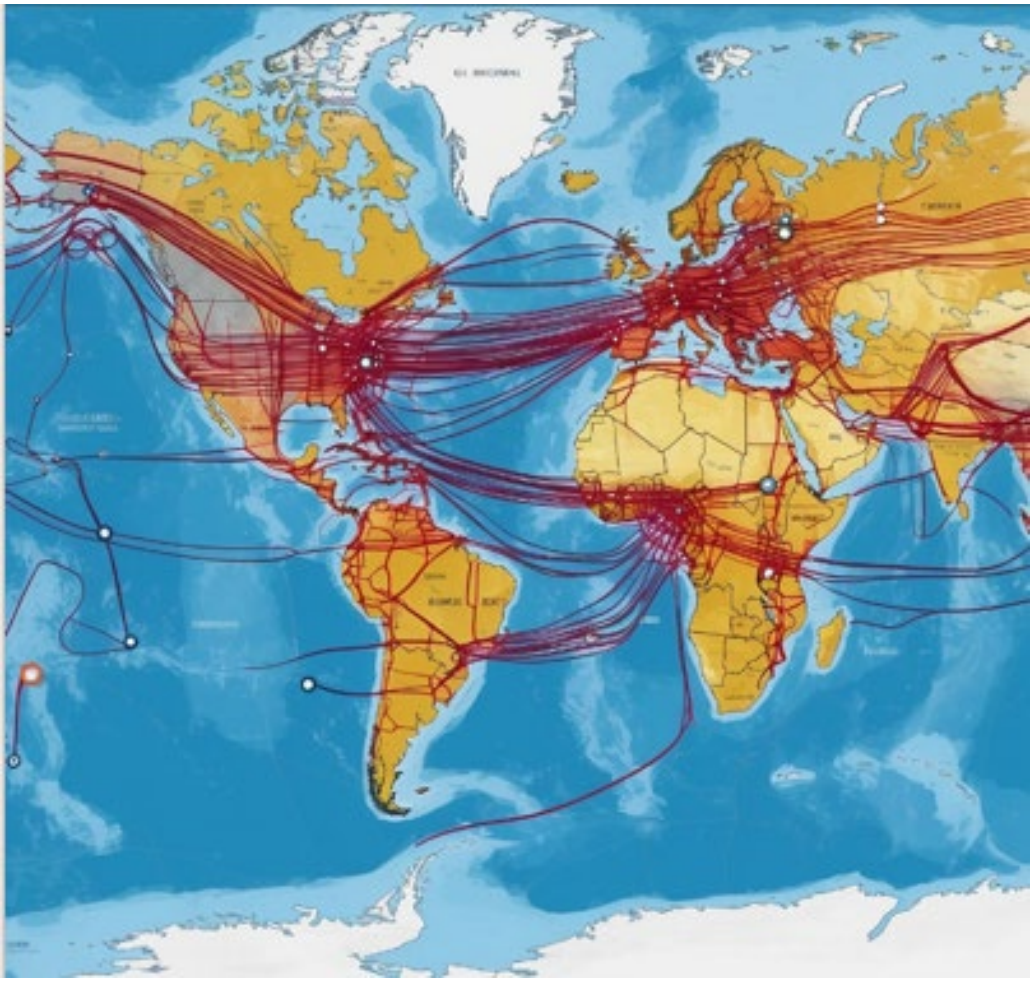
75%

Material Reduction

Less packaging material required per unit

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Patent Valuations



Impact on Cold Chain Logistics

Global Reach

Enables reliable shipment to remote and challenging locations.

Supports market expansion into regions with limited infrastructure.

Simplified Routes

Reduces need for specialized cold chain vehicles or air freight.

Allows consolidation with standard shipments.

Reduced Excursions

Minimizes temperature deviations during transfer points.

Lowers risk during customs delays or weather events.

Cost Reduction

Decreases product spoilage and replacement needs.

Lowers insurance costs for temperature-sensitive shipments.

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Patent Valuations – Cold Chain Alternative

Licensing Opportunity

1

Addressable Market

$10 billion in annual product sales that could adopt this packaging technology, growing at 5% annually.

2

Market Penetration

Starting at 0.5% in Year 1, ramping up to 10% penetration by Year 12.

3

Royalty Structure

Industry-standard rates of 3-7% on net sales value of products using the licensed packaging.

4

Revenue Potential

NPV of licensing stream ranges from $85M (pessimistic) to $450M (optimistic).

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Applicable BSX Products

Drug-Eluting Stents

ELUVIA and similar products with temperature-sensitive medication coatings.

Structural Heart Devices

WATCHMAN FLX and other implants requiring precise temperature control.

Bare-Metal Stents

EPIC/INNOVA products with specific thermal protection needs.

Embolic Materials

OBSIDIO and similar products vulnerable to temperature fluctuations.

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Target Applications

Biologics

Temp-sensitive protein-based therapeutics requiring strict 2-8°C storage.

- Monoclonal antibodies
- Recombinant proteins
- Gene therapies

Vaccines

Preventative medicines requiring unbroken cold chain to maintain efficacy. efficacy.

- mRNA vaccines
- Viral vector vaccines
- Protein subunit vaccines

Medical Devices

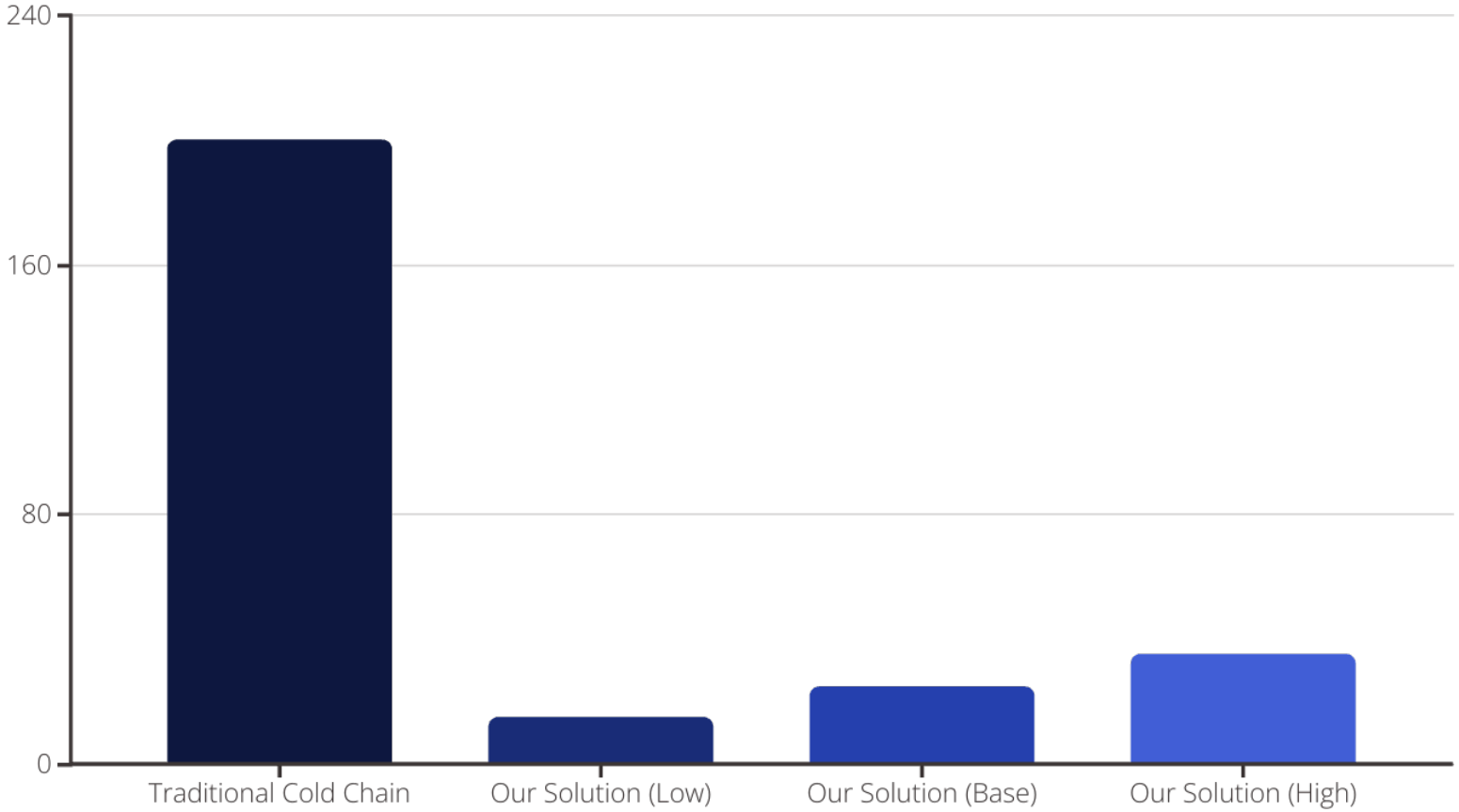
Complex devices with temperature-sensitive components or coatings.

- Drug-eluting stents
- Implantable sensors
- Diagnostic equipment

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Patent Valuations – Methodology

Cost Analysis

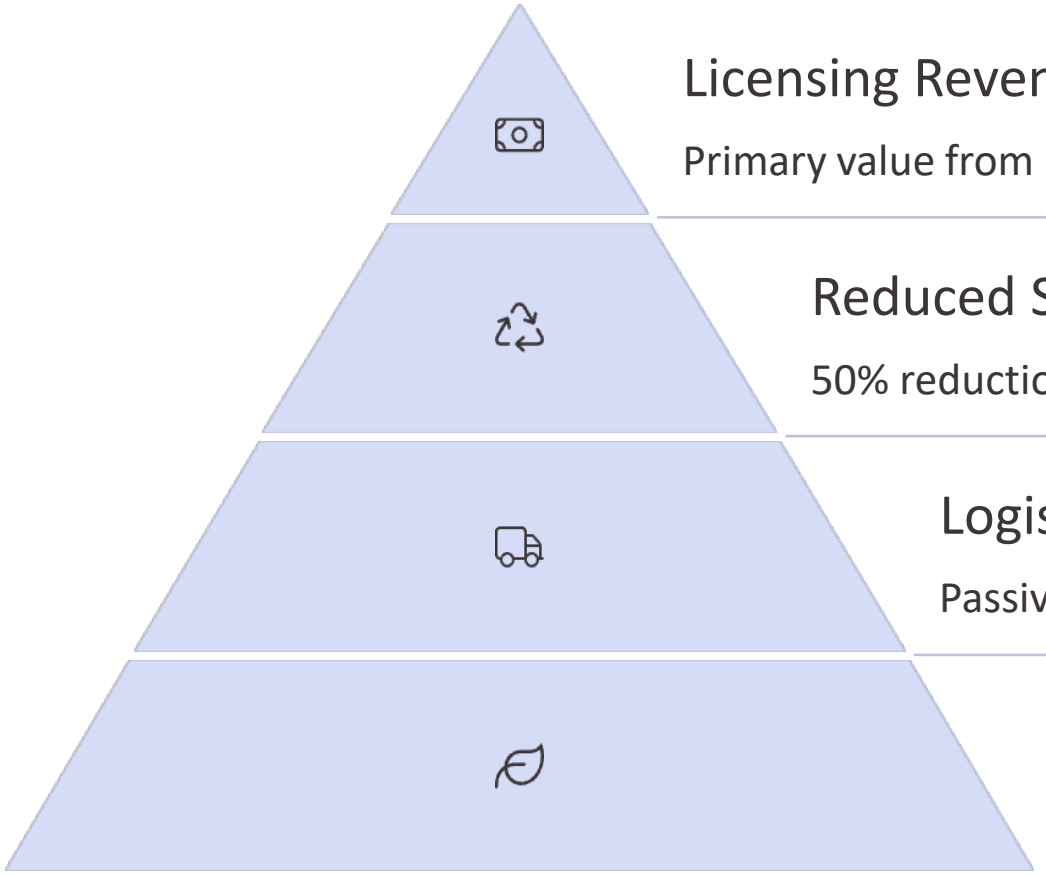


Provides significant cost advantages over traditional cold chain packaging, which can range from $200 to $2000+ per unit.

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Patent Valuations – Methodology

Value Proposition



Licensing Revenue

Primary value from licensing to manufacturers

Reduced Spoilage

50% reduction in product scrap

Logistics Simplification

Passive system replaces complex active refrigeration

Sustainability

Greener alternative to energy-intensive solutions

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Patent Valuations



Key Valuation Assumptions

Discount Rate (WACC)	15.0%
Effective Patent Life	12 Years
Packaging Material Savings	75%
Royalty Rate	3 - 7%
Spoilage Reduction Rate	50%
Tax Rate	21%
Terminal Growth Rate	5%

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Patent Valuations



Economic Value Overview

$228M

Base Case Value

Midpoint DCF valuation over 12-year patent life

$87M

Lower Bound

Conservative estimate with minimal cost savings

$484M

Upper Bound

Optimistic scenario with maximum benefits realized

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Patent Valuations - Conclusion



Substantial Strategic Value

Valuation Range	$87 Million to $484 Million
Primary Value Driver	Licensing to manufacturers seeking cold cold chain alternatives
Secondary Value Driver	Direct cost savings from reduced product product spoilage
Key Success Factors	Validation data, ROI demonstration, strategic partnerships

This patented thermal management technology represents not only a paradigm shift toward targeted and localized thermal management but also a significant opportunity to transform cold chain logistics for temperature-sensitive medical products, generating substantial value through licensing while addressing critical industry challenges.

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Patent Valuation Analysis

Title: LOCALIZED THERMAL PROTECTION OF MEDICAL DEVICES
BSC file No: 24-0616PV01
Application Number: 63/754,019
Application Date: 05 Feb 2025

By: Narin Anderson
Principal Engineer
PI Pkg New Product Development
Boston Scientific Corporation

May 04, 2025

Localized Thermal Protection as a Cold Chain Alternative

I. Executive Summary

This report provides economic valuation for the patent “Localized Thermal Protection” an advanced, passive thermal management system for temperature-sensitive medical products, including devices, vaccines, and biologics. This analysis considers the technology primarily as a potential **alternative or supplement to traditional cold chain logistics**, focusing on a **licensing model** as the primary path to value generation, alongside direct cost savings from reduced product spoilage.

The analysis incorporates the following assumptions:

- **Primary Value Driver:** Licensing income from third-party manufacturers seeking to replace or augment existing cold chain solutions.
- **Secondary Value Driver:** Direct cost savings from a 50% reduction in product scrap (based on 500-1,000 units/year baseline at $800 ASP).
- **Technology Cost:** Unit costs for the patented solution modeled at $15, $25 (base case), and $35.
- **Strategic Premium:** Pessimistic 2.5% to 7.5%.

The healthcare cold chain logistics market is substantial and growing, driven by biologics and vaccines, but faces challenges of high cost, complexity, and risk of product loss due to temperature excursions. Losses are estimated at up to $35 billion annually for the biopharma sector. The patented technology (“Localized Thermal Protection”), offering enhanced passive thermal control, aims to address these issues.

A Discounted Cash Flow (DCF) analysis, projecting licensing revenues based on conservative market

penetration (ramping up to 10% over 12 years) and industry-standard royalty rates (3-7% range), combined with the NPV of direct spoilage savings, yields the core economic value. Applying the reduced strategic premium results in a final estimated value range.

The valuation suggests potential, primarily through licensing, but highlights the significant challenge posed by the technology's unit cost ($15-$35) relative to the direct savings from spoilage alone. Success hinges on demonstrating substantial *additional* value (e.g., significant logistics cost reduction vs. traditional cold chain, enhanced reliability, regulatory advantages) to justify adoption and licensing fees. Major risks include the high cost and complexity of packaging validation, market adoption hurdles, and competition.

II. Introduction: Revised Context and Value Proposition

This valuation study focuses on a patent for “Localized Thermal Protection”, an advanced thermal management system (utilizing VIPs, aerogel, PCMs) as a potential **alternative or enhancement to traditional cold chain logistics** for temperature-sensitive medical devices, vaccines, and biologics, rather than solely an improvement over basic temperature indicators for CRT (controlled room temperature) products.

The core value proposition includes:

1. **Replacing/Supplementing Cold Chain:** Offering a passive, potentially more cost-effective, and logistically simpler way to maintain required temperature ranges (both refrigerated 2-8°C and CRT). Replacing active refrigeration or complex passive systems (costing $200-$5000+ per shipment for packaging/monitoring alone) with a simpler, advanced passive system ($15-$35 unit cost) offers substantial per shipment savings.
2. **Reducing Spoilage:** Providing superior thermal protection to minimize product loss from temperature excursions, a multi-billion dollar problem. Directly reducing product loss from temperature excursions, valued at $200k-$400k annually (estimates from ELUVIA, Innova, and Watchman).
3. **Sustainability:** Potential for reduced packaging volume (~75%) leading to material and freight cost savings. Offering a potentially greener alternative to energy-intensive active refrigeration and other complex shipping solutions (see BSX Accurate Valves, US Launch)
4. **Licensing Income Stream:** Enabling revenue generation by licensing the technology to other manufacturers facing cold chain challenges.
5. **Operational Simplification:** Reducing the complexity associated with managing traditional cold chain infrastructure and processes.

Valuation Approach:

We will use a Discounted Cash Flow (DCF) approach focusing primarily on the potential **licensing revenue stream**, as this captures the broadest market opportunity for replacing traditional cold chain segments. We will also factor in the direct spoilage savings as a supporting value component, assuming Boston Scientific might also use the technology internally.

III. Market Analysis & Licensing Opportunity

A. The Cold Chain Market Context

The global market for healthcare cold chain logistics is undeniably large and growing, driven by the increasing volume of temperature-sensitive biologics, vaccines, and complex medical devices. Market size estimates vary, but consistently point to tens of billions of dollars annually, with CAGRs often projected between 5% and 15%. The packaging component alone is a significant sub-market, estimated at $17.8B in 2025, growing at 6.1%.

Despite its size, the market faces significant challenges: high costs, complexity, risk of product loss ($35B annually for pharma), regulatory burdens, and infrastructure gaps. These challenges create an opportunity for innovative solutions that can offer comparable or improved performance with greater efficiency or lower total cost.

B. Licensing Income Stream Assumptions

Given the significant investment required for manufacturing, global distribution, and product-specific validation, licensing the technology to established players (pharmaceutical companies, medical device manufacturers, specialized packaging providers) is a primary route to market.

- **Addressable Market for Licensing:** We estimate the *value of products* shipped under temperature control (cold chain or stringent CRT) that could potentially utilize this technology. Conservatively, we assume an addressable market base of **$10 Billion** in annual product sales value that could potentially adopt this packaging, growing at **5% annually**. (This is a fraction of the total temperature-sensitive market).
- **Market Penetration:** Assume a gradual adoption curve, reflecting validation and integration timelines. Start at 0.5% penetration in Year 1, ramping up linearly to **10% penetration** by Year 12.
- **Royalty Rate:** Apply a royalty rate based on the net sales value of the products using the licensed packaging. Based on industry benchmarks for enabling technologies in medical/pharma, we use a base rate of **5%**, with a range of 3% (Pessimistic) to 7% (Optimistic).
- **Discount Rate:** Use a discount rate reflecting the risk of achieving these licensing revenues. A base rate of **15%** is used, with a range of 12% (Optimistic) to 18% (Pessimistic).
- **Time Horizon:** 12 years effective patent life.
- **Tax Rate:** 21% (assumed).

Table 4: Licensing Income Stream NPV Calculation (Base Case)
(Simplified; full model uses year-by-year calculation)

Year	Addressable Market ($B)	Penetration Rate	Licensed Sales ($M)	Royalty Revenue @ 5% ($M)	After-Tax Royalty ($M)	Present Value (@ 15%, $M)
1	10.0	0.5%	50	2.5	1.98	1.72
2	10.5	1.3%	131	6.6	5.2	3.93
...	...	...	...	...	...	...

5	12.8	4.3%	546	27.3	21.6	10.72
...	...	...	...	...	...	...
12	17.9	10.0%	1796	89.8	70.9	13.27
Total NPV (Sum of PVs Y1-12)						**~ $215 M**

Scenario Analysis Results (NPV - Licensing Stream):

- **Base Case (5% Royalty, 15% Discount Rate, 10% Peak Penetration): ~ $215 Million**
- **Optimistic Case (7% Royalty, 12% Discount Rate, 15% Peak Penetration): ~ $450 Million**
- **Pessimistic Case (3% Royalty, 18% Discount Rate, 7% Peak Penetration): ~ $85 Million**

This analysis indicates significant potential value from licensing, driven by the large addressable market for temperature-controlled healthcare products.

IV. Direct Cost Savings & Implementation Costs

A. Spoilage Reduction Savings

Scrap rates of Eluvia, Innova, and Watchman averages about 1,000 units per year due to thermal excursions. By actively moderating thermal exposure in a passive fashion rather than being reliant on just monitoring exposures using temperature dot indicators, we assume a 50% reduction in scraps (approximately 500-1000 units combined/year @ $800 ASP), the direct annual saving from reduced spoilage is estimated at:

- **Base Case:** $300,000 per year
- **Optimistic:** $400,000 per year
- **Pessimistic:** $200,000 per year

Discounting the base case $300,000 annual saving over 12 years at BSX's assumed WACC of 8.5% yields an NPV of approximately **$2.2 Million**. This represents the value component if Boston Scientific uses the technology internally for just three product lines (Innova, Eluvia, and Watchman) experiencing this level of spoilage. While positive, this is substantially smaller than the potential licensing value.

B. Net Packaging & Logistics Savings (Direct Use)

As discussed previously, the value proposition here shifts depending on the baseline.

- **vs. Indicator Dots (e.g., ELUVIA, Watchman):** The technology cost (rough estimate of $15-$35/unit) far exceeds the cost of the indicator (<$2/unit) plus the direct spoilage cost *per unit shipped*

(which is likely low if total scrap is only 750 units out of potentially hundreds of thousands or even millions). Additional savings from packaging material reduction ($22.5/unit gross) and potential standard freight optimization would need to offset the higher unit cost.

- **vs. Traditional Cold Chain (e.g., Obsidio, Vaccines, Biologics):** Here, the potential for net savings is much higher. If the patented solution ($15-$35/unit) can reliably replace traditional cold chain packaging ($200-$2000+/unit) and associated premium logistics, the net savings per unit could be substantial ($100s). This is where the technology holds the most promise as a *replacement* solution.

For the overall valuation focused on licensing, the *licensee's* internal cost-benefit analysis (considering their specific volumes, current costs, and spoilage rates) will determine their willingness to adopt and pay royalties.

V. Synthesized Valuation and Risk Assessment

A. Reconciliation and Combined Value

The primary value stem from the potential licensing revenue stream, targeting the broad market needing alternatives or improvements to cold chain logistics. The direct savings from spoilage reduction, while tangible, contribute less significantly based on the specific parameters provided, although this could change with higher spoilage rates or volumes. The potential savings from replacing *actual* cold chain (not just indicator dots) represent significant upside but depend on the technology proving effective and cost-efficient for stricter temperature ranges (e.g., 2-8°C).

Combining the mid-case NPV from licensing (~$45M) and the base-case NPV from direct spoilage savings for three internal product lines (~$2M) gives a core economic value estimate before the strategic premium. However, given the uncertainty and the focus on licensing, we will primarily base the final range on the licensing potential.

B. Strategic Premium (Revised)

Applying the reduced strategic premium range of **2.5% to 7.5%** to the licensing NPV range ($85M - $450M) accounts for the intangible benefits (exclusivity, brand enhancement, platform potential) while acknowledging the significant adoption risks and competitive landscape.

C. Final Estimated Economic Value Range

Based on the licensing potential as the primary driver and incorporating the reduced strategic premium, the final estimated economic value of this patent, positioned as a cold chain alternative/enhancement, is projected to be in the range of:

$87 Million to $484 Million

- *Lower Bound Calculation: $85M (Pessimistic Licensing NPV) * (1 + 2.5% Premium) = $87.1M*
- *Upper Bound Calculation: $450M (Optimistic Licensing NPV) * (1 + 7.5% Premium) = $483.75M*

The base case estimate (Mid-Case Licensing NPV $215M + 5.75% Premium) centers around **$227.4 Million**.

By focusing on licensing based on a percentage of *product sales* using the technology provides a more

realistic, albeit still assumption-driven, valuation range reflecting the potential to replace or supplement costly cold chain logistics across the industry. The direct spoilage savings for internal use remain a smaller, secondary component unless applied across many product lines or if baseline spoilage is much higher than initially estimated.

D. Key Risks and Considerations

- **Validation Hurdle:** The cost ($10k-$80k+ per validation) and time (months/years) for ISO 11607 validation remain the most significant barrier to adoption and licensing.
- **Cost vs. Benefit:** Demonstrating a clear ROI for licensees, especially given the $15-$35 unit cost, is critical. The value proposition needs to encompass more than just the specified spoilage reduction for many applications.
- **Performance & Reliability:** Real-world performance variability and long-term stability of the multi-material system (VIPs, PCMs, aerogels) must be proven.
- **Market Adoption Speed:** Gradual uptake is expected; achieving significant market penetration will take time and effort.[43]
- **Competition:** Strong competition exists from established cold chain providers, other advanced passive packaging solutions (VIP/PCM), and improving logistics technologies (IoT, AI).
- **IP Strength:** Ensuring broad, defensible claims is vital for licensing leverage.

VI. Conclusion and Strategic Recommendations

This patent offers the most value as a potential alternative or enhancement to traditional cold chain logistics, primarily monetized through licensing. While the direct cost savings from reduced spoilage (estimated at $200k-$400k annually per for Innova, Eluvia, and Watchman) are tangible, they may not independently justify the $15-$35 unit cost compared to basic indicator labels for CRT products. However, the potential to license this technology across the broader temperature-sensitive healthcare market (including biologics and vaccines requiring stricter control) presents a substantial opportunity.

Based on a DCF analysis of potential licensing revenues (assuming gradual market penetration up to 10% over 12 years and a 3-7% royalty rate) and incorporating the reduced strategic premium (2.5%-7.5%), the estimated economic value range for this patent is **$87 Million to $484 Million**. This range is highly sensitive to market adoption rates and royalty negotiations. The technology's ability to demonstrably reduce overall logistics costs (including spoilage, packaging materials, and potentially freight) compared to *both* basic monitoring *and* traditional cold chain will be key to realizing this value.

Strategic Recommendations:

1. **Focus on Licensing Model:** Prioritize developing a robust licensing strategy targeting major pharmaceutical, biotech, and medical device companies with significant temperature-sensitive product portfolios.
2. **Quantify Total Value Proposition:** Develop detailed cost-benefit analyses for potential licensees, quantifying not only spoilage reduction but also potential savings in packaging materials, freight (due to size/weight reduction), and the risk mitigation value compared to both indicator dots and traditional cold chain.
3. **Invest in Validation Data:** Generate comprehensive performance and stability data according to

relevant standards (e.g., ISTA 7D, ISO 11607) for various temperature profiles (e.g., 2-8°C, 15-25°C) to de-risk adoption for licensees.

4. **Tiered Product/Pricing Strategy:** Consider offering different versions of the technology (varying performance, cost) tailored to specific needs (e.g., CRT vs. 2-8°C) to broaden market appeal and address the $15-$35 unit cost concern.
5. **Strengthen IP:** Continue to build the patent portfolio around the core technology and potential improvements ("picket fence") to deter design-arounds.
6. **Strategic Partnerships:** Explore partnerships with packaging manufacturers or logistics providers to facilitate integration and market access.

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