Formal Request for Performance Re-Evaluation & Investigation

06 May 2025_Revised

Narin Anderson

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Agenda

1. **Executive Summary**
2. **Background**
3. ***Key Concern #1: Biased and Inconsistent Evaluation Process***
   - Lack of transparency in evaluation criteria
   - Rating was based entirely on subjective peer feedback without consideration for deliverables , actual outcomes, or context
   - Manager remarks on multiple occasions in 1:1 meetings
     - Repeatedly linking negative feedback to how it reflects on him personally
     - Repeatedly brings up the point about me being a Principal Engineer and not meeting the expected standards for that level
     - Repeatedly stating misses were due to compounding issues as a result of poor planning
     - Repeatedly questioning my interest and motivation in the Ranger 035 PDP Program for my poor performance
4. ***Key Concern #2: Overlooked Achievements***
   - Being passed over for a promotion without opportunity to interview
   - Lack of open or transparent selection process without competitive process
5. ***Key Concern #3: Potential Racial & Age Discrimination***
   - Only one promotion in 25 years despite consistent high-level contributions
   - Pattern of less-experienced peers (Caucasian colleagues) advancing more quickly
   - Being under-leveled relative to contribution and tenure

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Executive Summary & Background

This complaint addresses a significant disconnect between my actual contributions to Boston Scientific and my recent performance rating, as well as ongoing concerns about racial bias impacting my career progression over my 25-year tenure.

Key points include:

- Project outcomes despite challenging circumstances not factored into performance rating
- Discrepancy between achievements and performance rating
- Pattern of career stagnation despite consistent high-impact contributions
- Concerns about racial bias in promotion decisions

Background

- Name: Narin Anderson
- Position: Principal Packaging Engineer, PI Pkg NPD
- Tenure: 25 years with Boston Scientific
- Roles: Served As Pkg Core Team Member on Innova, ELUVIA, SAVAL, Ranger 035 PDP
- Led Technology Development on: Tactile Coatings, Localized Thermal Protection
- Joined BSC in: June 2000
  - 8 years in R&D
  - 17 Yrs in PI Pkg New Product Development

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Issue #1: Biased Performance Evaluation Process

Performance Rating: "*Improvement Required*"

- **Inconsistencies with Actual Performance**
  - Project Success
    - Ranger 035 Design Freeze Approval Milestone achieved ahead of schedule
    - US & OUS Launch brought in by 1-3 Qtrs
    - Critical role in enabling overall program acceleration
  - Innovation
    - Multiple patent filings demonstrating technical leadership
  - Cross-functional Impact
    - Support provided to other high-priority projects
- **Submitted six Peer Feedback**
  - Manager selects 12? Who were they? Why? What do they know about my work?

- **Mitigating Factors**
  - New to Product Line
    - Project kicked off approximately one year ago
    - Rapid learning curve demonstrated
  - Personal Sacrifices
    - Worked through holidays and weekends to meet compressed timelines
    - Worked 14-16 Hrs per Day, 7 Days per Week for 3.5 Months Straight
    - Sacrificed significant vacation time in 2024
  - Performance Improvement Plan (PIP) Burden
    - Met project demands while under additional PIP scrutiny
    - PIP did not consider project needs, priorities, nor context of a given situation

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

Peer Feedback: (9/12 responses)

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Repeated Criticisms From Manager

Repeated Criticisms	Narin's Comments
My negative feedback from other functions making him look bad	- As a manager, this is inappropriate and irrelevant. My performance evaluation should be based on objective measures of my contributions and project outcomes, not on how it makes my Manager looks. - If I was the Manager of PI Pkg NPD, I would focus on helping my team members improve and succeed, not worrying about how their performance reflects on me.
Not meeting expected standards for a Principal Engineer	- In my 25 years at Boston Scientific, I've made significant contributions to the business, the latest of which is the successful completion of the Ranger 035 Design Freeze ahead of schedule. - "Improvements Required" rating does not align with my track record of high-impact work and innovative solutions, as evidenced by my patent filings and the adoption of my packaging designs across multiple product lines. - I endured significant challenges on the Ranger 035 program with compressed timelines and last-minute design changes and this extraordinary circumstance required me to make significant personal sacrifices. - Yet despite all of this, I still delivered critical project outcomes.

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Repeated Criticisms From Manager

Repeated Criticisms	Narin's Comments
Poor planning at the beginning	- I acknowledge that there were some initial challenges as this was a new product line for me. I needed time to come up to speed and understand the nuances of the design but once I understand it, I become very effective at my job. - The last-minute design change by the team was a major disruption that required me to restart significant work, but I was still able to adapt and maintain the overall program schedule.
Compounding issues & misses due to poor planning	- The issues and challenges I faced were not due to poor planning on my part, but rather the timeline compression on an accelerated project that requires pragmatism in approach which leverages and heavily relies on the skills and expertise of team members for input. There is a degree of risk that comes with this approach like when they change their mind a week before Christmas. - Coiling plate design and development only looks simple on the surface but it required multiple iterations due to the inherent complexity of the components and the need to validate changes with physical prototypes. - I've communicated the challenges and interdependencies of the design elements to the team and worked to adapt to the evolving project needs as best I could by using the resources at my disposal wisely with intention and a focus on the respective strengths of supporting resources.

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Repeated Criticisms From Manager

Repeated Criticisms	Narin's Comments
Repeatedly commenting and asking me whether my poor performance is a result of a lack of interest and motivation in working on the Ranger 035 Program	- ***Demonstrated Commitment and Sacrifice:*** For the last 3.5 months straight, I worked on the Ranger 035 project for 14-16 hours per day, 7 days a week. I also sacrificed 40 hours of earned vacation time in 2024 to ensure that I could complete critical project deliverables on time. - ***Successful Project Outcomes***: Despite the challenging circumstances, I was able to help the team successfully complete the critical Design Freeze milestone for the Ranger 035 project ahead of schedule. That enabled the compression of multiple project timelines, including accelerating the US launch by over 1 quarter, the OUS approval by over 3 quarters, and the China launch by over 3 quarters. I was able to deliver results, even under significant time pressure with the added stress of operating under a Performance Improvement Plan (PIP). The magnification of my mis-steps and seeing clarity in hindsight but not in the moment of a particular challenge or situation was the reality of the effects of the PIP process. The successful outcomes were in spite of the PIP and it was a direct result of my skill, perseverance, and the support provided by my team members and colleagues who worked hand in hand alongside me. - ***Proactive Efforts to Address Concerns***: When I was first made aware of performance concerns on August 22, 2024, I immediately took steps to address the perception with the Ranger 035 team. I scheduled regular meetings with the project manager, technical lead, and other key contributors to provide updates and receive feedback more frequently. I also scheduled weekly 1-on-1 meetings with Aaron to keep him better informed.

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Projects Supported & Outcomes

Project	Key Milestones	Achievements	Challenges Overcome	Impact
Ranger 035 PDP	- Design Freeze Approval - Moving to Design Verification phase	- US launch advanced by >1 Qtr - OUS approval accelerated by >3 Qtr - China launch advanced by >3 Qtr	- Re-started design workstreams one week before Christmas 2024 - Negated data & work from previous 6-7 months - Compressed timelines - Worked extended hours (4-5AM to 11PM, 7 days/week)	- Enabled critical qualification activities - Facilitated Pulse builds at external partner - Allowed Cross Functional Teams to build, test, & acquire needed data
Localized Thermal Protection TDP	- Demonstrated concept feasibility with sustained Room Temperature control	- Patent Filed	- Initial proposal required further enhancements	- Customized solution - Programable performance
TheraSphere GBM	- Provided guidance to team	- AA Protocol Executed in timely manner	- Intruded on personal time to provide necessary project support	- Supported HFA clinical workstreams

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2024 – Lead Inventor on Two Patents

Patent Filing #1

From: Anderson, Narin
To: Robertson, Keith (he/him/his)
Subject: RE: Q2 2024 Filing Patent Awards
Date: Thursday, August 22, 2024 2:20:00 PM
Attachments: image001.png

I think so Keith. Legal told me this Provisional Patent was filed in May so this monetary award is for that filing. Once (and if) the patent gets approved, we should get another monetary award.

From: Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>
Sent: Thursday, August 22, 2024 12:28 PM
To: Anderson, Narin <Narin.Anderson@bsci.com>
Subject: FW: Q2 2024 Filing Patent Awards

Narin,

Was this the "official" notice of the patent filing? I'd like to send something to Tim/Heather and the rest of the team acknowledging the efforts as this was a HUGE accomplishment.

-Keith

From: Connors, Joan <Joan.Connors@bsci.com>
Sent: Friday, August 16, 2024 4:43 AM
To: Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>
Subject: Q2 2024 Filing Patent Awards

Dear Keith,

Thank you for your innovative contribution to Boston Scientific Corporation's intellectual property portfolio! As a result of your and other inventor's efforts, Boston Scientific remains a leader in patent procurement within the medical industry and a top patent producer in the country. The 2018 Patent Recognition Program rewards those Boston Scientific employees who were inventors on a provisional or original (non-provisional) US patent application with a monetary bonus.

In accordance with the 2018 Boston Scientific Patent Recognition Program, you are to be congratulated for the following activities which were filed in the 2nd Quarter of 2024.

FILE NUMBER	APPLICATION #	FILING DATE	TITLE	AWARD AMOUNT
24-0084PV01	63650165	21-May-24	PROVIDING INTERACTIVE INSTRUCTIONS FOR MEDICAL APPARATUS	750

Patent Filing #2

From: Rauniyar, Amit
To: Anderson, Narin
Cc: Williams, Brian; Robertson, Keith (he/him/his); Krona, Kirk
Subject: FW: New application for drafting 24-0616PV01
Date: Friday, November 8, 2024 9:29:25 AM
Attachments: image001.png
image002.png
24-D0897.pdf

Congratulations Narin!
You did and incredible job presenting yesterday.
Thank you,

Amit Rauniyar
Principal Packaging Engineer, R&D
Boston Scientific
Amit.Rauniyar@bsci.com

From: Mohess, Sabrina <Sabrina.Mohess@bsci.com>
Sent: Friday, November 8, 2024 8:33 AM
To: Scot Wickhem <scot.wickhem@stwiplaw.com>
Cc: Alex Marquardt <alex.marquardt@stwiplaw.com>; Nyquist, Benjamin <Benjamin.Nyquist@bsci.com>; Anderson, Narin <Narin.Anderson@bsci.com>; Williams, Brian <Brian.Williams@bsci.com>; Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>; Rauniyar, Amit <Amit.Rauniyar@bsci.com>; Krona, Kirk <Kirk.Krona@bsci.com>
Subject: New application for drafting 24-0616PV01

Invention Disclosure: Localized Thermal Protection of Temperature Sensitive Medical Devices/24-D0897
Our file No: 24-0616PV01
Legal Tracker Associated Matter ID: 392691
Assign to: Boston Scientific Scimed, Inc.
Technical Field: Mechanical

Dear Scot, and Inventors:

The above referenced disclosure has been approved for the drafting of a provisional patent application and has been uploaded into FIP.

The inventors are: Anderson, Narin Narin.Anderson@bsci.com; Williams, Brian Brian.Williams@bsci.com; Robertson, Keith (he/him/his) Keith.Robertson@bsci.com; Rauniyar, Amit Amit.Rauniyar@bsci.com; Krona, Kirk Kirk.Krona@bsci.com

Please contact them within the next 2 weeks to discuss this disclosure, per Section 5.2 in the guidelines. Please provide a provisional draft application to the inventor with a cc to me, Sabrina.mohess@bsci.com no later than **the dates as listed below** (potentially sooner). We do not need to be copied on scheduling emails.

First Draft Due: Dec 19, 2024
Final Draft Due: Jan 31, 2025
Application Filing Deadline: Feb 7, 2025

Please contact myself or Ben Nyquist at any time if circumstances arise that may prevent you from

From: Bradley, Joel <Joel.Bradley@bsci.com>
Sent: Wednesday, July 3, 2024 11:48 AM
To: Anderson, Narin <Narin.Anderson@bsci.com>; Mohess, Sabrina <Sabrina.Mohess@bsci.com>
Subject: Re: Status Inquiry - {External} Disclosure Meeting | US Provisional Application 24-0084PV01

Hi Narin:

The provisional application was filed on May 21, 2024. Thank you for the support and innovation.

Next steps will be in about ten months from now to see if anything can / should be added to the application before it converts to a non-provisional.

Take care,
Joel

Joel Bradley
Senior Intellectual Property Liaison
joel.bradley@bsci.com
One Scimed Place
Maple Grove, MN. 55311
www.bostonscientific.com

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Feedback – Feb 2024

From: Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>
Sent: Wednesday, February 21, 2024 3:57 PM
To: Anderson, Narin <Narin.Anderson@bsci.com>
Cc: Getty, Heather <Heather.Getty@bsci.com>
Subject: IP Presentation Follow Up

Narin,

Great job today presenting your Inventor disclosure to the IP board. I think your idea is very good and will ultimately be seen in the medical device industry in the near future. You did an excellent job responding to the questions presented and there seemed to be genuine interest in the speech to speech chatbox. Fingers crossed on the outcome of their decision.

As I was writing this, I see that the board has scheduled a follow up session for additional questions and have indicated that their intention is to pursue a patent application. Awesome job Narin.

Could you forward your slides to Heather when you have a moment. I'm sure she'd be interested in testing the demo.

-Keith

From: Anderson, Narin <Narin.Anderson@bsci.com>
Sent: Wednesday, February 21, 2024 7:41:00 PM
To: Mirviss, Jeff (he/him/his) <Jeff.Mirviss@bsci.com>
Subject: PI NPD Packaging IP - Presentation Follow Up

Hi Jeff,

I hope you don't mind me reaching out to you. I just wanted to share this with you because I know paper IFUs are huge pet peeve of yours. My team put something together for consideration by the Patent Review Board related to this matter. I figured this may bring a smile in your busy day. If you would like to learn more about it and have 15 minutes free for a cup of coffee, I can make time available for you. No worries otherwise as I think the slides and demo are self-explanatory.

I hope you like it.

-Narin

From: Anderson, Narin
Sent: Wednesday, February 21, 2024 7:32 PM
To: Getty, Heather <Heather.Getty@bsci.com>
Cc: Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>
Subject: RE: IP Presentation Follow Up

Hi Heather,

At Keith's request here is the presentation that was given to the Patent Review Board this afternoon. To get the full effect of the generated voices, put it into presentation mode and scroll through it normally. After that, take your phone and scan the QR code to interact with the demo. You can ask it questions related to information in the ELUVIA IFU and Patient Guide. Press the microphone icon on your phone to speak to it.

Please let me know if you have any questions.

-Narin

From: Mirviss, Jeff (he/him/his)
To: Anderson, Narin
Subject: Re: PI NPD Packaging IP - Presentation Follow Up
Date: Friday, February 23, 2024 10:36:21 AM

I love this! Thanks for sharing and yes, I'd like to meet to learn more. Enjoy the weekend.
Jeff

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Feedback – Feb 2024

From: Clark, Aaron <Aaron.Clark@bsci.com>
Sent: Wednesday, February 28, 2024 12:12 PM
To: Anderson, Narin <Narin.Anderson@bsci.com>; Kent, Anna (she/her/hers) <Anna.Kent@bsci.com>
Cc: Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>
Subject: Excellent Presentation! - Pkg CoP Event - MTAC & Pkg

Hey Narin & Anna!

Great job on your presentation today regarding the carton coatings assessments you performed and how you utilized the MTAC capabilities.

Narin…I also wanted to give you some "props" on how you answered the question raised around the "sustainability" of these coatings. Your feedback that the various coating embellishments you assessed actually use the same coating materials but only with variation in formulation and application processes is great information for all to hear! With the recent push for more "sustainable" packaging designs, new product development teams will continue to get questions on this nature and having this type of information available is awesome!

Nice work to you both!!!

Aaron

From: Anderson, Narin
Sent: Wednesday, February 28, 2024 12:18 PM
To: Clark, Aaron <Aaron.Clark@bsci.com>; Kent, Anna (she/her/hers) <Anna.Kent@bsci.com>
Cc: Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>
Subject: RE: Excellent Presentation! - Pkg CoP Event - MTAC & Pkg

Thank you Aaron. I lucked out by having Anna by my side. I wish I could have been as fluid as Anna. It was a good experience for us both.

I'm glad you caught that last point I was trying to make. I wasn't sure if I was clear enough. I've had many discussions with suppliers on these and did my own research on the topic as well. I always arrive at the same conclusion which I shared with the group today.

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Feedback – Sep 2024

From: Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>
Sent: Thursday, September 26, 2024 3:47 PM
To: Anderson, Narin <Narin.Anderson@bsci.com>
Cc: Clark, Aaron <Aaron.Clark@bsci.com>; PI RandD NPD Packaging Team <piranddnpdpackagingteam@bsci.com>
Subject: Exploratory Meeting Follow Up

Narin,

You put on a phenomenal performance this week with two really great presentations! I just wanted to acknowledge the level of passion present when you're discussing packaging technology advancement. We may not have gotten Jay over the fence today (and that's okay), but whatever you did, it sure won the hearts of Kari and Heather. I spoke with both of them separately today and they each indicated that PI NPD Pkg has their full support to continue exploratory efforts into 2025!!! Way to go Narin, this is all because of you man, I'm really proud of you. Heather offered up her entire discretionary fund just to keep us going if need be; Kari said "if you guys have ideas and need money, we'll figure it out". One thing is for sure, leadership in PI supports Packaging and that's refreshing!!!

Now, let's make it count! I'd like to see how pull together ideas on how we can move forward from an exploratory standpoint – given Jay's feedback today, I'd like to be strategic in how we move forward and think about which avenues we pursue, whether it be localized thermal protection, Everest, or otherwise.

I originally planned to just sent this to Narin and cc Aaron, but feel its great for the entire team to see this messaging.

-Keith

Keith Robertson
Pronouns: He, Him, His
Senior R&D Manager
Keith.Robertson@bsci.com
M. 919.412.7634
Boston Scientific
Advancing science for life™

From: Anderson, Narin
To: Robertson, Keith (he/him/his)
Cc: Clark, Aaron; PI RandD NPD Packaging Team
Subject: RE: Exploratory Meeting Follow Up
Date: Friday, September 27, 2024 7:27:00 AM
Attachments: image001.png
image002.png

Thank you for your kind words Keith. I'm glad I was able to make some small contribution to the group this week.

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Feedback – Nov 2024

From: Rauniyar, Amit <Amit.Rauniyar@bsci.com>
Sent: Friday, November 8, 2024 9:29 AM
To: Anderson, Narin <Narin.Anderson@bsci.com>
Cc: Williams, Brian <Brian.Williams@bsci.com>; Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>; Krona, Kirk <Kirk.Krona@bsci.com>
Subject: FW: New application for drafting 24-0616PV01

Congratulations Narin!
You did and incredible job presenting yesterday.
Thank you,

Amit Rauniyar
Principal Packaging Engineer, R&D
Boston Scientific
Amit.Rauniyar@bsci.com

From: Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>
Sent: Friday, November 8, 2024 9:44 AM
To: Rauniyar, Amit <Amit.Rauniyar@bsci.com>; Anderson, Narin <Narin.Anderson@bsci.com>
Cc: Williams, Brian <Brian.Williams@bsci.com>; Krona, Kirk <Kirk.Krona@bsci.com>
Subject: RE: New application for drafting 24-0616PV01

Agreed! Narin captivated them with his compelling outline of the idea and fielded their questions amazingly!

-Keith

From: Anderson, Narin
To: Robertson, Keith (he/him/his); Rauniyar, Amit
Cc: Williams, Brian; Krona, Kirk
Subject: RE: New application for drafting 24-0616PV01
Date: Friday, November 8, 2024 9:56:00 AM
Attachments: image001.png
image002.png

We're a team. Congratulations to us all!

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Ranger 035 PDP - Project Outcomes

Ranger 035 Project Achievements

- Initial Design Solutions Completed Nov 2024
- Despite last minute decision change by Team mid-Dec 2024
  - Design Freeze still successfully completed ahead of schedule
  - Multiple project timelines compressed:
    - US launch brought forward by >1 quarter
    - OUS approval accelerated by >3 quarters
    - China launch advanced by >3 quarters
- Critical Contributions
  - Responsible for all aspects of packaging design and development
  - Work directly enabled compression of overall program timeline
  - Completed Two Coiling Plate Designs That Enabled Critical Test Unit Builds By Cross Functional Team Members & External Partners
  - Met all expected deliverables in a timely manner
- Stakeholder Engagement
  - Conducted successful Pre-Sell meeting with deep-dive data presentation
  - No questions raised during Design Freeze presentation, indicating thorough preparation

Additional Contributions

- Led Localized Thermal Protection TDP project resulting in patent filing
- Patent Filings
  - Filed 2 patents in the past year (the only patents filed under PI NPD Pkg group)
- Cross-functional Support
  - Provided guidance for Therasphere GBM HFA workstreams

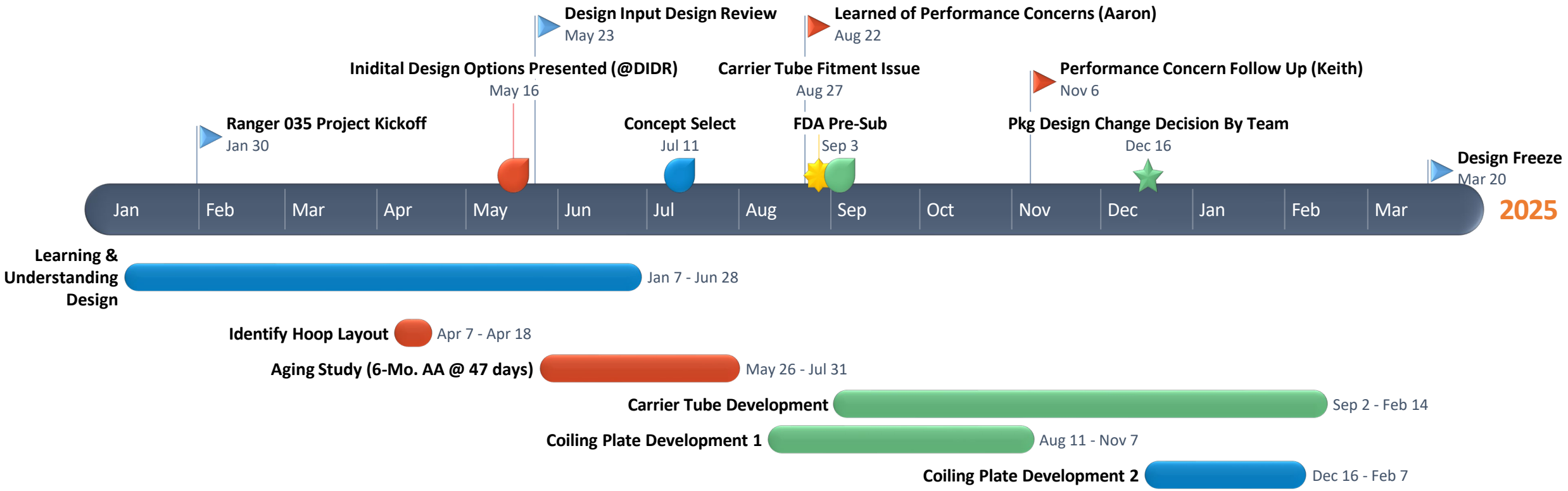
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Ranger 035 – Accelerated Project Timeline



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Design Change Mid-Dec 2024 (Team Decision)

Packaging Risk Summary

Risk ID	Risk Category	Workstream	Risk Summary	Risk Description	Risk Response Strategy	Risk Probability	Impact	Risk Level	Status
R24	Regulatory	Packaging	Packaging Equivalency	Packaging design evaluation post sterilization, distribution, and aging	Mitigate	1	3	1	Improving
R23	Technology	Packaging	Packaging Performance	Catheter removal force remains within spec	Mitigate	1	1	1	Improving

- Pre-DV evaluation of units (n=46) post sterilization and distribution
  - ✓ Evaluated 7.5 inch and 8.0 inch hoop diameter (moving forward with 8.0 inch diameter)
  - ✓ Distal segment of device kept straight
  - ✓ Catheter removal force (t=0) in progress (by 7/3)
  - ✓ Catheter removal force (6mo AA at 47oC) in progress (by 7/22)

- Initial Design Solutions Proposed to Team May 16, 2024 (DIDR Slide)
- Team Formalizes selection of 8.0 Hoop Diameter in Concept Select Meeting on July 11, 2024
- Reviewed w/ Subject Matter Experts
- *No questions or concerns raised by any attendee*
- Team changes mind on Dec 16, 2024 & negated cumulative work and effort to that point including all the effort that went to finalizing two coiling plate designs
- Decision was extremely disruptive and impactful w/ respect to its implications & cascading effects on subsequent Pkg workstreams
- *It necessitated re-start of whole process again involving coiling plate designs, print updates, building & testing new units, aging, etc…*

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Ranger 035 - Hours Worked Due to Dec. 16

Period	Days	Standard Hours	Actual Hours	Excess Hours	Vacation Time Sacrificed	Total Excess Hours	Total Hours Worked
Dec 14 - 31, 2024	18	144	288	144	40	184	318
Jan 01 - 31, 2025	31	176	496	320	-	320	496
Feb 01 - 28, 2025	28	160	448	288	-	288	448
Mar 1 - 20, 2025	20	160	320	160	-	160	320
Total	**97**	**640**	**1,552**	**912**	**40**	**952**	**1,592**

Notes:

1. Standard Hours are based on a 40-hour work week (8 hours per day, 5 days per week).
2. Actual Hours are based on average of 14-16-hour workdays, 7 days per week.
3. Excess Hours are calculated as Actual Hours minus Standard Hours.
4. The 30 hours of sacrificed vacation time is added to the Total Excess Hours.
5. Start: Dec 12, 2024 – Team Decision to Change Pkg Design (Ranger 035 PDP)
6. End: Mar 20, 2025 – Design Freeze (Ranger 035 PDP)

From: Anderson, Narin
To: Clark, Aaron
Subject: Vacation Hours Carryover
Date: Monday, December 9, 2024 10:48:00 AM

Aaron,

I forgot to bring up at our 1:1 meeting that I will have about 40 hours of vacation to carryover into next year I would eventually like to use. It's not that I don't want to use it this year, I do but I just have too many pressing activities for Ranger that I need to address in the immediate term.

-Narin

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Giving Ranger 035 PDP Top Priority

RE: Localized Thermal Protection Slide Updates



Anderson, Narin
To Robertson, Keith (he/him/his); Clark, Aaron
Retention Policy Delete Emails after 730 days (2 years) Expires 9/25/2026

Reply | Reply All | Forward

Wed 9/25/2024 9:07 AM

I'll take the blame about getting Jay up to speed. Let me rectify this as soon as possible. I've just been swamped with Ranger 035 activities so I gave those workstreams precedence in order to minimize risks from our function.

From: Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>
Sent: Wednesday, September 25, 2024 9:03 AM
To: Clark, Aaron <Aaron.Clark@bsci.com>; Anderson, Narin <Narin.Anderson@bsci.com>
Subject: RE: Localized Thermal Protection Slide Updates

Variable expenses are due tomorrow, so even if we don't have all of the information available, I'd say we "ballpark" it and get something in front of him to at least give ourselves a shot.

If we don't get it, we have no one but ourselves to blame here. Jay specifically reached out and asked for an update which we pretty much blew him off and never circled back. So I don't blame him, it's up to us to show him otherwise and I think Narin has an intriguing story that can turn it around if we get it in front of him, especially if we bring Ryan and Maggie in and pique their interest.

Best shot is 9:30-10am tomorrow morning. It's messy throwing something on last minute, but this is the bed we've made and it's our only shot, so I say we take it.

-Keith

From: Clark, Aaron <Aaron.Clark@bsci.com>
Sent: Wednesday, September 25, 2024 8:51 AM
To: Anderson, Narin <Narin.Anderson@bsci.com>
Cc: Robertson, Keith (he/him/his) <Keith.Robertson@bsci.com>
Subject: RE: Localized Thermal Protection Slide Updates
Importance: High

Hey Narin,

Nice job presenting your exploratory project update to Kari and Heather! It was clear you "tapped" into your "exploratory passion" as you were able to deliver a good message with some promising potential. You could sense there was definitely some interest from Kari and Heather.

That being said, with the approval to continue charging to the budget the rest of the year, it was also conveyed that in order to potentially pursue into 2025, you will need to present your update and future proposals to Jay Kokate as soon as possible (since 2025 budgets are in the process of being set as we speak). In addition to Jay; Kari and Heather suggested we pull in Ryan Hendrickson (R&D Director of DES portfolio) and Maggie Zeng (R&D Director reporting to Jay) to get them thinking about opportunities for this

- Ranger 035 PDP was given my top priority in terms of time and attention despite being committed to supporting other projects as well

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My Efforts to Remediate Concerns

RE: Follow Up - 1:1 Meeting w/ Narin



Anderson, Narin
To Clark, Aaron

Reply | Reply All | Forward

Tue 8/27/2024 7:15 AM

Retention Policy Delete Emails after 730 days (2 years) Expires 8/27/2026

This message is part of a tracked conversation. Click here to find all related messages or to open the original flagged message.

It's obvious you have very limited space in the header bag and that the proposed hoops for Ranger 035 have a "shorter" distance allowed for tube to "cross-over" to the outside which is causing additional "stress" on the tube securement contributing to clips popping lose. Looking at the Wind ODs for commercial Ranger, I notice that they are different with one being 6.75" and the other 7.25"; based on this you may want to consider reducing the hoop wind OD down from the current proposed 8" to something less as well as you may want to consider creating 2 separate coiling plates to allow for different Wind OD's if needed.

Thanks!
Aaron

-----Original Appointment-----
From: Anderson, Narin <Narin.Anderson@bsci.com>
Sent: Thursday, August 22, 2024 2:28 PM
To: Anderson, Narin; Clark, Aaron
Subject: Follow Up - 1:1 Meeting w/ Narin
When: Thursday, August 29, 2024 1:00 PM-2:00 PM (UTC-06:00) Central Time (US & Canada).
Where: Microsoft Teams Meeting

Bring you up to speed on the status of my activities on a more frequent basis as my first step to address the performance issue you brought to my attention today.

- When it was first brought to my attention on Aug 22, 2024 that my performance was below the expected standards of a Principal Engineer, I immediately took steps to address the perception with team members on the Ranger 035 PDP program
- I scheduled bi-weekly meetings with Orla (PM), Amy (Tech Lead), Mike (DES SME), Patrick (DA), and reached out to Kyle / Jeff (R&D) as needed to give and receive feedback more frequently
- I also scheduled weekly 1:1 Meetings w/ Aaron to provide him with more regular updates

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Addressing Concerns

RE: Summary of Ranger Commercial (OUS UPNs) - Legal Mfr Change Meeting

Anderson, Narin
To Robertson, Keith (he/him/his); Clark, Aaron

Reply | Reply All | Forward

Wed 11/6/2024 10:34 PM

Retention Policy Delete Emails after 730 days (2 years) Expires 11/6/2026

Keith,

I want to follow up on your message below. At the beginning of the project, I was told that Ranger 035 is a simple project meant to leverage the packaging design of Ranger 018 currently in commercialization. So I got acquainted with the BOM structure of Ranger 018 in Windchill for both the US and OUS UPNs. Then I later learned that Ranger Radial (Ranger 200) is supposed to be the latest and greatest of the Ranger family of designs that reflects the latest updates to all our Packaging requirements so I looked at the BOM structure of Ranger Radial as well and compared it to the BOM structure of Ranger 018 as you can see here:

Part No.	US Ranger (H74939419400480)	Qty	Find No.
50542588-01	Carton, MB, 11.20 x 9.75 x .5	1	6
50558401-02	Azzy, Carrier Tube, DCB, 4.0x40-80 dF	1	4
50586747-01	Header Bag, MB, 9.63 x 11.75	1	1
50759513-01	Label Stock, Carton, MB, 6.5 x 8.88	1	10
50839413-01	3 Cavity Angle Clip	1	12
51401272-01	Card, E Reference	1	8
51720521-01	EIFU, MB, Ranger, EN	1	7
51720522-01	Patient Guide, MB, Ranger, US, EN	1	9
51720522-02	ePatient Guide, MB, Ranger, US, EN	1	13
51720523-03	ePatient Guide, MB, Ranger, US, ES	1	14
90041405-01	3 Cavity Clip - Striated	2	5
90375893-01	Label Stock, Compliance, MB	1	3
90800663-01	Tear Tab Closure Strip, 1.25 x 2.75	1	11
91110619-01	Label Stock, Sterile Barrier, MB	1	2

Part No.	OUS Ranger (H74939670400380)	Qty	Find No.
50839413-01	3 Cavity Angle Clip	1	5
50971295-01	Label Stock, Pouch, MB, 6.5 x 7.5	1	3
51190295-01	Carton, MB, 9.75 x .50 x 11.20, BSC	1	8
51194032-01	IFU, MB, Ranger, Global 7	1	7
51195929-01	Header Bag, MB, 9.63 x 11.75	1	2
51294155-01	Label Stock, Carton, MB	1	9
51572817-01	Azzy, Carrier Tube, DCB, 4.0x30-80	1	1
90041405-01	3 Cavity Clip - Striated	2	4
90375893-01	Label Stock, Compliance, MB	1	6
90800663-01	Tear Tab Closure Strip, 1.25 x 2.75	1	10

Part No.	Ranger Radial 200cm (H74939733612020) - US	Qty	Find No.
50542588-01	Carton, MB, 11.20 x 9.75 x .5	1	6
50586747-01	Header Bag, MB, 9.63 x 11.75	1	1
50759513-01	Label Stock, Carton, MB, 6.5 x 8.88	1	9
50839413-01	3-Cavity Angle Clip	1	12
51401272-01	Card E Reference	1	8
51628642-01	EIFU, MB, Ranger 200cm, EN	1	11
51666441-19	Azzy, Carrier Tube, DCB, 6.0x120-200	1	4
51853750-01	ePatient Guide, MB, Ranger 200cm, EN	1	7
51853750-02	ePatient Guide, MB, Ranger 200cm, ES	1	13
90041405-01	3-Cavity Clip - Striated	5	5
90375893-01	Label Stock, Compliance, MB	1	3
90800663-01	Tear Tab Closure Strip, 1.25 x 2.75	1	10
91110619-01	Label Stock, Sterile Barrier, MB	1	2

Part No.	Ranger Radial 200cm (H74939734612020) - OUS	Qty	Find No.
50542588-01	Carton, MB 11.20 x 9.75 x .5	1	6
50586747-01	Header Bag, MB, 9.63 x 11.75	1	1
50617240-01	DFU, MB, UltraICE Plus, Global	1	8
50759513-01	Label Stock, Carton, MB, 6.5 x 8.88	1	9
50839413-01	3 Cavity Angle Clip	1	12
51666441-04	Azzy, Carrier Tube, DCB, 6.0x120-200	1	4
90041405-01	3 Cavity Clip - Striated	5	5
90375893-01	Label Stock, Compliance, MB	1	3
90800663-01	Tear Tab Closure Strip, 1.25 x 2.75	1	10
91110619-01	Label Stock, Sterile Barrier, MB	1	2

Part No.	Ranger 035 (75cm) - US	Qty	Find No.
50542588-01	Carton, MB, 11.20 x 9.75 x .5	1	
50586747-01	Header Bag, MB, 9.63 x 11.75	1	1
50759513-01	Label Stock, Carton, MB, 6.5 x	1	
50839413-01	3-Cavity Angle Clip	1	
51401272-01	Card E Reference	1	
51720521-01	EIFU, MB, Ranger, EN	1	
51720522-01	Patient Guide, MB, Ranger, US, EN	1	
51720522-02	ePatient Guide, MB, Ranger, US,	1	
51720523-03	ePatient Guide, MB, Ranger, US,	1	
90041405-01	3 Cavity Clip - Striated	2	
90375893-01	Label Stock, Compliance, MB	1	3
90800663-01	Tear Tab Closure Strip, 1.25 x 2.75	1	
91110619-01	Label Stock, Sterile Barrier, MB	1	2
90039800-01	Shipper Box		

Part No.	Ranger 035 (135cm) - US	Qty	Find No.
50542588-01	Carton, MB, 11.20 x 9.75 x .5	1	
50586747-01	Header Bag, MB, 9.63 x 11.75	1	
50759513-01	Label Stock, Carton, MB, 6.5 x	1	
50839413-01	3-Cavity Angle Clip	1	
51401272-01	Card E Reference	1	
51720521-01	EIFU, MB, Ranger, EN	1	
51918134-64	Azzy, Carrier Tube, 4.0x40-135	1	
51720522-01	Patient Guide, MB, Ranger, US, EN	1	
51720522-02	ePatient Guide, MB, Ranger, US,	1	
51720523-03	ePatient Guide, MB, Ranger, US,	1	
90041405-01	3 Cavity Clip - Striated	2	
90375893-01	Label Stock, Compliance, MB	1	
90800663-01	Tear Tab Closure Strip, 1.25 x 2.75	1	
91110619-01	Label Stock, Sterile Barrier, MB	1	

I decide to use the label stocks referenced in Ranger Radial only to later learn that it was MDD label stocks. We had a discussion about this in the team and I inform my team that given the accelerated timeline of the Pulse builds that it should be fine for us to use the MDD labels which I selected based off the Ranger Radial design. I explain to them that we will have time to update it to MDR label stocks for DV in January once we get through the Pulse build workstreams in November. The team, including labeling, buys off on this approach.

On Tuesday (yesterday), the team had a regular HTQ meeting going over the Packaging components in preparation for Top Assembly start for Pulse. HTQ asked to align with Ranger Commercial sustaining initiatives (involved with Legal Mfr change from HTQ to BSC) currently underway to minimize complexities and part confusion. That was the first time that I became aware of that initiative and the potential impact it had on my workstream in Ranger 035. I don't have this level of visibility since I am focused on day-to-day urgent and immediate needs of the project.

Five minutes before I was made aware of this and called into the team meeting to discuss the matter, you had informed me that you wanted to discuss my performance issues. I couldn't shake this so I go into my meeting dumbfounded still digesting your news as I am taking in new information.

To address the urgent needs of the project, I schedule a meeting with Amanda the same day to get calibrated on what was going on in Sustaining. As we go through the discussion, I got better information major activities, timing, and impacted components which I summarized below and shared with the team. I've assessed the impact and I'm addressing the changes we need as quickly as possible while trying to maintain all the various other workstreams like Packaging Pre-DV build support, coiling plate revisions, component and assembly print updates, CNs, carrier tube designs, purchasing strategy, etc...

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Peer Feedback – Essential Context

Topic	Peer Feedback	Narin's Comments (for Context) – Exhibit F
Attention to Detail	Work required corrections, causing delays and rework	- Made sincere efforts to avoid mistakes by double checking prints multiple times and regularly forward DRAFT versions to Kirk & team members for reviews prior to getting them onto CN - For example – reviewed carrier tube stack up tolerance calculations in Tech Team meeting as well as in 1:1 meetings w/ Aaron, Amy (Tech Lead), & Kyle (Device R&D) where I directly asked if they could see an issue with calculation methodology. No comments or questions raised but I still sensed something was off. Only confirmed & gained high visibility with Team when Mitch was involved and independently determined the correction that we needed.
Sense of Urgency	Needed prompting, lacked urgency	- Forfeited 40 hours of earned vacation in 2024 - Restarted design work a week before Christmas ***due to last minute team decision*** - Maintained overall program schedule despite challenges
Collaboration and Relationship Building	Worked independently, became defensive	- Responded quickly when collaboration gaps were identified - There was team decision to limit engagement with Hemoteq AG to certain members (Orla, Amy, and Mike) due to the sensitivity in our working relationship based on past experiences. - Credited team in response to Heather's shoutout - Sought input from team subset to understand feedback context

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Peer Feedback – Essential Context

Topic	Peer Feedback	Narin's Comments (for Context) – Exhibit F
Functional Expertise	Lacks strong grasp of history and requirements	▪ Thoroughly familiarized myself with the BOM structure of Ranger 018, including both US and OUS UPNs. ○ Proactively researched Ranger Radial (Ranger 200), the latest design in the Ranger family. ○ Conducted a comparative analysis of the BOM structures between Ranger 018 and Ranger Radial. ○ Made informed decisions based on the latest information available, such as using Ranger Radial's label stocks. ▪ Based my decision on the most up-to-date information from the Ranger Radial design. ○ Balanced immediate project needs with long-term requirements. ○ When faced with new information about MDD vs MDR label stocks, quickly adapted and proposed a strategic solution to meet immediate needs while planning for future updates. ○ Developed a forward-thinking plan to update to MDR label stocks for DV in January 2025.

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Peer Feedback – Essential Context

Topic	Peer Feedback	Narin's Comments (for Context) – Exhibit F
Functional Expertise	Lacks strong grasp of history and requirements	▪ Upon learning about the Ranger Commercial sustaining initiatives, I quickly took action: ○ Scheduled a meeting with Amanda to calibrate on ongoing Sustaining activities. ○ Actively sought out necessary information to address new challenges. ○ Rapidly assimilated the new information from the meeting. ▪ I synthesized and shared this new information with the team ○ To ensure transparency and alignment, I: - Summarized major activities, timing, and impacted components for the team. - Clearly communicated my label stock decision to the team. - Provided a detailed explanation of my rationale and timeline. - Gained agreement from the team, including the Labeling Specialist core team member, validating my approach.

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Peer Feedback – Essential Context

Topic	Peer Feedback	Narin's Comments (for Context) – Exhibit F
Functional Expertise	Lacks strong grasp of history and requirements	▪ Juggled multiple workstreams ○ Provided support for R&D Pre-DV builds in addition to Pkg Pre-DV builds in order to gain insight into design performance. ○ Managed coiling plate revisions. ○ Oversaw component and assembly print updates. ○ Handled CNs (Change Notifications). ○ Worked on carrier tube designs. ○ Developed purchasing strategies. ▪ Throughout the project, I maintained a keen awareness of the unique challenges we faced: ○ Acknowledged the complexities of working on an SFMD project. ○ Recognized the impact of ongoing commercialization changes. ○ Understood the pressure of working within a tight timeline. ○ This awareness allowed me to approach the project with a holistic perspective, considering both immediate tasks and long-term implications.

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Peer Feedback – Essential Context

Topic	Peer Feedback	Narin's Comments (for Context) – Exhibit F

Initial Concept Development	Lacks thoroughness, leading to delays and extra work	I respectfully disagree with the assessment that I lack thoroughness:
		- Ranger 035 Kickstarted in January 2024
		  ○ initial packaging designs identified in April 2024
		  ○ Thoroughly researched and compared BOM structures of Ranger 018 and Ranger Radial to ensure comprehensive understanding.
		  ○ Provided team with two design options to consider in May between 7.5 inch and 8.0 inch hoop diameter explaining that while there is no performance difference between the two, the smaller hoop diameter would provide us with more clearance in header bag;
		  ○ Team chose the 8.0 hoop diameter that immediately constrained viable alternative hoop layouts
		  ○ I've consistently explained this context in multiple 1:1 meetings with Aaron, both before and after receiving this feedback on August 22nd, 2024.

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Issue #1 – Collaboration on Coiling Plate Concern

FW: Brief Chat - Your Thoughts On Ranger 035 Coiling Plate Design



Anderson, Narin

Required Clark, Aaron; Harding, Mark

Optional Krona, Kirk; Janssen, Luke

Retention Policy Delete Emails after 730 days (2 years)

Accept | Tentative | Decline | Propose New Time

Thu 11/14/2024 2:59 PM

Friday, November 15, 2024 8:30 AM-9:00 AM Microsoft Teams Meeting

FYI -

-----Original Appointment-----
From: Anderson, Narin
Sent: Thursday, November 14, 2024 11:17 AM
To: Anderson, Narin; Harding, Mark
Cc: Krona, Kirk; Janssen, Luke
Subject: Brief Chat - Your Thoughts On Ranger 035 Coiling Plate Design
When: Friday, November 15, 2024 8:30 AM-9:00 AM (UTC-06:00) Central Time (US & Canada).
Where: Microsoft Teams Meeting

Hi Mark,

Keith suggested I reach out to you for your direct input on our Ranger 035 Coiling Plate design, given your experience with the Ranger 200. I'd like to schedule a brief meeting with you to review our current designs and get your insights. This is an urgent matter as we're preparing for Pulse builds next week.

Specifically, I'd like your input on incorporating Ranger 200 features into our design, particularly the spring-loaded clamps for cavity clips and compatibility with the spinning base. To minimize risks, we're working on two designs in parallel to optimize the angle clip placement. Both of these need to incorporate the rotating base features as well as the spring-loaded clamp.

Your expertise would be invaluable in ensuring we're considering all angles and avoiding potential issues we might have overlooked.

Thank you in advance for your help.

Thank you,

-Narin

- Reached out to peers & colleagues within PI Pkg (Caitlin & Mark) early on in the project to leverage their experiences with Coiling Plate designs on previous iterations of the product
- Acted on information that was actionable
- Each coiling plate design is unique so very little of the previous designs can be properly leveraged
- Mentioned multiple times on multiple occasions that these plates only appear simple on the surface but they are complex and require time because of all the interdependencies of various design elements
- Reiterated this in detailed explanation Nov. 14th email to Keith (see Exhibit J & K)

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Issue #1: Performance_Exhibit H – Comments

Performance Issues	Narin's Comments (for Context)
- Missed completion dates for component and assembly prints - Delayed deliverables pushing Packaging workstream to critical path - Reactive instead of proactive approach	• Successfully completed the critical Design Freeze milestone for the Ranger 035 project • Demonstrated flexibility by sacrificing vacation time and working extended hours • Proactively managed work with international team members • Completed critical project deliverables on time • Worked 14-16 hours per day, 7 days a week for 3.5 months straight • Maintained overall program schedule despite challenges • Forfeited 40 hours of earned vacation in 2024 • Restarted design work a week before Christmas due to last-minute team decision • Provided the necessary priorities to workstreams that had long lead times involving multiple interdependencies and high impact • On a project that is accelerated with a timeline that has been compressed, it is absolutely essential to prioritize resources and efforts

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Issue #1: Performance_Exhibit H – Comments

Performance Issues	Narin's Comments (for Context)
- Multiple iterations of coiling plate development (8th iteration) **- Print development issues (incorrect views, mistakes in carrier tube design)** **- Late changes to vendor strategy**	• There is an incorrect perception that coiling plates are simple and can be designed within a few iterations • Once changes are made, they need to be validated with a physical prototype to ensure intended changes are properly reflected • Sometimes designers make small subtle changes that can only be identified at a later point with a physical part • These steps are iterative in nature • Each coiling plate design is unique and complex, requiring multiple iterations • Explained complexities and interdependencies of design elements to team • We worked with approved suppliers on the carrier tubes; the design and resulting decisions were made based on the information that was provided to us • We have had to adapt our approaches given the circumstances under which we were operating • Changes to carrier tube vendor selection was due to input provided by the suppliers; initially Advant told us they couldn't fabricate a feature we needed and we only learned later that they could after their Technical Managers was consulted

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Issue #1: Performance_Exhibit H – Comments

Performance Issues	Narin's Comments (for Context)
- Not efficiently utilizing Pkg resources **- Lack of collaboration with Pkg resources on project design strategy** **- Insufficient collaboration with Hemoteq and PD function** **- Failing to include Pkg management for initial pre-sub submission review**	• We need to prioritize and utilize limited resources in an efficient manner and balance it against the needs of the program • Packaging Technicians and Interns were focused on top priority workstreams • Support from Costa Rica and India was used for Engineering Drawings and CN initiation • Proactively managed work with both US and India-based CAD designers • Worked with India and Arden Hills designer in parallel on the coiling plate designs in order iterate and refine the designs quickly to make full use of their respective work hours; • Team decided early on in the program to limit contact with Hemoteq AG to certain core team members due to the sensitive nature of the working relationship • Reached out to peers & colleagues within PI Pkg early in the project • Responded quickly when collaboration gaps were identified • Engaged PD resources on the coiling plates once the design was final so they can fabricate a metallic production version. This aligns with the experiences of Pkg Engineers who worked on other Ranger programs. • Respectfully disagree with the point about failing to involve Pkg Management in FDA Pre-Sub Preparation & Discussion (see Meeting Invite confirming discussion on September 2nd that I scheduled on August 28th). The team had just completed our preparation on August 27th.

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Issue #1: Performance_Exhibit H – Comments

Performance Issues	Narin's Comments (for Context)
- Mistakes in print development **- Multiple PO requests/pullbacks due to incorrect quotes or print changes**	• Errors can occur due to high workload and extremely tight deadlines • PO changes reflect evolving project needs • Made informed decisions based on the latest information available • Balanced immediate project needs with long-term requirements

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Issue #1: Performance_Exhibit H – Comments

Performance Issues	Narin's Comments (for Context)
- Not guiding Packaging Function as Principal Pkg Lead **- R&D team stepping in to lead FG prints and BOMs**	• I respectfully disagree with the comment about me not guiding the Packaging Function as Principal Pkg Lead: ○ I designed and developed the Packaging Solutions for Ranger 035 ○ I developed the experimentation plan and executed to get the necessary data to support the design ○ I prepared the slides to present to stakeholders ○ I provided the Packaging Input for the Engineering Spefications ○ I led, managed, and coordinated the workstreams of the resources that was at my disposal to use their respective strengths in an effective manner to meet the needs of the program ○ I provided the Packaging Input for the Regulatory submission with FDA ○ I mapped out the entire experimentation set anticipating worse case scenario where timing of various conditioning steps do not align. ○ When the team made a decision to change the Pkg Design on Dec. 16, I adapted, built, and packaged each individual test units during the holiday shutdown. ○ I coordinated the necessary conditioning, sterilization, and aging for the test units.

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Issue #1: Performance_Exhibit H – Comments

Performance Issues	Narin's Comments (for Context)
- Not guiding Packaging Function as Principal Pkg Lead **- R&D team stepping in to lead FG prints and BOMs**	○ I communicated with the PA testing lab to provide them with a heads up on timing for needed testing ○ I analyzed the results of the test units ○ I set up the meeting to pre-sell stakeholders and provide them with an opportunity to dig into the data and results ○ Given these contributions, I would appreciate clarification on what specific additional actions are expected in guiding the Packaging Function as Principal Pkg Lead. • I respectfully disagree with comment about R&D team stepping in to lead FG prints; that is absolutely false as I worked on that. I went through those prints and double checked each dimension and each note line by line so I categorically disagree with this comment. • I also respectfully disagree with the comment about R&D stepping in to create the BOM structure. I offered to do it as I've had experiences dealing with it before but Galway R&D said they can handle it as they need to address the device portion anyway. I obliged but I have been providing them with guidance on how to handle the final top assembly portion with respect to structure. When issues arise, I am working side by side with them. I explained this in multiple 1:1 meetings yet it continues to be brought up.

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Issue #3: Discriminatory Promotion Practices

- During my 25-year tenure, I've made significant contributions to BSC, particularly in innovative packaging design, but despite my expertise and dedication, career progression has been elusive due to the biased nature of promotional processes.
- I recognizes that all of my colleagues are very deserving of their promotions and titles;
  - It is the disparity in speed to achieve those levels and the correlation between Caucasian and an Asian colleague is where the concern lies

Key points include:

- Pattern of career stagnation despite contributions
- Comparison with peers of different racial backgrounds
- Promoted to Principal Engineer in September 2018 after 18 years with the organization only when both ELUVIA and the custom temperature controlled soft bag for SRAI applications was held in high regards for quality by both internal and external customers alike.
- Majority of my caucasian colleagues achieved their current positions (Principal Engineer or Manager) within 6 years
- There is a significant disparity in the time taken for career advancement between me (Asian) and my Caucasian colleagues.

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Issue #3: Discriminatory Promotion Practices

Key Achievements and Challenges:

- Innova Stent Delivery System Redesign:
  - Requested by PI Division President Jeff Mirviss
  - Resulted in groundbreaking improvements and delayed product launch to incorporate new design
  - Credit went to Keith, who assisted with DV activities and later became Sustaining Pkg Manager
- ELUVIA Drug Eluting Stent and SRAI Packaging:
  - Successful packaging design for ELUVIA
  - Additional requirement to develop SRAI solution for promotion to Principal Engineer

Specific Instances Where Bias Likely Played A Role:

- My Career Progression Obstacles:
  - When Diona Sommario (my former Pkg Mgr) left BSC in 2011, her manager role was given to a Caucasian male without interviews
  - A peer (Caucasian male) progressed rapidly to Fellow from Sr. Engineer in three or four years, the only one in Packaging Engineering
  - Applied for Sustaining Pkg Mgr I position vacated by Keith but ultimately went to Caucasian woman with less experience
  - Interested in applying for Mgr I PI Pkg NPD also vacated by Keith (given to Aaron) without competitive interview opportunities for other qualified personnel
  - Recent application for Manager of Packaging Acquisitions rejected without interview, citing lack of people management experience

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Issue #3: Discriminatory Promotion Practices

Manager I of PI Pkg NPD Role (2024):

- Background - role was most recently held by Keith
- Appointment Process - Position given to Aaron (Caucasian male)
  - No open interview process conducted
- My Experience - Lack of Opportunity
  - Keith was aware of Narin's interest in career progression
  - Position given to Aaron (Caucasian male)
  - Attempts to Understand the Decision
    - First Inquiry in Q1 2024 - Asked Keith directly about rationale
      - Keith's response was that HR didn't want to have an interview process & desire to rapidly fill role
      - Keith saw Narin more as a future Fellow
    - Second Inquiry in Q1 2025
      - Occurred during a 1:1 meeting on March 10th, 2024
      - Keith's response was there was no headcount increase, therefore no interviews were required
  - Contrasting Contributions
    - Narin played significant role helping to define strategies for PI Pkg group's future

Manager I of Pkg Acquisitions Role (2025):

- Background
  - New role under former Pkg Mgr (Richard Tuma)
  - Expressed Interests w/ Richard in December 2024
- Appointment Process
  - No interview w/ reason cited as lack of “experience in people management”
  - Cover letter (via e-mail) that Narin provided clearly conveyed past experiences managing technicians, interns, and mentoring of less experienced Engineers

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Mgr I Pkg Acquisitions – Email Chains

From: Anderson, Narin
Sent: Monday, February 10, 2025 6:20 PM
To: Tuma, Richard <Richard.Tuma@bsci.com>
Subject: Acquisitions Packaging Engineering Manager Role

Good Evening Richard,

I'm reaching out to inform you that I've applied for the Acquisitions Packaging Engineering Manager position that recently opened up within your group. Having worked closely with you in the past, I'm excited about the opportunity to potentially join your team again in this new capacity.

As you know from our time working together, I have a deep passion for packaging engineering and a track record of successfully leading complex projects and cross-functional teams. In my current role as Principal Packaging Engineer, I've had the chance to further develop and refine my skills in areas that I believe align well with this position, including:

- Managing critical packaging redesign projects across global teams
- Communicating complex information in a clear manner for Senior Management and various internal and external stakeholders
- Implementing innovative solutions to improve product quality and operational efficiency
- Mentoring team members and fostering high-performance environments
- Navigating ambiguous situations to buy down risks while meeting contradicting requirements and accelerated timelines.

I'm particularly drawn to the opportunity to lead packaging integration efforts for acquired companies. Having been involved in several key product launches and redesigns over the years, I'm eager to apply my experience to ensure smooth transitions and compliance with regulatory requirements during acquisitions.

I believe my combination of technical expertise, leadership experience, and familiarity with Boston Scientific's processes and culture would allow me to hit the ground running in this role. I'm excited by the chance to take on new challenges and contribute to the continued growth and success of the packaging organization.

I appreciate your consideration and would welcome the opportunity to discuss how I could add value in this position. Please let me know if you need any additional information from me.

Warm Regards,

From: Anderson, Narin <Narin.Anderson@bsci.com>
Sent: Wednesday, February 26, 2025 12:12 PM
To: Tuma, Richard <Richard.Tuma@bsci.com>
Subject: FW: Acquisitions Packaging Engineering Manager Role

Hi Richard,

I just want to do a quick check in with you on where you're at with your selection process for the new role of Packaging Acquisitions Manager. As I mentioned previously, I'm really interested in the new position and just wanted to know if I could be given the chance to interview for the role. Since my application submission a couple of weeks back, I haven't heard anything more about it.

If I've already been ruled out, I understand.

Thank you,

From: Tuma, Richard
To: Anderson, Narin
Subject: RE: Acquisitions Packaging Engineering Manager Role
Date: Monday, March 3, 2025 2:59:53 PM

Hey Narin,
Thank you for reaching out and expressing your interest in the Manager and Senior positions. After careful consideration and our recent discussion, we have decided not to move forward with an interview for the Senior position at this time.

We believe you are highly capable and have the potential to contribute significantly to our team. However, the responsibilities and expectations for the Senior role do not align with your current career trajectory and growth path. As we discussed, the Senior position in acquisition is an individual contribution, which may not be the best fit for your professional development goals. In addition, I would not advise moving from a principal position to a senior position.

We are confident that there will be future opportunities as our team continues to grow (principal level), especially with the recent approval of additional acquisitions. I will keep you informed about any new openings that may better align with your skills and aspirations.

As for the management role, we were looking for a people manager with people management experience at some level…interns, techs, small groups. In addition, experience in management activities that help drive the acquisitions group and support the infrastructure in the current growth.

I hope this explains the "why", but I'm interested in talking with you more about potential within my group (let's talk).

RT

- Despite me mentioning on multiple occasions that I've had experiences with Managing People & Teams, I couldn't even get an interview for this Manager I role with PI Pkg Acquisitions
- Richard T. was my former Manager when I worked on ELUVIA

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Internal Postings – Unsuccessful Applications

Boston Scientific

Boston Scientific | Home | Career Interests | Jobs | My Activity | People | Resources For Help | Search for job or keyword | NA

Project Manager I	596854	Jan 3, 2025	Rejected	Rejected	Feb 18, 2025	United States	Maple Grove	Project/Program Management
Project Manager I	597354	Jan 2, 2025	Rejected	Rejected	Mar 15, 2025	United States	Arden Hills	Project/Program Management
R&D Manager I	596534	Dec 13, 2024	Rejected	Rejected	Jan 29, 2025	United States	Arden Hills	Engineering
Project Manager I	595831	Dec 13, 2024	Rejected	Rejected	Jan 22, 2025	United States	Arden Hills	Project/Program Management
Senior Packaging Acquisition Engineer	595797	Dec 10, 2024	Rejected	BSC: Auto-Disqualified	Dec 11, 2024	United States	Arden Hills	Engineering
Global Labeling Systems (GLS) Project Manager I	594393	Dec 9, 2024	Rejected	Rejected	Jan 17, 2025	United States	Arden Hills	Project/Program Management
Customer Experience AI Marketing Manager	596354	Dec 7, 2024	Rejected	Rejected	Dec 13, 2024	United States	Maple Grove	Information Technology
Principal AI Delivery Program Manager	595449	Nov 30, 2024	Rejected	Rejected	Dec 3, 2024	United States	Arden Hills	Project/Program Management
Senior Manager Packaging Engineering R&D	587296	Aug 22, 2024	Rejected	Rejected	Sep 5, 2024	United States	Arden Hills	Engineering

Chat with our Recruiting Assistar

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Issue #3: Disparity of Speed of Career Progression

- At least 8 individuals whom I've worked with in the past who were all Senior Engineers at the same time working in the same projects who have since become Directors (2), Vice Presidents (2), Fellows (2). Senior Managers (2) all of whom are Caucasian
- The following table summarizes the career progression of colleagues from the attached organizational chart structure

Initial Position (2018)	Current Position	Time to Current Position	Gender	Ethnicity
Engineer II	Principal Engineer	6 years	Male	Caucasian
Sr. Engineer	Principal Engineer	6 years	Female	Caucasian
Engineer II	Manager	6 years	Female	Caucasian
Sr. Engineer	Manager	6 years	Female	Caucasian

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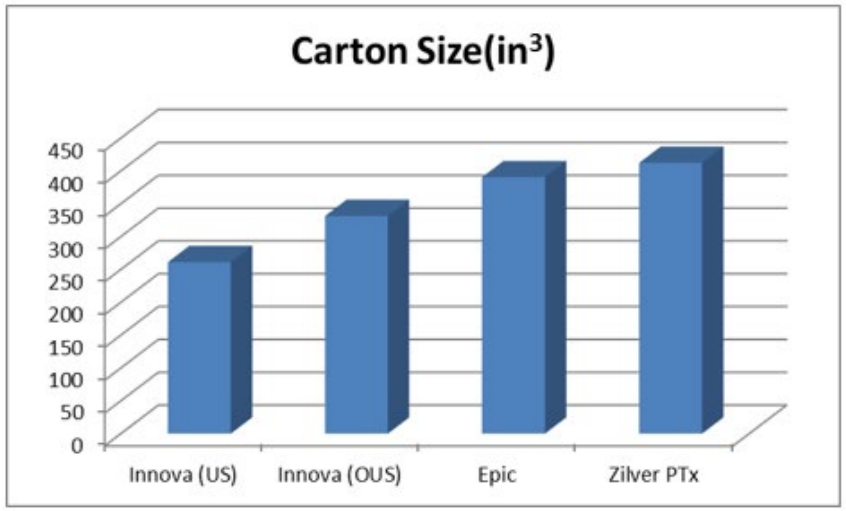
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Past Contributions – Innova Packaging





- 21% smaller than Innova, 33% smaller than Epic, 37% smaller than ZilverPTx pkg
- One-step carton opening; wider product access area
- Enhanced special effects – soft touch texture
- Accomodates Pyxis & Omnicell automated inventory management systems

- This is the carton structural design I introduced for Innova
- Structural Carton Design adopted across numerous BSC Products

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Past Contributions – Eluvia Packaging

IC/PI – SE Packaging (Narin)

ELUVIA PDP – Clinical and OUS Commercialization

Description: Apply new packaging system with different artwork

Problems:

- Premium packaging with corporate branding support
- How to depict marketing vision for stent length, flexibility & sustained drug release
- Two sided vs. Three sided carton labels
- Clinical deliverables
- OUS Commercialization deliverables
- Dekra submission packet



Solutions:

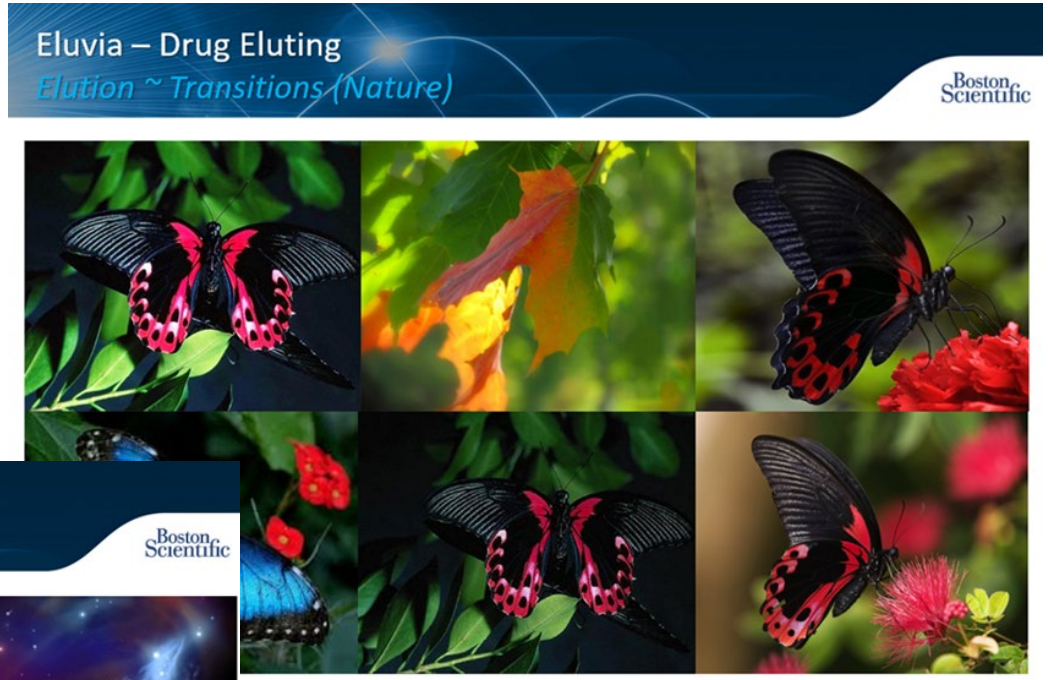
- Carton IP Disclosure submitted
- Successfully convinced corporate to go with two-sided label
- Design concepts – Evaluated more than 12 different tray designs, 18 carton concepts, and 19 artwork concepts within a span of about one year from project start
- Clinical – Dekra questions resolved, received FDA IDE approval, clinical enrollment in progress
- OUS Commercialization – Commercial builds in progress

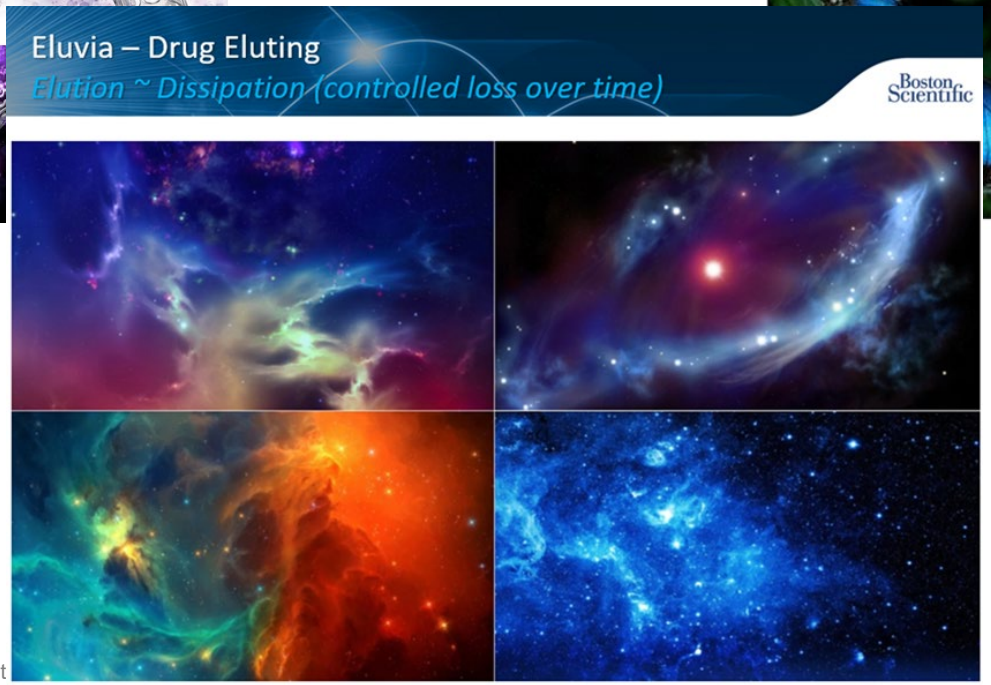
- This is the carton structural design I introduced for ELUVIA
- Structural Carton Design adopted across numerous BSC Products
- The appearance of using the BSC blue for drug elution against a black background was intentional

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Appearance of ELUVIA Drug Elution







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- My artwork concept for Drug Elution played a significant role differentiating ELUVIA from it's competitors at commercial launch
- The appearance of using the BSC blue for drug elution against a black background was intentional

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Strategy Dev Contribution - PI Pkg NPD

Design Approach

"Simplicity is about subtracting the obvious, and adding the meaningful."

Sole Purpose: Provide the minimum amount of information for a user to make a decision and act upon it by removing as much clutter as possible, thereby focusing the user's attention on the most important design element.

- What we cannot control, we organize.
- More accurate representation of the product
- Balance the design so the output resonates with our audience
  - Drug Elution (controlled)
  - Stent Flexibility
  - Stent Length

Drug Coating Vs. Drug Elution

What is the difference?

- Drug Coatings – What goes onto the stent
  - Droplets in space taking the form of a sphere due to the tendency for it to attain maximum entropy.
- Drug Elution – What comes off the stent
  - In vessels - a uniform, controlled dissipation
  - Emulate nature
  - More accurate depiction

- This is the Design Strategy I employed for Innova & ELUVIA that defines the look and feel of these classes of products
- Much of the work here was adapted to the PI Pkg Strategy Proposal to Senior Management in 2023
- When The Role of Manager I for PI NPD Pkg Became Available, Interviews Were ***NOT*** Allowed

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Past Contributions – Custom Temp Controlled
SRAI Bags for DES Products

Proposal

Plan: 3-4 Month Custom Development of Tertiary Packaging

- Determine most probable SRAI Quantity, Hold Duration, logistics flow, and account for temperature fluctuation by location
- Ideal solution: Custom trunk stock storage design to hold ELUVIA units in the trunk of a car for an extended duration that is also mobile which reps can take with them into the hospital
- Evaluate Various Options To Determine Best Path Forward For ELUVIA
  - Qualify existing solution from Drug Microsphere project
  - Alternative: Temp Controlled Insulated Shippers
  - Yeti Cooler + Dry Ice???
  - Alternative temp dot (at lower temp) that can be applied to the trunk storage unit



- Custom made solution designed & developed from scratch starting September 2017
- Impact: > $1.5 Million in Annual Sales via SRAI Sales Channel in 2019 (*Source*: Joe Fronius, Sr. Group Mktg Manager)
- Adopted by BSC Globally & Across Other Divisions

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Packaging Design Evolution

Visual Appeal
Compared To Existing Designs

"A simple, clean, premium package which emphasizes drug coating performance and best-in-class stent."





- Simple, clean, premium package
- Disrupts existing design patterns with minimalistic approach
- Continue to retain required information on back side

Why?





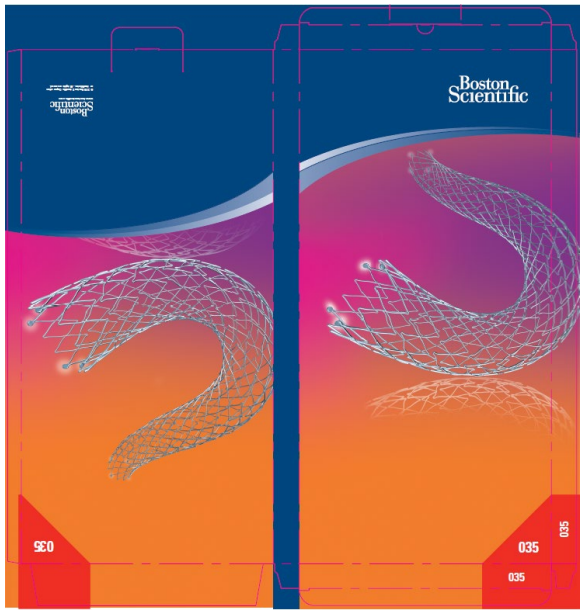


- Negative field feedbacks regarding Epic size
- Shelf Appearance concern
- Customer Perception

BSC Packaging Designs Before

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Past Contributions - Packaging Design



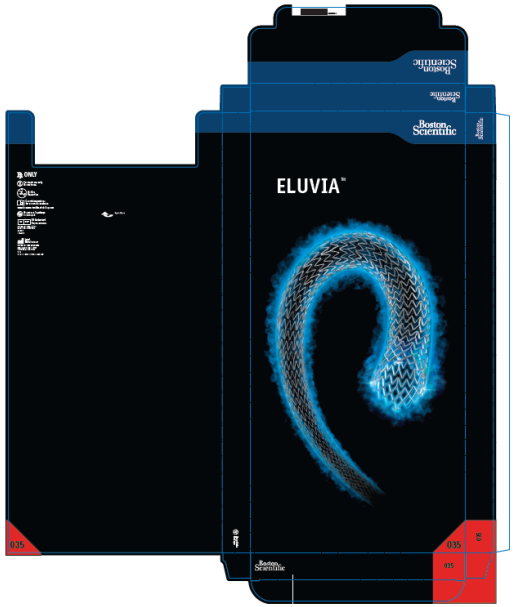
Epic

- UV/Gloss Coating
- Baseline footprint size



Innova

- Soft Touch Coating
- Tab Like Carton
- Smaller footprint size



ELUVIA

- Soft Touch Coating
- Smaller footprint size
- Drug Elution
- New Artwork



SAVAL

- Soft Touch Coating
- Smaller footprint size
- Drug Elution
- New Artwork

Before

[After] Narin's Work

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Exhibit C	Resume_Narin Anderson
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Exhibit E	Performance Review Dispute
Exhibit F	Additional Support w/ Management Criticism

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Addendum: 1:1 PIP Meeting Minutes_2025-Apr-10

Content of Actual Meeting:

- Project updates about tube flaring, Ranger project, and Localized Thermal Protection TDP
- Discussion about Brittany's upcoming role
- The transition to personal performance feedback
- Confrontational exchange about Narin's performance rating
- Narin's concerns about being evaluated primarily on peer feedback rather than deliverables
- Aaron's mention of a team requesting not to work with Narin
- Discussion about Narin's 25 years at the company
- Narin's concerns about the PIP adding stress without providing support

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Addendum: 1:1 PIP Meeting Minutes_2025-Apr-10

New Evidence in Formal Complaint - Narin Anderson



Anderson, Narin
To Harris, LaDeja

Reply | Reply All | Forward

Thu 4/17/2025 11:45 PM

Retention Policy Delete Emails after 730 days (2 years) Expires 4/17/2027

You replied to this message on 4/18/2025 10:19 PM.

04.1 - Addendum 2025-04-17_Meeting Minutes Discrepancy Analysis.pdf
210 KB

04.2 - Addendum 2025-04-17_RE_ 1_1 Aaron & Narin (Comments From 10-Apr-2025 Discussion).pdf
658 KB

04.3 - Addendum 2025-04-07_Meeting Transcript for 2025-04-10.pdf
133 KB

02 - BSC PI Pkg NPD - Complaint_Revised 2025-04-17.pdf
4 MB

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.

Narin Anderson
Principal Engineer
Boston Scientific
Packaging Engineering
narin.anderson@bsci.com
651-581-9203
Three Scimed Place
MS C120
Maple Groe, MN 55311
www.bostonscientific.com

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Critical Discrepancy Analysis

- **Executive Summary**: Manager's Minutes vs. Meeting Transcripts
  - Below is a factual comparison between the recorded meeting transcript and the subsequent written meeting minutes provided by Aaron Clark regarding the April 10, 2025 discussion with Narin Anderson. This analysis focuses solely on the most significant discrepancies that may impact performance evaluation integrity.
- **Critical Discrepancies**

1. Fabrication of Narin's Position on Work Hours

  - *Aaron's Minutes State*: "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."
  - *Actual Transcript Shows*: I never mentioned long workdays, nights, or weekends as justification for deserving a better rating. My actual concern was that his rating was "driven primarily by feedback" without consideration of successful project deliverables.
  - *Narin's actual statement*: "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.“
  - I have never made a stink about my efforts either to Aaron or my team, let alone divulge the inordinate number of hours I actually worked to pull off my deliverables under difficult circumstances. Only the people I work closest with (Orla, Amy, and Mike) have a surface level sense of what was happening due to my regular updates to them. This formal complaint documentation is the only place where my documented work hours reside.

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Critical Discrepancy Analysis

2. Omission of Serious Team Request Claim

- *Aaron's Minutes*: No mention of any team requesting not to work with Narin.
- *Actual Transcript*: Aaron stated: "And quite frankly, I had a team request that you weren't on their team."
- This significant claim was made without providing specific details or allowing Narin to address which team or why.

3. Mischaracterization of Meeting Tone and Conduct

- *Aaron's Minutes State*: "I appreciate the open, honest, and difficult discussion during our 1:1 last Thursday (April 10, 2025)."
- *Actual Transcript Shows*: A confrontational exchange with statements from Aaron such as: "I didn't do anything to you, Narin. I am not your enemy."
- The meeting contained multiple interruptions and emotional exchanges not reflected in the sanitized minutes.

4. Claims of Support Contradicted by Transcript

- *Aaron's Minutes State*: "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."
- *Actual Transcript Shows*: When Narin stated the PIP wasn't helpful ("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")
- Aaron did not address this concern or offer specific support.

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Critical Discrepancy Analysis

5. Misrepresentation of Performance Evaluation Criteria

- *Aaron's Minutes State*: "Your performance has been below the expected level for a P-5 Level Engineer in the areas of collaboration, planning, communication, and deliverable execution."
- *Actual Transcript Shows*: When I specifically asked about whether my successful project deliverables were considered in this evaluation, Aaron avoided directly answering and shifted focus to team dynamics.

➢ ***Request for Review***

- I respectfully request a review of this performance management documentation process to ensure it meets company standards for accuracy and fairness.
- I am concerned that such significant discrepancies between the actual conversation and official documentation may undermine the integrity of the performance management system.
- Creation of documentation that misrepresents employee statements undermines the integrity of the performance management system further supporting my claim of biased treatment.
- I surmise that my manager is using documentation to justify predetermined conclusions rather than fairly assessing my performance and manipulating the narrative to fit the fact I am on a PIP with an “Improvements Required” rating.
- The fabrication and selective documentation appear designed to manipulate the narrative and build a case against me rather than accurately record interactions. The omission of the 25-year tenure discussion is significant because that supports one of my other claims about age discrimination.

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Addendum: FDA Pre-Submission Alignment Incident

- **Incident Overview**: Manager's Mischaracterization vs. Evidence
  - My performance evaluation cited "Failing to include Pkg management for initial pre-sub submission review" (documented in Exhibit G, page 2 of the Performance Improvement Discussion follow-up dated November 18, 2024).
  - Aaron perpetuated this claim to his manager, Keith, leading to further negative scrutiny.
- **Contradictory Evidence**

  The following documentation demonstrates this claim is demonstrably false and represents a significant, deliberate omission:
  - *August 28, 2024 [9:30 AM CST]*: Team finalized content for FDA Pre-Sub Submission (Documented on page 66 of my formal complaint)
  - *August 28, 2024 [12:48 PM CST]*: I sent a meeting invitation directly to Aaron scheduling a specific discussion for September 3rd regarding this FDA Pre-Sub packet (Documented on page 68 of my formal complaint)
  - *September 3, 2024*: The meeting occurred as scheduled, where I briefed Aaron on the submission content.
  - *November 8, 2024*: I proactively addressed this discrepancy with Aaron via email after learning that Keith was under the impression consultation had not occurred (Documented on page 69 of my formal complaint).
  - *November 18, 2024*: Despite my documented consultation and follow-up, Aaron formalized the false claim in written performance documentation, copying Keith.

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FDA Pre-Submission Alignment Incident

- **Significance**: This incidence 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 (Documented on pages 66-70 of my formal complaint) 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.
- **Conclusions**:
  - 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.

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FDA Pre-Submission Alignment Incident

Boston Scientific

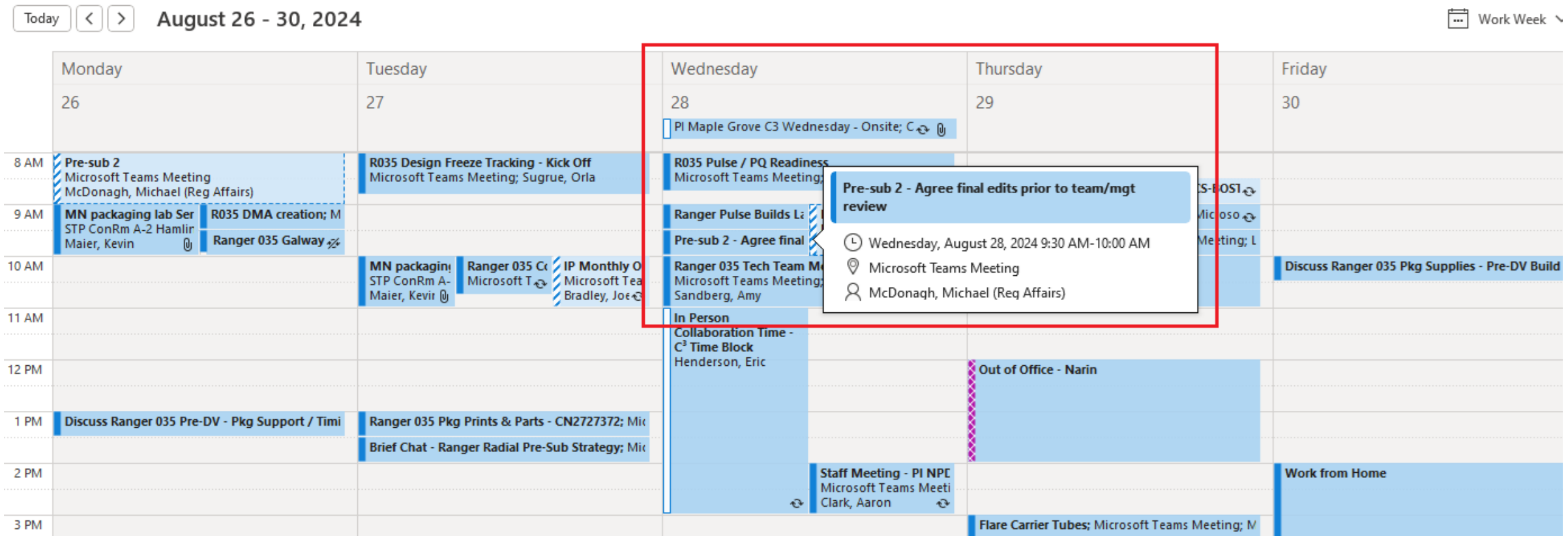
Results

To	Subject	Sent	Size
McDonagh, Michael (Reg Affairs)	Accepted: Ranger 035 Pre-sub	Mon 9/2/2024 11:05 AM	7 KB
Harding, Mark; Martell, Patrick	Brief Chat - Ranger Radial Pre-Sub Strategy	Fri 8/30/2024 1:26 PM	66 KB
Hi Mark - Ranger 035 is finalizing our Pre-Sub for which Management Review is in progress. I'm taking a similar approach as Ranger Radial with respect to packaging by testing our Pkg DRs at T=0 but leveraging Ranger Commercial f			
McDonagh, Michael (Reg Affairs)	RE: Ranger 035 Pre-sub 2 Team and Management Review	Wed 8/28/2024 12:52 PM	49 KB
For the shelf life testing, I'm fine with identifying what we don't test but I think it would more straightforward and clear to indicate that we plan to test for Manifold Removal and Catheter Withdrawal because if we leave it as it stand			
Clark, Aaron	Ranger 035 Pre-Sub Review / Discussion	Wed 8/28/2024 12:48 PM	71 KB
Aaron,			
McDonagh, Michael (Reg Affairs)	Accepted: Pre-sub 2 - Agree final edits prior to team/mgt review	Wed 8/28/2024 7:49 AM	8 KB
Martell, Patrick	Anderson, Narin replied to a comment in "Ranger 035 Pre-sub 2"	Mon 8/26/2024 8:23 AM	220 KB
Ranger 035 Pre-sub 2.docx Sandberg, Amy left a comment @Anderson, Narin@Martell, Patrick@McCleary, Kyle inspection and loading tool removal acceptance criteria will still align with Ranger 018, correct? McCleary, Kyle left a			
McCleary, Kyle	Anderson, Narin replied to a comment in "Ranger 035 Pre-sub 2"	Mon 8/26/2024 7:58 AM	219 KB
Ranger 035 Pre-sub 2.docx Sandberg, Amy left a comment @Anderson, Narin@Martell, Patrick@McCleary, Kyle inspection and loading tool removal acceptance criteria will still align with Ranger 018, correct? You left a comment I dor			

- *August 28, 2024 [9:30 AM CST]*: Team finalized content for FDA Pre-Sub Submission (Documented on page 66 of my formal complaint)
- *August 28, 2024 [12:48 PM CST]*: I sent a meeting invitation directly to Aaron scheduling a specific discussion for September 3rd regarding this FDA Pre-Sub packet (Documented on page 31 of my formal complaint)

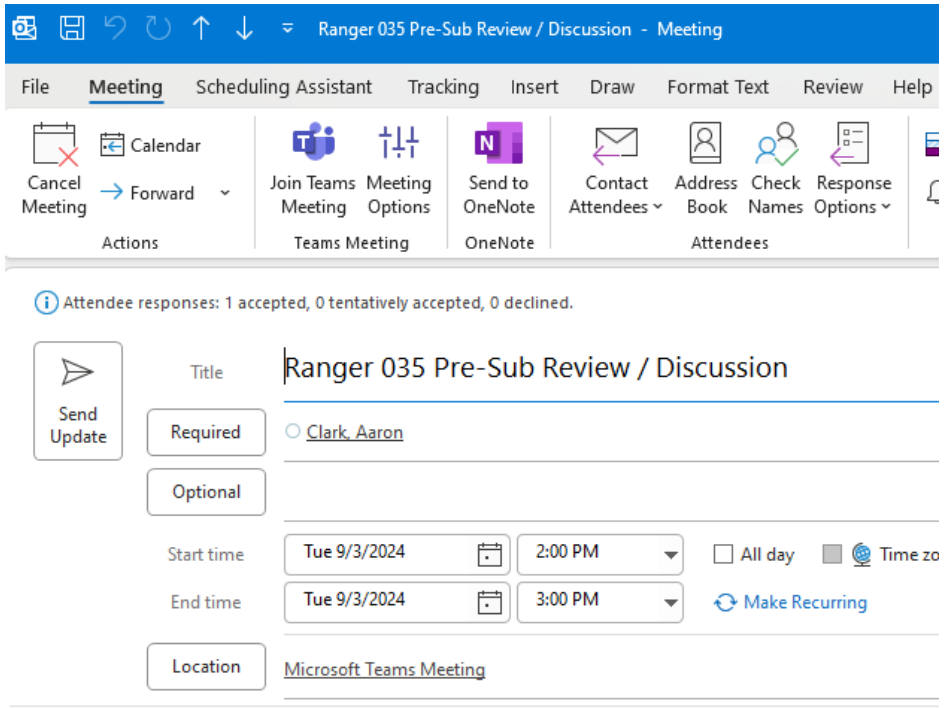
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FDA Pre-Submission Alignment Incident



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FDA Pre-Submission Alignment Incident



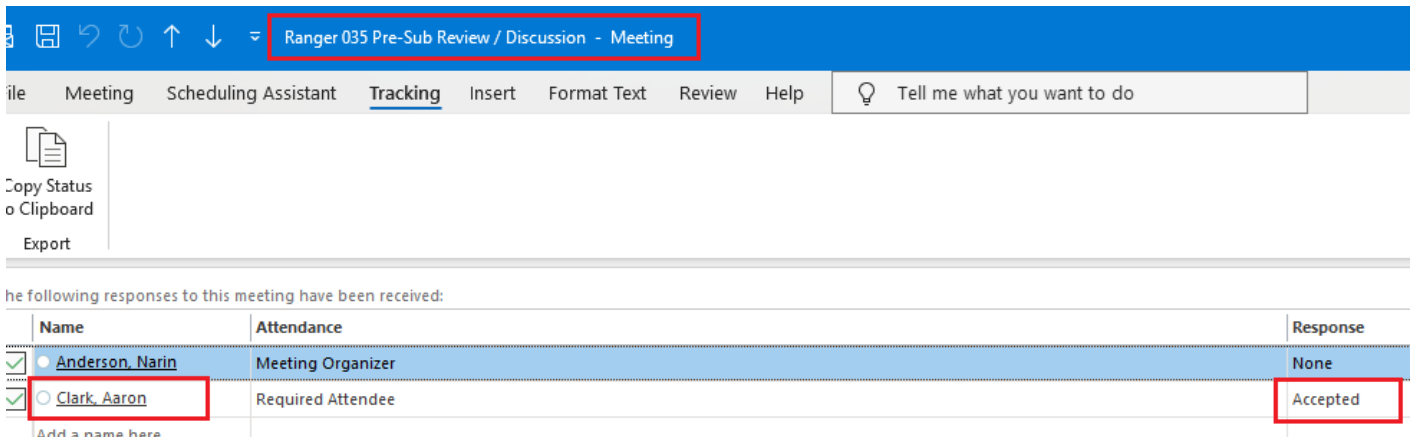
Aaron,

I'd like to get together with you to review the Ranger 035 Pre-Sub that will be sent to FDA:

Ranger 035 Pre-sub 2.docx

For packaging, we're going to follow a similar approach to Ranger Radial to test DRs at T=0 and lev
post aging.

-Narin



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FDA Pre-Submission Alignment Incident

RE: ISTA 2A vs. ASTM D4332 - Climatic Conditioning



Anderson, Narin
To Clark, Aaron

Reply | Reply All | Forward

Fri 11/8/2024 6:56 PM

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Expires 11/8/2026

Just an FYI, prior to the follow up meeting that Orla scheduled this morning for the Pre-Sub in preparation for the FDA meeting next week, I digested the information that you forwarded. I made Keith aware that the Ranger 035 Pre-Sub made a claim to be compliant with ASTM D4332 only to realize that we need to edit that and be prepared to defend. I took the information you forwarded below to me and examined various documentation more closely and consulted with Dan Burgess how best to address the matter. After that I had a 1:1 chat with RA to chat through it and Mike McDonagh informed me he was already aware of this matter in his consultation with RA from Ranger 200. I had prepared an analysis to discuss in the team meeting and learned that Mike M. had started something similar which made it a lot easier as we were both thinking along the same line.

We discussed this in the team meeting worked on the slide below together. I had Dan provide his input as well to make sure he was in alignment. He suggested a minor tweak to make a reference to just ISTA, rather than specifically ISTA 2A. The slide below is what will be presented to FDA next week. The gist of the message I'm going to convey is that BSC will be complying closely to the ISTA standard which is more rigorous than ASTM D4332. FDA has agreed to this already in Ranger 200.

I wanted Dan Burgess to be part of the call to help me if I get stumped for some reason but I'm pretty confident I can handle it now that I'm fully aware and caught up on the issue.

These past few months have been a little challenging for me as there is a lot going on simultaneously and I'm the kind of person who need time to think things through carefully before taking action. Keith inquired why I hadn't consulted with you and him prior and I told him that we just got the FDA feedback at noon the previous day and I barely had time to digest their feedback. He might bring this up with you so I want you to understand the background first.

Discussion on FDA Additional Written Feedback – Packaging Validation

BSC plans to subject the Ranger 035 to ASTM D4169 Distribution Conditioning Cycle DC 13

BSC plans to expose Ranger 035 to climatic conditions which are derived from the ISTA series of distribution simulation standards not ASTM D4332.

The Ranger 035 packaging test units will be exposed to all the appropriate conditions (desert, tropical, extreme cold) per ISTA in series prior to evaluating product performance. The table below presents proposed BSC conditioning parameters in comparison to ASTM D4332 with associated justifications:

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FDA Pre-Submission Alignment Incident

Ranger 035 Pre-Sub

Anderson, Narin
To Clark, Aaron

Reply | Reply All | Forward

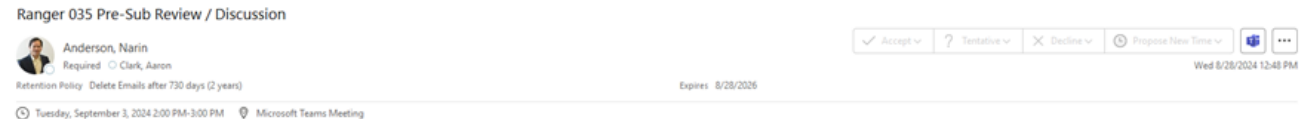
Fri 11/15/2024 8:09 PM

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Expires 11/15/2026

Hi Aaron,

Thanks for taking the time to discuss my performance today. I appreciate your feedback and take it seriously. I've been reflecting on our conversation and wish to clarify a point that was brought up concerning the Pre-Sub. I believe there might have been a misunderstanding because my records show that we did meet and discuss this matter. In future meetings I will ensure we have multiple discussions on something like this.


Ranger 035 Pre-Sub Review / Discussion

Anderson, Narin
Required Clark, Aaron

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Expires 8/28/2026

Tuesday, September 3, 2024 2:00 PM-3:00 PM Microsoft Teams Meeting

Ranger 035 Pre-Sub Review / Discussion

Anderson, Narin
Required Clark, Aaron

Accept | Tentative | Decline | Propose New Time

Wed 8/28/2024 12:48 PM

Retention Policy Delete Emails after 730 days (2 years)

Expires 8/28/2026

Tuesday, September 3, 2024 2:00 PM-3:00 PM Microsoft Teams Meeting

Aaron,

I'd like to get together with you to review the Ranger 035 Pre-Sub that will be sent to FDA:

Ranger 035 Pre-sub 2.docx

For packaging, we're going to follow a similar approach to Ranger Radial to test DRs at T=0 and leverage package shelf life from Ranger commercial supported by complaints analysis. However, the plan is to test for Manifold Removal and Catheter Withdrawal post aging.

-Narin

➢ We did discuss FDA Pre-Sub

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