From: Anderson, Narin
To: Clark, Aaron
Subject: RE: Therasphere Pkg Workstream Feedback / Concerns & Follow Up on 1:1 today (Oct 14)
Date: Wednesday, October 15, 2025 4:01:00 PM
Attachments: image001.png

Hi Aaron,

I just want to summarize our 1:1 discussion yesterday to ensure we're aligned. I appreciate your “excellent” complement on the Immunobead packaging development plan. Per your request, I will present in an upcoming staff meeting. I'm also glad we could clarify the situation with the TheraSphere DV testing.

To recap my update:

- As I mentioned, I've been supporting the TheraSphere project since November 2024, alongside my primary Ranger duties at the time despite urgent Ranger workstreams at the time and have continued to support it throughout this year even with the additional commitment to the Immunobead program.

- The label traceability issue had been fully resolved prior to my Evonik trip two weeks ago. It appears the project manager, Mike Heier, may not have had the complete picture when he spoke with you.

- The protocol was executed as planned. The discrepancy in shelf carton count (n=8 vs. the expected n=11) did not impact the validity of the overlabel data, as the overlabel adhesion & print quality in this instance is independent of the shelf carton. As I explained in our 1:1 meeting, back in March I received two shippers with a total of n=8 shelf cartons. I was actually surprised to get two shippers containing a total of n=8 cartons since I was expecting at least n=11 per the protocol because normally, there is a direct correlation between shelf carton count and overlabel placement. As I explained in our meeting, this case is more nuanced in that we actually apply multiple overlabels (given their smaller sizes to the primary label). Since we are evaluating the interactions of the overlabel to the other elements (carton substrate, existing CEA applied labels, and the primary label, that is the rate limiting component of the whole system and not the carton count.

  This was the reason I didn’t bring up my surprise to Elizabeth’s attention back in March when I learned of the discrepancy. It was a Packaging workstream that I owned and a design I would have needed to defend. Even with n=8 shelf cartons, the fact that each shelf carton had two of the larger overabels (and six of the smaller overlabel), suggest that we had n=2x8=16 of the larger of the two overlabels (or n=6x8=48 of the smaller of the two overlabels). Finally, the only difference between the two overlabels is size. The both have the same material and construction, providing additional assurance of the integrity of the design. I inspected the carton labels and there was no issue with any of the sample numbers. I had planned on meeting with Elizabeth to explain all of this and get her agreement to generate a clean data supplemented with a strong engineering rationale but due to my busy work schedule these past couple of weeks, I hadn’t had the chance to do so yet. My plan was that once she agreed, I’d put together a strong rationale for the team. However, your email to me on Thursday, October 9th suggested the team jumped the gun without proper input from me.

  Regardless, if the team wants a cleaner set of data and feels more comfortable repeating the exercise because of the need to repeat DV due to device related issues, we need to be on the same page that the reason is device related and not because of a Packaging misstep. I’ve scheduled a meeting with Elizabeth and Kirk to go over this tomorrow afternoon, October 16h.



Role Type	Part Number	Size	Face Stock	Adhesive	Substrate	Sterilization	Aging Time Points	DV Report
Primary	50879123-001	4.00 x 6.13	TT2C	S2550	Tyvek	EtO	T=0, 37 months, 61 months	92160282
Primary	50879123-001	4.00 x 6.13	TT2C	S2550	SBS Carton (unprinted, no coating/varnish)	N/A	T=0	92818781
Primary	51187476							
Over Label	Avery 8460	Unknown	Unknown	Unknown	Tyvek	N/A	T=0	92760101
Over Label	51117389	2.00 x 2.63	TT2C	S2550				New
Over Label	51869135	4.00 x 3.25	TT2C	S2550				New

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- Since the R&D team intends to re-execute the DV to address unrelated device issues, I agree this is a good opportunity to generate a "cleaner" packaging dataset for the team.

Please let me know if this doesn't accurately capture your understanding of our conversation.

Thanks,

Narin

From: Anderson, Narin
Sent: Monday, October 13, 2025 7:47 AM
To: Clark, Aaron <Aaron.Clark@bsci.com>
Subject: RE: Therasphere Pkg Workstream Feedback / Concerns

Thanks for sharing the detailed feedback. I agree that we should discuss this further to ensure we're aligned on priorities and expectations.

I'll be prepared to go over this in the upcoming 1:1 meeting later this afternoon.

From: Clark, Aaron <Aaron.Clark@bsci.com>
Sent: Friday, October 10, 2025 1:36 PM
To: Anderson, Narin <Narin.Anderson@bsci.com>
Subject: RE: Therasphere Pkg Workstream Feedback / Concerns

Hi Narin,

In 2025 you are listed as .5 FTE Ranger 035 / .2 FTE Immunobead / .1 FTE Therasphere / .2 FTE Available Capacity.

We can discuss allocations further for clarification; however regardless of whether a project appears on the official allocation list, if it is part of our division's portfolio, it requires appropriate prioritization based on business need and impact. Allocations are a starting point, not a boundary. We have been discussing Therasphere as a topic in our 1:1s throughout the year and you've been the assigned engineer supporting the program activities both this year and in previous years. While the level of involvement has been minimal at times, this project is on your list for support.

When a project becomes active and deliverables are requested, it's expected that we respond with urgency and ownership. If there are conflicts or concerns about bandwidth or competing priorities, those need to be raised early so adjustments and expectations can adjust accordingly. Justifying lower prioritization based solely on allocation status is not aligned with how we operate as a team.

Regarding the Therasphere Design Verification activity, a lot of concerns are raised when there are observations of missing traceability, missing datasheets, and units that were built incorrectly. If you felt unable to fully support it, that should have been brought to my attention so we could

explore resource options.

In our next 1:1 let's review your current workload and ensure we're aligned on how to best support the activities moving forward.

-Aaron

From: Anderson, Narin <Narin.Anderson@bsci.com>
Sent: Friday, October 10, 2025 8:22 AM
To: Clark, Aaron <Aaron.Clark@bsci.com>
Subject: RE: Therasphere Pkg Workstream Feedback / Concerns

Hi Aaron,

Let's chat more about the issues below in our upcoming 1:1 meeting. With respect to the DV issues, I'm in the process of sorting this out. Kirk and I inspected the units together and there was a mix up in my communication/expectations.

With respect to the second issue, I was brought into the first meeting on Friday, September 19 about additional support for the program. I was able to get my hands on samples on the current and proposed design on Monday, September 29th. On Tuesday, September 30th I was out of the office most of the day to attend to an important personal matter. On Wednesday Oct. 1-3, I was out of town at Evonik. This week, I've been in planning session all week. Since Ranger and Immunobead are my officially allocated project, they get my primary attention as I noted in our mid-year review. I'm not ignoring Therashere but prioritizing the needs of the program to which I'm officially allocated.

I just got done with Immunobead planning session yesterday. I have a meeting shortly with the Therasphere team. Attached is my proposal for the options. I couldn't meet with Elizabeth this past Monday, October 6 because she had a conflict so this morning and I've been stuck in planning all week so this is the earliest opportunity for the meeting.

I'm sure you have a different perspective on my priorities but this is what happened and how I've approached my work.

-Narin

From: Clark, Aaron <Aaron.Clark@bsci.com>
Sent: Thursday, October 9, 2025 12:43 PM
To: Anderson, Narin <Narin.Anderson@bsci.com>
Subject: Therasphere Pkg Workstream Feedback / Concerns
Importance: High

Hi Narin,

As you've been out traveling and in a planning session this week, we haven't had a chance to connect on this, however I wanted to pass along feedback from the Therasphere project manager (Mike Hier) regarding the execution of the packaging workstream and the recent DV testing activity that you were coordinating.

Here are the notes and items discussed with the PM (3-Oct-2025):

- *Feedback from Therasphere team regarding some concerns and frustrations regarding packaging workstream and testing execution issues.*
- *Request for packaging support initiated last November 2024; Narin pulled in to help with shelf-life study for label stock and over-label*
- *DA drafted protocol and gathered input/approval from Narin*
- *Narin agreed to coordinate builds and sending units through conditioning and then hand off to DA for device testing*
- *Project team providing feedback that there are fundamental deficiencies is execution and communication. There have been multiple instances through the year with Narin agreeing to activities and then team needs to follow up to push deliverables.*
- ***Pkg DV Execution Feedback/Observations:***
    - *In latest DV activity per protocol 97327094 there was feedback of multiple misses and errors observed during DV execution that resulted in team needing to assess the option of re-executing DV to create a "clean" dataset.*
    - *Component traceability for label stocks used in DV is in question; Packaging originally did not record lot numbers for label stock. Took two months from completion of testing to track down lot number and finalize data sheets. There are still errors within the data sheet as is (explanation of label configurations).*
    - *Packaging did not create data sheet for shelf carton data. Unsure if testing was completed for shelf cartons. Packaging has asked for the units to be returned to complete testing and generate data sheet. Even if testing was repeated we wouldn't meet the minimum sample size outlined in the protocol (didn't have enough shelf cartons to start with and some have been used for other testing).*
    - *Some of the units marked as passing didn't have the appropriate labeling configurations (missing or partially labeled) but*

were marked on the data sheet as "passing." The data sheet would need to be updated to note that these data points should be excluded from the data set.

- ***Open / Future Actions Items:***
  - ***Package Assessment*** *Feedback pending from Narin; Narin committed to completing by Sept. 24th and team would review by Oct. 3rd; Nothing has been provided anything yet*
  - ***Assembly Print*** *creation*
  - ***DV study repeat*** *activity; Team to repeat study and will need support approximately Jan 2026*

Mike informed me the team has been able to navigate the hurdles; however wanted to raise this feedback as awareness and so that we could discuss and ensure future activities would not experience the same observations. In addition, he informed me the team will be conducting additional DV testing for the device and will be electing to re-conduct the packaging testing to generate a “clean” dataset and minimize any questions or gaps there may be.

Let’s plan to discuss in our next 1:1 and understand what may have led to this feedback and what can be done to ensure the next round of testing does not experience these difficulties.

Thanks
Aaron