UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION	**Case No.: 2:18-md-2846**
	JUDGE EDMUND A. SARGUS, JR. **Magistrate Judge Kimberly A. Jolson**
This document relates to: **STEVEN JOHNS**	**Case No. 2:18-cv-01509**

DEFENDANTS C. R. BARD, INC. AND DAVOL INC.'S BRIEF REGARDING STRIKING EVIDENCE ON COMPOSIX KUGEL RECALL, FDA INSPECTION, AND AUDITS NOT LINKED TO THE ISSUES IN THIS CASE

Plaintiff now has presented all the evidence that he suggested would establish the predicate "link" between the Composix Kugel recall and subsequent FDA investigations and audits, namely the testimony of Roger Darois, Dan LaFever, Christopher Paolo, and Stephen Eldridge. 7/22/2021 Hrg. Tr., ECF No. 495, at 43:9-19, 45:2-9. Thus, the issue of striking previously admitted Composix Kugel and audit evidence is ripe for determination. *See* MIL Order No. 14, ECF No. 503, at 1-2 (choosing "to evaluate this evidence at trial where the Court can better ascertain whether Plaintiff has established a connection between the Composix Kugel evidence and the instant case, and weigh Federal Rule of Evidence 403 concerns"). A straightforward review of this testimony spotlights the nebulousness of any supposed link—if not an outright gap demonstrating a lack of such a link—between what happened with the evidence introduced thus far and anything that supposedly happened with the design of the Ventralight ST that allegedly led to an excessive risk of adhesions.

- **Mr. Darois**. The testimony from Mr. Darois touching on the Composix Kugel recall, FDA inspections, and related audits is entirely backwards-looking, with no reflections on the Ventralight ST's development.[1] *See* Darois Dep., Sept. 13, 2019, at 299:16-327:5. If anything, his testimony supports the conclusion that Bard's design control procedures had changed before the Ventralight ST was developed. *See id.*, at 194:24-195:12 ("There were some changes and retraining individuals."); *see also id.*, at 198:6-9 (testifying that the design process improved).

- **Mr. LaFever.** Mr. LaFever's testimony was also substantially rooted in the Composix Kugel history, as opposed to any reflections on Ventralight ST. To that end, he established that the design control issues that became the subject of the FDA inspections and audits pertained to the timeframe ***between 1998 and 2004***. LaFever Dep., Nov. 13, 2019, at 67:24-70:23. At the time of the deposition, he actually had "been away from the design control for 11 years," having left Davol in February 2008. *Id*. at 106:7-107:3. He certainly established no link to anything about Ventralight ST, let alone alleged design issues with its ST coating.

[1] Attached hereto as Exhibits 1 through 5 are the cited excerpts from the final run reports for videos played at trial from the depositions of Mr. Darois, Mr. LaFever, Mr. Paolo, and Mr. Eldridge.

- **Mr. Paolo.** Mr. Paolo refutes Plaintiff's premise: "We have different requirements and procedures now, so the reviews – there's more levels of review potentially than there were ***prior to '06***[.]" Paolo Dep., Oct. 30, 2019, at 251:9-252:4 (emphasis added); *see also* Paolo Dep., Dec. 19, 2019, at 601:18-602:11 (agreeing that in late 2006, early 2007, extensive energy was applied to upgrade quality controls).

- **Mr. Eldridge.** According to Plaintiff, Mr. Eldridge's testimony is significant for his acknowledgement that Bard's "Voice of the Customer" ("VOC") surveys of surgeons are important to the development of "user needs." Eldridge Dep., June 29, 2021, at 55:16-57:6. Plaintiff then offered a 2008 VOC survey, which included some responses suggesting a preference for a barrier that "lasted longer" than 14 to 30 days. P1.0467.58; *see also* Pl.'s Proffer, ECF No. 486, at 14. But, even if this did suggest a design issue with Ventralight ST, it does not link to anything about Composix Kugel or the audits and inspections. Any criticism of the design or warnings for a medical device could be attributed to an issue with the "design inputs" or "user needs." That does provide a link.

While this testimony establishes no link, Plaintiff may point to an August 15, 2007, memo by Roger Darois in which, on reflection of various design control corrective actions undertaken already, he wrote: "All specifications must be derived from defined and documented user needs. None of the older products have user needs identified." P1.1042.2. But Sepramesh IP and Ventralight ST were not existing Bard products then. Moreover, in 2007, Bard implemented a research and development procedure, RD-4.54, that required the creation of a Design Input Summary report to "document[] the sources and methods used to identify user needs required to create the Product Performance Specifications." D1.2202. And the Ventralight ST design history file, which contains documents created in 2009 and 2010, ***does identify user needs***: "Product must minimize tissue attachment." Product Performance Specification, Rev. 6, P1.1112-06.6. Whether Bard adequately addressed this user need is an issue that can be, and should be, decided on the ***Ventralight ST*** record.

In the absence of the "link" sought by the Court, the evidence at issue should be deemed inadmissible, and the jury should be ordered to disregard all such evidence admitted thus far.

DATED: August 17, 2021

Respectfully submitted,

/s/ Eric L. Alexander

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CERTIFICATE OF SERVICE

I hereby certify that on August 17, 2021, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of this electronic filing to all counsel of record.

/s/ Eric L. Alexander
Eric L. Alexander

EXHIBIT 1

Designation Run Report

ROGER DAROIS 091319 COMBINED FINAL PLAYED

Darois, Roger 09-13-2019

PLF AFFIRMATIVE 02:50:12

DEF COUNTER 00:48:01

PLF COUNTER-COUNTER 00:19:58

Total Time 03:58:11

Page/Line	Source	ID
	192:5 Kugel was over. It was relaunched in April, 192:6 May, and June of 2006. 192:7 Q. Well, there were findings that went 192:8 beyond just Composix Kugel. They looked at 192:9 your whole design-control process, right? 192:10 A. Yes.	
194:24 - 195:4	**Darois, Roger 09-13-2019 (00:00:11)** 194:24 Q. Because what happened was the design 195:1 control process at Bard changed -- Bard Davol 195:2 changed as a result of the FDA findings, which 195:3 then resulted in recommendations from 195:4 Quintiles, right?	RD1_v13.170
195:10 - 195:12	**Darois, Roger 09-13-2019 (00:00:03)** 195:10 A. There were some changes done in 195:11 procedures and retraining of individuals. 195:12 BY MR. O'BRIEN:	RD1_v13.171
195:13 - 195:20	**Darois, Roger 09-13-2019 (00:00:33)** 195:13 Q. At any point in time, did -- after the 195:14 changes to design control procedures occurred 195:15 as a result of these FDA -- FDA findings and 195:16 then the audit, did Bard ever -- for those 195:17 products, which had been designed before 2007, 195:18 did Bard ever recommence the design of those 195:19 products so those products went through the 195:20 correct design process?	RD1_v13.172
195:24 - 196:3	**Darois, Roger 09-13-2019 (00:00:08)** 195:24 A. We did it with every product that we 196:1 were marketing at the time, yes, and we found 196:2 no other specification deficiencies in any 196:3 other products.	RD1_v13.173
196:6 - 196:8	**Darois, Roger 09-13-2019 (00:00:05)** 196:6 Did you put them through 196:7 the design history file process -- the product 196:8 development process again?	RD1_v13.174
196:11 - 196:19	**Darois, Roger 09-13-2019 (00:00:21)** 196:11 A. That's not possible to do. You go 196:12 in -- you audit your documents and you look at 196:13 the deficiencies that were found in the audit, 196:14 specifically how specifications are derived. 196:15 And we went through the product performance	RD1_v13.175

Page/Line	Source	ID
	196:16 specifications for every product that we 196:17 manufactured and found no other deficiencies, 196:18 and that was the end of the program. And we 196:19 communicated all that to the FDA.	
196:21 - 197:9	**Darois, Roger 09-13-2019 (00:00:25)** 196:21 Q. So the "we" who looked at it was 196:22 Davol, not an outside group? 196:23 A. I was the team leader for that 196:24 activity. 197:1 Q. So it wasn't an outside agency who 197:2 came in and said, yes, Davol is correct. They 197:3 had looked at all these things, and now they 197:4 say they've got it all right. 197:5 There was no outside verification of 197:6 that other than to say, what did you do as 197:7 part of this CAPA for this particular finding, 197:8 and they said, okay, they've done the CAPA, 197:9 right?	RD1_v13.176
197:12 - 198:5	**Darois, Roger 09-13-2019 (00:00:33)** 197:12 A. The corporate quality group and 197:13 regulatory group was involved in all this. 197:14 BY MR. O'BRIEN: 197:15 Q. Right. But that's -- the corporation 197:16 you're talking about is Bard Davol, not 197:17 Quintiles or not some federal agency such as 197:18 the FDA, right? 197:19 A. No. Quintiles was also involved. 197:20 Q. But did they actually do the 197:21 specification audit or did they look at what 197:22 your work product was, that is, your 197:23 generation of information was, with regard to 197:24 that work product? 198:1 A. They were involved in the methodology 198:2 and approved the review process that we were 198:3 going through. What specific documents they 198:4 might have reviewed twelve years ago, I just 198:5 don't recall.	RD1_v13.177
198:6 - 198:11	**Darois, Roger 09-13-2019 (00:00:07)** 198:6 Q. Do you think the design process 198:7 improved?	RD1_v13.178

Page/Line	Source	ID
	198:8 A. Yes. 198:9 Q. Do you think it was necessary to 198:10 improve that design process? 198:11 A. We go through audits every year.	
198:17 - 199:4	**Darois, Roger 09-13-2019 (00:00:17)** 198:17 A. So we go through audits every year. 198:18 We -- we do self-audits. We have corporate 198:19 audits, and we actually hire outside auditors 198:20 to audit our systems. And every time there's 198:21 an audit, there's always a finding and there's 198:22 always an improvement. Its part of the 198:23 process. 198:24 BY MR. O'BRIEN: 199:1 Q. Well, that's fine. 199:2 A. The guidelines change all the time, so 199:3 we're always changing and upgrading 199:4 procedures.	RD1_v13.179
204:17 - 205:2	**Darois, Roger 09-13-2019 (00:00:32)** 204:17 Q. So we were talking about what was 204:18 going on in 2007 with regard to the 204:19 activities, with regard to the FDA findings 204:20 and the Quintiles audit findings, the due 204:21 diligence with regard to the Genzyme Sepramesh 204:22 license acquisition, and now this 204:23 interruption -- or excuse me, the Shakespeare 204:24 communication to you, that it found out about 205:1 the MSDS, the 2004 Phillips MSDS, right? 205:2 That's where 2007 was, right?	RD1_v13.180
205:5 - 205:10	**Darois, Roger 09-13-2019 (00:00:12)** 205:5 A. Yes. 205:6 BY MR. O'BRIEN: 205:7 Q. All right. Now, let's go back to 205:8 1.0202, which is the document we were talking 205:9 about some moments ago, the 2007 goal summary. 205:10 And go to .3 of that document.	RD1_v13.181
205:13 - 206:4	**Darois, Roger 09-13-2019 (00:00:30)** 205:13 BY MR. O'BRIEN: 205:14 Q. And there you're talking about the 205:15 Genzyme diligence activity. You're talking 205:16 about the due diligence, right?	RD1_v13.182

Page/Line	Source	ID
	290:15 for 90 percent of the other Davol products for 290:16 hernia mesh at that time.	
291:14 - 291:18	**Darois, Roger 09-13-2019 (00:00:05)** 291:14 Q. Okay. Now, did the Shakespeare supply 291:15 continue? 291:16 A. No. 291:17 Q. After 2007? 291:18 A. It did not.	RD1_v13.270
293:11 - 293:16	**Darois, Roger 09-13-2019 (00:00:15)** 293:11 Q. So in late 2007, Shakespeare 293:12 ultimately cut off the supply of the 293:13 monofilament to Secant because it knew that 293:14 Secant was going to use it for medical -- 293:15 knitting medical meshes, right? 293:16 A. Essentially, yes.	RD1_v13.271
293:23 - 294:4	**Darois, Roger 09-13-2019 (00:00:17)** 293:23 Q. So now, we talked about Shakespeare 293:24 and the issues there. 294:1 The information that Davol was 294:2 purchasing monofilament from Red Oaks was 294:3 being kept secret from Secant as well? 294:4 A. Oh, yes, very definitely.	RD1_v13.272
299:16 - 300:4	**Darois, Roger 09-13-2019 (00:00:23)** 299:16 Q. All right. Let's go back now to 2006 299:17 with regard to that, February 2006 -- 299:18 actually, January to February 2006, FDA 299:19 inspection of Cranston, the Rhode Island 299:20 facility. 299:21 You recall that, don't you? 299:22 A. I do. 299:23 Q. Let me hand you what we're marking as 299:24 Exhibit 1.0581. 300:1 300:2 (Exhibit No. 1.0581 marked for 300:3 identification.) 300:4	RD1_v13.273
300:5 - 300:19	**Darois, Roger 09-13-2019 (00:00:47)** 300:5 BY MR. O'BRIEN: 300:6 Q. And do you see there that there is a 300:7 series of observations throughout the	RD1_v13.274

Page/Line	Source	ID
	300:8 attachment, and then Bard or Davol's response 300:9 to the FDA's observations and findings, 300:10 right? 300:11 A. Yes. 300:12 Q. Now, was this on the heels of the 300:13 Composix Kugel recall? 300:14 A. The first recall of the two extra 300:15 large sizes and, I believe, the midline patch 300:16 was on or about the first of January of 2006. 300:17 So I think that recall probably triggered this 300:18 inspection, but I wasn't involved in the 300:19 communications with the FDA.	
301:13 - 301:13	**Darois, Roger 09-13-2019 (00:00:02)** 301:13 Q. Okay. Observation 5, and there you	RD1_v13.275 1_581.12.1
301:14 - 302:8	**Darois, Roger 09-13-2019 (00:00:52)** 301:14 see at the top, talking about MDR reports. 301:15 Do you see that? 301:16 A. Yes. 301:17 Q. And tell our jury, please, what an MDR 301:18 report is? 301:19 A. It's a medical device report. I 301:20 believe "R" stands for report. I'm not quite 301:21 sure. 301:22 But any time a serious injury is 301:23 reported to a manufacturer from a customer, 301:24 patient, surgeon, the company has a 302:1 responsibility of A) investigating it to try 302:2 to come up with some conclusion on whether it 302:3 was a lot problem or any other root cause that 302:4 could be identified and, secondarily, to 302:5 report those MDRs to the FDA. 302:6 And that's -- ultimately winds up in 302:7 the FDA's MAUDE database, which, I think, is 302:8 material and use database, something or other.	RD1_v13.276 1_581.12.2
303:10 - 303:14	**Darois, Roger 09-13-2019 (00:00:13)** 303:10 The FDA's findings and observations 303:11 included issues pertinent to design control, 303:12 issues pertinent to post-marketing 303:13 surveillance, and issues pertinent to 303:14 manufacturing, quality assurance, right?	RD1_v13.277 clear

RD1_v13-ROGER DAROIS 091319 COMBINED FINAL PLAYED

Page/Line	Source	ID
303:15 - 303:20	**Darois, Roger 09-13-2019 (00:00:10)** 303:15 A. I couldn't find the manufacturing 303:16 observation. 303:17 Q. But you found the design control and 303:18 post-marketing surveillance? 303:19 A. I found observations related to those 303:20 topics.	RD1_v13.278
304:6 - 304:11	**Darois, Roger 09-13-2019 (00:00:09)** 304:6 Q. I've been using the term CAPA, 304:7 C-A-P-A. Are you familiar with that acronym? 304:8 A. Yes. 304:9 Q. Can you tell the jury, please, what 304:10 that acronym stands for? 304:11 A. Corrective action, preventive action.	RD1_v13.279
305:7 - 305:17	**Darois, Roger 09-13-2019 (00:00:24)** 305:7 Q. Okay. But in any event, you were 305:8 tasked, in large response, with helping direct 305:9 certain efforts with regard to the CAPAs that 305:10 resulted from the Quintiles audit, which 305:11 resulted -- which was triggered be the FDA 483 305:12 findings, right? 305:13 A. Yes. I led several teams for some 305:14 corrective action items. 305:15 Q. Was that chiefly in the area of design 305:16 control or did it get into other areas? 305:17 A. Just design control.	RD1_v13.280
305:18 - 305:22	**Darois, Roger 09-13-2019 (00:00:11)** 305:18 Q. And so the CAPAs, with regard to 305:19 design control, they were not Kugel specific. 305:20 They were talking about the design control. 305:21 They were talking about the actual system 305:22 itself, right?	RD1_v13.281
306:1 - 306:8	**Darois, Roger 09-13-2019 (00:00:17)** 306:1 A. Yes. 306:2 BY MR. O'BRIEN: 306:3 Q. And changes had to be made, right? 306:4 A. Changes were made. 306:5 Q. And but for the FDA's findings and 306:6 then the follow-up audit, those changes would 306:7 not have been made at that time frame, in	RD1_v13.282

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	306:8 2006; is that right?	
306:11 - 306:16	**Darois, Roger 09-13-2019 (00:00:09)**	RD1_v13.283
	306:11 A. I don't know. 306:12 BY MR. O'BRIEN: 306:13 Q. Were the changes which were made, in 306:14 your mind, to the design control processes 306:15 feasible before 2006? 306:16 A. Yes.	
306:24 - 307:22	**Darois, Roger 09-13-2019 (00:00:44)**	RD1_v13.284
	306:24 Q. Are you familiar with the term called 307:1 "failure investigation worksheet"? 307:2 A. Yes. 307:3 Q. What is a failure investigation 307:4 worksheet? 307:5 A. It's a document that lists a 307:6 particular problem -- it could be a rejected 307:7 manufacturing lot. It could be a system 307:8 failure. It could be product adverse event 307:9 reported -- that tries to describe the problem 307:10 and tries to get to the root cause. Various 307:11 tools can be used to try to get to the root 307:12 cause of the problem described. 307:13 Q. And did you have responsibility with 307:14 regard to this time frame, 2006, for failure 307:15 investigations, in completing worksheets? 307:16 A. Yes. 307:17 Q. Let me hand to you what we're marking 307:18 as 1.0589. 307:19 307:20 (Exhibit No. 1.0589 marked for 307:21 identification.) 307:22	
307:23 - 308:12	**Darois, Roger 09-13-2019 (00:00:33)**	RD1_v13.285
	307:23 BY MR. O'BRIEN: 307:24 Q. And do you recognize this as one of 308:1 the failure investigation worksheets that you 308:2 would have generated pursuant to your job with 308:3 respect to the CAPAs, which were commenced as 308:4 a result of the FDA findings and then the 308:5 resulting audit -- external audit, I should	1_589.1.1

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	308:6 say?	
	308:7 A. Yes.	
	308:8 Q. And you see there, on the very last	
	308:9 page, .3, that it was completed and signed by	1_589.3.1
	308:10 you in November 2006 and accepted by another	
	308:11 individual, right?	
	308:12 A. Yes.	
308:20 - 311:21	**Darois, Roger 09-13-2019 (00:03:00)**	RD1_v13.286
	308:20 Well, let's go through the whys. Help	
	308:21 me understand. I'm looking at Page 2 of	1_589.2.1
	308:22 this, .2.	
	308:23 For instance, as you're just looking	
	308:24 at that block, it reads, "Whys, question and	1_589.2.2
	309:1 answers," and it has supporting evidence.	
	309:2 Tell me how this worksheet is supposed	
	309:3 to work. In other words, what do the columns	
	309:4 mean and what information are you responsible	
	309:5 for putting in there?	
	309:6 A. First of all, it's called the Five Why	
	309:7 Test. It starts out at a high level and	
	309:8 drills down, kind of a waterfall effect, to	
	309:9 get more and more specific, based on the	
	309:10 answers of each question.	
	309:11 So the first is, you know, why was the	
	309:12 system not sufficiently robust, et cetera, and	
	309:13 then you have a supporting evidence of, you	
	309:14 know, why that statement was in there.	
	309:15 So at the end, you know, you're	
	309:16 supposed to be able to -- this is supposed to	
	309:17 help you try to figure out exactly what the	
	309:18 gap might have been and to institute some	
	309:19 corrective actions.	
	309:20 Q. All right. So let's just kind of go	
	309:21 through some of these whys here.	
	309:22 Number one, "Why were the design	1_589.2.3
	309:23 controls not effectively implemented?"	
	309:24 And that answer: "The design control	
	310:1 system was not sufficiently robust to require	
	310:2 supporting evidence of all key activities or	
	310:3 to conduct effective design reviews."	

310:4 What would your role have been with
310:5 respect to those words? In other words, did
310:6 you type those in or did somebody else type
310:7 those in on your behalf, or would those have
310:8 been words of Quintiles?
310:9 A. They wouldn't have been Quintiles.
310:10 They would have been one of the team members
310:11 on the first page, either myself or Steve
310:12 Eldridge or Gus Felix or from Robert Krugal
310:13 (phonetic).
310:14 Q. So this is based on your own review of
310:15 the design control process at -- then in
310:16 existence at Davol and attempting to
310:17 understand the deficiency?
310:18 A. Yes.
310:19 Q. So you've written there, "The design
310:20 control system was not sufficiently robust to
310:21 require supporting evidence of all key
310:22 activities or to conduct effective design
310:23 reviews."
310:24 And again, was this, the design
311:1 control system, a system-wide design control
311:2 system review?
311:3 A. It was a system-wide review, yes.
311:4 Q. So this answer would apply to the
311:5 whole of the design control process -- or
311:6 system, I should say, for Davol with respect
311:7 to its hernia mesh products; is that right?
311:8 A. Well, that's not what we ended up
311:9 including at the end. So this is a -- again,
311:10 a waterfall list of activity, what -- you
311:11 know, what the theory was as we cascade down
311:12 this.
311:13 Q. Right. But there's not a design -- a
311:14 separate design control process for Ventralex
311:15 versus Ventrio versus PerFix, if I went
311:16 through design control process.
311:17 They're company wide, and then the
311:18 company employees are charged with the
311:19 responsibility of making sure that there's a

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	311:20 design control process in place that's adhered 311:21 and followed, right?	
311:24 - 312:8	**Darois, Roger 09-13-2019 (00:00:24)** 311:24 A. Correct. What I'm trying to 312:1 communicate is that not the whole system is at 312:2 fault. This process of CAPA and trying to go 312:3 through these different steps is to try to get 312:4 to the root of -- the kernel, if you will, of 312:5 what might have gone wrong that led to a low 312:6 specification, in this case, for the Kugel 312:7 welded ring, which is, obviously, what 312:8 triggered this audit, the recall.	RD1_v13.287
312:10 - 312:19	**Darois, Roger 09-13-2019 (00:00:28)** 312:10 Q. But really, the idea of this is to 312:11 make corrections to the design control process 312:12 because of the FDA findings and because of the 312:13 resulting audit to ensure -- or attempt to 312:14 ensure that whatever the design control 312:15 failure was in place, that it's changed so 312:16 that other products, other than Kugel, that in 312:17 the future go through the design control 312:18 process, don't have the same shortcomings, 312:19 right?	RD1_v13.288
312:22 - 313:5	**Darois, Roger 09-13-2019 (00:00:15)** 312:22 A. Two outcomes came out of this. One, 312:23 as I previously testified, we went in and did 312:24 a retrospective review of all the products 313:1 that are on the market. We found no 313:2 deficiencies in specification development, 313:3 which was the problem with Kugel. And yes, on 313:4 a go-forward basis, it makes it a more robust 313:5 system.	RD1_v13.289
313:7 - 314:24	**Darois, Roger 09-13-2019 (00:01:26)** 313:7 Q. Now, you described that you basically 313:8 starting macro with No. 1 and you're kind of 313:9 narrowing it down to more specific issues by 313:10 No. 5; is that right? 313:11 A. Yes. 313:12 Q. Did I characterize that fairly? 313:13 A. Yes.	RD1_v13.290

Page/Line	Source	ID
	313:14 Q. So No. 2, why was the design control	1_589.2.4
	313:15 system not sufficiently robust? Because in	
	313:16 No. 1 you referring refer to it being not	
	313:17 sufficiently robust, which then triggers	
	313:18 Question No. 2, right?	
	313:19 A. Uh-huh, yes.	
	313:20 Q. It reads, "Lack of document evidence	
	313:21 for user needs and in other areas made it	
	313:22 difficult to conduct effective design	
	313:23 reviews."	
	313:24 In the design control process, user	
	314:1 needs are critically important, aren't they?	
	314:2 A. Yes. And we tend to have them	
	314:3 sprinkled within our product performance	
	314:4 specifications. And the audit found that it	
	314:5 would be more effective if we had a separate	
	314:6 user-needs document that drove the	
	314:7 specifications --	
	314:8 Q. Right.	
	314:9 A. -- so we kind of included both of	
	314:10 them. You have to understand, the FDA	
	314:11 guidelines don't prescribe any of this.	
	314:12 They're very general, and it's the auditor's,	
	314:13 basically, interpretation of these guidelines	
	314:14 that leads to these audit findings.	
	314:15 Q. Well, I understand that the FDA	
	314:16 doesn't sell meshes to people.	
	314:17 A. company like Davol does, right?	
	314:18 A. Yes, they do.	
	314:19 Q. And it is the company's responsibility	
	314:20 to ensure that No. 1, there is an effective	
	314:21 and robust design control process, right?	
	314:22 A. Yes.	
	314:23 Q. And you found that it was not	
	314:24 sufficiently robust, right?	
315:3 - 317:13	**Darois, Roger 09-13-2019 (00:02:04)**	RD1_v13.291
	315:3 A. There were specific findings that were	
	315:4 corrected.	
	315:5 BY MR. O'BRIEN:	
	315:6 Q. All right.	

315:7 A. The whole system was not faulty.
315:8 Q. And one of the system problems was
315:9 about this user-needs area. The user needs is
315:10 the surgeon's needs and the patient's needs,
315:11 right?
315:12 A. Yes.
315:13 Q. And as a design control process works,
315:14 you commence with an understanding of what are
315:15 the user needs.
315:16 And then as you go through the design
315:17 process, that would be an input, what's the
315:18 user need. The output is the result, and you
315:19 see whether that output matches the input,
315:20 right?
315:21 A. That's called design validation.
315:22 Q. Right.
315:23 A. Uh-huh.
315:24 Q. And so if you don't have
316:1 well-documented user needs in the design
316:2 control process -- because that's at the very
316:3 beginning of the design control process, is
316:4 the identification and -- of the user needs,
316:5 right?
316:6 A. Again, we had the user needs kind of
316:7 sprinkled in on our product performance
316:8 specification and we thought it would be more
316:9 effective to have it a separate document that
316:10 it would then end of driving specifications.
316:11 So we did have a user needs identified, but it
316:12 wasn't separated out into something that was
316:13 more easily understood at design reviews.
316:14 Q. Well, what you wrote is, "Lack of
316:15 documented evidence for user needs."
316:16 That's what you wrote, right?
316:17 A. Uh-huh.
316:18 Q. Is that a yes?
316:19 A. That's what it says, yes.
316:20 Q. I'm sorry, "uh-huh" -- she has to hear
316:21 yes or no.
316:22 A. Yes.

Page/Line	Source	ID
	316:23 Q. Sorry about that. 316:24 But going back to my question a few 317:1 moments ago, the user-needs documentation -- 317:2 having documented evidence of the user needs 317:3 is really critically of paramount importance 317:4 in the design control process because that's 317:5 the beginning of the design control process, 317:6 right? 317:7 A. I'm not disagreeing with you. Yes. 317:8 Q. And then you look -- once the design 317:9 control process is completed, you look and see 317:10 whether the output of the design control 317:11 process matches that original input, which is 317:12 the documented evidence of user needs, right? 317:13 A. Exactly, yeah.	
317:14 - 318:18	**Darois, Roger 09-13-2019 (00:00:54)** 317:14 Q. And then -- and so following up this 317:15 user needs, this critically important area of 317:16 user needs, you've written there No. 3, "Why 317:17 was documented evidence of user needs and 317:18 design transfer traceability not required?" 317:19 Who wrote that question, you? 317:20 A. I don't remember which one of the team 317:21 members wrote it. 317:22 Q. But someone on the team -- 317:23 A. Yes. 317:24 Q. -- that is a Davol employee wrote that 318:1 question? 318:2 A. Yes. 318:3 Q. And then the team generated the 318:4 answer, which is reflected on this 318:5 worksheet? 318:6 A. Yes. 318:7 Q. Okay. So it was found, by this 318:8 process, that documented evidence of user 318:9 needs was not required. 318:10 That's what that question indicates, 318:11 doesn't it? 318:12 A. It wasn't required as a separate 318:13 document.	RD1_v13.292 1_589.2.5

Page/Line	Source	ID
	318:14 Q. It says, "Why was documented evidence 318:15 of user needs and design transfer traceability 318:16 not required?" 318:17 That's what it -- I've read that 318:18 verbatim, haven't I?	
318:20 - 319:5	**Darois, Roger 09-13-2019 (00:00:21)** 318:20 A. Yes. 318:21 BY MR. O'BRIEN: 318:22 Q. And in the design control process, 318:23 you -- it's important to identify the user 318:24 needs first because you can't generate the 319:1 user needs by the output of the design 319:2 process. In other words, you can't come up 319:3 with a product and then reverse engineer to 319:4 determine what the user needs should be in 319:5 light of what resulted through that process?	RD1_v13.293
319:8 - 320:10	**Darois, Roger 09-13-2019 (00:00:57)** 319:8 A. That's correct, and that wasn't what 319:9 was done at that time. 319:10 BY MR. O'BRIEN: 319:11 Q. And user needs are not only 319:12 effectiveness, but also safety, right? 319:13 A. Yes. I mean, we had other procedures 319:14 that dealt with safety. 319:15 Q. So the answer under No. 3 was, 319:16 "Current procedures do not require formal 319:17 documentation/summary of user-needs 319:18 sources/analysis (jump right to the actual PPS 319:19 requirements) and design transfer was captured 319:20 via DCS system." 319:21 What does that acronym, DCS, stand 319:22 for? 319:23 A. Document control system. 319:24 Q. And then, No. 4, getting a little bit 320:1 more specific now in this user-needs issue, 320:2 "Why were user-needs summary design transfer 320:3 procedures not required?" 320:4 And the answer is: "Lack of 320:5 benchmarking to FDA guidelines and lack of 320:6 previous audit, internal corporate FDA and	RD1_v13.294 1_589.2.6 1_589.2.7

Page/Line	Source	ID
	320:7 KEMA observations highlighting this 320:8 deficiency." 320:9 Did I read that correctly? 320:10 A. Yes.	
320:24 - 321:16	**Darois, Roger 09-13-2019 (00:00:34)** 320:24 Q. Let's look at No. 5. 321:1 It reads, "Why was benchmarking not 321:2 utilized in previous audits deficient?" 321:3 Is it important, in your estimation, 321:4 from a design control process, to benchmark 321:5 the design control process to FDA guidelines? 321:6 A. Yes. 321:7 Q. Why is it important? 321:8 A. Just to make sure we are in compliance 321:9 with them. 321:10 Q. All right. And what you all found was 321:11 that there was a lack of benchmarking to FDA 321:12 guidelines, right? 321:13 A. Yeah, it was not worded that 321:14 correctly. It's really -- 321:15 Q. It's worded exactly as it is, isn't 321:16 it?	RD1_v13.295 1_589.2.8 1_589.2.9
321:21 - 322:9	**Darois, Roger 09-13-2019 (00:00:30)** 321:21 A. So what was found here is the fact 321:22 that the guidelines are very general. And we 321:23 thought we actually met the guidelines, but 321:24 the -- but the auditors have increased the 322:1 diligence and specificity of these audits. 322:2 And if we could have somehow benchmarked with 322:3 other auditors that have been more privy to 322:4 some of these auditing techniques the FDA was 322:5 using, we might have been able to discover 322:6 this earlier. 322:7 BY MR. O'BRIEN: 322:8 Q. Well, let's see what the words 322:9 actually say.	RD1_v13.296
322:14 - 322:15	**Darois, Roger 09-13-2019 (00:00:09)** 322:14 Q. It reads, "Why were user-needs summary 322:15 and design transfer procedures not required?"	RD1_v13.297 1_589.2.7
322:17 - 322:22	**Darois, Roger 09-13-2019 (00:00:11)**	RD1_v13.298

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	322:17 "Lack of benchmarking to FDA 322:18 guidelines and lack of previous audit, 322:19 internal corporate FDA and KEMA observations, 322:20 highlighting this deficiency." 322:21 And it was, in fact, a deficiency, 322:22 wasn't it?	
323:1 - 324:3	**Darois, Roger 09-13-2019 (00:01:03)** 323:1 A. In the FDA's opinion, it was. 323:2 BY MR. O'BRIEN: 323:3 Q. And there was, in fact, a lack of 323:4 benchmarking to FDA guidelines in this 323:5 user-needs portion of the company-wide design 323:6 control process, wasn't there? 323:7 A. With respect to benchmarking for 323:8 auditing techniques, yes, but as far as 323:9 whether we met the guidelines in a general 323:10 form, I would disagree that we actually didn't 323:11 meet the guidelines. 323:12 Q. Where is that written here? 323:13 A. It's not written here. I'm telling 323:14 you what I went through as part of this team. 323:15 Q. No. 5, it reads, "Why was benchmarking 323:16 not utilized in previous audits deficient?" 323:17 So there, it's indicating that 323:18 benchmarking was just not utilized. That's 323:19 what it says there, right, No. 5? 323:20 A. Yes, for the specific item I just 323:21 described, what was the auditing techniques 323:22 that the FDA was using over the years. 323:23 Q. Okay. And then there's an answer 323:24 given here, "Lack of internal corporate audit 324:1 benchmarking and third-party independent 324:2 audits directed to design control system 324:3 adequacy" --	RD1_v13.299 1_589.2.9
324:4 - 325:19	**Darois, Roger 09-13-2019 (00:01:23)** 324:4 Let's underline that word, "Design 324:5 control system adequacy." 324:6 A. Uh-huh. 324:7 Q. Do you see there where that's 324:8 written?	RD1_v13.300 1_589.2.10

Page/Line	Source	ID
	324:9 A. Yes. 324:10 Q. -- "related to FDA control 324:11 guidelines." 324:12 So there, your team put that -- wrote 324:13 that down, typed it out, right? 324:14 A. Yes. 324:15 Q. And it says, "There's a lack of 324:16 internal corporate audit benchmarking." 324:17 And the benchmarking that's being 324:18 referred to, the FDA guidelines, right? 324:19 A. I'm referring to it as the auditing 324:20 techniques, not specifically just the 324:21 guidelines. 324:22 BY MR. O'BRIEN: 324:23 Q. Well, No. 4 -- because 5 is beget from 324:24 4, and 4 is beget from 3, and 3 is beget from 325:1 2, and 2 is beget from 1. 325:2 And the benchmarking used in No. 4 325:3 specifically refers to FDA guidelines, 325:4 right? 325:5 A. It does, in a general sense. I'm 325:6 telling you what we were focused on as part of 325:7 this process. 325:8 Q. And then under the supporting 325:9 evidence, it says, "Quintiles audit was the 325:10 first third-party nonregulatory agency 325:11 independent audit directed to a holistic FDA 325:12 requirement system -- quality system audit." 325:13 Did I read that correctly? 325:14 A. Yes, you did. 325:15 Q. And who wrote that? Was that someone 325:16 from your team? 325:17 A. Yes, it was. 325:18 Q. Wow. I mean, that's -- so was that 325:19 statement a lie?	1_589.2.11 1_589.2.12
325:22 - 326:12	**Darois, Roger 09-13-2019 (00:00:37)** 325:22 A. Of course not. Third-party audits, 325:23 first of all, they're not required. Second of 325:24 all, as I mentioned before, what we didn't 326:1 have the insight of is what the FDA	RD1_v13.301

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	326:2 inspections had evolved into relative to how 326:3 they interpret the guidelines. Quintiles has 326:4 been through FDA audits extensively as a 326:5 consulting firm. 326:6 Q. Sure. 326:7 A. So they were brought in because they 326:8 had that experience of participating in FDA 326:9 audits and could help us with our design 326:10 control system, to bring it up to the current 326:11 state of auditing techniques that the FDA was 326:12 using.	
326:20 - 326:21	**Darois, Roger 09-13-2019 (00:00:02)** 326:20 There was a failure, a 326:21 design control failure, right?	RD1_v13.302
326:24 - 327:5	**Darois, Roger 09-13-2019 (00:00:13)** 326:24 A. One failure among many, many products, 327:1 but yes, there was one failure. And the 327:2 independent auditing that we relied on in 327:3 previous years was an annual audit by a 327:4 corporate quality group, who we considered to 327:5 be an independent auditing agency.	RD1_v13.303
327:7 - 327:10	**Darois, Roger 09-13-2019 (00:00:12)** 327:7 Q. So was -- do you know whether Davol 327:8 was ISO certified before 13- -- ISO 13485 and 327:9 9001 certified at this time frame? 327:10 A. Yes.	RD1_v13.304 clear
330:3 - 330:16	**Darois, Roger 09-13-2019 (00:00:25)** 330:3 Q. And what your team wrote here under 330:4 No. 5 is that Quintiles audit, which happened 330:5 only because of the FDA's findings earlier in 330:6 2006 -- the Quintiles audit was the first 330:7 third-party nonregulatory agency independent 330:8 audit directed to a holistic FDA requirements 330:9 quality system audit. 330:10 And that was truthful when it was 330:11 written; is that right? 330:12 A. Yes. 330:13 Q. And it's truthful now? 330:14 A. Yes. 330:15 Q. Right?	RD1_v13.305 1_589.2.12

EXHIBIT 2

Designation Run Report

DAN LAFEVER 11-13-19 COMBINED FINAL PLAYED

Lafever, Daniel 11-13-2019

PLF AFFIRMATIVE 02:48:21

DEF COUNTER 00:06:15

PLF COUNTER-COUNTER 00:00:47

Total Time 02:55:23

Page/Line	Source	ID
	61:9 So it was only appropriate 61:10 that we not skip a chain of command 61:11 member here and that Brian Kelly be 61:12 included in this correspondence. 61:13 Q. Yes, sir. 61:14 And do you recall what role 61:15 or what title he had at this timeframe? 61:16 I presume he was at Bard corporate, then; 61:17 is that correct? 61:18 A. Yes. 61:19 Q. And what would his title 61:20 have been? 61:21 A. He would have been Bard 61:22 group president, Brian Kelly. 61:23 Q. All right. Thank you.	
67:10 - 67:21	**Lafever, Daniel 11-13-2019 (00:00:31)** 67:10 Q. And so do I 67:11 understand from -- that, ultimately, the 67:12 recall resulted in the FDA -- or at least 67:13 in sequence, resulted in the FDA 67:14 establishment inspection reports, which 67:15 resulted in the 483 warning letter, 67:16 then -- of course, we'll talk about this 67:17 in a moment -- but then several audits, 67:18 internal and external, corrective actions 67:19 and the like, is that correct, that, 67:20 basically, the Composix Kugel recall was 67:21 the triggering point for all of that?	DL1_v09.29 clear
67:24 - 68:21	**Lafever, Daniel 11-13-2019 (00:00:37)** 67:24 THE WITNESS: It's fair to 68:1 say that that event triggered a 68:2 lot of those things that you just 68:3 mentioned, yeah. 68:4 There was a cascade effect 68:5 to that recall, yes. 68:6 BY MR. O'BRIEN: 68:7 Q. All right. And we'll get 68:8 into it in just a moment. 68:9 But one of the findings and 68:10 areas that corrective action needed and	DL1_v09.30

Page/Line	Source	ID
	68:11 preventative action needed to be taken 68:12 was in the area -- certain areas of 68:13 design control. 68:14 Do you recall that 68:15 generally? 68:16 And we'll -- I'm not 68:17 going -- asking you to memorize anything, 68:18 but do you have a general memory that 68:19 there were design control issues that the 68:20 FDA found, as well as the auditors, which 68:21 followed that initial 483?	
68:24 - 69:12	**Lafever, Daniel 11-13-2019 (00:00:23)** 68:24 THE WITNESS: I do recall 69:1 one of the 483s being tied to 69:2 design control. I don't remember 69:3 the specifics. I'd have to read 69:4 through the 483 again to refresh 69:5 my memory. 69:6 BY MR. O'BRIEN: 69:7 Q. Yes, sir. 69:8 MR. O'BRIEN: In any 69:9 respect, if we can pull that 69:10 call-out down and go to 2001 to 69:11 2003, please, Mr. Wolfe, on the 69:12 chronology.	DL1_v09.31
69:13 - 70:16	**Lafever, Daniel 11-13-2019 (00:01:11)** 69:13 BY MR. O'BRIEN: 69:14 Q. So it says, 2001, product 69:15 codes -- and then it's got the codes -- 69:16 for large oval patch and large circle 69:17 patch launched, no complaints received. 69:18 2002, product codes -- and 69:19 it's got the numbers -- XL Composix 69:20 Kugels launched. No complaints received. 69:21 Is it accurate to say, Mr. 69:22 LaFever, that the actual design control 69:23 process, that is, the prelaunch and 69:24 preclearance design control process 70:1 happened during a time while you were not 70:2 the president of Davol, for these	DL1_v09.32 1_739.4.1

DL1_v09-DAN LAFEVER 11-13-19 COMBINED FINAL PLAYED

Page/Line	Source	ID
	70:3 Composix Kugel large and XL patches? 70:4 A. The design control process 70:5 would have happened between 1998 and 70:6 2004, where I was in different roles down 70:7 in Georgia and was not at Davol, that is 70:8 correct. 70:9 Q. And so, then, when you 70:10 became president of Davol in 2004, you 70:11 kind of inherited the progeny of some of 70:12 the design control problems from that 70:13 Composix Kugel design control process, 70:14 those years about which you just spoke, 70:15 which predated your returning to Davol as 70:16 the president of Davol; is that fair?	
70:19 - 70:23	**Lafever, Daniel 11-13-2019 (00:00:10)** 70:19 THE WITNESS: It is fair to 70:20 say that I inherited every product 70:21 in the portfolio at Davol in 2004 70:22 when I became president of Davol, 70:23 yes.	DL1_v09.33
81:12 - 84:18	**Lafever, Daniel 11-13-2019 (00:03:55)** 81:12 Q. Do you know a gentleman by 81:13 the name of Dr. Heniford? 81:14 A. I do. 81:15 Q. And what can you tell our 81:16 jury about Dr. Heniford, in terms of who 81:17 he is generally? 81:18 I know he's a doctor. I 81:19 assume he's a hernia surgeon. 81:20 Beyond that, what can you 81:21 say about Dr. Heniford, based upon your 81:22 time, really focusing on the 2004 to 2008 81:23 timeframe, while you were president of 81:24 Davol? 82:1 A. Todd Heniford was a surgeon 82:2 at Carolinas Medical Center. He was 82:3 actually, I believe, a partner of David 82:4 Iannitti, who I knew personally. I knew 82:5 his family, I knew -- his wife worked out 82:6 at the same gym that my wife did in Rhode	DL1_v09.34 clear

Page/Line	Source	ID
	105:4 following general comments were made by 105:5 Ron Moy during his review of the FDA 483 105:6 responses. 105:7 And I want to direct your 105:8 attention to that header, Observation 2. 105:9 That first bullet point reads: Ron 105:10 expressed concern that the response to 105:11 the FDA's observation on design control 105:12 issues may not fully address their issues 105:13 regarding verification and validation 105:14 activities in Davol. He also was 105:15 questioning why QA is not involved in all 105:16 aspects of the project design. 105:17 I know that you've not 105:18 worked in the R&D department at Davol, 105:19 but you've had responsibility, as the 105:20 president, for overseeing, on the 105:21 management board, the vice president of 105:22 R&D, who, I believe at this time, would 105:23 have been Roger Darois; is that right? 105:24 A. That's -- both of those are 106:1 correct. 106:2 Q. And so were you familiar 106:3 with what those terms "verification" and 106:4 "validation" refer to in terms of the 106:5 design control process? 106:6 A. Vaguely. 106:7 Q. And were you -- would it be 106:8 accurate, does your recollection include 106:9 that part of the design control process 106:10 is taking either specs or user needs, and 106:11 this is, again, loosely characterizing 106:12 it, but then making sure that those user 106:13 needs or specs are met either through the 106:14 verification or validation process? 106:15 You understand that that was 106:16 part of the design control process with 106:17 which the FDA had some concerns?	1_1089.6.2
106:20 - 107:12	**Lafever, Daniel 11-13-2019 (00:00:39)** 106:20 THE WITNESS: I've been away	DL1_v09.57

Page/Line	Source	ID
	106:21 from the design control process 106:22 for 11 years now. And I remember 106:23 the terms "validation" and 106:24 "verification." I don't recall 107:1 what specifically was involved in 107:2 those processes in the design 107:3 control process. 107:4 BY MR. O'BRIEN: 107:5 Q. Right. But you -- looking 107:6 at this, what we just read to our jury, 107:7 we can see that the FDA had made 107:8 observations about the design control 107:9 process and, specifically, the FDA had 107:10 issues regarding the verification and 107:11 validation activities in Davol, right? 107:12 A. I see --	
107:15 - 108:21	**Lafever, Daniel 11-13-2019 (00:01:08)** 107:15 THE WITNESS: I see that 107:16 that was Ron Moy's feedback to us, 107:17 yes. 107:18 BY MR. O'BRIEN: 107:19 Q. And he continues on: He was 107:20 also questioning why QA is not involved 107:21 in all aspects of the project design. 107:22 Is QA quality affairs? 107:23 A. QA is quality assurance, 107:24 yes. 108:1 Q. Quality assurance, I'm 108:2 sorry. Thank you for correcting me. 108:3 Then Observation 3: The 108:4 areas identified for QA review and 108:5 approval in the design control process -- 108:6 and so that's quality assurance -- the 108:7 design output form is the only form where 108:8 QA signature is mandated, may still be 108:9 inadequate. 108:10 Do you see there where 108:11 that's written? 108:12 A. I do see that, yes. 108:13 Q. Now, can you tell our jury a	DL1_v09.58 1_1089.6.3

EXHIBIT 3

Designation Run Report

CHRIS PAOLO 10-30-19 COMBINED FINAL PLAYED

Paolo, Christopher 10-30-2019

PLF AFFIRMATIVE 00:39:50

DEF COUNTER 00:12:05

Total Time 00:51:55

Page/Line	Source	ID
	248:3 A. So we have many audits that 248:4 challenge design controls, internal audits, 248:5 BSI audits, corporate audits that challenge 248:6 the design controls. So that happens 248:7 regularly. 248:8 BY MR. O'BRIEN: 248:9 Q. Did that happen also before 248:10 2006? 248:11 A. Yes. 248:12 Q. Okay. So my question is, 248:13 what's changed? What's changed since 2006 in 248:14 terms of the company testing itself to make 248:15 sure that history doesn't repeat itself with 248:16 respect to these design control system 248:17 failures?	
248:21 - 249:1	**Paolo, Christopher 10-30-2019 (00:00:13)** 248:21 A. I think the requirements are 248:22 still the same. As time has gone on, there's 248:23 been more conferences and, you know, 248:24 different sort of industry maturity around 249:1 it. But the process is still the same.	CP1_v06.102
251:9 - 251:16	**Paolo, Christopher 10-30-2019 (00:00:24)** 251:9 Q. So my question is, what new 251:10 processes are designed to ferret out the 251:11 non-compliance problems that are new in 2013 251:12 and after that were not already in existence 251:13 in 2006 and before which address this issue 251:14 that Quintiles was talking about, which is 251:15 the folks who were inclined to defy written 251:16 procedures?	CP1_v06.103
251:19 - 252:4	**Paolo, Christopher 10-30-2019 (00:00:33)** 251:19 A. We have different requirements 251:20 and procedures now, so the reviews -- there's 251:21 more levels of review potentially than there 251:22 were prior to '06 that were a result of some 251:23 of these CAPAs we're talking about. We have 251:24 implemented independent reviews for design 252:1 reviews in particular. So there have been 252:2 some changes. I think the risk profile of 252:3 our products in the field shows us that we	CP1_v06.104

Page/Line	Source	ID
252:4	have robust design control processes.	

PLF AFFIRMATIVE = 00:39:50
DEF COUNTER = 00:12:05
Total Time = 00:51:55

Documents Shown
1_762 REDACTED
1_913

EXHIBIT 4

Designation Run Report

CHRIS PAOLO 12-19-19 COMBINED FINAL PLAYED

Paolo, Christopher 12-19-2019

PLF AFFIRMATIVE 00:18:49

DEF COUNTER 00:32:02

PLF COUNTER-COUNTER 00:00:49

Total Time 00:51:40

Page/Line	Source	ID
	599:3 Q. -- you weren't 599:4 personally involved with them? 599:5 A. Correct, I wasn't personally 599:6 involved.	
599:22 - 600:10	**Paolo, Christopher 12-19-2019 (00:00:26)** 599:22 Q. If you go to the prior 599:23 paragraph, there's something we were just 599:24 talking about. It says, "He stated that he 600:1 had received the cover sheets" -- meaning the 600:2 FDA inspector -- "had received the cover 600:3 sheets to four management reviews." You were 600:4 just asked some questions now about 600:5 management reviews, correct? 600:6 A. Correct. 600:7 Q. And so back in 2006, 2007, 600:8 there were management reviews going on at 600:9 Davol? 600:10 A. Yes.	CP2_v07.70 1_313.2.1
601:4 - 602:11	**Paolo, Christopher 12-19-2019 (00:01:13)** 601:4 Q. So quality may comment on how 601:5 R&D is doing, R&D may comment on how quality 601:6 is doing, same thing for regulatory, sales, 601:7 manufacturing, shipping, whatever? 601:8 A. It's collaborative, yes. 601:9 Q. Okay. And the last sentence of 601:10 the paragraph, the next sentence after the 601:11 one we had looked at said, "Although 601:12 extensive energy and resources are being 601:13 applied to this issue, the ratings indicate 601:14 we have not yet accomplished the final goal 601:15 with regard to quality system." 601:16 Do you see that? 601:17 A. Yes. 601:18 Q. And was that your understanding 601:19 from what was going on in late 2006, early 601:20 2007, that extensive energy and resources 601:21 were being applied to essentially upgrading 601:22 various aspects of quality? 601:23 A. Yes. 601:24 Q. And there was a lot going on at	CP2_v07.71 clear 1_313.2.2

CP2_v07-CHRIS PAOLO 12-19-19 COMBINED FINAL PLAYED

Page/Line	Source	ID
	602:1 the same time involving recall, product 602:2 redesign, and self-imposed third-party audit 602:3 to identify root causes? 602:4 A. Yes. 602:5 Q. Did that get in the way of some 602:6 of the steps taken to change SOPs and do 602:7 other steps that might be indicated to 602:8 essentially upgrade or improve quality in 602:9 these various ways? 602:10 A. So we were trying to prioritize 602:11 all the efforts.	
622:2 - 622:7	**Paolo, Christopher 12-19-2019 (00:00:17)** 622:2 Q. From the questions plaintiffs' 622:3 counsel asked you, both in their first round 622:4 and then the second round, does any of that 622:5 make you think that there are problems with 622:6 the systems or the products that you weren't 622:7 aware of before their questioning began?	CP2_v07.72 clear
622:10 - 622:10	**Paolo, Christopher 12-19-2019 (00:00:00)** 622:10 A. No.	CP2_v07.73
622:12 - 622:17	**Paolo, Christopher 12-19-2019 (00:00:10)** 622:12 Q. And the testimony that you gave 622:13 when I asked you questions earlier, do you 622:14 stand by that despite whatever additional 622:15 documents or questions plaintiffs' counsel 622:16 has asked so far? 622:17 A. Yes.	CP2_v07.74

PLF AFFIRMATIVE = 00:18:49
DEF COUNTER = 00:32:02
PLF COUNTER-COUNTER = 00:00:49
Total Time = 00:51:40

Documents Shown
1_1524
1_313
1_913

EXHIBIT 5

Designation Run Report

STEVE ELDRIDGE COMBINED FINAL PLAYED

Eldridge, Stephen 06-29-2021

PLF AFFIRMATIVE 02:53:25

DEF COUNTER 01:20:55

PLF COUNTER-COUNTER 00:09:42

Total Time 04:24:02

SE_v10-STEVE ELDRIDGE COMBINED FINAL PLAYED

Page/Line	Source	ID
54:20 - 55:15	**Eldridge, Stephen 06-29-2021 (00:00:58)** 54:20 How did you come to learn about 54:21 the human anatomy and how hernia meshes 54:22 interact with the human anatomy while 54:23 specifically you were working at Davol? 54:24 A. Well, we used to have -- or I 55:1 used to, because I'm not really doing that 55:2 anymore, but we used to go out in the field 55:3 and observe surgeries. We would basically 55:4 get with a sales rep, because they have the 55:5 relationship with the surgeon, and we would 55:6 go out for a day and watch probably five or 55:7 six surgeries in a day with our products and 55:8 talk to the surgeons and try to find out, you 55:9 know, what are the issues, what are you 55:10 looking for; and also at the same time being 55:11 able to observe and seeing the anatomy and 55:12 seeing how the material or the product 55:13 interfaces with the anatomy. It was -- and 55:14 I've lost count of how many of those I've 55:15 seen over the years.	SE_v10.47
55:16 - 57:6	**Eldridge, Stephen 06-29-2021 (00:01:37)** 55:16 Q. Okay. And what about when 55:17 Bard -- excuse me -- when Davol does -- hires 55:18 a company to do detailed surgeon surveys, are 55:19 you familiar with those surgeon surveys where 55:20 they get feedback from potential customers in 55:21 the field about various product attributes? 55:22 A. Yes, we did those all the time. 55:23 Q. And are you familiar with a 55:24 term "user needs" in the design control 56:1 process? 56:2 A. Yes, user needs are -- the 56:3 surveys you're talking about we call Voice of 56:4 the Customer, VOC. And so once we get those 56:5 reports, then we analyze them and try to pull 56:6 out what are the user needs that they're 56:7 looking for. 56:8 And so, you know, a user need 56:9 could be we need this product to be durable	SE_v10.48

Page/Line	Source	ID

56:10 so that we can handle it during deployment
56:11 and it doesn't fall apart, that kind of
56:12 thing.
56:13 So we list the user needs based
56:14 on the Voice of the Customer and, you know,
56:15 in surgery type work that we -- like I
56:16 described before.
56:17 Q. All right. And is that how the
56:18 process is supposed to work at Davol back in
56:19 this time frame, 2007, 2008, 2009?
56:20 A. Yes.
56:21 Q. All right. And is it important
56:22 to listen to the Voice of the Customer for
56:23 purposes of developing the user needs?
56:24 A. Yes.
57:1 Q. Why do you think it's
57:2 important?
57:3 A. Well, the Voice of the
57:4 Customer, they're the people we're designing
57:5 the products for, so we need to find out what
57:6 is it they're looking for.

57:14 - 58:18 **Eldridge, Stephen 06-29-2021 (00:01:29)** SE_v10.49

57:14 Did you receive training
57:15 through your many years at Davol about how
57:16 bare polypropylene acts in the
57:17 intraperitoneal space?
57:18 A. Well, the training is really
57:19 doing experimentation and collecting data.
57:20 So we would do animal studies that would
57:21 simulate surgery. And, you know, it's not
57:22 exactly the same as a human, but it's a close
57:23 approximation, especially when you use pigs
57:24 for this. So we did that all the time to
58:1 look at, you know, in the intra-abdominal
58:2 cavity what's going on.
58:3 And then as far as the
58:4 materials, we would do biocompatibility
58:5 testing where we'd get actual data that would
58:6 show, you know, what is the tissue-device
58:7 interaction, and those would be written up in

EXHIBIT 6

R.F. Caffrey & Associates, Inc.

VENTRIO AND SEPRA-VENTRIO
ONE-ON-ONE INTERVIEWS
JULY 2008

Presented to Davol Inc.
August 2008

P.O. Box 319 • #3658 Rte. 44 • Brownsville, VT 05037 • PH: 802.484.5756 • FX: 802.484.3823

P1.0467.1

R.F. Caffrey & Associates, Inc.

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R.F. Caffrey & Associates, Inc.

A. BACKGROUND

The Ventrio Hernia Team would like to have a better understanding of the market segments that will convert to Ventrio and what message is most appropriate to each segment. Phase I of this research included a major web-based study undertaken to develop quantitative insights by key market segments: lost customers, lap and open (PROCEED, Parietex, and others) and non-lost customers. This research, Phase 2, included qualitative interviews with general surgeons from the same populations to complement this quantitative effort.

B. OBJECTIVES

The purpose of the combined Phase 1 and 2 research efforts are to:

1) Document the status of lost customers, the reasons they left, and their likelihood to convert to the Ventrio product;
2) Test alternative messages for PROCEED, Parietex and lap customers; and
3) Obtain insight into the price sensitivity by segment to provide Sales guidance for the product launch.

Key deliverables are:

1) An estimate of the percent of lost customers and new customers likely to be gained by Ventrio.
2) Key messages for positioning the product with each segment.
3) Pricing sensitivity analysis and recommendations.

C. METHODOLOGY

The Phase 2 research included one-on-one interviews in three locations: New York City, Baltimore, MD, and Houston, TX, during the week of July 21st, 2008. Participants were recruited to include respondents from each of the identified market segments. They were paid an honorarium for participation and required to sign a confidentiality agreement. Rich Caffrey of R.F. Caffrey & Associates, Inc. conducted the interviews, which were observed by key Davol management. Audio and video recordings of the interviews have been provided.

D. KEY FINDINGS

1. Participants' Backgrounds

Respondents are performing an average of 5.8 incisional repairs per month, with a range of 1 - 12 procedures. An average of 43% of these incisional repairs are done laparoscopically, with a range of 0 - 100%.

Respondents have been performing laparoscopic incisional repairs for an average of 6.9 years, with a range of 2 - 16. They foresee a relatively even split in their laparoscopic (51%) vs. open (49%) repairs two years from now. Those who predict doing the majority laparoscopically mention patient related benefits, such as shorter stay, reduced pain, etc. Those who foresee doing the majority as open procedures seem unwilling to learn the laparoscopic approach.

Most surgeons foresee an overall movement (within the profession) towards laparoscopic incisional hernia repairs. The reasons relate primarily to surgeon familiarity, and smaller, less painful incisions. The few who don't foresee any movement either see open as faster, or appear to be older and not trained on the procedure.

Close to half the participants perform incisional hernia repairs in a free-standing ambulatory surgery center, and most of them use the same brand(s) that they do in their hospitals.

2. Brand Preference/Use

Surgeons report using an average of 2.9 brands for incisional hernia repair, with 85% reported using two or more. Brand use patterns were affected by the recruiting requirements. Within this targeted population, Davol has, by far, the most number of company use mentions among participants (28), followed by Ethicon (20) and GORE (13). Composix and its variations had the highest Individual brand mentions, 14, followed closely by GORE DUALMESH, 13.

Surgeons appear to have the most influence in the brand of prosthetic used in incisional hernia repairs, either because they say they do or it is based on the nature of the repair or product performance, which they judge.

Product problems are the most often mentioned reason for dropping a brand. The company/brand mentioned most often was Bard/Davol, but there were a few mentions for Ethicon and GORE.

Bard/Davol brands received the highest number of mentions for best new brand, which mostly reflected variations of Composix or Sepramesh. Ethicon/PROCEED was second, with most of its mentions for PROCEED.

3. Concept Reactions

Ventrio

The majority, 19 of 27 or 70%, are likely to recommend Ventrio if it became available. Their very positive endorsement is related to its obvious features: the ring, pockets, ranges of sizes and shapes, and similarity to Kugel.

More than half of the initial reactions to Ventrio associated it specifically with Composix Kugel or with "familiar" products, and these were typically positive impressions. Other positive reactions related to its handling properties, pockets, or the edge of the mesh. A few thought the ring recoiled nicely but a small number associated it with the previous problematic ring.

The most frequently mentioned "likes" for Ventrio related to the ring, either that it is absorbable and/or springs back well. Several liked the pockets, two layers of mesh or handling properties.

Some surgeons took issue with the ring in Ventrio, a few thought the product was too thick, and others noted the lack of visibility during laparoscopic placement. A few suggested adding markings to help them position the prosthetic. Also, a few noted the inability to trim it but were generally satisfied that the range of available sizes would address this, if their facilities would stock the full array.

The majority, 21 of 27 or 78%, are likely to use Ventrio in open procedures, with one-quarter of these likely to use it in both open and lap. Only 2 of the 27 or 7% are likely to use it in only laparoscopic incisional hernia repairs.

Surgeons would expect to use the new Ventrio in three-quarters of their incisional hernia repairs, on average, and slightly more than half would use it in 100% of these cases.

In the vast majority of cases, Ventrio would replace other brands and not be used in addition to existing. Also, the brand most often replaced is likely to be Bard/Davol, and often a variation of Composix.

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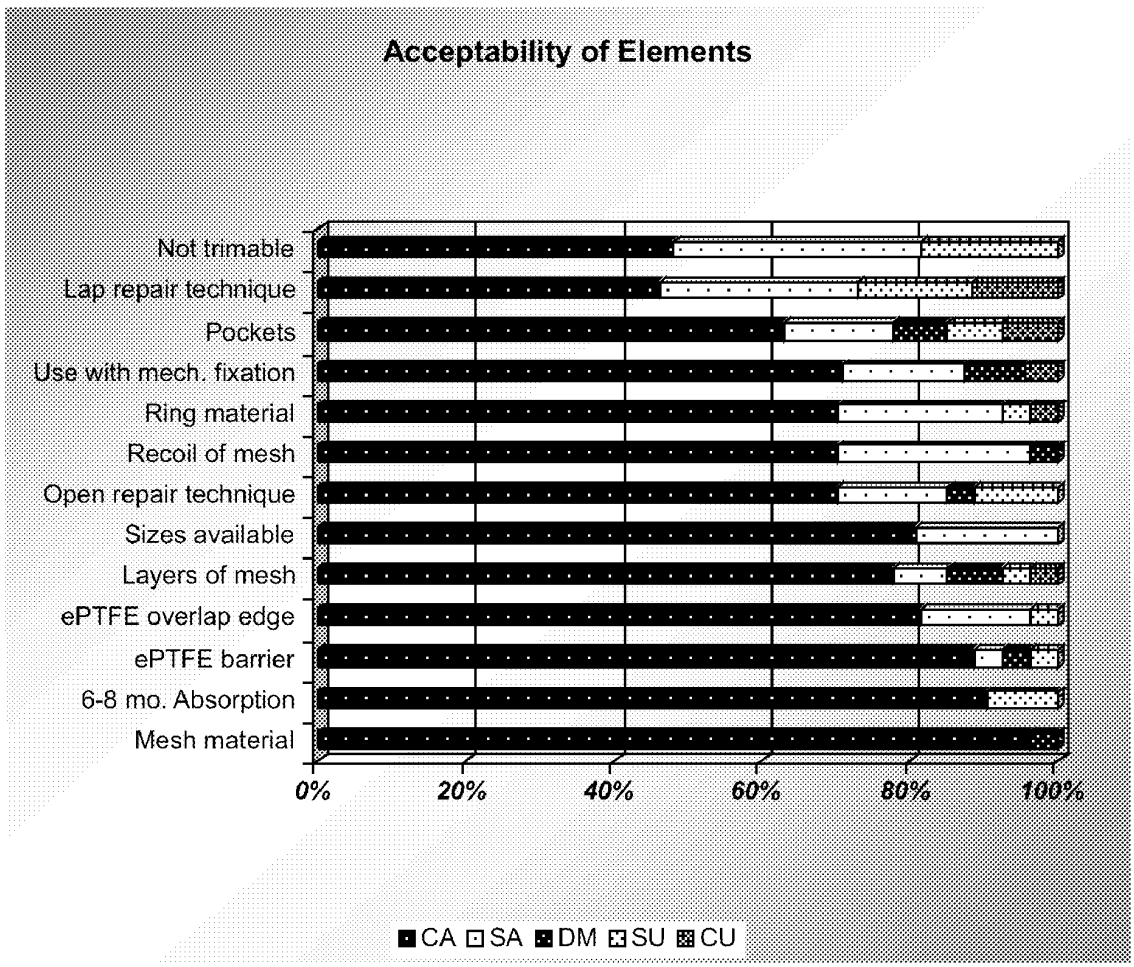
All but two of the 13 elements were “completely acceptable” to 60% or more of the surgeons interviewed, and all were either “completely acceptable” or “somewhat acceptable” to three-quarters of them. The four best received elements: “mesh material”, “6 - 8 month absorption time”, “ePTFE barrier” and “ePTFE overlap edge” were “completely acceptable” to 80% or more of the surgeons.

The two elements that were rated lowest: “not trimable” and “laparoscopic repair technique” were “completely acceptable” to less than half the surgeons.



Sepra-Ventrio

Initial reactions to Sepra-Ventrio were somewhat more negative than positive. The most frequently mentioned reaction was surgeons taking issue with the length of time to absorb, with some wanting it to last up to six months or longer. There was also concern that the mesh would adhere to the bowel. A few surgeons also were concerned about seromas and/or swelling.

The lightweight/low profile mesh was the most liked feature for Sepra-Ventrio, followed by its absorbability.

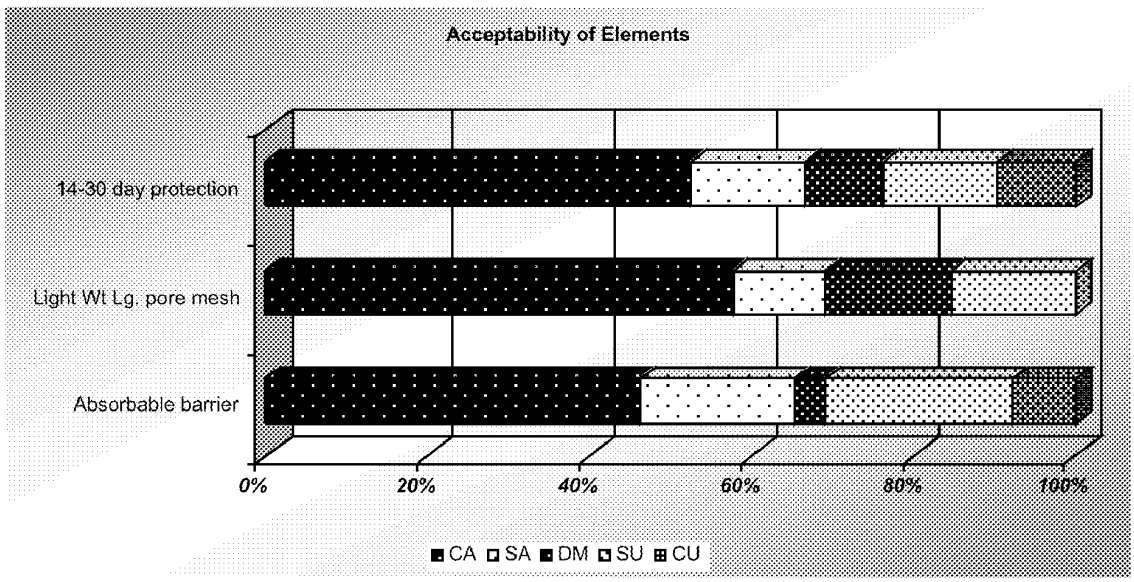
The most frequently mentioned dislike was an overall lack of appreciation for the concept, which was expressed by one-third of the surgeons. Also, several participants were concerned with its absorption time, or the unknowns about the product.

A slight majority, 16 of 27 or 59%, are likely to recommend Sepra-Ventrio if it became available. This level of endorsement, while quite positive, was less enthusiastic than the rating for Ventrio where 15 surgeons were “extremely likely” to recommend. The reasons for these positive “likelihood to recommend” ratings were somewhat varied and included a few who still had questions about the length of absorption time.

Those likely to use indicated a relatively even split for using Sepra-Ventrio in either lap or open procedures. However, the most often mentioned response was “none” by 10 of the 27 participants. This was in contrast to only four who indicated “none” for Ventrio, suggesting a more significant resistance to Sepra-Ventrio among a segment of the overall population.

Surgeons would expect to use Sepra-Ventrio in approximately two-thirds of their cases, on average, and almost half would use it in 90% or more of them.

Reactions to the three elements of Sepra-Ventrio: “14 - 30 day absorption”, “lightweight large pore mesh”, and “absorbable barrier” were generally positive, with with 60%+ rating them either “completely acceptable” or “somewhat acceptable”.



4. Price Sensitivity

Participants were asked a series of four questions to ascertain their impressions of price sensitivity for the new product they preferred versus their current product. Each of the questions identified costs above or below their current product at which they’d identify the preferred product as a “bargain”, “distrust its quality/performance”, “expensive but still want to use it”, or “too costly for consideration”. While the questions were only answered by some of the participants and, therefore, do not present a quantitative sample of merit, the responses suggest a premium price of 20% would be a bargain and surgeons are likely to endorse a premium of up to 50%. Once the price about doubles, resistance is too strong to overcome.

5. Advertising Message

Participants were shown several versions of a common ad: two-page vs. one-page, and headlines without much text vs. headlines with explanatory text. Both the two-page and one-page were equally popular, and there was no preference between the headlines with or without explanatory text. Pictures, photos, and/or graphics are the most important element.

The best approaches for each the surgeons to introduce new products are either one-on-one, e.g., sales call in the OR or MD's office, or at meetings, particularly the ACS. Journal ads and direct mail have much more limited appeal.

E. DETAILED FINDINGS

S1. Within the past few weeks, have you participated in a web study that discussed your use patterns for incisional hernia prosthetics and presented new concepts?

Only three of the 27 participants indicated that they had participated in a web study within the past few weeks regarding hernia products.

S2. Of the total number of hernia procedures you perform each month_____, approximately how many are incisional?

Respondents are performing an average of 5.8 incisional repairs per month, with a range of 1 - 12 procedures.

Repairs/Month	Number
1	2
2	2
3	3
4	2
5	6
6	3
7	1
8	4
10	1
12	3
Total responses	**27**
Mean	**5.8**

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S3. You perform _____% of these laparoscopically?

Participants are performing an average of 43% of these incisional repairs laparoscopically, with a range of 0 - 100%.

% Laparoscopic		Number
0		2
5		3
10		2
14		1
15		1
20		3
25		1
33		2
50		3
65		1
70		1
80		1
85		1
90		1
95		1
100		3
	Total responses	**27**
	Mean	**43**

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S5. What are you currently using _____ _____ (brand) most for incisional?

Surgeons report using an average of 2.9 brands for incisional hernia repair, with 85% reported using two or more.

Number of Brands	Number
1	4
2	5
3	11
4	5
5	2
Total responses	**27**
Mean	**2.9**

Brand mentions are profiled below. Since the recruiting effort focused on having participants who were current users of Covidien's Parietex, Ethicon's PROCEED, and Atrium's C-QUR, the sample is not random. Nevertheless, brand mentions are interesting to review.

In the first profile below, they are listed as provided and thus, to some degree, reflect brand recall. In strictly descending order of mention by the surgeons, PROCEED, Composix, PROLENE and AlloDerm represented 30 of 77 mentions, or 39%.

Brand	Number
PROCEED	10
Composix	9
PROLENE	6
AlloDerm	5
Marlex	4
GORE	4
GORE DUALMESH	4
Parietex	4
Ventralex	3
DUALMESH	3
Kugel	2
Composix Mesh E/X	2
Bard	2
Ethicon	2

Brand	Number
ULTRAPRO	2
C-QUR	1
Kugel Patch	1
Sepramesh	1
Composix Mesh	1
Composix Kugel	1
Composix L/P	1
Non-stick Bard	1
DUAL GORETEX	1
DUAL	1
Covidien	1
TiMESH	1
Polypropelene	1
Polyethylene Soft	1
Porcine	1
Biologics	1

When grouped by company, Davol has, by far, the most number of mentions, followed by Ethicon and GORE. Composix and its variations had the highest brand mentions, 14, followed closely by GORE DUALMESH, 13.

Brand	Number
Davol	**28**
Composix	9
Marlex	4
Ventralex	3
Kugel	2
Composix Mesh E/X	2
Bard	2
Kugel Patch	1
Sepramesh	1
Composix Mesh	1
Composix Kugel	1
Composix L/P	1
Non-stick Bard	1
Ethicon	**20**
PROCEED	10
PROLENE	6
Ethicon	2
ULTRAPRO	2

Brand	Number
GORE	**13**
GORE	4
GORE DUALMESH	4
DUALMESH	3
DUAL GORETEX	1
DUAL	1
Covidien	**5**
Parietex	4
Covidien	1
LifeCell	**5**
AlloDerm	5
Atrium:	
C-QUR	1
GFE	**1**
TiMESH	1
Other	**3**
Polypropelene	1
Polyethylene Soft	1
Porcine	1
Biologics	1

Comments:

- *GORE DUALMESH: works the best, not as stiff, thinner, goes in easily. Made my own products during residency. Thick meshes are hard to secure.*
- *Kugel for open. PROCEED for laps.*
- *GORE, Davol Sepramesh, Ventralex plug.*
- *Parietex, GORE or Bard occasionally.*
- *Lap: Double sided dual mesh. Open: Polypropylene or polyethylene soft.*
- *AlloDerm, Kugel patch, Composix.*
- *Composix mesh for open, Composix E/X and Parietex for lap.*
- *Davol Composix, Marlex, AlloDerm (rarely).*
- *Onlay: PROLENE. Inlay: Dual GORETEX and Parietex.*
- *Composix Kugel, PROLENE/PTEE, PROCEED and ULTRAPRO, depending upon what's available and where I work.*
- *Lap: PROCEED - handles well, easy to use. Open: small hernias Ventralex, easy to use. Large: Composix. Contaminated: AlloDerm.*

- *Lap: Dual 50%, PROCEED 50%. Open: Dual, AlloDerm, Ventralex, PROCEED.*
- *Lap: PROCEED. Open: PROLENE or Marlex. Rumors of problems with Marlex mesh but I haven't stopped using it.*
- *Open: Bard. Lap: Bard.*
- *Lap: C-QUR and TiMESH. Open: TiMESH, C-QUR light, ULTRAPRO.*
- *Lap: PROCEED. Open: PROLENE, GORE, Composix, DUALMESH.*
- *Lap: Ethicon, Covidien, because like tacker; PROCEED, GORE DUALMESH and Davol Composix. Open for infected: Use biologics, easy to put them in.*
- *Open: PROLENE Mesh, non-stick Bard. Lap: GORE DUALMESH. Trending towards open due to new products. AlloDerm for open bowel procedures.*
- *Bard Composix, Marlex or PROLENE, dual side up for the bowel. Handles well. Ethicon or PROLENE mesh.*
- *Composix L/P, switched over from Parietex. PROCEED occasionally.*
- *GORE DUALMESH.*
- *GORE: Pliability, durability, ease of use, laparoscopic, non-recurrence. Parietex and Ethicon just to try something else.*
- *Lap: Bard, Ethicon PROCEED, Composix. Open: Same, Kugel or Composix.*
- *Composix 90%. Porcine sometimes.*
- *Composix 70 -80%. DUALMESH.*
- *Bard Marlex mesh.*
- *Bard Composix Mesh E/X. Depends on hospital availability, or PROCEED. Discontinued Parietex.*

1) (IF DOES LAP, ASK) How many years have you been performing laparoscopic incisional hernia repair?

Respondents have been performing laparoscopic incisional repairs for an average of 6.9 years, with a range of 2 - 16.

Years	Number
2	4
3	1
6	1
5	5
6	1
7	1
10	5
11	1
13	1
16	1
Total responses	**21**
Mean	**6.9**

2) Do you see a movement towards laparoscopy for incisional hernia repairs?

Most surgeons foresee a movement towards laparoscopic incisional hernia repairs. The reasons relate primarily to surgeon familiarity, and smaller, less painful incisions. The few who don't foresee any movement either see open as faster, or appear to be older and not trained on the procedure.

Response	Number
Yes	16
No	9
Total	**25**

"Yes" comments:

- *Smaller incisions; see more of the wall, put in bigger grafts.*
- *Availability of meshes and tracking devices.*
- *Lots of experts demonstrating its safety.*
- *Slowly, more younger surgeons.*
- *MIS, advantages: smaller incisions, less stress.*
- *PROCEED easier to use.*
- *For primary, not for recurrent.*
- *Patient comfort, less pain, etc.*

- *If trained in it, many not comfortable with it. Expanding to large wounds, plus people with prior procedures.*
- *Depends on surgeon. Did laparoscopic fellowship.*
- *Familiarity by surgeons, patient request.*
- *I'm older, not changing much. Younger surgeons are doing more laparoscopic.*
- *Shorter recovery, less pain.*
- *Long learning curve, difficult to treat wound problems.*

"No" comments:

- *Open is faster.*
- *No significant advantage for recovery or time, e.g. pain reduction. Laparoscopic can be more expensive due to time.*
- *Those trained on laparoscopic stay there. Ones who did not, won't.*

3) What do you anticipate will be your mix in terms of open vs. laparoscopic (incisional repairs) two years from now, and why?

Participants foresee a relatively even split in their laparoscopic (51%) vs. open (49%) repairs two years from now. Those who predict doing the majority laparoscopically mention patient related benefits, such as shorter stay, reduced pain, etc. Those who foresee doing the majority as open procedures seem unwilling to learn the laparoscopic approach.

	Lap	Open		Number
	100	-		2
	98	2		1
	95	5		1
	90	10		2
	75	25		3
	70	30		2
	65	35		1
	60	40		1
	50	50		2
	33	67		1
	30	70		2
	25	75		2
	10	90		1
	5	95		2
	-	100		3
			Total	**26**
Mean	**51**	**49**		

Laparoscopic dominate comments:

- *Lap 100%. I don't like open, more difficult procedure.*
- *Lap 100%. Patient goes home same day, smaller incision, less pain, less wound infection.*

- *Lap 98% for incisional now.*
- *95%+ lap. Visualizing the defect from below, nicer repair - see the edge form below, faster.*
- *Same: Lap 90%, open 10%.*
- *Lap 75%, open 25%. Shorter recovery time, less pain.*
- *Lap 75%, open 25%. Equipment will improve, e.g. hand-held and other elements.*
- *Lap 70%, open 30%.*
- *Same: Lap 70%, open 30%. Small hernias lap. Large component separation.*
- *Lap 50 - 80%, open 20-50%. Ability to orient better, e.g. stented meshes.*
- *Lap 60%, open 40%. Lap doesn't always work, e.g. multiple previous surgeries.*

50% each comments:

- *Open 50%, lap 50%. I have a young partner.*
- *Lap 50% or higher, open 50%. Patient comfort, less pain.*

Open dominate comments:

- *Open 95%, lap 5%. Lap too much of a pain, difficult to place the mesh, e.g. transfacial suturing.*
- *Open 75%, lap 25%. Depends on type of hernia.*
- *Open 75%, lap 25%. No move to lap.*
- *Open 70 - 75%, lap 25 - 30%. Time consuming.*
- *Unchanged. Open 70%, lap 30%. I see patients with multiple operation history. Obesity also common. Prefer laparoscopic particularly for obese.*

BRANDS OF PROSTHETICS USED

Current:

4) Do you perform any of your incisional hernia repairs in a free-standing ambulatory surgery center?

Close to half the participants perform incisional hernia repairs in a free-standing ambulatory surgery center, and most of them use the same brand(s) that they do in their hospitals.

Response	Number	Percent
Yes	12	44
No	15	56
Total	**27**	**100**

Do you use the same prosthetics you use in the hospital for these repairs?

Response	Number	Percent
Yes	9	75
No	3	25
Total	**12**	**100**

5) How do you choose which brand of prosthetic you will use for open or laparoscopic incisional hernia repair?

Surgeons appear to have the most influence in the brand of prosthetic used in incisional hernia repairs, either because they say they do or it is based on the nature of the repair or product performance, which they judge.

Surgeons:

- *For lap, flexible. Open is stiffer. On-going battle regarding brands. But reps keep us involved with new brands. Trial is patient charge. Inguinal partly absorbable, good for thinner patients.*
- *I pick within the choices given me.*
- *Habit - detailing by reps. Parietex has adhesions and works.*
- *I pick it. Use the same for both. Composix Kugel a good product - open repairs have less tacking or transfacial suturing.*
- *Good tensile strength, good port travel, easy to insert. I, the director, basically decide.*
- *What I'm used to.*
- *Have to request.*
- *My group guides me; colleagues using longer than me influences my opinion, plus sales reps are influential.*
- (Use) *Same brand.*

Nature of Repair:

- *Size of hernia, intraperineal or extraperineal.*
- *Depends on size and recurrence.*
- *Depends on size, also trained on PROCEED.*
- *Just try to have a bioplastic - a risk of contamination, e.g. gastric bypass.*
- *Straight lap and size. Small: Plug. Large: Mesh.*

Product Performance:

- *Parietex handles best - easier to place intra-abdominally.*
- *Product features as demonstrated by Ethicon rep.*
- *Handling qualities and literature regarding adhesions and mesh contractions.*

Administration/Management/Economics:

- *Mostly the facility chooses.*
- *By purchasing - we input types of material and we make special requests.*
- *Surgery center gets better price from Bard. Prefer the wider mesh - thinner mesh with under openings, works better, flexible, less foreign materials.*
- *Based on what hospital makes available and reps input.*
- *What's available, center orders Bard in volume.*

6) (IF USING MORE THAN ONE BRAND ON SCREENER) Why do you use more than one brand of prosthetic?

When surgeons use more than one brand of prosthetic, it is typically for different handling or repair properties.

- *Incisional: GORE DUALMESH. Lap inguinal: Marlex mesh (cut and shape), Bard 3D Mesh.*
- *Determined by the graft. Don't care about the brand or company.*
- *That's what is available in the size.*
- *Mostly AlloDerm. Other brands when the defect is small, e.g. Ventralex.*
- *Infection equals biologics rather than Composix Kugel.*
- *Ease of tacking made me switch.*
- *Different characteristics of the prosthetics, e.g. coating on material, also selection available.*
- *Handling characteristics matched to patient conditions.*
- *Where I am putting it, top of the fascia or in the abdominal cavity. Ease of handling for either groin and/or incisional repairs.*

7) (IF DISCONTINUED ANY BRANDS) What are some of the reasons you stopped using some of the brands you have discontinued?

Product problems are the most often mentioned reason for dropping a brand. The company/brand mentioned most often was Bard/Davol, but there were a few mentions for Ethicon and GORE.

❑ Product problems, recalls, poor performance, or recurrences. PROBE: What were some of the issues?

Bard/Davol:

- *Composix L/P and Parietex. Not easy to use.*
- *Kugel: Design concept not valid. Large meshes had too bulky a ring and exposed it to the bowel. PP and PE had problems when exposed to the intestine. Stopping use in general was due to redos that showed "potato chip" changes.*
- *Only Composix mesh - too flimsy, didn't sit well.*
- *Composix Kugel.*
- *Composix Kugel. Marlex: Risk of fistula.*
- *Bard Composix E/X: Product problems, too stiff, one infected case.*
- *Kugel Patch: Delaminates. Composix PTFE and GORE: Too heavy, stiff. Will try Sepramesh, e.g. absorbable film and lightweight mesh, plus Berger paper/article regarding adhesions.*
- *Kugel: Infection issues, but stopped for six - eight weeks, however I like them a lot. Kugel for open, because I can reinforce doing a combined open/therapeutic lap.*
- *Composix Kugel: Too much polypropylene, infections are a problem.*

Ethicon/PROCEED:

- *PROCEED: Too flimsy.*
- *PROCEED: Bard Composix: Heavy when rolled, bulky.*
- *PROCEED: Due to the recall.*
- *Ethicon: Tried, didn't hold well anteriorly.*

GORE:

- *GORE Pure EPTFE: Several years ago. Seromas, infections.*
- *GORE DUALMESH: Too difficult to suture in place.*

All Other:

- *Surgesis: Messy, more cellulitis, ugly seromas. Disappears too quickly.*
- *Biological porcine collagen, CollaMend, Surgisis: Doesn't resist infections. CollaMend: Lots of seromas.*

- ❑ Availability:
  - *Parietex.*
  - *Bard Composix and Surgisis: Both not available.*
  - *GORE.*
  - *Parietex: Hospital doesn't stock as needed.*

- ❑ Economics:
  - *C-QUR.*
  - *GORE: And not well supported by a rep.*

- ❑ Preferred a different technique. PROBE: What in particular about the new technique did you prefer?
  - *Marlex: Handling properties, wide interstices.*

8) What in your opinion is the best new brand or type of prosthetic for incisional repairs to come on the market within the past year or so, and why?

Bard/Davol brands received the highest number of mentions for best new brand, which mostly reflected variations of Composix or Sepramesh. Ethicon/PROCEED was second, with most of its mentions for PROCEED.

Bard/Davol (10):

- *Bard/ Kugel: Due to memory but concerned about fracturing. Ventralex: Moved from prosthetics to biologics due to ability to become part of host tissue equals lower infections, etc.*
- *Bard products.*
- *Composix L/P: Soft, easy to roll, stick down the trocar. Doesn't unravel easily.*
- *GORE DUALMESH: Feels the thickest yet very pliable and strong barrier.*
- *Bard Composix: PTFE backing, mesh ingrowth.*
- *Bard Composix.*
- *Bard lightweight Composix: For lap, it's good getting into the abdominal area. Composix and PROCEED similar but a little flimsy.*
- *Sepramesh: Pliable, flexible, soft, can cut.*
- *Sepramesh: Minimum adhesion formation.*
- *Partial to Davol.*

Ethicon/PROCEED (4):

- *Ethicon products.*
- *PROCEED and DUALMESH.*
- *PROCEED: Learning curve for lap incisional is longer, therefore using PROCEED.*
- *PROCEED: Good but turns brown color inside the perineum. Composix: Thin, easy to fold product, large hernias these days and future is "very thin" prosthetics.*

Covidien/Parietex: (3):

- *Parietex: Easier handling, availability of sizes.*
- *Parietex: Absorbable barrier.*
- *Parietex: Very easy to handle. I have done 15 cases now. Longest is 1½ years out, doing fine. Ease of handling, inlay for larger people is better.*

C-QUR (2):

- *C-QUR: Handling properties. Can get through trocars, stays put, secures well, good value. I'm the point guy on value analysis!*
- *C-QUR: Colleagues referral.*

All Other (8)

- *None.* (3)
- *Partially reabsorbable - prevents adhesions, trimer, but has more ballooning. Requires only five trocars.*
- *Lighter weight polymer meshes backed with non sticky surfaces. Thinner, less seroma formation. Porous surface may be the next big item/design.*
- *Open: AlloDerm. Lap: PROCEED.*
- *Omega 3 fatty acid coated and AlloDerm. Coated PP is thin and comes in different sizes. AlloDerm easy to place, resistant to infection.*
- *Allograft: Biologic for ingrowth of open tissue. No appropriate patients yet. Very expensive.*

9) What percent, if any, of your incisional prosthetic use do you anticipate this new brand will represent in two years?

Most participants indicate that this best new brand will represent virtually all of their prosthetic use within two years. (Brands identified below are from responses to Q. 8)

Bard/Davol:

- *99%:* Sepramesh.
- *100%:* Composix L/P.
- *90%+:* Composix.

Covidien/Parietex:

- *100% of inlay procedures:* Parietex.
- *80-90%:* Parietex.

Ethicon/PROCEED:

- *100%: PROCEED.*
- *Depends upon what Bard does.* (Ethicon user).

Other comments:

- *100%:* Partially reabsorbable.
- *30% overall:* Open: AlloDerm, Lap: PROCEED.
- *70%:* Omega 3 fatty acid coated and AlloDerm.
- *75%:* C-QUR.
- *Same: GORE DUALMESH.*
- *5%: Allograft.*
- *100% if better, will try: Bard lightweight Composix*

10) What is your level of influence in the selection of incisional hernia prosthetics? Using a 5-point scale where 1 = Very important to 5 = Not important, where would you be? (*Show rating card)*

Surgeons give themselves relatively high ratings in terms of influence in the selection of incisional hernia prosthetics, 2.1 on a 5-point scale.

Response	Number
1	9
2	11
3	5
5	2
Total	**27**
Mean	**2.1**

Comments:

- *1: Get what I want.*
- *1: Medical Director of Surgery Center. 4. At the hospital, administration is important here.*
- *2: I'm Chairman of the OR Department. I try to form the consensus, talk to them privately.*
- *5: But only generic references.*

11) What other functions, if any, by job title have a significant role in the decision process for the hernia prosthetics you use?

While surgeons rate their own influence as high, purchasing/materials management is the most often mentioned other function involved in the decision process.

- *Purchasing people.*
- *Purchasing, always trying to get us to conform.*
- *Purchasing, we only give generic references.*
- *Purchasing and OR Committee and nurses.*
- *Purchasing department.*
- *Materials management.*
- *Materials Manager of the OR, contract/buying group.*
- *Materials management, Director of Surgery Center.*
- *Materials management, OR Supervisor.*
- *Materials management, Surgery Director - very cost driven.*
- *Buying contract for the hospital.*
- *Hospital corporation.*
- *None.* (Himself.) (3)
- *Surgeons only.*
- *Still the surgeons.*
- *More surgeons.*
- *1. Higher volume surgeons. 2. Administration.*
- *Other surgeons combined. Buying committee.*
- *Colleagues, also Materials Committee (rubber stamp).*
- *Charge, Materials Manager, surgeons.*
- *Committee - most important.*
- *Board members, OR Director and nurses.*
- *Pharmacy and Therapeutic Committee with surgeons' evaluations.*
- *Medical Director of Surgery Center. At the hospital, administration is important here.*

12) What is your most significant unmet need in an incisional hernia repair prosthetic?

Reducing infections and seromas are frequently mentioned as unmet needs, followed by improved tacking/orientation/handling properties.

Infection/seromas:

- *Fixing the mesh - seromas - annoying, solve the problem.*
- *Complete avoidance of getting an infection.*
- *Can't get infected.*
- *Decrease seroma formation.*
- *Lap: No infections, compatible to the body; leading to biologics graft but patients see the repair/bulging afterward.*
- *Doesn't change size or separate or infect. Both Poly and ePTFE change size.*
- *Mesh fixation - not more absorbable. Adhesion formations. Biologics for infection.*
- *1. A way to reduce risk of infection - surface body doesn't see as foreign, true natural repair. 2. Ingrowth issue - truly smooth surface, like the peroneum.*

Tacking/orientation/handling:

- *The way to orient the mesh, e.g. make it so it can be easily oriented.*
- *One you don't have to tack in place.*
- *Easy way to self-support in open procedure, to handle easily. Also for lap.*
- *1. Variety and selection - incisional hernia mesh the same size or location. Yet, facilities want to reduce inventories. 2. Ease of handling and durability, e.g. there for good, doesn't tear or fray, takes sutures without damage.*
- *Take a tack better and not tear. Sepra-film like barriers for less adhesions.*
- *Flexible, easy to place in the abdomen, no adhesions.*
- *Mesh that won't stick, no adhesions.*
- *Balance between conformability and substance enough to be positioned without corrugating.*

Sizes/shapes:

- *Variety of sizes and shapes.*
- *Correct size so you don't have to trim.*
- *Getting it down to a size to fold and go through a 5mm port.*

Lightweight/thin:

- *Lightest weight, flexible and yet strong - prefer lightest weight.*
- *Balance between thin enough for easy placement without compromising durability.*

All other:

- *Like ePTFE - solid grafts for what they do for the abdominal wall, however the mesh has the benefits - combined the features of both.*
- *Combination of features now only available in individual products.*
- *1. Gets through the trocar easily, big pieces. 2. Ease of handling - mesh. 3. Evidence-based papers regarding shrinkage of the mesh. 4. Cost - can't justify cost as more than surgeon gets to put it in e.g. $300 or $400 is the surgeon fee from Medicare.*
- *Tacky - 45º angle to deliver. Lighter, stronger; polypropylene a problem.*
- *Nothing.*

13) How would you describe your attitude towards adopting new prosthetics for incisional/ventral repairs? *(Show rating card.)*

The majority of surgeons appear willing to adopt new prosthetics after either FDA approval and some clinical reports, or after FDA approval, if the product is from a reliable manufacturer.

Number	Response
11	I will adopt after FDA approval, if a product is from a reliable manufacturer.
10	I will adopt after FDA approval and some clinical reports.
6	I will adopt only after multiple years of clinical data are available.

- *With FDA.*
- *Anybody can sell something. I want good, hard data. But not in Biology Today, rather a peer review journal, e.g. ACS, Archives of Surgery, and Annals of Surgery.*

CONCEPT "X" VENTRIO

- ❑ **X1 - for PROCEED user**
- ❑ **X2 - for Parietex user**
- ❑ **X3 - for C-QUR user**
- ❑ **X4 - for lap user**

(Four versions of the concept statement were available, each representing a slightly different wording to the basic concept.)

14) What is your initial reaction to this (Ventrio) concept?

More than half of the initial reactions to Ventrio associated it specifically with Composix Kugel or with "familiar" products, and these were typically positive impressions. Other positive reactions related to its handling properties, pockets, or the edge of the mesh. A few thought the ring recoiled nicely but a small number associated it with the previous problematic ring.

Same as/similar to Kugel:

- *Variation of Kugel - more pliable, more flexible.*
- *Same type of thing as Kugel concept, e.g. pocket, stiffening.*
- *Similar to Kugel. Makes a lot of sense, would use the minute it comes out. PDS addresses problem.*
- *Same concept as Composix Kugel. Good idea.*
- *Very similar to Composix L/P. If it works, it would be neat. Could the mesh come with different color sutures for positioning and/or orientation?*
- *Like the Kugel patch, used something similar.*

Familiar/like Bard/Davol:

- *Sounds familiar.* (2)
- *Don't see anything unique. Looks like other patches, not really new.*
- *Sounds like Bard/Davol.*
- *Same as one I'm using now. Better than current, stays open better. Absorbable ring concept is great, looks like a Bard mesh, which is bulky. My hernias are typically large.*
- *Nothing different in the words vs. what's already been done. I have not had problems in general. Only had one infection. Ideal is "never" getting infected.*
- *Like what I use.*
- *Quite like product I'm using. Sizes look good.*
- *Like what I use today, both for lap and open. The ring seems different, not sure if mine absorbs over time.*

Other positives:

- *Current one doesn't recoil well. This seems better. A bit concerned with pocket - tacking with stretch - the edge of the mesh could flip.*
- *Seems strong. Pliable enough to get into a port, matches the concept statement.*
- *I like it, very much like my experience with the Kugel. This has softer absorbable outer edge. This seems flexible and easy to move around. Absorbable recoil is a good idea.*
- *Love its appearance. PTFE is just what I want to see. Know about tissue ingrowth. Can you trim it?*
- *It's nice.*
- *Decrease adhesions to the mesh. Easy method for fixation and mobility.*

Negatives:

- *It doesn't fold - negative. I misinterpreted the concept statement. A mesh with a ring was taken off the market. I'd need a 15 trocar to get it in.*
- *Suspicious. Mimics the Bard product I bounced. The fixation breaks down, mesh delaminates, high level of infection. Also, top layer incorporates, but bottom layer does not, no interstices so seromas can form. Also, need to see long-term results.*
- *I understand that it's more for lap than for open. For open, e.g. large defect I'd sew it for open. Don't need double layer for that, or the ring. Also seroma with nonabsorbable ePTFE.*
- *Hole only provides for two fingers - maybe a cross slit would be better, or both. Recoils well.*
- *Why the ring for open repairs, don't need.*

15) What, if anything, do you particularly like about it?

The most frequently mentioned "likes" for Ventrio related to the ring, either that it is absorbable and/or springs back well. Several liked the pockets, two layers of mesh, or handling properties.

Ring/recoil property/absorbable:

- *Ring and absorbable.*
- *Maybe the ring for memory for lap procedures. Absorbable material for the recoil mechanism.*
- *PDS a good solution. Springs open quickly.*
- *Recoil ring for laparoscopic procedures. Also seroma with non-absorbable ePTFE.*
- *Absorbable spring.*
- *Recoil is a nice feature - issue is deployment through the trocar. 10 -12 trocar, will it fit?*
- *Springs back well; flattens nicely.*
- *More protection for bowel. Absorbable ring is nice.*

Similar/familiar:

- *Looks like what I use.* (2)
- *Similar to Bard which is nice, like fixation, like overlap.*
- *Not any different from what I currently use.*

Handling/flexibility:

- *The flexibility of a wide underlay; use of the pocket to tack; GORETEX to contact the bowel.*
- *Malleability is nice.*
- *Materials are excellent, efficacious. I like the pockets, handles well. Simple, nice concept.*
- *EPTFE gives strength polypropylene tissue for flexibility. Probably would use for lap and open.*
- *Slippery side is extended, so less chance of bowel fixation to PP. Absorbable; stiffer which helps to eliminate "potato chip" effect.*

Pockets:

- *Pocket and absorbable.*
- *The pocket. Particularly for open repairs, and the spring mechanism.*
- *More flexible - advantage for lap approach.*

Two layers:

- *Two layers of mesh, but not sure it's necessary.*
- *Two layers of mesh and PTFE barrier is good.*

All other comments:

- *For open primarily, the pocket should work well, good ergonomics.*
- *Nothing.*
- *Opens well, over-hanging edges, pockets.*
- *Nice for open repairs; will conform well.*

16) What, if anything, do you particularly dislike about it?

Some surgeons took issue with the ring in Ventrio, a few thought the product was too thick, and others noted the lack of visibility during laparoscopic placement. A few suggested adding markings to help them position the prosthetic. Also, a few noted the inability to trim it but were generally satisfied that the range of available sizes would address this, if their facilities would stock the full array.

Ring issues:

- *For suturing, the ring isn't as definite to suture as the previous. What will a suture/stitch do to the ring, fracture it? Why two rings on the large size?*
- *Huge piece of material and ring only 2 - 5% of total material. It's absorbed, big deal!*
- *I'd like a stiffer ring. It's somewhat contentious though, due to risk of breaking. It's almost not a recoil ring. Should work well for lap, since you're tacking all around.*
- *Not inspired by the recoil mechanism; not bad, could be better.*

Thick/stiff:

- *Its thickness - too thick. Difficult to make thinner; the ring makes it thicker, more cumbersome. Also, too thick where the tack will be.*
- *A bit thick for laparoscopic procedures. Still have to wait for biologic graft.*
- *Hard to get bulky material in; stiff, calcified mesh.*
- *Might tear up going through the trocar. Maybe have the recoil, but make it thinner.*
- *Don't know its difference vs. what's available. Minimize the bulk!*

Visibility:

- *Can't see through for lap procedures.*
- *Placing intraperitoneally laparoscopically, you're blind - you'll need tacks or sutures to know where the placement is. Three layers is thicker, most fixation tacks might not go through this three layers. I'm not sure Covidien's would. New Bard 6mm spike with spike tip - leveled edge cuts blood vessels. Also thin patients can get nailed through the abdominal wall. EMS Ethicon 4mm will probably penetrate. May be good small size for umbilical hernias, due to small size.*
- *Add orientation marks to tell where it is.*
- *Add circles to know where we are.*

Possible seromas:

- *Slippery side is non-porus, nothing will stick, which is good. However, worry about seromas forming above it, in lap repairs. Hard to maintain the geometry after you close, or the center will extrude. Also, edges tend to corrugate. Need to see if it's stiff enough to prevent this. Advantages multiply as size gets larger.*
- *Concern about seroma, causes pain and swelling. Can't trim it.*

Trimming:

- *Wish I could trim it, but no big deal. Any clinical data?*
- *Not able to trim it is a problem. Perhaps more edge and less area in the middle. Maybe difficult to get down a 12mm trocar site, particularly for larger sizes. Doesn't spring open quickly after open rolling it.*

Handling/slippery:

- *EPTFE side just looks like plastic - very rigid in appearance and feel. Doesn't have softness to the mesh.*

Nothing:

- *Nothing.* (3)
- *Nothing. A bit paranoid after my experience with GORE.*
- *Nothing. Uncertain about the pore size.*

All other comments:

- *Concern about underlap, 5cm for fascia edge, will it get done?*
- *Not appropriate for open, and double pocket does nothing for lap. Pockets open against the abdominal wall.*
- *Far cry from metal spring open, but still quite nice.*

17) Assuming the economics would be acceptable, how likely would you be to recommend this product for use if it became available? Please use the 5-point scale on the handout.

The majority, 19 of 27 or 70%, are likely to recommend Ventrio if it became available. Their very positive endorsement is related to its obvious features: the ring, pockets, ranges of sizes and shapes, and similarity to Kugel.

Recommend Rating	Number
Extremely likely	15
Somewhat likely	4
Neither likely nor unlikely	4
Somewhat unlikely	3
Extremely unlikely	1
Total	**27**

18) Why?

Extremely likely:

- *Novel features, particularly its similarity to what I use and it's ease of placement.*
- *New product. Composix to compare with it, which is what I am using.*
- *Flexibility of the Kugel. Like the idea of the two-ring layer version.*
- *Ring, materials, fixation pocket.*
- *Springs up faster than my current product.*
- *For largest size. It would represent 25% of my open procedures.*
- *Familiar with it. Only concern is report of ring breakage. Also like the bigger overlap. Seems better made than Composix Kugel.*
- *Using something similar with good success.*
- *Like the incorporation of the pocket, more absorbable than Kugel.*
- *Better than the current product. Makes lap approach easier; then I'd go back to more lap approaches.*
- *Variety of sized and shapes, plus recoil ring. Would love a softer sided ring feature combination.*
- *Like the shapes, how it attaches is also important. Also intra-abdominal utilization.*
- *Much like what I use, would work well. Remove pocket for the lap version.*
- *Using it.*
- *For open procedures.*

Somewhat likely:

- *Could be made to be "extremely likely" if other surgeons referred to its use history.*
- *Might work if I can get a good secure underlay.*
- *If it turns out faster* (procedure).
- *Like the materials but want to see some clinical trial and amount of fluid retention.*

Neither:

- *Very little concern about the ring I'm now using.*
- *Neither: Same as the other responses, nothing really different.*
- *Recoil ring for laparoscopic procedures. Also seroma with non-absorbable ePTFE.*
- *Already have, don't need this.*

Somewhat unlikely:

- *Thickness outside the ring. Not sure about the necessity of the ring, or the two layers of mesh.*
- *Don't think it improves what is out there. Parietex rolls up tighter. Can't put this through a 12 trocar.*
- *Doesn't seem to add anything. A bit more flimsy than Kugel.*

Extremely unlikely:

- *Placing intraperitoneally laparoscopically, you're blind - you'll need tacks or sutures to know where the placement is. Three layers is thicker, most fixation tacks might not go through this three layers*

19) On what type or types of surgery would you first use it . . . ?

The majority, 21 of 27 or 78%, are likely to use Ventrio in open procedures, with one-quarter of these likely to use it in both open and lap. Only 2 of the 27 or 7% are likely to use it in only laparoscopic incisional hernia repairs.

Response	Number
Open	16
Lap	2
Both	5
None	4
Total	**27**

Comments:

- Lap:
  - *Curiosity, waiting for SurgiMend product to help with this approach, then for open also.*
- Open:
  - *Patients with extensions to the xiphoid open, then maybe lap.*
  - *Like it more, probably still hard to get through a trocar.*

20) On what types of repairs.

This question was not asked.

21) In approximately what percent of your hernia repairs would you hope to use this new product?

Surgeons would expect to use the new Ventrio in three-quarters of their incisional hernia repairs, on average, and slightly more than half would use it in 100% of these cases.

Response		Number
0		1
5		2
25		1
50		1
70		1
75		2
80		1
100		11
	Total	**20**
	Mean	**74**

Comments:

- *25% duality, but potential for most. Not for large bilateral defects.*
- *75% for ventral abdominal.*
- *75% of lap, 5% of open.*
- *Near 100%.*
- *100%, if mandatory replacement, 0% if not mandatory.*
- *100%. We look for DUALMESH.*
- *100% of open.* (2)

22) How many patients would this amount to in a typical month or year? ____ ❑ Mo❑ Year

For these respondents, this 75%+ use level would equate to an average of five to six patients per month.

Response		Number
2		2
3		1
4		1
5		5
7		1
8		2
9		1
10		1
	Total	**14**
	Mean	**5.6**

23) If it performed as you anticipated, would your use be . . .?

In the vast majority of cases, Ventrio would replace other brands and not be used in addition to existing. Also, the brand most often replaced is likely to be Bard/Davol, and often a variation of Composix.

Number	Response
2	Additional to other brands
14	Replacing other brands

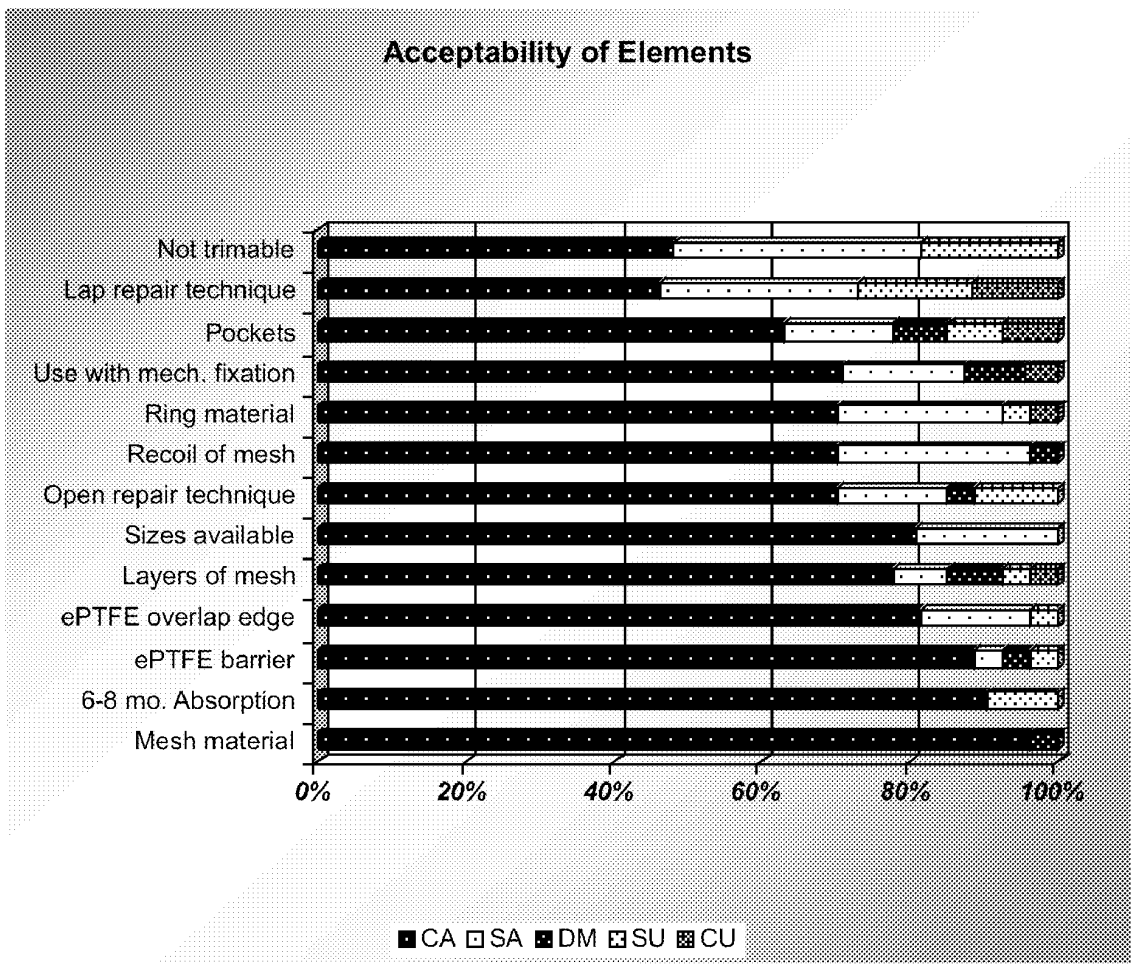
24) What brands?

- *Bard.*
- *Bard Kugel.*
- *Bard first, then probably PROCEED.*
- *Bard Composix.*
- *Composix - price will be important.*
- *Composix L/P.*
- *Composix. Not sure if replaces Composix.*
- *Composix and other.* (2)
- *Flat Marlex.*
- *DUALMESH. (2)*
- *Attempt to replace Parietex.*
- *PROCEED.*
- *GORE.*

25) Let's review different elements of the prosthetic and I'd like to know if you think each is completely acceptable (CA), somewhat acceptable (SA), doesn't matter (DM), somewhat unacceptable (SU), or completely unacceptable (CU).

All but two of the 13 elements were "completely acceptable" to 60% or more of the surgeons interviewed, and all were either "completely acceptable" or "somewhat acceptable" to three-quarters of them. The four best received elements: "mesh material", "6 - 8 month absorption time", "ePTFE barrier" and "ePTFE overlap edge" were "completely acceptable" to 80% or more of the surgeons.

The two elements that were rated lowest: "not trimable" and "laparoscopic repair technique" were "completely acceptable" to less than half the surgeons.



The following are the comments by element, in the order in which they were discussed:

a. Recoil of mesh

Some of the respondents would like more spring to the coil.

Completely acceptable:

- *For open. SA for lap.*

Somewhat acceptable:

- *Spring open even more.*
- *More spring.*
- *More recoil for lap.*
- *Would like better recoil.*
- *Open fuller, if possible.*
- *Stiffer.*
- *Stays bent a little bit.*

b. Open repair technique

A few respondents didn't find Ventrio appropriate for open repairs.

Somewhat acceptable:

- *Too loose, not stiff enough.*
- *Need to work with it.*
- *For small repairs. SU for large repairs: ePTFE too thick.*
- *Doesn't matter.*

Somewhat unacceptable:

- *Put this on top of the closure, don't need two sides.*
- *Doesn't function properly.*
- *Don't need it.*

c. Ability to use with mechanical fixation

A few surgeons found Ventrio too thick.

Completely acceptable:

- *What happens if tack contacts the ring? Also need thicker tack.*

Somewhat acceptable:

- *Penetration? Blend for lap approach.*
- *A bit cumbersome.*
- *Too thick, maybe.*
- *Only for lap.*

Completely unacceptable:

- *Too thick.*

d. Laparoscopic repair technique

Those who questioned Ventrio for laparoscopic repairs generally thought it would be too bulky to fit down the trocar site.

Somewhat acceptable:

- *May be difficult to get it in.*
- *Want less rigid, less bulk.*
- *Doesn't open completely as fast as desired.*
- *Don't need pockets.*
- *Don't want to pin up transfascial further.*
- *No problem with my current.*

Somewhat unacceptable:

- *Too bulky.*
- *Bulk an issue.*
- *Too bulky and stiff.*
- *More difficult than PROCEED.*

Completely unacceptable:

- *Won't use it.*
- *For lap approach.*

e. Pockets

A few found the pockets of little or no benefit.

Completely acceptable:

- *Great.*

Somewhat acceptable:

- *Can only fit two fingers, larger?*
- *Not much difference.*
- *Not a fan of others.*
- *No real benefit in laparoscopic.*

Doesn't matter:

- *Tough to tack, but I don't tack.*

Somewhat unacceptable:

- *Can push trough the pocket with the tacker.*
- *No need.*

Completely unacceptable:

- *For lap. SA for open.*
- *Sew it in, pockets not a help.*

f. Layers of mesh

There was no significant negative feedback regarding the layers of mesh.

Somewhat acceptable:

- *Adds strength, again, any difference?*
- *Not sure it's needed.*

Doesn't matter:

- *Need thick tack?*

Completely unacceptable:

- *The major issue!*

g. Mesh material

No comments.

h. ePTFE barrier

There were only a few minor comments regarding the ePTFE barrier, but none worth noting.

Completely acceptable:

- *Thicker.*

Somewhat acceptable:

- *Would like drain capability.*

Somewhat unacceptable:

- *Too thick, want bio-absorbables.*

i. ePTFE overlap edge

Virtually all of the comments regarding the ePTFE edge overlap were positive.

Completely acceptable:

- *Good idea.* (2)
- *Very nice.* (2)
- *Large one too skimpy.*
- *Good thing - unique to this?*
- *Important.*

Somewhat acceptable:

- *Smaller, almost to the mesh.*
- *50% wider is better.*
- *Doesn't make much difference.*
- *Pretty good.*

Somewhat unacceptable:

- *Thicker.*

j. Ring material (asked "PDO" material starting with #12)

There were some reservations regarding the ring material, mostly that it added too much bulk and/or was too stiff.

Completely acceptable:

- *Significant? Durability, what's the point.*
- *Not familiar with PDO.*

Somewhat acceptable:

- *Adds bulk.*
- *Less bulk.*
- *Make a little thicker? Spread better?*
- *Doesn't make much difference.*
- *Not sturdy enough to keep stretched.*

Somewhat unacceptable:

- *Adds too much bulk where you tack. May be unnecessary.*

Completely unacceptable:

- *Not stiff enough.*

k. Other information needs re. the ring?

- *None.* (19)
- *What is it made of? Will it crack?*
- *Don't see what it adds.*
- *See invivo absorption based on actual or projected information.*
- *Won't fracture?*
- *Outcomes, infection rates, complications.*
- *Can you fold in often without breaking it?*
- *Have fluid handling information.*
- *No marking on it, put "N" north arrow and measurement scale.*

l. Not trimable

Some participants took issue with the inability to trim Ventrio's material. Mostly they questioned whether their institution would make all of the desired sizes available.

Completely acceptable:

- *Incredible array of sizes.*
- *If I can get all the sizes.*

Somewhat acceptable:

- *Nice/like to be able to trim.* (7)
- *If you have the correct sizes available.*

Somewhat unacceptable:

- *Won't get all the sizes you want.*

m. Sizes available

A few surgeons wanted different sizes than those identified.

Completely acceptable:

- *OR will complain about the stocking.*
- *Cost a concern, will they inventory all sizes?*
- *Incredible array of sizes.*

Somewhat acceptable:

- *Need one more size.*
- *Large sizes of true round.*
- *Need smaller sizes.*
- *Always a limit.*
- *Sizes don't always work. More trach-like sizes.*

n. 6 -8 month absorption recoil mechanism (this question added at respondent #7 in NY)

Virtually all of the participants accepted the six - eight month absorption time.

Somewhat unacceptable:

- *Don't need it to stay in for 18 months.*
- *12 -14 weeks is better.*

o. Any other feature, not mentioned? Feature:

- *Trimable.*
- *Anti-adhesion barrier. More resilient than Parietex.*
- *Pliability, how soft after six months out? Shrinkage - none is good.*
- *Small pocket on ePTFE side to help hold in place.*
- *Add label, "this side up".*
- *What happens when wet? Hard to tell which side is where. Test with antimicrobial in mesh.*

Advertisement/Message

(AD PRESENTED FOR REVIEW)

26) If you saw this ad in a journal, how effectively will it get your attention?

Virtually all of the surgeons had positive reactions to the proposed ad, with about half providing very strong reactions.

Very Positive:

- *Good ad, positive, good features.*
- *Ventral incisional gets our attention, good colors, bold headlines very effective. Picture is super effective.*
- *Quite good. Features are good to point out.*
- *Very effective.*
- *Yes, it would get my attention. Picture looks familiar, afraid of getting sued.*
- *Very effective, visually pleasing.*
- *Very effective.*

Positive:

- *I'd read it.*
- *Seems okay.*
- *Pretty good.*
- *Effective, except unclear if it's for lap procedures. Prefer bigger pictures, which is better.*
- *A bit bland but effective. More succinct the better. Easy, catchy words. Graphics here a bit poor. Too much white area*
- *Effective.*
- *Equivalent to ads currently.*

Negatives:

- *Not at all effective. Similar to others. Why is this different?*

Other:

- No response/not enough time. (5)

26b) Which layout do you prefer?

Both the two-page and one-page ad layouts were popular.

Number	Response
10	Two page
8	One page
3	Doesn't matter
6	No response/not enough time
27	**Total Responses**

26c) Which content format do you prefer?

There was also no preference between headlines without much text and headlines with explanatory text.

Number	Response
9	Headlines without much text
9	Headlines with explanatory text
1	Doesn't matter
8	No response/not enough time
27	**Total Responses**

27) When you review a publication, what elements of an ad typically draw most of your attention?

Pictures of the product were by far the most popular element of an ad.

Number	Response
5	*Pictures of the product.*
3	*Pictures, photos, diagrams.*
3	*Pictures of product in use, in surgery.*
3	*Pictures, graphics, drawings.*
1	*Photos and color, plus words: "effective, proven and safe".*
1	*Absorb feature, plus memory.*
1	*Device, then drawings.*
1	*Prosthetic. Show tacker clearly in the middle of the picture.*
1	*Layout.*
8	No response/not enough time.
27	**Total Responses**

28) Where is the best place to catch your attention with new product announcements?

Direct calls by the reps and introductions at meetings, particularly the ACS, are, by far, the most preferred approaches to catching the surgeon's attention with new product announcements.

Number	Response
11	One-on-one, sales reps, in my office, in the OR suite
9	Meetings, conventions
5	Direct mail
4	Journals
1	Web
30	**Total Responses**
23	**Total Respondents**

Comments:

- *Meetings - on the floor, videos showing the mesh.*
- *Journal ads and meetings. No e-mail. Plus a detail person with knowledge of the product is very important.*
- *Journals, throw-aways, look at these first.*
- *Conventions and/ or reps - want to handle it and see it.*
- *ACS, but introduce it at SAGES which includes a more adventuresome group of attendees.*
- *Face-to-face; rep in the OR lounge.*
- *If you are under 40 years, it's the web. ACS is obvious, but difficult to focus, least effective. Come to my office, one-on-one interviews works best! Direct mail good but without too much clutter.*
- *Mail first, followed by a rep visit.*
- *Sales rep.*
- *Journals, rep.*
- *At meetings, concentrate on just the product.*
- *ACS, with sales follow-up.*
- *One-to-one approach.*
- *Call on me, major meetings, and also ads in major journals.*
- *1. Surgeons' mailing. 2. Lounge/ surgical environment in the hospital.*
- *Person-to-person, five minutes, review the benefits.*
- *1. In OR, face-to-face. 2. Setting with other doctors, e.g. dinner/talk.*
- *Office visit.*
- *Meetings, have more time, follow-up visits.*
- *Rep showing it to me, seeing the product. Then come to the OR for first or second placements.*
- No response/not enough time. (5)

CONCEPT "Z": SEPRA-VENTRIO

29) What is your initial reaction to this concept?

Initial reactions to Sepra-Ventrio were somewhat more negative than positive. The most frequently mentioned reaction was surgeons taking issue with the length of time to absorb, with some wanting it to last up to six months or longer. There was also concern that the mesh would adhere to the bowel. A few surgeons also were concerned about seromas and/or swelling.

On the positive side, some participants immediately perceived absorption as a plus feature.

Number	Response
8	Absorption time issues
6	Adhesions, bowel to mesh
4	Absorbable is positive
3	Seromas, swelling
3	Similar, like Sepramesh
2	Large pore is negative
2	Large pore is positive
1	Absorbable is negative
1	No seromas
1	Not familiar with it
31	**Total responses**
27	**Total respondents**

Positive:

- *The right direction to go. No good idea of the period of absorption and what is appropriate: If a coating on the poly side could be penetrated for drainage, it would be ideal.*
- *Good idea, not much improvement over Concept X* (Ventrio).
- *Good idea, lightweight, large pore is more effective, less contraction of the mesh.*
- *It would be nice.*
- *Much better, blunts a lot of the criticism of "X"* (Ventrio). *See through better, absorbs, no seromas.*
- *Good concept.*

Negative:

- *Absorbs too quickly, 14 days.*
- *Confused! Six to eight months vs. 14 - 30 days of adhesion protection. Want 12 weeks of adhesion prevention.*
- *Long term there is a concern when putting in mesh. What if bowel gets absorbed into the mesh? Paradox - absorption vs. protection. Don't understand how one goes with the other!*
- *I've seen the absorbable materials, didn't like them.*
- *Not familiar with the materials, e.g. safety, effectiveness a question. More guarded about it.*
- *Suspicious of swelling. Concern with seroma formation. See adhesions with both ePTFE and ABS.*
- *More concerned about erosion and adherence to the interior.*
- *Not too impressed. Lots need to go right to work well. How long to swell? Variability to absorb in 14 - 30 days. Absorption causes adhesions.*
- *What's the purpose? To absorb in one month?*
- *Not too excited. Concern about 14 days, is it long enough for ingrowth? How much inflammatory reactions, seromas?*

Positive and Negative:

- *What stops the bowel from sticking to it? Don't know about larger pores, any benefits? Absorbable side has advantages - window of absorption might be too long.*
- *More attractive for lap. Would want to see through it.*
- *Visual is fine. Large pore is a negative.*
- *Why would it go away? Can't bowel stick to it if it goes away? I'd worry about that. Swells beyond the edges? Interesting, don't understand how it would happen.*
- *Useful. Concern with 30 days. Can still get attachment.*
- *Like the lightweight, large pore because of contraction. Want longer absorption of the barrier, e.g. 60 days.*
- *Side 1: Large pore mesh doesn't add much; prefer small pore, which is better for suture strength. Side 2: Absorbable is interesting. Haven't yet used any.*
- *I like it. Absorbable barrier. Don't know about lightweight.*

Other:

- *Sounds like Sepramesh.*
- *Not really new - someone already has the absorbable under the surface.*
- *Good idea but Sepramesh is a handling issue. Need to handle it, which is difficult.*

30) What, if anything, do you particularly like about it?

The lightweight/low profile mesh was the most liked feature for Sepra-Ventrio, followed by its absorbability.

Lightweight/low profile mesh:

- *Lighter, flexible graft for lap approach. More tissue to be there as opposed to plastic.*
- *More modern approach. Lightweight for movement.*
- *Low profile, less foreign material is better for the body.*
- *Lighter weight is better.*
- *Maybe lightweight, but that's all.*
- *Lighter mesh might be more collapsible.*

Absorbable, biologics:

- *Absorption is fine.*
- *Absorbable.*
- *Absorbability.*
- *Concept of biologics, but not the individual features, e.g. 14 - 30 days.*

Less foreign, natural:

- *Less foreign, natural. Less risk of infection.*
- *Less foreign body in the patient.*

All other comments:

- *Large pore.*
- *Slippery stuff goes away!*
- *Faster in-growth seems likely.*
- *Some of the PROCEED benefits.*
- *Nothing really. No perceived advantage to the lightweight, large pore mesh.*
- *Promotes ingrowth and relies on scar tissue for working. Has less inflammatory response.*
- *ABS barrier.*
- *Nothing.* (4)
- No response. (4)

31) What, if anything, do you particularly dislike about it?

The most frequently mentioned dislike was an overall lack of appreciation for the concept, which was expressed by one-third of the surgeons. Also, several participants were concerned with the its absorption time, or the unknowns about the product.

- *Nothing (9)*
- *Absorbs too quickly. Not sure large pore is necessary. Need to see it to compare.*
- *14 - 30 days – things still change within that range. Ideal product has bottom coating. No interference but sticks at the top and is open at the bottom, e.g. drains, sticks to fascial, promote mesothelial ingrowth.*
- *14 days, doesn't give maximum wound strength.*
- *Make sure the absorbable barrier works.*
- *Questions regarding absorbability, same as Sepramesh.*
- *Adhesion property, it should be longer.*
- *Flimsiness of the mesh underneath. Need to feel it. Also, open mesh, what do the tacks attach to?*
- *Lightweight.*
- *Why is it better?*
- *What is the purpose, to absorb in one month?*
- *Counting that the body will coat the mesh. Need good long-term studies.*
- *The unknown about the materials.*
- *EPTFE and ABS.*
- *More concerned about erosion and adhesion to the interior. Less durable than PTFE, also less bulky, which is a negative for incisional repairs, e.g. reconstructive needs.*
- *Absorption causes adhesion.*
- *Large pore doesn't add much.*
- *Not in favor of it.*
- No response.

32) Assuming the economics would be acceptable, how likely would you be to use this product if it became available? Please use the 5-point scale on the handout.

A slight majority, 16 of 27 or 59%, are likely to recommend Sepra-Ventrio if it became available. This level of endorsement, while quite positive, was less enthusiastic than the rating for Ventrio where 15 surgeons were "extremely likely" to recommend. The reasons for these positive "likelihood to recommend" ratings were somewhat varied and included a few who still had questions about the length of absorption time.

Recommend Rating	Number
Extremely likely	5
Somewhat likely	11
Neither likely nor unlikely	2
Somewhat unlikely	3
Extremely unlikely	6
Total	**27**

33) Why?

Extremely likely:

- *Soft mesh and absorbable part.*
- *Skeptical regarding absorption time but with correct data, I would abandon use of non-absorbable mesh.*
- *Better features than PROCEED.*
- *Low profile, ring design, easy to deploy.*
- *Absorbability.*

Somewhat likely:

- *Lower profile - less foreign tissue. Don't have to remove if infection develops.*
- *Would not use for open procedures. Wait for others to try it, to see if it works. See if it would go down trocar easier and handle more easily in the abdomen.*
- *Lower risk of infection. So, for in those cases where infection is a risk.*
- *Nothing makes it clearly better than "X"* (Ventrio).
- *Like it better because of absorption, large pores for better tissue ingrowth. However, I would probably not change from my current brand.*
- *Worry about absorbable barrier not working.*
- *Want to try it.*
- *If an advantage exists, I want to find out why.*
- *Don't know about lightweight and I want to know absorbable barrier.*
- *No reason, but would try it.*
- (No response.)

Neither:

- *Lightweight.*
- *Due to the barrier, not adequate at 14 days.*

Somewhat unlikely:

- *Nothing new.*
- *Don't understand the benefits.*
- *14 - 30 day absorption is too short. Studies would alleviate my concern.*

Extremely unlikely:

- *Don't like 14 day absorption - need to see data to show lack of adhesion information.*
- *No benefit.*
- *Don't like absorbable aspects. Seems you get temporary benefit, but not permanent protection.*
- *Don't know enough about the materials.*
- No response. (2)

34) On what type or types of surgery would you first use it . . . ?

The positive responses indicated a relatively even split for using Sepra-Ventrio in either lap or open procedures, but the most often mentioned response was the "none" by 10 of the 27 participants. This was in contrast to only four who indicated "none" for Ventrio, suggesting a more significant resistance to Sepra-Ventrio among a segment of the overall population.

Response	**Number**
None	10
Lap	8
Open	6
Both	3
Total	**27**

35) And on what types of repairs?

Did not ask, this question was eliminated with interview #9.

36) In approximately what percent of your hernia repairs would you hope to use this new product?

Surgeons would expect to use Sepra-Ventrio in approximately two-thirds of their cases, on average, and almost half would use it in 90% or more of them.

Response	Number
0	1
5 - 100	1
15	1
30	1
50	2
75	2
90	1
95	1
100	4
Total	**14**
Mean	**66**

Comments:

- *5 - 100% if lap.*
- *10 - 20%, could improve.*
- *50% of lap.*
- *50%+. If coating was better, majority of the business. Depends on coating.*
- *75% , 25% Sepra.*
- *100% of lap.*
- *100%. If it proves out; virtually all of them.*
- *100% if it works.*
- *100% of open.*

37) How many patients would this amount to in a typical month or year? ____ ❑ Mo❑ Year

Most respondents were not asked about usage per month (due to time pressure) but among those who were, the responses most often were from one to 12 per month.

- Did not ask: (20)
- *Less than one per month for lap.*
- *Less than one per month to start.*
- *Five per month.*
- *Seven - eight per month.*
- *Ten - 12 per month.*
- *Thirty per month.*

38) If it performed as you anticipated, would your use be . . .?

The majority of surgeons who would use Sepra-Ventrio indicated they would use it to replace other brands.

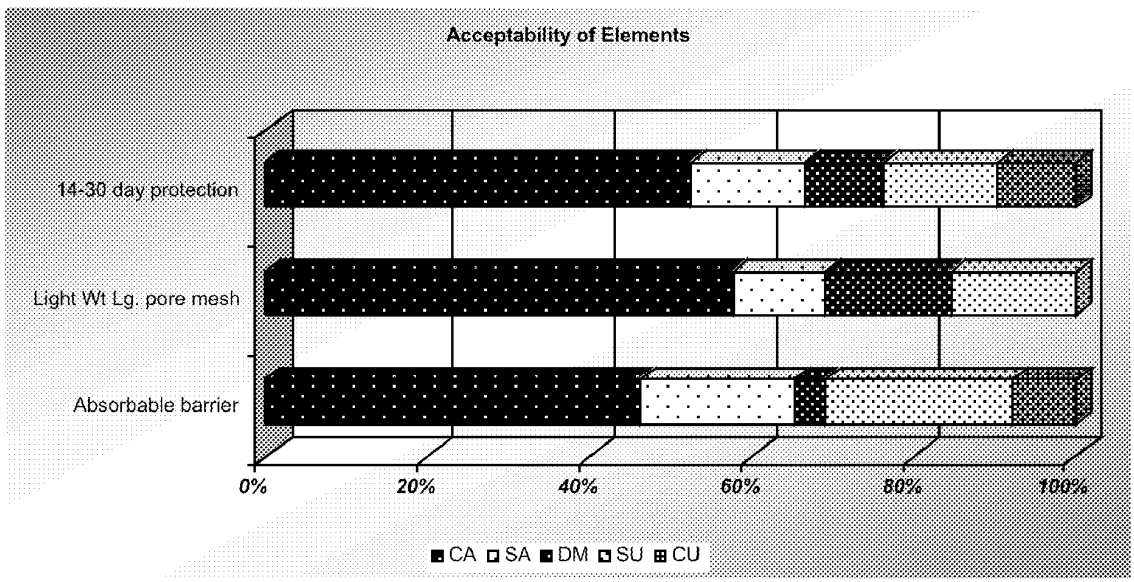
Number	Response
4	Addition to other brands
8	Replace other brands

39) (IF REPLACE) What brands?

- *Replace*. (No brand mention) (2)
- *Composix, Parietex.*
- *Composix.*
- *Sepramesh.*
- *Bard.*
- *DUALMESH.*
- *PROCEED.*

40) Let's review different elements of the prosthetic and I'd like to know if you think each is completely acceptable, somewhat acceptable, doesn't matter, somewhat unacceptable, or completely unacceptable.

Reactions to the three elements: "14 - 30 day absorption", "light weight large pore mesh", and "absorbable barrier" were generally positive, with 60%+ rating them either "completely acceptable" or "somewhat acceptable".



The following are the comments by element, in the order in which they were discussed.

a. Absorbable barrier

The absorbable barrier was, to a degree, controversial. Several surgeons were concerned that the 14 - 30 days was not long enough. A few questioned the validity of the absorbability claim. Others identified it with the Sepra film issues.

Completely acceptable:

- *Ideal concept - as presented a SA. Half-life better than VICRYL Mesh.*

Somewhat acceptable:

- *Sepra film issues.*
- *Absorbability and protective issues.*
- *Will it absorb?*
- *Show studies, randomized with benefits.*
- *Want more information. How does it swell? Adequate protective edge, easy to tack? Can it go though the trocar*

Doesn't matter:

- *Not long enough at 14 days.*

Somewhat unacceptable:

- *Some protection is better than none.*
- *Worry about bowel attachment after barrier forms.*
- *Adhesion and viability.*
- *Time of 14 days.*
- *I want a barrier to protect the bowel.*

Completely unacceptable:

- *Absorption issue.*

Don't know:

- *Don't know until I have more data.*

b. Lightweight large pore mesh

A few surgeons did not perceive any advantage to the large pore mesh.

Completely acceptable:

- *Some penetration better than most.*
- *No difference frankly.*

Somewhat acceptable:

- *Lack of experience, cost is reasonable.*
- *Want it heavier.*
- *No advantage.*

Doesn't matter:

- *No big issue with mesh.*

Somewhat unlikely:

- *Like the large pore.*
- *Tighter is better.*

c. Added 14 -30 day barrier protection after questionnaire #6:

Everyone who took issue with the 14 - 30 day barrier wanted it to last longer, generally in the 45 to 60 day time frame.

Somewhat acceptable:

- *45 - 60 days.*
- *45 - 60 days.*
- *Longer time.*

Doesn't matter:

- *Longer.*

Somewhat unlikely:

- *Longer, e.g. two - three months.*
- *Data to suggest it's not needed.*
- *Not enough time, e.g. months.*

Completely unacceptable:

- *Not as good as smaller pore.*
- *Need more information.*

d. Any other feature not mentioned, Feature:

- *Ring.*
- *Six - eight months* (2)

41) Which product would you prefer most?

A slight majority of surgeons indicated a preference for Ventrio, although the 11 of 27 who preferred Sepra-Ventrio clearly suggest a market for both products.

Number	Response
15	Ventrio
11	Sepra-Ventrio
1	Current brand
27	**Total**

Ventrio comments:

- *But Z* (Sepra-Ventrio) *better with complications.*
- *But Z* (Sepra-Ventrio*) if others prove it works.*
- *But both not really liked.*

Sepra-Ventrio comments:

- *Would not replace current product.*
- *Very intrigued by the issue of it not hanging around as long, potentially having less of an inflammatory response which means less seroma formation.*
- *Z* (Sepra-Ventrio), *if I had to choose only one. But Concept X* (Ventrio) *for Side One, Concept Z for Side Two. Large pore mesh absorbable.*

Current brand comments:

- *Biologic.*

The following presents a comparison of the change in ratings between the "likelihood to recommend for trial" for Ventrio (X) versus Sepra-Ventrio (Z).

Former Composix Kugel users are identified with an * after their first rating. There was no pattern among these six respondents in terms of "likelihood to recommend".

Fourteen surgeons gave higher ratings to Ventrio than Sepra-Ventrio, with six of these showing substantial differences.

Preferred Ventrio:

Ventrio	Sepra-Ventrio	Difference	Comments
EL	EU	-4	I d*on't like absorbable aspects. Seems like you get temporary, not permanent protection.*
EL	EU	-4	I don't know enough about the materials. *I want a barrier to protect the bowel.*
EL	EU	-4	*Barrier protection is not enough time; want heavier mesh.*
EL	EU	-4	*Tighter mesh is better; adhesion and viability.*
EL	SU	-3	*14 - 30 day absorption is too short.*
EL	SU	-3	*Worry about bowel attachment after barrier is gone; not as good as smaller pore.*
EL	SL	-1	*Worry about absorbable barrier not working.*
EL	SL	-1	(I want) *45 - 60 day barrier protection.*
EL*	SL	-1	I *don't know about lightweight and I want to know about the absorbable barrier.*
EL	SL	-1	*Flimsiness of mesh underneath; open mesh - what do the tacks attach to?*
EL*	SL	-1	*Make sure absorbable barrier works.*
SL*	N	-1	*Lightweight.*
SU	EU	-1	*Absorbs too quickly.*
SU	EU	-1	*Adhesion property should be longer.*

Only four gave higher ratings to Sepra-Ventrio than Ventrio.

Preferred Sepra-Ventrio:

Ventrio	Sepra-Ventrio	Difference	Comments
EU*	SL	+4	*See through better, absorbs, no seromas, lightweight is better.*
N	EL	+2	*Soft mesh and absorption.*
N	SL	+1	(However, Prefers X.) *Questions regarding absorbability, same as Sepramesh.*
N	SL	+1	*Absorption, large pore for better tissue ingrowth.*

A total of nine had no preference in their ratings, but the subsequent preference question (Q. 41) indicated that most of the respondents preferred Sepra-Ventrio (Z).

No Preference Between Both:

Ventrio	Sepra-Ventrio	Difference	Comments
EL	EL	0	Prefer Z. *Better features than PROCEED.*
EL	EL	0	Prefer Z. *Low profile, ring design, and easy to deploy.*
EL*	EL	0	*Concept Z, but Concept X* (Ventrio*) for side one, Concept Z for side two. Large pore mesh absorbable.*
EL*	EL	0	Prefer Z. *Skeptical regarding absorption time but with correct data, would abandon use of non-absorbable mesh.*
SL	SL	0	Prefer X. *Nothing makes Z clearly better than X* (Ventrio*).*
SL	SL	0	Prefer Z. *Large pore.*
SL	SL	0	Prefer Z. *Very intrigued by the issue of it not hanging around as long; potentially having less of an inflammatory response, which means less seroma formation.*
N	N	0	Prefer Z. (For X/Ventrio) *I'd sew it for open. Don't need double layer for that, or the ring.*
SU	SU	0	Prefer current brand: Biologics. (Both Concepts:) *Not really new.*

*Former Composix Kugel users.

Participants were asked a series of four questions to ascertain their impressions of price sensitivity for the new product they preferred versus their current product. Each of the questions identified costs above or below their current product at which they'd identify the preferred product as a "bargain", "distrust its quality/performance", "expensive but still want to use it", or "too costly for consideration". While the questions were only answered by some of the participants and, therefore, do not present a quantitative sample of merit, the responses suggest a premium price of 20% would be a bargain and surgeons are likely to endorse a premium of up to 50%. Once the price about doubles, resistance is too strong to overcome.

Mean % ±	Response
19	Bargain
102	Distrust its quality/performance
48	Expensive but still want to use
134	Too costly for consideration

42) At what percent above or below the cost of your current prosthetic would this product you prefer be a bargain?

Above:

- *+10%.* (3)
- *Same, or 10 - 20% more.*
- *20% more.*
- *+25%.* (2)
- *50% more.*

Below:

Same, less than 10 - 15%.

- *10 - 20% less.*
- *Less than 20%.* (2)
- *30% less.*

Above or Below:

- *+/- 10%.*
- *+/- 20%.*

Other:

- *10 - 20%*
- *33%. $300 for current.*
- *50%.* (2)
- *Same.* (2)
- *Don't know.* (2)
- Did not ask. (4)

43) At what percent above or below the cost of your current prosthetic would this product be so expensive/ inexpensive starting with interview #12, that you might distrust its quality and performance?

Above:

- *150% more.*

Below:

- *Less than 25%*
- *50% below. (2)*
- *60% less.*
- *60 - 70% less.*
- *Less than 100%.*

Other:

- *Never.*
- *Parity.*
- *33%.*
- *DM.* (2)
- *Not a factor.*
- *None.*(5)
- *200%.*
- *$1500 vs. $300, our current cost. (500%)*
- *Don't know.* (3)
- Did not ask. (4)

44) At what percent above or below the cost of your current prosthetic would this product become expensive but you'd still want to use it?

Above:

- *+20%.* (2)
- *+30%.* (2)
- *175% more.*

Other:

- *0%.*
- *None, not a premium product.*
- *5% at most.*
- *10%.* (4)
- *15%.*
- *25%.*
- *50%.* (3)
- *$500* (vs. $300 or 70%).
- *150%.*
- *200%.*
- *Don't know.* (2)
- Did not ask. (5)

45) At what percent above or below the cost of your current prosthetic would this product be too costly for consideration?

Above:

- *10% more.*
- *40% more.*
- *+50%.*
- *200% more.*

Other:

- *None, not a premium product.*
- *5% at most.*
- *20%.* (2)
- *25%.*
- *50% above, hopeless.*
- *50%.*
- *75%.* (2)
- *100%.* (2)
- *150%.*
- *200%.*
- *300%.* (2)
- *$3000* (vs $300 or 900%)
- *Don't know.* (2)
- Did not ask. (5)

46) What other challenges, if any, will the manufacturer need to overcome to have this product stocked and available at your hospital or surgery center?

- *Cost is the main issue for hospitals.*
- *Sizes and packaging, boxes and pouches, very confusing. Can't see what size product it is.*
- *Good reps at the hospital.*
- *Show clinical effectiveness and good economics, then no problem.*
- *Cost, use, getting sizes in.*
- *Fit into current contract - negotiate to be part of a package.*
- *Evidence-based medicine, e.g. minimal, then 100 patients.*
- *Have surgical request. If they could put in on consignment, that would help.*
- *None.*
- *Cost is key.*
- *Documenting ease of removal, inflammatory response.*
- *Going through committees even prior to sampling it in use, clinical data from others.*
- *Infection potential - we dip our meshes in Tamrex, a disinfectant. Side 2 antibiotically impregnated would be a very nice feature that would last for 14 days. Also, micropores on side 2 to prevent seromas.*
- *More science, technical aspects regarding successes and failures.*
- *Get past OR Director. Could save OR time, maybe a couple of hours.*
- Did not ask. (8)

47) Would you want us to pass your name on to the manufacturer so they could alert you when the products were available?

Virtually everyone who was asked would like to be contacted when the products become available.

- *Yes.* (9)
- *Yes, particularly for trial.* (2)
- *Yes. I want to know who is making it.*
- *Yes, clinical studies.*
- Did not ask. (14)

EXHIBIT 7

From: Darois, Roger
Sent: Wednesday, August 15, 2007 7:46 AM
To: LaFever, Dan; Kelly, Brian; DeFord, John; Hutchinson, Tom; Drago, Robin
Subject: Design control meeting Wednesday 8:00 AM
Attachments: Design Control Procedures.doc

The Quintiles, FDA audit and changes to various Davol procedures has impacted several projects significantly. Attached is a summary of the key changes and their impacts. In summary, the following projects have been affected:

1. TyRx…these projects have moved out approximately one year from the approved model. One quarter of this delay is not impacted by the procedure changes and can be attributed to a late start of the projects (one month delay in deal approval and recruiting of new engineers). Three quarters of the delay can be attributed to the amount of work (finalization of specifications and test method validation) now required prior to the starting of long lead time/critical path testing required for a 510(k) submission.
2. Absorbable ring…this project, originally estimated at a 1Q08 launch, has moved out approximately one quarter due to new supplier qualification requirements for critical components (e.g. the absorbable ring component).
3. EC3 and absorbable tack…since these projects have dozens of new components each, some critical to function or dFMEA severity, the new supplier qualification requirements that need to be done on the front end of projects is moving the commercialization dates out >3 months (exact timing still being worked out by AQE). This will not impact EC3 as it related to the TRIM trial since this is an IDE study not requiring a 510(k) and these components can be 100% inspected prior to supplier qualification at the low volumes required for the clinical study.

The launch date estimates for all of these projects were made prior to these changes and the teams are wrestling with now to mitigate and balance this impact. We are still challenging each other and the teams, but this is where the impact sits today.

Roger

Design Control Procedures
Impact from 2007 Revisions/Interpretations

Roger Darois
August 15, 2007

Quintiles audit CAPA design control corrective actions:

One of the significant corrective actions related to the Quintiles audit were the creation of a new user needs procedure (design input summary, or DIS) and an overhaul to the product performance specification (PPS) implemented in March/April, 2007. There are 3 items of note that impact both the TyRx and absorbable ring projects.

- All specifications must be derived from defined and documented user needs. None of our older products have user needs defined (e.g. deployment, stiffness, recoil, etc.). Since the TyRx and ring projects are upgrading older products, these all have to be created and documented from scratch.
- Once the user needs are identified, the specifications must be determined. In order to accomplish this, experiments must be conducted to demonstrate that the specifications meet user needs (e.g. the user need for the CK ring is that it "must be strong enough to withstand laparoscopic insertion without breaking" while the specification was determined to be 8 lbs to meet this…it took 2 months of testing to derive this 8 lb break strength requirement after the recall).
- It has been recently determined that no testing can be initiated until the user needs are defined and the relative specifications have been derived and documented.

Test method validations:

A new corporate procedure released a few months back require that all test methods be validated prior to any regulatory submissions or product commercialization. For all the mesh products released over the past 10 years no methods have been validation (burst, needle pull-out, trocar deployment, recoil, fixation strength, etc). Thus, even though the TyRx and ring projects involve data that is well known and characterized from many past projects, all these methods need significant work by AQE to validate. So, not only do we to develop new user needs & specs for all these older products which did not exist, the test methods used to verify that we meet the specs also need to be validated prior to the starting of any testing used in submissions. Examples of the impact to the TyRx projects include:

- The test methods used at TyRx for their polymer lot release testing are not validated. At this time, we can not spray mesh used for any submission testing prior to completion of this task. In case TyRx is unable to complete this, a parallel path is being explored with Pharmalytica for polymer characterization.
- All old tests used to for mesh as mentioned above need validated test methods prior to initiation of stability testing.

Stability testing:

All previous Davol products have utilized accelerated stability testing to determine shelf life. Since 1 year of shelf life can be determined in a few weeks at 150 F and the regulations require that shelf life testing be performed with products that are "equivalent" to marketed devices, the lots utilized for this historically have been produced concurrent with final design verification testing. In these cases since this was done just prior to product release then, by definition, the specifications were all locked, process validation was completed and there were no undocumented issues to rationalize. With the TyRx and ring projects, it has been determined that real time shelf life testing is required. The challenges include:

- PPS requirements for all functional requirements need to completed…something not normally this far along in the concept phase (typically upon the transition from feasibility to development). Both of these projects are in concept phase specifically because the specs are still being defined.
- As stated above, unless the specifications have been completed and the test methods used to verify that we meet the specs are validated, this long term testing can not start.

As reference, the previous plan for TyRx was to test the PC coated mesh at several coating levels (a bracketing approach) and evaluate the molecular weight to determine that the polymer was not effected by time (something that TyRx concluded by this type of testing approach with their gamma radiated PIVIT mesh so we were confident of this approach). This testing was planned to grandfather the Plug and 3DMax mesh products so we could conclude that the coating was unaffected by time. It has now been determined that we need stiffness specs for flats, Plugs and 3DMax products completed and the test methods validated for these prior to initiation of stability testing. We also need the burst, tensile and needle pull-out specifications since these now need to be tested with polymer coated devices for stability. This has had such a large impact that the PC flats was cancelled (little revenue impact and we can not longer use it to grandfather the other products). We are now focused on Plugs and stability testing is not planned to start until 2Q08…> one year impact.

Supplier qualification:

An additional outcome of the Quintiles audit included changes to supplier qualification. For all critical components, suppliers have to demonstrate the same level of process control as if the component were made in-house (e.g. process validation and CpK >1.33). In addition, all inspection methods must be the same at the supplier as at Davol and gage R&R studies must be completed prior to the inspection of components used for testing and marketed devices. Although this seems logical, the extra work was not factored into the timelines of the absorbable ring, EC3 or absorbable tacker projects. The impact on all three programs is approximately one calendar quarter since all this work is an early gate to many activities, for example:

- The first few batches of rings received from Samyang in April were going to be used for stability and animal trials. A decision was made to run OQ and PQ runs at Samyang prior to this testing to ensure that their process was stable prior to the start of this long term testing.

EXHIBIT 8

Click Here To Go To The Davol Self Study Training Form For RD-4.54

DAVOL INC.	RESEARCH AND DEVELOPMENT	ITEM # RD-4.54	Rev A
	Title: DESIGN INPUT SUMMARY	DCS# 20358 1/19/07	Page 1 of 3

1.0 Purpose

The purpose of this procedure is to describe the process and requirements for identifying user needs, the methods used to solicit user needs and the creation of the associated Design Input Summary (DIS) report. The DIS report documents the sources and methods used to identify user needs required to create the Product Performance Specifications (PPS), which serves as the basis for translating these needs into product specifications. The DIS report must be generated for a new/upgraded product or product family prior to creating a PPS since it is the source document leading to the development of the PPS. The DIS document should be updated and revised as the design inputs are further refined during a development project and used to subsequently provide for the justification of PPS changes related to user needs.

2.0 General Requirements

2.1 The Design Input Summary report is required for all new products, line extensions and product changes that impact design. The DIS is intended to be a tool used to organize, track and document the methods used to gather design inputs for a specific product or product family

2.2 User needs, intended uses, and information on desired characteristics should be identified and documented as part of the process leading up to the release of the DIS.

2.3 Changes to this procedure shall be approved by Research and Development (R&D), Quality Engineering (QE) and Regulatory Affairs.

3.0 Responsibility and Authority

3.1 Responsibilities

3.1.1 The marketing team member holds the primary responsibility for organizing the source, identification, gathering and documentation of user needs and market information.

3.1.2 Marketing, research and development (R&D), quality engineering (QE) and regulatory affairs (RA) team members share responsibility for researching and documenting applicable clinical, industry and regulatory standards and guidance documents.

3.1.3 R&D team members are responsible for translating user needs and desired characteristics and applicable standards into PPS design inputs.

3.1.4 R&D and RA have primary responsibility for determining how standards are applicable to a product design and providing rationales for those standards or sections of standards that are not applicable to the design.

3.1.5 The manufacturing engineering team member is primarily responsible for soliciting and documenting specific technology limitations of suppliers (working with purchasing) or manufacturing that should be considered in the DIS as input sources to the PPS.

4.0 Intended Use and User Needs

The intended uses and user needs form the foundation for subsequent design inputs.

4.1 Intended Use

The intended use, or multiple uses, is the functional purpose of the device and defined as the objective intent of the persons legally responsible for the labeling of the device and is typically described and articulated in labeling claims, advertising matter and/or oral or written statements.

4.2 User Needs

In general, user needs describe how the clinician or patient will use the device within the scope of the intended use. This may be related to procedures, device interfaces, medical specialties or use environments.

5.0 Specific Sources of Design Input

Sources of design input to identify and document user needs should include consideration of the following sources:

5.1 Industry and Regulatory Information

Applicability of industry and regulatory standards and guidance documents is based on the intended use of the product. These industry and regulatory documents may contain broad information on characteristics to consider, or they may provide specific requirement levels (e.g. biocompatibility, UL, IEEE, etc).

Circumstances may exist where all or part of a standard applicable to the design or use of a device may not be applied. The rationale for not including this standard or portion of the standard in the design input must be documented.

5.2 Information on Existing Davol and Competitive devices

Typical sources may include, but are not limited to the following:

- Complaint and recall data on previous or similar Davol or competitive products to provide historical information highlighting existing problems and possible design solutions.
- Similar Davol or competitive product evaluation and information contained in trip or test reports used to benchmark or highlight features to improve upon.
- FDA's Medial Device Reporting (MDR) system for reports on problems across a device type, including Davol and competitive products.
- Published literature regarding treatment alternatives, desired features, device performance and device shortcomings.
- Clinical discussions during site visits, conventions, meetings and the like can be used to solicit information on existing products as well as proposed design alternatives.

5.3 User Needs

User needs do not merely reflect stated user needs. Often marketing needs exceed the stated user needs in order to provide a competitive advantage. Also, some needs do not get stated by users requiring an appropriate research tool to be employed to identify these (e.g. observational research, brainstorming, procedure mapping, etc.). In addition to approaching the user needs from a features and benefits perspective, risk assessment and failure modes should also be employed to determine user needs.

5.4 Intellectual Property

Markets that contain significant patent activity may force certain design requirements to either avoid infringement or provide a market advantage via patent protection. As with marketing needs, these requirements are often beyond the scope of the stated user needs.

5.5 Manufacturing Requirements

Design solutions to user and other needs must be achievable in a manufacturing setting. New technologies, supplier capability, facility resources, environmental considerations and safety matters must be reviewed as part of defining user needs to ensure that a design can be delivered to meet these needs.

5.6 Bard Medical Services Group

The Bard Medical Services and Support Group (MS&S) can provide excellent input into customer questions and customer concerns regarding our products.

Note: When formulating the plan and approach to soliciting user needs, refer to the PPS procedure to capture all the potential PPS requirements are addressed during this research phase. This will ensure that the PPS requirements categories are not missed during this project phase.

6.0 DIS Report Content and Format

6.1 The DIS report should contain the sections listed in the DIS form # FM3790021. Additional sections or discussion may be added as needed.

7.0 Document Creation and Maintenance

A DIS is required for every new product or product family and released in the concept phase of a project with a DCS using the nomenclature of DIS-XXXXXXX. The DIS report must be revised as new/changing customer needs change or new/changed regulatory standards/guidelines are identified. DIS changes must be revised with a DCS. The DIS must be reviewed at the concept and feasibility design reviews and, if revised after the feasibility design review, again at the output design review.

8.0 Reference

FM3790021	Design Input Summary Report Form
FM3790015	Product Performance Specification (PPS) Form
RD-4.3	Product Performance Specification Procedure

EXHIBIT 9

DAVOL INC.	PRODUCT PERFORMANCE SPECIFICATION	ITEM # PPS3800472	Rev. 6
	Product Description: **Ventralight™ ST Mesh**	DCS #34059	Page 1 of 11

Procedure RD-4.3
Applicable revision at time of PPS release _U__

Product Item Codes Applicable to this PPS:

Item Number	Description (size, configuration, quantity per box, color, etc)	Design verification completed as referenced on report numbers documented on PPS (check √ as appropriate)
5954450	4.5" Circle with bioresorbable coating, 1 each per folding carton	√
5954460	4" x 6" Elliptical with bioresorbable coating, 1 each per folding carton	√
5954600	6.0" Circle with bioresorbable coating, 1 each per folding carton	√
5954680	6" x 8" Elliptical with bioresorbable coating, 1 each per folding carton	√
5954610	6" x 10" Oval with bioresorbable coating, 1 each per folding carton	√
5954790	7" x 9" Elliptical with bioresorbable coating, 1 each per folding carton	√
5954800	8.0" Circle with bioresorbable coating, 1 each per folding carton	√
5954810	8" x 10" Elliptical with bioresorbable coating, 1 each per folding carton	√
5954113	10" x 13" Elliptical with bioresorbable coating, 1 each per folding carton	√
5954124	12" x 14" Rectangle with bioresorbable coating, 1 each per folding carton	√

The following documents must be revised concurrent with any PPS change or an impact assessment provided with the rationale for not requiring a revision:

DIS # _DIS3800354_____ DIS # _____ DIS # _____

dFMEA # __DFM3800477_____ dFMEA # _____ dFMEA # _____

pFMEA # ____PFM3801079____ pFMEA # _____ pFMEA # _____

Related documents to be revised if applicable:

PPS # __PPS3799309_____ DHF # __DHF3800247_____ PRS# ____PRS3800473_____

EIS # _See Item Number_____ OTHER _____

User Need Category	User Needs DIS No	DIS User Needs/Requirement	Spec No	Specification	Documented Evidence to Support the Specification	dFMEA Severity Score	CdK Value, Attribute or Not Applicable	Test Sample size	Design Verification Test Report (Number)	Essential output (Y/N)	Design Transfer to Manufacturing or Quality Document Number(s)
1.0 Functional and/or Performance	1.1	Lighter weight, larger pore mesh as compared to Sepramesh IP.	1.1	The Ventralight ST mesh shall have a polypropylene / PGA mesh pore size greater than 0.00054" and a weight per unit area less than 0.151 g/sq. in. which are the characteristics of Sepramesh.IP.	RPT3801479 (Sepramesh characteristics)	N/A	N/A	Minimum n = 1	RPT3801462	Y	SA3792604 8.5"X12.5" CAST MESH SA3792606 12.5" X 14.5" CAST MESH
	1.2	Barrier intended for minimized tissue attachment must be fully resorbed / degraded by the body.	1.2	Absorbable barrier material must be the same composition as Sepramesh IP.	Sepramesh IP PPS3799309 Pg. 3 (RPT3796415, pg. 2&3) RPT3800073 Ventrio ST Specification Justification Pg. 3	9	N/A	Minimum n = 1	RPT3801548 (Note: Design Verification report, p.53 & 54 demonstates the materials used to manufacture Ventralight ST are the same as Sepramesh IP.) RPT3803924	Y	5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124
	1.3	The device must be of sufficient strength for the repair of soft tissue defects.	1.3	Burst Strength of ≥29 lbs using a 3/8" diameter ball.	RPT3797769	8	1.7	30	RPT3801548 RPT3803924	Y	5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124
			1.4	Suture Retention Strength of ≥1.33 lbs at 4mm in both Machine Direction and Cross Direction.	RPT3797898	9	1.62	50	RPT3801548 RPT3803924	Y	
							1.62	50	RPT3801548 RPT3803924	Y	
			1.5	Tear Strength of ≥1.27 lbs in both Machine Direction and Cross Direction.	RPT3797897	8	1.7	30	RPT3801548 RPT3803924	Y	
							1.7	30	RPT3801548 RPT3803924	Y	

User Need Category	User Needs DIS No	DIS User Needs/Requirement	Spec No	Specification	Documented Evidence to Support the Specification	dFMEA Severity Score	CdK Value, Attribute or Not Applicable	Test Sample size	Design Verification Test Report (Number)	Essential output (Y/N)	Design Transfer to Manufacturing or Quality Document Number(s)
1.0 Functional and/or Performance	1.3	The device must be of sufficient strength for the repair of soft tissue defects.	1.6	During the Ball Burst test, the crosshead must have a maximum extension ≤ 0.212 inches from point of contact (applied load of 0.06 pounds force) to applied load of 14 pounds force for polypropylene portion of the mesh.	RPT3801405 Ventralight ST Spec Derivation for Dimensional Stability	5	1.7	30	RPT3801548 RPT3803924	N	5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124
	1.4	Components must remain intact during surgical preparation and application to the site (i.e. no delaminating).	1.7	PGA Pullout Strength ≥8.99 lbs	Sepramesh IP PPS3799309 Pg. 5	9	1.7	30	RPT3801548 RPT3803924	Y	5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124
			1.8	Dry Bond Strength ≥7.87 lbs; no film or PGA bond failures.			Attribute	149	RPT3801548 RPT3803924	Y	
			1.9	Hydrogel displacement during normal usage single largest disruption of hydrogel will be either ≤ 1.7 in sq. or total hydrogel disruption must be ≤ 3.1 % of total device area.	RPT 3801132		1.7	30	RPT3801548 RPT3803924	Y	
	1.5	Must be able to differentiate sidedness.	1.10	Barrier side must be visually and tactilely different from the mesh side.	Sepramesh IP PPS3799309 Pg. 3	9	N/A	Minimum n = 1	RPT3801815	Y	5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124

DAVOL INC.	PRODUCT PERFORMANCE SPECIFICATION	ITEM # PPS3800472	Rev. 6
	Product Description: **Ventralight™ ST Mesh**	DCS #34059	Page 4 of 11

User Need Category	User Needs DIS No	DIS User Needs/Requirement	Spec No	Specification		Documented Evidence to Support the Specification	dFMEA Severity Score	CdK Value, Attribute or Not Applicable	Test Sample size	Design Verification Test Report (Number)	Essential output (Y/N)	Design Transfer to Manufacturing or Quality Document Number(s)
				Dimension Nominal / Shape	Tolerance							
1.0 Functional and/or Performance	1.6	Ventralight ST must be provided in an adequate array of sizes to repair a wide range of soft tissue defects.	1.11	4.5" dia. Circle (11.4 cm)	+/-.25" (.64 cm)	RPT3799419 Sepramesh IP Market Justification Product Spec RPT RPT3800868 Summary of Various Size Changes to Ventralight ST RPT3801250 Summary of Data Supporting User Needs RPT3803889 Justification for Additional Ventralight ST Mesh Sizes	N/A	N/A	Minimum n = 1	RPT3801551	Y	SA3792607
				4" x 6" Ellipse (10.2 x 15.2 cm)	+/-.25" (.64 cm)		N/A	N/A	Minimum n = 1	RPT3801551	Y	SA3792608
				6" dia. Circle (15.2 cm)	+/-.25" (.64 cm)		N/A	N/A	Minimum n = 1	RPT3803924	Y	SA3792705
				6" x 8" Ellipse (15.2 x 20.3 cm)	+/-.25" (.64 cm)		N/A	N/A	Minimum n = 1	RPT3801551	Y	SA3792609
				6" x 10" Oval (15.2 x 25.4 cm)	+/-.25" (.64 cm)		N/A	N/A	Minimum n = 1	RPT3801551	Y	SA3792610
				7" x 9" Ellipse (17.8 x 22.9 cm)	+/-.25" (.64 cm)		N/A	N/A	Minimum n = 1	RPT3801551	Y	SA3792611
				8" dia. Circle (20.3 cm)	+/-.25" (.64 cm)		N/A	N/A	Minimum n = 1	RPT3803924	Y	SA3792706
				8" x 10" Ellipse (20.3 x 25.4 cm)	+/-.25" (.64 cm)		N/A	N/A	Minimum n = 1	RPT3801551	Y	SA3792612
				10" x 13" Ellipse (25.4 x 33.0 cm)	+/-.25" (.64 cm)		N/A	N/A	Minimum n = 1	RPT3801551	Y	SA3792613
				12" x 14" Rectangle (30.5 x 35.6 cm)	+/-.25" (.64 cm)		N/A	N/A	Minimum n = 1	RPT3801551	Y	SA3792614

User Need Category	User Needs DIS No	DIS User Needs/Requirement	Spec No	Specification	Documented Evidence to Support the Specification	dFMEA Severity Score	CdK Value, Attribute or Not Applicable	Test Sample size	Design Verification Test Report (Number)	Essential output (Y/N)	Design Transfer to Manufacturing or Quality Document Number(s)
1.0 Functional and/or Performance	1.6	Ventralight ST must be provided in an adequate array of sizes to repair a wide range of soft tissue defects.	See Spec 1.11	Circle, Ellipse, Oval, and Rectangle.	RPT3800929 Sizes Based on existing Composix L/P RPT3803889 Justification for Additional Ventralight ST Mesh Sizes	N/A	N/A	Minimum n = 1	RPT3801551 RPT3803924	Y	SA3792607 SA3792608 SA3792705 SA3792609 SA3792610 SA3792611 SA3792706 SA3792612 SA3792613 SA3792614
	1.7	Ventralight ST must be tailorable.	1.12	Product must be compatible with surgical scissors.	Sepramesh IP PPS3799309 Pg 7 Davol IFU as documented in RM5959360 – RM5959124	N/A	N/A	Minimum n = 1	RPT3801551 RPT3803924	Y	5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124
	1.8	Ventralight ST must be able to be adequately fixated with commonly used methods of fixation (i.e. sutures and tacks).	See Spec 1.4	Suture Retention Strength of ≥1.33 lbs at 4mm in both Machine Direction and Cross Direction.	RPT3797898	9	1.62 1.62	50 50	RPT3801548 RPT3803924	Y	5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124

DAVOL INC.	PRODUCT PERFORMANCE SPECIFICATION	ITEM # PPS3800472	Rev. 6
	Product Description: **Ventralight™ ST Mesh**	DCS #34059	Page 6 of 11

User Need Category	User Needs DIS No	DIS User Needs/Requirement	Spec No	Specification	Documented Evidence to Support the Specification	dFMEA Severity Score	CdK Value, Attribute or Not Applicable	Test Sample size	Design Verification Test Report (Number)	Essential output (Y/N)	Design Transfer to Manufacturing or Quality Document Number(s)
1.0 Functional and/or Performance	1.8	Ventralight ST must be able to be adequately fixated with commonly used methods of fixation (i.e. sutures and tacks).	1.13	Laproscopic Fixation: Device burst strength for Sorbafix, Permafix and Permasorb of > 4.25 PSI.	RPT3796676 Burst Test Rationale RPT3796573 4.25 PSI Rationale PPS3798080, PPS3794632 & PPS3798301 Specs 3.2 & 3.3 ensure mesh does not affect tack performance	9	1.7	30	RPT3801548 RPT3803924	Y	5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124
			1.14	Sorbafix / Permafix device must be able to deliver tacks with less than 0.059 in. average gap between bottom of the tack head and the top of the prosthetic.	RPT3797690 Maximum Allowable Tack Height Spec Rationale	9	1.70	30	RPT3801816	Y	
	1.9	Product must minimize tissue attachment.	See Spec 1.2	Absorbable barrier material must be the same composition as Sepramesh IP.	Sepramesh IP PPS3799309 Pg. 3 (RPT3796415, pg. 2&3) RPT3800073 Ventrio ST Specification Justification Pg. 3	9	N/A	Minimum n = 1	RPT3801548 (Note: Design Verification report, pgs 53 & 54 demonstate the materials used to manufacture Ventralight ST are the same as Sepramesh IP.) RPT3803924	Y	5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124

User Need Category	User Needs DIS No	DIS User Needs/Requirement	Spec No	Specification	Documented Evidence to Support the Specification	dFMEA Severity Score	CdK Value, Attribute or Not Applicable	Test Sample size	Design Verification Test Report (Number)	Essential output (Y/N)	Design Transfer to Manufacturing or Quality Document Number(s)
2.0 Device Interfaces	2.1	Ventralight ST must be able to be used through an appropriately-sized commercially available port.	See Spec 1.1	The Ventralight ST mesh shall have a pore size greater than 0.00054" and a weight per unit area less than 0.151 g/sq. in. which are the characteristics of Sepramesh.IP.	RPT3801479 (Sepramesh characteristics)	N/A	N/A	Minimum n = 1	RPT3801462	Y	SA3792604 8.5"X12.5" CAST MESH SA3792606 12.5" X 14.5" CAST MESH
	2.2	The size of port through which Ventralight ST can be inserted effectively should be minimized.	2.1	The 12x14" rectangle must deploy through a 15 mm trocar without damage to product or barrier. All other sizes must deploy through same or smaller trocars commonly used with low profile mesh products without damage to product or barrier.	Sepramesh IP PPS3799309 Pg 5 Davol IFU as documented in RM5959360 – RM5959124	9	1.70	30	RPT3801548 RPT3803924	Y	5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124
	2.3	Ventralight ST must interface with commonly used surgical equipment/ materials in both open and laparoscopic repairs.	2.2	Ventralight ST must meet all functional specifications following the use of saline, graspers, tines, and trocars.	Sepramesh IP PPS3799309 Pg 6 Davol IFU as documented in RM5959360 – RM5959124 RPT3800073 Ventrio ST Spec Justification Pg 4 & 5	N/A – refer to FDV protocol RPT3801317 for CpKs (if applicable) and sample sizes for applicable functional specs.			RPT3801548 – Applicable test on pgs 10 & 11 RPT3803924	Y	5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124

DAVOL INC.	PRODUCT PERFORMANCE SPECIFICATION	ITEM # PPS3800472	Rev. 6
	Product Description: **Ventralight™ ST Mesh**	DCS #34059	Page 8 of 11

User Need Category	User Needs DIS No	DIS User Needs/Requirement	Spec No	Specification	Documented Evidence to Support the Specification	dFMEA Severity Score	CdK Value, Attribute or Not Applicable	Test Sample size	Design Verification Test Report (Number)	Essential output (Y/N)	Design Transfer to Manufacturing or Quality Document Number(s)
2.0 Device Interfaces	2.4	Product must be compatible with non-absorbable and absorbable sutures and tacks.	See Spec 1.4	Suture Retention Strength of ≥1.33 lbs at 4mm in both Machine Direction and Cross Direction	RPT3797898	9	1.62	50	RPT3801548 RPT3803924	Y	5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124
							1.62	50	RPT3801548 RPT3803924		
			See Spec 1.13	Laproscopic Fixation: Device burst strength for Sorbafix, Permafix and Permasorb of ≥4.25 PSI	RPT3796676 Burst Test Rationale RPT3796573 4.25 PSI Rationale PPS3798080, PPS3794632 & PPS3798301 Specs 3.2 & 3.3 ensure mesh does not affect tack performance	9	1.7	30	RPT3801548 RPT3803924	Y	
3.0 Packaging and Labeling	3.1	The packaging shall ensure the integrity and sterility of the product during the anticipated normal hazards encountered in the distribution, handling and storage environments.	3.1	Upon package qualification testing: • Device shall remain intact • Packaging shall provide sterile barrier	RSSS-STD-06 RD-4.11	9	Attibute	60	RPT3801470 PA10-031 Sterile Adoption – TBD	Y	5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124
			3.2	Product packaging shall not leak when subject to bubble emission test.	RSSS-STD-06	9	Attribute	60	RPT3801470	Y	

DAVOL INC.	PRODUCT PERFORMANCE SPECIFICATION	ITEM # PPS3800472	Rev. 6
	Product Description: **Ventralight™ ST Mesh**	DCS #34059	Page 9 of 11

User Need Category	User Needs DIS No	DIS User Needs/Requirement	Spec No	Specification	Documented Evidence to Support the Specification	dFMEA Severity Score	CdK Value, Attribute or Not Applicable	Test Sample size	Design Verification Test Report (Number)	Essential output (Y/N)	Design Transfer to Manufacturing or Quality Document Number(s)
3.0 Packaging and Labeling	3.2	The product and packaging must have adequate shelf-life.	3.3	Product must meet all functional requirements at desired shelf life (minimum 6 months)	RD 4.25	Refer to RD 4.31 and FDV protocol RPT3801317 for each specific functional requirement, Cpk, and sample size			RPT3801340 RPT3803924	Y	5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124
			3.4	Labeling must remain legible and intact at desired shelf life (minimum 6 months)	RD 4.25	6	Attribute	10	RPT3801340 RPT3803924	Y	
	3.3	IFU and label should be easy to comprehend and be legible.	3.5	Must meet the requirements of Corporate procedure and artwork NPAA.	RD4.38 R-004 R-004-GUI	9	N/A	1	RPT3801782 RPT3803924	Y	PK3797000 (IFU Specification)
	3.4	Product labeling must comply with applicable standards	3.6	Product labeling must specify the device description (including patient contacting component materials) intended use of the device, contraindications warnings and precautions, directions for use, handling/storage/disposal instructions, lot and expiration date	21 CFR 820, EN 1041, EN 980, ISO 639-1	9	N/A	1	RPT3801782 RPT3803924	Y	PK3797000 (IFU Specification)
			3.7	Label must state that device is for single use only	21 CFR 820, EN 1041, EN 980, ISO 639-1	9	N/A	1	RPT3801782 RPT3803924	Y	

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3.0 Packaging and Labeling	3.5	The product primary sterile packaging must provide ease of opening for end-user to extract product via aseptic transfer technique and be compatible with standard hospital practices including disposal.	3.8	Packaging materials for Ventralight ST must be the same as Sepramesh IP or similar products utilizing absorbable components.	General medical device requirement	9	N/A	Minimum n = 1	RPT3801470 describes the packaging components of Ventralight ST as compared to Sepramesh IP.	Y	5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124
4.0 Regulatory Standards and/or Guidelines	4.1	Product must comply with applicable standards.	4.1	Sterilant Residual Levels (Post 1X EtO): EO: 24 hrs 20 mg; 30 days 60 mg; Life-time 2.5 g; Add 0.1 mg/day ECH: 12 mg; 60 mg; 50 g; 2.0 mg/day	ISO11135 EN550 EN556 Sepramesh IP PPS3799309 Pg 11 ISO10993-7 Biological Evaluation of Medical Devices Part 7: EO Residuals	9	N/A	Per CQA-STD-13	PA10-031 Sterile Adoption – TBD	Y	Device Master Record 5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124
			4.2	Sterility Assurance Level (SAL) $\leq 10^{-6}$	ISO 11135-1&2 ISO 11138-1&2 ISO 11737-1&2	9	N/A	Per CQA-STD-13	PA10-031 Sterile Adoption – TBD	Y	
			4.3	Device must meet all functional requirements after sterilization.	N/A – Internal requirement	Refer to RD 4.31 and FDV protocol RPT3801317 for each specific functional requirement, Cpk, and sample size			RPT3801548 RPT3803924	Y	

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4.0 Regulatory Standards and/or Guidelines	4.1	Product must comply with applicable standards.	4.4	Device must pass the following: **Test # / Description** 1 Cytoxicity 2 Sensitization 3 Intracutaneous Toxicity 4 Systemic Toxicity 5 Sub-acute Toxicity 6 Genotoxicity 7 Implantation 8 Sub-Chronic Toxicity 9 Carcinogenicity (if pos. Genotoxicity results) 10 Pyrogenicity	ISO 10993-1 RD 4.10	9	N/A	Refer to RD 4.10	RPT3801341 RPT3803924	Y	Device Master Record 5954450 5954460 5954600 5954610 5954680 5954790 5954800 5954810 5954113 5954124
5.0 Other											

SEE DCS DOCUMENT FOR APPROVALS.