1 UNITED STATES PATENT AND TRADEMARK OFFICE

2 _____

3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4 _____

5 IMPERATIVE CARE, INC.,
Petitioner,
6 v.

7 INARI MEDICAL, INC.,
Patent Owner.

8

9 _____

10 Case No. IPR2025-01021
U.S. Patent No. 11,969,333

11

Case No. IPR2025-01025
12 U.S. Patent No. 11,974,910

13 Case No. IPR2025-01264
U.S. Patent No. 12,016,580

14

15 TESTIMONY OF

16 TROY LANE THORNTON

17 WEDNESDAY, JULY 1, 2026

18 San Francisco, California

19

9:16 a.m. PDT

20

to

21

1:11 p.m. PDT

22

23 Stenographically Reported by:
Burgundy B. Ryan, RPR,
24 CSR No. 11373
Job No. 638725
25 Pages 1-84

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2
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15 ALSO PRESENT:
16 Philip Astor, Videographer
Planet Depos
17
18
19
20
21
22
23
24
25

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1 DEPOSITION SUPPORT INDEX
2
3 QUESTIONS INSTRUCTED NOT TO ANSWER:
4 PAGE LINE
5 (None)
6
7
8 REQUEST FOR PRODUCTION OF DOCUMENTS
9 PAGE LINE
10 (None)
11
12
13 STIPULATIONS
14 PAGE LINE
15 (None)
16
17
18 QUESTIONS MARKED
19 PAGE LINE
20 (None)
21
22
23 REPORTER'S NOTE:
24 QUOTATION MARKS ARE USED FOR CLARITY AND DO NOT
25 NECESSARILY REFLECT A DIRECT QUOTE.

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1 I N D E X
2 PAGE
3 EXAMINATION BY MR. HAMILTON..... 6
4
5 --o0o--
6
7 E X H I B I T S
8 EXHIBIT DESCRIPTION PAGE
9
10 (The following previously-marked exhibits were
11
12 discussed: 1020, 1038, 1039, 1067 (IPR2025-01264),
13
14 1067 (IPR2025-01025), 1067 (IPR2025-01021), 1068,
15
16 1075, 1078, and 1079.)
17
18 --o0o--
19
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21
22
23
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25

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1 BE IT REMEMBERED that, pursuant to Notice
2 of Taking Deposition, and on Wednesday, July 1,
3 2026, commencing at 9:16 a.m. PDT thereof, at Knobbe
4 Martens Olson & Bear, 333 Bush Street, San
5 Francisco, California, before me, Burgundy B. Ryan,
6 a Certified Shorthand Reporter in and for the State
7 of California, personally appeared
8 TROY LANE THORNTON,
9 a witness called on behalf of PATENT OWNER, and who, 08:48:26
10 having been first duly sworn by me to testify to the 08:48:26
11 truth, was examined and testified as follows: 08:48:26
12 THE VIDEOGRAPHER: Here begins Media No. 1 09:15:51
13 in the videotaped deposition of Troy Lane Thornton 09:15:53
14 in the matter of Imperative Care, Inc. versus Inari 09:15:56
15 Medical, Inc., in the United States Patent and 09:16:00
16 Trademark Office before the Patent Trial and Appeal 09:16:02
17 Board, case numbers IPR2025-01021, 01025, and 01264. 09:16:05
18 Today's date is July 1st, 2026. 09:16:18
19 The time on the video monitor is 9:16 09:16:22
20 Pacific. 09:16:25
21 The videographer today is Philip Astor 09:16:26
22 representing Planet Depos headquartered at 451 09:16:28
23 Hungerford Drive, Suite 400, Rockville, Maryland 09:16:32
24 20850. 09:16:36
25 This video deposition is taking place at 09:16:38

1 333 Bush Street, 21st Floor, San Francisco, 09:16:40
2 California. 09:16:44
3 Would Counsel please voice-identify 09:16:45
4 themselves and state whom they represent? 09:16:48
5 MR. HAMILTON: This is Joseph Hamilton from 09:16:49
6 Perkins Coie for Patent Owner. 09:16:52
7 MR. STOWELL: Joshua Stowell of Knobbe 09:16:53
8 Martens on behalf of the Petitioner Imperative Care 09:16:56
9 and the witness. 09:16:59
10 THE VIDEOGRAPHER: The court reporter today 09:17:00
11 is Burgundy Brooke Ryan representing Planet Depos. 09:17:01
12 The witness will now be sworn. 09:17:05
13 COURT REPORTER: Good morning everyone. My 09:17:21
14 name is Burgundy Brooke Ryan, California CSR License 09:17:21
15 No. 11373. 09:17:21
16 (Whereupon, the witness was sworn.) 09:17:22
17 COURT REPORTER: Thank you very much. 09:17:22
18 Counsel, you may proceed. 09:17:22
19 TROY LANE THORNTON, 09:17:22
20 having been first duly sworn to tell the whole 09:17:22
21 truth, testified as follows: 09:17:22
22 EXAMINATION 09:17:22
23 By MR. HAMILTON: 09:17:24
24 Q. Good morning, Mr. Thornton. Welcome back. 09:17:24
25 Do you understand you're under oath? 09:17:27

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1 A. Yes. 09:17:29
2 Q. Are you on any medications that might 09:17:32
3 prevent your full complete and truthful testimony 09:17:35
4 today? 09:17:38
5 A. No. 09:17:39
6 Q. Is there any reason you can't give your 09:17:40
7 full, complete, and truthful testimony here today? 09:17:42
8 A. No. 09:17:45
9 Q. So we've had several depositions in these 09:17:49
10 matters. 09:17:52
11 Do you understand what patents are at 09:17:53
12 issue -- at issue in the depositions here today? In 09:17:54
13 the matters here today? Excuse me. 09:17:57
14 A. I believe so. 09:18:00
15 Q. Would that be the '333 patent, the '580 09:18:02
16 patent, and the '910 patent? 09:18:06
17 A. Yes. 09:18:08
18 Q. Do you understand which patents I'm 09:18:09
19 referring to when I refer to the '333, '580, and 09:18:10
20 '910 patents? 09:18:15
21 A. Yes. 09:18:16
22 Q. I'm going to hand you three documents. 09:18:52
23 Do you recognize these three documents? 09:19:30
24 A. Yes. 09:19:34
25 Q. What are these documents? 09:19:36

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1 A. This is my supplemental declaration in 09:19:40
2 support of Petitioner's reply regarding patent 09:19:45
3 number 11,969,333, the second one is the same but 09:19:50
4 relates to a different patent, 12,016,580, and the 09:19:59
5 third one relates to patent number 11,974,910. 09:20:07
6 Q. If you look, each of the documents is 09:20:15
7 marked with an exhibit number at the bottom. 09:20:17
8 Do you see that? 09:20:20
9 A. Yes. 09:20:21
10 Q. And the exhibit number for each one is 09:20:23
11 1067. 09:20:25
12 Do you see that? 09:20:27
13 A. Yes. 09:20:27
14 Q. So to avoid confusion, I'm going to refer 09:20:28
15 to these three declarations as the '580 09:20:31
16 declaration, the '333 declaration -- excuse me. Let 09:20:34
17 me -- let me clarify that. 09:20:39
18 So for each of these matters, this -- this 09:20:40
19 is the second declaration you've submitted in the 09:20:42
20 matter; is that correct? 09:20:45
21 A. Yes. 09:20:45
22 Q. So when I refer to these three 09:20:46
23 declarations, I'm going to refer to them as the '580 09:20:48
24 supplemental declaration, the '333 supplemental 09:20:51
25 declaration, and the '910 supplemental declaration. 09:20:55

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1 And if I do that, will you understand which 09:20:58
2 declaration I'm referring to? 09:21:00
3 A. Yes. 09:21:03
4 Q. If at any point there is any confusion and 09:21:03
5 you don't know what document I'm referring to, 09:21:06
6 please feel free to -- to ask. If you don't, we're 09:21:09
7 going to assume you understand which document we're 09:21:11
8 looking at. Is that fair? 09:21:14
9 A. Yes. 09:21:16
10 Q. If you could take a look at the '910 09:21:26
11 declaration. 09:21:30
12 A. Supplemental? 09:21:33
13 Q. Supplemental. Thank you. 09:21:36
14 And if you could turn to page 2, paragraph 09:21:44
15 7. Do you see in paragraph 7 in the first sentence 09:21:48
16 they quote for your opinion for -- the 09:22:22
17 qualifications for a person of ordinary skill in the 09:22:27
18 art. 09:22:30
19 A. Yes. 09:22:31
20 Q. And in the art you're referring to the -- 09:22:33
21 the technical field of the '333, '910, or '580 09:22:35
22 patent; is that right? 09:22:40
23 A. Yes. 09:22:43
24 Q. Are you aware of any differences between 09:22:44
25 the technical field of the '333, '910, and '580 09:22:46

1 patents? 09:22:49
2 A. I believe two of them use the exact same 09:22:57
3 specification. The third one, the '580, I believe 09:23:01
4 has a slightly different specification. But I would 09:23:05
5 have to look at the details for each one to see 09:23:10
6 if -- if that '580 is significantly different in its 09:23:14
7 scope. 09:23:17
8 Q. So as you sit here today, are you aware of 09:23:24
9 any difference in the technical field between the 09:23:26
10 three patents the '333, '910, and '580 patents? 09:23:28
11 A. I would have to look at the '580 patent 09:23:37
12 to confirm my thoughts on that. 09:23:40
13 Q. Have you proposed the same definition for a 09:23:44
14 person of ordinary skill in the art in the three -- 09:23:47
15 in your three declarations? 09:23:50
16 MR. STOWELL: Objection. Vague. 09:23:55
17 THE WITNESS: It's the same -- it's the 09:24:21
18 same definition in all three of these supplemental 09:24:33
19 declarations. 09:24:36
20 By MR. HAMILTON: 09:24:57
21 Q. If you look at the -- your proposed 09:24:57
22 definition in paragraph 7 of the '910 supplemental 09:25:00
23 declaration, do you see where it says, "two to four 09:25:07
24 years of catheter design experience?" 09:25:14
25 A. Yes. 09:25:17

1 Q. Would an individual meeting the other 09:25:23
2 requirements of your definition and having two to 09:25:28
3 four years of any catheter design experience qualify 09:25:31
4 as a person of ordinary skill in the art, in your 09:25:35
5 opinion? 09:25:37
6 MR. STOWELL: Objection. Vague. 09:25:38
7 THE WITNESS: Well there are a wide range 09:25:56
8 of catheters that engineers may have worked on, but 09:25:57
9 I think having two to four years of general catheter 09:26:03
10 experience would be sufficient to consider that 09:26:07
11 person as a person of ordinary skill in the art. 09:26:15
12 By MR. HAMILTON: 09:26:17
13 Q. And when you say "catheter design 09:26:17
14 experience," you mean designing any catheter; is 09:26:20
15 that correct? 09:26:25
16 A. I didn't specify any types of catheters, I 09:26:26
17 just said catheter design experience -- 09:26:28
18 Q. So is there any limit on the -- excuse me, 09:26:30
19 please. 09:26:32
20 A. Experience is what I meant to say. 09:26:33
21 Q. Is there -- is there any further 09:26:35
22 qualification for catheter design experience that 09:26:37
23 you would like to add? 09:26:39
24 A. No. 09:26:41
25 Q. So it's your opinion that a person of 09:26:43

1 ordinary skill in the art that meets the other 09:26:45
2 requirements in your definition and has two to four 09:26:48
3 years of catheter design experience, regardless of 09:26:50
4 the type of catheter, what that catheter is used 09:26:54
5 for, qualifies as a person of ordinary skill in the 09:26:57
6 art; is that correct? 09:26:59
7 A. What I said was two to four years of 09:27:04
8 catheter design experience and I didn't limit it to 09:27:07
9 any certain types of catheters, correct. 09:27:10
10 Q. So when you say "two to four years of 09:27:13
11 catheter design experience," you mean any catheter 09:27:16
12 design experience regardless of the type of catheter 09:27:19
13 or what the catheter is used for; is that correct? 09:27:21
14 A. I didn't provide any more limitations 09:27:24
15 beyond catheter design experience of two to four 09:27:27
16 years. 09:27:30
17 Q. And are there any other limitations besides 09:27:31
18 catheter design experience of two to four years in 09:27:35
19 your definition of a person of ordinary skill in the 09:27:39
20 art? 09:27:41
21 A. It's what I said -- 09:27:42
22 Q. So that's a no? 09:27:44
23 A. -- in paragraph 7. 09:27:45
24 Q. So is that a no? 09:27:46
25 A. I didn't put any additional limits or 09:27:52

1 considerations or requirements as to the type of 09:27:55
2 catheter design experience in my definition. 09:28:00
3 Q. In the context of the field of the patents 09:28:15
4 at issue here, what does thrombectomy mean? 09:28:17
5 MR. STOWELL: Objection. Lack of 09:28:23
6 foundation. 09:28:24
7 THE WITNESS: Well, in these patents 09:28:34
8 thrombectomy refers to removal of thrombus from a 09:28:36
9 patient. 09:28:41
10 By MR. HAMILTON: 09:29:23
11 Q. And what's a thrombus? 09:29:23
12 A. A blood clot. 09:29:33
13 Q. In the context of the technical field of 09:29:57
14 the patents at issue here, the '333, '910, and '580 09:30:01
15 patents, what does the term mechanical thrombectomy 09:30:05
16 mean? 09:30:14
17 MR. STOWELL: Objection. Lack of 09:30:21
18 foundation. 09:30:22
19 THE WITNESS: I think it just means 09:30:34
20 removing a clot from the patient. 09:30:36
21 By MR. HAMILTON: 09:30:39
22 Q. What's the difference between mechanical 09:30:39
23 thrombectomy and thrombectomy? 09:30:43
24 A. I think they both describe removing 09:30:45
25 thrombus from a patient. 09:30:49

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1 Q. Is there any difference between those two 09:30:50
2 terms? 09:30:52
3 A. I'm not sure. I would have to look at the 09:30:54
4 patents in question to see if they differentiate 09:30:55
5 those two terms. 09:30:58
6 Q. So as an -- do you believe you are an 09:31:04
7 expert in the technical field of the '333, '910, and 09:31:07
8 '580 patents? 09:31:12
9 A. Yes, I believe I meet the definition of -- 09:31:15
10 that is proposed in paragraph 7 that we're 09:31:19
11 discussing. 09:31:28
12 Q. And as an expert in the field of the '333, 09:31:29
13 '910, and '580 patents, are you telling me you 09:31:33
14 can't -- you don't know the difference between a 09:31:36
15 mechanical thrombectomy and a thrombectomy? 09:31:38
16 MR. STOWELL: Objection. Lack of 09:31:41
17 foundation. Asked and answered. 09:31:42
18 THE WITNESS: I'm not sure if the patents 09:31:43
19 describe them differently. 09:31:46
20 By MR. HAMILTON: 09:31:55
21 Q. So if patents don't describe them 09:31:55
22 differently, is it your understanding that those 09:31:57
23 terms mean the same thing? 09:31:59
24 A. I think mechanical thrombectomy is just a 09:32:07
25 more specific description of using mechanical means 09:32:09

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1 or aspiration means to remove thrombus from a 09:32:13
2 patient. 09:32:18
3 Q. So a mechanical thrombectomy is a subset of 09:32:21
4 thrombectomy; is that right? It's a specific type 09:32:26
5 of thrombectomy? 09:32:28
6 A. I think they're using it as a more specific 09:32:32
7 description of removing thrombus from a patient. 09:32:35
8 Q. By more specific you mean using some kind 09:32:37
9 of mechanical means; is that right? 09:32:40
10 A. That's what the term mechanical would 09:32:45
11 imply. 09:32:47
12 Q. Other than mechanical thrombectomy, are 09:32:55
13 there other types of thrombectomy? 09:32:57
14 A. Well certainly surgeons have done open 09:33:08
15 procedures to remove thrombus from patients. I'm 09:33:11
16 not sure if a surgeon would consider that mechanical 09:33:14
17 thrombectomy or surgical thrombectomy. Either way, 09:33:19
18 you're removing thrombus from a patient. 09:33:22
19 Q. What's the difference between mechanical 09:33:24
20 thrombectomy and surgical thrombectomy? 09:33:27
21 A. Example I gave was a surgeon who has the 09:33:34
22 vessel opened or the heart opened in order to remove 09:33:36
23 the thrombectomy directly with direct vision. I 09:33:40
24 might still consider that mechanical thrombectomy if 09:33:46
25 he's using a tool to remove a thrombus. 09:33:49

1 Q. Other than mechanical, surgical -- 09:34:02
2 mechanical or surgical thrombectomy, are there any 09:34:06
3 other types of thrombectomy? 09:34:09
4 A. Well these patent talk about aspiration a 09:34:18
5 lot. I think that's a subset of mechanical 09:34:21
6 thrombectomy. 09:34:23
7 Q. Other than surgical, mechanical, 09:34:25
8 aspirational, are there any other types of 09:34:28
9 thrombectomy? 09:34:30
10 A. There may be. I'm not sure that the 09:34:32
11 patents describe others. 09:34:33
12 Q. Are you aware of any others? 09:34:35
13 A. Yeah, I'm not sure if there are others or 09:34:53
14 not, other categories that physicians may term -- 09:34:56
15 use different terms for removing thrombus. 09:35:00
16 Q. What is -- what do you mean by "removing 09:35:06
17 thrombus?" 09:35:08
18 A. Thrombectomy is the act of removing 09:35:11
19 thrombus from a patient. 09:35:13
20 Q. Is there a term in the art -- when I say 09:36:16
21 "the art," the field of the '333, '910, and '580 09:36:20
22 patents, for preventing a formation of a thrombus? 09:36:24
23 A. Certainly there are pharmaceuticals that 09:36:53
24 are given to patients to prevent thrombus 09:36:56
25 formations. 09:36:59

1 Q. Is there a term for taking steps to prevent 09:37:10
2 the formation of a thrombus in a patient? 09:37:14
3 A. Patients are given anticoagulants, 09:37:21
4 antiplatelet medications. There probably are other 09:37:25
5 categories of medicines that are given to patients 09:37:30
6 to prevent formation of thrombus. 09:37:33
7 Q. Are you familiar with the firm -- excuse 09:38:14
8 me -- the term thrombogenicity? 09:38:17
9 A. Yes. 09:38:21
10 Q. What does that term mean? 09:38:21
11 A. Usually refers to materials that might be 09:38:30
12 more prone to develop thrombus on their surface 09:38:34
13 would be higher in its thrombogenicity potential. 09:38:38
14 Q. When you say materials that are more likely 09:38:54
15 to -- did you say form a thrombus on their surface? 09:38:56
16 Is that how you termed it? 09:39:01
17 A. I would have to read back the exact words I 09:39:03
18 used. I'm not sure exactly how I termed it. 09:39:06
19 Q. Is that an issue when -- where is that an 09:39:10
20 issue in the design of medical devices? 09:39:17
21 MR. STOWELL: Objection. Vague. 09:39:21
22 THE WITNESS: Can you re-ask the question? 09:39:24
23 By MR. HAMILTON: 09:39:45
24 Q. In your experience, would a person of 09:39:45
25 ordinary skill in the art look to prevent the 09:39:48

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1 formation of a thrombus on the surface of the 09:39:53
2 material in designing a medical device? 09:39:55
3 A. Yes, certainly that is a design 09:40:02
4 consideration in the products that I've worked on 09:40:05
5 that are all blood contacting devices, whether they 09:40:08
6 were temporary blood contacting devices like 09:40:13
7 short-term use catheters or whether they were 09:40:18
8 long-term permanent implants. 09:40:21
9 Q. Would you consider that formation of a 09:40:26
10 thrombus a negative side effect from a medical 09:40:30
11 device? 09:40:33
12 A. Certainly it -- it can result in 09:40:43
13 complications to the patient if it's -- if a 09:40:45
14 thrombus is formed and emboli are created. 09:40:48
15 Q. And you had said in devices you designed 09:40:53
16 that's a consideration; is that right? 09:40:56
17 Let me just -- I said you designed -- you 09:41:02
18 have designed in the past -- let me just clarify 09:41:07
19 that -- that has been a consideration; correct? 09:41:10
20 A. Yeah, as I state on page 4, paragraph 9, I 09:41:20
21 described a number of devices on which I have worked 09:41:28
22 over the years. All of -- all of these devices were 09:41:31
23 in blood contact, and choosing materials that were 09:41:35
24 biocompatible was a key component of these projects. 09:41:39
25 Knowledge of the potential complications related to 09:41:43

1 blood clots, thrombus, thromboemboli was a critical 09:41:46
2 part of every project I worked on. 09:41:51
3 Q. For the devices you've designed, were there 09:42:16
4 other complications -- potential complications? 09:42:19
5 A. Every medical device has multiple potential 09:42:22
6 complications. 09:42:26
7 Q. And did you take steps to prevent those 09:42:27
8 other complications when designing the device? 09:42:29
9 A. We certainly took steps to design devices 09:42:40
10 appropriately for the application to minimize the 09:42:44
11 chance of any patient complication. 09:42:48
12 Q. So if you look at paragraph 10 of your 09:43:30
13 declaration, the last sentence, you see reference to 09:43:32
14 the MitraClip device? 09:43:38
15 A. Yes. 09:43:40
16 Q. Is the MitraClip device designed to remove 09:43:51
17 a thrombus or a blood clot? 09:43:55
18 A. No. 09:43:57
19 Q. So is it fair to say that your 09:44:09
20 consideration of a thrombus embolism or blood clot 09:44:12
21 when designing the MitraClip device consisted of 09:44:21
22 evaluating the device's potential to cause a 09:44:28
23 thromboembolism; is that right? 09:44:33
24 A. We certainly iterated the design and made 09:44:40
25 modifications in order to minimize the likelihood of 09:44:45

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1 thrombus developing on the device. We certainly 09:44:49
2 tested it in animals and bench studies before use in 09:44:54
3 patients. 09:45:03
4 Q. And did that -- any of that work include 09:45:04
5 using the MitraClip device to perform a 09:45:10
6 thrombectomy? 09:45:15
7 A. No. We did not perform thrombectomy with 09:45:15
8 the MitraClip device. It was used to treat patients 09:45:18
9 with mitral valve regurgitation using a catheter 09:45:21
10 based system. 09:45:26
11 Q. So is it fair to say your extent -- the 09:45:34
12 extent of your experience related to thrombectomy -- 09:45:37
13 let me -- let me rephrase that. 09:45:40
14 Is it fair to say the extent of your 09:45:42
15 experience gathered from your work with the 09:45:44
16 MitraClip device is the prevention of the formation 09:45:45
17 of a thrombus? 09:45:51
18 A. There were many, many design considerations 09:45:58
19 in play during development of the MitraClip system, 09:46:04
20 the catheters, the clip, et cetera, the physician 09:46:08
21 use of the device. Minimizing thrombosis of the 09:46:12
22 device was one of many important design 09:46:19
23 considerations. 09:46:22
24 Q. And did any of those design considerations 09:46:25
25 include performing a thrombectomy? 09:46:28

1 A. We did not perform thrombectomy with the 09:46:35
2 MitraClip device. 09:46:38
3 Q. Do you believe your experience with the 09:46:48
4 MitraClip device design and its potential to cause 09:46:50
5 thromboembolism makes you an expert in 09:46:59
6 thrombectomy? 09:47:03
7 A. I believe that my experience in developing 09:47:17
8 the many different devices that I list on section 9, 09:47:22
9 from thermodilution catheters to left ventricular 09:47:28
10 assist devices, a centrifugal blood pump for bypass 09:47:32
11 procedures, angioplasty catheters, abdominal aortic 09:47:37
12 aneurysm implants, and the MitraClip device, plus 09:47:39
13 some other devices I worked on that I neglected to 09:47:47
14 mention, certainly provides comparable industry 09:47:50
15 experience as the patent owner proposed for the 09:47:58
16 person of ordinary skill in the art definition as 09:48:06
17 shown on paragraph 6. 09:48:09
18 Q. Do you believe you're an expert in 09:48:12
19 thrombectomy? 09:48:14
20 A. I believe my comparable industry experience 09:48:21
21 gives me enough expertise to evaluate the content of 09:48:26
22 these patents and the claims involved. 09:48:30
23 Q. And do you believe you're an expert in 09:48:33
24 thrombectomy? 09:48:36
25 A. Can you read back what I just said. 09:48:39

1 MR. STOWELL: Objection. Asked and 09:48:42
2 answered. 09:48:43
3 By MR. HAMILTON: 09:48:53
4 Q. I'm sorry. Are you finished with your 09:48:53
5 answer? 09:48:55
6 A. If you can read back what I just said. 09:48:56
7 Q. Do you believe you are an expert in 09:49:01
8 thrombectomy? 09:49:02
9 MR. STOWELL: Objection. Asked and 09:49:03
10 answered. 09:49:04
11 THE WITNESS: I think my comparable 09:49:06
12 industry experience provides sufficient expertise to 09:49:08
13 evaluate these patents at issue here. 09:49:11
14 By MR. HAMILTON: 09:49:18
15 Q. Do you believe you're an expert in 09:49:18
16 mechanical thrombectomy? 09:49:20
17 A. Same answer. 09:49:23
18 Q. In designing the MitraClip device, you had 09:49:45
19 said one of the complications is its potential to 09:49:49
20 cause thromboembolism; is that right? 09:49:53
21 A. Yes. 09:49:58
22 Q. Are there other complications that can -- 09:49:58
23 that the -- the MitraClip device may cause? 09:50:01
24 A. Well if you read the instructions for use, 09:50:07
25 there are probably dozens of potential complications 09:50:09

1 listed in that IFU. So, yes, there are many 09:50:15
2 others. 09:50:18
3 Q. And in designing the MitraClip device, did 09:50:20
4 you take into account how to prevent those 09:50:24
5 complications or mitigate those complications? 09:50:30
6 A. Certainly that was the goal of the 09:50:40
7 engineers and the clinical team, to minimize patient 09:50:42
8 complications while achieving the intended clinical 09:50:48
9 result. 09:50:52
10 Q. And you said there were many; is that 09:50:53
11 right? 09:50:55
12 A. There are many potential complications 09:50:58
13 during the procedure of a MitraClip device which are 09:51:00
14 outlined in the instructions for use. 09:51:03
15 Q. About how many do you think? 09:51:09
16 A. I would have to look at the instructions. 09:51:12
17 Q. And is potential to cause thrombo -- 09:51:17
18 thromboembolism one of those many? 09:51:22
19 A. Yes, it is. 09:51:26
20 Q. And do you believe because -- withdraw the 09:51:48
21 question. 09:51:51
22 I'm going to hand you what's been 09:51:54
23 previously marked as Exhibit 1075 in IPR2025-01025. 09:51:58
24 Do you see the document? 09:52:11
25 A. Exhibit 1075? 09:52:18

1 Q. Yes. 09:52:20
2 A. Is that what you said? Yes. 09:52:20
3 Q. Do you recognize this document? 09:52:23
4 A. Yes. It's the MitraClip delivery system 09:52:27
5 instructions for use. It looks like it's from 2013 09:52:33
6 based on the sub -- subscript. 09:52:37
7 Q. If you take a look at what's labeled page 6 09:52:46
8 of 54. Is this a list of potential complications in 09:52:49
9 adverse events that you took into account when 09:53:05
10 designing the MitraClip device? 09:53:08
11 A. It is the list of potential complications 09:53:16
12 in adverse events -- potentially anticipated events. 09:53:18
13 Many of these are clinically related, not 09:53:24
14 necessarily directly related to designing the 09:53:28
15 device. 09:53:30
16 Q. What do you mean "clinically related" 09:53:32
17 versus "not necessarily directly related to 09:53:35
18 designing the device?" What's the difference? 09:53:38
19 A. For instance, it lists fever. It lists it 09:53:55
20 dyspnea. These are not necessarily caused by the 09:54:03
21 device. It could be more related -- many of these 09:54:16
22 are related more to the recovery after the procedure 09:54:20
23 being on general anesthesia, for instance. 09:54:22
24 Q. Did you consider all of these potential 09:54:32
25 complications in adverse events when designing the 09:54:34

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1 MitraClip device? 09:54:39
2 A. Not all of them, no. 09:54:53
3 Q. Which ones did you consider? 09:54:58
4 A. I'm not sure. I know we didn't consider 09:55:01
5 things like urinary tract infection. That's related 09:55:03
6 to the procedure of putting in a drainage catheter 09:55:08
7 during the procedure, it's not related to performing 09:55:13
8 the procedure so we would not have considered that 09:55:17
9 as an example when designing the MitraClip device. 09:55:20
10 Q. Can you identify any of these potential 09:55:29
11 complications in adverse events that you did 09:55:32
12 consider when designing the MitraClip device? 09:55:34
13 A. Yes. 09:55:38
14 Q. Which ones? 09:55:39
15 A. Allergic reaction. Arrhythmias. Atrial 09:55:44
16 fibrillation. Atrial septal defect. AV fistula. 09:55:52
17 Bleeding. Cardiac perforation. Cardiac tamponade. 09:56:04
18 Pericardial effusion. MitraClip erosion, migration, 09:56:19
19 malposition. MitraClip device thrombosis. 09:56:25
20 MitraClip system component embolization. Conversion 09:56:31
21 to standard valve surgery. Dislodgement of 09:56:43
22 previously implanted devices. Emboli. Emergency 09:56:54
23 cardiac surgery. Failure to deliver MitraClip to 09:57:05
24 the intended site. Failure to retrieve MitraClip 09:57:39
25 system components. Hematoma. Hemolysis. 09:57:43

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1 Hypotension, hypertension. Infection at the 09:58:08
2 insertion site, infection at the incision site was 09:58:20
3 considered by way of performing sterilization 09:58:26
4 validation. Injury to the mitral valve. Mitral 09:58:31
5 stenosis. Mitral valve injury. Myocardial 09:58:43
6 infarction. Peripheral ischemia I guess we 09:59:07
7 considered as it relates to the diameter of the 09:59:18
8 sheath that went into the leg. Prolonged 09:59:22
9 ventilation I guess we considered from the 09:59:38
10 standpoint of wanting a reasonably short procedure 09:59:40
11 time. Single leaflet device attachment. Stroke or 09:59:43
12 TIA. Vascular trauma dissection or occlusion. 10:00:15
13 Vessel spasm. Vessel perforation or laceration. 10:00:24
14 Worsening mitral regurgitation. That's it. 10:00:31
15 Q. So let's start with the -- the first one on 10:00:51
16 that list, allergic reaction. What did you do when 10:00:53
17 designing the MitraClip with respect to considering 10:01:01
18 allergic reaction? 10:01:08
19 A. We chose materials that were known to be 10:01:16
20 biocompatible and we performed testing to look at 10:01:22
21 nickel -- nickel and other elements that might come 10:01:35
22 out of the metal components. 10:01:42
23 Q. So it would be fair to say that you 10:01:49
24 attempted to design the device to minimize causing 10:01:52
25 allergic reaction? 10:01:59

1 A. Yes. 10:02:00
2 Q. Did you design the device to treat an 10:02:04
3 allergic reaction? 10:02:06
4 A. No. 10:02:08
5 Q. Do you believe you're an expert in treating 10:02:09
6 allergic reactions? 10:02:12
7 A. No. 10:02:14
8 Q. So just because you designed the device to 10:02:16
9 prevent or reduce the chances of a complication 10:02:21
10 doesn't mean you're an expert in treating that 10:02:24
11 complication, does it? 10:02:26
12 MR. STOWELL: Objection. Vague. 10:02:28
13 THE WITNESS: Designing a device to 10:02:38
14 minimize these complications was a normal part of 10:02:39
15 the engineering development experience. 10:02:47
16 By MR. HAMILTON: 10:02:50
17 Q. Is it fair to say that designing a device 10:02:50
18 to minimize a complication does not make you an 10:02:52
19 expert in treating that complication, does it? 10:02:55
20 MR. STOWELL: Objection. Vague. 10:02:57
21 THE WITNESS: Depends on the 10:03:02
22 complication. 10:03:03
23 By MR. HAMILTON: 10:03:15
24 Q. So for allergic reactions -- you've said it 10:03:15
25 doesn't make you an expert in treating allergic 10:03:18

1 reactions; right? 10:03:21
2 A. I'm not an allergist, no. 10:03:23
3 Q. What about arrhythmias? Are you an expert 10:03:25
4 in treating arrhythmias? 10:03:30
5 A. No. 10:03:32
6 Q. What about atrial fibrillation? Are you an 10:03:33
7 expert in treating atrial fibrillation? 10:03:38
8 A. No. 10:03:41
9 Q. If you go down to -- I will withdraw the 10:03:59
10 question. 10:04:05
11 If you turn to page 3 of 54 of that same 10:04:34
12 document, Exhibit 1075. Do you see 10:04:39
13 contraindications? 10:04:46
14 A. Yes. 10:04:48
15 Q. What does that mean, contraindications? 10:04:49
16 A. Well in the world of instructions for 10:04:55
17 medical devices, there is an indication for how it 10:04:58
18 should be used and there are specific 10:05:01
19 contraindications where the device should not be 10:05:04
20 used. 10:05:09
21 Q. What does that mean "where the device 10:05:11
22 should not be used?" What do you mean by that? 10:05:13
23 A. In patients for whom the device is not 10:05:16
24 indicated. 10:05:19
25 Q. So if you look at the last bullet point 10:05:20

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1 there. Do you see that bullet point? 10:05:22
2 A. Yes. 10:05:24
3 Q. What does that mean? 10:05:31
4 A. It says, "Evidence of intracardiac inferior 10:05:34
5 vena cava or femoral venous thrombus." That means 10:05:38
6 if patients are -- present -- I'm sorry. If 10:05:44
7 patients present with evidence of thrombus in the 10:05:48
8 cardiac chambers, the IVC, or in the femoral vein 10:05:54
9 where the doctor is going to insert the device, that 10:06:00
10 this is not a patient that should be treated with a 10:06:02
11 MitraClip system. 10:06:05
12 Q. And why not? 10:06:28
13 A. If there is thrombus in the femoral vein, 10:06:34
14 it could get dislodged when trying to advance the 10:06:37
15 delivery system. If there's thrombus -- massive 10:06:41
16 thrombus in the cardiac chambers, it could get 10:06:47
17 dislodged during the procedure. 10:06:51
18 Q. So you mentioned cardiac chambers, femoral 10:07:01
19 vein; is that right? 10:07:06
20 A. Yes. Intracardiac thrombus, inferior vena 10:07:09
21 cava thrombus, or femoral vein thrombus are the 10:07:14
22 three contraindications listed there. 10:07:16
23 Q. And would any of those include pulmonary 10:07:20
24 embolisms? 10:07:24
25 A. We didn't list that there, no. 10:07:25

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1 Q. And is it your understanding that those 10:07:27
2 three terms don't include a pulmonary embolism? 10:07:29
3 A. Correct. Those three terms do not. 10:07:39
4 Q. Would it include a deep vein thrombosis? 10:07:51
5 A. Femoral venous thrombosis could -- could be 10:08:10
6 a deep vein thrombosis, yes. 10:08:14
7 Q. If you go to paragraph 7, I'm going to ask 10:09:13
8 you a question about page 3 of your '910 10:09:18
9 supplemental declaration. Let me know when you're 10:09:24
10 ready for the question. 10:09:42
11 What are the primary components of an 10:09:59
12 aspiration system for mechanical thrombectomy? 10:10:02
13 A. I think it depends a bit on the system, but 10:10:19
14 generally for the thrombectomy systems in -- at 10:10:22
15 issue in these patents, there's the thrombectomy 10:10:27
16 catheter, syringes, potentially pumps, filters, 10:10:36
17 collection chambers. Depends on the procedure. If 10:10:47
18 they are using a stentriever type device, then it 10:10:56
19 would involve another catheter system like a 10:11:01
20 stentriever, for instance. 10:11:04
21 Q. What about valves, would that be a primary 10:11:13
22 component of a aspiration system for a mechanical 10:11:17
23 thrombectomy? 10:11:21
24 A. I think it depends on the system that the 10:11:27
25 physician is using but certainly valves like 10:11:28

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1 stopcocks are used in many of these types of systems 10:11:33
2 and all types of medical procedures. 10:11:37
3 Q. So then would you consider a valve a 10:11:45
4 primary component of an aspirational system for 10:11:47
5 mechanical thrombectomy? 10:11:52
6 A. I think it depends on the system in 10:11:55
7 question, whether they use a valve or not. 10:11:57
8 Q. So if you go to the last sentence in that 10:12:05
9 paragraph 7, it says, "because the catheter is a 10:12:09
10 primary component of any aspiration system." 10:12:14
11 Do you see that? 10:12:17
12 A. Yes. 10:12:18
13 Q. I'm trying to figure out what are the other 10:12:19
14 primary components of any aspiration system. And 10:12:21
15 you had said pumps, collection chambers, syringes, 10:12:25
16 filters, maybe valves. Are there any others? 10:12:31
17 MR. STOWELL: Objection. Misstates the 10:12:36
18 testimony. 10:12:38
19 THE WITNESS: I think what my sentence -- 10:12:44
20 the last sentence says, "the catheter is a primary 10:12:45
21 component of any aspiration system." The other 10:12:49
22 components that I mentioned like filters, they don't 10:12:52
23 have to use a filter if they're not returning blood 10:12:54
24 to the patient, for instance. Pumps. They could 10:12:58
25 use a syringe. They don't need electric pump, for 10:13:01

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1 instance, during aspiration thrombectomy procedures. 10:13:05
2 So the common -- certainly the common component is 10:13:12
3 the catheter itself. Items like syringes and 10:13:14
4 stopcocks are very standard procedure so I'm not 10:13:21
5 could say it was primary -- of primary importance. 10:13:24
6 By MR. HAMILTON: 10:13:30
7 Q. Are there any components that are primary 10:13:30
8 components of a aspiration system for mechanical 10:13:32
9 thrombectomy besides a catheter? 10:13:35
10 A. Certainly depends on the type of 10:13:39
11 thrombectomy that's being performed. If it's purely 10:13:41
12 aspiration, the catheter is a primary component, a 10:13:44
13 vacuum source is a primary component, and maybe 10:13:50
14 there are others that could be considered. 10:13:55
15 Q. You have said -- one of the terms used was 10:14:34
16 collection chamber. What did you mean by that? 10:14:37
17 A. Well the term canister is used frequently 10:14:53
18 for aspiration type systems, collection canisters. 10:14:56
19 Commercial devices tend to use that term for 10:15:03
20 aspiration systems. That's where the blood is 10:15:07
21 collected after aspirating from the patient. 10:15:17
22 Q. Is a collection chamber a required 10:15:31
23 component of an aspiration system for mechanical 10:15:33
24 thrombectomy? 10:15:37
25 A. For aspiration thrombectomy using a 10:15:49

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1 syringe, I guess a syringe would be considered the 10:15:52
2 collection canister. 10:15:55
3 Q. Are you finished with your answer? 10:16:21
4 A. Yes. 10:16:23
5 Q. Is a collection chamber necessary in an 10:16:23
6 aspiration system for mechanical thrombectomy? 10:16:35
7 A. Depends on the system that the physician is 10:16:41
8 using. There may be systems where the blood is 10:16:42
9 withdrawn and -- and provided back to the patients. 10:16:47
10 I think in -- even in those systems there is a 10:16:54
11 filter -- blood would go through a filter before 10:16:57
12 providing it back to the patient. 10:17:01
13 Q. If you turn to paragraph 11 of that same 10:17:30
14 declaration, '910 supplemental declaration. 10:17:33
15 A. Paragraph 11 or page 11? 10:17:40
16 Q. Paragraph 11 that is on page 5. And four, 10:17:42
17 five -- six lines down at the end of that sixth line 10:17:52
18 there is that term thrombogenicity. Is that how you 10:17:56
19 pronounce that term? 10:18:01
20 A. Yes. 10:18:02
21 Q. In designing the MitraClip device, was that 10:18:11
22 the primary concern related to the formation of a 10:18:25
23 thrombus that you considered? 10:18:28
24 A. Well that's certainly the primary test that 10:18:49
25 is performed to confirm that the device meets the 10:18:51

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1 requirements for thrombogenicity. 10:18:54
2 Q. So other than considering whether the 10:19:04
3 device the MitraClip, I believe you said meets the 10:19:07
4 test for thrombogenicity, did you consider any other 10:19:11
5 aspect of that device with respect to its potential 10:19:16
6 to cause a thrombus? 10:19:18
7 A. Yes. For example in paragraph 12 toward 10:19:38
8 the end I list that "In prior iterations of the 10:19:45
9 MitraClip our engineering team experimented with 10:19:50
10 uncovered metal components, different shapes of 10:19:53
11 metal components" -- that's not a direct quote -- 10:19:56
12 "and alternative covering materials in order to 10:19:59
13 minimize the buildup of thrombus on the implant." 10:20:06
14 Q. And is that different than 10:20:10
15 thrombogenicity? 10:20:13
16 A. Well, the real test for thrombogenicity on 10:20:21
17 the implant is really acute animal studies -- 10:20:25
18 sorry -- chronic animal studies -- acute and chronic 10:20:28
19 animal studies can show areas of thrombus 10:20:32
20 accumulation. The thrombogenicity testing that was 10:20:36
21 done per an ISO requirement, ISO 10993, is a more -- 10:20:44
22 it's more of a bench test evaluation. 10:20:56
23 Q. So then is it fair to say that your work 10:21:15
24 with the MitraClip in preventing the formation of a 10:21:18
25 thrombus related to whether the device would cause 10:21:23

1 the formation of a thrombus either from the 10:21:39
2 materials chosen or the shape of the device? 10:21:42
3 A. Surface finishes, the materials in contact 10:21:53
4 with the blood, and even on the catheter -- the 10:21:58
5 outside of the catheter, the smoothness of that is a 10:22:06
6 consideration for minimizing the development of 10:22:12
7 thrombus during the use. 10:22:16
8 Q. So then would it be fair to say that 10:22:21
9 you're -- the primary issue with respect to your 10:22:23
10 design of the MitraClip device was minimizing the 10:22:26
11 formation of a thrombus through the use of the 10:22:30
12 device or components associated with the device? 10:22:33
13 A. Primary development aspects of the 10:22:38
14 MitraClip device were to be able to deploy it on the 10:22:40
15 mitral leaflets appropriately to actuate the device, 10:22:46
16 open and close and be able to remove the device, to 10:22:54
17 be able to lock the device permanently on the micro 10:22:58
18 leaflets, to be able to detach the device from the 10:23:01
19 delivery system. We had a whole long list of design 10:23:08
20 requirements, one of which was that it should be 10:23:10
21 non-thrombogenic. 10:23:13
22 Q. Were any of those design requirements 10:23:19
23 related to the formation of a thrombus other than 10:23:22
24 that you could use the device and make sure it's 10:23:28
25 non-thrombogenic? 10:23:30

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1 A. Certainly we had design requirements around 10:23:33
2 minimizing thrombogenicity. Yes. 10:23:38
3 Q. So other than minimizing or preventing 10:24:13
4 the -- excuse me -- the formation of a thrombus, 10:24:16
5 what other design considerations related to a 10:24:21
6 thrombus with respect to designing the MitraClip 10:24:25
7 device? 10:24:29
8 A. We certainly had requirements to be -- I'll 10:24:43
9 start again. 10:24:45
10 We certainly had requirements relating to 10:24:46
11 flushing through the lumens of the catheter to 10:24:49
12 prevent blood from stagnating inside the small 10:24:54
13 lumens of the catheter. That's another example of 10:24:57
14 working to minimize thrombus on the system or in the 10:25:03
15 system. 10:25:08
16 Q. What's the issue -- and that -- and that 10:25:09
17 was to prevent the formation of a thrombus; 10:25:12
18 correct? 10:25:15
19 A. Yes, we had to be able to flush through the 10:25:17
20 lumens of a delivery catheter, for instance. 10:25:19
21 Q. How does stagnation of blood relate to the 10:25:23
22 formation of a thrombus? 10:25:25
23 A. Blood can clot when it -- when it's in a 10:25:34
24 stagnant location for a long time. These patients 10:25:37
25 are well heparinized during procedure -- before, 10:25:40

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1 during, and after the procedure, but still that was 10:25:45
2 a design consideration. 10:25:48
3 Q. So that you -- you wanted to prevent the 10:25:52
4 stagnation of blood; is that correct? 10:25:55
5 A. We needed -- we wanted to be able to have a 10:25:57
6 constant flush of heparinized saline through the 10:26:00
7 catheter so that blood did not get in the lumens 10:26:05
8 partly for -- well I will say primarily for keeping 10:26:09
9 those lumens free of blood so that the actuation 10:26:17
10 mechanisms, we had cables and pull lines within 10:26:27
11 those lumens, so that those could still work 10:26:30
12 appropriately so we needed to be able to flush 10:26:35
13 heparinized saline through the system constantly. 10:26:38
14 Q. If you look at paragraph 13, first 10:27:03
15 sentence. You recite, "I was also an author of the 10:27:10
16 MitraClip chronic animal study results published in 10:27:16
17 the journal Circulation." 10:27:20
18 Do you see that? 10:27:21
19 A. Yes. 10:27:22
20 Q. What did you mean by that? 10:27:23
21 A. That I was one of the authors of that 10:27:29
22 chronic animal study result -- chronic animal study 10:27:31
23 whose results were published in Circulation 10:27:34
24 magazine -- Circulation journal. 10:27:37
25 Q. I'm going to hand you another document. 10:27:48

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1 This is Exhibit 1078 from IPR2025-01025. 10:27:53
2 Is this the article you reference in 10:28:05
3 paragraph 13 of your -- your '910 supplemental 10:28:07
4 declaration? 10:28:11
5 A. I'm not sure because my name is not listed 10:28:28
6 as an author. It does look like the one that we 10:28:30
7 provided as Exhibit 1078 but I'm not listed as an 10:29:22
8 author here. I may have provided the wrong 10:29:25
9 reference to the patent asset. 10:29:27
10 Q. So just to be clear, in paragraph 13 you 10:29:33
11 cite Exhibit 1078 stating that you are an author, 10:29:38
12 but for the Exhibit 1078 you are not an author of 10:29:44
13 that article; correct? 10:29:48
14 A. Correct. I'm not listed as an author of 10:29:56
15 this Exhibit 1078 which could have been a mistake on 10:29:59
16 my part. I would have to go back and double-check 10:30:02
17 some other publications. Having said that, I was 10:30:07
18 certainly involved with the entire study. This 10:30:27
19 referenced I was -- approved the protocols and the 10:30:32
20 reports and was at probably all of these clip 10:30:35
21 implants and probably almost all of the clip 10:30:42
22 ex-plants so I'm quite familiar with the -- the 10:30:45
23 study that's described here. 10:30:47
24 Q. But you're not an author of that study; 10:30:51
25 correct? 10:30:54

1 A. I'm not listed as an author on this study, 10:30:55
2 that's correct. 10:30:58
3 Q. Do you believe you should be listed as an 10:30:58
4 author of Exhibit 1078? 10:31:01
5 A. No. I think the mistake is either I 10:31:06
6 provided a different reference -- I provided this 10:31:09
7 reference in error to counsel or I mistakenly 10:31:11
8 thought I was an author. 10:31:19
9 Q. If you would look at paragraph 14 of your 10:31:35
10 '910 supplemental declaration. That's also on page 10:31:40
11 6. You reference work that led to the development 10:31:44
12 of a novel stent graph to treat abdominal aortic 10:32:00
13 aneurysms. 10:32:04
14 Do you see that? 10:32:07
15 A. Yes. 10:32:08
16 Q. Did your work described in paragraph 14 10:32:11
17 relate to designing a device to perform a 10:32:14
18 thrombectomy? 10:32:18
19 A. No. The device was used to treat abdominal 10:32:20
20 aortic aneurysms with a catheter based system 10:32:24
21 instead of open -- open belly surgery. 10:32:27
22 Q. And if you look at the next paragraph, 15, 10:32:41
23 and then I want to ask you a question about the 10:32:46
24 bullet point that's on page 7 in that paragraph. 10:32:49
25 A. Yes. 10:32:56

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1 Q. You see reference to a delivery catheter 10:33:14
2 that may be used to deliver other types of devices? 10:33:17
3 Do you see that? 10:33:21
4 A. Yes. 10:33:23
5 Q. Let me -- let me -- I want to give you the 10:33:35
6 document. I'm handing what's been marked as Exhibit 10:33:40
7 1079 in IPR2025-01025. 10:34:01
8 Do you recognize Exhibit 1079? 10:34:21
9 A. Yes. 10:34:24
10 Q. Is this the exhibit referenced in paragraph 10:34:28
11 15 of your '910 supplemental declaration? 10:34:30
12 A. Yes. 10:34:37
13 Q. And you are an author on this one; 10:34:38
14 correct? 10:34:40
15 A. Yes. 10:34:41
16 Q. If you want to turn to paragraph 245. This 10:34:49
17 is the paragraph that's partially quoted in 10:34:59
18 paragraph 15 of the '910 supplemental declaration. 10:35:00
19 Let me know when you're there and you're ready for a 10:35:05
20 question. 10:35:08
21 A. Okay. 10:35:50
22 Q. Does Exhibit 1079 disclose a device for the 10:36:04
23 treatment of a thrombus or embolism or blood clot? 10:36:11
24 MR. STOWELL: Objection. Vague. 10:36:20
25 THE WITNESS: Certainly the thrush -- 10:36:35

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1 sorry -- I mean thrust of this continuation -- this 10:36:36
2 continuation part in the claims are related to a 10:36:42
3 two-part steerable after system where one catheter 10:36:49
4 is, say, telescoped within the other and both 10:36:53
5 catheters have steerable capabilities in its design. 10:36:59
6 And in paragraph 245 we listed a number of different 10:37:06
7 potential applications for a nested or telescoped 10:37:12
8 two-part catheter system with steering. One of 10:37:19
9 those that we disclose in here is related to embolic 10:37:25
10 filtration and embolic removal, among a number of 10:37:31
11 other potential uses for this two-part catheter 10:37:36
12 system. 10:37:44
13 By MR. HAMILTON: 10:37:48
14 Q. And when you say uses for the two-part 10:37:48
15 system, you mean the ability of the delivery 10:37:51
16 catheter to deliver other devices; is that 10:37:54
17 correct? 10:37:56
18 A. Well certainly that sentence in 245 says 10:38:10
19 that "The delivery catheter of the present invention 10:38:20
20 may be used to deliver other types of devices, 10:38:23
21 particularly endovascular and minimally invasive 10:38:25
22 surgical devices used in angioplasty, et cetera, to 10:38:29
23 include the last items mentioned about -- I'm 10:38:37
24 sorry -- the prior item mentioned related to embolic 10:38:48
25 filtration and removal." And the sentence -- the 10:38:58

1 paragraph wraps up by saying, "Thus, the delivery 10:39:16
2 catheter may be used for applications in which a 10:39:19
3 highly flexible, kink-resistant device is desirable 10:39:19
4 with high compressive, tensile and torsional 10:39:22
5 strength." 10:39:27
6 Q. So does that mean that the delivery 10:39:55
7 catheter disclosed in Exhibit 1079 may be used to 10:39:58
8 deliver other devices to treat various conditions? 10:40:03
9 A. Well, the designs discussed here a two-part 10:40:13
10 steerable catheter system through which other 10:40:16
11 devices could be employed including a -- for 10:40:19
12 instance, a suction catheter, including a 10:40:24
13 stentriever, for instance. 10:40:33
14 Q. Do you believe that the fact that this 10:40:42
15 document discloses that its delivery catheter can be 10:40:46
16 used to deliver other devices, including devices for 10:40:50
17 embolic filtration removal, contributes to your 10:40:57
18 qualifications as an expert in thrombectomy? 10:41:03
19 A. I think it contributes to my experience in 10:41:10
20 comparable -- comparable design fields, comparable 10:41:15
21 industry experience related to catheter design and 10:41:23
22 procedures, yes. 10:41:28
23 Q. This same paragraph says that it can be 10:41:34
24 used -- that the delivery catheter may also be used 10:41:36
25 to deliver devices used in angioplasty. 10:41:39

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1 Do you see that? 10:41:48
2 A. Yes. 10:41:50
3 Q. Do you believe that makes you qualified as 10:41:51
4 an expert in devices for angioplasty? 10:41:53
5 A. I'm not sure that sentence does but I have 10:42:03
6 developed balloon catheters used in angioplasty and 10:42:06
7 am quite familiar with the procedure and the 10:42:10
8 devices. 10:42:13
9 Q. But that sentence doesn't make you 10:42:14
10 qualified; correct? You need other experience; 10:42:16
11 correct? 10:42:19
12 A. I think what I said before was that 10:42:21
13 comparable industry experience is what I am -- is 10:42:23
14 what I have and it makes me expert enough to 10:42:30
15 evaluate these -- these types of patents. 10:42:34
16 Q. And one of the things that you refer to for 10:42:37
17 comparable industry experience is developing a 10:42:42
18 delivery catheter that can deliver all these 10:42:45
19 different types of devices; correct? 10:42:46
20 A. Certainly developing a two-part steerable 10:42:51
21 system is pretty extensive industry experience in 10:42:53
22 the catheter design world. And as we state, it 10:43:00
23 could be used for thrombectomy removing embolic 10:43:03
24 material. 10:43:08
25 Q. And it doesn't actually say it could be 10:43:11

1 used for that, it says it could be used to deliver a 10:43:13
2 device for that purpose; correct? 10:43:16
3 A. That's how the sentence is written. 10:43:19
4 Deliver a device to remove embolic material which 10:43:23
5 could be another vacuum kind of -- a single lumen 10:43:26
6 simple thrombectomy catheter could be advanced 10:43:32
7 through this two-part steerable system. 10:43:35
8 Q. And it has a long list of other devices 10:43:40
9 that could be delivered as well; correct? 10:43:42
10 A. There's a long list. 10:43:44
11 Q. And just because this delivery catheter set 10:43:45
12 forth in Exhibit 1079 can deliver other types of 10:43:50
13 devices doesn't necessarily make you an expert in 10:43:55
14 development of those other types of devices, does 10:43:59
15 it? 10:44:01
16 A. I think my -- this helps to confirm my 10:44:13
17 comparable industry experience as it relates to 10:44:18
18 thrombectomy procedures and devices. 10:44:22
19 Q. And -- and just to -- to -- to clarify, the 10:44:25
20 fact that you've developed a catheter that can 10:44:28
21 deliver a device to perform thrombectomy and many 10:44:31
22 other procedures contributes to your expertise in 10:44:34
23 mechanical thrombectomy; is that correct? Is that 10:44:38
24 your testimony? 10:44:41
25 A. I think my testimony includes the 10:44:44

1 description of the -- my comparable industry 10:44:50
2 experience as detailed through section -- I'm 10:44:58
3 sorry -- paragraph 9 through paragraph 18 of the 10:45:04
4 supplemental declaration '910. Excuse me. 10:45:15
5 MR. STOWELL: We have been going about an 10:45:28
6 hour and a half so whenever you get to a stopping 10:45:29
7 point. 10:45:32
8 By MR. HAMILTON: 10:45:33
9 Q. Do you need a break or a couple more 10:45:33
10 minutes? 10:45:36
11 A. As soon as possible, yeah. 10:45:36
12 Q. Okay. Why don't we take a break and then 10:45:37
13 we can come back. 10:45:39
14 THE VIDEOGRAPHER: We are going off the 10:45:41
15 record at 10:45. 10:45:42
16 (Recess.) 10:57:28
17 THE VIDEOGRAPHER: We are back on the 10:57:35
18 record at 10:57. 10:57:36
19 By MR. HAMILTON: 10:57:41
20 Q. Mr. Thornton, do you understand you are 10:57:41
21 still under oath? 10:57:43
22 A. Yes. 10:57:43
23 Q. Did you communicate with anyone in any way 10:57:48
24 during the break regarding the substance of this 10:57:50
25 matter? 10:57:52

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1 A. No. 10:57:53
2 Q. Did you review any documents during the 10:57:55
3 break? 10:57:57
4 A. No. 10:57:57
5 Q. For this matter, do you bill your time by 10:58:08
6 the hour? 10:58:11
7 A. Yes. 10:58:13
8 Q. What's your hourly rate? 10:58:13
9 A. $500. 10:58:16
10 Q. Has that rate changed since the onset of 10:58:18
11 this case? 10:58:20
12 A. No. 10:58:21
13 Q. Prior to the break we were looking at your 10:58:27
14 '910 supplemental declaration page 7. Do you see 10:58:32
15 the top bullet point on page 7? 10:58:40
16 A. Yes. 10:58:43
17 Q. Do you see the bold and italic phrase? 10:58:47
18 A. Yes. 10:58:53
19 Q. Does that mean preventing the formation of 10:58:53
20 the thrombus emboli or blood clot? 10:58:59
21 A. Yeah. It says, reducing -- it says, "The 10:59:10
22 device 14 may have a smooth surface which prevents 10:59:16
23 cellular adhesion thereby reducing the accumulation 10:59:22
24 of cells having the potential -- I mean potential" 10:59:23
25 -- poorly written -- to form -- it should say to 10:59:26

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1 form instead of for -- "form and emboli." 10:59:31
2 Q. So does that mean reducing the formation of 10:59:46
3 a thrombus clot or emboli? 10:59:56
4 A. Well, certainly thrombus -- the goal was to 11:00:02
5 prevent accumulative cells which would cause a 11:00:06
6 thrombus. A thrombus which releases into the 11:00:09
7 patient is generally termed an emboli. 11:00:13
8 Q. Does that phrase relate to removing or 11:00:20
9 treating an already formed thrombus emboli or 11:00:27
10 clot? 11:00:31
11 A. No. It's discussing preventing a thrombus 11:00:35
12 from forming in or on a device. 11:00:40
13 Q. And then if you look at paragraph 16. Same 11:00:43
14 questions. Does this discussion relate to 11:00:54
15 preventing or reducing the chances of the formation 11:00:58
16 of a thrombus clot or emboli? 11:01:02
17 A. Yes. Certainly in this patent publication 11:01:12
18 '721 we discuss the issues of current stem designs 11:01:16
19 which included the use of thrombogenic materials 11:01:23
20 which are exposed to blood and may lead to 11:01:26
21 thromboembolism. 11:01:30
22 Q. Does the discussion in this paragraph 16 11:01:39
23 relate to the removal or treatment of an already 11:01:40
24 formed thrombus emboli or clot? 11:01:42
25 A. No. We're discussing the prevention of 11:01:56

1 clot that may lead to thromboembolism. 11:02:02
2 Q. If you turn to paragraph 12. Same 11:02:06
3 questions. I'll just -- I'll just go to the second 11:02:17
4 one. Does -- does your discussion in paragraph 12 11:02:19
5 relate to the removal or treatment of an already 11:02:22
6 formed thrombus emboli or clot? 11:02:24
7 A. No. As the last sentence says, it relates 11:02:30
8 to preventing the development of thrombus on the 11:02:33
9 device. 11:02:36
10 Q. If you go to paragraph 17. Same question. 11:02:50
11 Does the discussion in this paragraph relate to the 11:02:56
12 removal or treatment of an already formed thrombus, 11:03:01
13 emboli, or clot? 11:03:04
14 A. No. It discusses the prevention -- it 11:03:14
15 discusses potential site for thrombogenic material 11:03:19
16 to build up and how we design the device so that 11:03:23
17 that did not form a wrinkle. 11:03:30
18 Q. And then paragraph 18. Same question. 11:03:36
19 Does the discussion in paragraph 18 relate to the 11:03:39
20 removal or treatment of an already formed thrombus, 11:03:43
21 emboli, or clot? 11:03:46
22 A. No. This is discussing the importance of 11:03:53
23 avoiding the buildup of thrombogenic material which 11:03:55
24 could lead to thromboembolism. 11:04:00
25 Q. If you look at the last sentence in that 11:04:06

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1 paragraph. How does -- that the catheter may be 11:04:08
2 outside of the blood flow path which may reduce -- 11:04:27
3 how does that contribute to reducing clotting and 11:04:31
4 hemolysis during the use of the blood flow control 11:04:36
5 device? 11:04:40
6 A. I would have to look at the patent to be 11:05:18
7 more specific, but for this project I was developing 11:05:20
8 a device that was better than something that was 11:05:25
9 already out there which had a number of control 11:05:31
10 wires and the catheter itself down the center of the 11:05:36
11 flow channel, and my design put the catheter on the 11:05:40
12 outside of the flow channel and all the control 11:05:50
13 wires to control the blood controller -- blood flow 11:05:53
14 control device were outside of the blood flow path 11:05:59
15 thereby reducing the likelihood of thromboembolism 11:06:06
16 or hemolysis of the blood flowing through the 11:06:16
17 device. 11:06:21
18 Q. Does that mean that the -- these portions 11:06:28
19 of the catheter that you reference here don't 11:06:31
20 contact blood? 11:06:34
21 A. No, they are in blood contact but most of 11:06:39
22 the blood is flowing through the inside of this 11:06:49
23 ePTFE liner, let's say. 11:06:56
24 Q. So how does having portions of the catheter 11:07:06
25 that are in contact with blood but are outside the 11:07:10

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1 flow path -- the blood flow path, excuse me, 11:07:13
2 contribute to reducing blood clot or hemolysis? 11:07:18
3 A. Because I'm comparing to a similar but 11:07:25
4 different device which has numerous wires in the 11:07:27
5 flow path and the delivery catheter itself -- I'm 11:07:31
6 sorry -- the guidewire lumen of the catheter itself 11:07:34
7 also in the center of the flow path. So getting rid 11:07:39
8 of all that mass of material that's in the flow path 11:07:42
9 of the large lumen, which is the size of the 11:07:45
10 inferior vena cava, should decrease the risk of any 11:07:52
11 hemolysis or thromboembolic material. 11:07:59
12 Q. And is that because those portions of the 11:08:04
13 catheter don't disrupt the flow path or interfere 11:08:07
14 with the flow path? Is that a fair statement? 11:08:11
15 A. Yes. Those wires in the catheter are 11:08:20
16 disrupting the flow path to some extent so removing 11:08:25
17 those I thought was a good -- a good idea. 11:08:29
18 Q. So earlier we had discussed that if blood 11:09:04
19 remained stagnant it's more likely to form a clot; 11:09:11
20 is that correct? 11:09:14
21 A. I think it can happen, yes. 11:09:18
22 Q. Does this sentence at the end of paragraph 11:09:20
23 18 relate to blood being stagnant? 11:09:24
24 A. Not necessarily. It's really relating to 11:09:33
25 removing the multiple wires and the guidewire lumen 11:09:35

1 of the catheter that exists in a different device. 11:09:39
2 Q. So then would it be fair to say that 11:09:44
3 disrupting blood flow, for example, causing -- I'll 11:09:54
4 withdraw the question. Let me rephrase that. 11:10:01
5 So in the prior art device, those wires and 11:10:14
6 other components, they would disturb the blood flow, 11:10:16
7 maybe cause turbulent flow or something else; is 11:10:19
8 that -- is that fair? 11:10:23
9 A. I certainly think they were a site for 11:10:27
10 potential thrombus buildup. In fact, the prior art 11:10:30
11 device I had seen photos at a presentation showing a 11:10:36
12 bunch of blood clot on these wires after it was 11:10:40
13 taken out of a patient. 11:10:44
14 Q. And -- and why -- why are they -- they a 11:10:45
15 location that is more likely to have buildup of a 11:10:47
16 thrombus? Is that because the blood flow is 11:10:52
17 disrupted by those wires or is it something else? 11:10:55
18 A. I'm not sure if it was the material choices 11:11:09
19 of change in the fluid -- fluid mechanics involved 11:11:11
20 to flow around those wires, but removing those wires 11:11:17
21 certainly seemed like the right -- a good design 11:11:23
22 path for me. 11:11:27
23 Q. So you -- you said two things. The 11:11:29
24 material of the wires and the fluid mechanics of the 11:11:32
25 flow around or -- or that's changed because of the 11:11:36

1 wires; is that right? 11:11:39
2 A. It could be multiple things; surface finish 11:11:42
3 of the wires, the patient's own coagulability, the 11:11:45
4 ability of the blood to clot more easily. Multiple 11:11:58
5 things can affect even though these patients are 11:12:02
6 well heparinized. 11:12:08
7 Q. And one of those things that can increase 11:12:09
8 the chances of clotting are a change in -- in the 11:12:11
9 fluid mechanics; is that right? 11:12:14
10 MR. STOWELL: Objection. Misstates the 11:12:16
11 testimony. 11:12:17
12 THE WITNESS: I think in general for large 11:12:33
13 devices in the flow path, and I'm thinking also 11:12:35
14 about my experience with abdominal aortic aneurysm 11:12:38
15 devices, that having a more laminar fluid flow is 11:12:45
16 generally considered beneficial for implanting 11:12:58
17 devices. 11:13:01
18 By MR. HAMILTON: 11:13:13
19 Q. And when you say a more laminal -- laminar 11:13:13
20 flow is beneficial for devices, does that mean a 11:13:16
21 less laminar flow is more likely to form a thrombus 11:13:25
22 clot or a clot? 11:13:29
23 A. I think that can be a consequence of 11:13:37
24 disturbing flow -- normal flow patterns. 11:13:39
25 Q. And part of this disclosure set forth in 11:13:46

1 paragraph 18 is to minimize changes to -- withdraw 11:13:50
2 the question. 11:13:57
3 If you could turn to paragraph 53 of your 11:14:11
4 '910 supplemental declaration. Let me know when you 11:14:22
5 are ready for a question. 11:14:39
6 A. Okay. 11:15:30
7 Q. Do you see the phrase, "I observed many 11:15:45
8 intravascular medical procedures in which physicians 11:15:47
9 reinfused a patient's blood that had been collected 11:15:50
10 in a syringe?" 11:15:53
11 Do you see that? 11:15:55
12 A. Yes. 11:15:55
13 Q. What did you mean by "observed?" 11:15:56
14 A. That I have attended numerous procedures. 11:16:00
15 Here I'm thinking mostly about the MitraClip device 11:16:08
16 procedure that I attended dozens if not hundreds of 11:16:12
17 human cases. 11:16:16
18 Q. So you said mostly MitraClip -- are 11:16:35
19 there -- MitraClip cases. Are there any other you 11:16:40
20 can think of that you have observed in which 11:16:41
21 physicians reinfused a patient's blood that had been 11:16:46
22 collected in a syringe? 11:16:49
23 A. I think there have been. I can't remember 11:16:57
24 which procedures they might have been. 11:16:59
25 Q. When did you last work on the MitraClip? 11:17:02

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1 A. 2012. 11:17:08
2 Q. When did you last observe one of these 11:17:11
3 procedures in wish -- in which physicians reinfused 11:17:14
4 a patient's blood that had been collected in a 11:17:18
5 syringe? 11:17:21
6 A. After 2012 I worked -- I continued to work 11:17:27
7 for Abbott but I was working in their business 11:17:29
8 development, venture capital side of the business, 11:17:34
9 but I think I still saw a few cases between 2015 and 11:17:41
10 2012. Most of the cases I'm referring to would have 11:17:46
11 been prior to 2012. 11:17:50
12 Q. When you say "observed," were you 11:17:54
13 physically present in the room where that physician 11:17:55
14 reinfused a patient's blood that had been collected 11:18:00
15 in a syringe? 11:18:03
16 A. Yes. And I will add that in the early days 11:18:04
17 I was frequently scrubbed in to the case and helping 11:18:07
18 the staff with preparing the devices and I was in 11:18:15
19 the sterile field with the physician while he was 11:18:21
20 doing the procedure acting as a proctor, especially 11:18:23
21 during the early -- early years. 11:18:29
22 Q. You used the term "many." How many? 11:18:32
23 A. How many what? 11:18:35
24 Q. In your sentence you said, "I observed many 11:18:37
25 intravascular medical procedures in which physicians 11:18:41

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1 reinfused a patient's blood that had been collected 11:18:44
2 in a syringe." How many? 11:18:46
3 A. Before I said dozens or hundreds. I think 11:18:50
4 it was really hundreds. I scrubbed in to dozens, I 11:18:54
5 would say. 11:19:03
6 Q. So whether you scrubbed in or not, for 11:19:15
7 those hundreds you were present in the room where 11:19:17
8 this occurred? 11:19:19
9 A. Yes. 11:19:20
10 Q. And where did this occur? 11:19:22
11 A. In catheterization labs all over the 11:19:24
12 world -- Europe and the US. 11:19:28
13 Q. Did you -- have you ever reinfused a 11:19:52
14 patient's blood that had been collected in a 11:20:12
15 syringe? 11:20:14
16 A. No. Pigs, yes, not animals -- not 11:20:15
17 humans. 11:20:22
18 Q. When you say "physicians," who are these 11:20:23
19 physicians? 11:20:25
20 A. Generally these are interventional 11:20:28
21 cardiologists, although some cardiothoracic surgeons 11:20:33
22 also were trained and learned the procedure and 11:20:36
23 performed procedures usually in partnership with an 11:20:37
24 interventional cardiologist. 11:20:43
25 Q. Can you identify any of these physicians so 11:20:49

1 we can contact them? 11:20:52
2 A. Sure. 11:20:54
3 Q. Can you do that now? 11:20:55
4 A. Yes. 11:21:02
5 Q. Who would be one of these physicians? 11:21:05
6 A. Saibal, S-a-i-b-a-l, Kar, K-a-r. 11:21:09
7 Q. Where is Saibal Kar located? 11:21:19
8 A. He's at this point down in Orange County 11:21:22
9 somewhere. At the time he was at Cedars-Sinai in 11:21:24
10 Beverly Hills. 11:21:31
11 Q. And if -- if we asked for others, could you 11:21:31
12 identify others? 11:21:34
13 A. Yes. 11:21:35
14 Q. How much blood was reinfused? 11:21:44
15 A. They generally used a 60cc syringe. I'm 11:21:57
16 not sure that it was -- I'm not sure of the amount 11:22:04
17 but it was less than 60ccs is what the -- the lumen 11:22:07
18 of the guiding catheter would -- would contain. 11:22:14
19 Q. Would it have been less than 30ccs? 11:22:19
20 A. I don't know for sure. 11:22:23
21 Q. Could it have been less than 30ccs? 11:22:30
22 A. I'm not sure. 11:22:32
23 Q. So other than you believe a 60cc syringe 11:22:37
24 was used -- are you sure it was a 60cc syringe? 11:22:40
25 A. I could look in the IFU. I think we might 11:22:48

1 specify it in there. 11:22:52
2 Q. So as you sit here, are you sure it was a 11:22:53
3 60cc syringe? 11:22:56
4 A. I'm not sure if it was a 30 or a 60. 11:22:58
5 Different hospitals use different syringes. 11:23:04
6 Q. And whatever syringe was used, some lesser 11:23:07
7 amount was reinfused; is that correct? 11:23:09
8 A. Certainly if it was a 60cc syringe, less 11:23:14
9 than that amount of blood was typically aspirated 11:23:18
10 and then provided back to the patient. 11:23:22
11 Q. Why was that blood aspirated? 11:23:25
12 A. To assure that there was not air inside the 11:23:31
13 guiding catheter. 11:23:35
14 Q. Any other reason? 11:23:36
15 A. That was the clinical reason to do so. 11:23:45
16 Q. Are you aware of any other reason that that 11:23:47
17 blood was aspirated? 11:23:49
18 A. No. It was to be sure there was no air 11:23:55
19 that would then be injected into the patient at a 11:23:58
20 later step. 11:24:02
21 Q. Was it ever used to perform a 11:24:06
22 thrombectomy? 11:24:12
23 A. Was the guiding catheter ever used? 11:24:13
24 Q. These procedures that you observed, were 11:24:16
25 any of those procedures in which a patient's blood 11:24:17

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1 that had been collected in a syringe came from 11:24:20
2 aspiration for a thrombectomy? 11:24:25
3 A. No. The procedure was not a thrombectomy 11:24:29
4 procedure. 11:24:32
5 Q. And was this something that would occur at 11:24:56
6 the beginning of a procedure involving the 11:24:59
7 MitraClip? 11:25:01
8 A. It was early on in the procedure. It's one 11:25:06
9 of the earlier steps where the guiding catheter and 11:25:08
10 dilator are inserted into the patient, the dilator 11:25:11
11 is removed and then aspiration of the guide catheter 11:25:14
12 occurred before proceeding to the next step. 11:25:22
13 Q. And how long after the physician would 11:25:32
14 aspirate blood out of the catheter was that blood 11:25:35
15 reinfused into a patient? 11:25:38
16 A. I would say almost immediately, as long as 11:25:42
17 time it took to disconnect the syringe and reconnect 11:25:46
18 it to the port that they were going to infuse it 11:26:01
19 into. 11:26:05
20 Q. Was that blood ever filtered before it was 11:26:26
21 reinfused? 11:26:30
22 A. No, I don't believe so. 11:26:31
23 Q. If you could turn to page 15, paragraph 32 11:27:22
24 of the '910 supplemental declaration. 11:27:26
25 A. Page 15? 11:27:40

1 Q. Page 15, yes, paragraph 32. I have some 11:27:41
2 questions about this figure on page 15. Let me know 11:28:15
3 when you're ready for questions. 11:28:19
4 A. Okay. 11:28:21
5 Q. How does the pump shown on page 15 generate 11:28:35
6 a negative pressure differential? 11:28:41
7 A. Well, it's described as a vacuum pump which 11:28:50
8 is connected to the reception canister 707, so a 11:28:55
9 vacuum pump creates a vacuum in that chamber. 11:29:02
10 Q. What is reception canister 707? 11:29:10
11 A. That is where the blood would be deposited 11:29:19
12 from the catheter. 11:29:31
13 Q. So for this reception canister, how is a 11:29:36
14 vacuum created in that reception canister? 11:29:40
15 A. By the vacuum pump. 11:29:44
16 Q. And is that via this tube labeled 705? 11:29:46
17 A. I would have to look at the patent to see 11:29:56
18 how they labeled 705. I didn't label it in here. 11:29:58
19 That does appear to be the means of connection to 11:30:02
20 the vacuum pump into the canister -- the means of 11:30:06
21 connection between the pump and the canister. 11:30:13
22 Q. Is canister 707 sealed? 11:30:21
23 A. Yes. 11:30:30
24 Q. So other than this connection that -- is it 11:30:32
25 705 and then the other connection to 706, canister 11:30:40

1 707 is sealed; correct? 11:30:53
2 A. It is because if it were not sealed, you 11:30:58
3 wouldn't be able to create a vacuum within the 11:31:00
4 canister. 11:31:04
5 Q. How does blood get from the patient to 11:31:37
6 canister 707 -- reception canister 707 -- excuse 11:31:44
7 me -- vacuum chamber. You've -- you've labeled it 11:31:50
8 reception canister but in quotes a vacuum chamber; 11:31:54
9 correct? 11:31:59
10 A. That's what it's labeled here, yes. 11:31:59
11 Q. And how does blood get from the patient to 11:32:01
12 that vacuum chamber? 11:32:04
13 A. Blood will flow through tubing 708 through 11:32:10
14 the rotating valve 711 through tube 706 and into the 11:32:20
15 vacuum chamber. 11:32:27
16 Q. What does rotating valve 711 do? 11:32:30
17 A. 711 is a rotating valve that may be closed 11:32:56
18 after the vacuum pump is turned on such that tube 11:32:58
19 708 is no longer exposed to the vacuum within the 11:33:02
20 canister 707. 11:33:05
21 Q. Does rotating valve 711 create a pulsing 11:33:13
22 vacuum? 11:33:22
23 A. As Brady says -- as I say on page 18, 11:33:27
24 "Brady then explains that the valve may be opened so 11:33:31
25 that a vacuum pulse may be delivered through the 11:33:34

1 tube 708 to aspirate the clot material." 11:33:38
2 Q. And once blood goes from the patient to 11:33:46
3 vacuum chamber 707, where does it go after that? 11:33:50
4 A. It depends what the physician wants to do 11:34:02
5 with it. 11:34:04
6 Q. Does it go through tube 705? 11:34:07
7 A. No. 11:34:13
8 Q. Can it go through tube 705? 11:34:20
9 A. It certainly would not be the intent. I 11:34:28
10 guess if they overfilled the canister and the port 11:34:35
11 was low enough into the canister, it's possible but 11:34:40
12 that would certainly not be the intent. 11:34:45
13 Q. Does vacuum pump 714 -- excuse me -- 714, 11:34:58
14 can that vacuum pump be used to move the blood out 11:35:09
15 of vacuum chamber 707? 11:35:15
16 A. I don't think that's the intent. The 11:35:19
17 intent is to create a air vacuum, let's say, within 11:35:21
18 the reception canister. 11:35:28
19 Q. If the pump -- vacuum pump 714 is turned on 11:35:56
20 and operating, would that apply a continuous 11:36:00
21 pressure differential to vacuum chamber 707? 11:36:05
22 A. Assuming the pump is on, the intent is to 11:36:15
23 create a vacuum in that chamber. 11:36:18
24 Q. So then would it be a fair summary to say 11:36:55
25 that the pump shown here on page 15 generally 11:36:59

1 operates by having a sealed vacuum chamber? 11:37:29
2 A. Certainly if it weren't sealed, you 11:37:37
3 wouldn't be able to create a significant vacuum that 11:37:39
4 the physician wants to use -- wants in order to 11:37:43
5 perform a thrombectomy procedure. 11:37:46
6 Q. And then if we look at the pump shown on 11:37:51
7 page 16, that operates from essentially the same 11:37:59
8 principle, correct, a sealed vacuum chamber? 11:38:03
9 A. Yes because you're using vacuum to -- it's 11:38:24
10 using pumps to create a vacuum in a chamber. 11:38:27
11 Q. And that -- just like the pump we discussed 11:38:31
12 on page 15, this one on page 16 creates a vacuum and 11:38:36
13 in that sealed vacuum chamber -- withdraw the 11:38:46
14 question. 11:38:50
15 Is there an outlet for blood in the vacuum 11:38:57
16 chamber on figure 19? 11:39:00
17 A. They're not showing an outlet connected to 11:39:10
18 the chamber that I can see in this rough hand sketch 11:39:15
19 from the patent. 11:39:23
20 Q. And for the pump -- vacuum pump 502 to 11:39:24
21 apply a vacuum to the aspiration catheter, there 11:39:34
22 couldn't be an outlet for vacuum chamber -- for 11:39:44
23 blood in vacuum chamber -- in the vacuum chamber in 11:39:48
24 figure 19; correct? 11:39:52
25 A. Well there couldn't be an open connecter. 11:39:54

1 It would need to be a closed system to create a 11:39:56
2 vacuum. 11:40:00
3 Q. And is that the same -- I just want to -- 11:40:00
4 let's see. 11:40:09
5 We have got a couple different pumps here. 11:40:10
6 So you got another one on page 19. Does that pump 11:40:11
7 operate by the same principle of a sealed vacuum 11:40:15
8 chamber? 11:40:18
9 A. Yes, I believe the pumps that we show from 11:40:22
10 Pons, Penumbra, and Medela all function similarly in 11:40:26
11 creating a vacuum in a chamber in order to perform a 11:40:36
12 thrombectomy. 11:40:46
13 Q. Do you have any personal experience with a 11:40:47
14 Medela pump? 11:40:49
15 A. No. 11:40:51
16 Q. Did you identify the Medela pump to include 11:40:54
17 in your declaration? 11:40:57
18 A. No. I think counsel provided this 11:40:59
19 example. 11:41:03
20 Q. What about the other pumps identified in 11:41:55
21 your supplemental declaration, did you identify any 11:41:58
22 of those pumps or did counsel provide those to 11:42:01
23 you? 11:42:03
24 A. Yeah, I think the commercial pumps shown, 11:42:13
25 Pons, Penumbra, Medela, I believe these were 11:42:18

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1 provided by counsel. 11:42:22
2 Q. So just to clarify, you had said Pons is a 11:42:27
3 commercial pump but Pons is a patent; correct? 11:42:31
4 A. I seem to remember it's assigned to 11:42:38
5 Penumbra so I'm assuming it's led into their pump 11:42:42
6 but I'm not sure. 11:42:47
7 Q. Do you have any personal experience with 11:42:58
8 any of the pumps set forth in your supplemental 11:43:00
9 declaration -- '910 supplemental declaration? 11:43:03
10 A. I have not used any of these pumps -- these 11:43:09
11 specific pumps, no. 11:43:12
12 Q. Have you ever seen any of these in 11:43:14
13 person? 11:43:18
14 A. No. 11:43:18
15 Q. Other than the documents supplied with your 11:43:18
16 declaration, are you aware of how these pumps 11:43:22
17 operate or what they're used for? 11:43:25
18 MR. STOWELL: Objection. Vague. 11:43:27
19 THE WITNESS: I'm aware of how they operate 11:43:31
20 and what they're used for. 11:43:33
21 By MR. HAMILTON: 11:43:34
22 Q. And is that based on the documents supplied 11:43:34
23 with your declaration? 11:43:38
24 A. Yes. 11:43:49
25 Q. Is it based on anything else? 11:43:50

1 A. Well I did do a Google search recently to 11:43:56
2 find out what type of vacuum pump Penumbra MAX uses 11:44:00
3 inside its housing. Also the Medela pump. 11:44:07
4 Q. And do you know the answer to that 11:44:17
5 question? 11:44:19
6 A. I can't remember which is which but one of 11:44:22
7 them is a variable vein type vacuum pump and one is 11:44:25
8 a piston type pump. 11:44:30
9 Q. I'm going to hand you what's been marked as 11:44:47
10 Exhibit 1039. 11:44:50
11 Do you recognize Exhibit 1039? 11:45:06
12 A. Yes. 11:45:09
13 Q. And what is Exhibit 1039? 11:45:17
14 A. It's a brochure for the AXS, A-X-S, 11:45:29
15 Universal Aspiration Set. I can't read what the 11:45:41
16 date -- copyright date would be. 11:45:57
17 Q. So in looking at your declaration, the '910 11:46:02
18 supplemental declaration, paragraph 40, with respect 11:46:06
19 to this Medela pump, the only document you cite is 11:46:09
20 Exhibit 1039. 11:46:15
21 Do you see that? 11:46:18
22 A. Yes. 11:46:20
23 Q. In coming to your understanding of how the 11:46:21
24 Medela pump works, did you rely on any other 11:46:24
25 information beyond Exhibit 1039? 11:46:28

1 A. No. 11:46:34
2 Q. Focusing on the Penumbra Pump MAX that's on 11:48:42
3 page 21 of your declaration, is that pump used to 11:48:45
4 return blood to a patient during an aspiration 11:48:58
5 thrombectomy? 11:49:03
6 A. Yeah. My understanding is that pump is 11:49:27
7 used to evacuate the canister to perform a 11:49:29
8 thrombectomy procedure, not to reinfuse -- the same 11:49:35
9 pump isn't necessarily -- isn't used to reinfuse 11:49:40
10 blood to the patient. 11:49:44
11 Q. Do you know if blood that is aspirated from 11:49:50
12 a patient using the Penumbra Pump MAX is reinfused 11:49:52
13 into that patient? 11:49:59
14 A. I think it depends on the physician and 11:50:05
15 what they want to do and how much blood might be 11:50:06
16 removed during the procedure. 11:50:08
17 Q. Is the Penumbra Pump MAX designed so that 11:50:10
18 blood can be reinfused into a patient from the 11:50:14
19 collection canister found in that pump? 11:50:17
20 A. I'm sure there is a means to remove blood 11:50:23
21 from a collection canister if the patient -- if the 11:50:26
22 physician wanted to reinfuse it to the patient. 11:50:29
23 Q. And is it your understanding that a 11:50:31
24 physician would reinfuse blood from the Penumbra 11:50:33
25 Pump MAX that was collected during an aspiration 11:50:39

1 thrombectomy? 11:50:44
2 A. I think it depends on the physician and the 11:50:45
3 procedure and how much blood may have been collected 11:50:47
4 in the canister. 11:50:50
5 Q. Are you aware of any physician ever 11:50:51
6 reinfusing blood that was collected during an 11:50:54
7 aspiration thrombectomy with a Penumbra Pump MAX? 11:50:59
8 A. I haven't personally witnessed a procedure 11:51:04
9 with this pump, no. 11:51:06
10 Q. Are you aware of any procedure that's ever 11:51:10
11 been performed with this pump? 11:51:12
12 A. I presume it is a commercially -- it was a 11:51:26
13 commercially available pump at the time so I'm 11:51:29
14 presuming that it's been used many times 11:51:33
15 commercially. 11:51:35
16 Q. But you're not aware of any instance where 11:51:35
17 it's actually been used to perform a thrombectomy; 11:51:37
18 correct? 11:51:40
19 A. I haven't observed it myself, no. 11:51:42
20 Q. Are you aware of any instance where it's 11:51:44
21 actually been used for a thrombectomy? 11:51:46
22 A. I believe that's the indication for this 11:51:52
23 pump is to use for mechanic -- for aspiration 11:51:54
24 thrombectomy. 11:52:01
25 Q. So you're assuming it's been used for its 11:52:02

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1 indication; is that correct? 11:52:05
2 A. I'm assuming that it's used for its 11:52:07
3 indication as it says on page 22, "Pons describes 11:52:10
4 the prior art Penumbra mechanical thrombectomy 11:52:19
5 system which is a fully integrated system designed 11:52:22
6 specifically for mechanical thrombectomy by 11:52:25
7 aspiration." 11:52:28
8 Q. And beyond that statement, are you aware of 11:52:29
9 any actual use of this pump in a mechanical 11:52:32
10 thrombectomy by aspiration? 11:52:36
11 A. I have not witnessed any myself. 11:52:39
12 Q. Are you aware of any? 11:52:40
13 A. I'm -- I think I've answered the 11:52:44
14 question. 11:52:47
15 Q. And is that answer no? 11:52:50
16 A. I haven't witnessed any myself. I assume 11:52:52
17 that it has been used commercially. 11:52:55
18 Q. Are you aware of any instance in which 11:53:06
19 blood collected during a mechanical thrombectomy by 11:53:08
20 aspiration using the Penumbra pump was returned to a 11:53:14
21 patient? 11:53:19
22 A. I have not witnessed that, no. 11:53:25
23 Q. Do you believe a -- a physician would do 11:53:26
24 that? 11:53:28
25 A. I believe a physician would do that if it 11:53:31

1 was a significant amount of blood and it made sense 11:53:33
2 for the patient to give it back. 11:53:38
3 Q. Do you believe the Penumbra Pump MAX is 11:53:49
4 designed so that a physician can reinfuse blood 11:53:51
5 that's been collected during a mechanical 11:53:54
6 thrombectomy by aspiration using that pump? 11:53:57
7 A. Can you repeat the question. 11:54:00
8 Q. Do you believe the Penumbra Pump MAX is 11:54:02
9 designed so that a physician can reinfuse blood that 11:54:04
10 has been collected during a mechanical thrombectomy 11:54:08
11 by aspiration using the Penumbra Pump MAX? 11:54:12
12 A. I certainly believe that it would be 11:54:23
13 designed to be able to remove the blood from the 11:54:26
14 canister, collected in a syringe, and given back to 11:54:30
15 the patient. 11:54:36
16 Q. And that's your understanding in forming 11:54:36
17 your opinions in your -- in this matter -- in these 11:54:38
18 matters? 11:54:43
19 A. I certainly think there probably would be 11:54:49
20 connectors such that the physician could remove 11:54:52
21 blood into a syringe and provide it back to the 11:54:56
22 patient. 11:55:03
23 Q. Are you assuming that there's connectors or 11:55:03
24 are you aware of connectors actually existing to do 11:55:08
25 that? 11:55:13

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1 A. I'm assuming that that would be possible 11:55:14
2 with this system. 11:55:15
3 Q. And that was your understanding in forming 11:55:20
4 your opinions in these matters; correct? 11:55:22
5 A. Well that aspect I don't think was a 11:55:32
6 significant feature of this declaration. We provide 11:55:34
7 this example to show that a person of skill in the 11:55:45
8 art would have had several options to choose from 11:55:48
9 when choosing a vacuum pump. 11:55:54
10 MR. STOWELL: We have about another hour if 11:56:59
11 you want. 11:57:01
12 MR. HAMILTON: Do you want a break? It's 11:57:01
13 noon. I'm happy to break for lunch. 11:57:04
14 THE WITNESS: Yeah, whenever is good stop 11:57:06
15 -- stopping time. 11:57:11
16 MR. HAMILTON: Yeah, why don't we -- yeah, 11:57:12
17 don't we take a break. 11:57:15
18 THE VIDEOGRAPHER: We are going off the 11:57:16
19 record at 11:57. 11:57:17
20 (Lunch recess.) 12:42:40
21 THE VIDEOGRAPHER: We are back on the 12:43:07
22 record at 12:43. 12:43:07
23 By MR. HAMILTON: 12:43:13
24 Q. Mr. Thornton, do you understand you're 12:43:13
25 still under oath? 12:43:14

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1 A. Yes. 12:43:15
2 Q. Did you communicate with anyone in any way 12:43:16
3 regarding the subject of these matters during the 12:43:18
4 break? 12:43:21
5 A. No. 12:43:22
6 Q. Did you review any documents during the 12:43:23
7 break? 12:43:25
8 A. No. 12:43:25
9 Q. If you go to paragraph -- let's look at 12:43:47
10 your '910 supplemental declaration, paragraph 29, 12:43:50
11 and I'm going to ask you a question about the top of 12:43:56
12 page 14 which is at the end of paragraph 29. Let me 12:44:01
13 know when you're ready for the question. 12:44:29
14 A. Okay. 12:44:52
15 Q. Do you see the phrase "cardiopulmonary 12:44:53
16 bypass pumps" on the top of page 14? 12:44:57
17 A. Yes. 12:45:00
18 Q. Do you understand what a cardiopulmonary 12:45:02
19 bypass pump is? 12:45:05
20 A. Yes. 12:45:07
21 Q. Do you generally understand how those types 12:45:08
22 of pumps operate? 12:45:10
23 A. Generally. 12:45:13
24 Q. What is a cardiopulmonary bypass pump? 12:45:17
25 A. It's a pump used to perform cardiopulmonary 12:45:22

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1 bypass during open heart surgery. 12:45:26
2 Q. Does that pump allow the circulation of 12:45:36
3 blood? 12:45:39
4 MR. STOWELL: Objection. Vague. 12:45:42
5 THE WITNESS: The pumps are designed to 12:45:51
6 take blood from the venous circulation, pump it 12:45:57
7 through an oxygenator, and return it back to the 12:46:03
8 patient. 12:46:08
9 By MR. HAMILTON: 12:46:13
10 Q. Do those pumps generally have an inlet 12:46:13
11 port? 12:46:16
12 A. Yes. 12:46:21
13 Q. And is that where those pumps take blood? 12:46:22
14 A. The inlet port is connected to the return 12:46:32
15 cannula, the -- the venous cannula that is inserted 12:46:37
16 in the patient. 12:46:40
17 Q. So does the inlet port receive blood or 12:46:42
18 expel blood? 12:46:47
19 A. Receives blood from the venous cannula. 12:46:49
20 Q. And would the cardiopulmonary bypass pump 12:46:53
21 create negative pressure at the inlet port? 12:46:59
22 A. They do provide negative pressure or vacuum 12:47:07
23 in order to pull the blood into the pump. 12:47:09
24 Q. And is that negative pressure provided at 12:47:13
25 the inlet port? 12:47:16

1 A. Sure. It creates a negative pressure at 12:47:29
2 the inlet port which is attached to the cannula in 12:47:32
3 the patient. 12:47:35
4 Q. And would a cardiopulmonary bypass pump 12:47:36
5 have a -- a discharge port? 12:47:39
6 A. Yes. 12:47:42
7 Q. And would the cardiopulmonary bypass pump 12:47:44
8 create positive pressure at the discharge pump? 12:47:49
9 A. Yes. 12:47:52
10 Q. For catheters used for aspirating, 12:48:11
11 generally speaking, would a larger catheter aspirate 12:48:16
12 more blood than a smaller catheter in terms of 12:48:21
13 French size? 12:48:24
14 A. Given the same vacuum applied to the 12:48:29
15 catheter, yes. 12:48:32
16 Q. Is there a French size you would consider 12:48:41
17 small for an aspiration catheter? 12:48:44
18 A. It depends on the application, the location 12:48:50
19 being aspirated. 12:48:55
20 Q. So it depends on the context to determine 12:49:07
21 whether a catheter is large or small for aspiration; 12:49:10
22 is that right? 12:49:16
23 A. Large and small and a wide range of 12:49:19
24 definitions. 12:49:23
25 Q. So for treating a clot in the cerebral 12:49:25

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1 vasculature, would a 8 French catheter be considered 12:49:30
2 large or small? 12:49:34
3 A. I don't know. I think there are ones that 12:49:38
4 are smaller and larger. 12:49:40
5 Q. What about treating a clot in the pulmonary 12:49:57
6 system, would a 8 French catheter be considered 12:50:02
7 large or small? 12:50:05
8 A. I think typically they would use a larger 12:50:08
9 catheter size than an 8 French to treat most 12:50:12
10 pulmonary embolisms. 12:50:19
11 Q. How much larger? 12:50:22
12 A. I think some of these patents discuss sizes 12:50:28
13 up to maybe 22 French. So there's a wide range that 12:50:31
14 could be used I believe. 12:50:38
15 Q. I'm going to hand you what has been 12:51:43
16 previously marked Exhibit 1068 in IPR2025-01025. 12:51:45
17 Do you recognize Exhibit 1068? 12:52:00
18 A. Yes. 12:52:03
19 Q. What is Exhibit 1068? 12:52:05
20 A. It's a brochure or ordering -- ordering 12:52:16
21 information for the Penumbra MAX pump. 12:52:20
22 Q. And is this the same Penumbra Pump MAX 12:52:25
23 referenced in paragraph 38 of your '910 supplemental 12:52:30
24 declaration? 12:52:35
25 A. Yes. Certainly the image looks the same as 12:52:49

1 what we have on page 21. 12:52:52
2 Q. And, in fact, your declaration in the first 12:53:11
3 instance is the 1068? 12:53:15
4 A. Yes. 12:53:19
5 Q. Has the Penumbra Pump MAX; correct? 12:53:19
6 A. Yes. 12:53:24
7 Q. Do you see on page 1 of Exhibit 1068 the 12:53:33
8 notation on the right saying, "Large 0.088 inch ID 12:53:40
9 reinforced tubing for efficient flow?" 12:53:48
10 A. Yes. 12:53:50
11 Q. Do you have an understanding for what .088 12:54:02
12 inch ID is in French size? 12:54:10
13 A. If you divide by .01312, you can calculate 12:54:16
14 French size. 12:54:21
15 Q. And what is the French size for a .088 inch 12:54:26
16 ID reinforced tubing? 12:54:32
17 A. I don't want to do the math in my head 12:54:34
18 right now. 12:54:36
19 Q. Why don't I -- I'll -- I'll do it for you 12:54:38
20 and you tell me if this sounds about right. 12:54:41
21 So did you say you divide that number by -- 12:54:49
22 A. .01312, I believe. 12:54:52
23 Q. 6.7? Does that sound about right? 12:54:59
24 A. Seems pretty close. I notice on the next 12:55:04
25 page where they list an inner diameter of .088 12:55:07

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1 inches they list a distal OD of 8 French so it seems 12:55:14
2 reasonable to have something close to 7 French 12:55:18
3 inside diameter. 12:55:23
4 Q. What's the largest French size listed on 12:55:24
5 the second page? 12:55:27
6 A. I think that 8 French example that I see on 12:55:34
7 the bottom half of the page. 12:55:39
8 Q. And that is the external diameter; 12:55:42
9 correct? 12:55:44
10 A. Yes. It says distal OD. 12:55:45
11 Q. So the internal diameter would be less than 12:55:47
12 that and then 7 is not a -- not a bad estimate of 12:55:50
13 what that probably is; is that right? 12:55:53
14 A. Yes. It's .088 inches. 12:55:56
15 Q. And it can't be larger than 8 French; 12:55:59
16 right? 12:56:01
17 A. Correct. 12:56:02
18 Q. And what's the smallest French shown on 12:56:03
19 that page 2? 12:56:08
20 A. There is only one sheath -- there's only 12:57:00
21 one sheath size listed for the long sheath is .088 12:57:03
22 inner diameter. They show a select catheter at .04 12:57:09
23 inches inside diameter. Microcatheter lists even 12:57:14
24 smaller, .025 inner diameter. That's the smallest 12:57:26
25 number I see. 12:57:35

1 Q. So is it fair to say that this document 12:57:36
2 shows catheters with the French size between 3 and 8 12:57:40
3 approximately? 12:57:48
4 A. Well, the microcatheter goes within the 12:57:48
5 sheath but, yeah, it's 2.6 French OD up to 8 French 12:57:55
6 OD for the long sheaths. 12:58:01
7 Q. I'm going to hand you another document. 12:58:51
8 This one has been marked Exhibit 1020. 12:58:53
9 Do you recognize Exhibit 1020? 12:59:06
10 A. Yes. 12:59:18
11 Q. Is this the Brady reference referred to in 12:59:19
12 paragraph 31 of your '910 supplemental 12:59:24
13 declaration? 12:59:32
14 A. Yes. 12:59:32
15 Q. If you would turn to page 9 of Exhibit 12:59:49
16 1020. If you go down to line 25. 12:59:53
17 Do you see reference to a large aspiration 13:00:13
18 lumen? 13:00:15
19 A. Yes. 13:00:27
20 Q. And Brady discloses that that large 13:00:28
21 aspiration lumen has a cross-sectional area greater 13:00:33
22 equivalent to .030 diameter. 13:00:37
23 Do you see that? 13:00:41
24 A. Yes. 13:00:42
25 Q. Is that about 2.3 French? 13:00:45

1 A. Something less than 2.6 French is what it 13:01:33
2 would -- 13:01:38
3 Q. And then -- 13:01:39
4 A. 2.4, 2.5 French probably. 13:01:39
5 Q. Thank you. Two lines down, line 28, do you 13:01:42
6 see .040 diameter lumen? 13:01:46
7 A. Yes. 13:01:49
8 Q. Is that about 3 French? 13:01:49
9 A. Yeah. I seem to remember 3 French is 13:02:04
10 around 039 so pretty close, yeah. 13:02:07
11 Q. I'm going to hand you what's marked Exhibit 13:02:25
12 1038. 13:02:31
13 Do you recognize Exhibit 1038? 13:03:00
14 A. Yes. 13:03:11
15 Q. What is Exhibit 1038? 13:03:12
16 A. It's a notice from the FDA to Penumbra in 13:03:43
17 March of 2018 regarding their 510(k) review for the 13:03:47
18 Indigo aspiration system Penumbra engine pump and 13:04:01
19 canister. 13:04:06
20 Q. In that context -- in the context of 13:04:10
21 Exhibit 1038, do you understand what predicate 13:04:12
22 device means? 13:04:16
23 A. Yes. 13:04:21
24 Q. What does predicate device mean in that 13:04:21
25 context? 13:04:24

1 A. On their FDA regulations for a 510(k) 13:04:27
2 pre-market notification, you need to show 13:04:30
3 substantial equivalence to a existing approved 13:04:39
4 device. 13:04:43
5 Q. So if you turn to page 2 of 8. Labeled 2 13:04:44
6 of 8. I don't believe it's the second page of the 13:04:50
7 document but at the bottom it's labeled 2 of 8. 13:04:55
8 Do you see the heading "Predicate 13:04:59
9 Comparison?" 13:05:00
10 A. Yes. 13:05:04
11 Q. And if you go down to "Aspiration Pump." 13:05:05
12 What is the predicate device in this 13:05:11
13 document? 13:05:13
14 A. Penumbra Pump MAX and canister. 13:05:19
15 Q. And is that the Penumbra Pump MAX 13:05:22
16 referenced in paragraph 38 of your '910 supplemental 13:05:29
17 declaration? 13:05:32
18 A. It has the same name. I'm not completely 13:05:38
19 sure if they had other iterations along the years. 13:05:41
20 So I'm not sure. 13:05:46
21 Q. Do you have any reason to doubt if it's the 13:05:47
22 same or to know one way or the other? 13:05:49
23 A. Yeah, I don't know. They would have to 13:06:32
24 provide catalog numbers and more specifics to be 13:06:34
25 sure but it certainly could be the same -- same 13:06:37

1 device. 13:06:43
2 Q. And you see the second and third column, 13:06:44
3 it's titled "Predicate Device" and "Subject Device?" 13:06:46
4 A. Yes. 13:06:51
5 Q. Is that comparing the predicate device to 13:06:52
6 the new or updated device in terms of if they're the 13:06:56
7 same or different? 13:07:00
8 A. Yeah, that's how FDA approves a 510(k) 13:07:08
9 application. 13:07:16
10 Q. So with respect to say a particular 13:07:16
11 feature, and let's just say -- take the aspirational 13:07:18
12 pump and frequency. 13:07:22
13 Do you see that? 13:07:25
14 A. Yes. 13:07:30
15 Q. For frequency, the FDA has determined that 13:07:31
16 the Penumbra Pump MAX and canister is the same as 13:07:35
17 the Penumbra engine pump -- excuse me -- engine pump 13:07:38
18 and canister; is that right? 13:07:41
19 A. It says "same," yes. 13:07:43
20 Q. And what does that mean, "same?" 13:07:44
21 A. That it's substantially equivalent in FDA 13:07:51
22 language. 13:07:54
23 Q. So it would operate essentially in the same 13:07:55
24 way? 13:07:57
25 A. It meets FDA's requirements for substantial 13:08:00

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1 equivalence. 13:08:04
2 Q. And what are the requirements for 13:08:05
3 substantial equivalence? 13:08:08
4 A. There's a big long document of 510(k) 13:08:11
5 regulations that are shown there on page 1 of 8 that 13:08:15
6 would expand on those requirements and 13:08:19
7 definitions. 13:08:25
8 Q. So let's look at the next row, 13:08:25
9 "Sterilization." 13:08:30
10 Do you see that? 13:08:31
11 A. Yes. 13:08:32
12 Q. For the Penumbra Pump MAX and canister it 13:08:33
13 says, "not sterile." 13:08:35
14 Do you understand what that means? 13:08:37
15 A. Yes. 13:08:38
16 Q. What does that mean? 13:08:38
17 A. That it's provided in the non-sterile 13:08:40
18 state. 13:08:43
19 Q. And the Penumbra engine pump and canister 13:08:46
20 it says "same;" correct? 13:08:49
21 A. Yes. 13:08:52
22 Q. So for the state of the Penumbra engine 13:08:52
23 pump and canister, that would also be non-sterile 13:08:55
24 just like the Penumbra Pump MAX and canister; 13:08:58
25 correct? 13:09:03

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1 A. Yes. 13:09:03
2 Q. If the Penumbra Pump MAX and canister are 13:09:26
3 non-sterile, would a person of ordinary skill in the 13:09:29
4 art reintroduce blood into a patient that's been 13:09:32
5 collected by that canister? 13:09:36
6 A. Not if the blood -- not if it's not 13:10:10
7 sterile. 13:10:13
8 Q. When using a catheter for aspirating in a 13:10:48
9 thrombectomy procedure, is it desirable for that 13:10:53
10 catheter to clog? 13:10:57
11 A. No. 13:11:01
12 Q. Would one skilled in the art design a 13:11:02
13 device so that the catheter clogs or -- or increases 13:11:05
14 the chance -- the chances that the catheter clogs? 13:11:09
15 A. That wouldn't be the design intent, no. 13:11:13
16 Q. It would be the opposite, right, you would 13:11:16
17 try to design a device that doesn't clog; correct? 13:11:17
18 A. Yes. But depending on the size of the 13:11:25
19 clot, it not infrequently happens and other 13:11:27
20 maneuvers have to be performed. 13:11:32
21 MR. HAMILTON: All right. Well, thank you 13:11:38
22 for your time. I have no further questions. 13:11:39
23 MR. STOWELL: I don't have any questions 13:11:41
24 either. 13:11:43
25 THE VIDEOGRAPHER: All right. This marks 13:11:44

1 the end of the deposition of Troy Lane Thornton. We 13:11:45
2 are going off the record at 13:11. 13:11:48
3 (Proceedings concluded.)
4 ---o0o---
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1 CERTIFICATE OF STENOGRAPHIC REPORTER
2
3
4 I, BURGUNDY B. RYAN, a Certified Shorthand
5 Reporter, hereby certify that the witness in the
6 foregoing deposition,
7 TROY LANE THORNTON,
8 was by me duly sworn to tell the truth, the whole
9 truth, and nothing but the truth, in the
10 within-entitled cause; that said deposition was
11 taken at the time and place therein named; that the
12 testimony of said witness was stenographically
13 reported by me, a disinterested person, and was
14 thereafter transcribed into typewriting.
15 I further certify that I am not of counsel
16 or attorney for either or any of the parties to said
17 deposition, nor in any way interested in the outcome
18 of the cause named in said caption.
19
20 DATED: Friday, July 3, 2026.
21
22
23 Burgundy B. Ryan, CSR No. 11373, RPR
24
25

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