


Trial v04

Designation List Report

	Holste, Joerg	2012-12-14
	Holste, Joerg	2012-12-15
	Holste, Joerg	2013-07-29

Our Designations	00:39:06
TOTAL RUN TIME	00:39:06

-  Documents linked to video:
- PX61
 - PX71
 - PX97
 - PX113
 - PX133
 - PX208

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DESIGNATION	SOURCE	DURATION	ID
8:14 - 8:19	Holste, Joerg 2012-12-14 8:14 Q. Guten morgen, Dr. Holste. 8:15 A. (In German) Guten morgen. 8:16 Q. My name is Ben Anderson, and I'm 8:17 going to be taking your deposition today. 8:18 Do you understand that? 8:19 A. Yes.	00:00:18	Holste.1
9:21 - 10:09	Holste, Joerg 2012-12-14 9:21 Q. Where did you grow up? 9:22 A. I grew up in Germany, in Lower 9:23 Saxony, near Hanover. 9:24 Q. And you currently live in Hamburg? 9:25 A. I currently live in Hamburg, yes. 10:01 Q. And as you were growing up in school, 10:02 did you take English classes, English language 10:03 classes? 10:04 A. Yes. 10:05 Q. You can speak English. Correct? 10:06 A. I can speak English, yes. 10:07 Q. And you understand English, too. 10:08 Correct? 10:09 A. I understand English, yes.	00:00:47	Holste.2
10:24 - 11:10	Holste, Joerg 2012-12-14 10:24 Q. And Johnson & Johnson and Ethicon 10:25 have facilities in various countries around the 11:01 world. Correct? 11:02 A. That's correct. 11:03 Q. And you have worked with American 11:04 colleagues at Ethicon here in the United States. 11:05 Correct? 11:06 A. That is correct. 11:07 Q. And you have met with US 11:08 English-speaking colleagues in Germany from Ethicon 11:09 as well. Correct? 11:10 A. That is correct.	00:00:53	Holste.3
22:23 - 23:06	Holste, Joerg 2012-12-14 22:23 Q. Was there ever a surgical or clinical 22:24 pathologist at Norderstedt since you've been there 22:25 since 1983 who actually reviewed histopathological	00:01:00	Holste.4

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DESIGNATION	SOURCE	DURATION	ID
	23:01 samples from explanted mesh?		
	23:02 A. I conducted those evaluations.		
	23:03 Q. You conducted histopathological		
	23:04 evaluations for Ethicon at the Norderstedt facility		
	23:05 of explanted surgical meshes?		
	23:06 A. That is correct.		
23:15 - 23:18	Holste, Joerg 2012-12-14	00:00:22	Holste.5
	23:15 Q. And you are not a general		
	23:16 pathologist. Correct?		
	23:17 A. My education is veterinarian, and I		
	23:18 have specialized in pathology of inflammation.		
28:07 - 28:12	Holste, Joerg 2012-12-14	00:00:15	Holste.6
	28:07 Q. And you and your colleagues at		
	28:08 Ethicon Norderstedt have worked closely with		
	28:09 Dr. Klinge and Dr. Schumpelick and the Aachen group		
	28:10 in the '90s and in the 2000s on surgical mesh		
	28:11 projects. Correct?		
	28:12 A. That is correct.		
31:01 - 31:09	Holste, Joerg 2012-12-14	00:00:41	Holste.7
	31:01 Q. You've been working with Dr. Klinge		
	31:02 since the early 1990s. Correct?		
	31:03 A. That is correct.		
	31:04 Q. And while he was a consultant to		
	31:05 Ethicon, you met with him in person numerous times.		
	31:06 Correct?		
	31:07 A. How often is "numerous times"?		
	31:08 Q. Dozens?		
	31:09 A. Over the years, yes.		
31:23 - 32:05	Holste, Joerg 2012-12-14	00:00:43	Holste.8
	31:23 Q. And you've attended conferences over		
	31:24 the years at which Dr. Klinge spoke. Correct?		
	31:25 A. That is correct.		
	32:01 Q. And you've attended meetings, both in		
	32:02 Norderstedt and in Aachen, in which Dr. Klinge		
	32:03 presented findings of various projects he was		
	32:04 working on with Ethicon. Correct?		
	32:05 A. That is correct.		
32:11 - 32:14	Holste, Joerg 2012-12-14	00:00:21	Holste.9
	32:11 Q. You personally, Dr. Holste, have		

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DESIGNATION	SOURCE	DURATION	ID
	32:12 worked with Dr. Klosterhalfen since the 1990s as 32:13 well. Correct? 32:14 A. That is correct.		
62:05 - 62:21	Holste, Joerg 2012-12-14	00:01:29	Holste.10
	62:05 Q. You started working for Ethicon in 62:06 October 1983? 62:07 A. That is correct. 62:08 Q. Had you ever performed any work 62:09 related to surgical meshes or surgical sutures prior 62:10 to your work with -- beginning your work with 62:11 Ethicon in October 1983? 62:12 A. No. 62:13 Q. Prior to becoming employed by Ethicon 62:14 in October 1983, had you ever performed any work 62:15 related to polymers intended for human use as a 62:16 medical device? 62:17 A. No. 62:18 Q. When you were hired by Ethicon in 62:19 October 1983, what was your understanding as to the 62:20 relationship between Ethicon in Germany and Ethicon 62:21 in the United States?		
62:25 - 63:03	Holste, Joerg 2012-12-14	00:00:21	Holste.11
	62:25 Q. When you were hired into Ethicon in 63:01 October 1983, what was your understanding as to 63:02 the relationship between Ethicon and Johnson & 63:03 Johnson?		
63:05 - 63:06	Holste, Joerg 2012-12-14	00:00:03	Holste.12
	63:05 A. Ethicon is a daughter company of 63:06 Johnson & Johnson.		
66:04 - 66:12	Holste, Joerg 2012-12-14	00:00:37	Holste.13
	66:04 Q. Over the last 30 years that you've 66:05 been employed at Ethicon as the head of the 66:06 preclinical department, when Ethicon meshes have 66:07 been explanted from human beings and returned to 66:08 Ethicon for analysis, would you agree that 66:09 Dr. Klosterhalfen has primarily been the pathologist 66:10 that has performed the pathological analysis and the 66:11 histopathological analysis of those returned 66:12 explanted Ethicon surgical meshes?		

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DESIGNATION	SOURCE	DURATION	ID
66:14 - 66:18	Holste, Joerg 2012-12-14 66:14 A. He did that as long as he was working 66:15 for us as a consultant, yes. 66:16 Q. He was the primary pathologist who 66:17 reviewed Ethicon explanted surgical meshes up until 66:18 the time he left. Correct?	00:00:22	Holste.14
66:20 - 66:20	Holste, Joerg 2012-12-14 66:20 A. Yes.	00:00:01	Holste.15
67:14 - 67:19	Holste, Joerg 2012-12-14 67:14 Q. Dr. Holste, as head of the 67:15 preclinical department at Ethicon in Norderstedt 67:16 over the last 30 years, have you been involved in 67:17 various surgical mesh product development for 67:18 Ethicon? 67:19 A. Yes, I was. I have been.	00:00:32	Holste.16
72:07 - 72:15	Holste, Joerg 2012-12-14 72:07 Q. And leaving less material in the 72:08 patient's tissues is important because it will 72:09 reduce the amount of foreign body reaction. 72:10 Correct? 72:11 A. That is correct. 72:12 Q. And another advantage of leaving less 72:13 mesh material in the human tissue for the patient is 72:14 that there will be less of an inflammatory reaction. 72:15 Correct?	00:00:24	Holste.17
72:17 - 72:17	Holste, Joerg 2012-12-14 72:17 A. That is correct.	00:00:03	Holste.18
72:18 - 72:21	Holste, Joerg 2012-12-14 72:18 Q. And for surgical meshes to have less 72:19 of an inflammatory response in the patient's post 72:20 tissue, it will also reduce the risk of contraction 72:21 or shrinkage of the mesh. Correct?	00:00:16	Holste.106
72:23 - 73:04	Holste, Joerg 2012-12-14 72:23 A. That is connected. If you have a 72:24 stronger tissue reaction, you also have a stronger 72:25 fibrotic reaction. That is correct. 73:01 Q. And if you have a stronger fibrotic 73:02 reaction, you increase the risk that it will shrink	00:00:18	Holste.19

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	73:03 or contract the mesh. Correct?		
	73:04 A. That is correct.		
81:16 - 81:21	Holste, Joerg 2012-12-14	00:00:16	Holste.20
	81:16 Q. And at the time that the concept of		
	81:17 fibrotic bridging was brought forth to the		
	81:18 scientific community, both Klinge and Klosterhalfen		
	81:19 were consultants for Ethicon on their Vypro mesh.		
	81:20 Correct, sir?		
	81:21 A. That's correct.		
82:07 - 82:16	Holste, Joerg 2012-12-14	00:00:37	Holste.21
	82:07 Q. My question		
	82:08 was that during this time period in the late '90s		
	82:09 when Professor Klosterhalfen and Dr. Klinge were		
	82:10 consultants to Ethicon, there were Ethicon-funded		
	82:11 studies during the development of Vypro in which		
	82:12 Dr. Klosterhalfen and Dr. Klinge stated that pore		
	82:13 sizes less than one millimeter in polypropylene		
	82:14 surgical meshes leads to fibrotic bridging. Correct?		
	82:15 A. That should have been during the		
	82:16 development of Vypro, yes, that's correct.		
87:07 - 87:13	Holste, Joerg 2012-12-14	00:00:24	Holste.25
	87:07 Q. One of the things that they did		
	87:08 through their research was Dr. Klinge and		
	87:09 Klosterhalfen looked at reducing the amount of		
	87:10 material that would be left in a patient's body		
	87:11 after a hernia repair, so that less material would		
	87:12 create less of an inflammatory response and less of		
	87:13 a foreign body reaction. Correct?		
87:15 - 87:19	Holste, Joerg 2012-12-14	00:00:17	Holste.26
	87:15 A. That is correct.		
	87:16 Q. And what they found was that the		
	87:17 first generation surgical meshes like Marlex and		
	87:18 Prolene were too strong for their intended purpose		
	87:19 of supporting the abdominal wall tissues. Correct?		
87:21 - 88:12	Holste, Joerg 2012-12-14	00:00:54	Holste.27
	87:21 A. As far as I know, that was one of the		
	87:22 backgrounds, yes.		
	87:23 Q. And Vypro actually had 30 percent of		
	87:24 the weight of the old Prolene mesh. Correct?		

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DESIGNATION	SOURCE	DURATION	ID
	87:25 A. Yes.		
	88:01 Q. And Vypro had pore sizes that were 5		
	88:02 to 600 percent larger than the pore sizes of Prolene		
	88:03 mesh. Correct?		
	88:04 A. That is correct.		
	88:05 Q. With the development of the Vypro		
	88:06 mesh between Klinge and Klosterhalfen and Ethicon		
	88:07 was born what we call the second generation surgical		
	88:08 meshes. Correct?		
	88:09 A. The macroporous meshes, yes. That's		
	88:10 correct.		
	88:11 Q. And that was what was termed the		
	88:12 lightweight, large pore concept. Correct?		
88:14 - 88:19	Holste, Joerg 2012-12-14	00:00:16	Holste.28
	88:14 A. That's correct.		
	88:15 Q. So in addition to the concept of		
	88:16 fibrotic bridging and scar plates, the work of Dr.		
	88:17 Klinge and Dr. Klosterhalfen with Ethicon on the		
	88:18 Vypro work also led to the lightweight, large pore		
	88:19 concept. Correct?		
88:21 - 89:07	Holste, Joerg 2012-12-14	00:00:40	Holste.29
	88:21 A. That's correct. Yes.		
	88:22 Q. Are you aware of the Amid		
	88:23 classification of hernia meshes?		
	88:24 A. I've heard about it, yes.		
	88:25 Q. And that Amid classification came out		
	89:01 in 1997. Does that refresh your memory?		
	89:02 A. Yes.		
	89:03 Q. And at the time that the Amid		
	89:04 classification came out, a Type 1 so-called		
	89:05 macroporous mesh was a pore size larger than 75		
	89:06 microns. Do you remember that?		
	89:07 A. Yes. That was published that way.		
90:04 - 90:16	Holste, Joerg 2012-12-14	00:00:57	Holste.30
	90:04 Q. Because the second generation of		
	90:05 lightweight, large pore meshes came about a year		
	90:06 later, in 1998, with Klinge and Klosterhalfen's work		
	90:07 with your company. Correct?		
	90:08 A. That's correct. Yes.		
	90:09 Q. So even though Amid's classification		

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DESIGNATION	SOURCE	DURATION	ID
	90:10 sought to define "large pore" as 75 microns or 90:11 greater, with the development of the second 90:12 generation of lightweight, large pore meshes, the 90:13 work that Klinge and Klosterhalfen did with Ethicon 90:14 found that actually large pore meshes greater than 90:15 one millimeter were actually safer for patients than 90:16 pore sizes less than 1 millimeter. Correct?		
90:18 - 90:21	Holste, Joerg 2012-12-14	00:00:18	Holste.31
	90:18 A. At that time the new development of 90:19 Vypro took place, and they had significantly larger 90:20 pore sizes, and as far as I can recall, it was two 90:21 to three millimeters.		
94:12 - 94:18	Holste, Joerg 2012-12-14	00:00:31	Holste.32
	94:12 Q. Have you ever seen anywhere in the 94:13 scientific literature a study by any surgeon, any 94:14 scientist in the world who studied explanted 94:15 surgical meshes from human beings who refuted the 94:16 theory by Klinge and Klosterhalfen that pore sizes 94:17 of polypropylene surgical meshes less than 1 94:18 millimeter in diameter lead to fibrotic bridging?		
94:20 - 95:05	Holste, Joerg 2012-12-14	00:00:43	Holste.33
	94:20 Q. Anyone in the world. 94:21 A. I'm not aware of any. 94:22 Q. Are you aware of anyone in your 30 94:23 years of service at Ethicon and Norderstedt within 94:24 your company who has done an explant study of 94:25 polypropylene surgical meshes and looked at the 95:01 fibrotic bridging of various pore sizes who refuted 95:02 the work of Klinge and Klosterhalfen done with 95:03 Ethicon that pore sizes less than one millimeter in 95:04 diameter, surgical polypropylene meshes creates 95:05 fibrotic bridging?		
95:07 - 95:07	Holste, Joerg 2012-12-14	00:00:03	Holste.34
	95:07 A. I'm not aware of any.		
99:10 - 100:02	Holste, Joerg 2012-12-14	00:01:09	Holste.35
	99:10 Q. One way to discuss biocompatibility 99:11 in terms of whether a permanent medical implant in a 99:12 person's body will be biocompatible with the host 99:13 would be: A medical device that's going to be		

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	99:14 implanted permanently in a human being is		
	99:15 biocompatible if it performs its intended function		
	99:16 with the least amount of short- or long-term		
	99:17 complications.		
	99:18 Would that be an acceptable		
	99:19 definition?		
	99:20 A. That's an acceptable definition, yes.		
	99:21 Q. And in order for a surgical mesh to		
	99:22 be biocompatible and to perform its intended		
	99:23 function in the host with the least amount of short-		
	99:24 and long-term complications, it needs to adapt to		
	99:25 the physiological environment in which it's		
	100:01 implanted. True?		
	100:02 A. That's correct.		
153:11 - 153:14	Holste, Joerg 2012-12-14	00:00:11	Holste.36
	153:11 Q. So a severe inflammatory reaction and		
	153:12 scar contraction can cause severe contraction of the		
	153:13 mesh. Correct?		
	153:14 A. Yes.		
154:06 - 154:09	Holste, Joerg 2012-12-14	00:00:08	Holste.37
	154:06 Q. And so the greater the inflammatory		
	154:07 response, and the greater the scar contraction, the		
	154:08 greater the bunching and shrinkage of this mesh.		
	154:09 Correct?		
154:11 - 154:11	Holste, Joerg 2012-12-14	00:00:02	Holste.38
	154:11 A. That is correct.		
231:21 - 232:19	Holste, Joerg 2012-12-15	00:01:19	Holste.39
	231:21 Q. Dr. Holste, yesterday we marked as		
	231:22 Exhibit 1 a copy of your curriculum vitae. Do you		
	231:23 remember that?		
	231:24 A. Yes.		
	231:25 Q. And Reference 29 to your CV was		
	232:01 "Hellhammer, Koehler, Holste; "Shrinking Meshes?		
	232:02 Ethicon GmbH, R&D Europe; Unpublished Report, 2001"		
	232:03 Reference 29.		
	232:04 Do you see that, sir?		
	232:05 A. Yes.		
	232:06 Q. And this was a report that you		
	232:07 contributed to in terms of authorship. Correct?		

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DESIGNATION	SOURCE	DURATION	ID
	232:08 A. Yes.		
	232:09 (Whereupon, Exhibit Plaintiffs-1298,		
	232:10 E-Mail Chain ending 3-13-2006 and Attachment, Bates		
	232:11 ETH.MESH.05446127 to 139 is marked for		
	232:12 identification by the reporter.)		
 PX71.1	232:13 Q. Handing you what I have marked as		
	232:14 Plaintiffs' Exhibit 1298, on the cover page is an		
	232:15 e-mail. If you would just go down with me to the		
	232:16 bottom, March 13, 2006 e-mail from Dieter Engel to		
	232:17 Quentin Manley, with a cc to Joerg Holste, and		
 PX71.1.1	232:18 the subject line is: "Mesh and Tissue Contraction		
	232:19 in Animal."		
232:22 - 232:22	Holste, Joerg 2012-12-15	00:00:02	Holste.40
	232:22 A. Yes.		
233:05 - 233:17	Holste, Joerg 2012-12-15	00:00:34	Holste.41
 PX71.1.2	233:05 Q. Okay. And in this e-mail, it says,		
	233:06 "Dear Quentin, there are numerous articles		
	233:07 published on shrinkage and we have also done some		
	233:08 work internally. Joerg Holste is the most		
	233:09 knowledgeable person on that question.		
	233:10 "Joerg, can you answer Quentin?		
	233:11 Regards, Dieter."		
	233:12 Did I read that correctly?		
	233:13 A. Yes.		
	233:14 Q. Were you considered at Ethicon in		
	233:15 March of 2006 to be the most knowledgeable person on		
	233:16 the question of mesh and tissue shrinkage or		
	233:17 contraction in animals?		
233:19 - 233:19	Holste, Joerg 2012-12-15	00:00:04	Holste.42
	233:19 A. For internal studies, yes.		
234:10 - 235:05	Holste, Joerg 2012-12-15	00:01:06	Holste.43
 PX71.1.3	234:10 Q. And you respond with attachments, and		
	234:11 you say: "Quentin, this was our scientific statement		
	234:12 on mesh shrinkage."		
	234:13 When you say "our," do you mean		
	234:14 Ethicon?		
	234:15 A. I was referring to the three authors		
	234:16 listed here, which is Mrs. Koehler, Mrs. Hellhammer		
	234:17 and myself.		

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DESIGNATION	SOURCE	DURATION	ID
	<p>234:18 Q. And all three of those authors, 234:19 including yourself, were employees of Ethicon at the 234:20 time of the publication in -- I'm sorry, at the time 234:21 of the report in 2001? 234:22 A. Yes. 234:23 Q. Okay. Then your next sentence is: 234:24 "Basically small pores, heavy weight meshes induce 234:25 more fibrotic, bridging tissue reaction causing more 235:01 mesh shrinkage during maturing of the collagenous 235:02 tissue. See my presentation about 235:03 biocompatibility." 235:04 Did I read that correctly? 235:05 A. Yeah.</p>		
 PX71.1.4			
 Clear			
237:25 - 238:05	<p>Holste, Joerg 2012-12-15</p> <p>237:25 Q. So as of 2001, internally at Ethicon, 238:01 you and two other employees, including one from the 238:02 mesh group, Brigitte Hellhammer, found it necessary 238:03 to write an internal article regarding mesh 238:04 shrinkage. Yes? 238:05 A. Yes.</p>	00:00:20	Holste.44
267:08 - 267:11	<p>Holste, Joerg 2012-12-15</p> <p>267:08 Q. You have less of an inflammatory 267:09 reaction and less shrinkage if you have larger pore 267:10 sizes. Correct? 267:11 A. Yes.</p>	00:00:08	Holste.47
268:16 - 268:19	<p>Holste, Joerg 2012-12-15</p> <p>268:16 Q. When you have larger pore sizes, the 268:17 mesh itself is more biocompatible with the tissues 268:18 in which it is implanted. Correct? 268:19 A. Yes.</p>	00:00:08	Holste.48
277:15 - 278:05	<p>Holste, Joerg 2012-12-15</p> <p>277:15 Q. So as of the time that you wrote this 277:16 paper in 2001, it appears that you respected the 277:17 work of Dr. Klinge. Correct? 277:18 A. Yes. 277:19 Q. It also appears that you as an 277:20 Ethicon employee in writing an article on shrinking 277:21 meshes in 2001 also relied upon the expertise of Dr. 277:22 Klinge in the area of shrinking meshes and</p>	00:00:49	Holste.49



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DESIGNATION	SOURCE	DURATION	ID
	277:23 inflammation and foreign body reaction. Correct?		
	277:24 A. Yes.		
	277:25 Q. And, in fact, although this was		
	278:01 written in 2001, you had circulated this e-mail five		
	278:02 years later, in March of 2006. Correct?		
	278:03 A. Yes.		
	278:04 Q. And nowhere in this e-mail, when you		
	278:05 attach the scientific statement --		
278:07 - 278:20	Holste, Joerg 2012-12-15	00:00:46	Holste.50
 PX71.1.5	278:07 Q. You say, "This was our scientific		
	278:08 statement on mesh shrinkage."		
	278:09 Did I read that correctly?		
	278:10 A. Yes.		
	278:11 Q. And nowhere in this e-mail do you		
	278:12 state to the people who you sent it to that you have		
	278:13 any reason to doubt the expertise and qualifications		
	278:14 of Dr. Klinge, do you?		
	278:15 A. Yes. That's correct.		
	278:16 Q. And you wouldn't have circulated this		
	278:17 to your colleagues who asked you for it if you		
	278:18 didn't believe that it was truthful, accurate, and		
	278:19 scientifically reliable. Correct?		
 Clear	278:20 A. That's correct.		
290:15 - 290:17	Holste, Joerg 2012-12-15	00:00:11	Holste.51
	290:15 Q. Mesh shrinkage for surgical meshes in		
	290:16 the human body that shrink 30 to 50 percent, that is		
	290:17 a long-term complication. Correct?		
290:19 - 290:19	Holste, Joerg 2012-12-15	00:00:02	Holste.52
	290:19 A. Yes.		
291:04 - 291:20	Holste, Joerg 2012-12-15	00:00:31	Holste.53
	291:04 According to Klinge and Klosterhalfen		
	291:05 in this article that you sent to your colleagues in		
	291:06 October of 2006, they believed that you needed a		
	291:07 pore size of greater than one millimeter in		
	291:08 diameter. Correct?		
	291:09 A. That's correct, yes.		
	291:10 Q. And in all of your dealings with		
	291:11 Klinge and Klosterhalfen in the '90s and the 2000s,		
	291:12 you understood that was their position. Correct?		

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	291:13 A. Yes.		
	291:14 Q. And they were consultants to Ethicon.		
	291:15 Correct?		
	291:16 A. Yes.		
	291:17 Q. They were consultants to Ethicon		
	291:18 regarding Ethicon's development of surgical meshes.		
	291:19 Correct?		
	291:20 A. Yes.		
292:25 - 293:05	Holste, Joerg 2012-12-15	00:00:14	Holste.54
	292:25 Q. So according to your consultants		
	293:01 Klinge and Klosterhalfen, in this article that		
	293:02 you're circulating to your colleagues in 2006, they		
	293:03 believed that small pores were less than one		
	293:04 millimeter in diameter. Correct?		
	293:05 A. Yes.		
298:21 - 298:23	Holste, Joerg 2012-12-15	00:00:08	Holste.55
	298:21 Q. Would you agree with me that a mesh		
	298:22 that shrinks and contracts like that in the human		
	298:23 body could be dangerous to a patient?		
298:25 - 299:03	Holste, Joerg 2012-12-15	00:00:06	Holste.56
	298:25 A. Yes.		
	299:01 Q. Okay. It could be dangerous to a		
	299:02 patient because it could cause nerve damage and		
	299:03 pain. Correct?		
299:05 - 299:05	Holste, Joerg 2012-12-15	00:00:03	Holste.57
	299:05 A. That can be assumed.		
299:12 - 299:22	Holste, Joerg 2012-12-15	00:00:42	Holste.58
	299:12 Q. Well, if an implant has been put in		
	299:13 the human body and now we're looking at an explant,		
	299:14 clearly someone went in and took the mesh out.		
	299:15 Correct, sir?		
	299:16 A. Yes.		
	299:17 Q. Part of the reason for the		
	299:18 contraction and the shrinkage of meshes like you see		
	299:19 in Figure A is when pore sizes are not large enough		
	299:20 and they cause fibrotic bridging and excessive		
	299:21 scarring and there's a scar plate formation.		
	299:22 Correct?		
299:24 - 300:03	Holste, Joerg 2012-12-15	00:00:19	Holste.59

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DESIGNATION	SOURCE	DURATION	ID
	299:24 A. A part, yes.		Holste.59
	299:25 Q. Okay. And that's due to a foreign		
	300:01 body reaction and the body's inflammatory response		
	300:02 to the mesh material. Correct?		
	300:03 A. Yes.		
304:20 - 305:03	Holste, Joerg 2012-12-15	00:00:37	Holste.60
 PX208.1	304:20 Q. I'm going to hand you what's been		
	304:21 previously marked in this litigation as Plaintiffs'		
	304:22 Exhibit 1160, and I wrote that in the corner there.		
	304:23 (A discussion is held off the		
	304:24 record.)		
 PX208.1.1	304:25 Q. This document says it's the "Ethicon		
	305:01 Expert Meeting, Meshes for Pelvic Floor Repair,		
	305:02 Friday, June 2, 2006; Location," something-1,		
	305:03 "Norderstedt, Meeting Room Forum."		
305:16 - 305:17	Holste, Joerg 2012-12-15	00:00:03	Holste.61
	305:16 You were at this meeting. Correct?		
	305:17 A. Yes.		
305:25 - 306:02	Holste, Joerg 2012-12-15	00:00:04	Holste.62
	305:25 Q. And Professor Klosterhalfen was there		
	306:01 as well. Yes?		
	306:02 A. Yes.		
306:17 - 307:21	Holste, Joerg 2012-12-15	00:01:25	Holste.63
 PX208.1.2	306:17 Q. Okay. And then if you look		
	306:18 underneath that, it says "Highlights from the		
	306:19 presentations." Let's turn to the next page, and if		
 PX208.2.1	306:20 you look at Number 3 at the top of the page, it says		
	306:21 "Contraction." Right?		
	306:22 A. Yes.		
 PX208.2.2	306:23 Q. And if you come down to "Biological		
	306:24 response to surgical mesh (Professor		
	306:25 Klosterhalfen)." Do you see that?		
	307:01 A. Yes.		
	307:02 Q. So these would be the things that --		
	307:03 or at least a highlight of some of the things that		
	307:04 he shared at that meeting that you attended.		
	307:05 Correct?		
	307:06 A. Yes.		
 PX208.2.4	307:07 Q. And he says there's a "huge surface		

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DESIGNATION	SOURCE	DURATION	ID
	307:08 area of meshes (...more than 300 meters of suture)"		
	307:09 material. "Even after 20 years, the tissue is still		
	307:10 reacting to the mesh."		
	307:11 Did you know prior to this meeting		
	307:12 that even after 20 years, that the human's tissue is		
	307:13 still reacting biologically to the mesh?		
	307:14 A. Yes.		
 PX208.2.5	307:15 Q. "Fibrosis is responsible for		
	307:16 complications in mesh usage."		
	307:17 And you knew that to be true even		
	307:18 before you attended this meeting, that fibrosis was		
	307:19 responsible for complications in mesh usage.		
	307:20 Correct?		
 Clear	307:21 A. Yes.		
333:13 - 334:08	Holste, Joerg 2012-12-15	00:00:56	Holste.66
	333:13 Q. If you'll turn to the third		
	333:14 page, one, two -- right there. If you look at the		
 PX208.3.1	333:15 top there, the second line says, "Meshes can cause		
	333:16 Nerve damage due to mechanical irritation (mesh		
	333:17 bears on nerve)."		
	333:18 Did I read that correctly?		
	333:19 A. Yes.		
	333:20 Q. So Professor Klosterhalfen was		
	333:21 telling the group at this meeting that at least from		
	333:22 his perspective, that meshes could cause nerve		
	333:23 damage because of mechanical irritation. Right?		
	333:24 A. Yes.		
	333:25 Q. Okay. And of course, shrinkage of		
	334:01 meshes could lead to mechanical irritation of		
	334:02 tissue. Correct?		
	334:03 A. Yes.		
	334:04 Q. And if it created mechanical		
	334:05 irritation, as least according to Professor		
	334:06 Klosterhalfen, it could also cause nerve damage.		
	334:07 Correct?		
 Clear	334:08 A. Yes.		
40:12 - 40:15	Holste, Joerg 2013-07-29	00:00:09	Holste.67
	40:12 Q. And Prolene old-construction mesh		
	40:13 at 100 to 110 grams per meter squared is		
	40:14 considered a heavyweight mesh; correct?		

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DESIGNATION	SOURCE	DURATION	ID
	40:15 A. Yes.		
40:19 - 40:20	Holste, Joerg 2013-07-29	00:00:04	Holste.68
 PX133.1	40:19 Q. Showing you Plaintiffs' Exhibit 40:20 T-1196.		
43:17 - 43:22	Holste, Joerg 2013-07-29	00:00:15	Holste.69
 PX133.1.1	43:17 Q. Okay. At the top of this Ethicon 43:18 document it says, "Material Specification for 43:19 TVT Prolene Polypropylene Mesh Roll Stock." 43:20 Do you see that at the top of 43:21 the page, sir? 43:22 A. That's how it's stated here, yes.		
44:24 - 45:04	Holste, Joerg 2013-07-29	00:00:13	Holste.70
 PX133.2.1	44:24 Q. Okay. And then the last sentence 44:25 in that block says, in the case of this 45:01 document, old construction Prolene mesh is the 45:02 same as TVT Prolene mesh. 45:03 Did I read that correctly? 45:04 A. Yes.		
 Clear			
47:14 - 47:20	Holste, Joerg 2013-07-29	00:00:38	Holste.71
 PX113.1	47:14 Q. I'm showing you what we will mark 47:15 as Plaintiffs' Exhibit T-1198. The last four 47:16 Bates are 6492. 47:17 T-1198, if we look at the first 47:18 page of T-1198, it's an E-mail from you to 47:19 various people on February 16, 2011; correct? 47:20 A. That's what it states here, yes.		
49:14 - 50:02	Holste, Joerg 2013-07-29	00:00:39	Holste.72
 PX113.12.1	49:14 Q. All right. And if you look up to 49:15 the middle of the page of this document that 49:16 you had -- this -- this article that you had 49:17 sent to Judi Gauld, Piet Hinoul and Sandy 49:18 Savidge -- and before I ask you that question, 49:19 Piet Hinoul was a medical affairs director at 49:20 Ethicon; correct? 49:21 A. Yes. 49:22 Q. Okay. And so if we look at this 49:23 document, if you -- if you look at where it 49:24 has a Number 10 over to the side, it says, in 49:25 the past decade -- so that would be 1999 to		

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DESIGNATION	SOURCE	DURATION	ID
	50:01 when this article was published in 2009; 50:02 correct?		
50:22 - 50:25	Holste, Joerg 2013-07-29	00:00:11	Holste.73
	50:22 THE WITNESS: I don't know when 50:23 this publication was submitted. 50:24 That's probably what this past decade 50:25 refers to.		
51:03 - 51:12	Holste, Joerg 2013-07-29	00:00:27	Holste.74
	51:03 Q. So in the -- in the ten years 51:04 prior to when this publication was written, it 51:05 says, due to increasing numbers of reported 51:06 mesh-related complications, several research 51:07 companies developed new mesh systems to 51:08 increase efficiency and patient comfort and 51:09 decrease the side effects and amount of 51:10 foreign material left in the patient. 51:11 Do you see that? 51:12 A. Yes.		
51:25 - 52:04	Holste, Joerg 2013-07-29	00:00:13	Holste.75
	51:25 One of the reasons that Ethicon 52:01 developed a lighter-weight, larger-pore mesh 52:02 was so that less foreign material would be 52:03 left behind in the tissue; correct? 52:04 A. That is correct, yes.		
55:22 - 56:01	Holste, Joerg 2013-07-29	00:00:16	Holste.76
	55:22 Q. And so as a scientist at Ethicon 55:23 for 29 years and 9 months working on the 55:24 reaction to meshes in tissue, do you believe 55:25 that greater inflammatory reaction can entrap 56:01 nerves and lead to pain?		
56:04 - 56:05	Holste, Joerg 2013-07-29	00:00:03	Holste.77
	56:04 THE WITNESS: That may happen, 56:05 yes.		
56:08 - 56:10	Holste, Joerg 2013-07-29	00:00:05	Holste.78
	56:08 Q. Another thing that a greater 56:09 inflammatory reaction can cause are mesh 56:10 erosions; correct?		
56:13 - 56:13	Holste, Joerg 2013-07-29	00:00:04	Holste.79





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DESIGNATION	SOURCE	DURATION	ID
	56:13 THE WITNESS: That is possible.		Holste.79
56:15 - 56:19	Holste, Joerg 2013-07-29	00:00:14	Holste.80
	56:15 Q. And because more foreign body		
	56:16 cause -- is a greater foreign body reaction, a		
	56:17 heavier-weight mesh will cause a greater		
	56:18 inflammatory reaction than a lighter-weight		
	56:19 mesh; correct?		
56:21 - 56:21	Holste, Joerg 2013-07-29	00:00:01	Holste.81
	 Clear		
	56:21 THE WITNESS: Yes.		
57:16 - 58:08	Holste, Joerg 2013-07-29	00:01:25	Holste.82
	57:16 Q. And as we saw from the first two		
	57:17 exhibits from today's deposition, Ethicon was		
	57:18 one of those companies that was developing new		
	57:19 mesh systems, at least for hernia and for		
	57:20 pelvic floor, that was trying to leave less		
	57:21 foreign material in the patient; correct?		
	57:22 A. Yes.		
	57:23 Q. However, with the TVT sling, for		
	57:24 the classic, the obturator and the S, Ethicon		
	57:25 did not develop a new mesh that would be		
	58:01 lightweight and large pore, as compared to the		
	58:02 original 6-mil construction; correct?		
	58:03 A. Yes, that's what it looks like.		
	58:04 We are, however, in the process		
	58:05 of mixing up some things. On the one side,		
	58:06 there are meshes for pelvic floor repair,		
	58:07 meshes for pelvic organ prolapse, and meshes		
	58:08 for the treatment of urinary incontinence.		
59:02 - 59:04	Holste, Joerg 2013-07-29	00:00:04	Holste.83
	59:02 Q. and I want you to		
	59:03 look at Paragraph 20. Okay?		
	59:04 A. (In English) Yes.		
59:10 - 59:10	Holste, Joerg 2013-07-29	00:00:02	Holste.84
	59:10 Q. The basic ideas for the		
59:11 - 59:16	Holste, Joerg 2013-07-29	00:00:20	Holste.85
	 PX113.12.2		
	59:11 construction of gynecological mesh are similar		
	59:12 to the ones used in hernia surgery. The ideal		
	59:13 material should be chemically inert,		
	59:14 non-toxic, non-allergic, non-inflammatory,		

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DESIGNATION	SOURCE	DURATION	ID
	59:15 resistant to infection, non-carcinogenic, 59:16 sterilizable, convenient and affordable.		
59:20 - 60:05	Holste, Joerg 2013-07-29	00:00:36	Holste.86
	59:20 Q. Do you see that?		
	59:21 A. Yes.		
	59:22 Q. So even though there's a different		
	59:23 application between polypropylene meshes that		
	59:24 Ethicon made for hernia versus Ethicon meshes		
	59:25 for the pelvic floor, the principle of		
	60:01 lightweight, large-pore mesh is the same in		
	60:02 that the heavyweight mesh, whether it's in the		
	60:03 abdomen or the pelvic floor, will create a		
	60:04 greater inflammatory response than the		
	60:05 lightweight, larger-pour meshes; correct?		
60:08 - 60:09	Holste, Joerg 2013-07-29	00:00:04	Holste.87
	60:08 THE WITNESS: Conceptually,		
 Clear	60:09 that's correct.		
61:03 - 61:09	Holste, Joerg 2013-07-29	00:00:13	Holste.88
	61:03 Q. So even though there was a		
	61:04 different application between hernia and the		
	61:05 pelvic floor, the principle of using a		
	61:06 lighter-weight, larger-pore mesh to reduce		
	61:07 patient complications is the same principle;		
	61:08 correct?		
	61:09 A. Yes.		
62:06 - 62:15	Holste, Joerg 2013-07-29	00:00:45	Holste.89
	62:06 Q. Dr. Holste, showing you what we		
	62:07 have marked as Plaintiffs' T-1199, last four		
 PX97.1.1	62:08 Bates 8431, you see this was an E-mail from		
	62:09 you to Jonathan Meek and Peter Meier on April		
	62:10 22, 2009; correct?		
	62:11 A. Yes.		
	62:12 Q. And the first paragraph, first		
	62:13 line, it says, Jonathan, the border for scar		
	62:14 plate formation in small-pore, standard-weight		
	62:15 meshes		
62:21 - 62:23	Holste, Joerg 2013-07-29	00:00:08	Holste.90
	62:21 Q. And let me just say the -- the		
	62:22 old-construction, 6-mil Prolene would be a		

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DESIGNATION	SOURCE	DURATION	ID
	62:23 small-pore, standard-weight mesh; correct?		
63:01 - 63:05	Holste, Joerg 2013-07-29	00:00:07	Holste.91
	63:01 THE WITNESS: Yes.		
	63:02 BY MR. ANDERSON:		
 PX97.1.2	63:03 Q. Was set around 1,000 microns.		
	63:04 Did I read that correctly?		
 Clear	63:05 A. That's how it's written here, yes.		
76:12 - 76:21	Holste, Joerg 2013-07-29	00:00:27	Holste.96
	76:12 Q. And whether it's in the		
	76:13 hernia for an abdominal application or whether		
	76:14 it's in the pelvic floor for either prolapse		
	76:15 or stress urinary incontinence, having less		
	76:16 material and larger pores -- and by less		
	76:17 material I mean less polypropylene -- and		
	76:18 larger pores, it will also incite less of an		
	76:19 inflammatory reaction in the pelvic tissues,		
	76:20 just like it will in the abdominal tissues;		
	76:21 correct?		
76:25 - 77:01	Holste, Joerg 2013-07-29	00:00:01	Holste.97
	76:25 THE WITNESS: That can be		
	77:01 assumed.		
82:05 - 83:02	Holste, Joerg 2013-07-29	00:01:04	Holste.98
	82:05 Q. Now I'll show you what we will		
 PX61.1.1	82:06 mark as Plaintiffs' Exhibit T-1201. And this		
	82:07 is a better version of the lightweight,		
	82:08 large-pore concept so that it's easier for you		
	82:09 and I to look at as we ask questions. Okay?		
	82:10 (Exhibit T-1201 was marked for		
	82:11 identification.)		
	82:12 BY MR. ANDERSON:		
	82:13 Q. And, again, this was one of the		
	82:14 other documents attached to your E-mail of		
	82:15 April 22, 2009, to Jonathan Meek and Peter		
	82:16 Meier.		
	82:17 If you'd turn, please, with me,		
	82:18 Dr. Holste, to the fourth page of this		
 PX61.4.1	82:19 document, on Table 1-A -- 1 at the top there,		
	82:20 and it has a listing of heavyweight,		
	82:21 small-pore meshes.		


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DESIGNATION	SOURCE	DURATION	ID
	82:22 Do you see that?		
	82:23 A. Yes.		
	82:24 Q. And it has Marlex, Prolene and		
	82:25 Atrium listed as heavyweight, small-pore		
	83:01 meshes. Yes?		
	83:02 A. That's how it's stated here, yes.		
92:16 - 93:11	Holste, Joerg 2013-07-29	00:01:12	Holste.99
 PX61.7.1	92:16 Q. Continuing on with our sentence, 92:17 meanwhile, the authors' center has more than 92:18 700 explants of different meshes on record and 92:19 has already analyzed more than 300. The 92:20 results of the study are quite similar to data 92:21 published in 2000 as a preliminary report with 92:22 121 specimens. 92:23 Briefly, the data demonstrate 92:24 that heavyweight, small porous meshes have to 92:25 be explanted due to chronic pain more 93:01 frequently than lightweight, large porous 93:02 meshes, e.g., or for example, 40 percent for 93:03 Prolene versus 6 percent for Vypro. 93:04 Do you see that? 93:05 A. Yes.		
 PX61.7.2	93:06 Q. And then you see the table up 93:07 above, Table 3, where it shows that of the 347 93:08 explanted meshes, Prolene mesh, 40 percent of 93:09 the time it was explanted due to chronic pain, 93:10 57 percent of the time due to recurrence, 22 93:11 percent of the time due to infection; correct?		
93:14 - 93:15	Holste, Joerg 2013-07-29	00:00:04	Holste.100
 Clear	93:14 THE WITNESS: That's how it's 93:15 stated here, yes.		
95:04 - 95:11	Holste, Joerg 2013-07-29	00:00:22	Holste.101
	95:04 Q. And whether or not the tissue is 95:05 abdominal tissue or pelvic tissue in and 95:06 around the bladder neck or around the vagina, 95:07 heavyweight, small-pore meshes tend to have a 95:08 greater inflammatory reaction in any of those 95:09 tissues versus lightweight, large-pore meshes; 95:10 true? 95:11 A. Yes.		

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DESIGNATION	SOURCE	DURATION	ID
96:18 - 96:21	Holste, Joerg 2013-07-29 96:18 Q. the lightweight, 96:19 large-pore concept was not used by Ethicon in 96:20 its TVT slings; correct? 96:21 A. No.	00:00:08	Holste.102
108:21 - 109:01	Holste, Joerg 2013-07-29 108:21 Q. So Ethicon sells a heavyweight, 108:22 small-pore mesh that is ten times stronger 108:23 than is necessary to support the abdominal 108:24 wall as a sling product to support a woman's 108:25 urethra; correct? 109:01 A. Yes.	00:00:16	Holste.103
116:10 - 116:14	Holste, Joerg 2013-07-29 116:10 Q. Do you believe that a lightweight, 116:11 large-pore mesh like Ultrapro that is used in 116:12 Prolift+M would have less of an inflammatory 116:13 response in the tissues around the urethra and 116:14 through the groin?	00:00:22	Holste.104
116:17 - 116:18	Holste, Joerg 2013-07-29 116:17 THE WITNESS: That can be 116:18 assumed.	00:00:03	Holste.105

Our Designations	00:39:06
TOTAL RUN TIME	00:39:06

-  Documents linked to video:
- PX61
 - PX71
 - PX97
 - PX113
 - PX133
 - PX208