DOUBLE INCLINE CLAIMS

IPR2020-00129, -00132, -00135, -00136, -00137, -00138

Double Incline Claims

27. The system of claim 26, wherein the side opening includes at least two different inclined slopes. 2020IPR-00129, Ex-1001 (RE45,380)

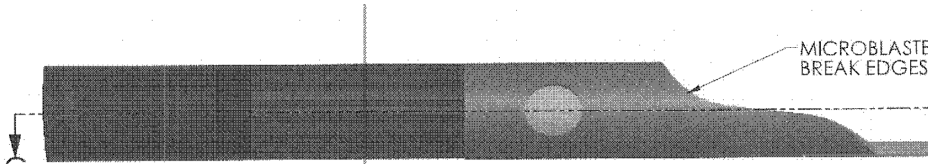
32. The system of claim 25, wherein the segment defining the side opening includes at least two inclined slopes. 2020IPR-00132, Ex-1001 (RE45,760)

52. A guide extension catheter for use with a guide catheter, comprising: a substantially rigid segment; a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end . . . wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions. 2020IPR-00135, Ex-1001 (RE45,776)

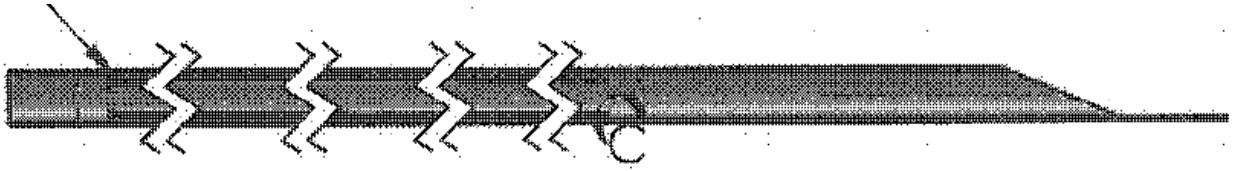
44. The method of claim 38, wherein defining the side opening portion includes forming a first inclined sidewall, forming a second inclined sidewall, and separating the first inclined sidewall and the second inclined sidewall by a non-inclined region. 2020IPR-00137, Ex-1001 (RE47,379)

PO's Inventor and Expert Agree: No Difference in Inclines

Guideliner V1



Guideliner V2



Guideliner V3

Ex-2138, Appendix B (citing Ex-2139, -2140, -2141)
See Paper No. 39 (PO's Response) at 52, IPR2020-00130

PO's Inventor and Expert Agree: No Difference in Inclines

And I'm trying to figure out, what is the angled side opening, like what's shown in Figure 4 -- what do you understand that that provides, other than a transition?

Does it have an advantage?

A. Not in my view.

Q. So it could -- the invention could be formed -- could be made with a perpendicular side opening, like Figure 1. And it would work just as well as an angled side opening, like Figure 4?

A. I believe so. If it's done right.

Ex-1108 (Inventor Sutton Dep. Tr.), 75:13-23

Q. Okay. And so the benefits that you talk about, stents catching, balloons tearing, as we discussed, are those benefits achieved with just a single angle or single incline side opening?

A. I think largely they are, yes.

Q. Are they achieved with a two-angled side opening, or two inclined side openings?

A. Certain two inclined side openings, I think, also provide that.

Q. Okay. So the issues that you mention, stent hang-up, balloon tear, et cetera, can you identify any difference in the improvement you discuss here for a single incline versus a double incline opening?

A. I think there are -- there may be some differences and some further advantages, but -- I mean, I certainly haven't elaborated on that in this part of my report.

Ex-1800 (Keith Dep. Tr.), 39:1-18

PO's Inventor and Expert Agree: No Difference in Inclines

As you sit here today, is there any reason you can think of, as an interventional cardiologist, that you would want to use a two incline proximal opening versus a one incline proximal opening.

MR. WINKELS: Objection, form. Objection, scope.

A. I have not considered it, so I -- I -- there may well be; and if I read up on it, I may come back and say, yes, there is. But at the moment, I have not considered it.

Ex-1813 (Graham Dep. Tr.), 98:6-15

Double Incline Claims

Ressemann Collar

Ressemann Collar

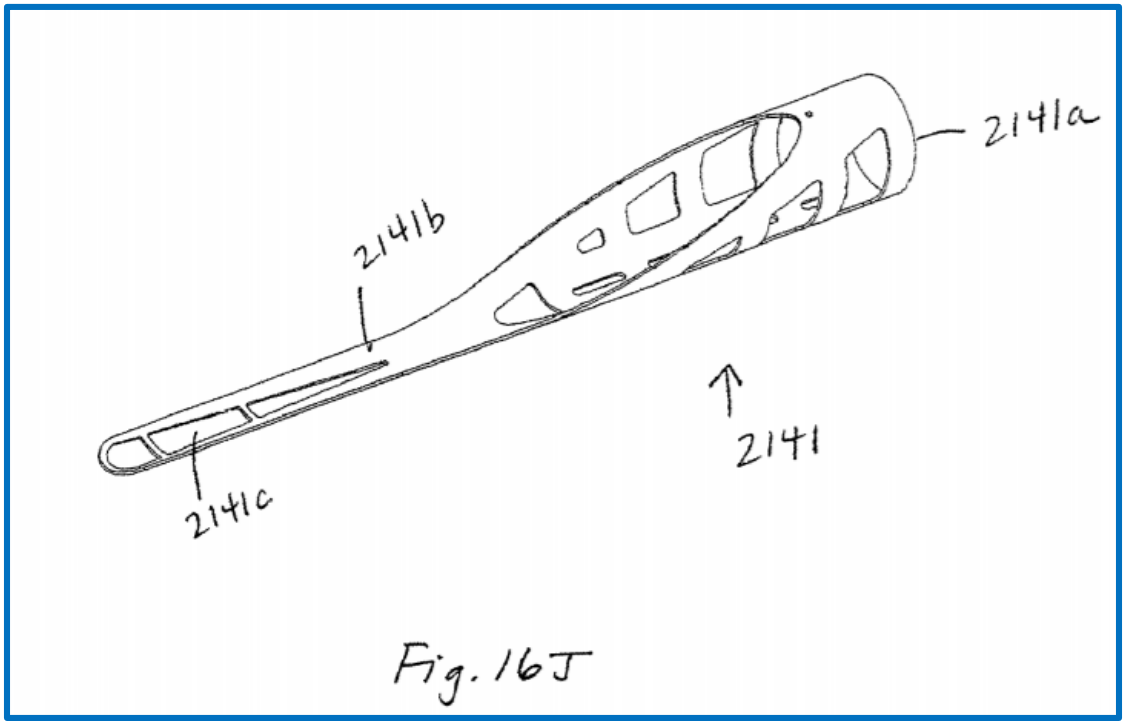


Fig. 16J

IPR2020-00132, Ex-1008

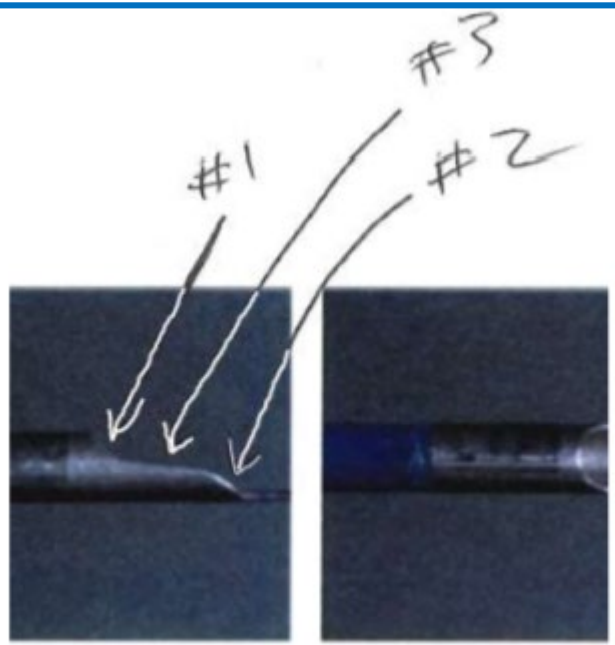
Incline – PO's Expert Says Incline is "Just Sort of By Eye"

How do you know where incline 1 ends and incline 3 begins?

A. To me it's just sort of by eye, that incline 1 has a -- sort of a relatively steeper quality to it. Incline 3 has a shallower quality to it. So somewhere in between there is where that goes from one to the next.

Q. Okay. And so if you can identify an incline relative to the longitudinal axis, even if it's shallow, that constitutes an incline; is that fair?

A. I don't know if it's quite that specific. I think -- in this example, I think that works.



IPR2020-00132, Ex-1800 (Keith Tr), 45:21-46:2; 47:3-8; Ex-1122 (color aded to arrows for visibility)

Incline – Petitioner's Expert Uses PO's Testimony

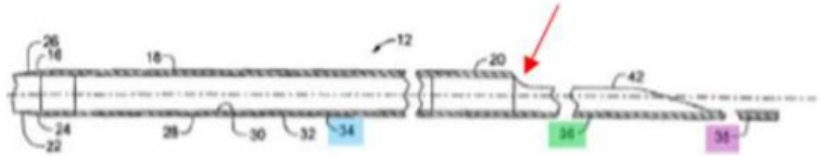
81. I have also reviewed the testimony of Mr. Root and Mr. Keith. While Teleflex's position in its Response is that the first incline on collar 2141 is a barely-there curve" and "extremely tiny," that position seems at odds with their testimony, as discussed below.

82. Mr. Keith did not opine that patent claims require an inclined slope of any particular size or shape. Ex-2138 (IPR2020-00132); Ex-1805, 104:5-107:3; 176:10-177:16. An incline may be shallow. Ex-1800, 47:3-8. This was also the view of Mr. Root. Ex-1762, 91:24-93:25; Ex-1116. Based on Mr. Root's testimony, there are two inclines in the figure shown below.

IPR2020-00132, Ex-1806 (Brecker Supplemental Decl.)

Incline – Petitioner's Expert Uses PO's Testimony

84. Mr. Keith has also opined that the curved area in Fig. 4 from the patent, indicated by an arrow below, is also an incline.

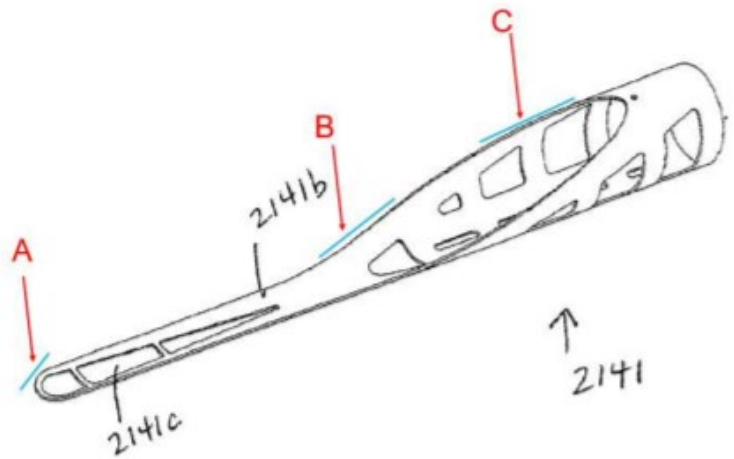


Ex-2138, ¶93 (red arrow added) (IPR2020-00129).

86. Given the testimony of Teleflex's witnesses, it is my opinion that collar 2141 of Ressemann discloses more than two inclines. I understand that Mr. Keith has testified that collar 2141 has at least one incline leading up to its fully circumferential portion. Ex-1805, 173:14-174:3. He also admitted that collar 2141 has a second incline at the tip of tab 2141b. Ex-1800, 166:8-12, 168:9-19.

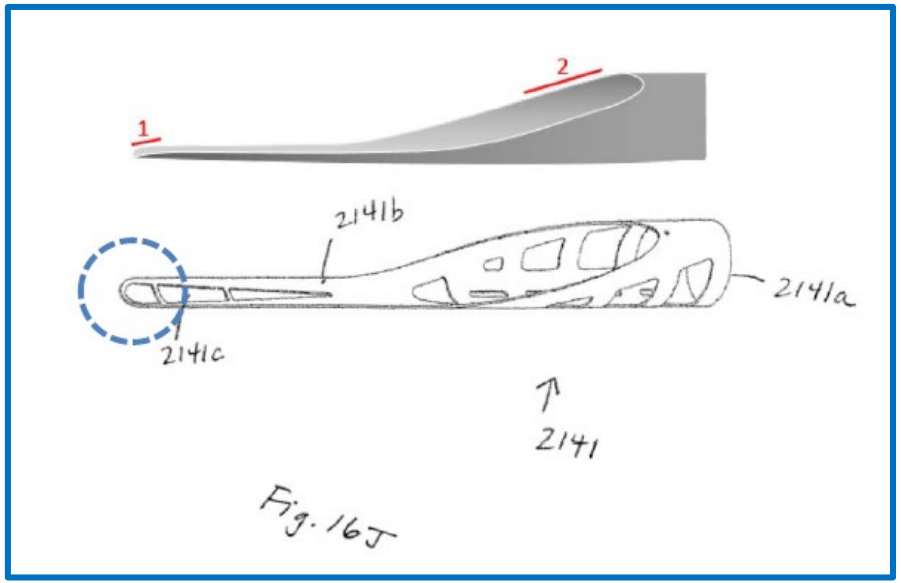
Incline – Ressemann Has More Than Two Inclines

87. In addition to two inclines, A and C, the collar has at least a third incline, at the transition between 2141a and 2141b, which is a curve shape similar to the curve that Mr. Keith identifies as an incline in Fig. 4 of the patent.



Ex-1008, Fig. 16J (annotated).

Incline – PO's Expert Says Ressemann's Tip Has An Incline



IPR2020-00129, Ex-2138 ¶ 170
See also Paper No. 43 (PO's Response) at 29

8 Q. Okay. That tip in the circle does show an
9 initial incline as you come into the collar,
10 right?
11 A. Yeah. I described that as a miniscule
12 incline. And this is looking at the collar, you

Ex-1800 (Keith. Dep. Tr.), 166:8-12

9 Q. And I just want to be clear; a miniscule
10 incline counts as an incline in the context of
11 these patent claims we're talking about, right?
12 A. I would argue that it counts as a -- it may
13 count as an incline in an abstract when we're just
14 trying to put labels on to this device in free
15 space, but in the context of an incline that would
16 be part of a side opening, you know, I don't --
17 certainly, when it's in the device as disclosed in
18 Ressemann, this does not form an incline that's
19 part of the side opening.

Ex-1800 (Keith. Dep. Tr.), 168:9-19
See Paper No. 82 (Petitioner's Reply) at 15

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry
2. Provide a Flexibility Transition

B. Expectation of Success

1. Taper Pushwire and Put Collar 2141 On Top
2. Weld Collar Directly to Itou's Pushwire
3. Patent Owner's Interpretation of Tab

Ressemann's Proximal Opening Disclosure is Relevant to Itou

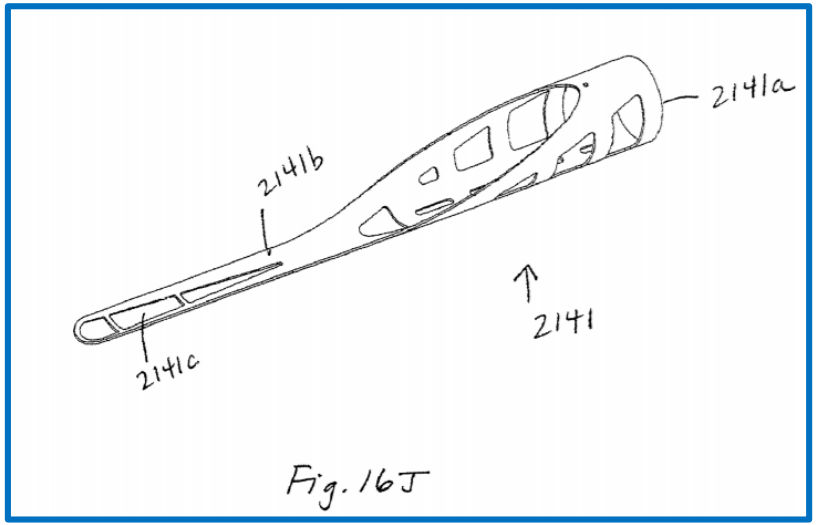
The first and preferably larger of the lumens, an evacuation lumen **140**, is designed to allow for the passage of interventional devices such as, but not limited to, stent delivery systems and angioplasty catheters. The evacuation lumen **140** is also designed to allow for fluid flow, such as blood, blood/solid mixtures, radiographic dye and saline, within the evacuation lumen **140**. This flow of fluid may occur regardless of whether an interventional device is within the evacuation lumen **140**. The proximal and distal ends **140***a*, **140***b* of the evacuation lumen **140** are preferably angled to allow for smoother passage of the evacuation sheath assembly **100** through a guide catheter, and into a blood vessel, and to facilitate smoother passage of other therapeutic devices through the evacuation lumen **140** of the evacuation head **132**. The larger area of the angled open ends also allows for larger deformable particulate matter to pass through the lumen more smoothly.

Ex-1008 (Ressemann), 6:45-61
see also Ex-1123 (Keith Patent), 7:54-60

Q. That's the identical passage we talked about earlier discussing that the proximal and distal ends are advantageous for smoother passage to the guide catheter, smoother passage of therapeutic devices and allowing for larger deformable particulate matter to pass through the lumen more smoothly, correct?
A. It looks to be the same, yeah.
Q. And, again, you would have had a chance to review this, and you agree with this passage as you sit here today, right?
A. Yes.
Q. And this patent where you have your name on it, nowhere in this patent is there anything about the use of a flare or a reverse bevel, correct?
A. I don't see it in any of the figures.

Ex-1800 (Keith Dep. Tr.), 149:3-18

Ressemann's Collar 2141 "Reinforces" And Is the Proximal Opening

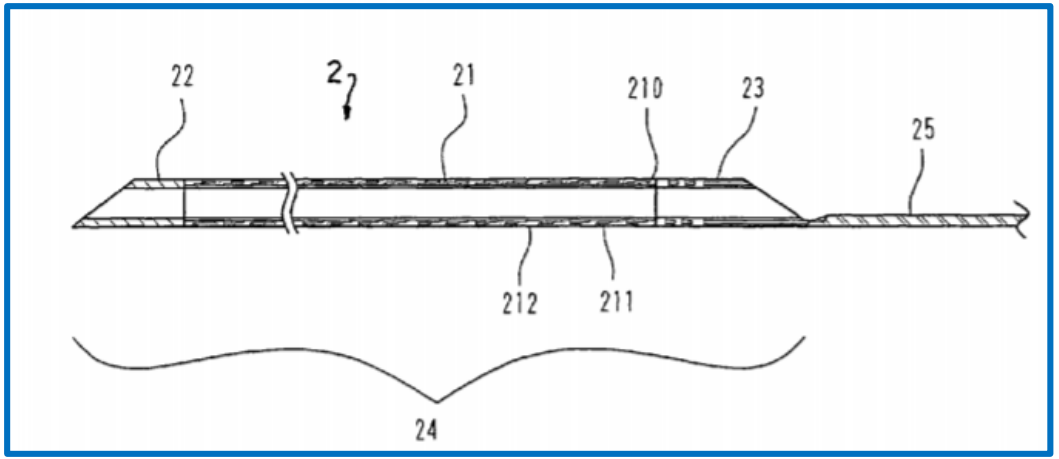


Ex-1008 (Ressemann) Fig. 16J

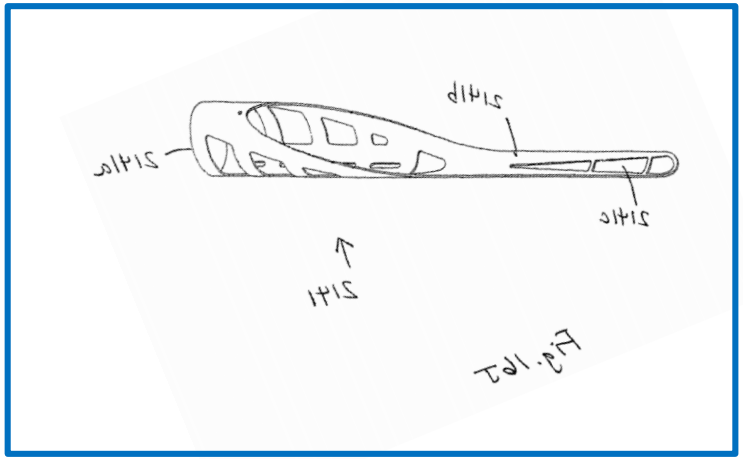
As embodied herein and shown in FIGS. **16**D and **16**J, the evacuation head **2132** may include a structure to reinforce the proximal opening of the multi-lumen tube **2138**. A support collar **2141** is positioned about the proximal end of the multi lumen tube **2138** and serves to reinforce the proximal opening of the evacuation lumen **2140** in the presence of deforming forces, particularly torsional stresses that may be created unintentionally by rotation of the catheter shaft near its proximal end. As shown in FIG. **16**J, the support collar **2141** includes a cylindrical portion **2141***a* that fits into the proximal opening of the evacuation lumen **2140** and provides hoop support to the opening of the multi-lumen tube **2138**. The cylindrical portion **2141***a* of the support collar **2141** tapers

Ex-1008 (Ressemann), 24:47-58

Modifying Itou with Ressemann Collar



Ex-1007 (Itou), Fig. 3



Ex-1008, Fig. 16J (orientatiion reversed)

IPR2020-00132

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry

2. Provide a Flexibility Transition

B. Expectation of Success

1. Taper Pushwire and Put Collar 2141 On Top

2. Weld Collar Directly to Itou's Pushwire

3. Patent Owner's Interpretation of Tab

Modifying Itou with Ressemann Collar

272. First, a POSITA had the motivation to modify the proximal end of the tubular portion of Itou's suction catheter because s/he understood that it was configured to receive one or more stents or balloon catheters. *Supra*, ¶¶ 172-84. And by modifying the proximal opening of suction catheter (2) with Ressemann's collar 2141, a larger area for receiving a stent and/or balloon catheter would be achieved.

Ex-1005 (Brecker Decl.)

91. The larger the opening area, the less coaxially aligned the interventional device (guidewire or balloon catheter) must be to enter the catheter lumen. By including features such as a concave track and angled opening, easier insertion of the interventional device is facilitated during a procedure.

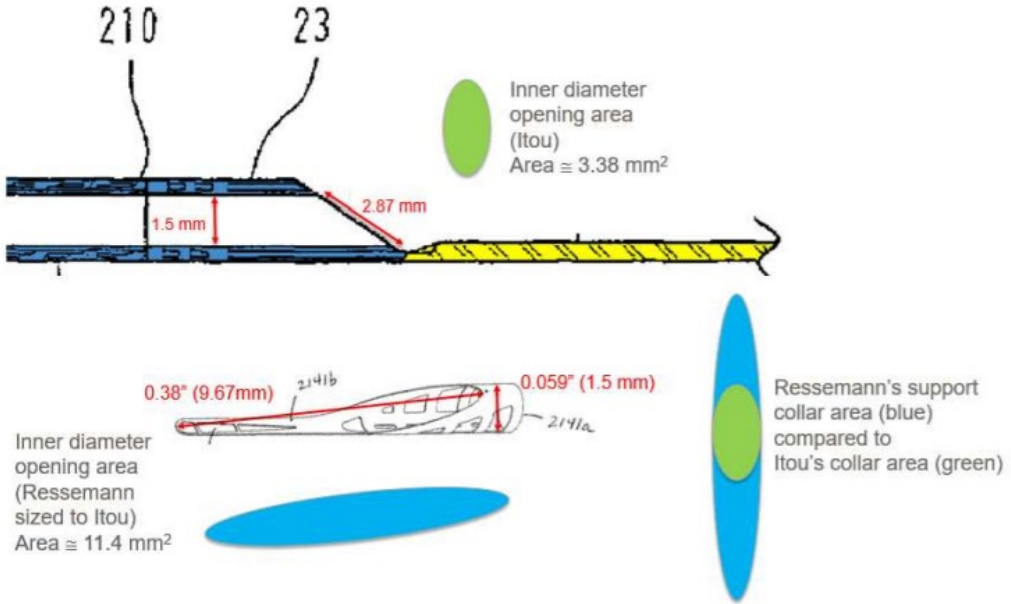
Ex-1042 (Hillstead Decl.)

Modifying Itou with Ressemann Collar

124. While Itou and Ressemann do not report the area of each of their angled side openings, these areas can be estimated based on the figures and dimensions reported in each patent. I compared what the area of the opening would be based on the inner diameter of Itou's catheter 2, which is 1.5 mm. Ex-1007, Table 1, 7:60. To compare to Ressemann's support collar, I scaled Ressemann's support collar such that it has the same inner diameter of Itou. Since Ressemann's support collar's inner diameter is ~0.067 inches (1.7mm) (Ex-1008, 23:4), I scaled Ressemann's collar down by 12% to achieve the same 1.5 mm inner diameter.

IPR2020-00132, Ex-1807 (Jones Decl.)

Modifying Itou with Ressemann Collar



Schematic illustrating scaled comparison of Itou's collar area as compared to Ressemann's collar area.

IPR2020-00132, Ex-1807 (Jones Decl.), ¶ 125

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry

2. Provide a Flexibility Transition

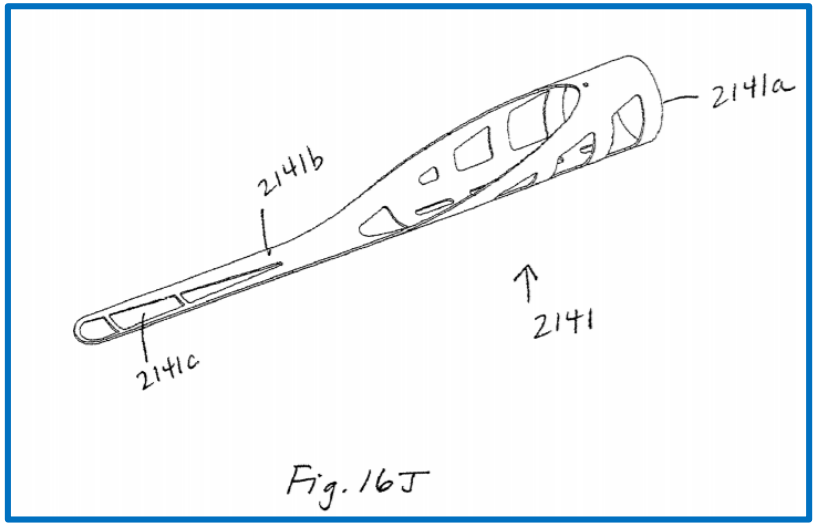
B. Expectation of Success

1. Taper Pushwire and Put Collar 2141 On Top

2. Weld Collar Directly to Itou's Pushwire

3. Patent Owner's Interpretation of Tab

Ressemann's Collar 2141 Reinforces the Proximal Opening



Ex-1008 (Ressemann), Fig. 16J

support to the opening of the multi-lumen tube **2138**. The cylindrical portion **2141***a* of the support collar **2141** tapers into a tab portion **2141***b* that extends proximally and in a direction parallel to a longitudinal axis of the evacuation lumen **2140**. The tab portion **2141***b* lies adjacent the exterior walls of the multi-lumen tube **2138** which define the core wire lumen **2143** and the inflation lumen **2142** and provides a flexibility transition between the proximal end of the evacuation head **2131** and the shaft of the evacuation sheath assembly **2100**.

Ex-1008 (Ressemann), 24:58-67

Modifying Itou with Ressemann Collar

52. By the relevant time frame it was well known to a POSITA that a critical region where kinking and buckling can occur in coronary catheters was at the interface between the stiff proximal portion and the flexible distal portion of the catheter due to the change in stiffness at this interface." Ex-1829, 2:38-49.

IPR2020-00132, Ex-1807 (Jones Decl.)

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry
2. Provide a Flexibility Transition

B. Expectation of Success

1. Taper Pushwire and Put Collar 2141 On Top
2. Weld Collar Directly to Itou's Pushwire
3. Patent Owner's Interpretation of Tab

Modifying Itou with Ressemann is Routine Engineering

131. A POSITA also appreciates that tab 2141b could be placed on top of a push rod, like wire-like portion (25), similar to the manner I have described for tab 2141b and Ressemann's shaft 120. In the alternative, wire-like portion 25 could be flattened or tapered at its distal end, at the point at which it is affixed to collar 2141b. *See, e.g.* Ex-1015, 551 ("The basic guidewire consists of a solid core (stainless steel or the superelastic alloy known as Nitinol that is ground to a progressive taper in its distal portion"; Ex-1033, [0071], [0078]-[0079] (teaching tapering of the distal end of a pushwire attached to a distal tubular body). In addition to securing support collar 2141 to pushrod by adhesive and polymer encasement, the metal support collar could be spot-welded to the pushrod, as taught by both Itou and Ressemann. *See, e.g.,* Ex-1007, 4:33-35; Ex-1008, 37:12-

Ex-1807 (Jones Decl.) ¶ 131

Motivation to Combine and Expectation of Success

A. Motivation to Combine

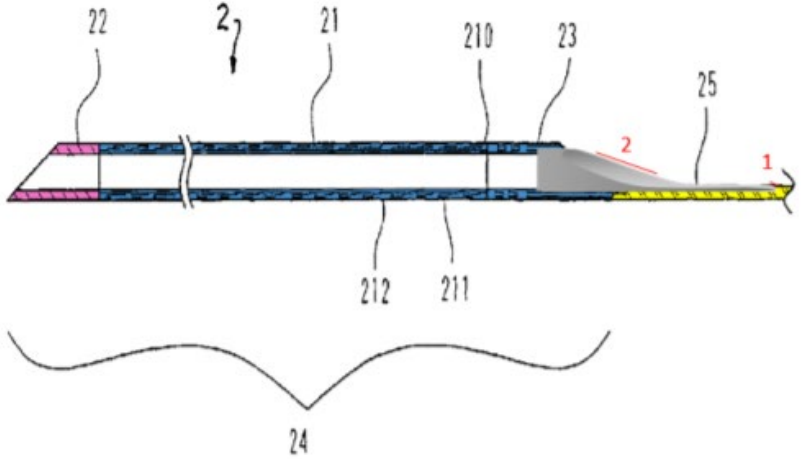
1. Larger Area of Entry
2. Provide a Flexibility Transition

B. Expectation of Success

1. Taper Pushwire and Put Collar 2141 On Top
2. Weld Collar Directly to Itou's Pushwire
3. Patent Owner's Interpretation of Tab

Modifying Itou with Ressemann Collar

277. Adding support collar (2141) to Itou's suction catheter 2 discloses a side opening according to claim 32, which includes "at least two inclined slopes."



Ex. 1007, Fig. 3 (color added) (modified with support collar 2141 (shown in gray)).

IPR2020-00132, Ex-1805 (Brecker Decl.)

Modifying Itou with Ressemann Collar

127. The second way that collar 2141 is an improvement over Itou's metal collar relates to the way that Itou teaches wire-like portion 25 should be attached to the proximal opening of the tubular portion of catheter (2). As discussed above, Itou teaches a weld point that is crushed flat. This requires plastic deformation of the metal, resulting in work hardening and a decrease in the metal's ductility at that location. Ex-1818 (Materials Science & Engineering textbook), 117-18, 121-23. A reduction in ductility at a critical stiffness transition point is known in the art to be susceptible to kinking. Including tab 2141b on top of Itou's pushrod would decrease the risk that the device failed at the crushed weld point.

IPR2020-00132, Ex-1807 (Jones Decl.)

Modifying Itou with Ressemann is Routine Engineering

17 Q. Okay. But as you said, certainly adhesive
18 was something that was well known, something a
19 person of skill in the art would know and
20 understand and be able to at least try; is that
21 right?
22 A. Yeah, I would say so.

Ex-1922 (Keith Dep. Tr.), 29:17-22

23 Q. Okay. And how about the next thing in the
24 list, which I'm continuing in your list in
25 paragraph 62, but the use of a polymer coating.
1 That was certainly known basically how to do that
2 in 2005, right?
3 A. Well, it was known in the context of various
4 devices. You know, that doesn't mean that if it
5 worked here, that it necessarily works for a
6 different device, but it certainly was known in
7 some contexts.

Ex-1922 (Keith Dep. Tr.), 29:23-30:7

Modifying Itou with Ressemann is Routine Engineering

13 Q. Okay. And then again, if you were -- if
14 you're motivated to do this and you were going to
15 put the push wire on the bottom, would you, as an
16 engineer, just use Itou's push wire as it is or
17 would you taper it down when connecting it to the
18 collar?
19 A. Again, I haven't come up with my own opinion
20 on what I would do if I were asked to do that. I
21 think Itou's push wire is relatively large, you
22 know. It's in a position so close to the proximal
23 opening. So if you said, now we're motivated to,
24 you know, change this design of Itou, I think, you
25 know, some sort of methodology to try to get rid

1 of that obstruction does make sense. I don't know
2 that tapering to, you know, less than
3 five-thousandths of an inch is what I would do.
4 Q. You certainly knew how to taper a wire back
5 in 2005; is that right?
6 A. In a general sense, yes.

Ex-1922 (Keith Dep. Tr.), 29:23-30:7

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry

2. Provide a Flexibility Transition

B. Expectation of Success

1. Taper Pushwire and Put Collar 2141 On Top

2. Weld Collar Directly to Itou's Pushwire

3. Patent Owner's Interpretation of Tab

Modifying Itou with Ressemann is Routine Engineering

FIG. **4** is a view illustrating an example of a method of joining the wire-like portion **25** and the tubular portion **24** together. Referring to FIG. **4**, the proximal tip **23** includes a body which in turn includes a proximal end portion **231** formed by obliquely cutting one end of a metal pipe such as a pipe of stainless steel and a distal end portion **232** formed by working the other end portion of the metal pipe into a spiral shape. The inner and outer faces of the body are coated with a resin. The proximal end portion **231** is secured firmly by being welded to the distal end of the wire-like portion **25** crushed into a form of a flat plate so that it may not be broken during use. The resin layers which cover the inner and outer faces of the proximal tip **23** are secured to the tubular body portion **21** by fusion. Where the proximal tip **23** is formed from such a metal material as described above, the surface of the proximal tip **23** is plated with gold. The portion plated with gold functions as an X-ray contrast marker (radiopaque marker).

Ex-1007 (Itou), 4:33-36

Q. How is that rod attached to incline -- the area by incline 2?
A. I don't know the exact details of that, but I believe it's some sort of welding process.
Q. Okay. And that's something you would know how to do as an engineer?
A. Well, at a high level, yes. I mean, there may be particulars about this specific design, any design that you would need to do some work to -- you know, to perfect that, say. But, certainly, you know, welding is -- two metal components on a catheter, I think that's fairly well established as something that has been done.

Ex-1800 (Keith Dep. Tr.), 48:5-17

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry

2. Provide a Flexibility Transition

B. Expectation of Success

1. Taper Pushwire and Put Collar 2141 On Top

2. Weld Collar Directly to Itou's Pushwire

3. Patent Owner's Interpretation of Tab

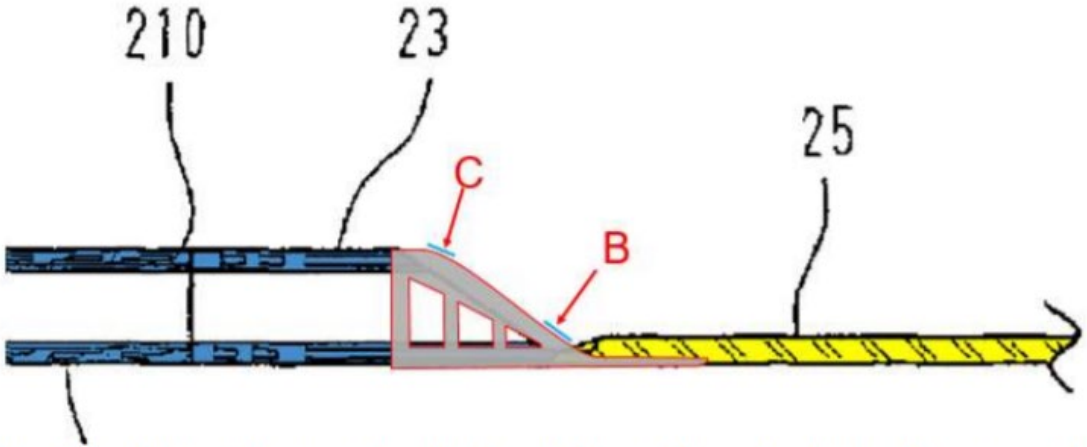
Modifying Itou with Ressemann Collar

132. I understand Patent Owner has argued that the collar of Ressemann, if combined with Itou, would be placed beneath pushrod wire 25, and not on top of wire 25. *See, e.g.,* Paper 44 (IPR2020-00132), 38-43. If the collar were placed beneath pushrod wire 25, the collar would provide support at the proximal opening, improved flexibility transition and improved trackability. In such a scenario, the incline formed at the proximal end of the tab portion would be buried beneath wire 25. The inclines located at B and C of the collar (as shown schematically below) would still be present at the proximal opening as shown schematically below.

IPR2020-00132, Ex-1807 (Jones Decl.)

Modifying Itou with Ressemann Collar

Ex-1008, Fig. 16J (annotations showing at least three inclines on the support collar at the proximal end (A), the transition from the concave track of the tab portion and incline (B), and the incline near the distal most portion of the opening (C)).



Schematic of Itou with support collar located beneath pushrod wire 25, as argued by Patent Owner.

IPR2020-00132, Ex-1807 (Jones Decl.) ¶ 132 (con't.)

Modifying Ressemann with Ressemann Collar

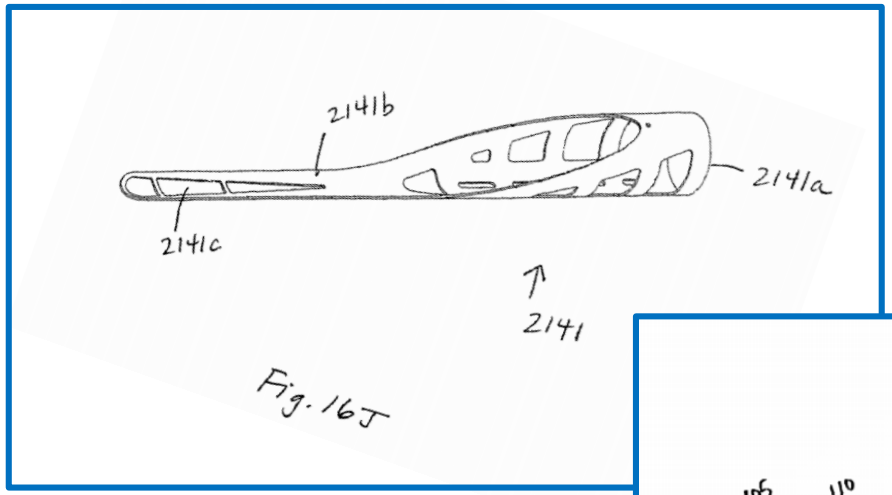


Fig. 16J

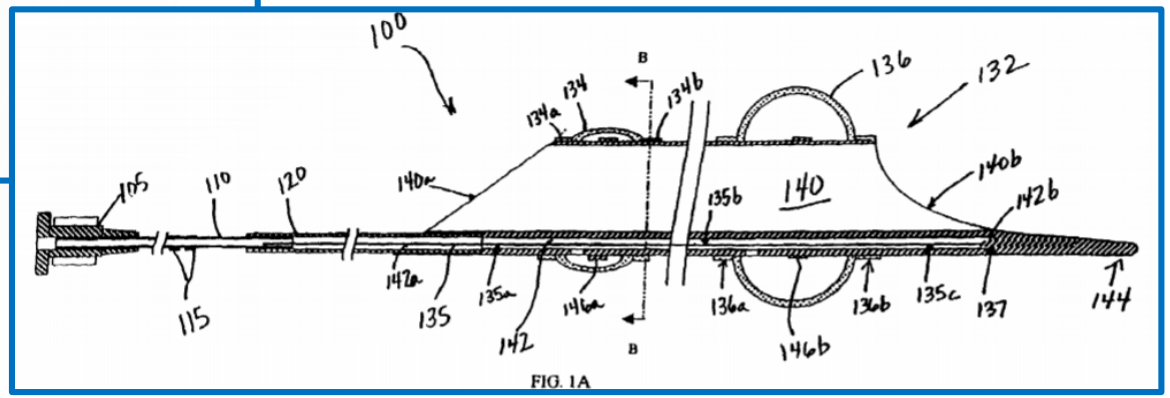
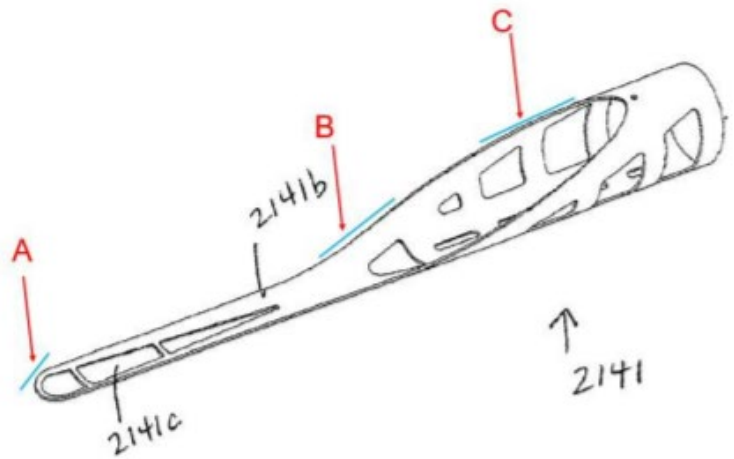


FIG. 1A

IPR2020-00138, Ex-1208

Incline – Ressemann Has More Than Two Inclines

87. In addition to two inclines, A and C, the collar has at least a third incline, at the transition between 2141a and 2141b, which is a curve shape similar to the curve that Mr. Keith identifies as an incline in Fig. 4 of the patent.



Ex-1008, Fig. 16J (annotated).

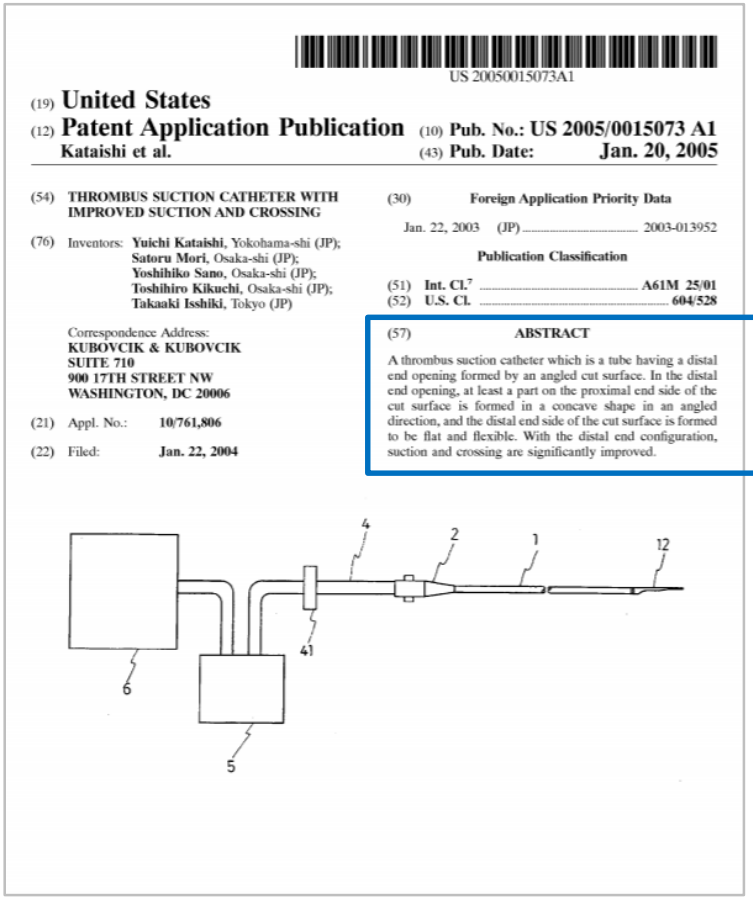
Modifying Ressemann with Ressemann Collar

103. I see nothing in Ressemann that would teach against incorporating collar 2141 into assembly 100 as shown below. While apparatus 100 includes a stiffness transition member, Ressemann teaches that apparatus 100 may be further modified to include additional structure to assist in resisting kinking. *See id.*, 6:66-7:4, 7:19-21, 24:10-12. In addition, Ressemann explicitly identifies collar 2141 as a suitable structure for this purpose. *Id.*, 24:55-67. Furthermore, even though Ressemann already discloses a stiffness transition member 135 that "extends from the proximal shaft portion 110 to the soft tip 144," (*Id.*, 11:30-44) POSITA would be motivated to employ the collar to also transition the stiffness between the shaft 120 and the more flexible tubular portion because, not only does the support collar defend against kinking, transitioning the stiffness improves trackability (*see* § XI,

Double Incline Claims

Kataishi

Kataishi



US 20050015073A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2005/0015073 A1**

Kataishi et al. (43) **Pub. Date: Jan. 20, 2005**

(54) **THROMBUS SUCTION CATHETER WITH IMPROVED SUCTION AND CROSSING**

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(21) Appl. No.: **10/761,806**

(22) Filed: **Jan. 22, 2004**

(30) **Foreign Application Priority Data**

Jan. 22, 2003 (JP) 2003-013952

Publication Classification

(51) **Int. Cl.**[7] **A61M 25/01**

(52) **U.S. Cl.** **604/528**

(57) **ABSTRACT**

A thrombus suction catheter which is a tube having a distal end opening formed by an angled cut surface. In the distal end opening, at least a part on the proximal end side of the cut surface is formed in a concave shape in an angled direction, and the distal end side of the cut surface is formed to be flat and flexible. With the distal end configuration, suction and crossing are significantly improved.

(57) **ABSTRACT**

A thrombus suction catheter which is a tube having a distal end opening formed by an angled cut surface. In the distal end opening, at least a part on the proximal end side of the cut surface is formed in a concave shape in an angled direction, and the distal end side of the cut surface is formed to be flat and flexible. With the distal end configuration, suction and crossing are significantly improved.

Ex-1025 (Kataishi)

Kataishi

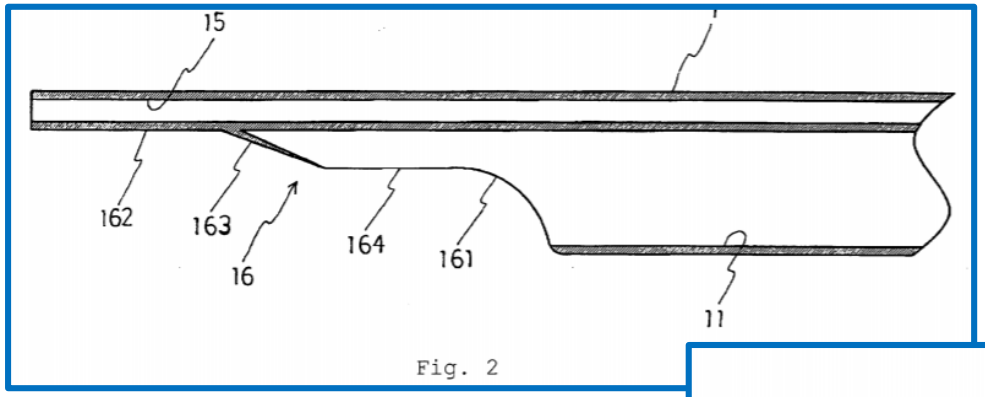


Fig. 2

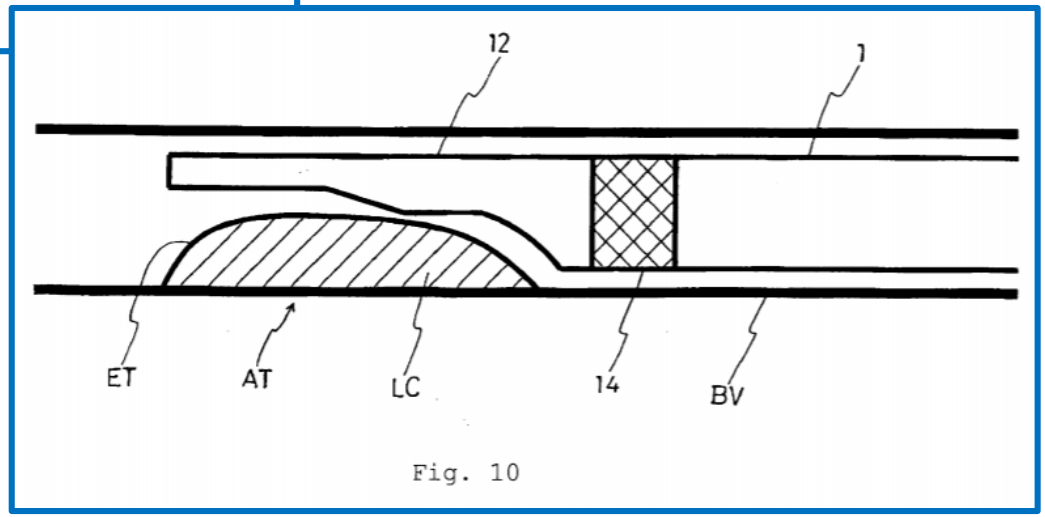


Fig. 10

Ex-1025 (Kataishi), Figs. 2 & 10

Motivation to Combine and Expectation of Success

A. Motivation to Combine

   1. Larger Area of Entry for Thrombus and Devices

   2. Improved Trackability

B. Expectation of Success

Ressemann Discloses Benefits of Distal and Proximal Openings

The first and preferably larger of the lumens, an evacuation lumen **140**, is designed to allow for the passage of interventional devices such as, but not limited to, stent delivery systems and angioplasty catheters. The evacuation lumen **140** is also designed to allow for fluid flow, such as blood, blood/solid mixtures, radiographic dye and saline, within the evacuation lumen **140**. This flow of fluid may occur regardless of whether an interventional device is within the evacuation lumen **140**. The proximal and distal ends **140***a*, **140***b* of the evacuation lumen **140** are preferably angled to allow for smoother passage of the evacuation sheath assembly **100** through a guide catheter, and into a blood vessel, and to facilitate smoother passage of other therapeutic devices through the evacuation lumen **140** of the evacuation head **132**. The larger area of the angled open ends also allows for larger deformable particulate matter to pass through the lumen more smoothly.

Ex-1008 (Ressemann), 6:45-61
see also Ex-1123 (Keith Patent), 7:54-60

Q. That's the identical passage we talked about earlier discussing that the proximal and distal ends are advantageous for smoother passage to the guide catheter, smoother passage of therapeutic devices and allowing for larger deformable particulate matter to pass through the lumen more smoothly, correct?
A. It looks to be the same, yeah.
Q. And, again, you would have had a chance to review this, and you agree with this passage as you sit here today, right?
A. Yes.
Q. And this patent where you have your name on it, nowhere in this patent is there anything about the use of a flare or a reverse bevel, correct?
A. I don't see it in any of the figures.

Ex-1800 (Keith Dep. Tr.), 149:3-18

Kataishi – Motivation to Combine

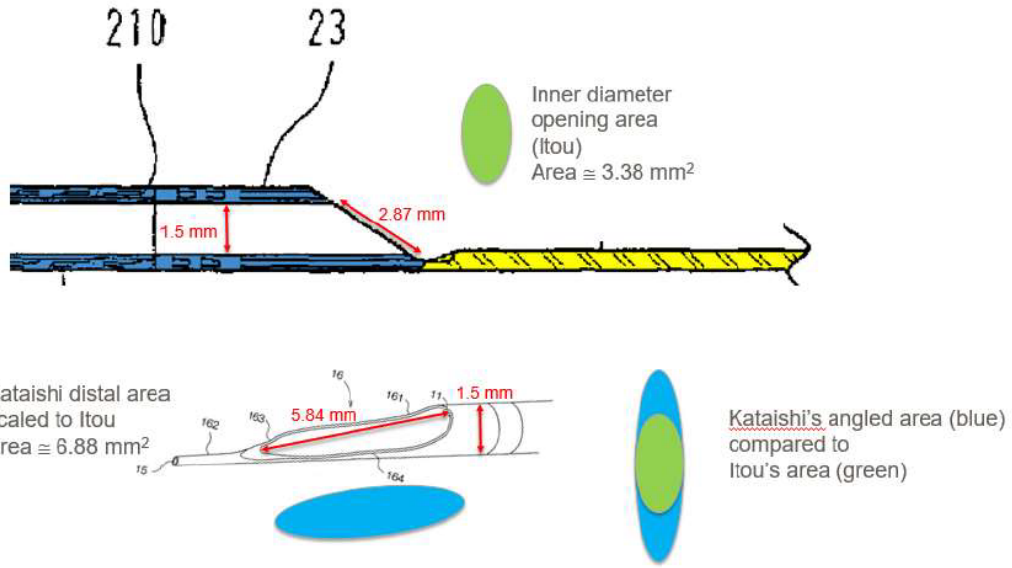
137. Thus, a POSITA knew that an angled opening was beneficial ***both*** for suctioning material out of the vasculature as well as for introducing a stent or balloon catheter. Patent Owner's expert witness, Mr. Keith, agrees. Ex-1800, 140:18-143:7; *see id.*,146:16-147:8, 148:21-149:14.

138. It follows that if the distal tip of Kataishi is more beneficial for allowing larger, deformable particulate matter to pass through the lumen more smoothly (i.e. suction thrombus), the same shape would be more beneficial for receiving a stent catheter of balloon catheter.

IPR2020-00132, Ex-1807 (Jones Decl.)

Kataishi – Motivation to Combine

146. Applying the shape of Kataishi to Itou's proximal opening also increase the effective are of the opening, as approximated by the following scaled comparison.



Ex-1807 (Jones Decl.), ¶ 145

PO Ignores the Explicit Teaching in Ressemann as "Hindsight"

Second, the cited passage of Ressemann is ambiguous, and Petitioner's interpretation of it is hindsight-driven. Reply, 16. The passage states that the ends of Ressemann's evacuation head are angled to do two things, but that does not mean that ***both*** angles serve ***both*** functions. *See* Ex-1008, 6:52-57. Indeed, contrary to Petitioner's hindsight-driven reading, Ressemann later assigns one function to each angled portion. *Id.*, 7:48-53; 23:17-20.

IPR2020-00132, Paper No. 101 at 19

PO's Expert on Ressemann's Benefits of Distal/Proximal Opening

Q. Okay. And you would agree with that, right, that the proximal and distal angles allow for smoother passage through the guide catheter?
A. I don't know that I formed an opinion on that, but I think that is probably true.
Q. Okay. And then it continues -- well, first it says that you then pass it into a blood vessel.
You see that, right?
A. Yep.
Q. And it also, in talking about the proximal and distal angles, it says that they "facilitate smoother passage of other therapeutic devices through the evacuation lumen 140 of the evacuation head 132," right?
A. Yes.
Q. And you would agree with that as well?
A. Yeah, I think that's probably true.

Q. Okay. And Ressemann also teaches that the larger area of the angled open ends -- again, referring to both ends -- also allows for larger deformable particulate matter to pass through the lumen more smoothly.
Do you see that?
A. Yes.
Q. And you would agree with that as well?
A. I think so, yes.

Ex. 1800 (Keith Dep. Tr.), 142:4-143:4

Motivation to Combine and Expectation of Success

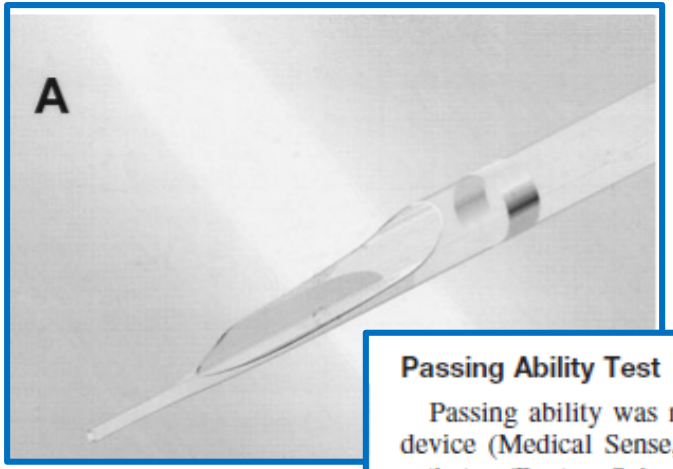
A. Motivation to Combine

1. Larger Area of Entry for Thrombus and Devices

2. Improved Trackability

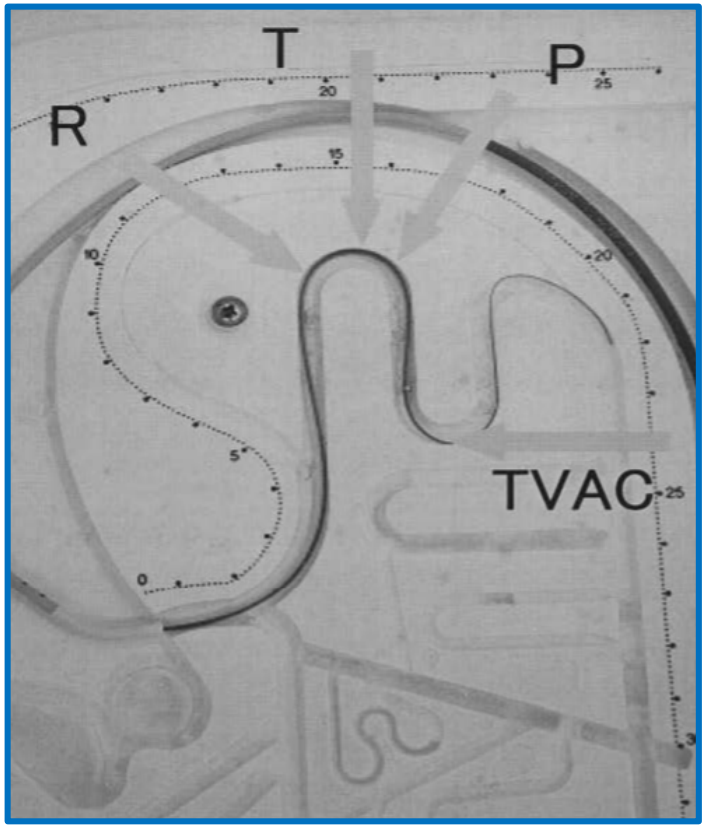
B. Expectation of Success

Sakurada Confirms Benefits of Kataishi's Shape



Passing Ability Test

Passing ability was measured using a PTCA training device (Medical Sense, Japan). A 7 Fr JL4 Wiseguide catheter (Boston Scientific) was inserted and a 0.014″ BMW guidewire (Guidant, Indianapolice, IN) was passed into a bending left anterior descending artery (LAD) of the training device. TVAC was pushed with a constant mechanical pressure until the guide catheter was dislodged from the coronary ostium. The length between the ostium and the distal tip of the aspiration catheters was measured. Other aspiration catheters such as Rescue, PercuSurge, and Thrombuster were compared under the same conditions. The experiment was repeated six times for each catheter.



IPR2020-00132, Ex-1055, 6-7

Sakurada

TABLE I. Comparison of Aspiration Catheters for 7 Fr Guide Catheter

	TVAC	Thrombuster	PercuSurge	Rescue
Guide catheter	7 Fr	7 Fr	7 Fr	7 Fr
Larger outer diameter	4.5 Fr	5.7 Fr	5.6 Fr	4.5 Fr
Smaller outer diameter	4.5 Fr	4.5 Fr	3.7 Fr	4.5 Fr
Distal inner lumen (mm2)	0.9	1.13	0.95	0.65
Proximal inner lumen (mm2)	0.98	1.37	0.92	0.65
inner support	yes	no	no	yes
shape of distal tip	duckbill	oblique straight	oblique straight	oblique straight
original device for negative pressure	motor drive	30 ml syringe	20 ml syringe	motor drive
aspiration time in a test tube (sec)	20.35 ± 4.07	11.81 ± 1.13	39.50 ± 6.40	61.63 ± 2.73

Passing Ability

Quantitative measurements of passing ability is shown in Figure 2. Only TVAC was able to pass the third bend. PercuSurge and Thrombuster catheters were able to reach the second bend. The Rescue catheter was only able to pass the first bend.

IPR2020-00132, Ex-1055, 6, 8

Sakurada

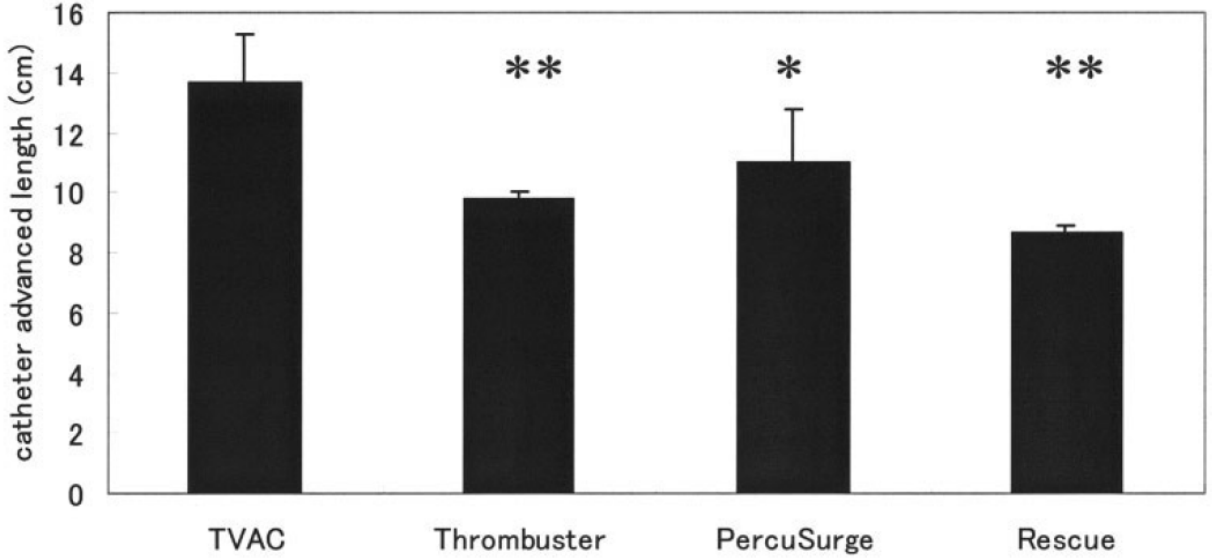


Figure 2. Passing ability test. Passing ability was measured using a PTCA training device (Medical Sense, Japan). Each catheter was pushed with a constant mechanical pressure until the guide catheter was dislodged from the coronary ostium. Average catheter position is shown by arrows. Average length from the ostium was measured in six experiments. Error bars show the standard deviation. T, Thrombuster; P, PercuSurge; R, Rescue. Asterisk represents $P < 0.05$ compared to TVAC; double asterisk, $P < 0.01$ compared to TVAC.

IPR2020-00132, Ex-1055, 7

Kataishi's Shape Has Better Trackability

139. Kataishi also describes the shape of the distal tip of the catheter as improving crossing ability, which relates to the flexibility of the catheter. Ex-1025, [0009]-[0010]; Ex-1055, Figs. 1A, 2, 302 (explaining that the catheter with the unique shape performed quantitatively better when subjected to a "Passing Ability Test" in which the ability to navigate past multiple bends was assessed). Kataishi illustrates a "crossing test" in its patent application. Ex-1025, Fig. 8, ¶ 20. This is similar to Sakurada's "Passing Ability Test." Ex-1055 , Figs. 1A, 2, 302. What Kataishi and Sakurada illustrate is how Kataishi's distal tip design improves, what is commonly referred to in the art as, "trackability." Whether it is called

IPR2020-00132, Ex-1807 (Jones Decl.)

Kataishi's Shape Has Better Trackability

trackability or crossability, Kataishi's distal tip design is such that increases the distance in which the device can navigate around bends. Whether the design of Kataishi is placed on a distal end of a device or at a proximal opening of a device, the design will improve trackability through a patient's vasculature.

140. Patent Owner has argued that having the shape of the Kataishi distal end on the proximal portion of a catheter like Itou's catheter (2), or Ressemann's evacuation lumen (140) would have no benefit to catheter crossability because the proximal opening does not "'see' the vasculature." IPR2020-00129, POR at 46, 59. This ignores the fact that the proximal opening of catheter (2) and evacuation lumen (140) "see" the inside of a guide catheter.

IPR2020-00132, Ex-1807 (Jones Decl.)

Motivation to Combine and Expectation of Success

A. Motivation to Combine

1. Larger Area of Entry for Thrombus and Devices

2. Improved Trackability

B. Expectation of Success

Kataishi – Expectation of Success

16 Q. Okay. So once you have that shape of the side
17 opening, your position here as a person of skill in the
18 art would know how to make that shape out of different
19 materials, I assume, including the materials of the
20 reinforced portion or tubular portion?
21 A. Sure, I think that's a possibility.

Ex-1764 (Keith Dep. Tr.), 31:16-21

tially equal to actual pump pressure when the cut surface **16** completely adsorbs the atheroma AT), and enables suction of the lipid core (LC) in a vascular endothelium (ET). Thus, the concave cut surface or portion **161** may have any shape, as long as it is angled in an angled direction, i.e., a proximal direction. Generally, the concave cut portion **161** is formed so as to be gently concave so that atheroma can be covered and the gap minimized. The concave cut portion **161** is provided at least partially on the proximal end side of the cut surface **16**. More specifically, the concave portion **161** may

Ex-1025 (Kataishi), ¶ [0027]

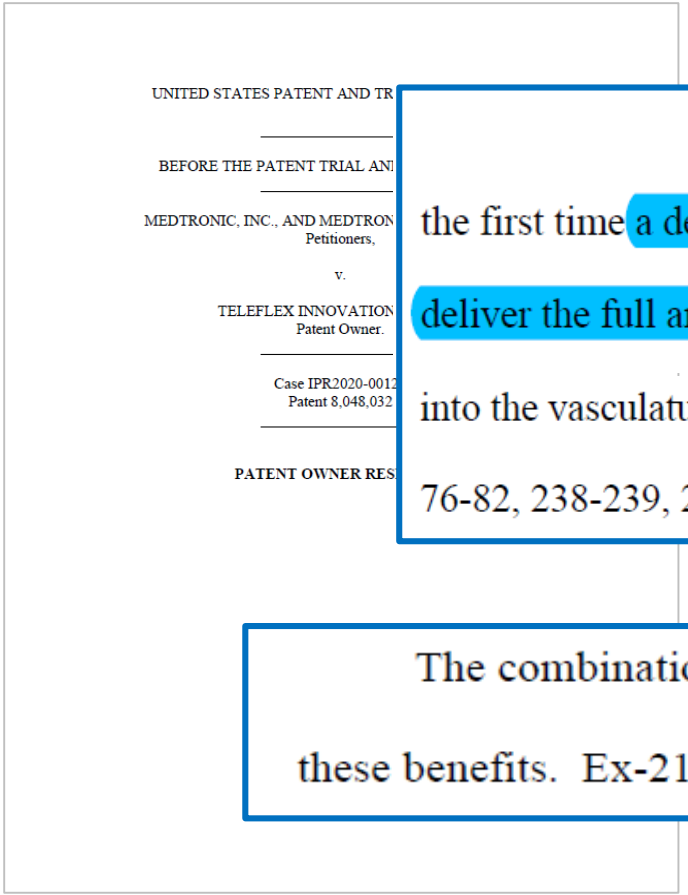
6 Q. Right, once you know the shape from Kataishi.
7 And I know you're going to dispute motivation and
8 whatnot, but I'm just saying, from an engineering
9 standpoint, once you have the shape, can you make
10 the Itou collar in that shape?
11 A. Well, I think you'd have to make it longer,
12 for one, to really have room for that. So could
13 you make it longer? I suppose you could make it
14 longer.
15 Again, you're right; I will dispute
16 that there's any motivation to do that. But I
17 think one could say, I want to put a different
18 shape. I think one could do that. Again, I don't
19 think there's any motivation to do that, certainly
20 not from this reference.

Ex-1922 (Keith Dep. Tr.), 66:6-20

SECONDARY CONSIDERATIONS

IPR2020-00126, -00127, -00128, -00129, -00130,
-00132, -00134, -00135, -00136, -00137, -00138

Secondary Considerations – Nexus



UNITED STATES PATENT AND TR

BEFORE THE PATENT TRIAL AN

MEDTRONIC, INC., AND MEDTRON
Petitioners,

v.

TELEFLEX INNOVATION
Patent Owner.

Case IPR2020-0012
Patent 8,048,032

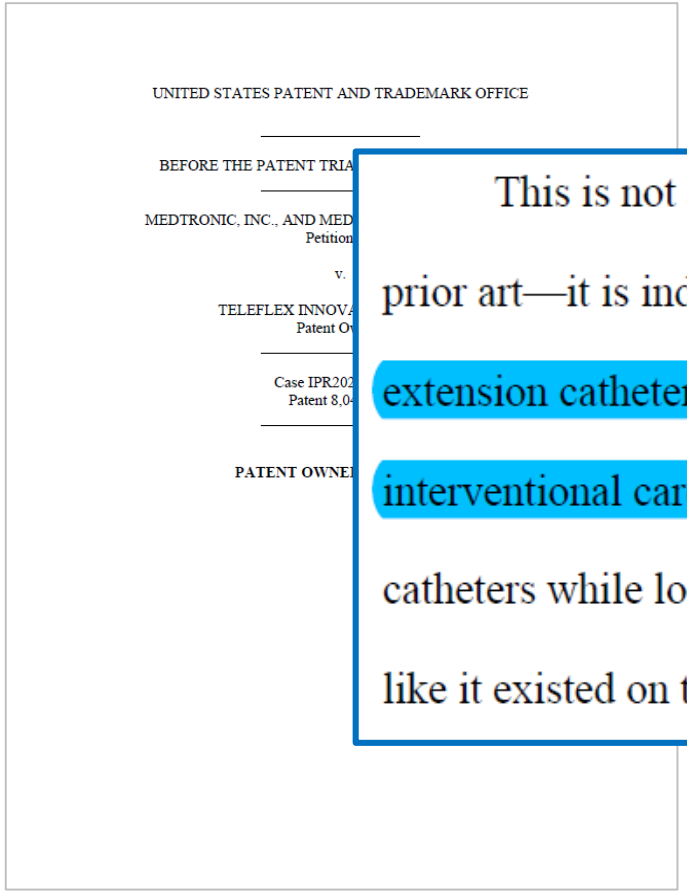
PATENT OWNER RES

The GuideLiner provided for the first time a device with "rapid exchange" functionality that could receive and deliver the full array of interventional cardiology devices (including stents) deep into the vasculature by providing markedly improved backup support. Ex-2145, ¶¶ 76-82, 238-239, 243; Ex-2138, ¶¶ 217-218.

The combination of features claimed by claims 3 and 13 is what provided these benefits. Ex-2138, ¶¶ 219-221; Ex-2145, ¶¶ 238-241.

POR at 58-59 (-00126 IPR)

Secondary Considerations – Nexus


UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIA

MEDTRONIC, INC., AND MED
Petition

v.

TELEFLEX INNOV
Patent O

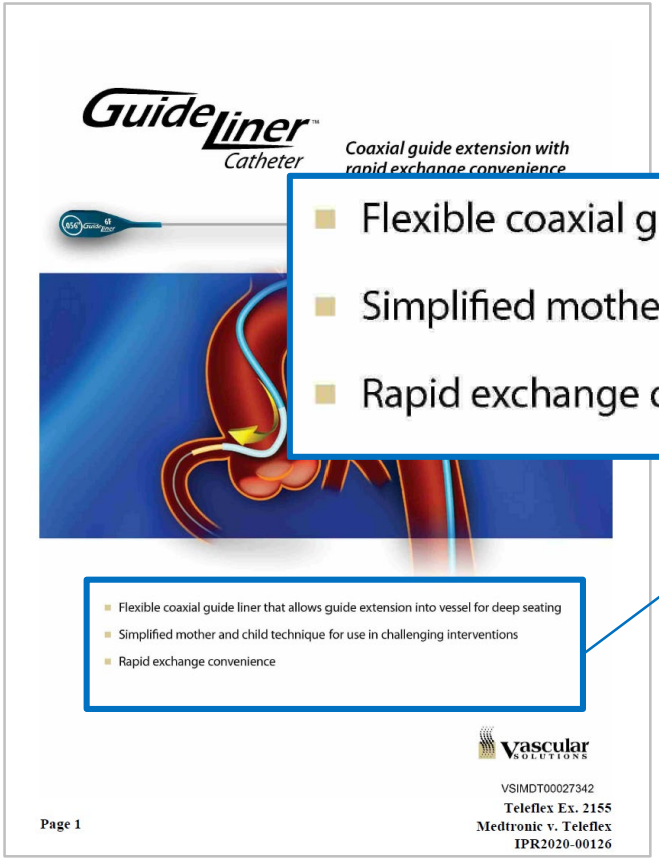
Case IPR202
Patent 8,0

PATENT OWNE

This is not a situation where success can be attributed to something in the prior art—it is indisputable that no one had a single-lumen, rapid exchange guide extension catheter with a proximal side opening designed to receive and deliver interventional cardiology devices including balloon catheters, stents, and stent catheters while located inside a guide catheter before VSI's GuideLiner; nothing like it existed on the market. Ex-2138, ¶¶ 69-75; Ex-2145, ¶¶ 239, 247, 249, Ex-

POR at 60 (-00126 IPR)

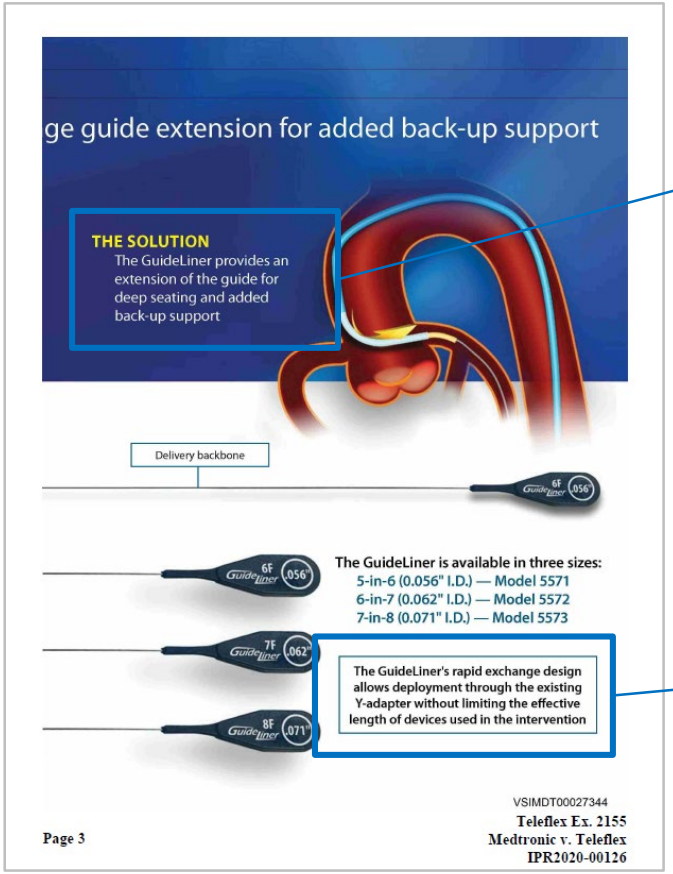
Secondary Considerations – Nexus

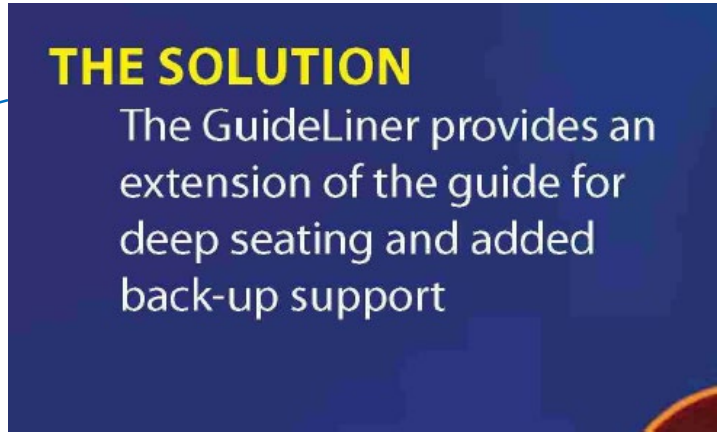


- Flexible coaxial guide liner that allows guide extension into vessel for deep seating
- Simplified mother and child technique for use in challenging interventions
- Rapid exchange convenience

IPR2020-00126, Ex-2155

Secondary Considerations – Nexus





The GuideLiner's rapid exchange design allows deployment through the existing Y-adapter without limiting the effective length of devices used in the intervention

IPR2020-00126, Ex-2155

Secondary Considerations – Nexus – Prior Art

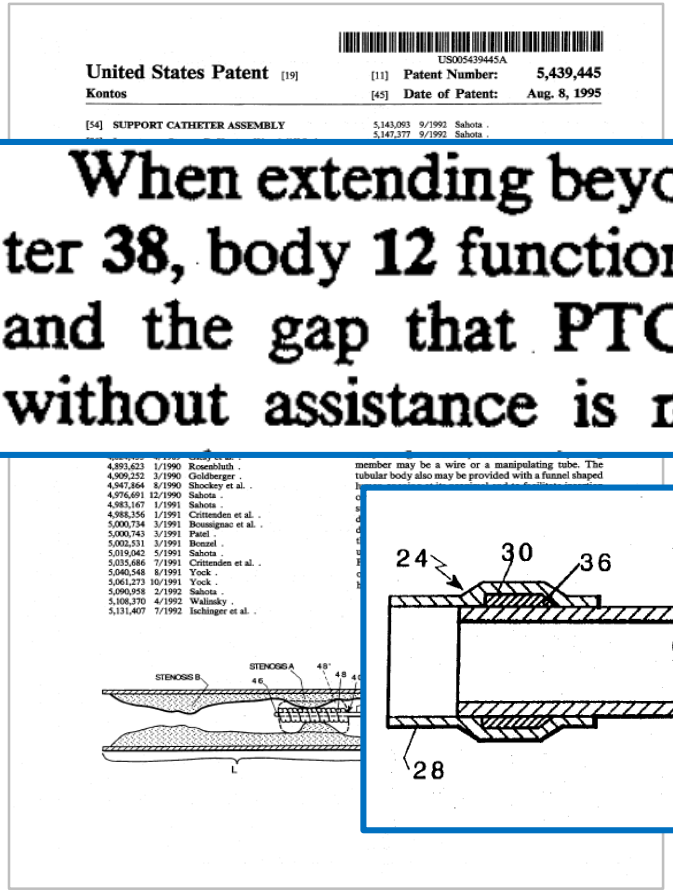
Q. Right. But in general, you didn't come up with guide extension; you didn't come up with rapid exchange. Your testimony is you came up with the combination of the two; is that right?

MR. VANDENBURGH: Objection; form.

THE WITNESS: Yeah. We did not invent rapid exchange, and we did not invent guide extension, but we invented rapid exchange guide extension.

IPR2020-00126, Ex-1762 (Root Tr), 39:14-22

U.S. Patent No. 5,439,445 (Kontos)



US005439445A

United States Patent [19]
Kontos

[11] **Patent Number: 5,439,445**
[45] **Date of Patent: Aug. 8, 1995**

[54] **SUPPORT CATHETER ASSEMBLY**

5,143,093 9/1992 Sahota .
5,147,377 9/1992 Sahota .

4,893,623 1/1990 Rosenbluth .
4,909,252 3/1990 Goldberger .
4,947,864 8/1990 Shockey et al. .
4,976,691 12/1990 Sahota .
4,983,167 1/1991 Sahota .
4,988,356 1/1991 Crittenden et al. .
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5,002,531 3/1991 Bonzel .
5,019,042 5/1991 Sahota .
5,035,686 7/1991 Crittenden et al. .
5,040,548 8/1991 Yock .
5,061,273 10/1991 Yock .
5,090,958 2/1992 Sahota .
5,108,370 4/1992 Walinsky .
5,131,407 7/1992 Ischinger et al. .

member may be a wire or a manipulating tube. The tubular body also may be provided with a funnel shaped

STENOSIS B
STENOSIS A

When extending beyond the distal end of guide catheter **38**, body **12** functions as a guide catheter extension, and the gap that PTCA catheter **40** must negotiate without assistance is made much shorter. It will be

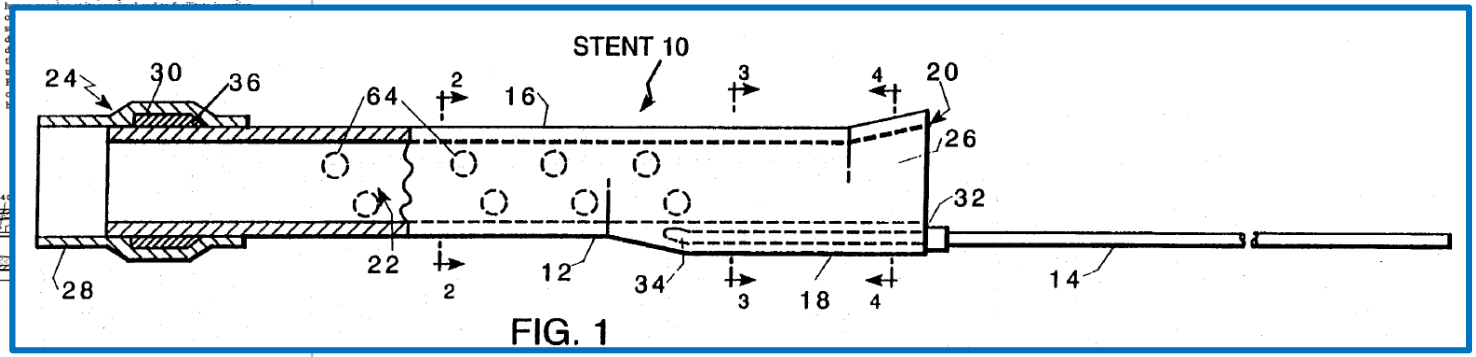

FIG. 1

Ex-1409, Fig. 1; 5:49-52

U.S. Patent No. 7,604,612 (Ressemann)

US007604612B2

(12) **United States Patent**
Ressemann et al.

(10) **Patent No.: US 7,604,612 B2**
(45) **Date of Patent: Oct. 20, 2009**

(54) **EMBOLI PROTECTION DEVICES AND RELATED METHODS OF USE**

(75) Inventors: **Thomas V Ressemann**, St. Cloud, MN (US); **Steven S Hackett**, Maple Grove, MN (US); **Andrew J Dusbabek**, Dayton, MN (US); **Dennis W Wahr**, Minnetonka, MN (US)

(73) Assignee: **St. Jude Medical, Cardiology Division, Inc.**, St. Paul, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 560 days.

(21) Appl. No.: **10/214,712**

(22) Filed: **Aug. 9, 2002**

(65) **Prior Publication Data**

US 2003/0050600 A1 Mar. 13, 2003

(51) **Int. Cl.**
A61M 29/00 (2006.01)

(52) **U.S. Cl.** **604/101.01**

(58) **Field of Classification Search** 604/101.04, 604/284, 524, 96.01, 101.01, 101.03–101.05, 604/102.01–102.03, 103.06–103.08; 606/191, 606/194

See application file for complete search history.

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4,921,478	A	5/1990	Solano et al.	

(Continued)

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EP 0 427 429 A2 5/1991

(Continued)

OTHER P

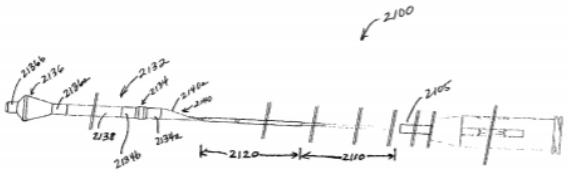
Kachel, Reiner, M.D., "Results Arteries," J. Endovas Surg. 19

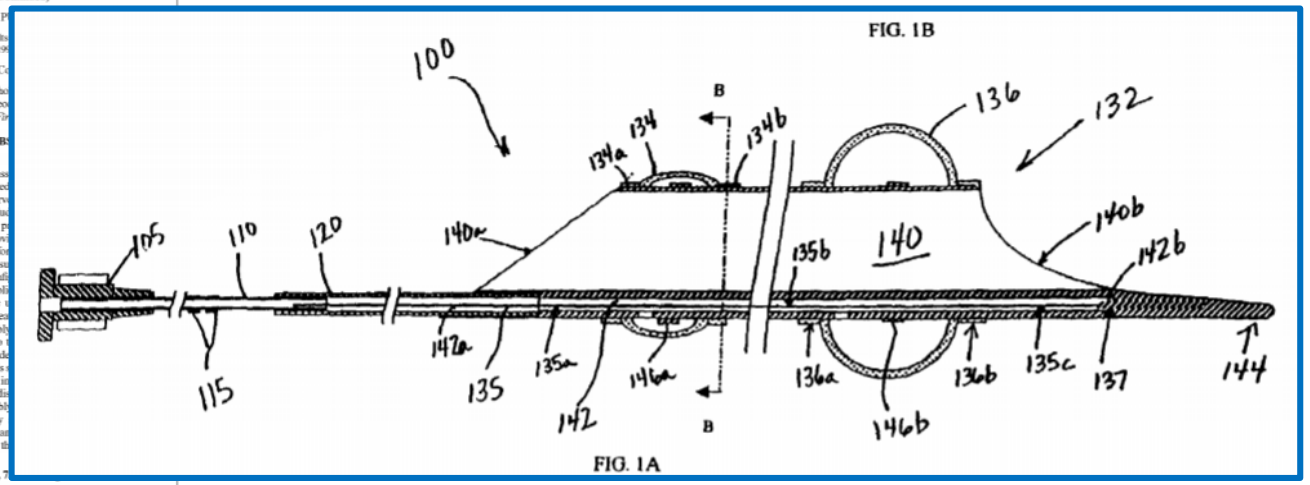
Primary Examiner—Nichc
Assistant Examiner—Theo
(74) *Attorney, Agent, or Fir*

(57) ABS

An evacuation sheath ass occluded vessels which re tion during vascular interv tion sheath assembly inclu evacuation lumen having p mal sealing surface is provi tube and is configured to fo catheter. A distal sealing su tion of the tube and is confi vessel. Obturator assembl blies are provided to be u assembly. A method of trea evacuation sheath assembl tion sheath assembly into catheter. Normal antegrade proximate to the stenosis is Retrograde blood flow is i carry embolic material da evacuation sheath assembl grade flow, the coronary occluded. Alternatively, a while flow is occluded at th

15 Claims, 7





IPR2020-00126, Ex-1008, Fig. 1A

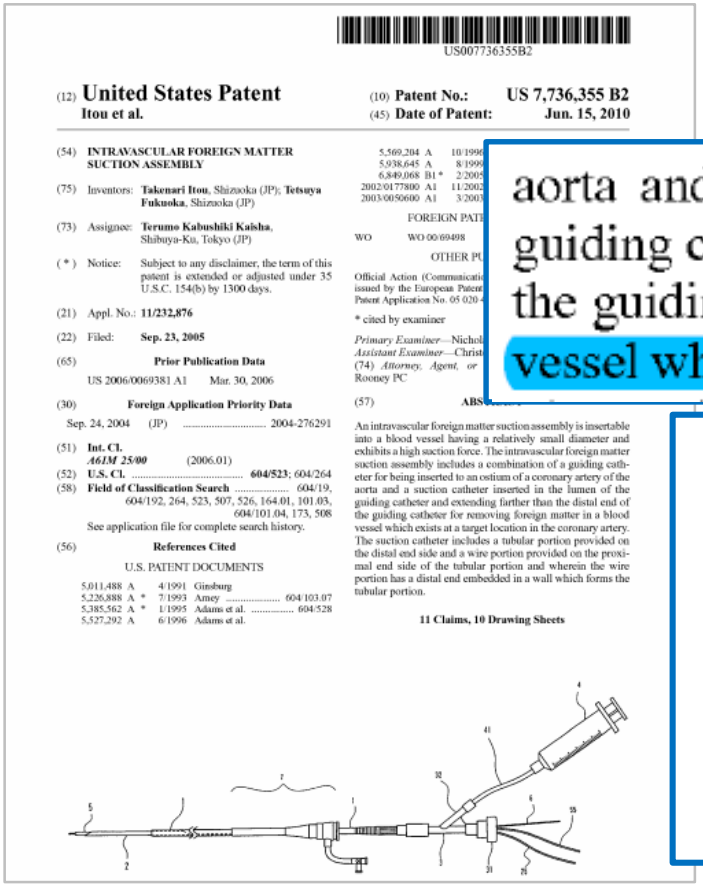
U.S. Patent No. 7,604,612 (Ressemann)

As embodied herein and shown in FIG. **1**A, an evacuation sheath assembly **100** is provided. Evacuation sheath assembly **100** includes an evacuation head and a shaft. As embodied herein and shown in FIG. **5**A, the evacuation sheath assembly **100** is sized to fit inside a guide catheter to advance a distal end of the evacuation sheath assembly into a blood vessel to treat a stenosis.

Additionally, although the method of use of the evacuation sheath assembly will be described with respect to placing a stent within a vessel, the evacuation sheath assembly **100** can be used during other therapies, such as angioplasty, atherectomy, thrombectomy, drug delivery, radiation, and diagnostic procedures.

IPR2020-00126, Ex-1008, 6:18-26, 29-34

U.S. Pat. No. 7,736,355 (Itou)



US007736355B2

(12) **United States Patent**
Itou et al.

(10) **Patent No.: US 7,736,355 B2**
(45) **Date of Patent: Jun. 15, 2010**

(54) **INTRAVASCULAR FOREIGN MATTER SUCTION ASSEMBLY**

(75) Inventors: **Takenari Itou**, Shizuoka (JP); **Tetsuya Fukuoka**, Shizuoka (JP)

(73) Assignee: **Terumo Kabushiki Kaisha**, Shibuya-Ku, Tokyo (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1300 days.

(21) Appl. No.: **11/232,876**

(22) Filed: **Sep. 23, 2005**

(65) **Prior Publication Data**

US 2006/0069381 A1 Mar. 30, 2006

(30) **Foreign Application Priority Data**

Sep. 24, 2004 (JP) 2004-276291

(51) **Int. Cl.**
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/523**; 604/264

(58) **Field of Classification Search** 604/19, 604/192, 264, 523, 507, 526, 164.01, 101.03, 604/101.04, 173, 508
See application file for complete search history.

(56) **References Cited**

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5,938,645 A 8/1999
6,849,068 B1 * 2/2005
2002/0177800 A1 11/2002
2003/0050600 A1 3/2003

FOREIGN PATE

WO WO 00/69498

OTHER PU

Official Action (Communicati
issued by the European Patent
Patent Application No. 05 020

* cited by examiner

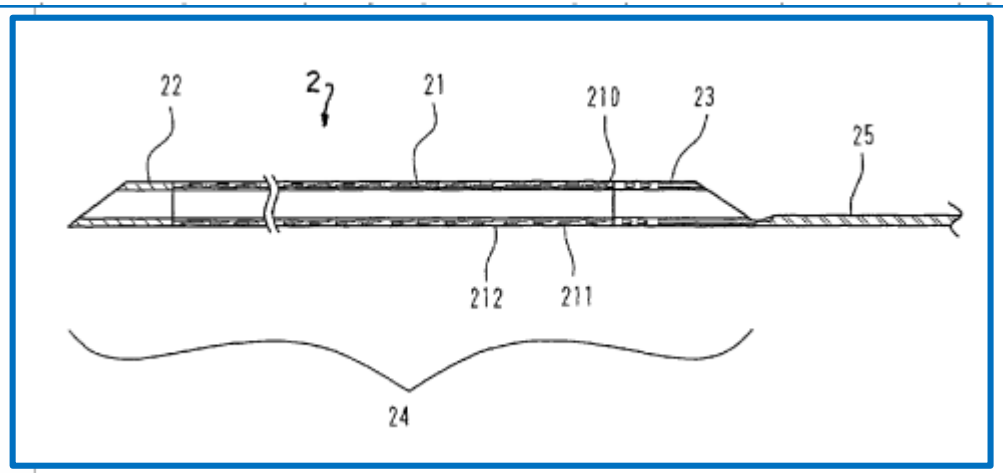
Primary Examiner—Nichol
Assistant Examiner—Christ
(74) *Attorney, Agent, or* Rooney PC

(57) ABS

An intravascular foreign matter suction assembly is insertable into a blood vessel having a relatively small diameter and exhibits a high suction force. The intravascular foreign matter suction assembly includes a combination of a guiding catheter for being inserted to an ostium of a coronary artery of the aorta and a suction catheter inserted in the lumen of the guiding catheter and extending farther than the distal end of the guiding catheter for removing foreign matter in a blood vessel which exists at a target location in the coronary artery. The suction catheter includes a tubular portion provided on the distal end side and a wire portion provided on the proximal end side of the tubular portion and wherein the wire portion has a distal end embedded in a wall which forms the tubular portion.

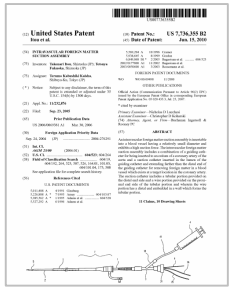
11 Claims, 10 Drawing Sheets

aorta and a suction catheter inserted in the lumen of the guiding catheter and extending farther than the distal end of the guiding catheter for removing foreign matter in a blood vessel which exists at a target location in the coronary artery.

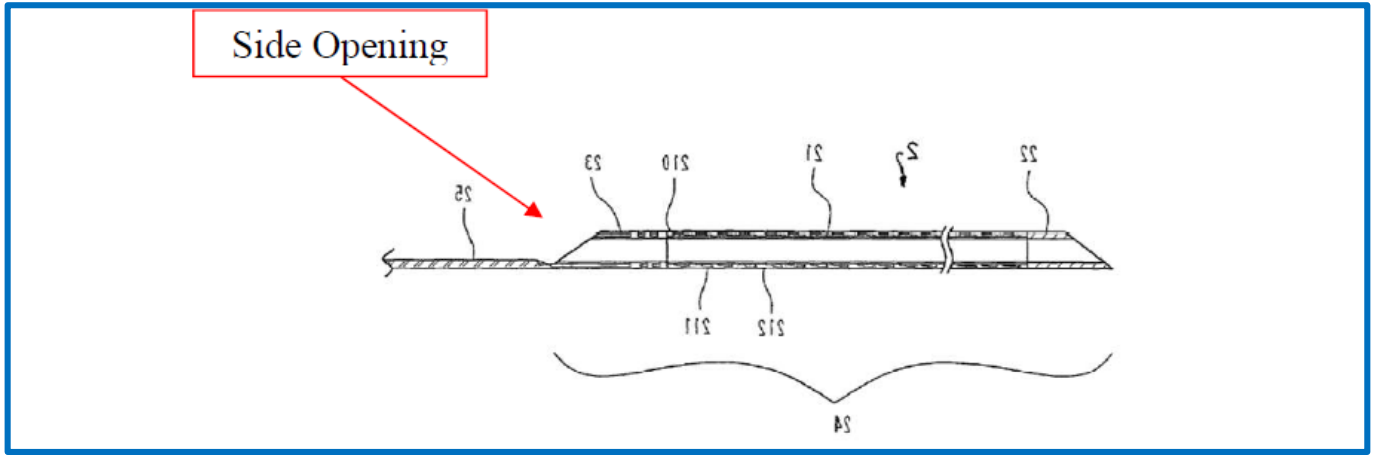


IPR2020-00126, Ex-1007, Abstract; Fig. 3

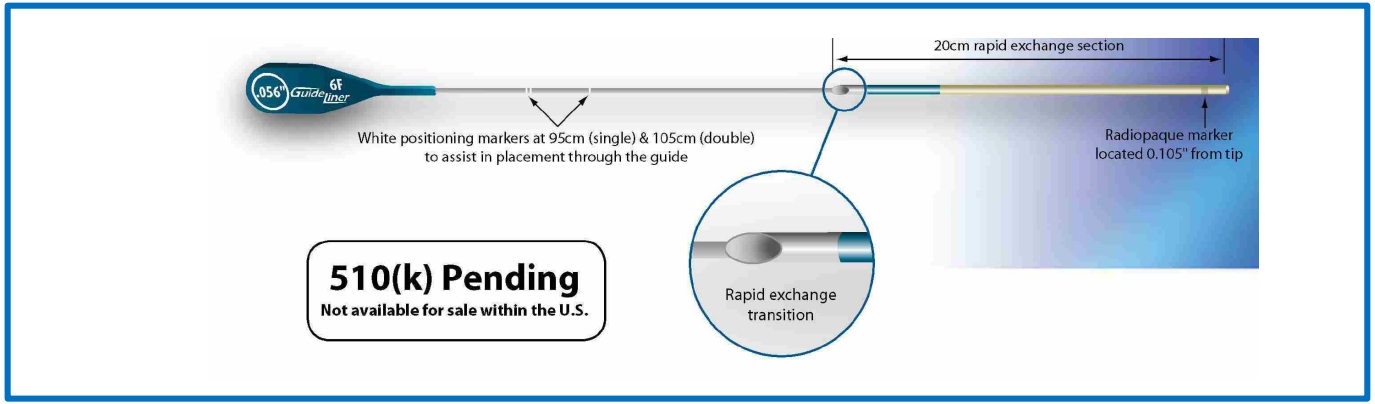
Secondary Considerations – Nexus – Side Opening



IPR2020-00127 (Itou), Ex-1007, Fig. 3



IPR2020-00127, Ex-2155



Secondary Considerations – Nexus

"Where the offered secondary consideration[s] actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention."

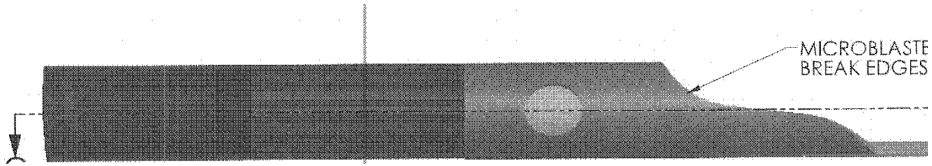
In re Kao, 639 F.3d 1057, 1068 (Fed. Cir. 2011)

"So to if the feature that creates the commercial success was known in the prior art, the success is not pertinent."

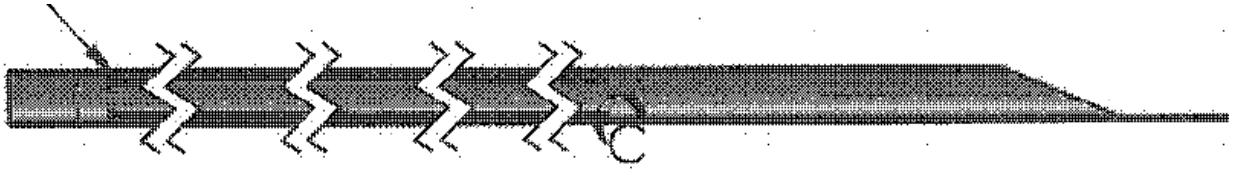
Ormco Corp. v. Align Tech, Inc.,
463 F.3d 1299, 1312 (Fed. Cir. 2006)

Secondary Considerations – Nexus – Side Opening

Guideliner V1



Guideliner V2



Guideliner V3

Ex-2138, Appendix B (citing Ex-2139, -2140, -2141)
See Paper No. 39 (PO's Response) at 52, IPR2020-00130

Secondary Considerations – Nexus – Side Opening

Setting aside the issue of the guide wire getting stuck at the proximal opening, I'm just trying to understand whether you think there's any difference in version 3 of the GuideLiner versus version 2 of the GuideLiner in terms of receiving and passing interventional devices through the proximal opening?

A. I can't say there is.

IPR2020-00127, Ex-1813 (Graham Tr), 91:1-7

Secondary Considerations – Nexus – Side Opening

Secondary Considerations – Copying

"Our primary concern in each of these cases has been to avoid treating mere infringement as copying simply because the claims of a patent arguably read on a competitor product."

"[M]ore is needed than merely showing that similarity exists between the patent and the competitor's accused product."

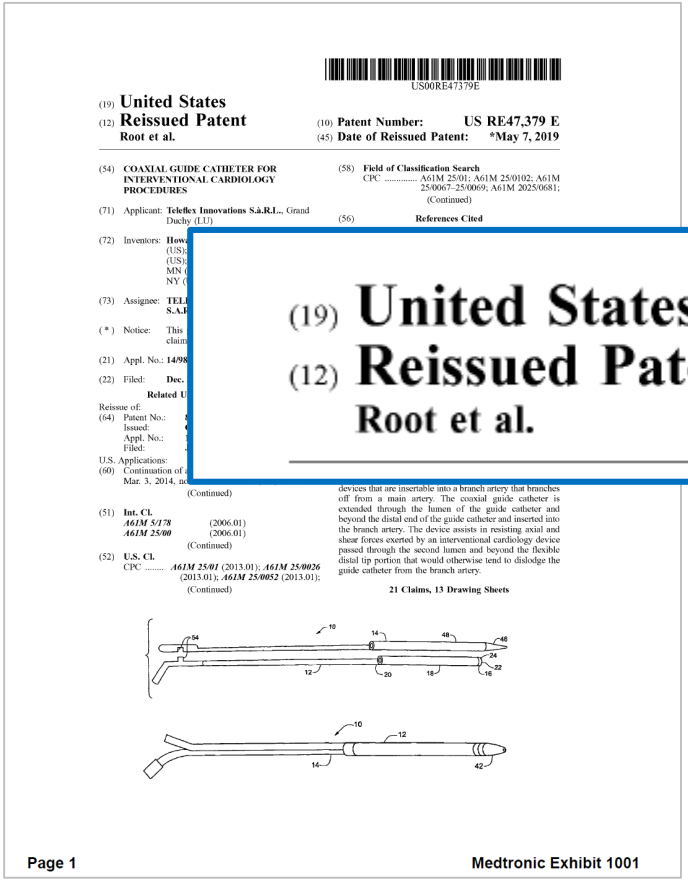
Liqwd, Inc. v. L'Oreal USA, Inc.,
941 F.3d 1133, 1137-38 (Fed. Cir. 2019)

Secondary Considerations – Copying

"Not every competing product that arguably falls within the scope of a patent is evidence of copying. Otherwise every infringement suit would automatically confirm the nonobviousness of the patent. Rather, copying requires the replication of a specific product."

Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1325 (Fed. Cir. 2004)

Secondary Considerations – ’379 Issuance



US00RE47379E

(19) **United States**
(12) **Reissued Patent**
Root et al.

(10) **Patent Number: US RE47,379 E**
(45) **Date of Reissued Patent: *May 7, 2019**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(71) Applicant: **Teleflex Innovations S.à.R.L.**, Grand Duchy (LU)

(72) Inventors: **How**
(US);
(US);
MN (
NY (

(73) Assignee: **TEL**
S.A.

(*) Notice: This
claim

(21) Appl. No.: **14/98**

(22) Filed: **Dec.**

Related U

Reissue of:
(64) Patent No.:
Issued:
Appl. No.:
Filed:

U.S. Applications:
(60) Continuation of
Mar. 3, 2014, n

(Continued)

(51) **Int. Cl.**
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61M 25/01*** (2013.01); ***A61M 25/0026*** (2013.01); ***A61M 25/0052*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61M 25/01; A61M 25/0102; A61M 25/0067-25/0069; A61M 2025/0681;
(Continued)

(56) **References Cited**

devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

21 Claims, 13 Drawing Sheets

Page 1 Medtronic Exhibit 1001

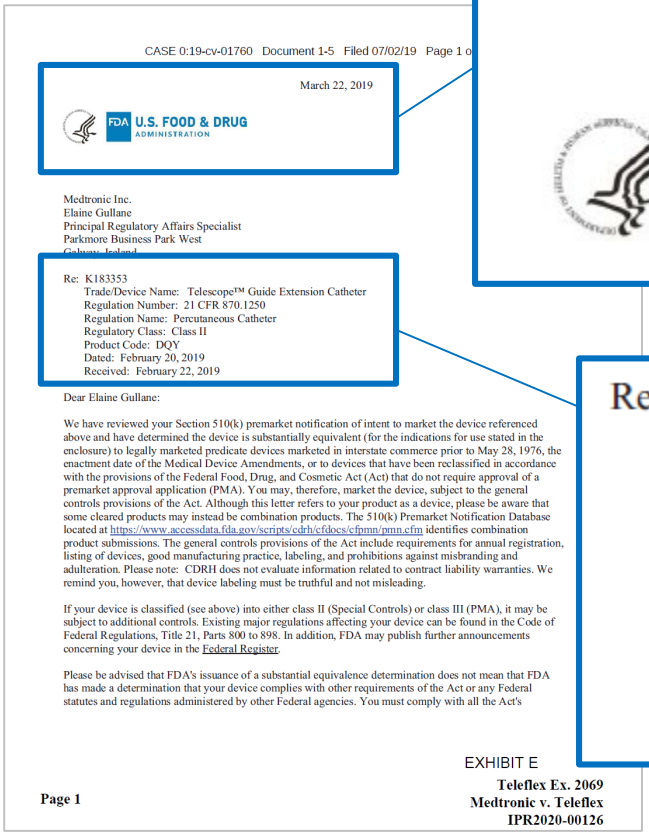
US00RE47379E

(19) **United States**
(12) **Reissued Patent**
Root et al.

(10) **Patent Number: US RE47,379 E**
(45) **Date of Reissued Patent: *May 7, 2019**

IPR2020-00137, -138, Ex-1001

Secondary Considerations – ’379 Issuance



CASE 0:19-cv-01760 Document 1-5 Filed 07/02/19 Page 1 o

March 22, 2019

U.S. FOOD & DRUG ADMINISTRATION

Medtronic Inc.
Elaine Gullane
Principal Regulatory Affairs Specialist
Parkmore Business Park West
Galway, Ireland

Re: K183353
Trade/Device Name: Telescope™ Guide Extension Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 20, 2019
Received: February 22, 2019

Dear Elaine Gullane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

EXHIBIT E

Teleflex Ex. 2069
Medtronic v. Teleflex
IPR2020-00126

Page 1

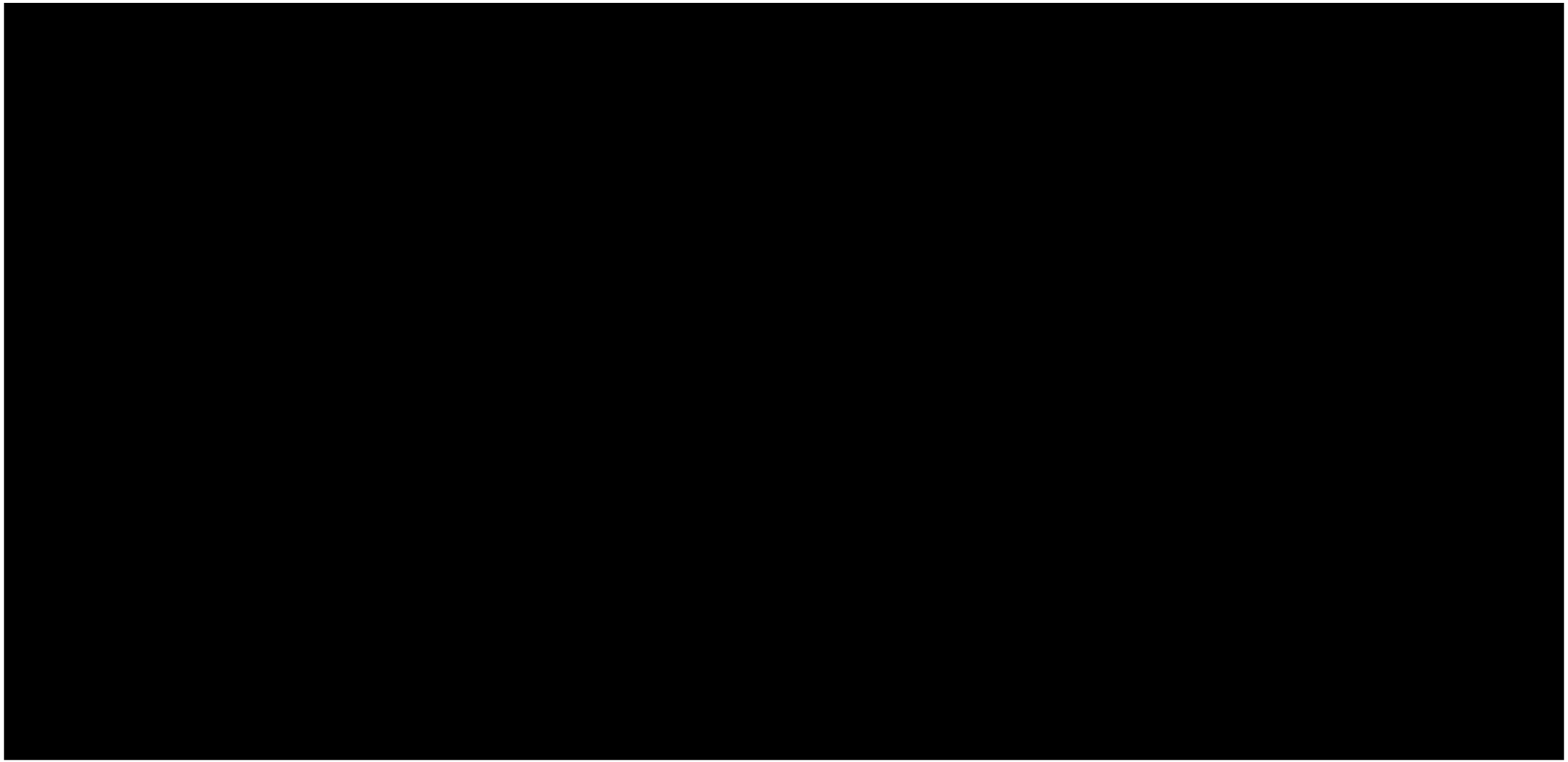
March 22, 2019

U.S. FOOD & DRUG ADMINISTRATION

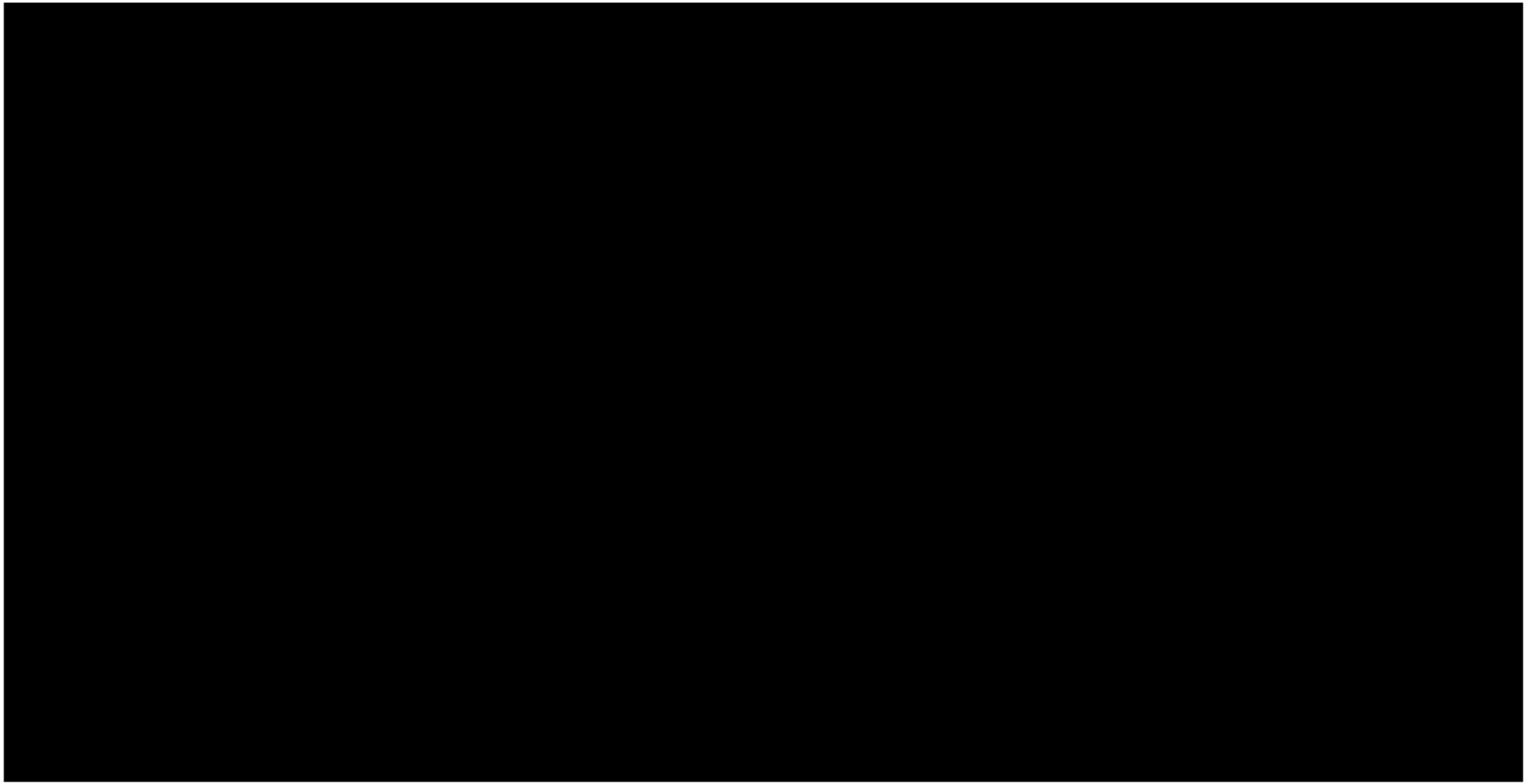
Re: K183353
Trade/Device Name: Telescope™ Guide Extension Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 20, 2019
Received: February 22, 2019

IPR2020-00126, Ex-2069

Secondary Considerations – ’379 Issuance



Secondary Considerations – Copying



Secondary Considerations – Nexus – Side Opening

Guideliner V3

Telescope

Ex-2070
See Paper No. 43 (PO's Response) at 64, IPR2020-00132

Secondary Considerations

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,

Petitioners,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner.

DECLARATION OF PAUL ZALESKY SUBMITTED IN CONNECTION WITH PETITIONERS' REPLIES TO PATENT OWNER'S RESPONSES

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

Medtronic Ex. 1830
Medtronic v. Teleflex
Page 1

DECLARATION OF PAUL ZALESKY SUBMITTED IN CONNECTION WITH PETITIONERS' REPLIES TO PATENT OWNER'S RESPONSES

18. Telescope employs a significantly different proximal pushwire design:

Ex-2071 at 7. The design of the proximal pushwire is critical to guide extension catheter (GEC) pushability, torque control, and overall device handling.

IPR2020-00127, Ex-1830 ¶ 18

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

Secondary Considerations

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,

Petitioners,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner.

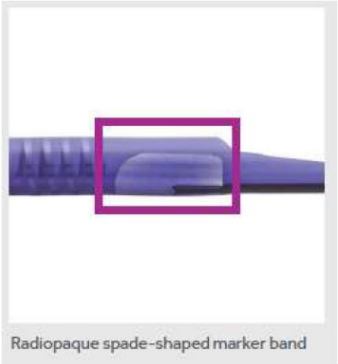
DECLARATION OF PAUL ZALESKY SUBMITTED IN CONNECTION WITH PETITIONERS' REPLIES TO PATENT OWNER'S RESPONSES

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

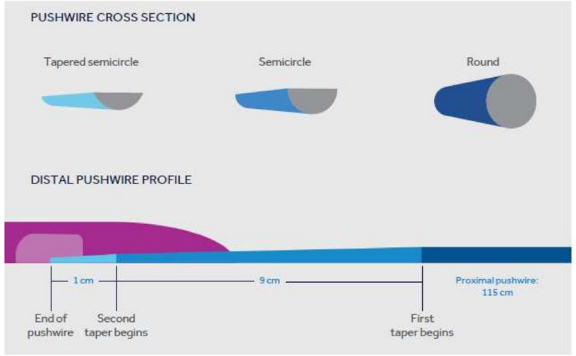
Medtronic Ex. 1830
Medtronic v. Teleflex
Page 1

DECLARATION OF PAUL ZALESKY SUBMITTED IN CONNECTION WITH PETITIONERS' REPLIES TO PATENT OWNER'S RESPONSES

19. The termination end of the pushwire is critically different for the two devices. Telescope employs a tapered distal pushwire profile, which is fused to a spade-shaped marker band as shown below.



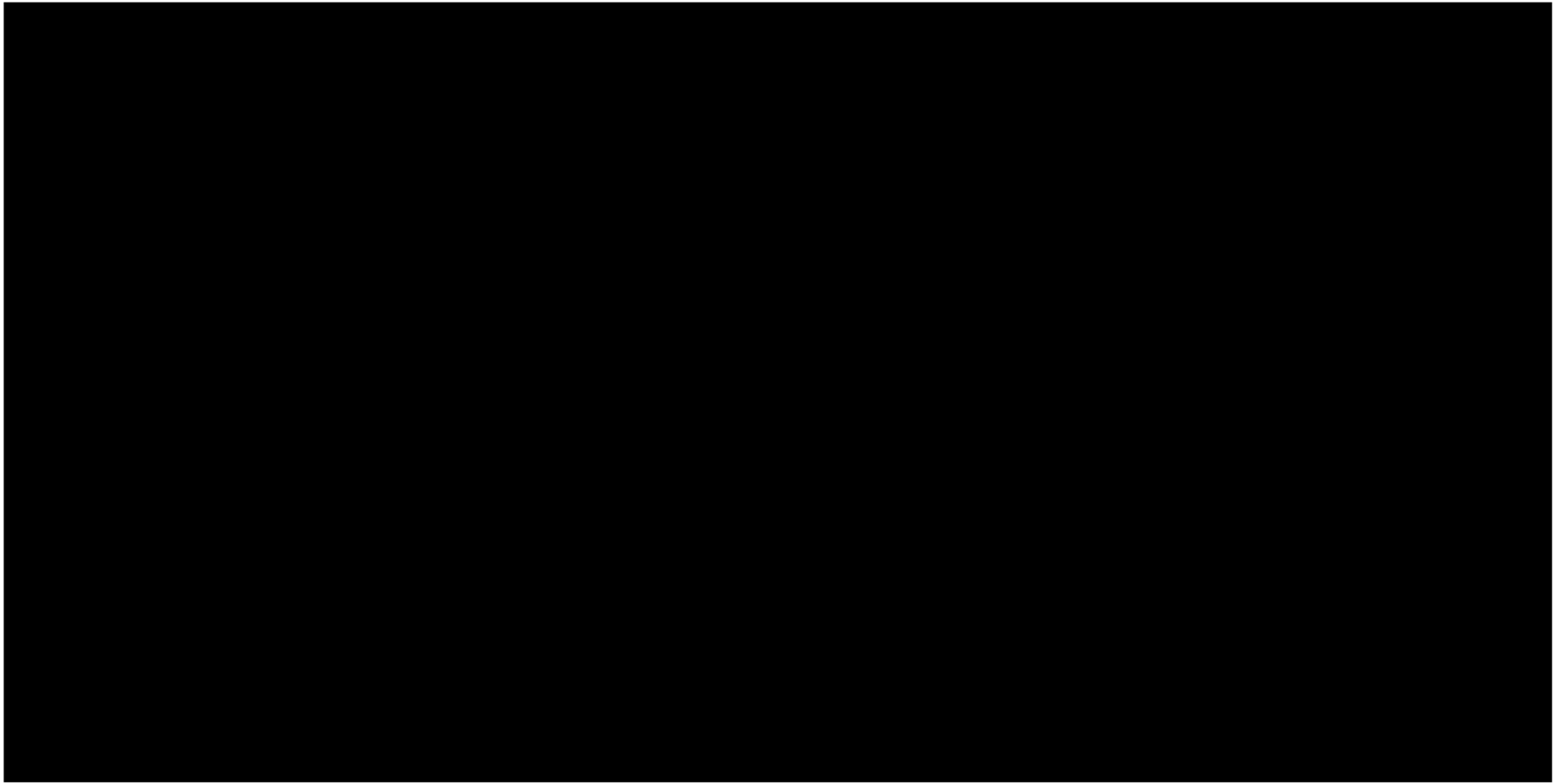
Radiopaque spade-shaped marker band



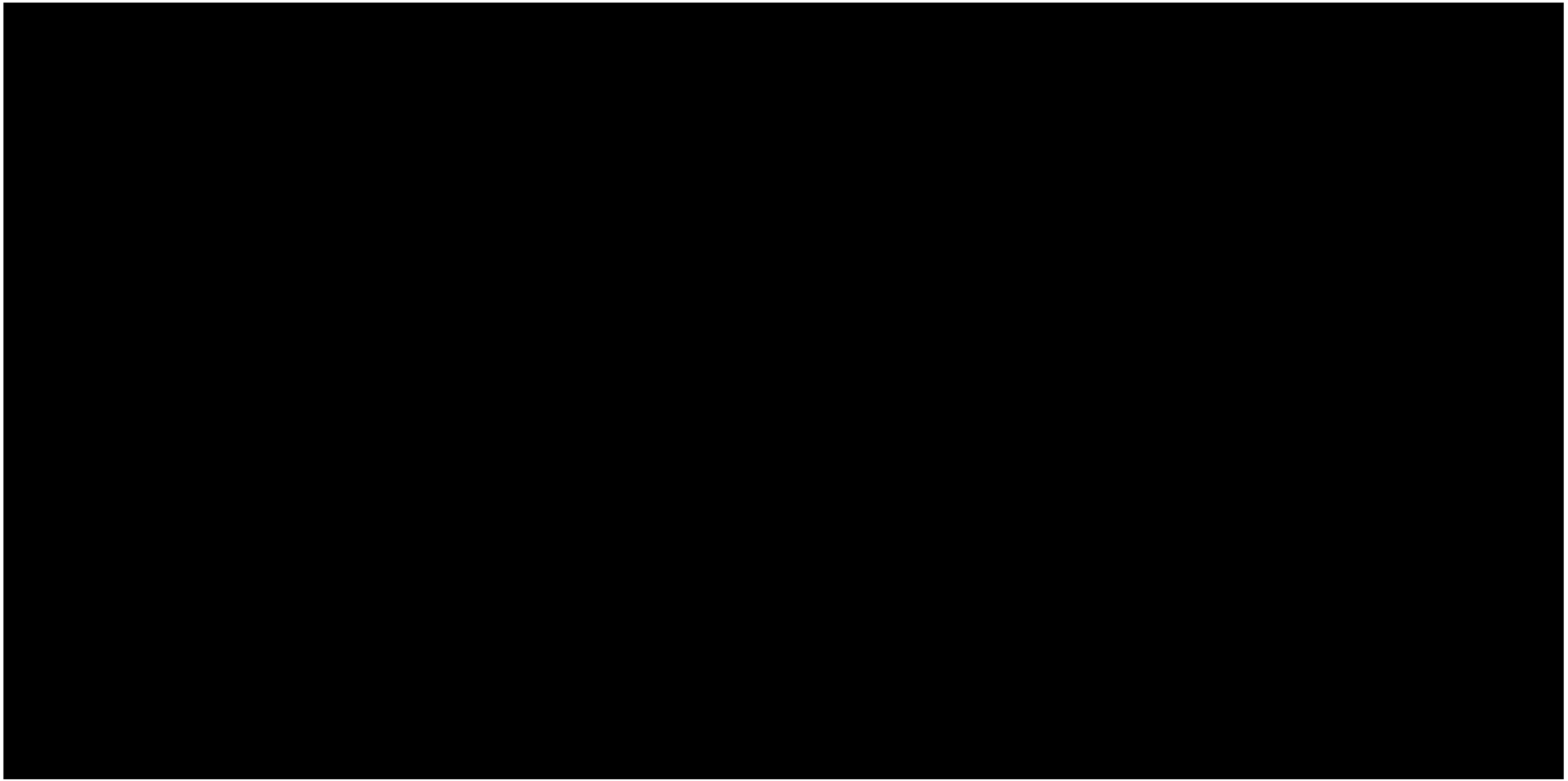
IPR2020-00127, Ex-1830 ¶ 19

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

Secondary Considerations



Secondary Considerations



Secondary Considerations

Patent	IPR	One French Claim Language
’760	-132**	30. … wherein the guide catheter includes a lumen … wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.
	-134	53. … a tubular structure defining a lumen ..the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and
’776	-135**	53. … a tubular structure defining a lumen and positioned distal to the substantially rigid segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter
	-136	
’379	-138	33. … wherein providing the reinforced segment includes forming or obtaining a reinforced segment including a lumen having a uniform inner diameter that is about one French smaller than an inner diameter of the continuous lumen of the guide catheter.

**Denotes IPR where only alleged secondary consideration is alleged “copying”

Secondary Considerations

French Size (F)	GEC Name	I.D. (in)	O.D. (in)	Required GC I.D. (in)	Extension Length (cm)	Polymer Channel (cm)	Full Length (cm)
5.5	GuideLiner™* V3 GEC[1]	0.051	0.063	6 F ≥ 0.066	25	17	150
6	Telescope™ GEC	0.056	0.067	6 F ≥ 0.070	25	4	150
6	GuideLiner™* V3 GEC[1]	0.056	0.067	6 F ≥ 0.070	25	17	150
6	Guidezilla™* II GEC[2]	0.057	0.067	6 F ≥ 0.070	25	N/A, metal collar	150
7	Telescope™ GEC	0.062	0.075	7 F ≥ 0.078	25	4	150
7	GuideLiner™* V3 GEC[1]	0.062	0.075	7 F ≥ 0.078	25	17	150
7	Guidezilla™* II GEC[2]	0.063	0.073	7 F ≥ 0.078	25	N/A, metal collar	150

IPR2020-00132, Ex-1082 Ex-A at 39

MEANS-PLUS-FUNCTION PETITION

IPR2020-00129

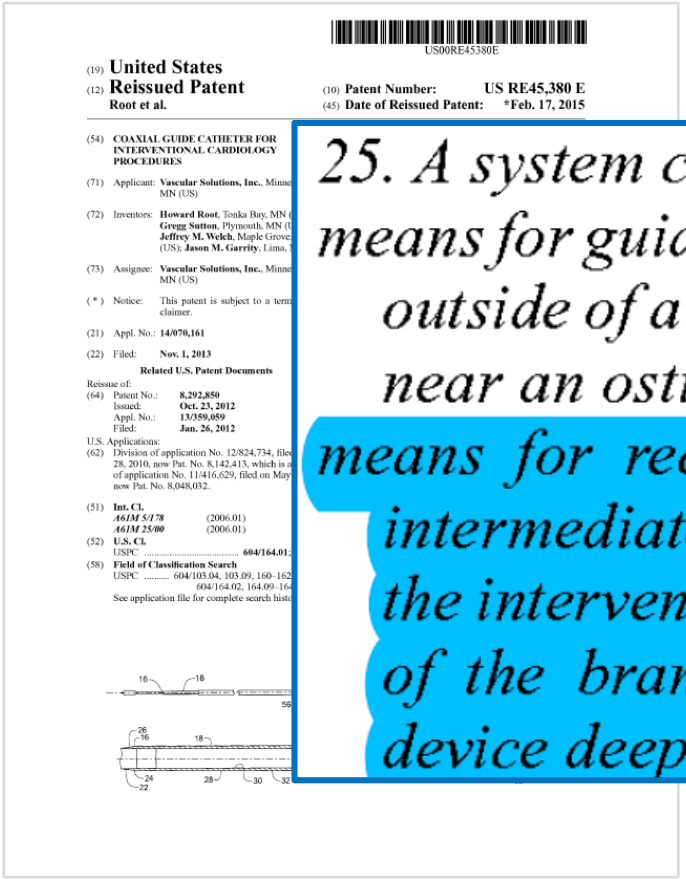
IPR2020-00129

RE45,380 claims	Instituted Ground	References
25-27, 29-33, 35-37, 41-45, 47-49	1	Ressemann
27	2	Ressemann and knowledge of a POSITA
27	3	Ressemann, Kataishi
27	4	Ressemann, Enger
32-33	5	Ressemann, Takahashi
38	6	Ressemann, Berg
25-26, 28-30, 32-37, 39	7	Itou
31	8	Itou and knowledge of a POSITA
27	9	Itou, Kataishi
27	10	Itou, Berg

IPR2020-00129

1. Claim Construction: Means for “receiving . . . and guiding”
   - Presumption is Overcome
   - Corresponding Structure
2. Claim 25
   - Ressemann Anticipates
   - Itou Anticipates
3. Itou: Configured to Receive a Stent/Balloon
4. Ressemann: Achieve 1 French
5. Itou/Ressemann: Double-Incline Side Opening

IPR2020-00129: Claim Language



US00RE45380E

(19) **United States**
(12) **Reissued Patent**
Root et al.

(10) **Patent Number:** **US RE45,380 E**
(45) **Date of Reissued Patent:** ***Feb. 17, 2015**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(71) Applicant: **Vascular Solutions, Inc.**, Minne MN (US)

(72) Inventors: **Howard Root**, Tonka Bay, MN (**Gregg Sutton**, Plymouth, MN (**Jeffrey M. Welch**, Maple Grove (US); **Jason M. Garrity**, Lima,

(73) Assignee: **Vascular Solutions, Inc.**, Minne MN (US)

(*) Notice: This patent is subject to a term claimer.

(21) Appl. No.: **14/070,161**

(22) Filed: **Nov. 1, 2013**

Related U.S. Patent Documents

Reissue of:
(64) Patent No.: **8,292,850**
Issued: **Oct. 23, 2012**
Appl. No.: **13/359,059**
Filed: **Jan. 26, 2012**

U.S. Applications:
(62) Division of application No. 12/824,734, file 28, 2010, now Pat. No. 8,142,413, which is a of application No. 11/416,629, filed on May now Pat. No. 8,048,032.

(51) **Int. Cl.**
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)

(52) **U.S. Cl.**
USPC **604/164.01**

(58) **Field of Classification Search**
USPC 604/103.04, 103.09, 160–162 604/164.02, 164.09–16
See application file for complete search histo

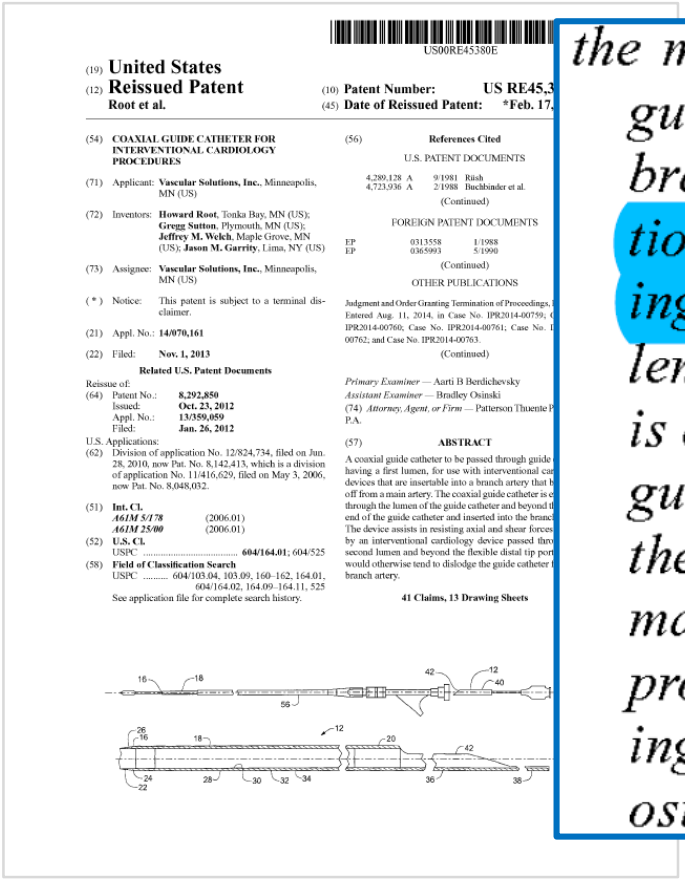
25. A system comprising:

means for guiding an interventional device from a location outside of a subject, through a main vessel, to a location near an ostium of a branch vessel; and

means for receiving the interventional device from an intermediate or distal portion of the means for guiding the interventional device to the location near the ostium of the branch vessel and guiding the interventional device deeper into the branch vessel,

Ex-1201, claim 25 (-00129 IPR)

IPR2020-00129: Claim 25 Recites Extensive Structure



US0RE45380E

(19) **United States**
(12) **Reissued Patent**
Root et al.

(10) **Patent Number:** US RE45,3
(45) **Date of Reissued Patent:** *Feb. 17,

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(71) Applicant: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(72) Inventors: **Howard Root**, Tonka Bay, MN (US); **Gregg Sutton**, Plymouth, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Lima, NY (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/070,161**

(22) Filed: **Nov. 1, 2013**

Related U.S. Patent Documents

Reissue of:
(64) Patent No.: **8,292,850**
Issued: **Oct. 23, 2012**
Appl. No.: **13/359,059**
Filed: **Jan. 26, 2012**

U.S. Applications:
(62) Division of application No. 12/824,734, filed on Jun. 28, 2010, now Pat. No. 8,142,413, which is a division of application No. 11/416,629, filed on May 3, 2006, now Pat. No. 8,048,032.

(51) **Int. Cl.**
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)

(52) **U.S. Cl.**
USPC **604/164.01**; 604/525

(58) **Field of Classification Search**
USPC 604/103.04, 103.09, 160–162, 164.01, 604/164.02, 164.09–164.11, 525
See application file for complete search history.

(56) **References Cited**

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EP 0365993 5/1990
(Continued)

OTHER PUBLICATIONS

Judgment and Order Granting Termination of Proceedings, Entered Aug. 11, 2014, in Case No. IPR2014-00759; Case No. IPR2014-00760; Case No. IPR2014-00761; Case No. IPR2014-00762; and Case No. IPR2014-00763.
(Continued)

Primary Examiner — Aarti B Berdichevsky
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente P.A.

(57) **ABSTRACT**

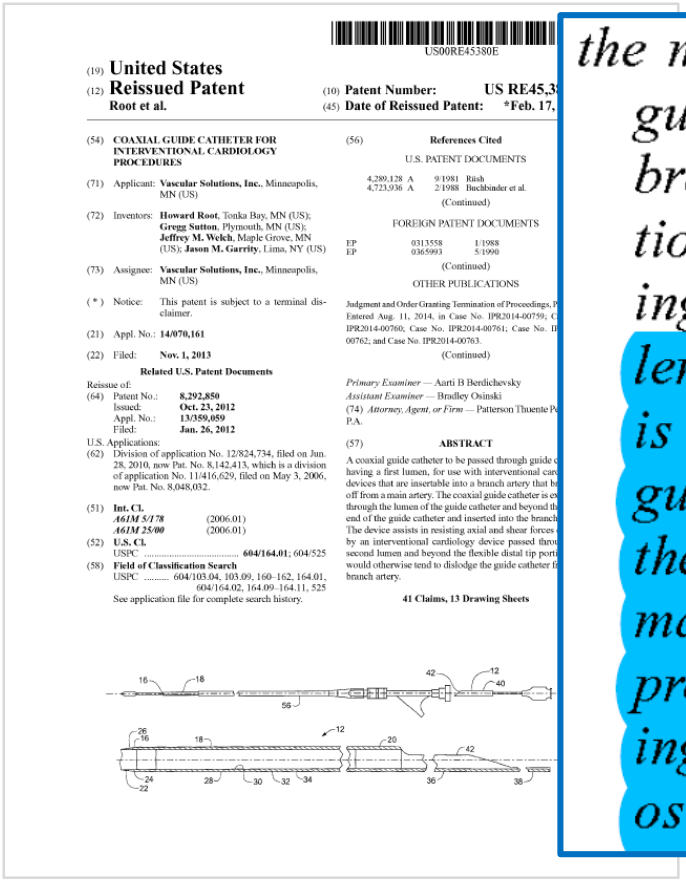
A coaxial guide catheter to be passed through guide having a first lumen, for use with interventional devices that are insertable into a branch artery that off from a main artery. The coaxial guide catheter through the lumen of the guide catheter and beyond end of the guide catheter and inserted into the branch. The device assists in resisting axial and shear forces by an interventional cardiology device passed second lumen and beyond the flexible distal tip would otherwise tend to dislodge the guide catheter branch artery.

41 Claims, 13 Drawing Sheets

the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel including, in a distal to proximal direction, a tip portion, a reinforced portion, a side opening, and a substantially rigid portion, and having a length such that when the distal end of the tip portion is extended distally of the distal end of the means for guiding the interventional device to the location near the ostium of the branch vessel, a portion of the proximal end of the substantially rigid portion extends proximally of the proximal end of the means for guiding the interventional device to the location near the ostium of the branch vessel,

Ex-1201, claim 25 (-00129 IPR)

IPR2020-00129: Claim 25 Recites Extensive Structure



US00RE45380E

(19) **United States**
(12) **Reissued Patent**
Root et al.

(10) **Patent Number:** US RE45,3
(45) **Date of Reissued Patent:** *Feb. 17,

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(71) Applicant: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(72) Inventors: **Howard Root**, Tonka Bay, MN (US); **Gregg Sutton**, Plymouth, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Lima, NY (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/070,161**

(22) Filed: **Nov. 1, 2013**

Related U.S. Patent Documents

Reissue of:
(64) Patent No.: **8,292,850**
Issued: **Oct. 23, 2012**
Appl. No.: **13/359,059**
Filed: **Jan. 26, 2012**

U.S. Applications:
(62) Division of application No. 12/824,734, filed on Jun. 28, 2010, now Pat. No. 8,142,413, which is a division of application No. 11/416,629, filed on May 3, 2006, now Pat. No. 8,048,032.

(51) **Int. Cl.**
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)

(52) **U.S. Cl.**
USPC **604/164.01**; 604/525

(58) **Field of Classification Search**
USPC 604/103.04, 103.09, 160–162, 164.01, 604/164.02, 164.09–164.11, 525
See application file for complete search history.

(56) **References Cited**

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(Continued)

FOREIGN PATENT DOCUMENTS

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EP 0365993 5/1990
(Continued)

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(Continued)

Primary Examiner — Aarti B Berdichevsky
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente P... P.A.

(57) **ABSTRACT**

A coaxial guide catheter to be passed through guide c... having a first lumen, for use with interventional car... devices that are insertable into a branch artery that br... off from a main artery. The coaxial guide catheter is co... through the lumen of the guide catheter and beyond th... end of the guide catheter and inserted into the branch... The device assists in resisting axial and shear forces ... by an interventional cardiology device passed thro... second lumen and beyond the flexible distal tip porti... would otherwise tend to dislodge the guide catheter f... branch artery.

41 Claims, 13 Drawing Sheets

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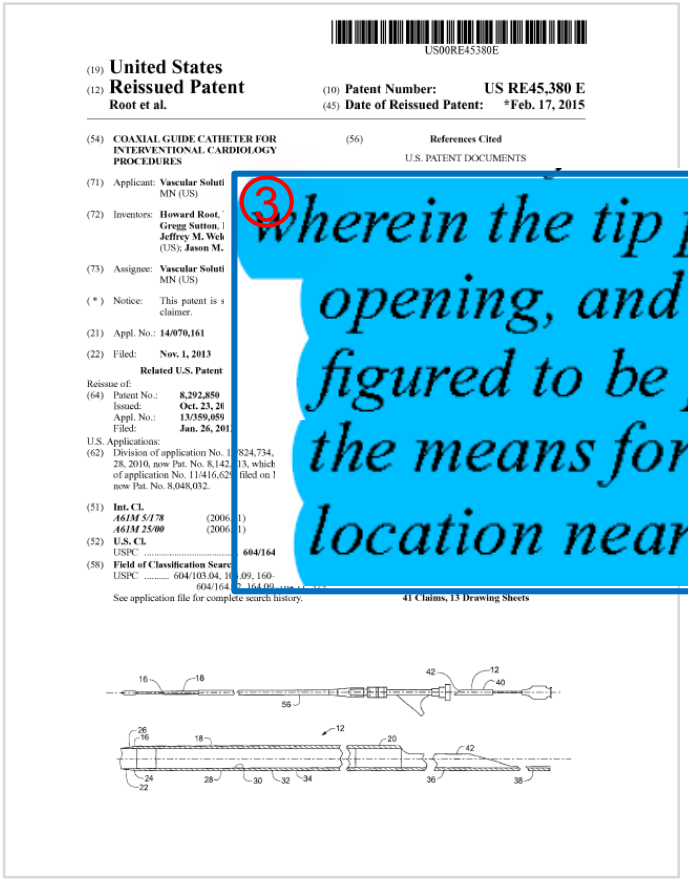

US00RE45380E

(19) **United States**
(12) **Reissued Patent**
Root et al.

(10) **Patent Number: US RE45,380 E**
(45) **Date of Reissued Patent: *Feb. 17, 2015**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(56) **References Cited**
U.S. PATENT DOCUMENTS

(71) Applicant: **Vascular Soluti** MN (US)

(72) Inventors: **Howard Root,** **Gregg Sutton,** **Jeffrey M. Web** (US); **Jason M.**

(73) Assignee: **Vascular Soluti** MN (US)

(*) Notice: This patent is s claimer.

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(22) Filed: **Nov. 1, 2013**

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A61M 5/178 (2006.1)
A61M 25/00 (2006.1)

(52) **U.S. Cl.**
USPC **604/164**

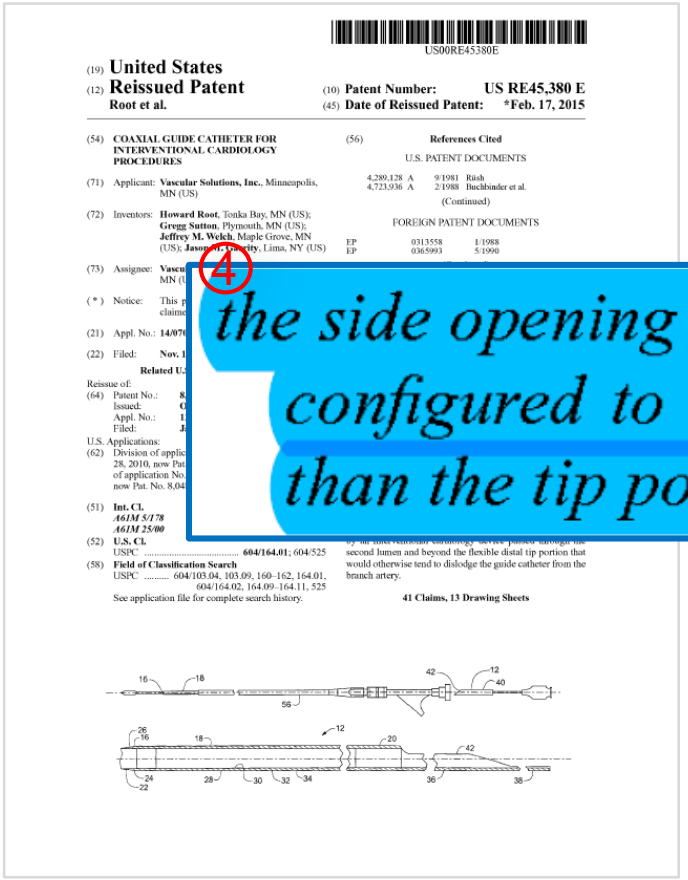
(58) **Field of Classification Searc**
USPC 604/103.04, 1 09, 160-604/164 164.09
See application file for complete search history.

41 Claims, 13 Drawing Sheets

③ *wherein the tip portion, the reinforced portion, the side opening, and the substantially rigid portion are configured to be passed, at least in part, into a lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel, and*

Ex-1201, claim 25 (-00129 IPR)

IPR2020-00129: Claim 25 Recites Extensive Structure



US00RE45380E

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(12) **Reissued Patent**
Root et al.

(10) **Patent Number: US RE45,380 E**
(45) **Date of Reissued Patent: *Feb. 17, 2015**

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(72) Inventors: **Howard Root**, Tonka Bay, MN (US); **Gregg Sutton**, Plymouth, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Lima, NY (US)

(73) Assignee: **Vascu** MN (U

(*) Notice: This p claime

(21) Appl. No.: **14/076**

(22) Filed: **Nov. 1**

Related U.

Reissue of:
(64) Patent No.: **8**
Issued: **C**
Appl. No.: **1**
Filed: **J**

U.S. Applications:
(62) Division of applic 28, 2010, now Pat of application No. now Pat. No. 8,04

(51) **Int. Cl.**
A61M 5/178
A61M 25/00

(52) **U.S. Cl.**
USPC **604/164.01**; 604/525

(58) **Field of Classification Search**
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4,723,936 A 2/1988 Buchbinder et al.
(Continued)

FOREIGN PATENT DOCUMENTS

EP 0313558 1/1988
EP 0365993 5/1990

by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

41 Claims, 13 Drawing Sheets

④ *the side opening and the substantially rigid portion are configured to be more rigid along a length thereof than the tip portion.*

Ex-1201, claim 25 (-00129 IPR)

IPR2020-00129: Teleflex Argues that Lumen is Missing

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.
Petitioners,

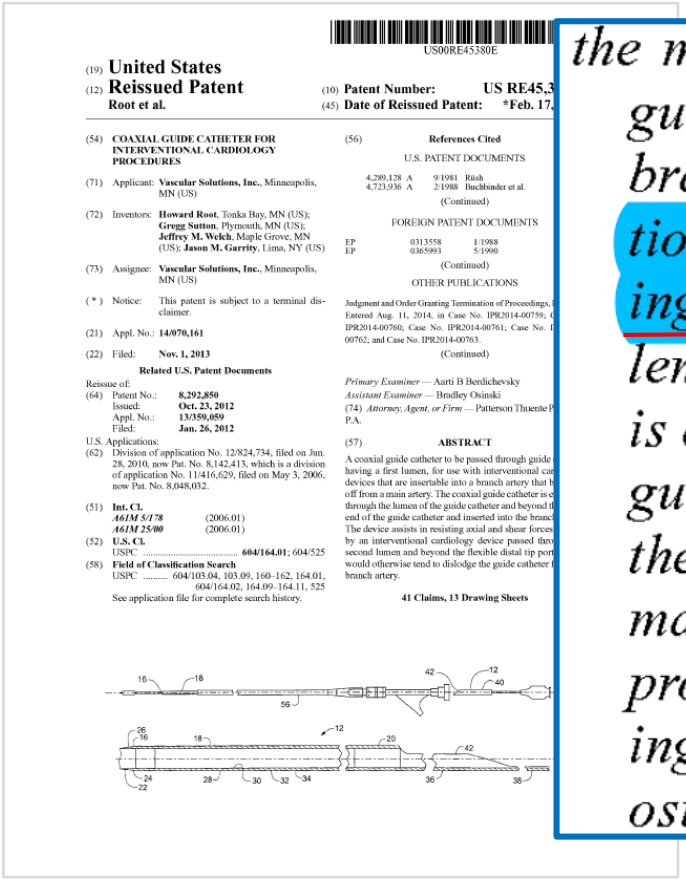
v.

TELEFLEX INNOVATIONS S.A.R.L.
Patent Owner.

For example, the claim does not recite that the tip portion and reinforced portion have ***a lumen*** that communicates with the claimed opening.

POR at 11 (-00129 IPR)

IPR2020-00129: Claim 25 Side Opening Has Lumen



US0RE45380E

(19) **United States**
(12) **Reissued Patent**
Root et al.

(10) **Patent Number: US RE45,3**
(45) **Date of Reissued Patent: *Feb. 17,**

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(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

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(52) **U.S. Cl.**
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4,723,936 A 2/1988 Buchbinder et al.
(Continued)

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EP 0365993 5/1990
(Continued)

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(Continued)

Primary Examiner — Aarti B Berdichevsky
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente P.A.

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A coaxial guide catheter to be passed through guide having a first lumen, for use with interventional devices that are insertable into a branch artery that off from a main artery. The coaxial guide catheter through the lumen of the guide catheter and beyond end of the guide catheter and inserted into the branch. The device assists in resisting axial and shear forces by an interventional cardiology device passed second lumen and beyond the flexible distal tip would otherwise tend to dislodge the guide catheter branch artery.

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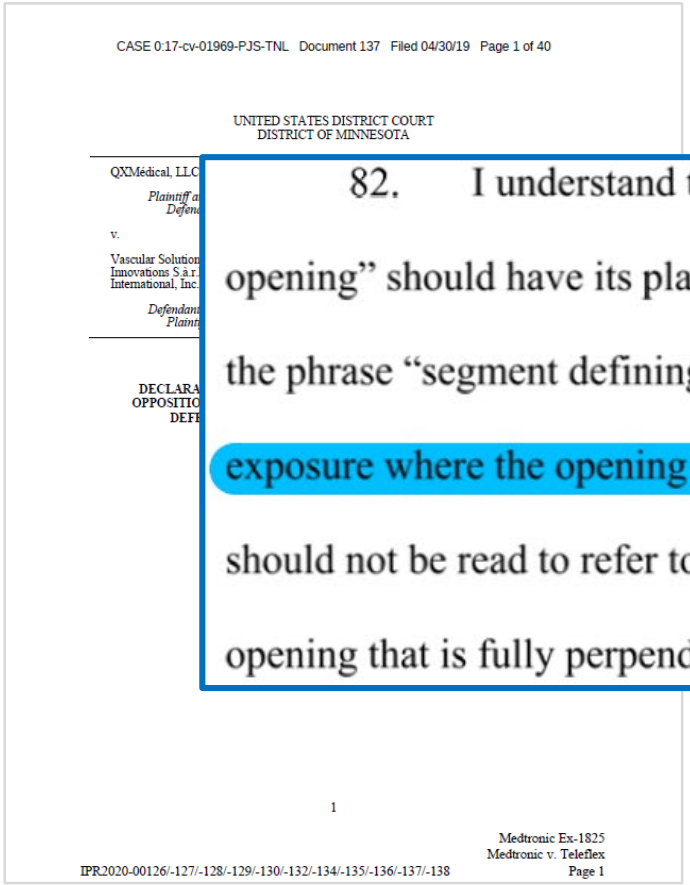
Ex-1201, claim 25 (-00129 IPR)

IPR2020-00129: Keith Agrees that Side Opening Fully Circumferential



CASE 0:17-cv-01969-PJS-TNL Document 137 Filed 04/30/19 Page 1 of 40

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

QXMédical, LLC

Plaintiff a
Defen

v.

Vascular Solution
Innovations S.à.r.
International, Inc.

Defendan
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DEF

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Medtronic Ex-1825
Medtronic v. Teleflex
Page 1

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

82. I understand that the Court has ruled that the phrase "segment defining a side opening" should have its plain and ordinary meaning. It is my opinion that the plain meaning of the phrase "segment defining a side opening" is that the opening has some amount of side exposure where the opening transitions into the fully circumferential portion, and that that phrase should not be read to refer to a segment that consists only of full circumference structure with an opening that is fully perpendicular to the axis of the device.

Ex-1825, ¶ 82 (Keith)

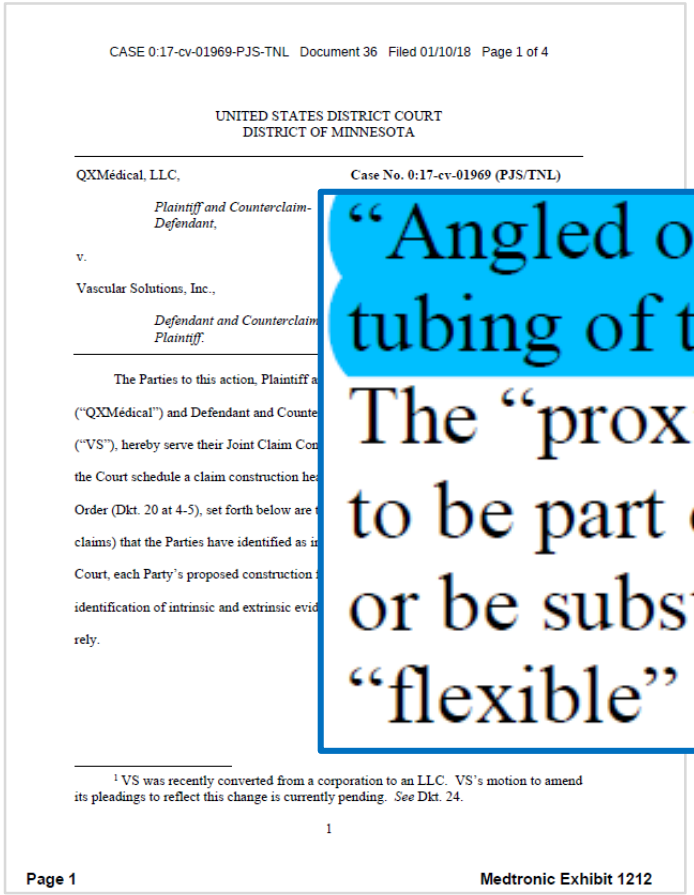
IPR2020-00129: Side Openings do not Terminate into Lumenless Portion

SUPPLEMENTAL DECLARATION OF
STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

I am unaware of any catheter assembly (i.e., means for receiving and guiding) having a side opening where the lumen terminates prior to the distally-located portions (i.e., the sections found distal to the side opening). In my opinion, there would be no reason to have a side opening if the lumen terminated prior to the distally-located portion(s). I cannot think of any function or reason to have a catheter assembly with a side opening that terminates into a lumenless portion.

Ex-1806, ¶ 31 (Brecker)

IPR2020-00129: Teleflex's Construction of "side opening"



CASE 0:17-cv-01969-PJS-TNL Document 36 Filed 01/10/18 Page 1 of 4

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

QXMédical, LLC,

Plaintiff and Counterclaim-Defendant,

v.

Vascular Solutions, Inc.,

Defendant and Counterclaim Plaintiff.

Case No. 0:17-cv-01969 (PJS/TNL)

The Parties to this action, Plaintiff a
("QXMédical") and Defendant and Counte
("VS"), hereby serve their Joint Claim Co
the Court schedule a claim construction he
Order (Dkt. 20 at 4-5), set forth below are t
claims) that the Parties have identified as i
Court, each Party's proposed construction
identification of intrinsic and extrinsic evid
rely.

[1] VS was recently converted from a corporation to an LLC. VS's motion to amend its pleadings to reflect this change is currently pending. *See* Dkt. 24.

1

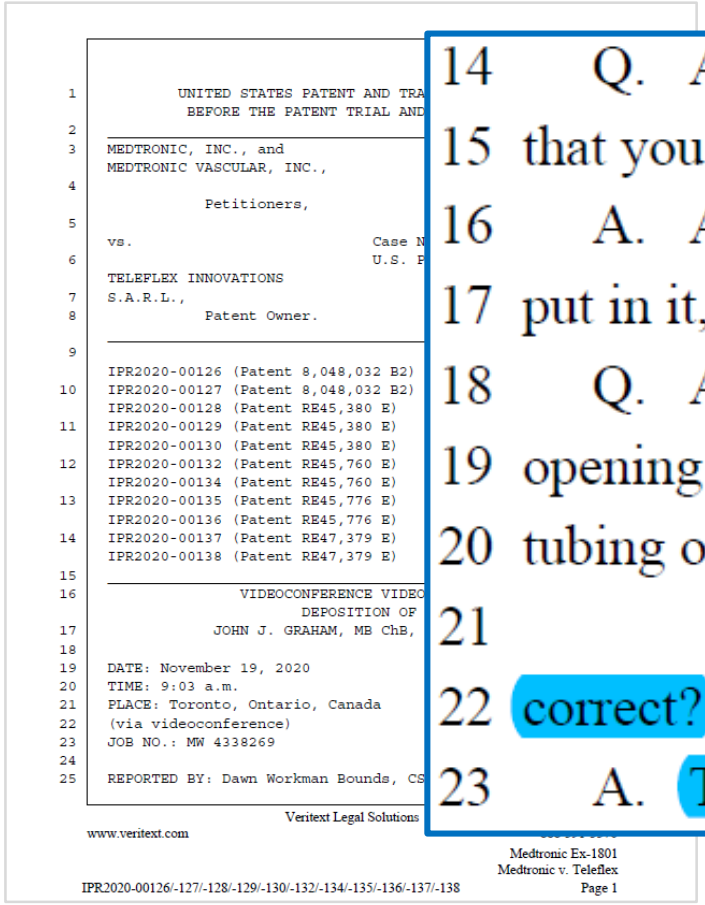
Page 1 Medtronic Exhibit 1212

"Angled opening at the proximal end of the tubing of the guide extension catheter."

The "proximal side opening" does not have to be part of the substantially rigid portion or be substantially rigid, but can be either "flexible" or "substantially rigid."

Ex-1212 at 17-18

IPR2020-00129: Teleflex's Construction of "side opening"



UNITED STATES PATENT AND TRA
BEFORE THE PATENT TRIAL AND

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case N
U.S. P

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEO
DEPOSITION OF
JOHN J. GRAHAM, MB ChB,

DATE: November 19, 2020
TIME: 9:03 a.m.
PLACE: Toronto, Ontario, Canada
(via videoconference)
JOB NO.: MW 4338269

REPORTED BY: Dawn Workman Bounds, CS

Veritext Legal Solutions
www.veritext.com

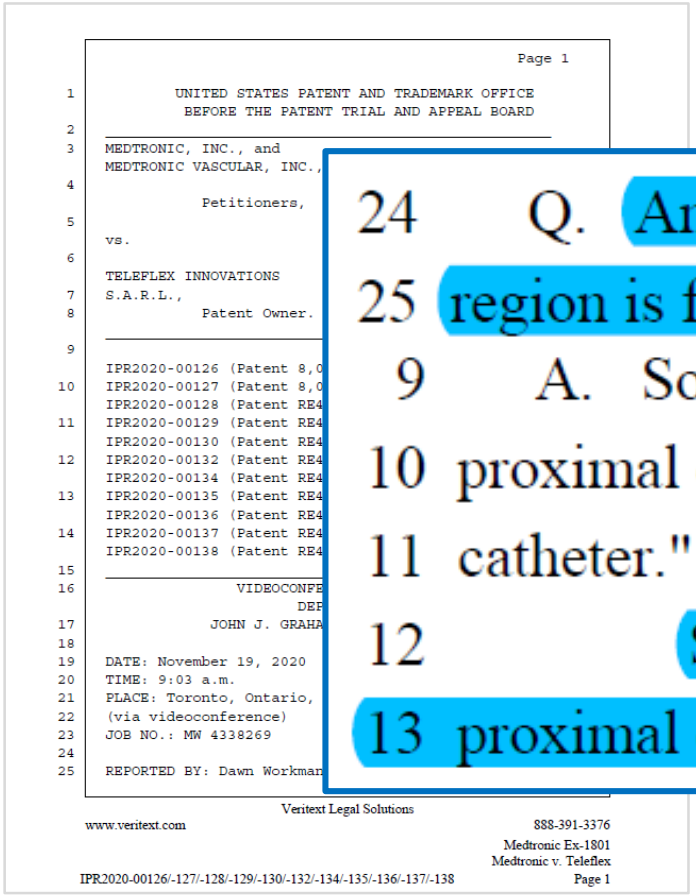
Medtronic Ex-1801
Medtronic v. Teleflex
Page 1

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

14 Q. And is that the construction of side opening
15 that you applied in your declaration?
16 A. As I state, other than the claim terms that I
17 put in it, the rest comes from 1012, so that would be it.
18 Q. All right. And it states here that a side
19 opening is an angled opening at the proximal end of the
20 tubing of the guide extension catheter.
21 That's the construction you applied,
22 correct?
23 A. That is correct.

Ex-1801, 11:14-23 (Graham)

IPR2020-00129: Lumen is Present Distal to Side Opening



Page 1

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TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,0
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IPR2020-00128 (Patent RE4
IPR2020-00129 (Patent RE4
IPR2020-00130 (Patent RE4
IPR2020-00132 (Patent RE4
IPR2020-00134 (Patent RE4
IPR2020-00135 (Patent RE4
IPR2020-00136 (Patent RE4
IPR2020-00137 (Patent RE4
IPR2020-00138 (Patent RE4

VIDEOCONFE
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JOHN J. GRAHA

DATE: November 19, 2020
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Veritext Legal Solutions
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888-391-3376

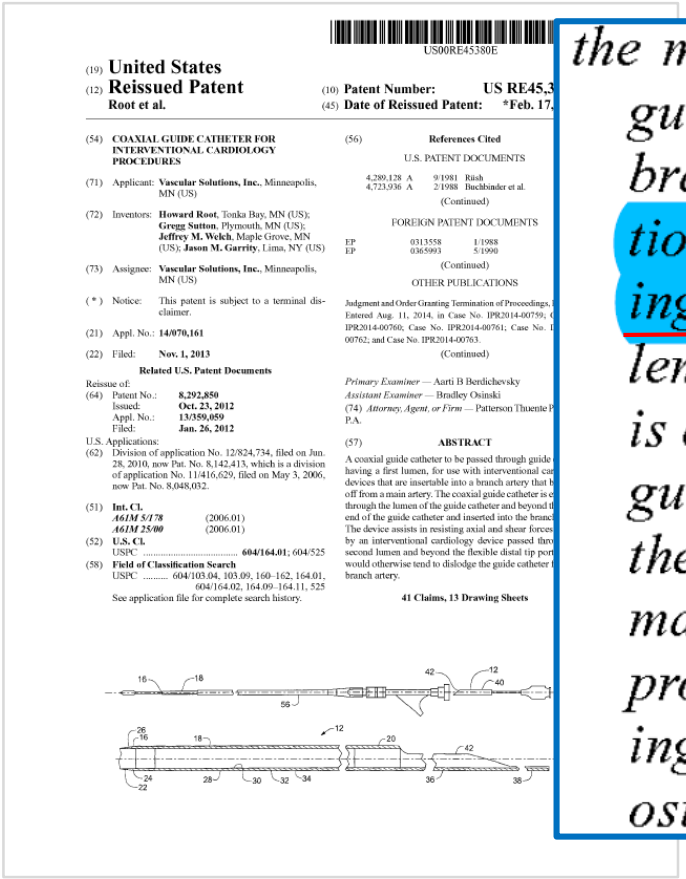
Medtronic Ex-1801
Medtronic v. Teleflex

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

24 Q. And that language would indicate that a tubular
25 region is found distal to the side opening, correct?
9 A. So the it says, "The angled opening at the
10 proximal opening of the tubing of the guide extension
11 catheter."
12 So the proximal -- the opening is at the
13 proximal end of the tubing, yes.

Ex-1801, 11:24-12:13 (Graham)

IPR2020-00129: Claim 25



US0RE45380E

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(58) **Field of Classification Search**
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(Continued)

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Primary Examiner — Aarti B Berdichevsky
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41 Claims, 13 Drawing Sheets

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Ex-1201, claim 25 (-00129 IPR)

IPR2020-00129: Reinforcement is to Protect Lumen

SUPPLEMENTAL DECLARATION OF
STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

32. Further, by the time of the alleged invention, reinforcing catheters—in particular, with metallic braiding or coiling—was common practice in the art. *E.g.* Ex-1008, 7:4-7. The reason for reinforcement is to allow the catheter to maintain its shape in regions of tortuosity and calcification. *E.g. id.*, 6:66-7:4. In other words, by recited the claim language "reinforced portion," a POSITA would have understood that a lumen was found therein, otherwise there would be no need for reinforcement.

Ex-1806, ¶ 32 (Brecker)

IPR2020-00129: Not Necessary, but Appropriate to Consult Specification

"[W]here the claims recite the term 'means,' we have considered the written description to inform the analysis of whether the claim recites sufficiently definite structure to overcome the presumption that § 112, ¶ 6 governs the construction of the claim."

Inventio AG v. Thyssenkrupp Elevator Ams. Corp., 649 F.3d 1350, 1357 (Fed. Cir. 2011)

"The written description also supports this choice by stating that 'the spring 46 is an example of spring means tending to keep the door closed.'"

Unidynamics Corp. v. Automatic Prods. Int'l, 157 F.3d 1311, 1319 (Fed. Cir. 1998)

IPR2020-00129: No Example of Lumenless Catheter

SUPPLEMENTAL DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

34. I do not believe it is necessary to do so here, but the specification of the '380 patent, if consulted, reinforces my conclusion that the means-plus-function presumption is overcome. For example, each Figure showing the reinforced portion 18 or the tip portion 16 show a lumen. *See* Ex-1001, Figs. 1, 3, 4. The specification also explains that interventional devices are "inserted through the lumen of coaxial guide catheter 12." *Id.*, 10:16-20. And "[t]he coaxial guide catheter includes a tip portion, a reinforced portion, and a substantially rigid portion." *Id.*, 4:51-53. There are no examples or discussion of a lumenless reinforced portion or tip portion in the specification of the '380 patent. In other

Ex-1806, ¶ 34 (Brecker)

1. Claim Construction: Means for “receiving . . . and guiding”
   - Presumption is Overcome
   - Corresponding Structure
2. Claim 25
   - Ressemann Anticipates
   - Itou Anticipates
3. Itou: Configured to Receive a Stent/Balloon
4. Ressemann: Achieve 1 French
5. Itou/Ressemann: Double-Incline Side Opening

IPR2020-00129: Standard for Corresponding Structure

Trials@uspto.gov
571-272-7822

Paper 22
Date: June 8, 2020

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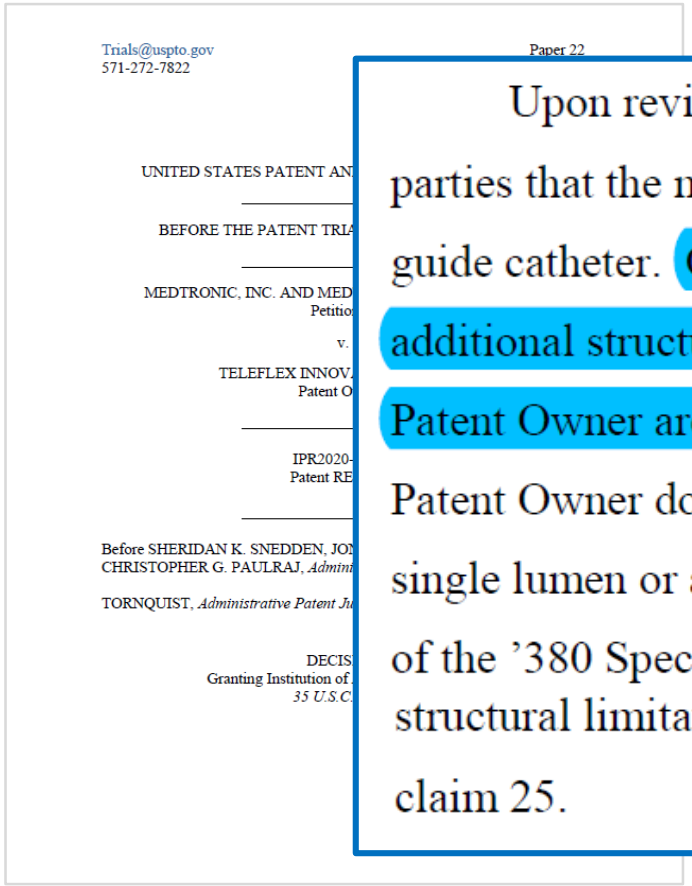
"Structure disclosed in the specification qualifies as 'corresponding structure' if the intrinsic evidence clearly links or associates that structure to the function recited in the claim." *Williamson*, 792 F.3d at 1352. In conducting this analysis, we may not incorporate structure from the written description beyond that which is necessary to perform the claimed function(s). *See Micro Chemical, Inc. v. Great Plains Chemical Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999).

Institution Decision at 19-20 (-00129 IPR)

IPR2020-00129: Institution Decision Rejected Teleflex's Structure


Trials@uspto.gov
571-272-7822

Paper 22

UNITED STATES PATENT AN

BEFORE THE PATENT TRIA

MEDTRONIC, INC. AND MED
Petitio

v.

TELEFLEX INNOV
Patent O

IPR2020-
Patent RE

Before SHERIDAN K. SNEDDEN, JO
CHRISTOPHER G. PAULRAJ, *Admini*

TORNQUIST, *Administrative Patent Ju*

DECIS
Granting Institution of
35 U.S.C.

Upon review of the claims and the Specification, we agree with both parties that the means for receiving and guiding in claim 25 is a coaxial guide catheter. On this record, however, we are not persuaded that the additional structural limitations for the coaxial guide catheter asserted by Patent Owner are necessary to perform the recited functions. In particular, Patent Owner does not explain sufficiently why the Specification requires a single lumen or a lumen that is circular in cross-section. Nor do the portions of the '380 Specification cited by Patent Owner clearly indicate that these structural limitations are required to perform the functions set forth in claim 25.

Institution Decision at 19-20 (-00129 IPR)

IPR2020-00129: Teleflex's Additional Proposed Structure

SUPPLEMENTAL DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

36. I understand that Mr. Keith and Dr. Graham agree that the corresponding structure in the specification is a guide catheter, but they believe that the guide catheter must also have the following structure:

> *a distal tubular portion with a single lumen[3] that is coaxial with the lumen of the guide catheter attached to a substantially rigid rail structure that allows interventional devices to be advanced alongside and into the lumen of the tubular portion, with the total length of the device being longer than the guide catheter, and at least a distal part of the tubular portion is flexible.[4]*

IPR2020-00129: Coaxial and Single Lumen are Unnecessary

SUPPLEMENTAL DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

To perform this means for receiving and guiding, I do not believe that the additional structure recited by Patent Owner is necessary. In particular, I do not agree with Patent Owner's position that the receiving and guiding function requires an extension catheter with a coaxial tubular portion and a single lumen.

38. For example, Ressemann is an example of a non-coaxial (under Patent Owner's construction),[5] multi-lumen catheter that receives and guides an interventional device. Ex-1008, Figs. 6A-6F.

1. Claim Construction: Means for “receiving . . . and guiding”
   - Presumption is Overcome
   - Corresponding Structure
2. Claim 25
   - Ressemann Anticipates
   - Itou Anticipates
3. Itou: Configured to Receive a Stent/Balloon
4. Ressemann: Achieve 1 French
5. Itou/Ressemann: Double-Incline Side Opening

IPR2020-00129: Ressemann Anticipates Claim 25

Ressemann Anticipates Claim 25:

- Means-Plus-Function Presumption is Overcome
- The Corresponding Structure is an Extension Catheter
- Ressemann is an Equivalent Structure

IPR2020-00129: Ressemann Anticipates Claim 25

Ressemann Anticipates Claim 25:

- Means-Plus-Function Presumption is Overcome
- The Corresponding Structure is an Extension Catheter
- Ressemann is an Equivalent Structure

IPR2020-00129: Ressemann Anticipates Claim 25

Ressemann Anticipates Claim 25:

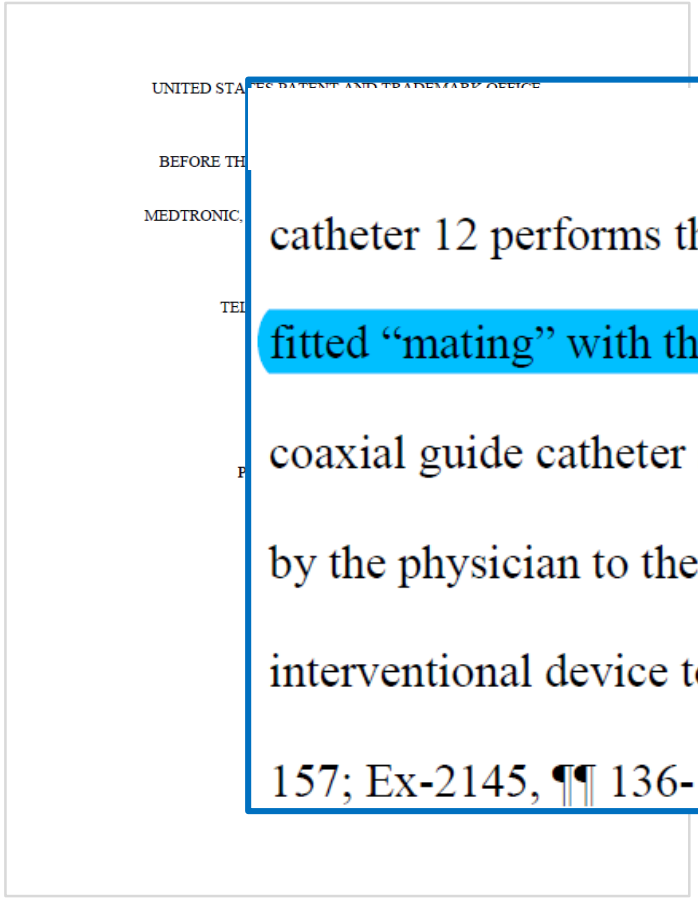
- Means-Plus-Function Presumption is Overcome
- The Corresponding Structure is an Extension Catheter
- Ressemann is an Equivalent Structure

IPR2020-00129: Ressemann Discloses an Equivalent Structure

Structural equivalence under § 112, ¶ 6 is met when the "differences are insubstantial … that is, if the assertedly equivalent structure performs *the claimed function* in substantially the same way to achieve substantially the same result as the corresponding structure described in the specification."

Odetics, Inc. v. Storage Tech. Corp.,
185 F.3d 1259, 1267 (Fed. Cir. 1999)

IPR2020-00129: Teleflex's "way"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Thus, the "way" in which the coaxial guide catheter 12 performs the claimed function is by ① using a combination of the close-fitted "mating" with the interior of the guide catheter, the distal portion of the coaxial guide catheter seated deeper in the coronary artery, and back force applied by the physician to the substantially rigid portion, as needed, to allow the interventional device to be guided deeper into the branch artery. Ex-2138, ¶¶ 155-157; Ex-2145, ¶¶ 136-139.

POR at 23-24 (-00129 IPR)

IPR2020-00129: “Close-Fitted Mating” is Unnecessary

130. As an initial matter, I do not agree that a closely-fitted mating is required to perform the function of receiving and guiding. The specification of the ’380 patent does not state that any particular spatial relationship between the outer wall of the extension catheter and the inner wall of the guide catheter is necessary. The ’380 patent only requires that the extension catheter fit within the guide catheter. *See* Ex-1001, 8:4-33, 10:5-7, 10:16-20, Figs. 3, 8-9 (IPR2020-00128).

Ex-1806, ¶ 130 (Brecker)

IPR2020-00129: “Close-Fitted Mating” is Unnecessary

130. As an initial matter, I do not agree that a closely-fitted mating is required to perform the function of receiving and guiding. The specification of the

Therefore, I would amend Mr. Keith’s recitation of [1] above as follows: “using a ~~combination of the closely fitting or closely mating of the exterior of the~~ coaxial guide catheter ~~with the interior of the~~ [inside a] guide catheter.” Ressemann teaches that its evacuation assembly 100 (extension catheter) fits inside the guide catheter. Ex-1008, Fig. 6B.

Ex-1806, ¶ 130 (Brecker)

IPR2020-00129: Graham Confirms that Close Fitting is Unnecessary

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR2020-00126
U.S. Patent No. 8,048,

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
JOHN J. GRAHAM, MB ChB, MRCP (UK)

DATE: November 19, 2020
TIME: 9:03 a.m.
PLACE: Toronto, Ontario, Canada
(via videoconference)
JOB NO.: MW 4338269

REPORTED BY: Dawn Workman Bounds, CSR

I just want to know if you could receive and guide an interventional device when you use a 7 French guide catheter with a 5 French extension inside?

A. So I have personally --

MR. KOHLHEPP: Sorry.

Same objections; form and scope.

A. So I have personally undertaken similar endeavors; not with 5 French, but with 6 French in 7 or 8 French guides; and I have used that to deliver devices; not as intended in the IFU - that's the Instruction for Use - but I have performed that.

Ex-1801, 25:13-23 (Graham)

IPR2020-00129: Teleflex's "way"

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Thus, the "way" in which the coaxial guide catheter 12 performs the claimed function is by using a combination of the close-fitted "mating" with the interior of the guide catheter, ② the distal portion of the coaxial guide catheter seated deeper in the coronary artery, and back force applied by the physician to the substantially rigid portion, as needed, to allow the interventional device to be guided deeper into the branch artery. Ex-2138, ¶¶ 155-157; Ex-2145, ¶¶ 136-139.

POR at 23-24 (-00129 IPR)

IPR2020-00129: Teleflex's "way"

UNITED STA

BEFORE TH

MEDTRONIC,

TEL

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Thus, the "way" in which the coaxial guide catheter 12 performs the claimed function is by using a combination of the close-fitted "mating" with the interior of the guide catheter, the distal portion of the coaxial guide catheter seated deeper in the coronary artery, and ③ back force applied by the physician to the substantially rigid portion, as needed, to allow the interventional device to be guided deeper into the branch artery. Ex-2138, ¶¶ 155-157; Ex-2145, ¶¶ 136-139.

POR at 23-24 (-00129 IPR)

1. Claim Construction: Means for “receiving . . . and guiding”
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   - Itou Anticipates
3. Itou: Configured to Receive a Stent/Balloon
4. Ressemann: Achieve 1 French
5. Itou/Ressemann: Double-Incline Side Opening

IPR2020-00129: Relevant Inquiry

Whether the identified structure is “capable of performing the functional limitation of the ‘means.’”

In re Mott, 557 F.2d 266, 269 (C.C.P.A. 1977)

1. Claim Construction: Means for “receiving . . . and guiding”
   - Presumption is Overcome
   - Corresponding Structure
2. Claim 25
   - Ressemann Anticipates
   - Itou Anticipates
3. Itou: Configured to Receive a Stent/Balloon
4. Ressemann: Achieve 1 French
5. Itou/Ressemann: Double-Incline Side Opening

KONTOS

IPR2020-00127, -00130, -00136

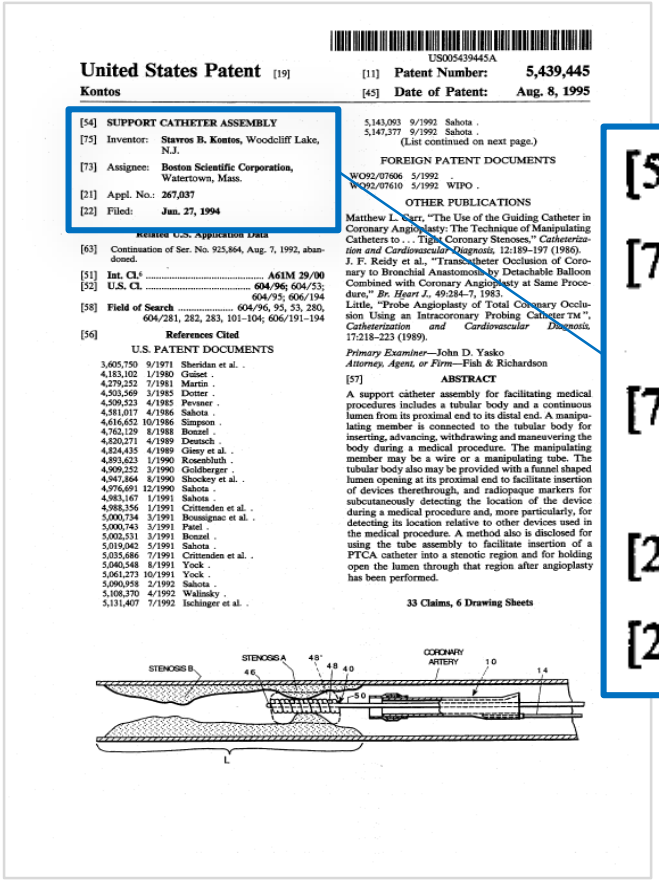
IPR2020-00127 & IPR2020-00130

8,048,032 claims	Instituted Ground	References
1-7, 9, 11-16, 18-19	1	Kontos, Adams
8, 17	2	Kontos, Adams, Takahashi
20	3	Kontos, Adams, Berg

RE45,380 claims	Instituted Ground	References
1-4, 6-7, 9, 12-17, 19-20	1	Kontos, Adams
8, 18	2	Kontos, Adams, Takahashi
21	3	Kontos, Adams, Berg

1. Overview of Kontos
2. Kontos Receives "*interventional cardiology devices*"
3. Kontos Necessarily Provides Back-Up Support
4. Obvious to Replace Kontos's Funnel with a Side Opening
5. Obvious to Achieve 1 French
6. Kontos has "*flexible cylindrical reinforced portion*"

U.S. Patent No. 5,439,445 (Kontos)



US005439445A

United States Patent [19]
Kontos

[11] **Patent Number: 5,439,445**
[45] **Date of Patent: Aug. 8, 1995**

[54] **SUPPORT CATHETER ASSEMBLY**

[75] Inventor: **Stavros B. Kontos**, Woodcliff Lake, N.J.

[73] Assignee: **Boston Scientific Corporation**, Watertown, Mass.

[21] Appl. No.: **267,037**

[22] Filed: **Jun. 27, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 925,864, Aug. 7, 1992, abandoned.

[51] **Int. Cl.**[6] **A61M 29/00**
[52] **U.S. Cl.** **604/96**; 604/53; 604/93; 606/194
[58] **Field of Search** 604/96, 95, 53, 280, 604/281, 282, 283, 101–104; 606/191–194

[56] **References Cited**

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4,279,252	7/1981	Martin	.
4,503,569	3/1985	Dotter	.
4,509,523	4/1985	Pevsner	.
4,581,017	4/1986	Sahota	.
4,616,652	10/1986	Simpson	.
4,762,129	8/1988	Bonzel	.
4,820,271	4/1989	Deutsch	.
4,824,435	4/1989	Giesy et al.	.
4,893,623	1/1990	Rosenbluth	.
4,909,252	3/1990	Goldberger	.
4,947,864	8/1990	Shockey et al.	.
4,976,691	12/1990	Sahota	.
4,983,167	1/1991	Sahota	.
4,988,356	1/1991	Crittenden et al.	.
5,000,734	3/1991	Boussignac et al.	.
5,000,743	3/1991	Patel	.
5,002,531	3/1991	Bonzel	.
5,019,042	5/1991	Sahota	.
5,035,686	7/1991	Crittenden et al.	.
5,040,548	8/1991	Yock	.
5,061,273	10/1991	Yock	.
5,090,958	2/1992	Sahota	.
5,108,370	4/1992	Walinsky	.
5,131,407	7/1992	Ischinger et al.	.
5,143,093	9/1992	Sahota	.
5,147,377	9/1992	Sahota	.

(List continued on next page.)

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WO92/07610	5/1992	WIPO .

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Matthew L. Carr, "The Use of the Guiding Catheter in Coronary Angioplasty: The Technique of Manipulating Catheters to . . . Tight Coronary Stenoses," *Catheterization and Cardiovascular Diagnosis*, 12:189–197 (1986).
J. F. Reidy et al., "Transcatheter Occlusion of Coronary to Bronchial Anastomosis by Detachable Balloon Combined with Coronary Angioplasty at Same Procedure," *Br. Heart J.*, 49:284–7, 1983.
Little, "Probe Angioplasty of Total Coronary Occlusion Using an Intracoronary Probing Catheter ™", *Catheterization and Cardiovascular Diagnosis*, 17:218–223 (1989).

Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—Fish & Richardson

[57] **ABSTRACT**

A support catheter assembly for facilitating medical procedures includes a tubular body and a continuous lumen from its proximal end to its distal end. A manipulating member is connected to the tubular body for inserting, advancing, withdrawing and maneuvering the body during a medical procedure. The manipulating member may be a wire or a manipulating tube. The tubular body also may be provided with a funnel shaped lumen opening at its proximal end to facilitate insertion of devices therethrough, and radiopaque markers for subcutaneously detecting the location of the device during a medical procedure and, more particularly, for detecting its location relative to other devices used in the medical procedure. A method also is disclosed for using the tube assembly to facilitate insertion of a PTCA catheter into a stenotic region and for holding open the lumen through that region after angioplasty has been performed.

33 Claims, 6 Drawing Sheets

[54] SUPPORT CATHETER ASSEMBLY

[75] Inventor: Stavros B. Kontos, Woodcliff Lake, N.J.

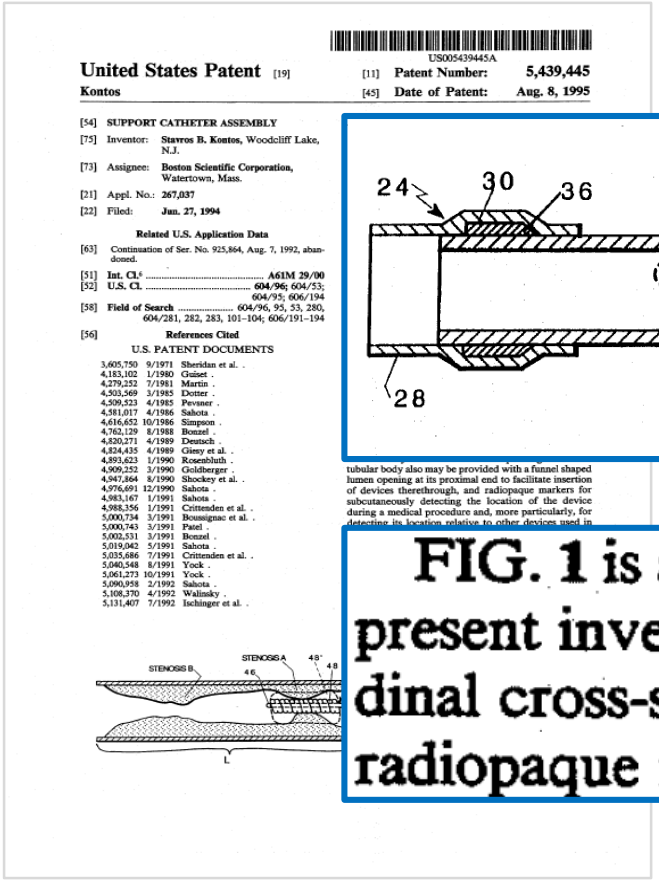
[73] Assignee: Boston Scientific Corporation, Watertown, Mass.

[21] Appl. No.: 267,037

[22] Filed: Jun. 27, 1994

Ex-1409

U.S. Patent No. 5,439,445 (Kontos)



US005439445A

United States Patent [19]
Kontos

[11] **Patent Number:** 5,439,445
[45] **Date of Patent:** Aug. 8, 1995

[54] **SUPPORT CATHETER ASSEMBLY**

[75] Inventor: **Stavros B. Kontos**, Woodcliff Lake, N.J.

[73] Assignee: **Boston Scientific Corporation**, Watertown, Mass.

[21] Appl. No.: **267,037**

[22] Filed: **Jun. 27, 1994**

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[51] **Int. Cl.**[6] **A61M 29/00**
[52] **U.S. Cl.** **604/96**; 604/53; 604/93; 606/194
[58] **Field of Search** 604/96, 95, 53, 280, 604/281, 282, 283, 101-104; 606/191-194

[56] **References Cited**
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4,279,252	7/1981	Martin	.
4,503,569	3/1985	Dotter	.
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4,616,652	10/1986	Simpson	.
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4,824,435	4/1989	Giesy et al.	.
4,893,623	1/1990	Rosenbluth	.
4,909,252	3/1990	Goldberger	.
4,947,864	8/1990	Shockey et al.	.
4,976,691	12/1990	Sahota	.
4,983,167	1/1991	Sahota	.
4,988,356	1/1991	Crittenden et al.	.
5,000,734	3/1991	Boussignac et al.	.
5,000,743	3/1991	Patel	.
5,002,531	3/1991	Bonzel	.
5,019,042	5/1991	Sahota	.
5,035,686	7/1991	Crittenden et al.	.
5,040,548	8/1991	Yock	.
5,061,273	10/1991	Yock	.
5,090,958	2/1992	Sahota	.
5,108,370	4/1992	Walinsky	.
5,131,407	7/1992	Ischinger et al.	.

tubular body also may be provided with a funnel shaped lumen opening at its proximal end to facilitate insertion of devices therethrough, and radiopaque markers for subcutaneously detecting the location of the device during a medical procedure and, more particularly, for detecting its location relative to other devices used in

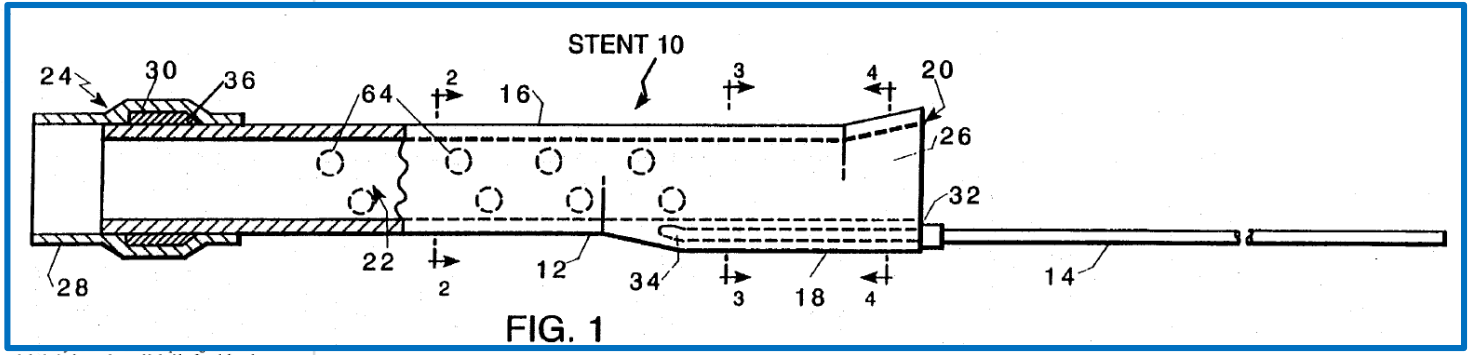
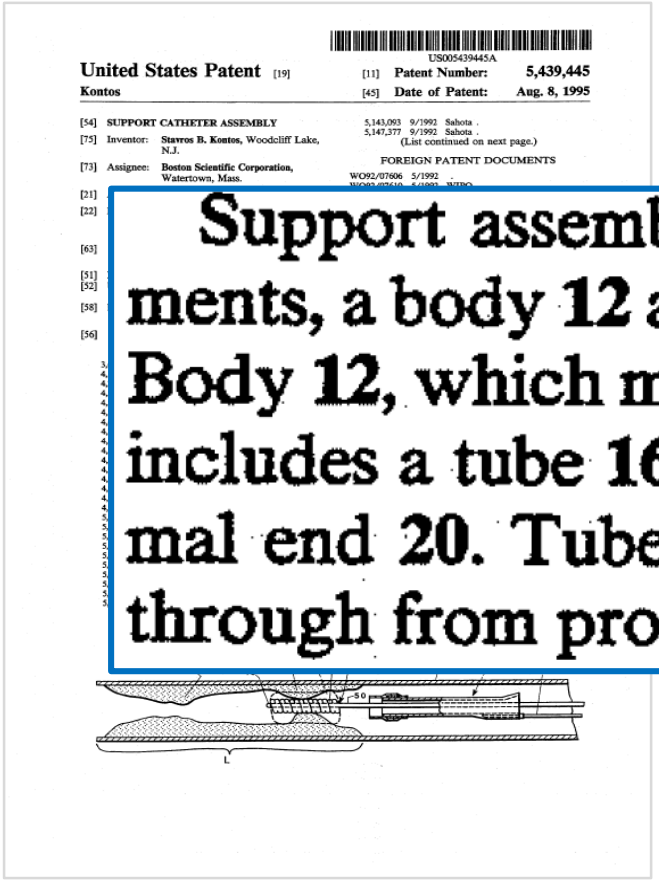


FIG. 1

FIG. 1 is a side plan view of a support catheter of the present invention, cut-away in part to show in longitudinal cross-section a tubular body having a soft tip and radiopaque marker, and a manipulating wire.

Ex-1409, 2:51-54, Fig. 1

U.S. Patent No. 5,439,445 (Kontos)



US005439445A

United States Patent [19]
Kontos

[11] **Patent Number: 5,439,445**
[45] **Date of Patent: Aug. 8, 1995**

[54] **SUPPORT CATHETER ASSEMBLY**

[75] Inventor: **Stavros B. Kontos**, Woodcliff Lake, N.J.

[73] Assignee: **Boston Scientific Corporation**, Watertown, Mass.

[21]
[22]
[63]
[51]
[52]
[58]
[56]

5,143,093 9/1992 Sahota .
5,147,377 9/1992 Sahota .
(List continued on next page.)

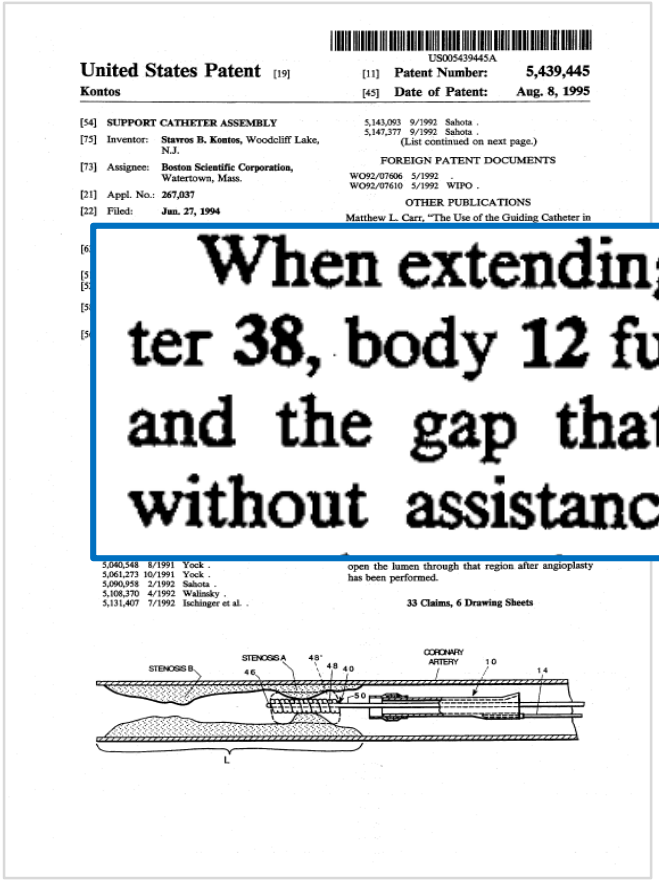
FOREIGN PATENT DOCUMENTS

WO92/07606 5/1992 .

Support assembly **10** is composed of two major elements, a body **12** and an insertion/manipulation wire **14**. Body **12**, which may be viewed as a **mini guide catheter**, includes a tube **16** having a base portion **18** at its proximal end **20**. Tube **16** has a continuous lumen **22** therethrough from proximal end **20** to distal end **24**. Body **12**

Ex-1409, 3:45-49

U.S. Patent No. 5,439,445 (Kontos)



US005439445A

United States Patent [19]
Kontos

[11] **Patent Number: 5,439,445**
[45] **Date of Patent: Aug. 8, 1995**

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[73] Assignee: **Boston Scientific Corporation**, Watertown, Mass.

[21] Appl. No.: **267,037**

[22] Filed: **Jun. 27, 1994**

5,143,093 9/1992 Sahota .
5,147,377 9/1992 Sahota .
(List continued on next page.)

FOREIGN PATENT DOCUMENTS

WO92/07606 5/1992 .
WO92/07610 5/1992 WIPO .

OTHER PUBLICATIONS

Matthew L. Carr, "The Use of the Guiding Catheter in

5,040,548 8/1991 Yock .
5,061,273 10/1991 Yock .
5,090,958 2/1992 Sahota .
5,108,370 4/1992 Walinsky .
5,131,407 7/1992 Ischinger et al. .

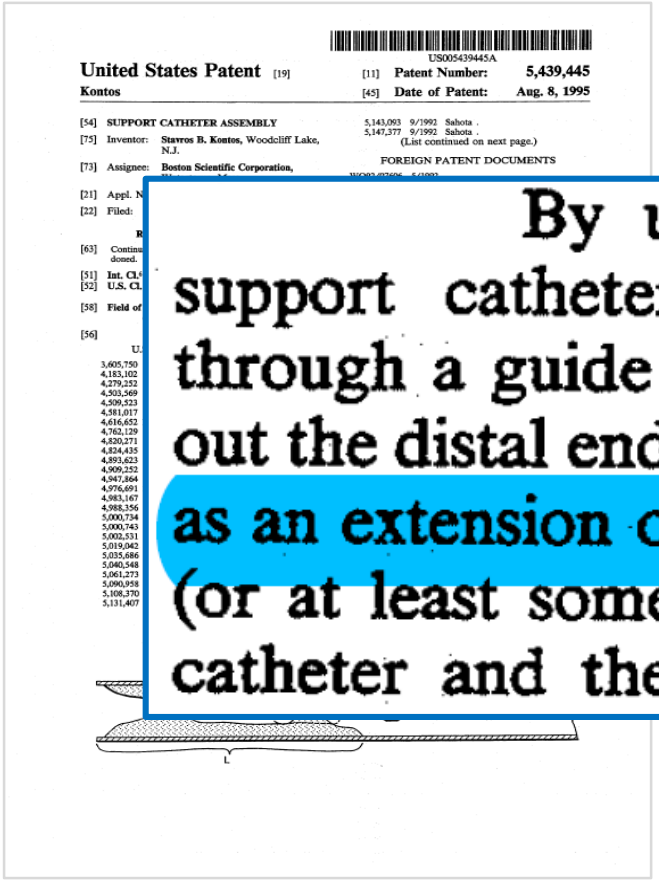
open the lumen through that region after angioplasty has been performed.

33 Claims, 6 Drawing Sheets

When extending beyond the distal end of guide catheter 38, body 12 functions as a guide catheter extension, and the gap that PTCA catheter 40 must negotiate without assistance is made much shorter.

Ex-1409, 5:49-52

U.S. Patent No. 5,439,445 (Kontos)



US005439445A

United States Patent [19]
Kontos

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[45] **Date of Patent: Aug. 8, 1995**

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[75] Inventor: **Stavros B. Kontos**, Woodcliff Lake, N.J.

[73] Assignee: **Boston Scientific Corporation,**

[21] Appl. N

[22] Filed:

[63] Continu doned.

[51] Int. Cl.
[52] U.S. Cl.

[58] Field of

[56]

U.

3,605,750
4,183,102
4,279,252
4,503,569
4,509,523
4,581,017
4,616,652
4,762,129
4,820,271
4,824,435
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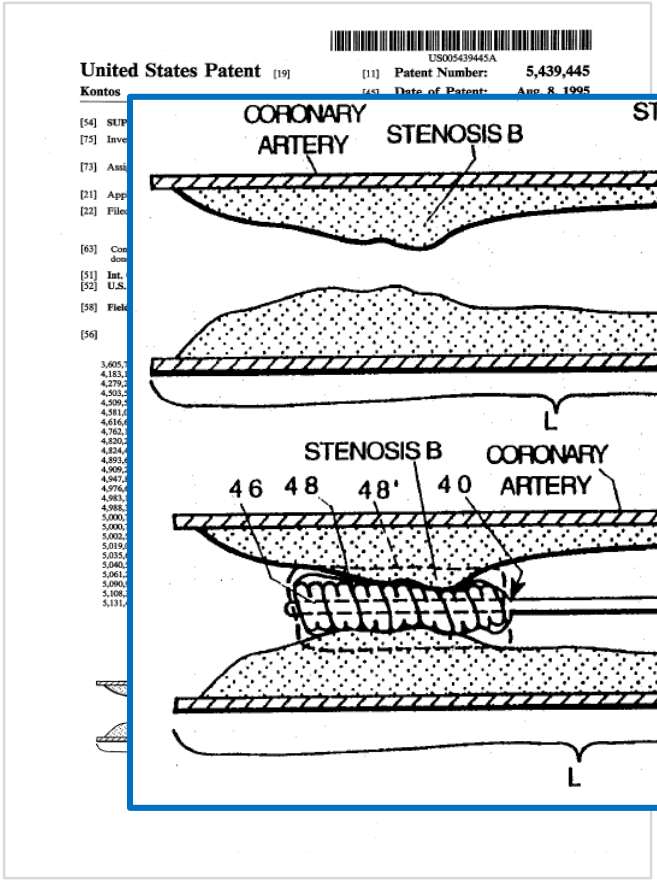
5,143,093 9/1992 Sahota .
5,147,377 9/1992 Sahota .
(List continued on next page.)

FOREIGN PATENT DOCUMENTS

By use of such manipulating means, the support catheter can be inserted into and passed through a guide catheter, over a PTCA catheter, and out the distal end of the guide catheter so as to function as an extension of the guide catheter to bridge the gap (or at least some of it) between the end of the guide catheter and the stenosis to be opened.

Ex-1409, 2:16-32

U.S. Patent No. 5,439,445 (Kontos)


United States Patent [19]
Kontos

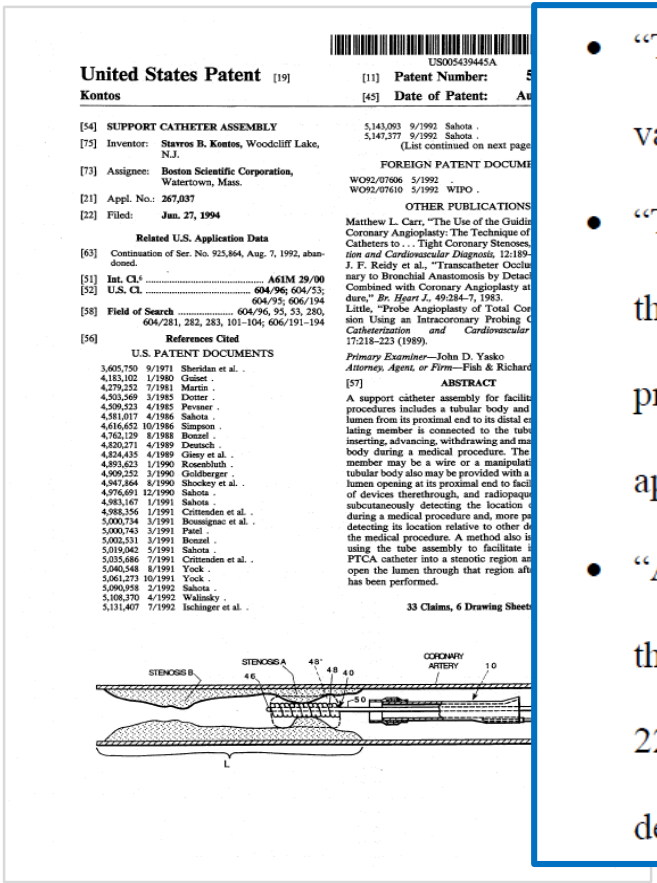
US005439445A
[11] Patent Number: 5,439,445
[45] Date of Patent: Aug. 8, 1995

FIG. 6B

FIG. 6C

Ex-1409, Figs. 6B-C

U.S. Patent No. 5,439,445 (Kontos)



United States Patent [19]
Kontos

[11] Patent Number: 5
[45] Date of Patent: Au

US005439445A

[54] SUPPORT CATHETER ASSEMBLY

[75] Inventor: Stavros B. Kontos, Woodcliff Lake, N.J.

[73] Assignee: Boston Scientific Corporation, Watertown, Mass.

[21] Appl. No.: 267,037

[22] Filed: Jun. 27, 1994

Related U.S. Application Data

[63] Continuation of Ser. No. 925,864, Aug. 7, 1992, abandoned.

[51] Int. Cl.[6] A61M 29/00
[52] U.S. Cl. 604/96; 604/53; 604/93; 606/194
[58] Field of Search 604/96, 95, 53, 280, 604/281, 282, 283, 101-104; 606/191-194

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5,131,407 7/1992 Ischinger et al. .
5,143,093 9/1992 Sahota .
5,147,377 9/1992 Sahota .
(List continued on next page.

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Coronary Angioplasty: The Technique of
Catheters to . . . Tight Coronary Stenoses.
tion and Cardiovascular Diagnosis, 12:189-
J. F. Reidy et al., "Transcatheter Occlu
nary to Bronchial Anastomosis by Detac
Combined with Coronary Angioplasty at
dure," Br. Heart J., 49:284-7, 1983.
Little, "Probe Angioplasty of Total Cor
sion Using an Intracoronary Probing C
Catheterization and Cardiovascular
17:218-223 (1989).

Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—Fish & Richard

[57] ABSTRACT

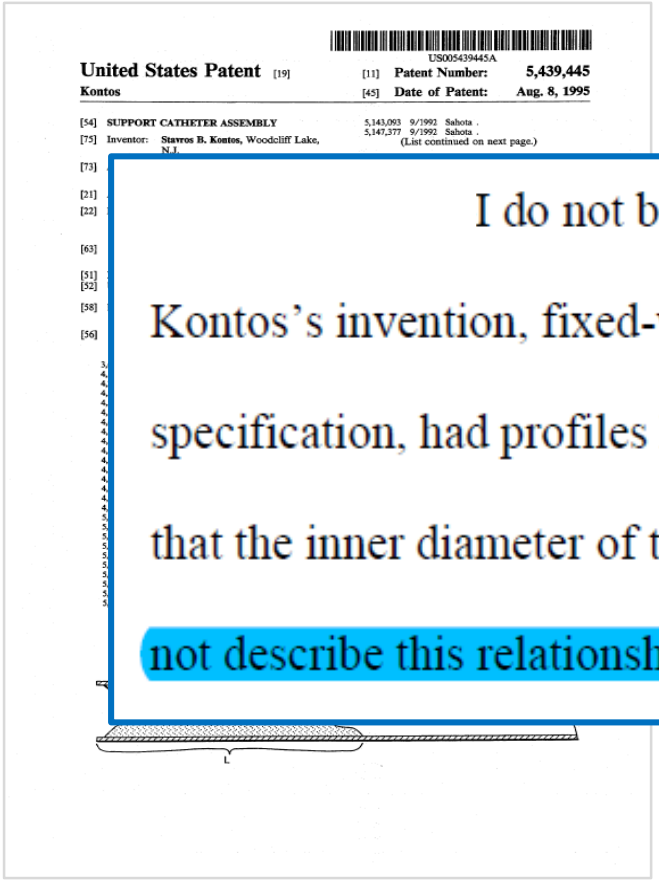
A support catheter assembly for facilit
procedures includes a tubular body and
lumen from its proximal end to its distal e
lating member is connected to the tub
inserting, advancing, withdrawing and ma
body during a medical procedure. The
member may be a wire or a manipulat
tubular body also may be provided with a
lumen opening at its proximal end to facil
of devices therethrough, and radiopaqu
subcutaneously detecting the location
during a medical procedure and, more pa
detecting its location relative to other d
the medical procedure. A method also is
using the tube assembly to facilitate i
PTCA catheter into a stenotic region an
open the lumen through that region aft
has been performed.

33 Claims, 6 Drawing Sheet

- "The size and shape of the various elements of support assembly 10 may vary depending on the desired application." Ex-1009, 4:46-48.
- "These sizes generally are suitable for existing PTCA catheters, such as the INTEGRA catheter marketed by Datascope Corp., the assignee of the present invention. Of course, other sizes may be used for other applications." *Id.*, 4:61-65.
- "As noted, these sizes may vary depending upon the application to which the device is to be put. When it is to be used with a PTCA catheter, lumen 22 should be at least large enough to permit passage therethrough of the deflated PTCA balloon." *Id.*, 4:66-5:2.

Ex-1807, ¶ 161 (Jones)

U.S. Patent No. 5,439,445 (Kontos)



US005439445A

United States Patent [19]
Kontos

[11] **Patent Number:** **5,439,445**
[45] **Date of Patent:** **Aug. 8, 1995**

[54] **SUPPORT CATHETER ASSEMBLY**

[75] Inventor: **Stavros B. Kontos**, Woodcliff Lake, N.J.

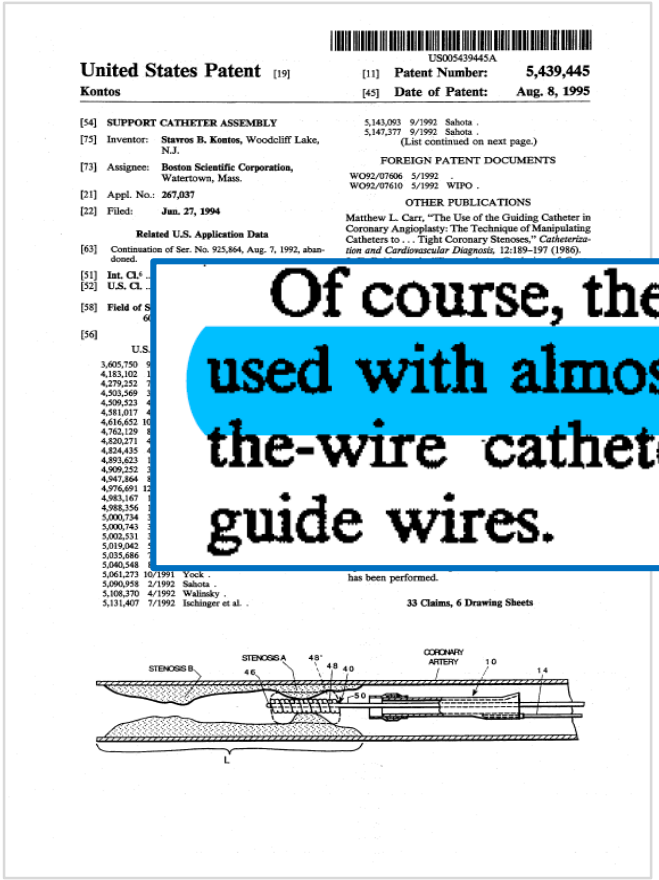
5,143,093 9/1992 Sahota .
5,147,377 9/1992 Sahota .
(List continued on next page.)

[73]
[21]
[22]
[63]
[51]
[52]
[58]
[56]

I do not believe it would have resulted in a tight fit. At the time of Kontos's invention, fixed-wire balloons, including the Integra mentioned in the specification, had profiles less than 0.030 inches. Ex-1833, 113. Kontos teaches that the inner diameter of tube 16 can be 0.045 inches. Ex-1009, 4:48-50. I would not describe this relationship as being "snug."

Ex-1807, ¶ 161 (Jones)

U.S. Patent No. 5,439,445 (Kontos)



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United States Patent [19]
Kontos

[11] **Patent Number: 5,439,445**
[45] **Date of Patent: Aug. 8, 1995**

[54] **SUPPORT CATHETER ASSEMBLY**

[75] Inventor: **Stavros B. Kontos**, Woodcliff Lake, N.J.

[73] Assignee: **Boston Scientific Corporation**, Watertown, Mass.

[21] Appl. No.: **267,037**

[22] Filed: **Jun. 27, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 925,864, Aug. 7, 1992, abandoned.

[51] **Int. Cl.**[6] ...
[52] **U.S. Cl.** ...
[58] **Field of S** ...
[56] ...

U.S.

3,605,750 ...
4,183,102 ...
4,279,252 ...
4,503,569 ...
4,509,523 ...
4,581,017 ...
4,616,652 ...
4,762,129 ...
4,820,271 ...
4,824,435 ...
4,893,623 ...
4,909,252 ...
4,947,864 ...
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5,040,548 ...
5,061,273 10/1991 Yock .
5,090,958 2/1992 Sahota .
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5,143,093 9/1992 Sahota .
5,147,377 9/1992 Sahota .
(List continued on next page.)

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...
has been performed.

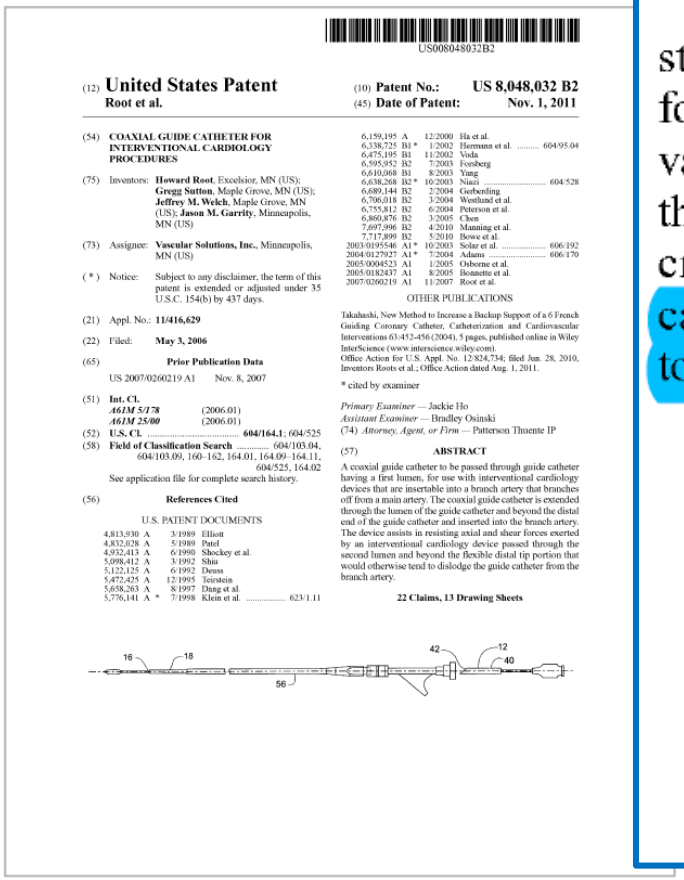
33 Claims, 6 Drawing Sheets

Of course, the device of the present invention may be used with almost any type of catheter, including over-the-wire catheters as well as catheters with captive guide wires.

Ex-1409, 9:47-50

1. Overview of Kontos
2. Kontos Receives "*interventional cardiology devices*"
3. Kontos Necessarily Provides Back-Up Support
4. Obvious to Replace Kontos's Funnel with a Side Opening
5. Obvious to Achieve 1 French
6. Kontos has "*flexible cylindrical reinforced portion*"

IPR2020-00127, -00130: "*interventional cardiology devices*"



US008048032B2

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,048,032 B2**
(45) **Date of Patent: Nov. 1, 2011**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(75) Inventors: **Howard Root**, Excelsior, MN (US); **Gregg Sutton**, Maple Grove, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Minneapolis, MN (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 437 days.

(21) Appl. No.: **11/416,629**

(22) Filed: **May 3, 2006**

(65) **Prior Publication Data**

US 2007/0260219 A1 Nov. 8, 2007

(51) **Int. Cl.**
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/164.1**; 604/525

(58) **Field of Classification Search** 604/103.04, 604/103.09, 160–162, 164.01, 164.09–164.11, 604/525, 164.02
See application file for complete search history.

(56) **References Cited**

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5,098,412	A	3/1992	Shiu
5,122,125	A	6/1992	Deuss
5,472,425	A	12/1995	Teirstein
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5,776,141	A *	7/1998	Klein et al. 623/1.11
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Office Action for U.S. Appl. No. 12/824,734; filed Jun. 28, 2010, Inventors Roots et al.; Office Action dated Aug. 1, 2011.

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Primary Examiner — Jackie Ho
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente IP

(57) **ABSTRACT**

A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

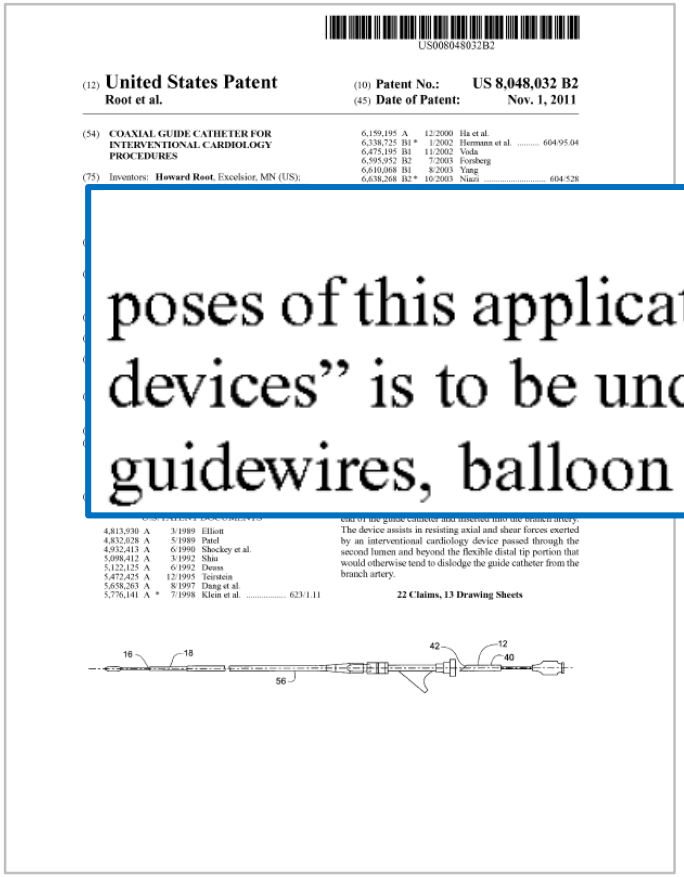
22 Claims, 13 Drawing Sheets

1. A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:

a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and

Ex-1401, claim 1 ('032 patent)

IPR2020-00127, -00130: "*interventional cardiology devices*"



US008048032B2

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,048,032 B2**
(45) **Date of Patent: Nov. 1, 2011**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(75) Inventors: **Howard Root**, Excelsior, MN (US);

6,159,195	A	12/2000	Ha et al.	
6,338,725	B1 *	1/2002	Hermann et al.	604/95.04
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6,595,952	B2	7/2003	Forsberg	
6,610,068	B1	8/2003	Yang	
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5,122,125	A	6/1992	Deuss	
5,472,425	A	12/1995	Teirstein	
5,658,263	A	8/1997	Dang et al.	
5,776,141	A *	7/1998	Klein et al.	623/1.11

end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

22 Claims, 13 Drawing Sheets

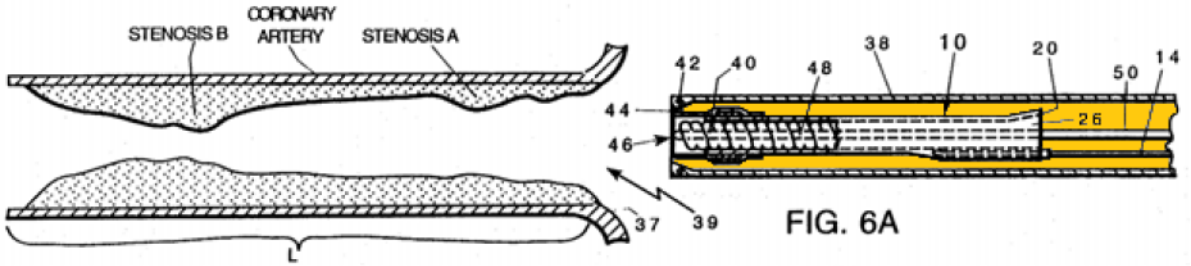
For the purposes of this application, the term "interventional cardiology devices" is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters.

Ex-1401, 1:17-21 ('032 patent)

IPR2020-00127, -00130: "*interventional cardiology devices*"

DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC

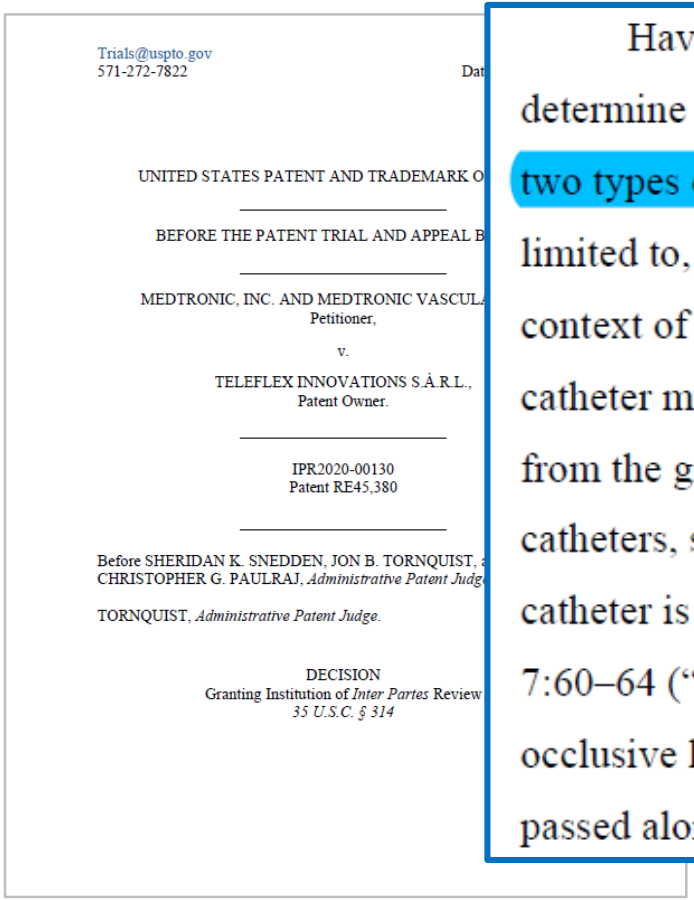
Figure 6A of Kontos shows a guide catheter that is sized to allow an interventional cardiology device, such as a PTCA catheter 40 with balloon 48, to be inserted into and travel through the guide catheter 38. (Ex-1409, 5:16-20, Figs. 6A-C.)



(Ex-1409, Fig. 6A (color added).)

Ex-1405, ¶ 165 (-00127 IPR) (Brecker)

IPR2020-00127, -00130: "*interventional cardiology devices*"



Trials@uspto.gov
571-272-7822

UNITED STATES PATENT AND TRADEMARK O

BEFORE THE PATENT TRIAL AND APPEAL B

MEDTRONIC, INC. AND MEDTRONIC VASCUL
Petitioner,

v.

TELEFLEX INNOVATIONS S.À.R.L.,
Patent Owner.

IPR2020-00130
Patent RE45,380

Before SHERIDAN K. SNEDDEN, JON B. TORNQUIST,
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judg*

TORNQUIST, *Administrative Patent Judge.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

Having considered the parties' positions and evidence of record, we determine that the term "interventional cardiology devices" refers to at least two types of the devices selected from the group that includes, but is not limited to, guidewires, balloon catheters, stents, and stent catheters. In the context of independent claims 1 and 12, the lumen of the recited guide catheter must be sized to receive at least two types of the devices selected from the group that includes, but is not limited to, guidewires, balloon catheters, stents, and stent catheters. For example, the diameter of the guide catheter is sized to receive a guidewire and a stent or balloon. Ex. 1401, 7:60–64 ("Once the guidewire 64 is pushed past stenotic lesion 66 or occlusive lesion . . . , a treating catheter including a stent or balloon can be passed along the guidewire to stenotic lesion 66 or occlusive lesion . . . .").

Institution Decision, Paper 20 at 10 (-00130 IPR)

IPR2020-00127, -00130: "*interventional cardiology devices*"

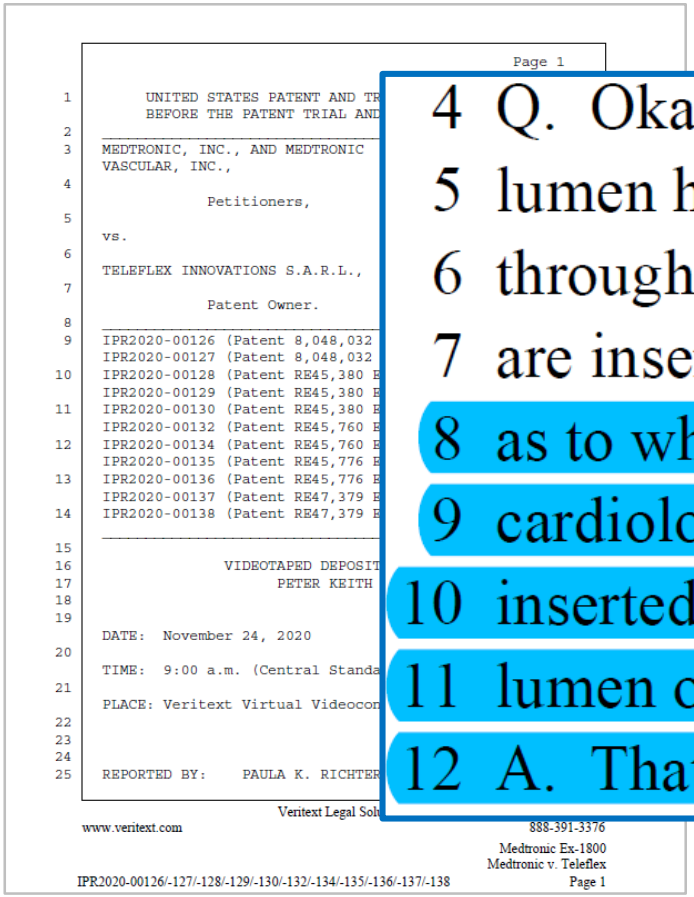
SUPPLEMENTAL DECLARATION OF
STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

153. Guidewires were known to range in size from 0.010 to 0.018 inches. Ex-1015, 98. They would therefore be insertable through body 12 and into the vasculature.

154. Kontos explicitly teaches that PTCA catheter 40 with balloon 48 can be passed through guide catheter 38 and into the vasculature. Ex-1009, Figs. 6A-C.

Ex-1806, ¶¶ 153-54 (Brecker)

IPR2020-00127, -00130: Keith Gave No Thought



Page 1

UNITED STATES PATENT AND TR
BEFORE THE PATENT TRIAL AND

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,

Petitioners,

vs.

TELEFLEX INNOVATIONS S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032
IPR2020-00127 (Patent 8,048,032
IPR2020-00128 (Patent RE45,380 E
IPR2020-00129 (Patent RE45,380 E
IPR2020-00130 (Patent RE45,380 E
IPR2020-00132 (Patent RE45,760 E
IPR2020-00134 (Patent RE45,760 E
IPR2020-00135 (Patent RE45,776 E
IPR2020-00136 (Patent RE45,776 E
IPR2020-00137 (Patent RE47,379 E
IPR2020-00138 (Patent RE47,379 E

VIDEOTAPED DEPOSIT
PETER KEITH

DATE: November 24, 2020

TIME: 9:00 a.m. (Central Standa

PLACE: Veritext Virtual Videocon

REPORTED BY: PAULA K. RICHTER

Veritext Legal Sol
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888-391-3376

Medtronic Ex-1800
Medtronic v. Teleflex
Page 1

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

4 Q. Okay. So the claim element is a coaxial
5 lumen having a cross-sectional inner diameter
6 through which interventional cardiology devices
7 are insertable, and you have not given any thought
8 as to whether there are other interventional
9 cardiology devices in the '90s that could be
10 inserted through the inner diameter through the
11 lumen of Kontos?
12 A. That's correct.

Ex-1800, 122:4-12 (Keith)

IPR2020-00127, -00130: "*interventional cardiology devices*"

155. There were also a variety of stents with crossing profiles that were small enough to be advanced through a lumen of 0.045 inches (1.14 mm) that I discuss below. Necessarily, each of the stents that are discussed were advanced into the coronary vasculature on a "stent catheter."

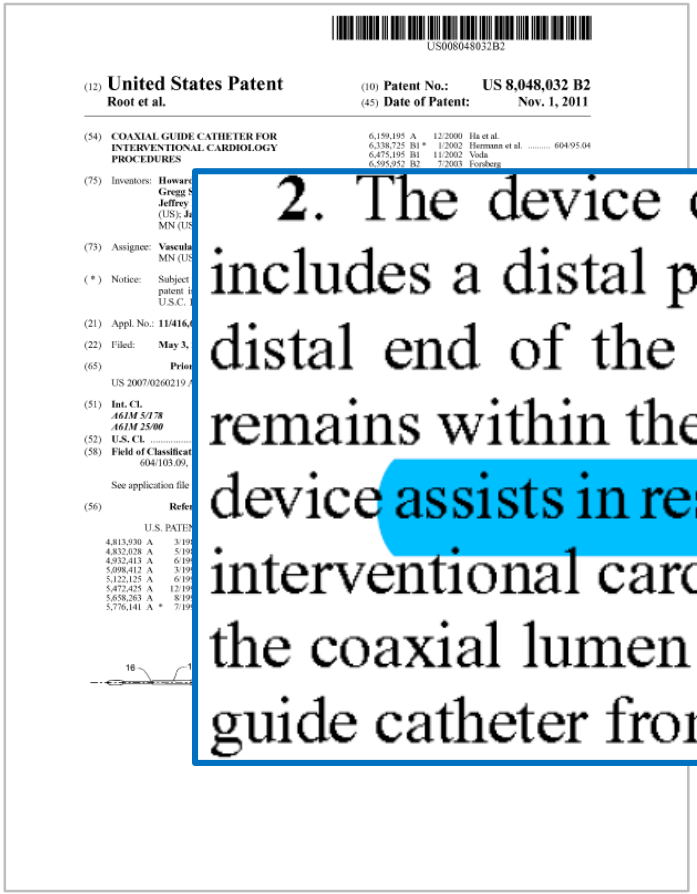
156. Baim explains that "[a]ll current slotted tube designs are 'bare mounted' on a delivery balloon, with deflated profiles smaller than 0.040-in. (1mm)" Ex-1015, 641.

157. The 4th edition of the Handbook of Coronary Stents describes the Genic® stent with a profile of less than 0.9 mm (0.035 inches), the Lunar stent with a 0.0382 inch profile, the Spiral Force stent with a profile of 0.039 to 0.042 inches, and the Tsunami stent with a profile of 0.038 inches (0.95 mm). Ex-1802, 7, 15, 21, 25.

Ex-1806, ¶¶ 155-57 (Brecker)

1. Overview of Kontos
2. Kontos Receives "*interventional cardiology devices*"
3. Kontos Necessarily Provides Back-Up Support
4. Obvious to Replace Kontos's Funnel with a Side Opening
5. Obvious to Achieve 1 French
6. Kontos has "*flexible cylindrical reinforced portion*"

IPR2020-00127, -00130: Representative Back-Up Claim



US008048032B2

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,048,032 B2**
(45) **Date of Patent: Nov. 1, 2011**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

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6,595,952 B2 7/2003 Forsberg

(75) Inventors: Howard
Gregg S
Jeffrey
(US); Ja
MN (US

(73) Assignee: Vascula
MN (US

(*) Notice: Subject
patent
U.S.C.

(21) Appl. No.: 11/416,

(22) Filed: May 3,

(65) Prio
US 2007/0260219

(51) **Int. Cl.**
A61M 5/178
A61M 25/00

(52) **U.S. Cl.** .....

(58) **Field of Classificat**
604/103.09,

See application file

(56) Refer

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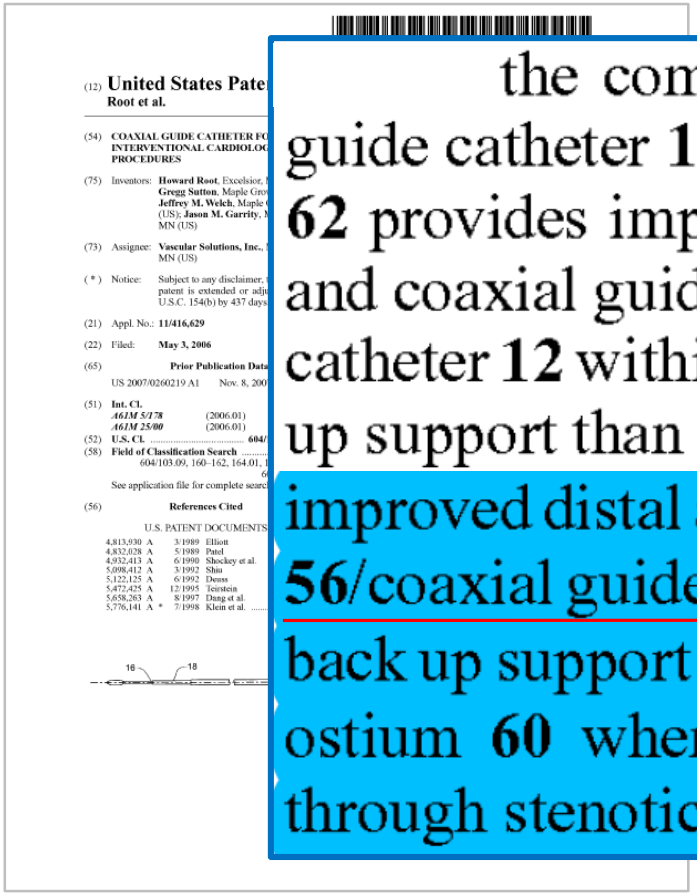
4,813,930 A 3/19
4,832,028 A 5/19
4,932,413 A 6/19
5,098,412 A 3/19
5,122,125 A 6/19
5,472,425 A 12/19
5,658,263 A 8/19
5,776,141 A * 7/19

16

2. The device of claim **1** wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.

Ex-1401, claim 2 ('032 patent)

IPR2020-00127, -00130: What Patents Teach About Backup Support



(12) **United States Pate**
Root et al.

(54) **COAXIAL GUIDE CATHETER FO**
INTERVENTIONAL CARDIOLOG
PROCEDURES

(75) Inventors: **Howard Root**, Excelsior,
Gregg Sutton, Maple Gro
Jeffrey M. Welch, Maple
(US); **Jason M. Garrity**,
MN (US)

(73) Assignee: **Vascular Solutions, Inc.,**
MN (US)

(*) Notice: Subject to any disclaimer,
patent is extended or adj
U.S.C. 154(b) by 437 days

(21) Appl. No.: **11/416,629**

(22) Filed: **May 3, 2006**

(65) **Prior Publication Data**

US 2007/0260219 A1 Nov. 8, 200

(51) **Int. Cl.**
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/**

(58) **Field of Classification Search** .....
604/103.09, 160–162, 164.01,
See application file for complete searc

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5,472,425	A	12/1995	Teirstein
5,658,263	A	8/1997	Dang et al.
5,776,141	A *	7/1998	Klein et al.

16 18

the combination of guide catheter **56** with coaxial guide catheter **12** inserted into ostium **60** of coronary artery **62** provides improved distal anchoring of guide catheter **56** and coaxial guide catheter **12**. The presence of coaxial guide catheter **12** within guide catheter **56** also provides stiffer back up support than guide catheter **56** alone. The combination of improved distal anchoring and stiffening of the guide catheter **56**/coaxial guide catheter **12** combination provides additional back up support to resist dislodging of guide catheter **56** from ostium **60** when force is applied to guidewire **64** to pass through stenotic lesion **66** or another lesion.

Ex-1401, 7:61-8:5 ('032 patent)

IPR2020-00127, -00130: How Patents Teach Backup Support

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.

Petitioners,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner

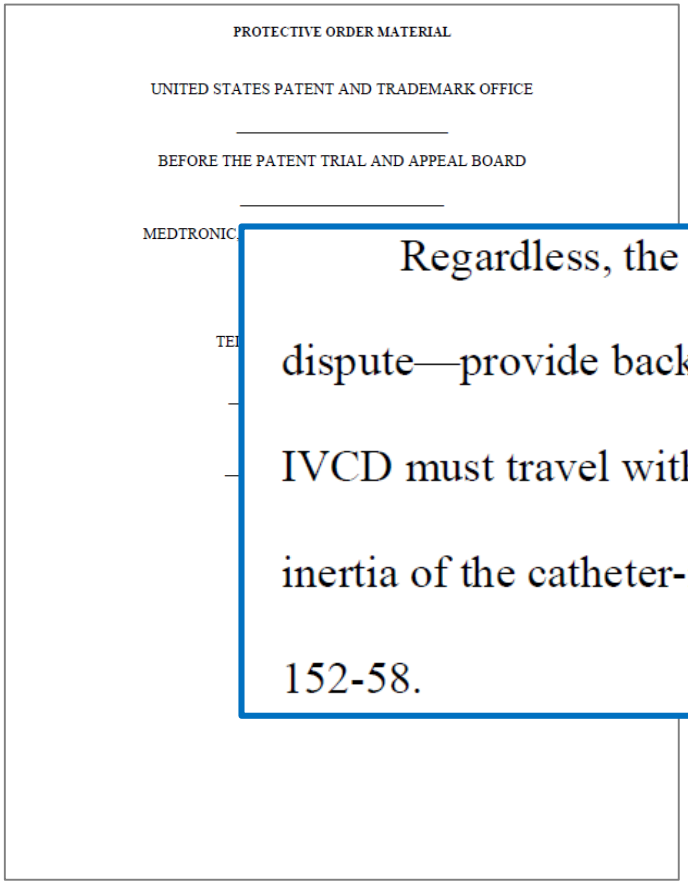
Case No.: IPR2020-00127
U.S. Patent No. 8,048,032

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,048,032

As discussed for claim 1, Kontos discloses that "a physician inserts a guide catheter 38 through the aorta 37 and into a patient's coronary ostia 39 using known medical procedures." Ex-1409, at 5:11-15. Kontos further provides that "the support catheter can be inserted into and … out the distal end of the guide catheter so as to function as an extension of the guide catheter to bridge the gap (or at least some of it) between the end of the guide catheter and the stenosis to be opened." *Id.*, 2:16-22, Figs 6A-C (showing proximal end of body 12 within guide catheter 38). For this reason, because Kontos and the '032 patent contain the same teachings, to the extent the '032 patent has adequate written description support, a POSITA would understand that Kontos must inherently disclose or, at a minimum, render obvious when combined with the knowledge of a POSITA, the limitation of claim 2. Ex-1405, ¶ 179.

Paper 1 at 40 (-00127 IPR)

IPR2020-00127 & IPR2020-00130


PROTECTIVE ORDER MATERIAL

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC

TE

Regardless, the structural characteristics of Kontos—which PO does not dispute—provide back-up support in two ways: (i) shortening the distance that the IVCD must travel within the vasculature and (ii) by increasing the moment of inertia of the catheter-in-catheter assembly. Ex-1806 ¶159-67; Ex-1807 ¶¶14-27, 152-58.

Reply at 6 (-00127)

IPR2020-00127, -00130: Shorter Distance

DECLARATION OF MICHAEL JONES
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

20. By using a catheter-in-catheter assembly, it is possible to extend the inner catheter (sometime referred to as the "child catheter") beyond the ostium of the coronary artery. In so doing, the interventional cardiology device has to travel a shorter distance in the vasculature, which in turn reduces the amount of force necessary to advance the interventional cardiology device to the target location. This is because the vasculature can be tortuous and/or calcified, thereby requiring more force to advance the interventional cardiology device.

IPR2020-00127, -00130: Increased Moment of Inertia

DECLARATION OF MICHAEL JONES
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

23. The moment of inertia, I_0, of the cross section of a catheter with respect to its neutral axis, is expressed by the following, and is proportional to flexural rigidity and buckling force. *Id.* at 12. The cross section of a catheter is a hollow circle with an outer diameter D and an inner diameter d. *Id.*

$$I_0 = \frac{\pi(D^4 - d^4)}{64}$$

Ex-1807, ¶ 23 (Jones)

IPR2020-00127, -00130: Increased Moment of Inertia

DECLARATION OF MICHAEL JONES
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

23. The moment of inertia, I_0, of the cross section of a catheter with respect to its neutral axis, is expressed by the following, and is proportional to flexural

24. The polar moment of inertia of a catheter shaft with outer diameter D and inner diameter d is expressed as follows, and is proportional to the torsional rigidity of a catheter. *Id.*, 12-15.

$$J_0 catheter = \frac{\pi(D^4 - d^4)}{32}$$

Ex-1807, ¶ 24 (Jones)

IPR2020-00127, -00130: Increased Moment of Inertia

DECLARATION OF MICHAEL JONES
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

23. The moment of inertia, I_0, of the cross section of a catheter with respect to its neutral axis, is expressed by the following, and is proportional to flexural

24. The polar moment of inertia of a catheter shaft with outer diameter D and inner dia rigidity of a c

25. From these equations it is clear that when placing a catheter within a catheter, the outer diameter remains defined and the effective inner diameter decreases, which results in the following consequences:

a. Flexural rigidity increases;

b. Torsional rigidity increases; and

c. Resistance to buckling force increases.

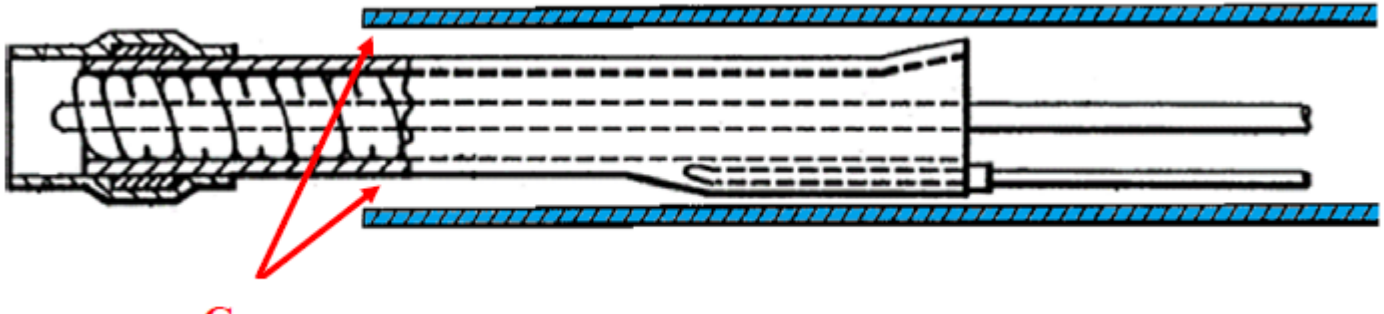
Ex-1807, ¶ 25 (Jones)

IPR2020-00127, -00130: Teleflex's Argument

A POSITA would understand that, because of its disclosed structure, Kontos' device likely would not resist axial and shear forces as required by claims 2 and 12. Ex-2138, ¶¶ 145-147; Ex-2145, ¶ 147.

Case IPR2020-00127
Patent 8,048,032

PATENT OWNER



Paper 41 at 23-24 (-00127 IPR)

IPR2020-00127, -00130: Jones Addresses Teleflex's Argument

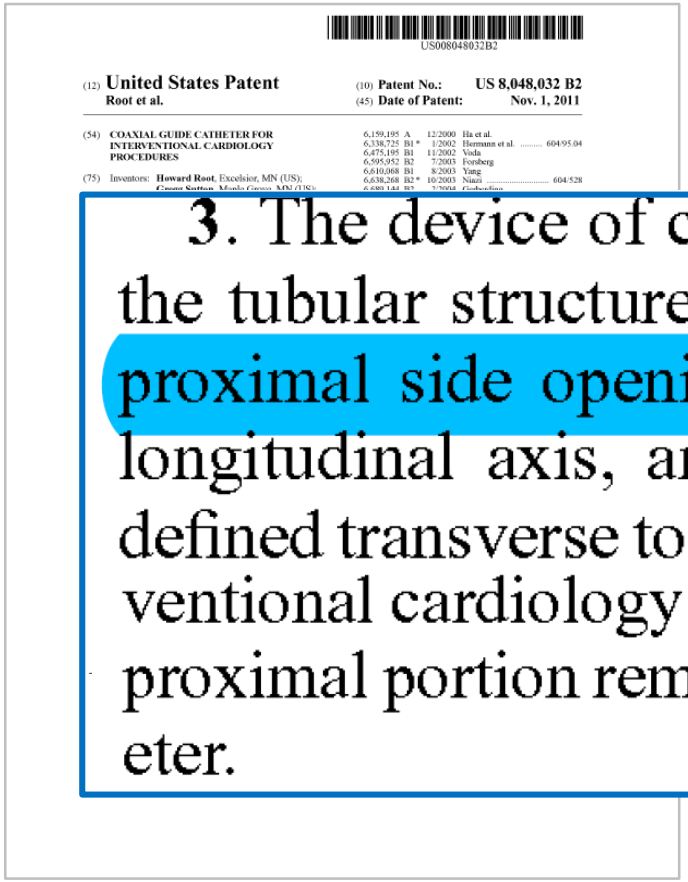
DECLARATION OF MICHAEL JONES
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

154. By comparison to a single-catheter assembly, the use of Kontos's support assembly with a guide catheter will increase flexural rigidity, torsional rigidity, and increase resistance to buckling force. In reaching this conclusion, I have considered (i) the material that comprises tube 16, (ii) the dimensions, including the inner/outer diameter and length, and (ii) the relationship between tube 16 and the guide catheter, including that the inner diameters of the nested catheters is more than 1 French.

Ex-1807, ¶ 154 (Jones)

1. Overview of Kontos
2. Kontos Receives "*interventional cardiology devices*"
3. Kontos Necessarily Provides Back-Up Support
4. Obvious to Replace Kontos's Funnel with a Side Opening
5. Obvious to Achieve 1 French
6. Kontos has "*flexible cylindrical reinforced portion*"

IPR2020-00127, -00130: Representative Side Opening Claim



US008048032B2

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,048,032 B2**
(45) **Date of Patent: Nov. 1, 2011**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

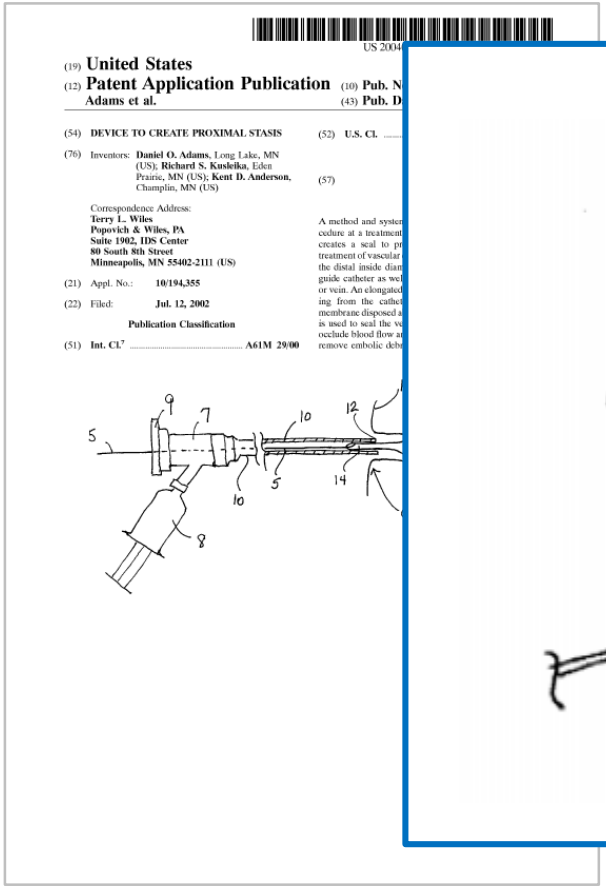
(75) Inventors: **Howard Root**, Excelsior, MN (US);

6,159,195	A	12/2000	Ha et al.	
6,338,725	B1 *	1/2002	Hermann et al.	604/95.04
6,475,195	B1	11/2002	Voda	
6,595,952	B2	7/2003	Forsberg	
6,610,068	B1	8/2003	Yang	
6,638,268	B2 *	10/2003	Niazi	604/528

3. The device of claim 2 wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

Ex-1401, claim 3 ('032 patent)

IPR2020-00127, -00130: Adams



(19) **United States**

(12) **Patent Application Publication** (10) **Pub. N**

Adams et al. (43) **Pub. D**

(54) **DEVICE TO CREATE PROXIMAL STASIS**

(52) **U.S. Cl.** .....

(76) Inventors: **Daniel O. Adams**, Long Lake, MN (US); **Richard S. Kusleika**, Eden Prairie, MN (US); **Kent D. Anderson**, Champlin, MN (US)

(57)

Correspondence Address:
Terry L. Wiles
Popovich & Wiles, PA
Suite 1902, IDS Center
80 South 8th Street
Minneapolis, MN 55402-2111 (US)

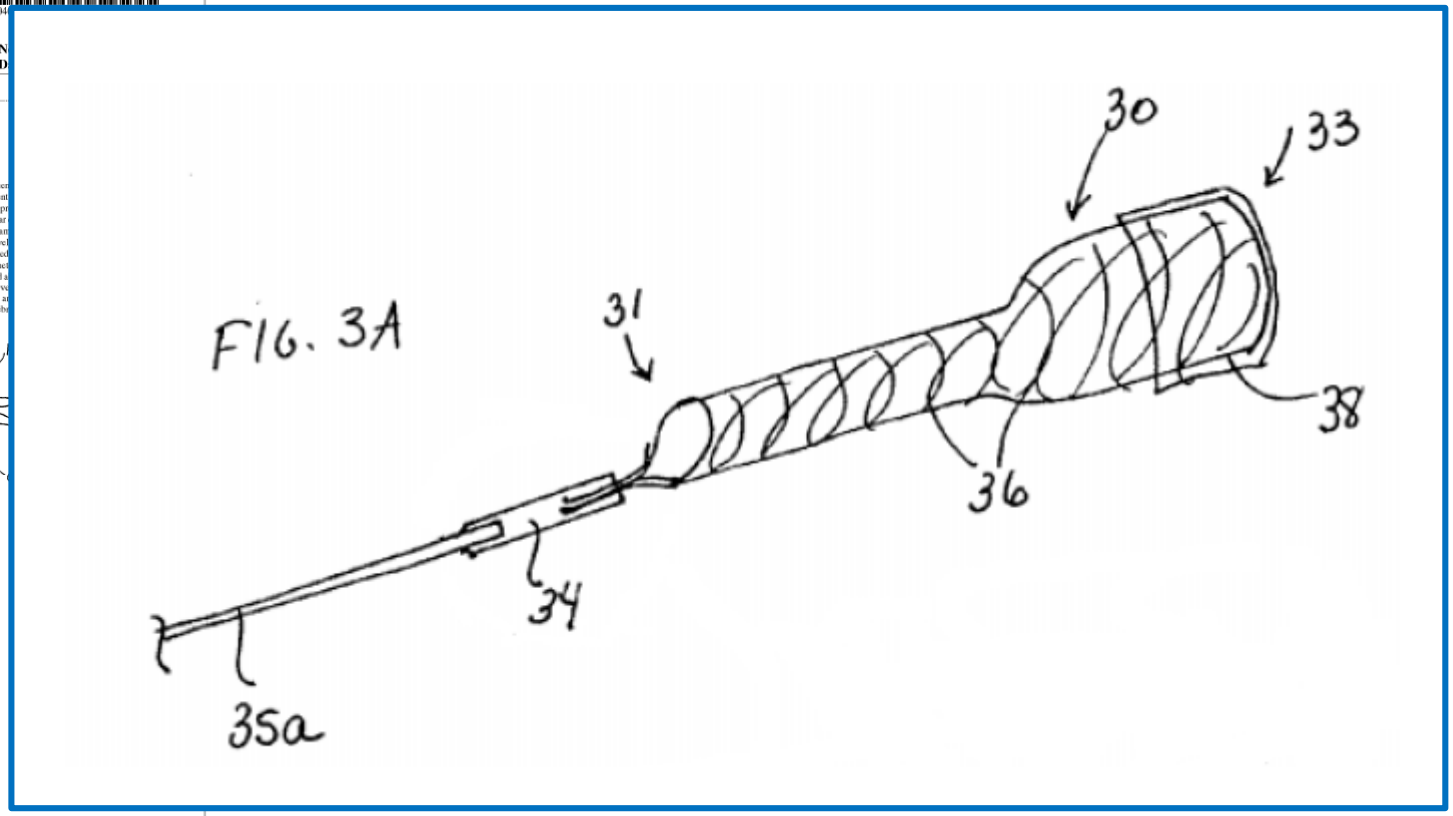
(21) Appl. No.: **10/194,355**

(22) Filed: **Jul. 12, 2002**

Publication Classification

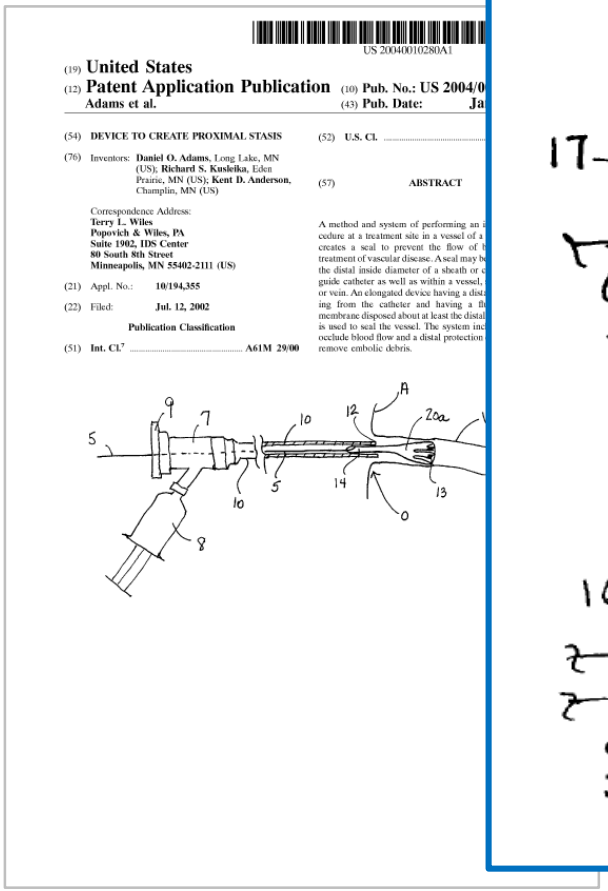
(51) **Int. Cl.**[7] **A61M 29/00**

A method and system
cedure at a treatment
creates a seal to pr
treatment of vascular
the distal inside diam
guide catheter as well
or vein. An elongated
ing from the catheter
membrane disposed a
is used to seal the va
occlude blood flow a
remove embolic debr



Ex-1435, Fig. 3A

IPR2020-00127, -00130: Adams



US 20040010280A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2004/0**

Adams et al. (43) **Pub. Date: Ja**

(54) **DEVICE TO CREATE PROXIMAL STASIS**

(76) Inventors: **Daniel O. Adams**, Long Lake, MN (US); **Richard S. Kusleika**, Eden Prairie, MN (US); **Kent D. Anderson**, Champlin, MN (US)

Correspondence Address:
Terry L. Wiles
Popovich & Wiles, PA
Suite 1902, IDS Center
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Minneapolis, MN 55402-2111 (US)

(21) Appl. No.: **10/194,355**

(22) Filed: **Jul. 12, 2002**

Publication Classification

(51) **Int. Cl.**[7] **A61M 29/00**

(52) **U.S. Cl.** .....

(57) **ABSTRACT**

A method and system of performing an
cedure at a treatment site in a vessel of a
creates a seal to prevent the flow of b
treatment of vascular disease. A seal may b
the distal inside diameter of a sheath or
guide catheter as well as within a vessel,
or vein. An elongated device having a dis
ing from the catheter and having a
membrane disposed about at least the distal
is used to seal the vessel. The system inc
occlude blood flow and a distal protection
remove embolic debris.

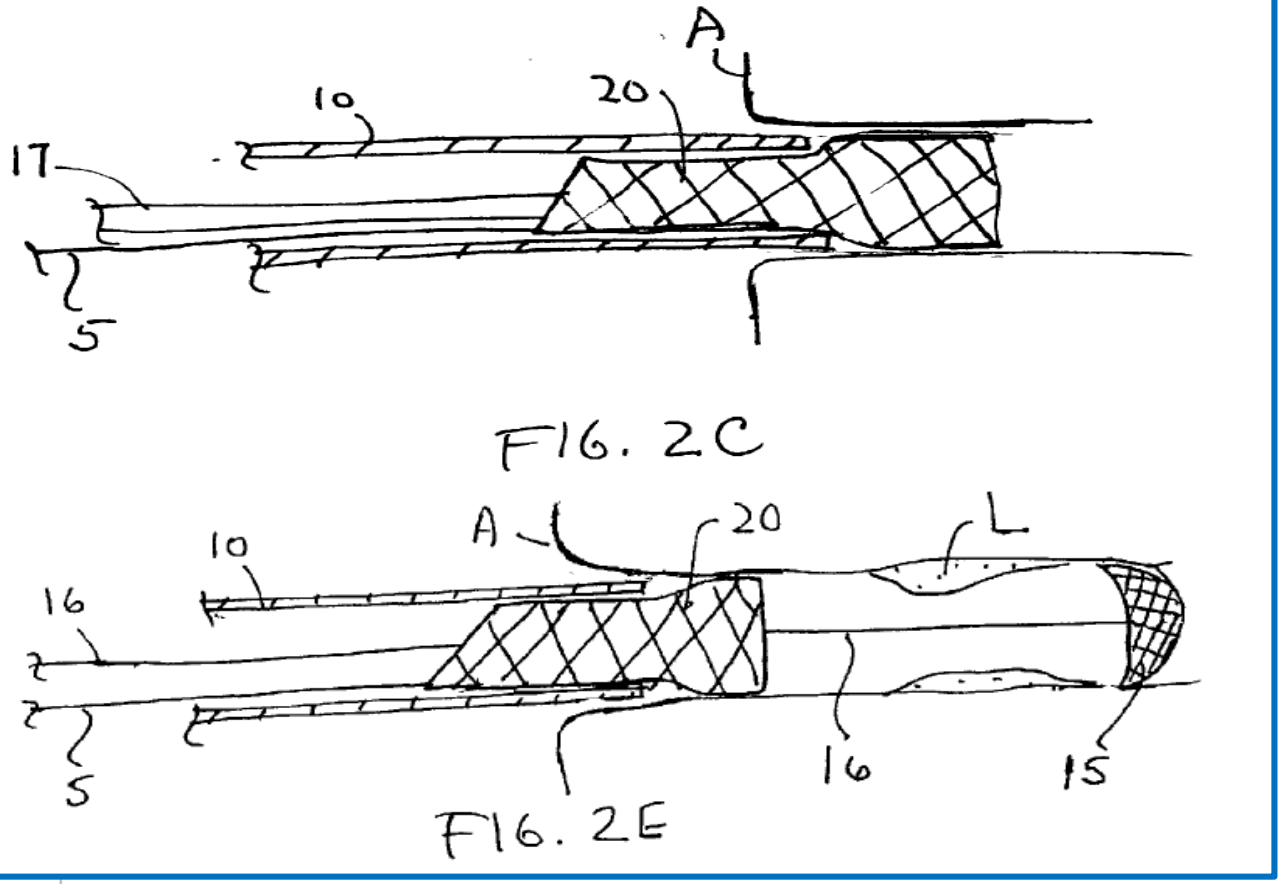


FIG. 2C

FIG. 2E

Ex-1435, Figs. 2C, 2E

IPR2020-00127 & IPR2020-00130: Motivation for Side Opening

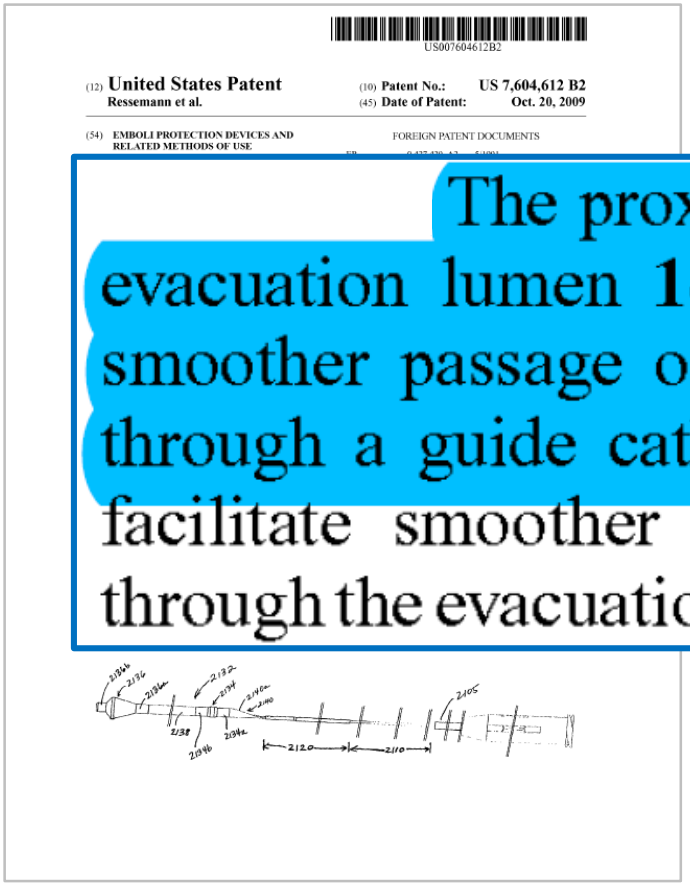
1. Smooth Passage of Extension Catheter Through Guide Catheter
2. Safe Retrieval of Extension Catheter
3. Maximize “Real Estate” Inside Catheter Assembly
4. Smooth Receipt of Interventional Cardiology Devices

IPR2020-00127, -00130: Smooth Passage of Extension Catheter

DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC

199. Further, a POSITA would additionally have wanted to use a proximal side opening because such a design promotes "smoother passage" of the extension catheter as it is advanced through the guide catheter (i.e., navigates a patient's vasculature) from the site of insertion into the body to the occlusion site. (Ex-1408, 6:52-57; Ex-1425, Abstract, [0034].) This is equally a concern is using a femoral or radial access point. Using an angled side opening can reduce the amount of force necessary to advance the catheter through tortuous vessels.

IPR2020-00127, -00130: Smooth Passage of Extension Catheter



US007604612B2

(12) **United States Patent**
Ressemann et al.

(10) **Patent No.: US 7,604,612 B2**
(45) **Date of Patent: Oct. 20, 2009**

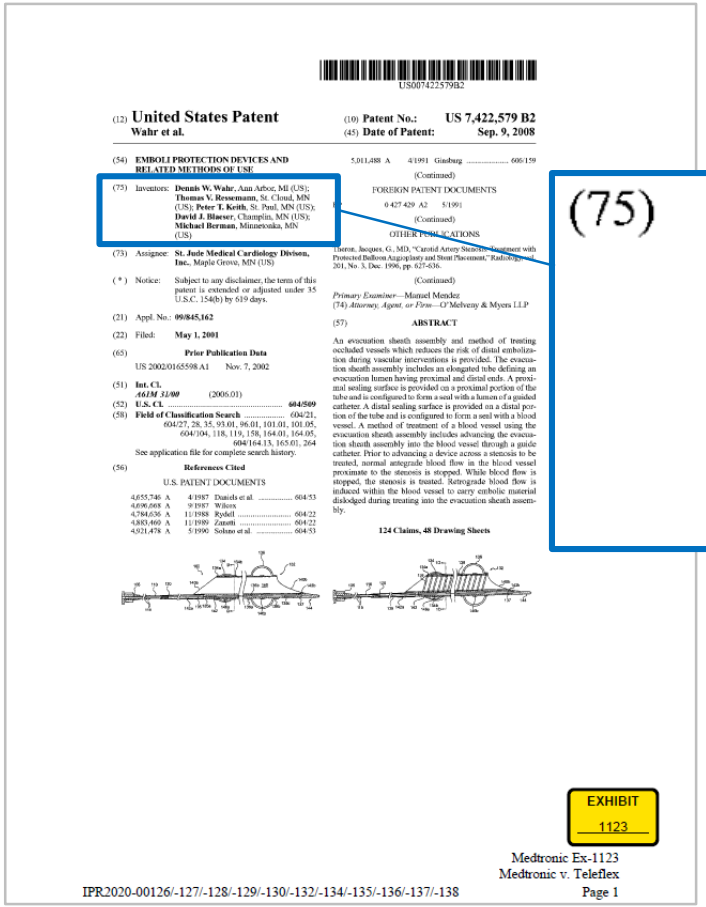
(54) **EMBOLI PROTECTION DEVICES AND RELATED METHODS OF USE**

FOREIGN PATENT DOCUMENTS

The proximal and distal ends **140***a*, **140***b* of the evacuation lumen **140** are preferably angled to allow for smoother passage of the evacuation sheath assembly **100** through a guide catheter, and into a blood vessel, and to facilitate smoother passage of other therapeutic devices through the evacuation lumen **140** of the evacuation head **132**.

Ex-1408, 6:52-57 (Ressemann)

IPR2020-00127, -00130: Smooth Passage of Extension Catheter



US007422579B2

(12) **United States Patent**
Wahr et al.

(10) **Patent No.: US 7,422,579 B2**
(45) **Date of Patent: Sep. 9, 2008**

(54) **EMBOLI PROTECTION DEVICES AND RELATED METHODS OF USE**

(75) Inventors: **Dennis W. Wahr**, Ann Arbor, MI (US); **Thomas V. Ressemann**, St. Cloud, MN (US); **Peter T. Keith**, St. Paul, MN (US); **David J. Blaeser**, Champlin, MN (US); **Michael Berman**, Minnetonka, MN (US)

(73) Assignee: **St. Jude Medical Cardiology Divison, Inc.**, Maple Grove, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 619 days.

(21) Appl. No.: **09/845,162**

(22) Filed: **May 1, 2001**

(65) **Prior Publication Data**

US 2002/0165598 A1 Nov. 7, 2002

(51) **Int. Cl.**
A61M 31/00 (2006.01)

(52) **U.S. Cl.** **604/509**

(58) **Field of Classification Search** 604/21, 604/27, 28, 35, 93.01, 96.01, 101.01, 101.05, 604/104, 118, 119, 158, 164.01, 164.05, 604/164.13, 165.01, 264
See application file for complete search history.

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(Continued)

Primary Examiner—Manuel Mendez
(74) *Attorney, Agent, or Firm*—O'Melveny & Myers LLP

(57) **ABSTRACT**

An evacuation sheath assembly and method of treating occluded vessels which reduces the risk of distal embolization during vascular interventions is provided. The evacuation sheath assembly includes an elongated tube defining an evacuation lumen having proximal and distal ends. A proximal sealing surface is provided on a proximal portion of the tube and is configured to form a seal with a lumen of a guided catheter. A distal sealing surface is provided on a distal portion of the tube and is configured to form a seal with a blood vessel. A method of treatment of a blood vessel using the evacuation sheath assembly includes advancing the evacuation sheath assembly into the blood vessel through a guide catheter. Prior to advancing a device across a stenosis to be treated, normal antegrade blood flow in the blood vessel proximate to the stenosis is stopped. While blood flow is stopped, the stenosis is treated. Retrograde blood flow is induced within the blood vessel to carry embolic material dislodged during treating into the evacuation sheath assembly.

124 Claims, 48 Drawing Sheets

EXHIBIT
1123

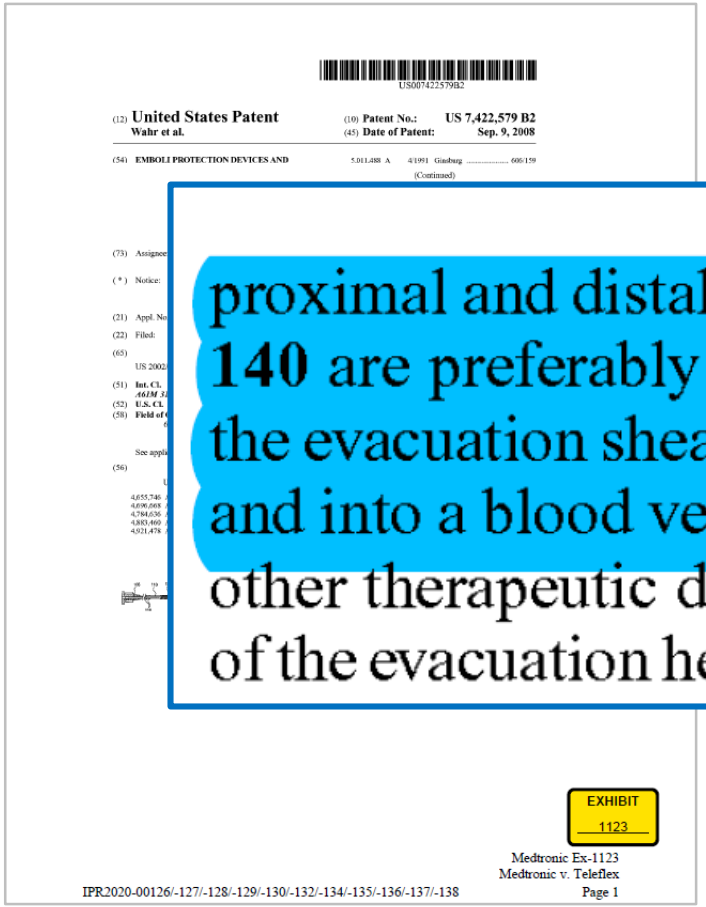
Medtronic Ex-1123
Medtronic v. Teleflex

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

(75) Inventors: **Dennis W. Wahr**, Ann Arbor, MI (US); **Thomas V. Ressemann**, St. Cloud, MN (US); **Peter T. Keith**, St. Paul, MN (US); **David J. Blaeser**, Champlin, MN (US); **Michael Berman**, Minnetonka, MN (US)

Ex-1123 (Keith)

IPR2020-00127, -00130: Smooth Passage of Extension Catheter



US007422579B2

(12) **United States Patent**
Wahr et al.

(10) **Patent No.: US 7,422,579 B2**
(45) **Date of Patent: Sep. 9, 2008**

(54) **EMBOLI PROTECTION DEVICES AND**

5,011,488 A 4/1991 Ginsburg 606/159
(Continued)

(73) Assignee:
(*) Notice:
(21) Appl. No.:
(22) Filed:
(65)
US 2002/
(51) **Int. Cl.**
A61M 3
(52) **U.S. Cl.**
(58) **Field of**
See appl
(56)
4,655,746
4,690,668
4,784,636
4,883,460
4,921,478

The proximal and distal ends **140***a*, **140***b* of the evacuation lumen **140** are preferably angled to allow for smoother passage of the evacuation sheath assembly **100** through a guide catheter, and into a blood vessel, and to facilitate smoother passage of other therapeutic devices through the evacuation lumen **140** of the evacuation head **132**.

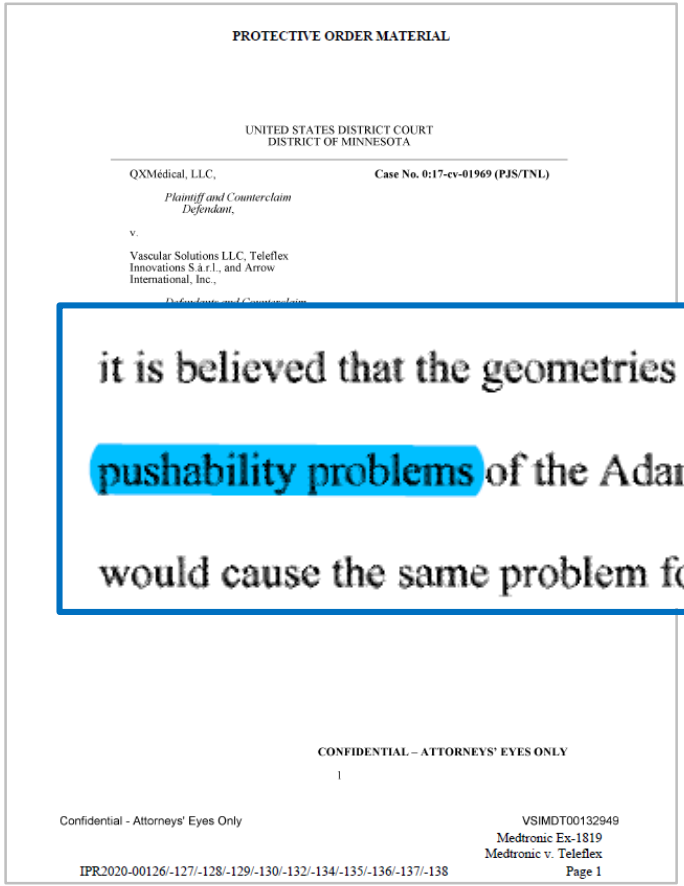
EXHIBIT
1123

Medtronic Ex-1123
Medtronic v. Teleflex

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

Ex-1123, 7:54-60 (Keith)

IPR2020-00127, -00130: Smooth Passage of Extension Catheter



PROTECTIVE ORDER MATERIAL

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

QXMédical, LLC,
Plaintiff and Counterclaim Defendant,

v.

Vascular Solutions LLC, Teleflex Innovations S.à.r.l., and Arrow International, Inc.,

Case No. 0:17-cv-01969 (PJS/TNL)

it is believed that the geometries of the funnel and balloon embodiments contribute to the pushability problems of the Adams device, discussed above, and that the same configuration would cause the same problem for the Crittenden and Kontos devices.

CONFIDENTIAL – ATTORNEYS' EYES ONLY

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Confidential - Attorneys' Eyes Only

VSIMDT00132949
Medtronic Ex-1819
Medtronic v. Teleflex
Page 1

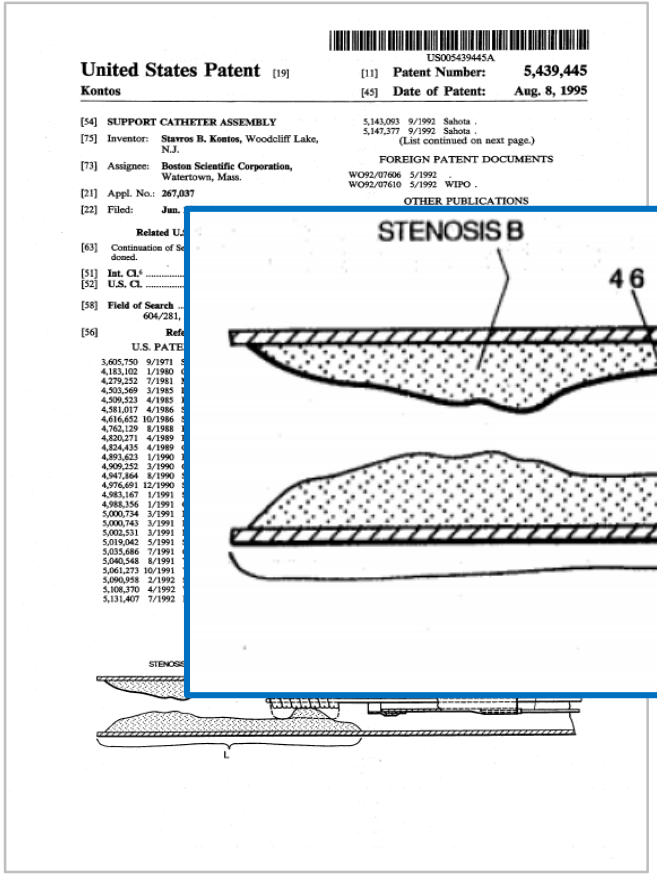
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

Ex-1819, ¶ 113 (Keith)

IPR2020-00127 & IPR2020-00130: Motivation for Side Opening

1. Smooth Passage of Extension Catheter Through Guide Catheter
2. Safe Retrieval of Extension Catheter
3. Maximize “Real Estate” Inside Catheter Assembly
4. Smooth Receipt of Interventional Cardiology Devices

IPR2020-00127, -00130: Retrieval of Extension Catheter



US005439445A

United States Patent [19]
Kontos

[11] **Patent Number: 5,439,445**
[45] **Date of Patent: Aug. 8, 1995**

[54] **SUPPORT CATHETER ASSEMBLY**

[75] Inventor: **Stavros B. Kontos**, Woodcliff Lake, N.J.

[73] Assignee: **Boston Scientific Corporation**, Watertown, Mass.

[21] Appl. No.: **267,037**

[22] Filed: **Jun.**

Related U.S.

[63] Continuation of Se... doned.

[51] **Int. Cl.**[6] .....
[52] **U.S. Cl.** .....

[58] **Field of Search** ... 604/281,

[56] **Refe...**

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STENOSIS A
CORONARY ARTERY
46
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FIG. 7

Ex-1409, Fig. 7

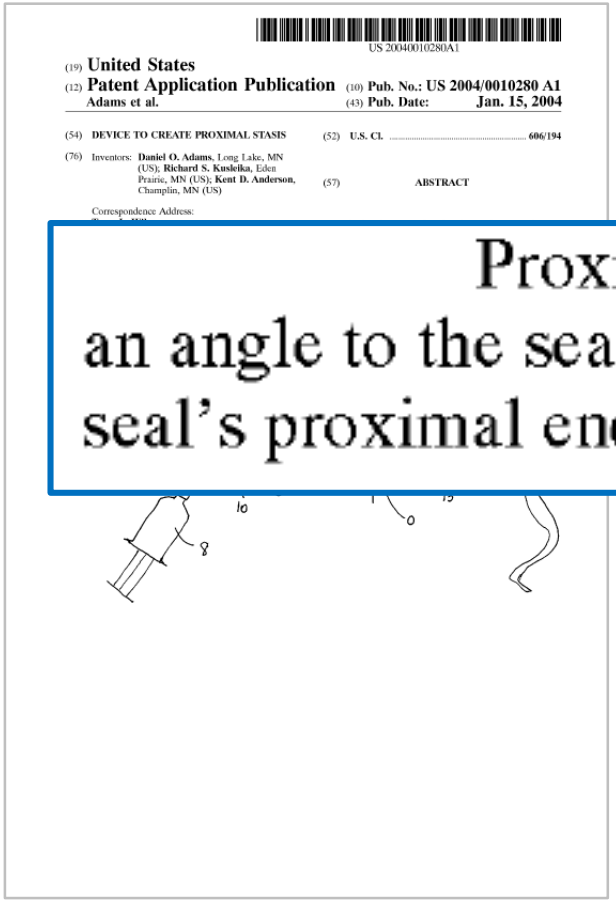
IPR2020-00127, -00130: Retrieval of Extension Catheter

DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC

201. In this embodiment, after the procedure, the support assembly 10 must return to the guide catheter 38. A POSITA would appreciate that the flared proximal opening of the tubular structure (body 12) was a poor design choice. This protrusion could damage the internal coronary wall (intimal lining) and hinder re-entry of the tubular structure into the guide catheter as the tubular structure travels proximally toward the guide catheter. The smaller cross-sectional diameter of an angled proximal opening would likely reduce the likelihood of damaging the coronary artery and result in easier re-insertion into the guide catheter.

Ex-1405, ¶ 201 (Brecker)

IPR2020-00127, -00130: Retrieval of Extension Catheter



US 2004/0010280A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2004/0010280 A1**

Adams et al. (43) **Pub. Date: Jan. 15, 2004**

(54) **DEVICE TO CREATE PROXIMAL STASIS**

(52) **U.S. Cl.** **606/194**

(76) Inventors: **Daniel O. Adams**, Long Lake, MN (US); **Richard S. Kusleika**, Eden Prairie, MN (US); **Kent D. Anderson**, Champlin, MN (US)

(57) **ABSTRACT**

Correspondence Address:

Proximal end **31** is preferably cut or formed at an angle to the seal axis to facilitate unimpeded entry of the seal's proximal end into the distal end of the guide catheter.

Ex-1435, [0066]

IPR2020-00127, -00130: Retrieval of Extension Catheter

UNITED STATES PATENT AND TRADEMARK O
BEFORE THE PATENT TRIAL AND APPEAL

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR2
U.S. Patent No

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
JOHN J. GRAHAM, MB ChB, MRCP (U

DATE: November 19, 2020
TIME: 9:03 a.m.
PLACE: Toronto, Ontario, Canada
(via videoconference)
JOB NO.: MW 4338269

REPORTED BY: Dawn Workman Bounds, CSR

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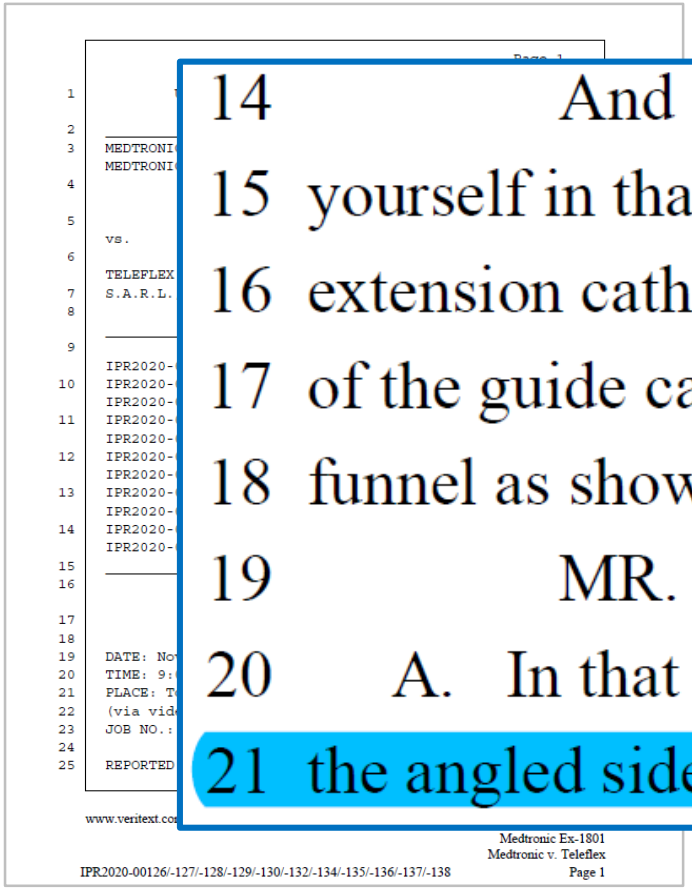
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

Your question is, would an angled side opening be more easy to retrieve into the guide. I have extruded angled guide extensions out of a guide catheter, and I have been able to safely retrieve them. But I have never extruded such a device as this. So your question is, would it be easier for the angled one? I have retrieved angled ones, yes; but I have never used such a catheter. So it's going to be difficult for me to say definitively, but I do know that angled proximal catheters like the GuideLiner I have extruded and have retrieved.

Ex-1801, 72:21-73:6 (Graham)

IPR2020-00127, -00130: Retrieval of Extension Catheter



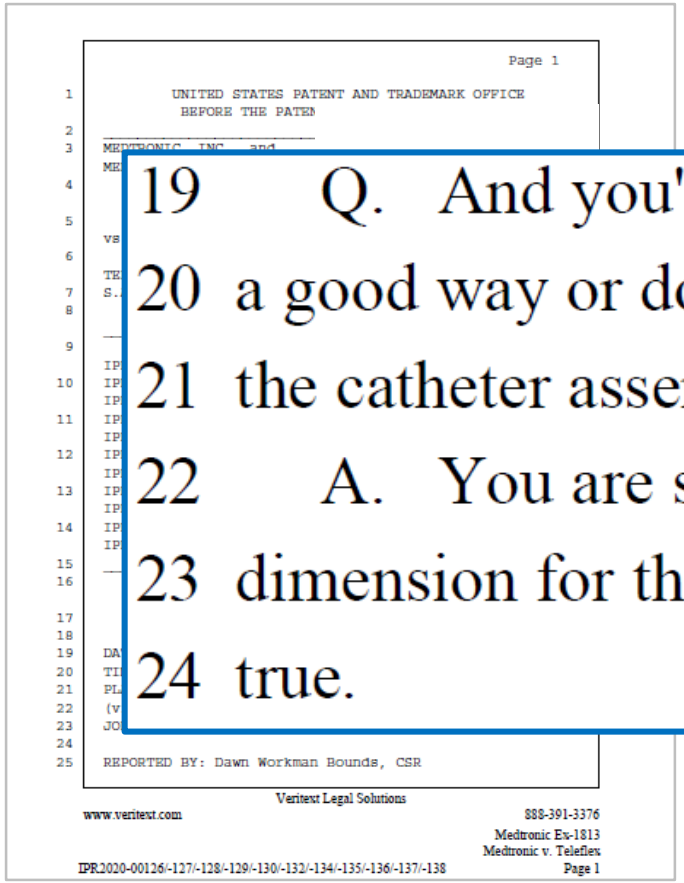
14 And so my question is if you found
15 yourself in that situation, where the proximal end of the
16 extension catheter was distal to the distal-most portion
17 of the guide catheter, would you prefer to have the
18 funnel as shown in Kontos or a proximal side opening?
19 MR. KOHLHEPP: Objection, form.
20 A. In that hypothetical situation, I would prefer
21 the angled side opening.

Ex-1801, 79:14-21 (Graham)

IPR2020-00127 & IPR2020-00130: Motivation for Side Opening

1. Smooth Passage of Extension Catheter Through Guide Catheter
2. Safe Retrieval of Extension Catheter
3. Maximize “Real Estate” Inside Catheter Assembly
4. Smooth Receipt of Interventional Cardiology Devices

IPR2020-00127, -00130: Side Opening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UNITED STATES PATENT AND TRADEMARK OFFICE
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REPORTED BY: Dawn Workman Bounds, CSR

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Medtronic Ex-1813
Medtronic v. Teleflex

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138
Page 1

19 Q. And you'd agree that that type of funnel is not
20 a good way or does not maximize the usable real estate in
21 the catheter assembly, right?
22 A. You are sacrificing some of your inner
23 dimension for that funnel; so yes, what you are saying is
24 true.

Ex-1813, 92:19-24 (Graham)

IPR2020-00127, -00130: Transition from 7 French to 6 French GC

DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC

194. In 1995, when Kontos issued, the guide catheter was typically 7-8 French in diameter. (See Paragraph 46, supra.) By 2006, a 6 French guide catheter had become more common. (See Paragraph 46, supra.) These smaller guide catheters had several advantages: (i) permitted radial access of the catheter assembly[9] and (ii) reduced the size of the access point, regardless of whether femoral or radial access is used. But as the diameter of a guide catheter decreases, that also means that the diameter of the extension catheter must decrease. Because of this, the proximal opening 20 of the tubular structure 12 must decrease. (See Ex-1409, Fig. 6B.)

Ex-1405, ¶ 194 (-00127 IPR) (Brecker)

IPR2020-00127, -00130: Transition from 7 French to 6 French GC

DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC

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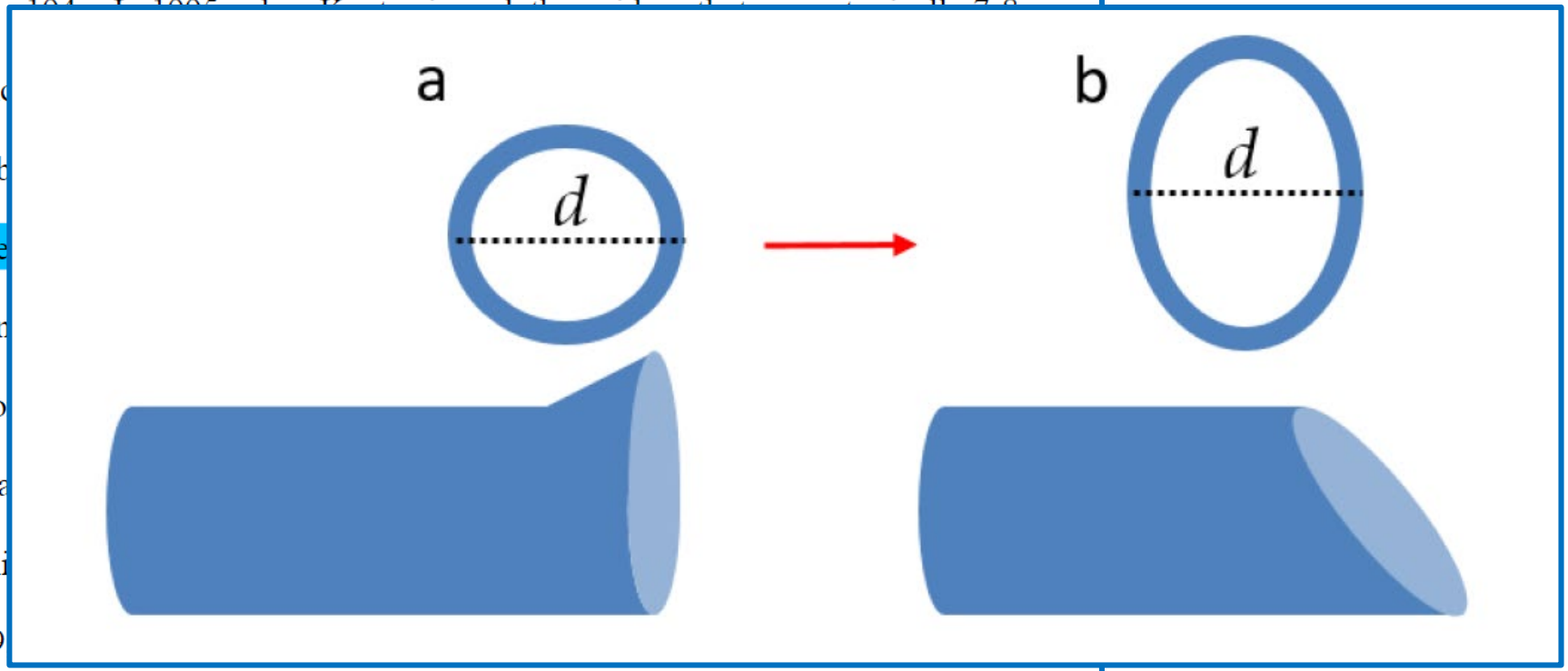

IPR2020-00127, -00130: Teleflex Argues Kontos Already Used in 6 French GC

DECLARATION OF PETER T. KEITH

179. In my opinion, a POSITA would not have been motivated to reduce the outer diameter of Kontos's device because I believe that the Kontos device as disclosed would already have been expected to fit inside a 6 French guide catheter.

Ex-2138, ¶ 179 (-00127 IPR) (Keith)

IPR2020-00127, -00130: Funnel Height is 0.005 Inches in 6 French GC

DECLARATION OF MICHAEL JONES SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

If Kontos is deployed in, for example, a 6 French guide catheter[4] with in inner diameter of 0.070 inches[5], the maximum the outer diameter of the funnel's apex can be is 0.070 inches. This means the maximum height that the funnel adds to catheter 10's outer diameter is 0.005 inches. This is schematically represented in the figure below.

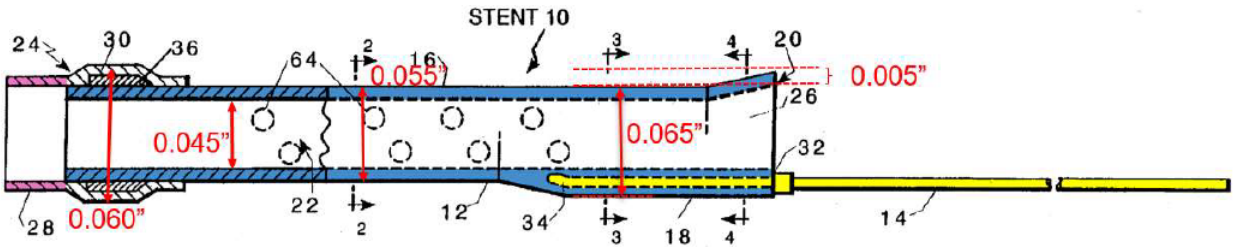

FIG. 1

Ex-1807, ¶ 166 (Jones)

IPR2020-00127, -00130: No Funnel Function in 6 French GC

DECLARATION OF MICHAEL JONES
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

167. A funnel with only a maximum inclination of 0.005 inches over a longitudinal distance of 0.1 inches provides a less than 3-degree angle of inclination. Such a small angle would provide minimal funneling function.

Ex-1807, ¶ 167 (Jones)

IPR2020-00127, -00130: Danger of Advancing Assembly in 6 French GC

SUPPLEMENTAL DECLARATION OF
STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC
SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

Any actual funneling function would be outwieghed by the potential danger of advancing a catheter assembly that "rubbed" against the guide catheter during passage from the hemostatic valve to a location distal the distal-most portion of the guide catheter.

Ex-1806, ¶ 170 (Brecker)

IPR2020-00127, -00130: Graham "would not expect it to go" in 6 French GC

UNITED STATES PATENT AND TRADEMARK OFF
BEFORE THE PATENT TRIAL AND APPEAL BO

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR202
U.S. Patent No.

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
JOHN J. GRAHAM, MB ChB, MRCP (UK)

DATE: November 19, 2020
TIME: 9:03 a.m.
PLACE: Toronto, Ontario, Canada
(via videoconference)
JOB NO.: MW 4338269

REPORTED BY: Dawn Workman Bounds, CSR

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IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

If the outer diameter of Kontos' funnel at the proximal end was 0.070 inches, that would at least -- or that would hinder the ability to facilitate smooth passage of the catheter through the guide catheter?

A. I would expect it to be a not easy insertion. It depends on the deformability of it. You may be able to compress it down and crimp it down on get in that way. But you -- for your argument, .07 inside .07 doesn't -- doesn't equate. I would not expect it to go or go easily.

Q. And smooth passage is something that you prefer to have if possible as an interventional cardiologist?

A. Agreed, yes.

DEMONSTRATIVE EXHIBIT—NOT EVIDENCE

Ex-1801, 116:20-117:7 (Graham)

IPR2020-00127, -00130: Small Extension Catheter can Hinder Entry of Therapy Catheter

And if the cross-sectional diameter of the proximal opening of the tubular structure becomes too small, it can hinder entry and/or advancement of the therapy catheter. Ex-1405, ¶ 195.

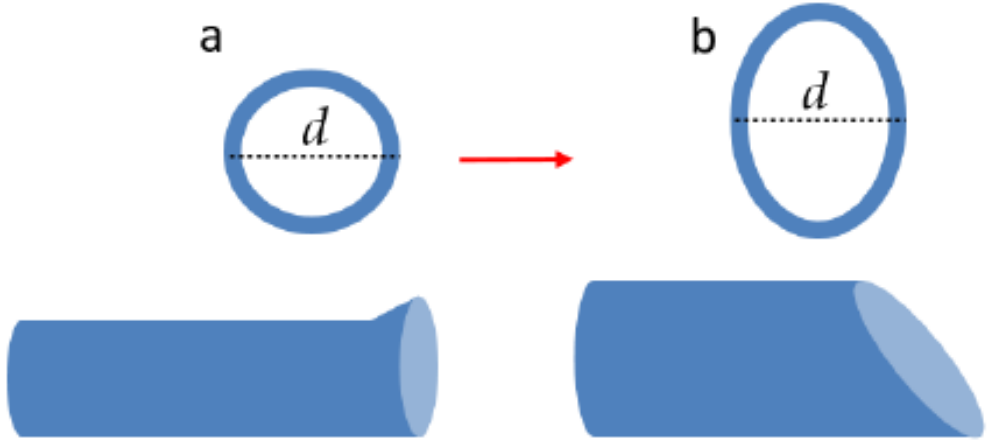
PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 8,048,032

Paper 1 at 44 (-00127 IPR)

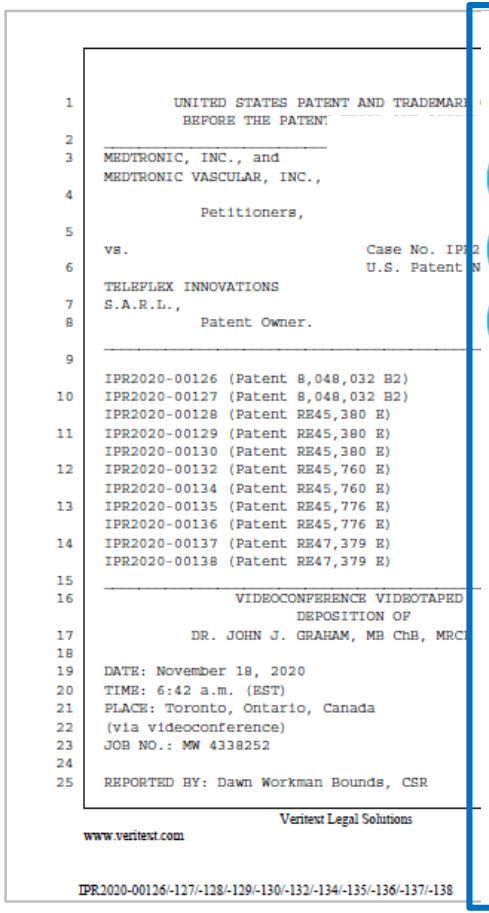
IPR2020-00127, -00130: Small Extension Catheter can Hinder Entry of Therapy Catheter

DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC

For example, as shown below, I have demonstrated how the cross-sectional inner diameter of the tubular structure must be reduced when using a funnel as opposed to a side opening.



IPR2020-00127, -00130: Motivation to Increase ID of Extension Catheter



UNITED STATES PATENT AND TRADEMARK
BEFORE THE PATENT

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR2
U.S. Patent N

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
DR. JOHN J. GRAHAM, MB ChB, MRC

DATE: November 18, 2020
TIME: 6:42 a.m. (EST)
PLACE: Toronto, Ontario, Canada
(via videoconference)
JOB NO.: MW 4338252

REPORTED BY: Dawn Workman Bounds, CSR

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IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

Q. All right. So is another way to think about that, that you want to try to have the largest possible inner diameter of the extension catheter without having to increase the outer diameter of the guide catheter?

A. Yes. You want to -- you want to maximize the usable inner diameter without having to compromise with a bigger outer diameter or catheter it goes in, yes.

Q. And that goal is similarly important in the 2005-2006 time frame as it is today?

A. Real estate is -- we are more aware of real estate. The phrase hadn't really been described then. It's used more often now, but the concept would have been similar.

IPR2020-00127, -00130: Kontos's Diameter Greatest at Funnel

Schematic Based on Patent Owner Argument that Kontos Used with 6 French GC

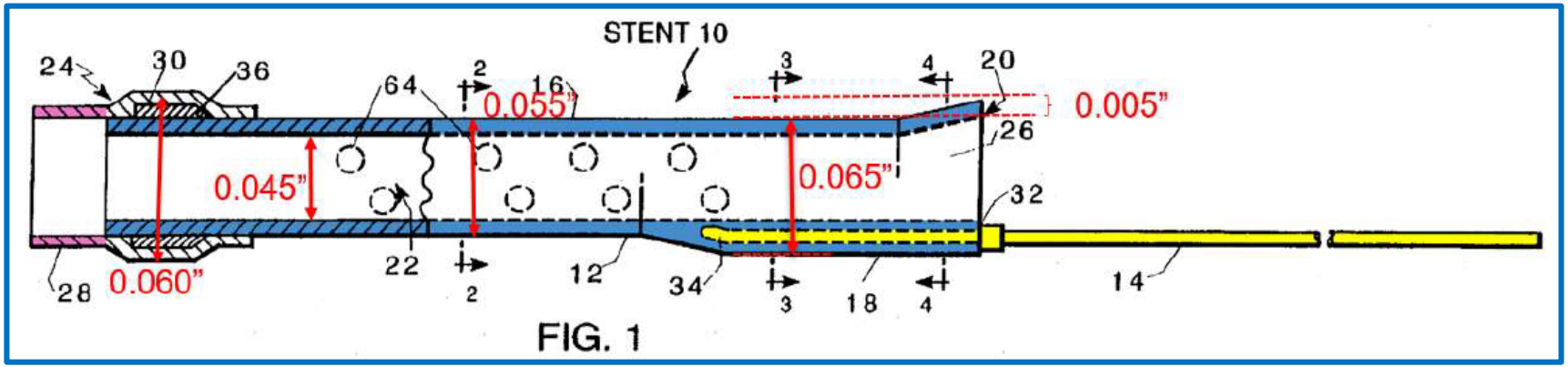


FIG. 1

Ex-1807, ¶ 166 (Jones)

IPR2020-00127, -00130: 7 French or 6 French GC

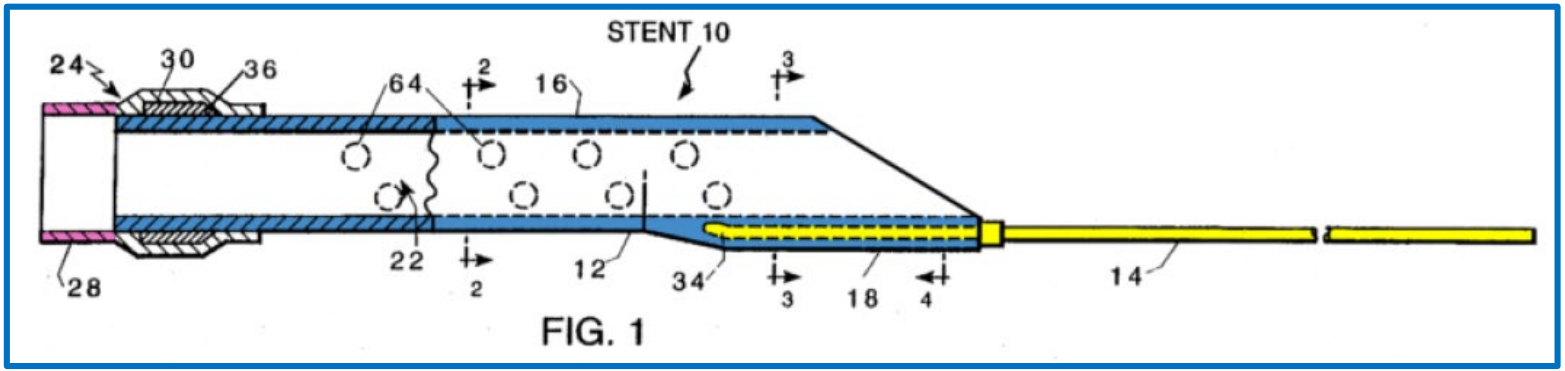


FIG. 1

Ex-1405, ¶ 203 (-00127 IPR) (Brecker)

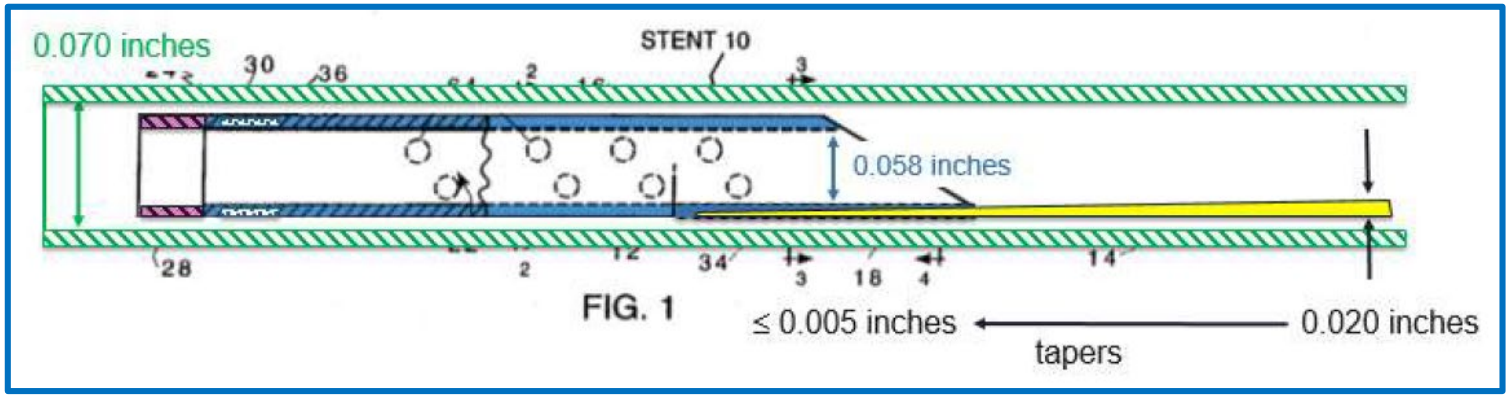
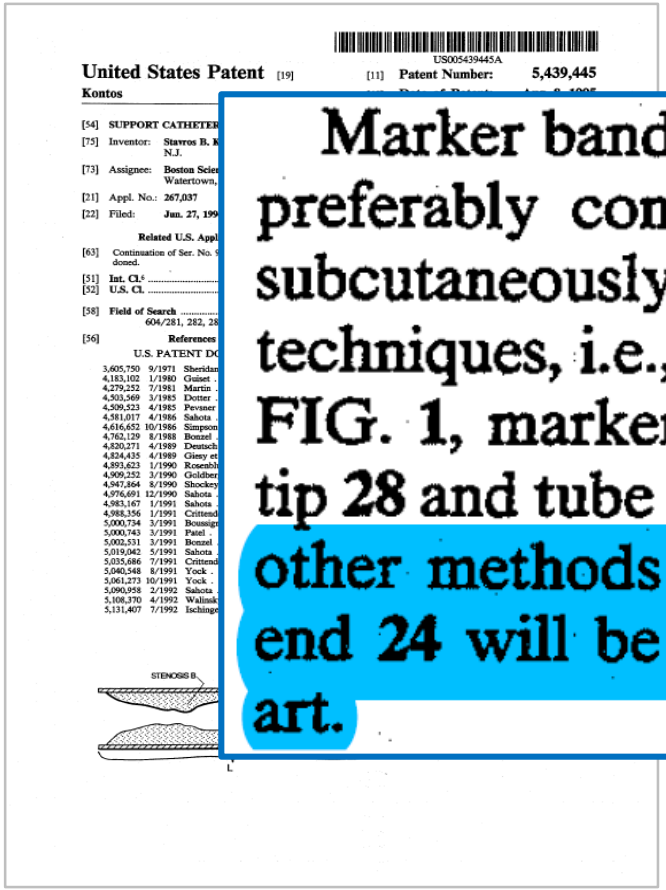


FIG. 1

Ex-1806, ¶ 182 (Brecker)

IPR2020-00127, -00130: Kontos's Marker Bands



US005439445A

United States Patent [19]
Kontos

[11] Patent Number: 5,439,445

[54] SUPPORT CATHETER
[75] Inventor: Stavros B. K... N.J.
[73] Assignee: Boston Scien... Watertown,
[21] Appl. No.: 267,037
[22] Filed: Jun. 27, 199...
Related U.S. Appl...
[63] Continuation of Ser. No. ... doned.
[51] Int. Cl.[6] .....
[52] U.S. Cl. .....
[58] Field of Search ..... 604/281, 282, 28...
[56] References
U.S. PATENT DO...

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4,988,356 1/1991 Crittend
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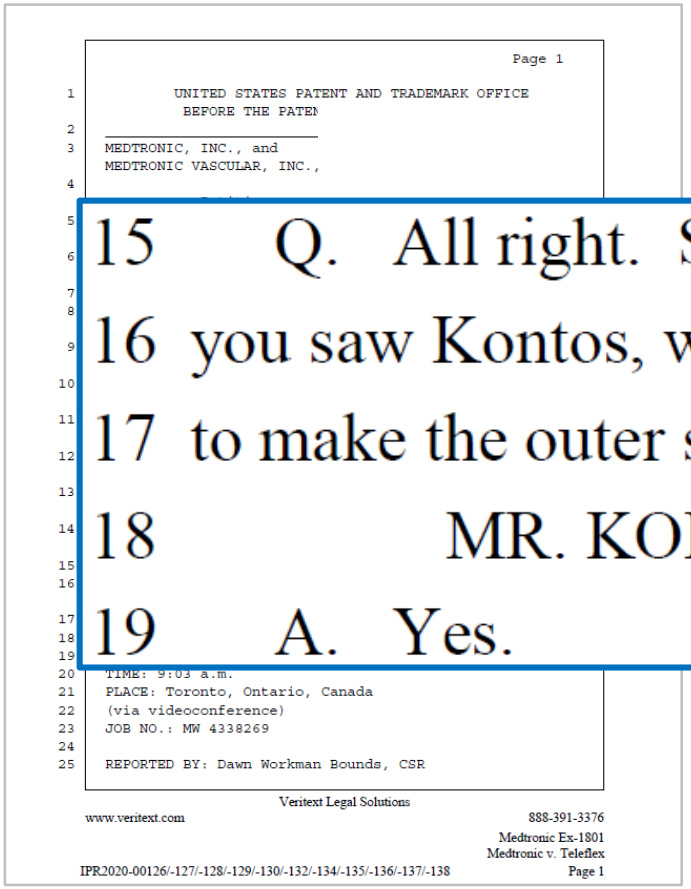
5,061,273 10/1991 Yock .
5,090,958 2/1992 Sahota .
5,108,370 4/1992 Walinsk
5,131,407 7/1992 Ischinge

STENOSIS B

Marker band **30**, which is disposed at distal end **24**, is preferably composed of a material that is detectable subcutaneously through the use of X-ray or fluoroscopy techniques, i.e., it is preferably radiopaque. As shown in FIG. **1**, marker band **30** may be retained between soft tip **28** and tube **16** within recess **36**. Of course, numerous other methods for disposing marker band **30** at distal end **24** will be readily apparent to those skilled in the art.

Ex-1409, 4:16-24

IPR2020-00127, -00130: Graham Says Recess Marker Bands



Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATEN

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

TIME: 9:03 a.m.
PLACE: Toronto, Ontario, Canada
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JOB NO.: MW 4338269

REPORTED BY: Dawn Workman Bounds, CSR

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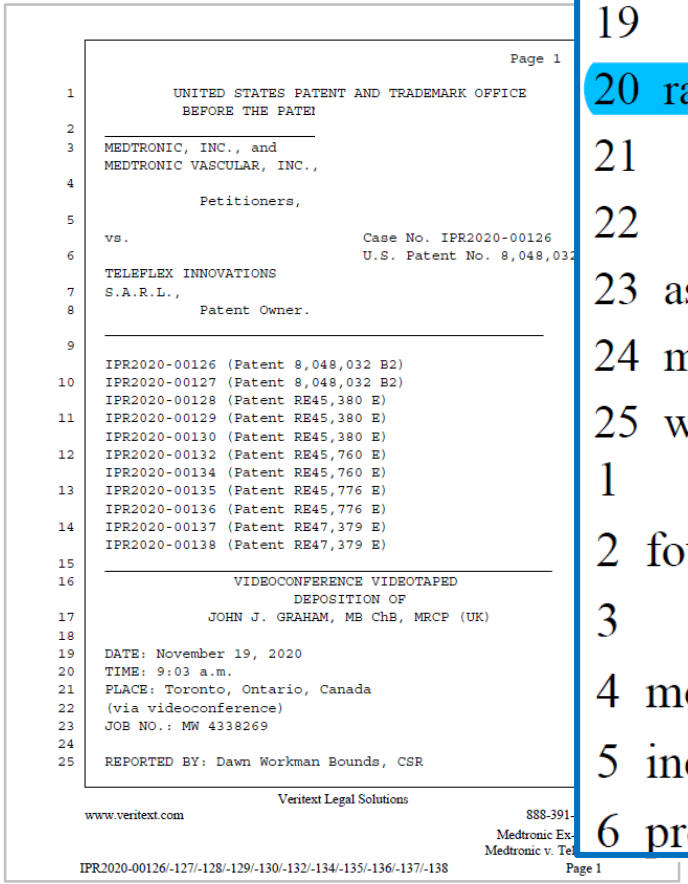
Medtronic Ex-1801
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

15 Q. All right. So in the 2005, 2006 time frame, if
16 you saw Kontos, would you want to recess the marker bands
17 to make the outer surface smooth?
18 MR. KOHLHEPP: Objection, scope.
19 A. Yes.

Ex-1801, 75:15-19 (Graham)

IPR2020-00127, -00130: Graham Never Used Raised Marker Bands



Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATE

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR2020-00126
U.S. Patent No. 8,048,032

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
JOHN J. GRAHAM, MB ChB, MRCP (UK)

DATE: November 19, 2020
TIME: 9:03 a.m.
PLACE: Toronto, Ontario, Canada
(via videoconference)
JOB NO.: MW 4338269

REPORTED BY: Dawn Workman Bounds, CSR

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IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

19 Q. Have you ever used a catheter assembly with
20 raised marker bands as shown in Kontos?
21 A. No.
22 Q. In the 2005 to 2006 time frame, then, I'm
23 assuming you'd agree it was common practice to dispose
24 marker bands within the extension catheter such that they
25 weren't raised as shown in Kontos Figure 1?
1 MR. KOHLHEPP: Objection to form;
2 foundation.
3 A. The idea was to have a smooth outer profile, so
4 most marker bands were -- tried to -- the attempt was to
5 incorporate them into the catheter to try to minimize the
6 protuberance from the exterior surface.

Ex-1801, 66:19-67:6 (Graham)

IPR2020-00127 & IPR2020-00130: Motivation for Side Opening

1. Smooth Passage of Extension Catheter Through Guide Catheter
2. Safe Retrieval of Extension Catheter
3. Maximize “Real Estate” Inside Catheter Assembly
4. Smooth Receipt of Interventional Cardiology Devices

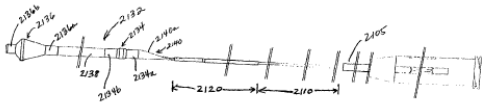
IPR2020-00127, -00130: Ressemann Teaches Smooth Receipt of IVCD

US007604612B2

(12) **United States Patent**
Ressemann et al.

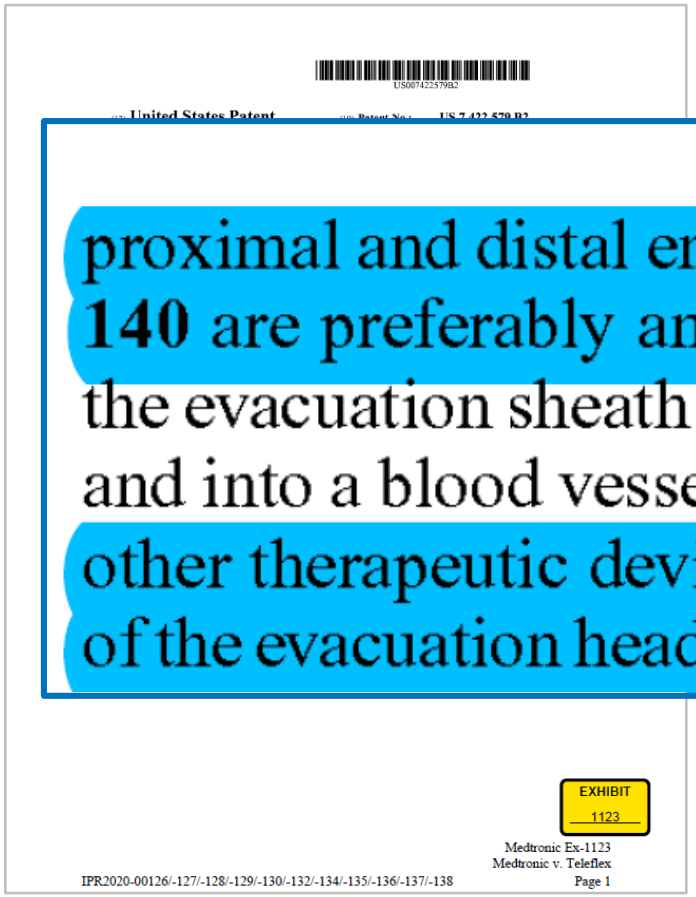
(10) Patent No.: US 7,604,612 B2
(45) Date of Patent: Oct. 20, 2009

lumen **140**. The proximal and distal ends **140***a*, **140***b* of the evacuation lumen **140** are preferably angled to allow for smoother passage of the evacuation sheath assembly **100** through a guide catheter, and into a blood vessel, and to facilitate smoother passage of other therapeutic devices through the evacuation lumen **140** of the evacuation head **132**.



Ex-1405, ¶ 199 (-00127 IPR) (Resseamnn)

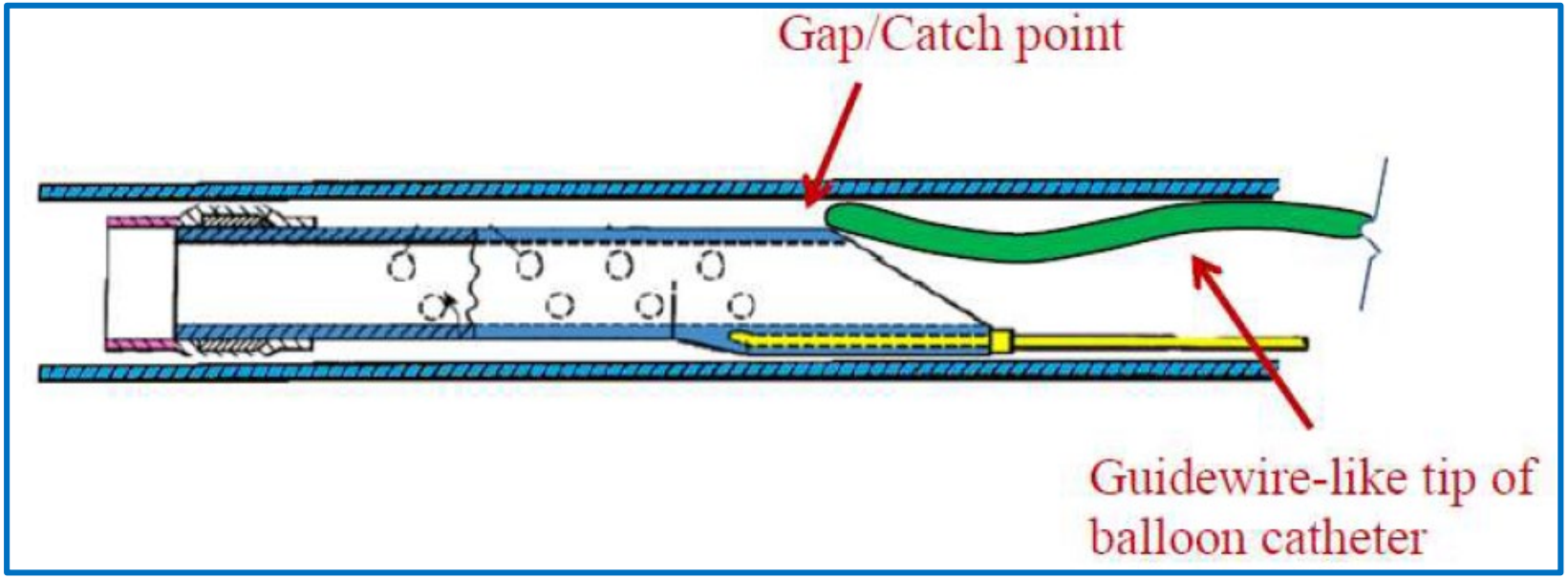
IPR2020-00127, -00130: Keith Teaches Smooth Receipt of IVCD



The proximal and distal ends **140***a*, **140***b* of the evacuation lumen **140** are preferably angled to allow for smoother passage of the evacuation sheath assembly **100** through a guide catheter, and into a blood vessel, and to facilitate smoother passage of other therapeutic devices through the evacuation lumen **140** of the evacuation head **132**.

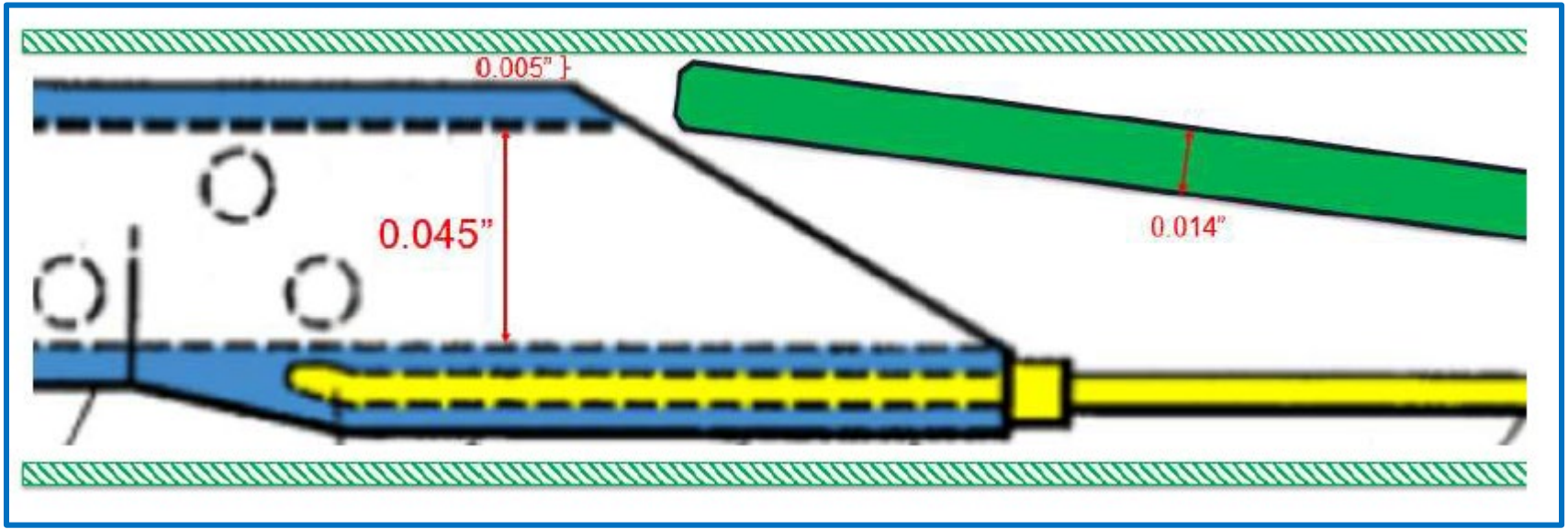
Ex-1123, 7:54-60 (Keith)

IPR2020-00127, -00130: Teleflex's Catch-Point Argument



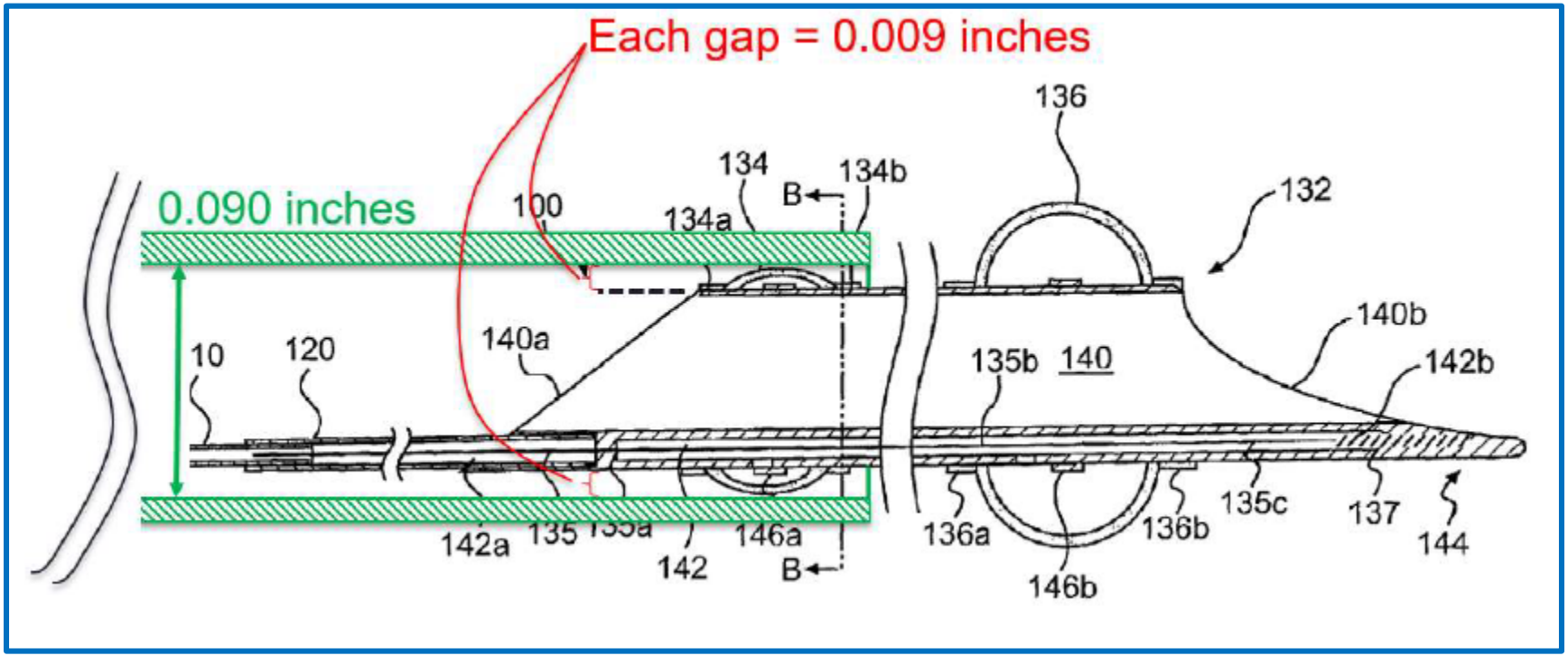
Ex-2145, ¶ 214 (Keith)

IPR2020-00127, -00130: Brecker Shows no Catch Point



Ex-1806, ¶ 176 (Brecker)

IPR2020-00127, -00130: Ressemann/Keith Gap is Larger



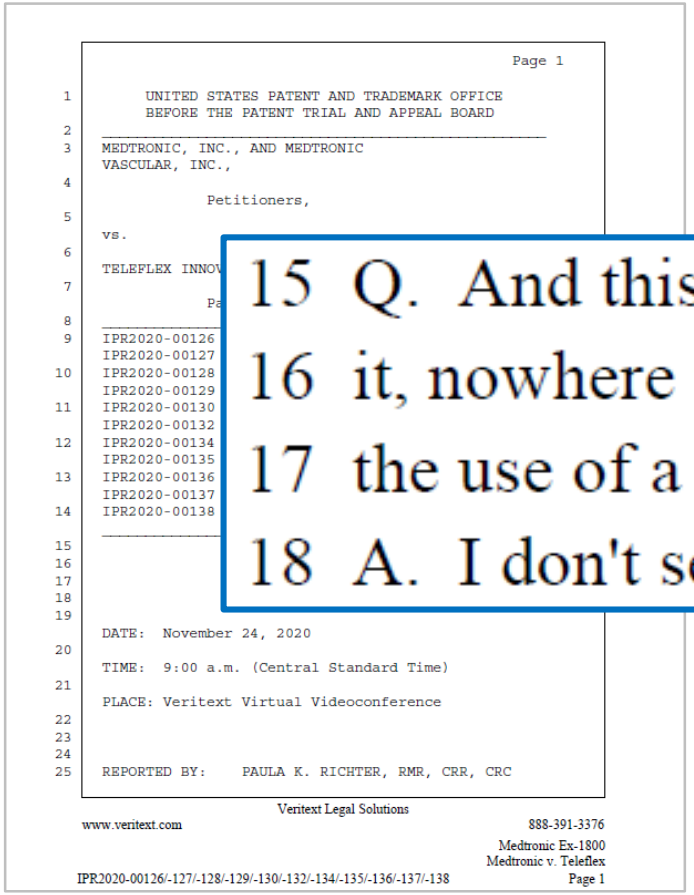
Ex-1806, ¶ 179 (Brecker)

IPR2020-00127, -00130: Brecker Testimony

Not only do Ressemann and Keith not suggest that the relationship between guide catheter and extension catheter will cause device hang-up, but both teach that their proximal opening will "facilitate smoother passage of the other therapeutic devices through the evacuation lumen 140 of the evacuation head 132." Ex-1008, 6:52-60; Ex-1123, 7:54-60. Because Ressemann and Keith's gap is nearly twice as big as the alleged problematic gap in Kontos, I do not believe that replacing Kontos's funnel with a side opening (and making no further modification) will cause device hang-up.

Ex-1806, ¶ 179 (Brecker)

IPR2020-00127, -00130: Keith Patent Has No Funnel/Bevel



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IPR2020-00128
IPR2020-00129
IPR2020-00130
IPR2020-00132
IPR2020-00134
IPR2020-00135
IPR2020-00136
IPR2020-00137
IPR2020-00138

DATE: November 24, 2020

TIME: 9:00 a.m. (Central Standard Time)

PLACE: Veritext Virtual Videoconference

REPORTED BY: PAULA K. RICHTER, RMR, CRR, CRC

Veritext Legal Solutions
www.veritext.com 888-391-3376

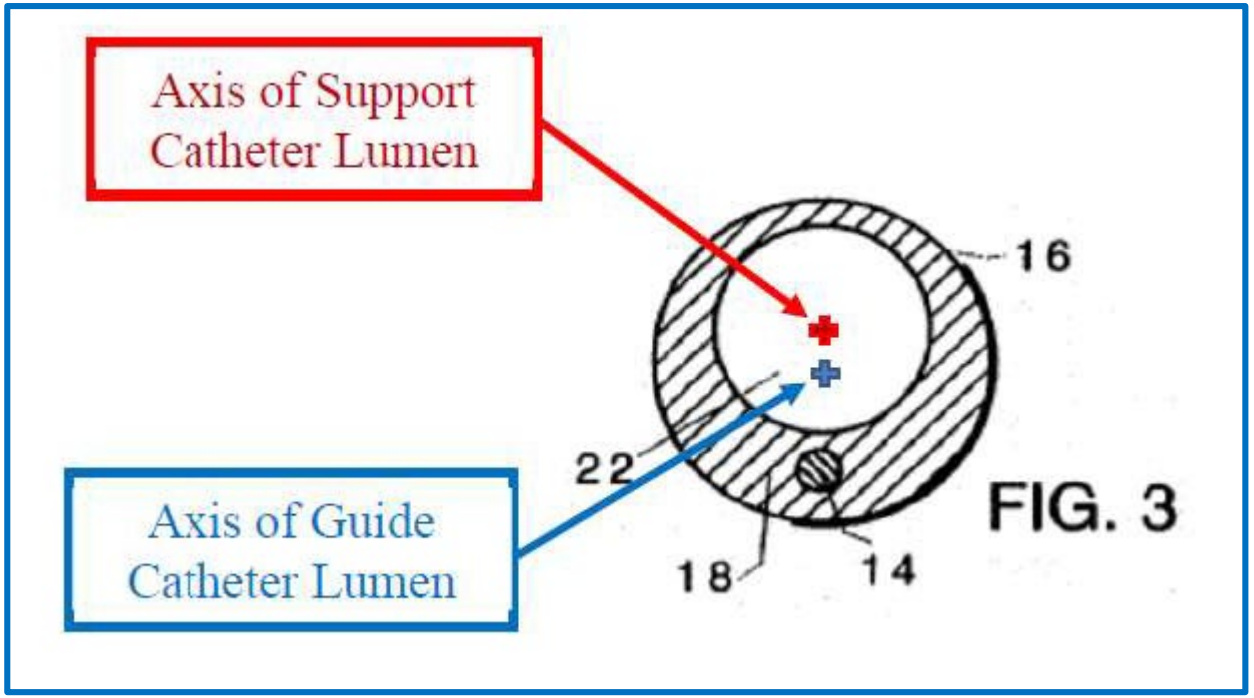
Medtronic Ex-1800
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

15 Q. And this patent where you have your name on
16 it, nowhere in this patent is there anything about
17 the use of a flare or a reverse bevel, correct?
18 A. I don't see it in any of the figures.

Ex-1800, 149:15-18 (Keith)

IPR2020-00127, -00130: Coaxial

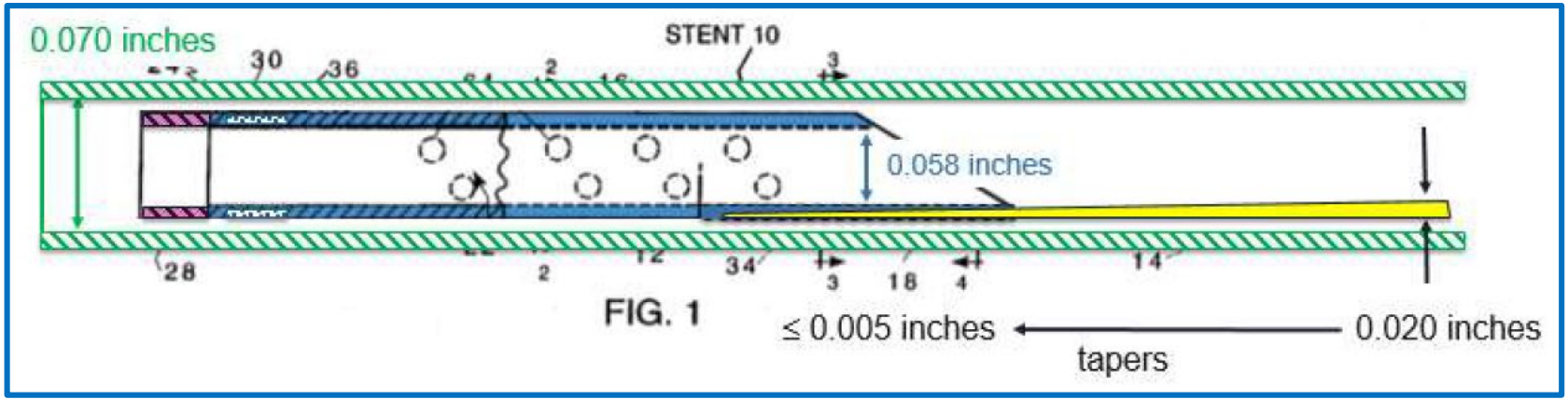
DECLARATION OF PETER T. KEITH



Ex-2138, ¶ 190 (Keith)

IPR2020-00127, -00130: Coaxial

SUPPLEMENTAL DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

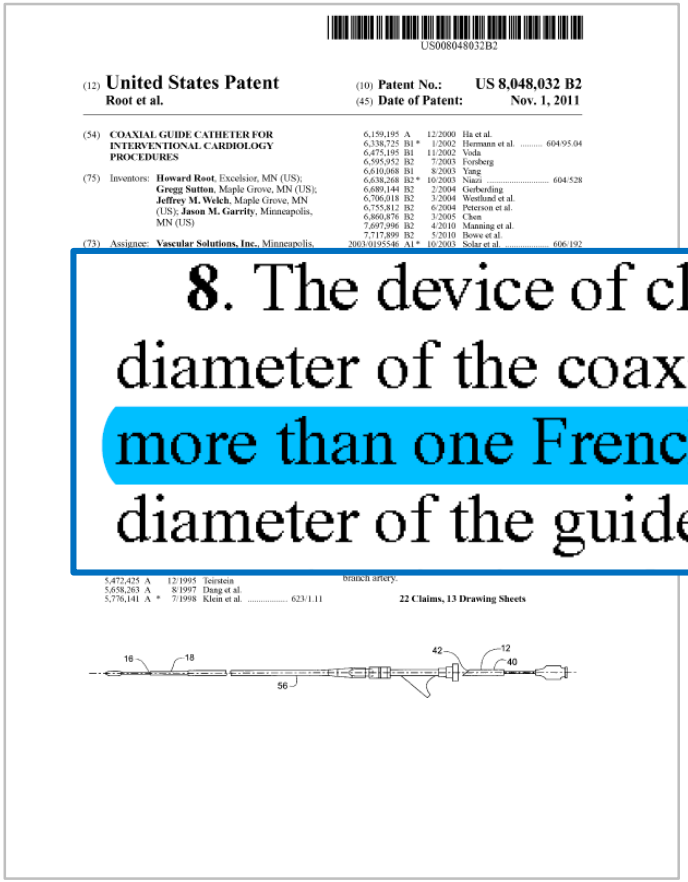


Ex-1806, ¶ 182

IPR2020-00127 & IPR2020-00130

1. Overview of Kontos
2. Kontos Receives "*interventional cardiology devices*"
3. Kontos Necessarily Provides Back-Up Support
4. Obvious to Replace Kontos's Funnel with a Side Opening
5. Obvious to Achieve 1 French
6. Kontos has "*flexible cylindrical reinforced portion*"

IPR2020-00127, -00130: 1 French



US008048032B2

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,048,032 B2**
(45) **Date of Patent: Nov. 1, 2011**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(75) Inventors: **Howard Root**, Excelsior, MN (US); **Gregg Sutton**, Maple Grove, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Minneapolis, MN (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis,

6,159,195 A 12/2000 Ha et al.
6,338,725 B1 * 1/2002 Hermann et al. 604/95.04
6,475,195 B1 11/2002 Voda
6,595,952 B2 7/2003 Forsberg
6,610,068 B1 8/2003 Yang
6,638,268 B2 * 10/2003 Niazi 604/528
6,689,144 B2 2/2004 Gerberding
6,706,018 B2 3/2004 Westlund et al.
6,755,812 B2 6/2004 Peterson et al.
6,860,876 B2 3/2005 Chen
7,697,996 B2 4/2010 Manning et al.
7,717,899 B2 5/2010 Bowe et al.
2003/0195546 A1 * 10/2003 Solar et al. 606/192

5,472,425 A 12/1995 Teirstein
5,658,263 A 8/1997 Dang et al.
5,776,141 A * 7/1998 Klein et al. 623/1.11

branch artery.

22 Claims, 13 Drawing Sheets

16 18 42 12 40 56

8. The device of claim **1** wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

Ex-1401, claim 8 ('032 patent)

IPR2020-00127, -00130: Takahashi Teaches Improved Back-Up Support

Basic Science Review

New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter

Saeko Takahashi,[1*] MD, Shigeru Saito,[1] MD, Shinji Tanaka,[1] MD, Yusuke Miyashita,[1] MD, Takaaki Shiono,[1] MD, Fumio Arai,[1] MD, Hiroshi Domae,[1] MD, Shutaro Satake,[1] MD, and Takenari Itoh,[2] PhD

A 6 Fr guiding catheter is commonly used in the percutaneous coronary intervention (PCI). However, one of the limitations of the 6 Fr guiding catheter is its weak backup support compared to a 7 or an 8 Fr guiding catheter. In this article, we present a new system for PCI called the five-in-six system. Between March 2003 and September 2003, this system was tried on eight chronic total occlusion cases. The advantage of the five-in-six system is that it increases backup support of a 6 Fr guiding catheter. *Catheter Cardiovasc Interv 2004;63:452–456.* © 2004 Wiley-Liss, Inc.

Key words: five-in-six system; backup support; 6 Fr guiding catheter; chronic total occlusion

INTRODUCTION

Currently, a 6 Fr guiding catheter is commonly used in percutaneous coronary intervention (PCI), since its use can decrease access site complication, enable early ambulation, and reduce the consumption of the contrast dye [1–4]. Major limitations of a 6 Fr guiding catheter are the inner lumen is not big enough to accommodate bulky atherectomy devices, and its backup support is not strong compared to a 7 or an 8 Fr catheter. In this report, we demonstrate a new technique for PCI called the five-in-six system, which increases a backup support of a 6 Fr guiding catheter.

MATERIALS AND METHODS

The Five-in-Six System

The five-in-six system is a method of inserting a 5 Fr guiding catheter (Heartrail, Terumo, Japan) into a 6 Fr guiding catheter to increase backup support. As we insert the 5 Fr inner guiding catheter into the target artery through the outer 6 Fr guiding catheter, stronger backup support can be generated (Fig. 1A).

This 5 Fr Heartrail straight guiding catheter is 120 cm in length, whereas the 6 Fr guiding catheter is 100 cm. The 5 Fr Heartrail catheter has a very soft 13 cm end portion. This soft end portion can easily negotiate the tortuous coronary artery with the minimal damage and then it can be inserted more deeply into the artery. The inner lumen of the 5 Fr Heartrail catheter is 0.059′ in diameter; it can accept normal balloons or stent delivery systems less than 4.0 mm in diameter. The inner lumen of the outer 6 Fr catheter needs to be more than 0.071′ in diameter to accommodate the 5 Fr Heartrail catheter; Launcher (Medtronic), Heartrail, and Radiguide (Terumo) guiding catheters can meet this inner lumen diameter.

In Vitro Experiments

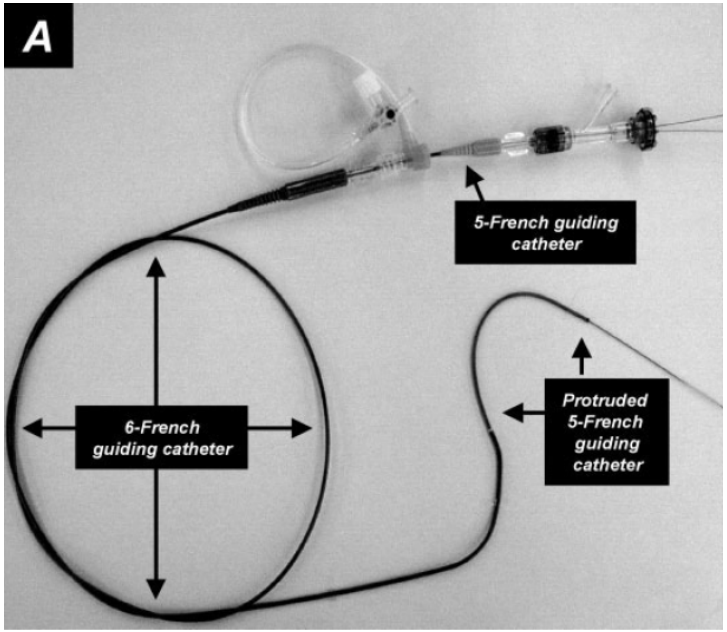
We measured the backup support of this five-in-six system in vitro using an experimental system. The artery model had three curves simulating tortuous coronary arteries. It was filled with water that was kept at 37°C (Fig. 1B). A guiding catheter was engaged into the ostium of the artery model. Then a rapid-exchange balloon catheter (Ryujin 2.5 × 20 mm; Terumo) was pushed into

[1]Division of Cardiology, Center of ShonanKam... Japan [2]Research and ... tory, Terumo Corporat...

*Correspondence to: Dr. ... Catheterization Laborato... eral Hospital, 1202-1 Y... E-mail: saekot@wa2.so-...

Received 8 October 200...

DOI 10.1002/ccd.20223
Published online in Wiley InterScience (www.interscience.wiley.com).

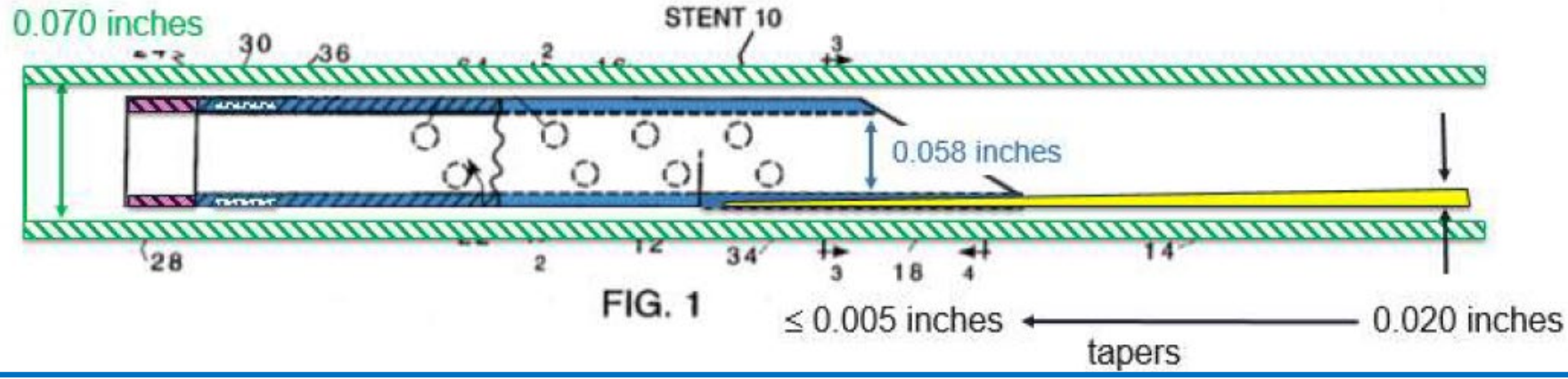


system for PCI called the five-in-six system. Between March 2003 and September 2003, this system was tried on eight chronic total occlusion cases. The advantage of the five-in-six system is that it increases backup support of a 6 Fr guiding catheter. *Catheter Cardiovasc Interv 2004;63:452–456.* © 2004 Wiley-Liss, Inc.

IPR2020-00126, Ex-1010

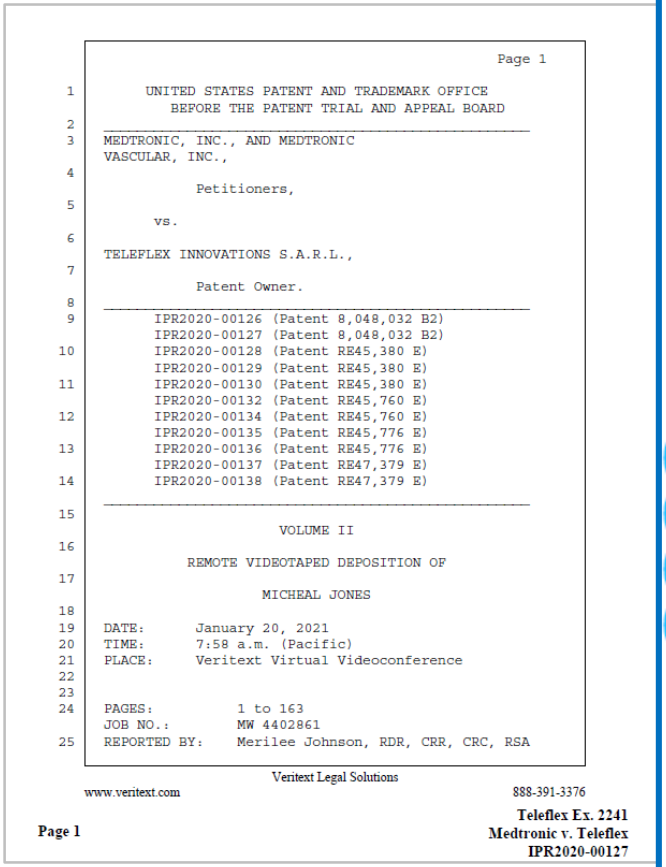
DECLARATION OF MICHAEL JONES SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES

179. Making these straightforward modifications results in a configuration schematically represented below.



Ex-1807, ¶ 179 (Jones)

IPR2020-00127, -00130: Jones Testimony



UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,

Petitioners,

vs.

TELEFLEX INNOVATIONS S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VOLUME II

REMOTE VIDEOTAPED DEPOSITION OF

MICHEAL JONES

DATE: January 20, 2021
TIME: 7:58 a.m. (Pacific)
PLACE: Veritext Virtual Videoconference

PAGES: 1 to 163
JOB NO.: MW 4402861
REPORTED BY: Merilee Johnson, RDR, CRR, CRC, RSA

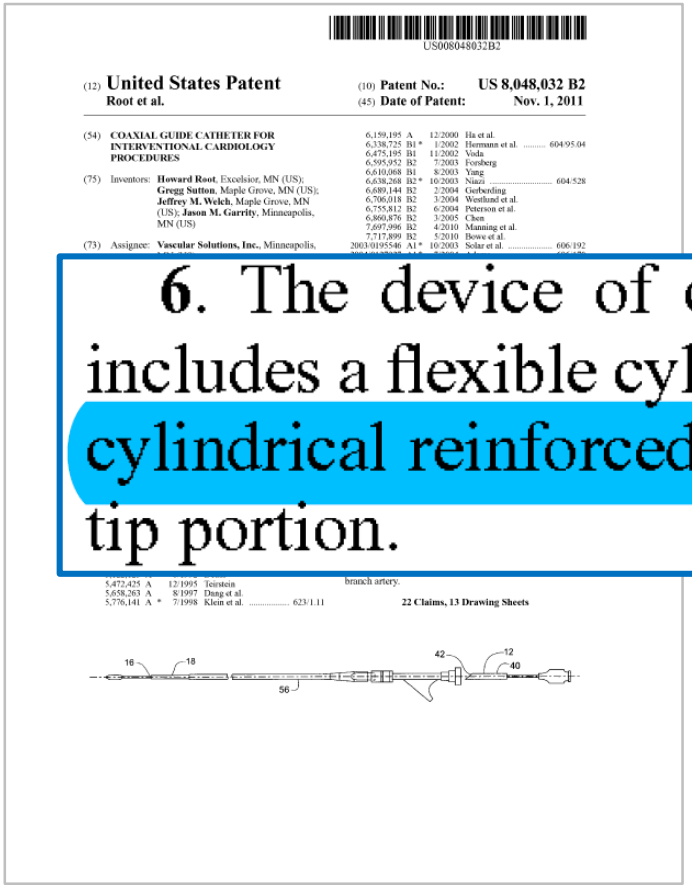
Teleflex Ex. 2241
Medtronic v. Teleflex
IPR2020-00127

6 Q. Okay. And you don't see any
7 inconsistencies by saying that one of ordinary
8 skill in the art would pound Kontos's wire flat,
9 even though with respect to another piece of prior
10 art, you criticized that prior art because that
11 prior art pounds the wire flat.
12 A. Yeah. Because the -- again, I stand by
13 that statement. The difference in producing a flat
14 spot in a very short distance, as shown in Itou,
15 and the difference between creating a flat
16 cross-section in -- as shown in the Figure 179 is
17 rather substantial.
18 There's a whole lot less work -- or
19 work-hardening in the relatively large size that's
20 been flattened versus the very end that's
21 flattened.

Ex-2241, 133:6-21 (Jones)

1. Overview of Kontos
2. Kontos Receives "*interventional cardiology devices*"
3. Kontos Necessarily Provides Back-Up Support
4. Obvious to Replace Kontos's Funnel with a Side Opening
5. Obvious to Achieve 1 French
6. Kontos has "*flexible cylindrical reinforced portion*"

IPR2020-00127, -00130: "*flexible cylindrical reinforced portion*"



US008048032B2

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,048,032 B2**
(45) **Date of Patent: Nov. 1, 2011**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(75) Inventors: **Howard Root**, Excelsior, MN (US); **Gregg Sutton**, Maple Grove, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Minneapolis, MN (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis,

6,159,195 A 12/2000 Ha et al.
6,338,725 B1 * 1/2002 Hermann et al. 604/95.04
6,475,195 B1 11/2002 Voda
6,595,952 B2 7/2003 Forsberg
6,610,068 B1 8/2003 Yang
6,638,268 B2 * 10/2003 Niazi 604/528
6,689,144 B2 2/2004 Gerberding
6,706,018 B2 3/2004 Westlund et al.
6,755,812 B2 6/2004 Peterson et al.
6,860,876 B2 3/2005 Chen
7,697,996 B2 4/2010 Manning et al.
7,717,899 B2 5/2010 Bowe et al.
2003/0195546 A1 * 10/2003 Solar et al. 606/192

5,472,425 A 12/1995 Teirstein
5,658,263 A 8/1997 Dang et al.
5,776,141 A * 7/1998 Klein et al. 623/1.11

branch artery.

22 Claims, 13 Drawing Sheets

6. The device of claim **1** wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.

Ex-1401, claim 6 ('032 patent)

IPR2020-00127, -00130: "*flexible cylindrical reinforced portion*"

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.

Petitioners,

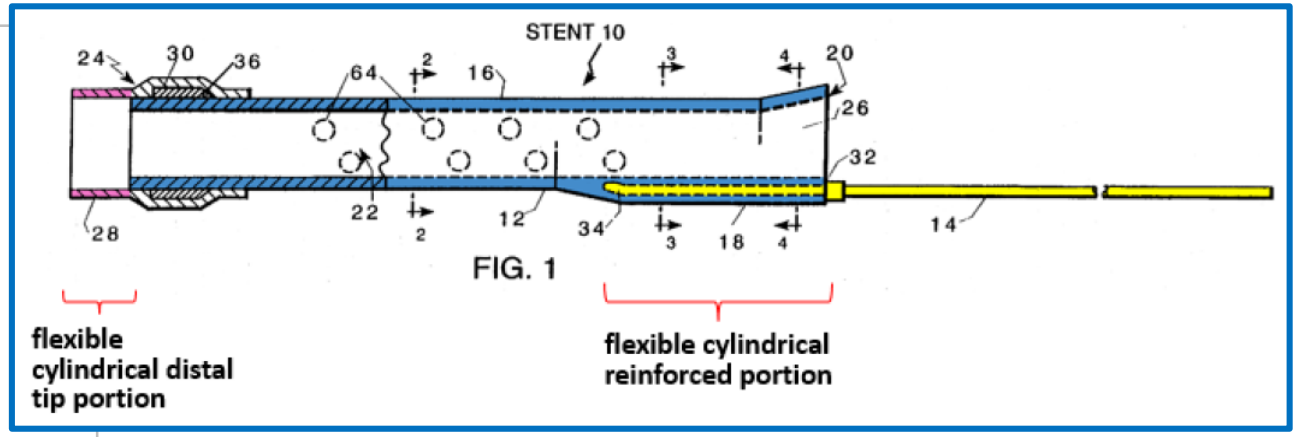
v.

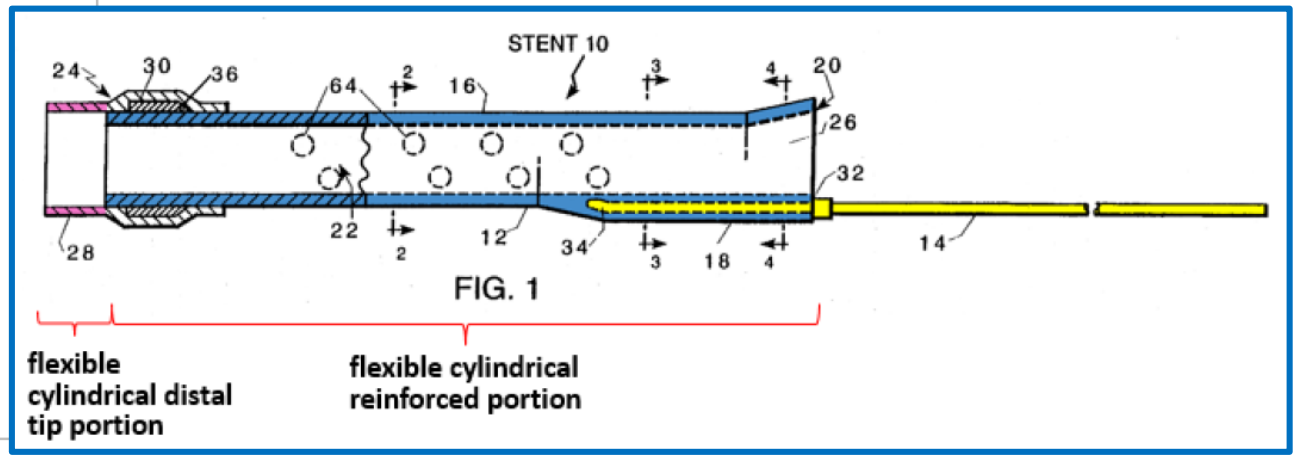
TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner

Case No.: IPR2020-00127
U.S. Patent No. 8,048,032

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,048,032





IPR2020-00127, -00130: "*flexible cylindrical reinforced portion*"

UNITED STATES PATENT AND TRADEMARK OFFICE

BEF

MEDT

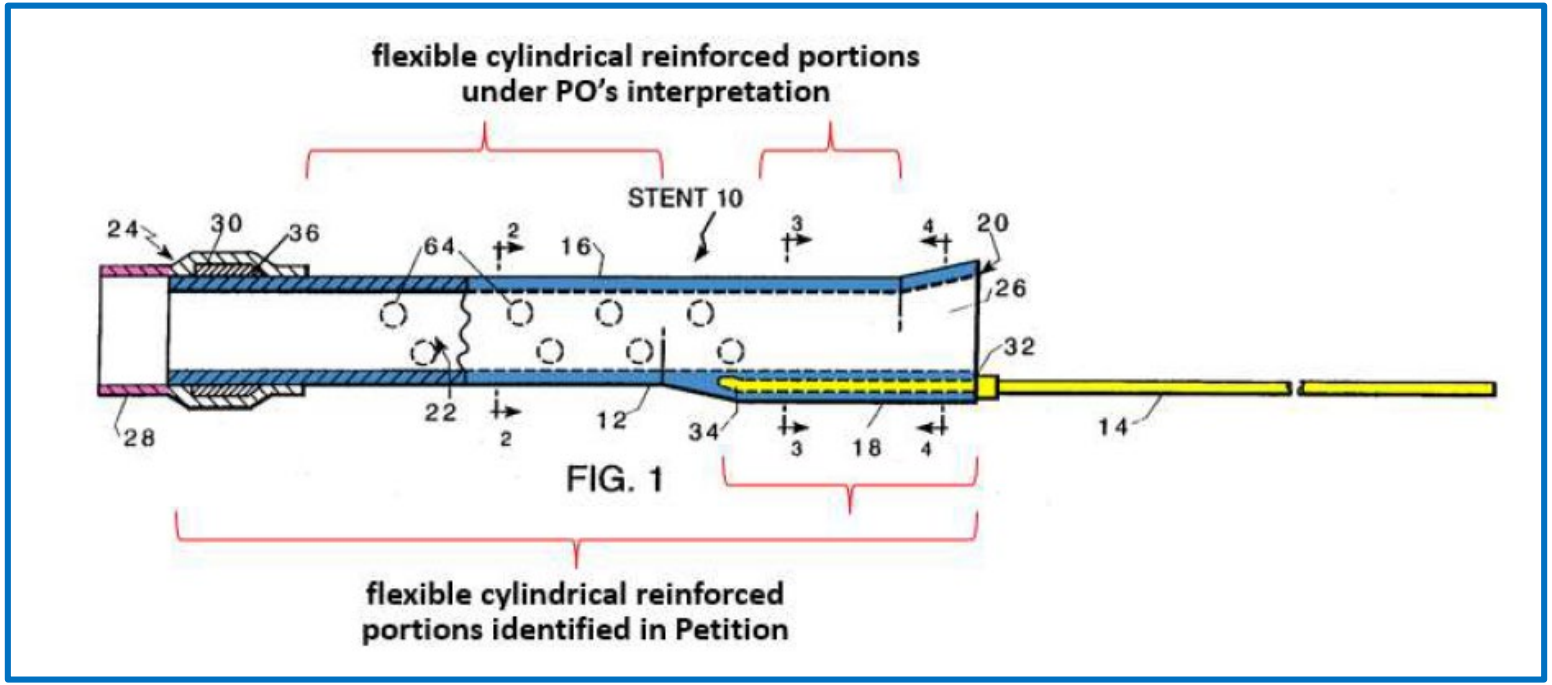
PATENT OWNER RESPONSE

But what the Petition points to is not a "cylindrical" shape. Ex-2138, ¶ 194. It is irregularly shaped, with a protruding funnel portion 26 and a base portion 18 that tapers inward where the "reinforcing" pushwire ends. *Id.*

Paper 40 at 42 (-00127 IPR)

IPR2020-00127, -00130: "*flexible cylindrical reinforced portion*"

SUPPLEMENTAL DECLARATION OF STEPHEN JON DAVID BRECKER, MD, FRCP, FESC, FACC SUBMITTED IN SUPPORT OF PETITIONER'S REPLIES



Ex-1806, ¶ 185 (Brecker)

IPR2020-00136

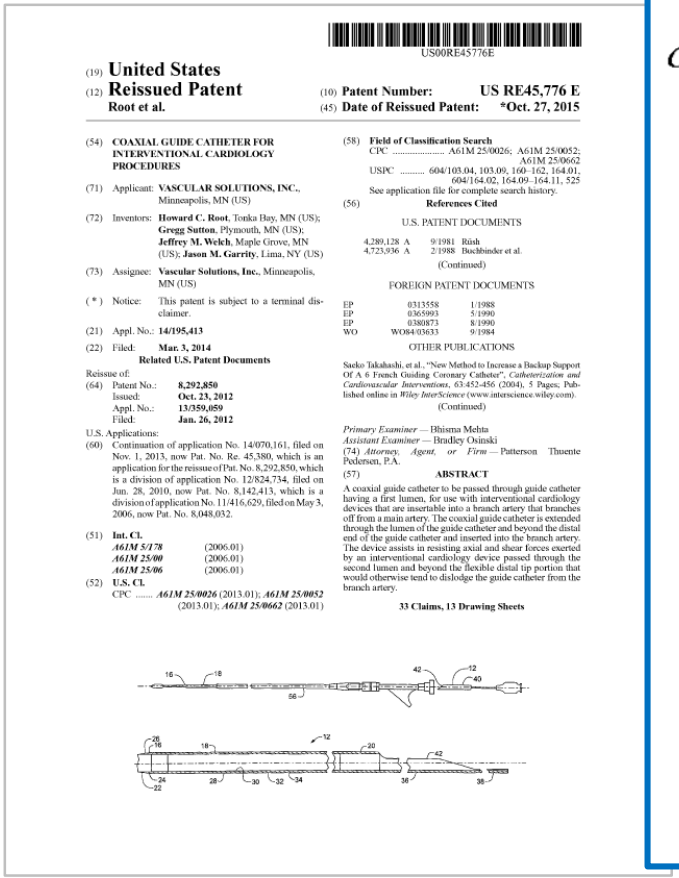
RE45,776 claims	Instituted Ground	References
25-27, 29, 33, 35-37, 39, 41-49, 52	1	Kontos, Ressemann
30-32, 53-56	2	Kontos, Ressemann, Takahashi
52	3	Kontos, Ressemann, Kataishi
53-56	4	Kontos, Ressemann, Takahashi, Kataishi

1. Kontos Necessarily Provides Back-Up Support

2. Achieve 1 French

3. Single-Incline & Double-Incline Side Opening

IPR2020-00136: Side Opening



US00RE45776E

(19) **United States**
(12) **Reissued Patent**
Root et al.

(10) **Patent Number: US RE45,776 E**
(45) **Date of Reissued Patent: *Oct. 27, 2015**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(71) Applicant: **VASCULAR SOLUTIONS, INC.**, Minneapolis, MN (US)

(72) Inventors: **Howard C. Root**, Tonka Bay, MN (US); **Gregg Sutton**, Plymouth, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Lima, NY (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/195,413**

(22) Filed: **Mar. 3, 2014**

Related U.S. Patent Documents

Reissue of:
(64) Patent No.: **8,292,850**
Issued: **Oct. 23, 2012**
Appl. No.: **13/359,059**
Filed: **Jan. 26, 2012**

U.S. Applications:
(60) Continuation of application No. 14/070,161, filed on Nov. 1, 2013, now Pat. No. Re. 45,380, which is an application for the reissue of Pat. No. 8,292,850, which is a division of application No. 12/824,734, filed on Jun. 28, 2010, now Pat. No. 8,142,413, which is a division of application No. 11/416,629, filed on May 3, 2006, now Pat. No. 8,048,032.

(51) **Int. Cl.**
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)
A61M 25/06 (2006.01)

(52) **U.S. Cl.**
CPC ***A61M 25/0026*** (2013.01); ***A61M 25/0052*** (2013.01); ***A61M 25/0662*** (2013.01)

(58) **Field of Classification Search**
CPC A61M 25/0026; A61M 25/0052; A61M 25/0662
USPC 604/103.04, 103.09, 160–162, 164.01, 604/164.02, 164.09–164.11, 525
See application file for complete search history.

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(Continued)

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WO WO84/03633 9/1984

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Saeko Takahashi, et al., "New Method to Increase a Backup Support Of A 6 French Guiding Coronary Catheter", *Catheterization and Cardiovascular Interventions*, 63:452-456 (2004), 5 Pages; Published online in *Wiley InterScience* (www.interscience.wiley.com).
(Continued)

Primary Examiner — Bhisma Mehta
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente Pedersen, P.A.

(57) **ABSTRACT**

A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

33 Claims, 13 Drawing Sheets

25. A guide extension catheter for use with a guide catheter, comprising:

a substantially rigid segment;

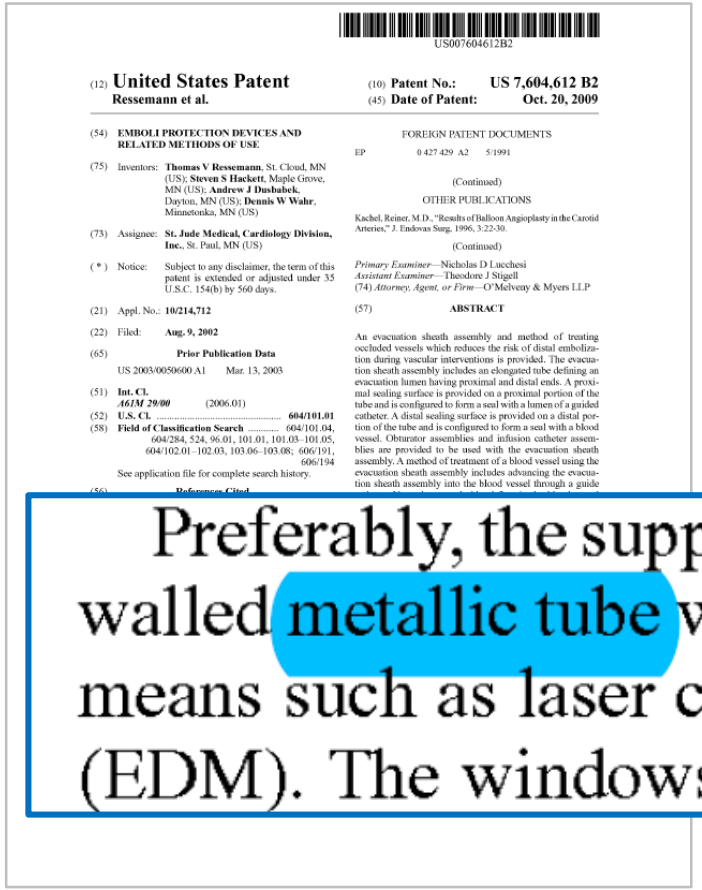
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and

a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material more rigid than a material or material combination forming the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,

wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.

Ex-1401, claim 25 ('776 patent)

IPR2020-00136: Side Opening



US007604612B2

(12) **United States Patent**
Ressemann et al.

(10) **Patent No.: US 7,604,612 B2**
(45) **Date of Patent: Oct. 20, 2009**

(54) **EMBOLI PROTECTION DEVICES AND RELATED METHODS OF USE**

(75) Inventors: **Thomas V Ressemann**, St. Cloud, MN (US); **Steven S Hackett**, Maple Grove, MN (US); **Andrew J Dusbabek**, Dayton, MN (US); **Dennis W Wahr**, Minnetonka, MN (US)

(73) Assignee: **St. Jude Medical, Cardiology Division, Inc.**, St. Paul, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 560 days.

(21) Appl. No.: **10/214,712**

(22) Filed: **Aug. 9, 2002**

(65) **Prior Publication Data**

US 2003/0050600 A1 Mar. 13, 2003

(51) **Int. Cl.**
A61M 29/00 (2006.01)

(52) **U.S. Cl.** **604/101.01**

(58) **Field of Classification Search** 604/101.04, 604/284, 524, 96.01, 101.01, 101.03–101.05, 604/102.01–102.03, 103.06–103.08; 606/191, 606/194

See application file for complete search history.

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

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(Continued)

OTHER PUBLICATIONS

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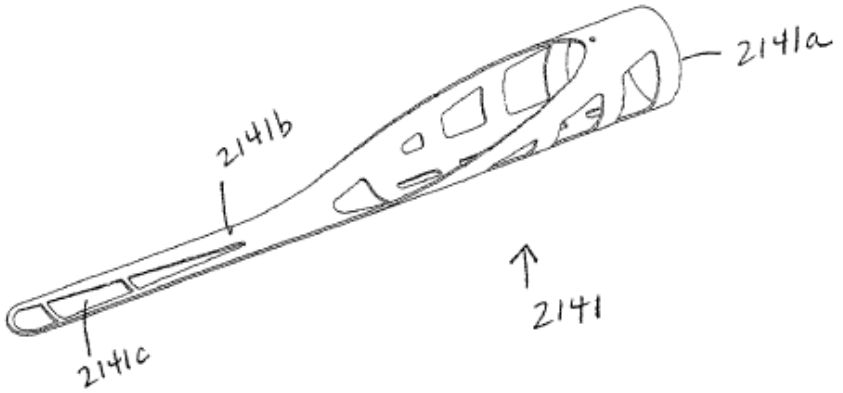
(Continued)

Primary Examiner—Nicholas D Lucchesi
Assistant Examiner—Theodore J Stigell
(74) *Attorney, Agent, or Firm*—O'Melveny & Myers LLP

(57) **ABSTRACT**

An evacuation sheath assembly and method of treating occluded vessels which reduces the risk of distal embolization during vascular interventions is provided. The evacuation sheath assembly includes an elongated tube defining an evacuation lumen having proximal and distal ends. A proximal sealing surface is provided on a proximal portion of the tube and is configured to form a seal with a lumen of a guided catheter. A distal sealing surface is provided on a distal portion of the tube and is configured to form a seal with a blood vessel. Obturator assemblies and infusion catheter assemblies are provided to be used with the evacuation sheath assembly. A method of treatment of a blood vessel using the evacuation sheath assembly includes advancing the evacuation sheath assembly into the blood vessel through a guide



Preferably, the support collar **2141** is fabricated from a thin walled metallic tube with a series of windows cut by suitable means such as laser cutting, or electro-discharge machining (EDM). The windows **2141***c* allow for some flexibility and

Ex-1408, 25:1-4, Fig. 16J (Ressemann)

IPR2020-00136: Side Opening

Trials@uspto.gov
571-272-7822

Paper 20
Date: June 26, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

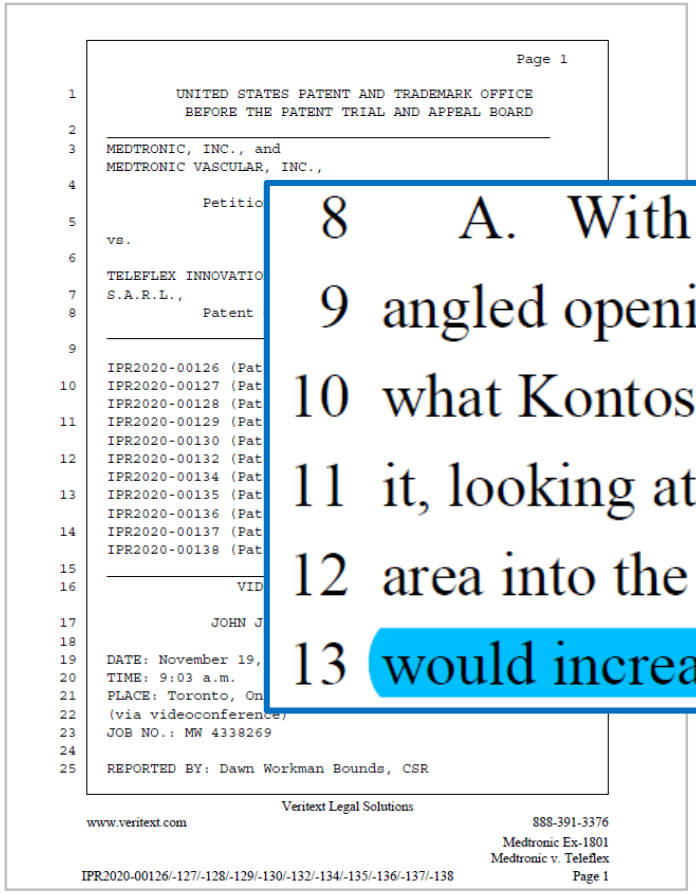
Based on the evidence and arguments of record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing as to this ground with respect to at least claim 25 of the '776 patent. We are not persuaded by Patent Owner's arguments at this preliminary stage.

Institution Decision, Paper 20 at 21 (-00136 IPR)

IPR2020-00136: Ressemann's Side Opening

1. Motivation to Replace Kontos's Funnel with a Side Opening
    - — Trackability Within Guide Catheter
    - — Safe Retrieval of Extension Catheter
    - — Maximizes "Real Estate"
    - — Smooth Receipt of Interventional Devices
    - — Motivations Specific to Ressemann Collar
2. Reasonable Expectation of Success to Replace Kontos's Funnel with Side Opening

IPR2020-00136: Ressemann's Side Opening



Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitio

vs.

TELEFLEX INNOVATIO
S.A.R.L.,
Patent

IPR2020-00126 (Pat
IPR2020-00127 (Pat
IPR2020-00128 (Pat
IPR2020-00129 (Pat
IPR2020-00130 (Pat
IPR2020-00132 (Pat
IPR2020-00134 (Pat
IPR2020-00135 (Pat
IPR2020-00136 (Pat
IPR2020-00137 (Pat
IPR2020-00138 (Pat

VID

JOHN J

DATE: November 19,
TIME: 9:03 a.m.
PLACE: Toronto, On
(via videoconference)
JOB NO.: MW 4338269

REPORTED BY: Dawn Workman Bounds, CSR

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888-391-3376

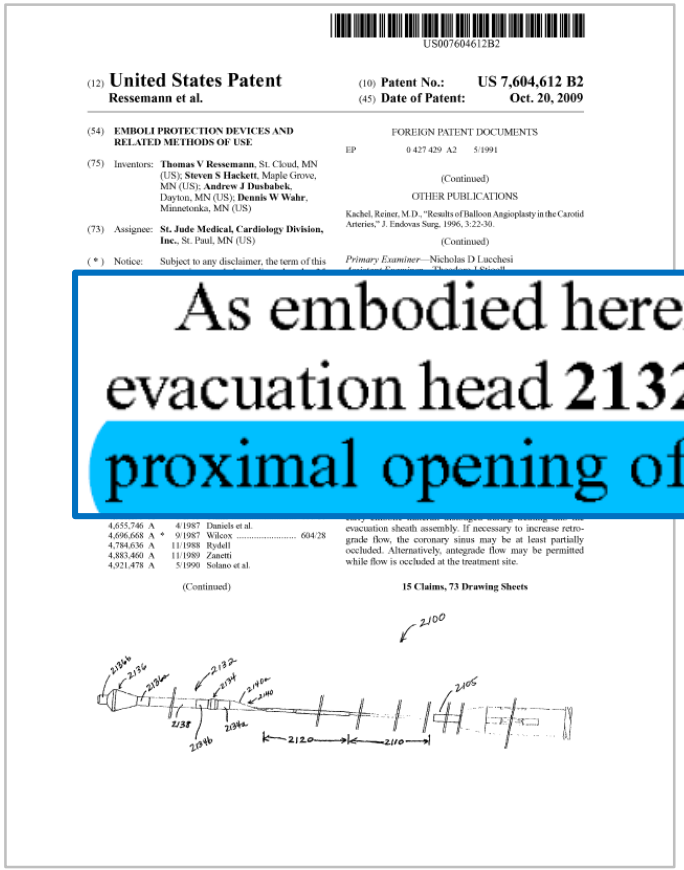
Medtronic Ex-1801
Medtronic v. Teleflex

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

A. With the -- the combination, using the -- the angled opening at 2141 tab from Ressemann compared to what Kontos has originally described, the 2141 tab onto it, looking at this diagram, would increase the opening area into the distal catheter stent or 10 in Kontos. It would increase the area.

Ex-1801, 120:16-121:13 (Graham)

IPR2020-00136: Ressemann's Side Opening



US007604612B2

(12) **United States Patent**
Ressemann et al.

(10) **Patent No.: US 7,604,612 B2**
(45) **Date of Patent: Oct. 20, 2009**

(54) **EMBOLI PROTECTION DEVICES AND RELATED METHODS OF USE**

(75) Inventors: **Thomas V Ressemann**, St. Cloud, MN (US); **Steven S Hackett**, Maple Grove, MN (US); **Andrew J Dusbabek**, Dayton, MN (US); **Dennis W Wahr**, Minnetonka, MN (US)

(73) Assignee: **St. Jude Medical, Cardiology Division, Inc.**, St. Paul, MN (US)

(*) Notice: Subject to any disclaimer, the term of this

FOREIGN PATENT DOCUMENTS

EP 0 427 429 A2 5/1991

(Continued)

OTHER PUBLICATIONS

Kachel, Reiner, M.D., "Results of Balloon Angioplasty in the Carotid Arteries," J. Endovas Surg. 1996, 3:22-30.

(Continued)

Primary Examiner—Nicholas D Lucchesi

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4,883,460 A 11/1989 Zanetti
4,921,478 A 5/1990 Solano et al.

(Continued)

evacuation sheath assembly. If necessary to increase retrograde flow, the coronary sinus may be at least partially occluded. Alternatively, antegrade flow may be permitted while flow is occluded at the treatment site.

15 Claims, 73 Drawing Sheets

As embodied herein and shown in FIGS. **16**D and **16**J, the evacuation head **2132** may include a structure to reinforce the proximal opening of the multi-lumen tube **2138**.

Ex-1408, 24:47-49 (Ressemann)

IPR2020-00136: Side Opening

1. Motivation to Replace Kontos's Funnel with a Side Opening
    - — Maximizes Useable "real estate"
    - — Trackability Within Guide Catheter
    - — Receive Interventional Devices
    - — Retrieve into Guide Catheter
    - — Specific to Ressemann Collar
2. Reasonable Expectation of Success to Replace Kontos's Funnel with Side Opening

IPR2020-00136: Expectation of Success

189. A POSITA was also aware that the tab portion of collar 2141 could be affixed to Kontos's wire 14 in a manner similar to what I have already discussed in connection with combining collar 2141 with Ressemann's embodiment 100 or Itou's catheter 2. Namely, the collar could either be spot welded or secured with adhesive, and encased in polymer.

Ex-1807, ¶ 189 (Jones)

IPR2020-00136: Expectation of Success

189. A POSITA was also aware that the tab portion of collar 2141 could be affixed to Kontos's wire 14 in a manner similar to what I have already discussed in connection w
Itou's cathet
adhesive, an

190. With such an encasement of collar and wire 14, there would be no "catch points". Furthermore, solvent casting, as taught by Ressemann is a process that yields a thin encapsulation over a device, and therefore the incline located at the proximal end of Ressemann's tab portion would be preserved as illustrated in the schematic below.

Ex-1807, ¶ 190 (Jones)

IPR2020-00136: Expectation of Success

189. A POSITA was also aware that the tab portion of collar 2141 could be affixed to Kontos's wire 14 in a manner similar to what I have already discussed in connection w Itou's cathet adhesive, an

190. With such an encasement of collar and wire 14, there would be no "catch points" that yields a t the proximal the schematic

191. Patent Owner, again, argues that forces would tend to push the collar's tab off the wire 14. Paper 40 (IPR2020-00136), 41. I disagree. With the use of either spot welding as taught by Itou and Ressemann (*see* ¶¶ 93-96, 129-131, *supra*) or the use of adhesive and polymer encapsulation (as shown in the schematics above) to join the collar to the wire pushrod, the collar would not pop off. Indeed, there are numerous examples in the art of convex up and convex down structures adjacent one another in the art that function properly. *See, e.g.*, ¶¶ 93-96, *supra* (discussing Solar and Mihara).

MOTIONS TO AMEND

IPR2020-00126, -00127, -00128, -00129, -00130,
-00132, -00134, -00135, -00136, -00137, -00138

Motions to Amend: Agenda

1. The Amended Claims Lack Written Description Support
2. The Amended Claims are Indefinite
3. Patent Owner Broadens the Scope of the Amended Claims
4. The Amended Claims are Invalid Under §§ 102/103

There is no Written Description Support for a Side Opening Outside the Substantially Rigid Portion

reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the he

devices that are insertable

a side opening posit

and a distal end of the sub

inclined sidewall that tape

second inclined sidewall;

wherein the device

extends into the branch ar

portion assist in resisting f

passed through and beyon

dislodge the guide cathete

Claim 25 (replaces

reinforced portion is reinforced with metallic elements in a braided or coiled pattern, wherein the standard guide catheter is a standard 6 French guide catheter, and wherein each of the flexible tip portion and reinforced portion has a cross-sectional inner diameter greater than or equal to 0.056 inches through which the interventional cardiology devices are insertable.

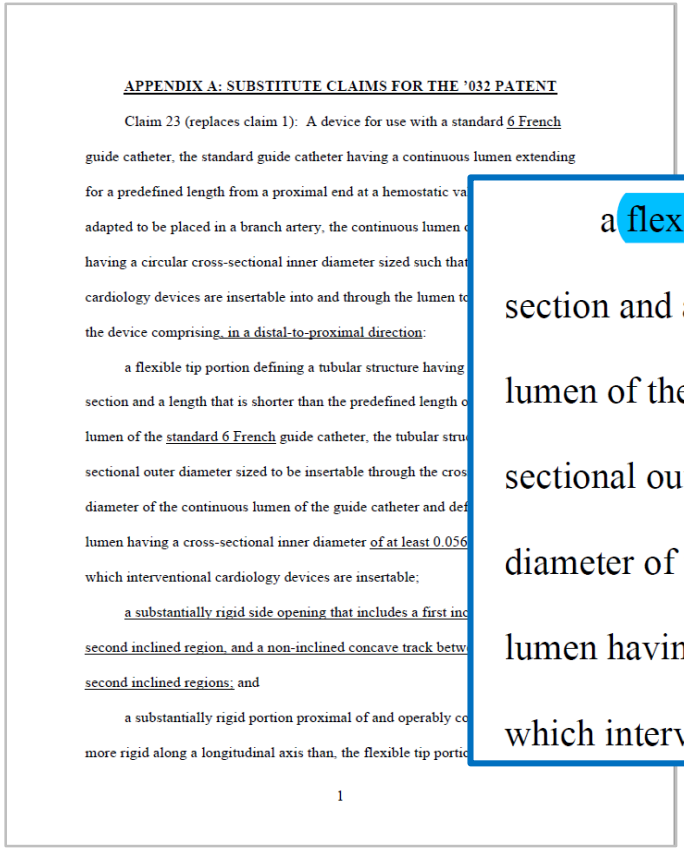
4

Claim 24 (replaces claim 11):

a side opening positioned between a proximal end of the reinforced portion and a distal end of the substantially rigid portion, the side opening having a first inclined sidewall that tapers into a non-inclined concave track that is proximate a second inclined sidewall;

IPR2020-00126, Paper 96 App'x A at 4 ('032 patent)

There is no Written Description Support for a Side Opening Outside the Substantially Rigid Portion



APPENDIX A: SUBSTITUTE CLAIMS FOR THE '032 PATENT

Claim 23 (replaces claim 1): A device for use with a standard 6 French guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic va adapted to be placed in a branch artery, the continuous lumen having a circular cross-sectional inner diameter sized such that cardiology devices are insertable into and through the lumen to the device comprising, in a distal-to-proximal direction:

a flexible tip portion defining a tubular structure having section and a length that is shorter than the predefined length o lumen of the standard 6 French guide catheter, the tubular stru sectional outer diameter sized to be insertable through the cros diameter of the continuous lumen of the guide catheter and def lumen having a cross-sectional inner diameter of at least 0.056 which interventional cardiology devices are insertable;

a substantially rigid side opening that includes a first inc second inclined region, and a non-inclined concave track betw second inclined regions; and

a substantially rigid portion proximal of and operably co more rigid along a longitudinal axis than, the flexible tip portio

1

Claim 23 (replaces claim 1):

a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard 6 French guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter of at least 0.056 inches through which interventional cardiology devices are insertable;

IPR2020-00126, Paper 96 App'x A at 1 ('032 patent)

There is no Written Description Support for a Side Opening Outside the Substantially Rigid Portion

APPENDIX A: SUBSTITUTE CLAIMS FOR THE '032 PATENT

Claim 23 (replaces claim 1): A device for use with a standard 6 French guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continu having a circular cross-sectional inner diameter siz cardiology devices are insertable into and through the device comprising, in a distal-to-proximal dire

a flexible tip portion defining a tubular struc section and a length that is shorter than the predefi lumen of the standard 6 French guide catheter, the sectional outer diameter sized to be insertable thro diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter of at least 0.056 inches through which interventional cardiology devices are insertable;

a substantially rigid side opening that includes a first inclined region, a second inclined region, and a non-inclined concave track between the first and second inclined regions; and

a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail

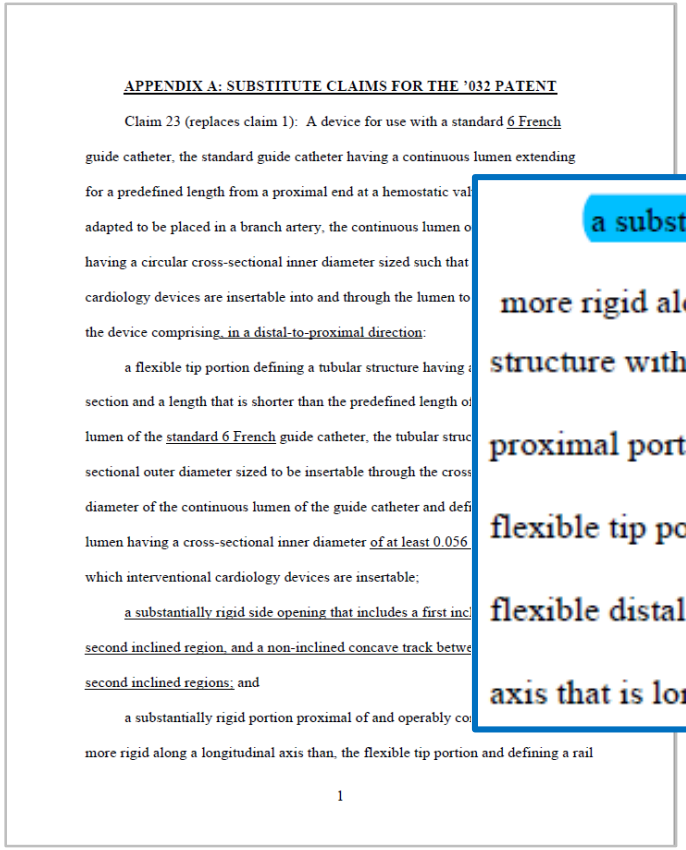
1

Claim 23 (replaces claim 1):

a substantially rigid side opening that includes a first inclined region, a second inclined region, and a non-inclined concave track between the first and second inclined regions; and

IPR2020-00126, Paper 96 App'x A at 1 ('032 patent)

There is no Written Description Support for a Side Opening Outside the Substantially Rigid Portion



APPENDIX A: SUBSTITUTE CLAIMS FOR THE '032 PATENT

Claim 23 (replaces claim 1): A device for use with a standard 6 French guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic val adapted to be placed in a branch artery, the continuous lumen o having a circular cross-sectional inner diameter sized such that cardiology devices are insertable into and through the lumen to the device comprising, in a distal-to-proximal direction:

a flexible tip portion defining a tubular structure having section and a length that is shorter than the predefined length o lumen of the standard 6 French guide catheter, the tubular struc sectional outer diameter sized to be insertable through the cross diameter of the continuous lumen of the guide catheter and defi lumen having a cross-sectional inner diameter of at least 0.056 which interventional cardiology devices are insertable;

a substantially rigid side opening that includes a first inc second inclined region, and a non-inclined concave track betwe second inclined regions; and

a substantially rigid portion proximal of and operably co more rigid along a longitudinal axis than, the flexible tip portion and defining a rail

1

Claim 23 (replaces claim 1):

a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter,

IPR2020-00126, Paper 96 App'x A at 1 ('032 patent)

There is no Written Description Support for a Side Opening Outside the Substantially Rigid Portion

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTR

Petitioner

v.

TELEFLEX INNOVATI

Patent Own

IPR2020-00126 (U.S. Pate
IPR2020-00127 (U.S. Pate
IPR2020-00128 (U.S. Pate
IPR2020-00129 (U.S. Pate
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IPR2020-00132 (U.S. Pate
IPR2020-00134 (U.S. Pate
IPR2020-00135 (U.S. Pate
IPR2020-00136 (U.S. Pate
IPR2020-00137 (U.S. Pate
IPR2020-00138 (U.S. Pate

DECLARATION OF PAUL ZALESKY SUBMITTED IN SUPPORT OF PETITIONERS' OPPOSITIONS TO PATENT OWNER'S MOTIONS TO AMEND

Medtronic Ex. 1919
Medtronic v. Teleflex
Page 1

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

28. There is no written description support for a guide extension catheter with a side opening outside of the substantially rigid portion. The only disclosure in the '629 application (including in the abstract, figures, specification, and claims) for a side opening is in the substantially rigid portion.

IPR2020-00126, Ex-1919 ¶ 28 (Zalesky)

There is no Written Description Support for a Side Opening Outside the Substantially Rigid Portion

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

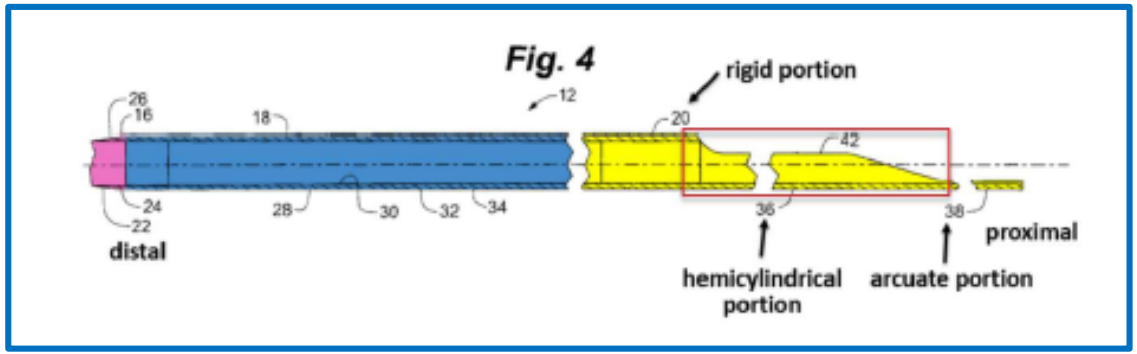
MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.
Petitioner,

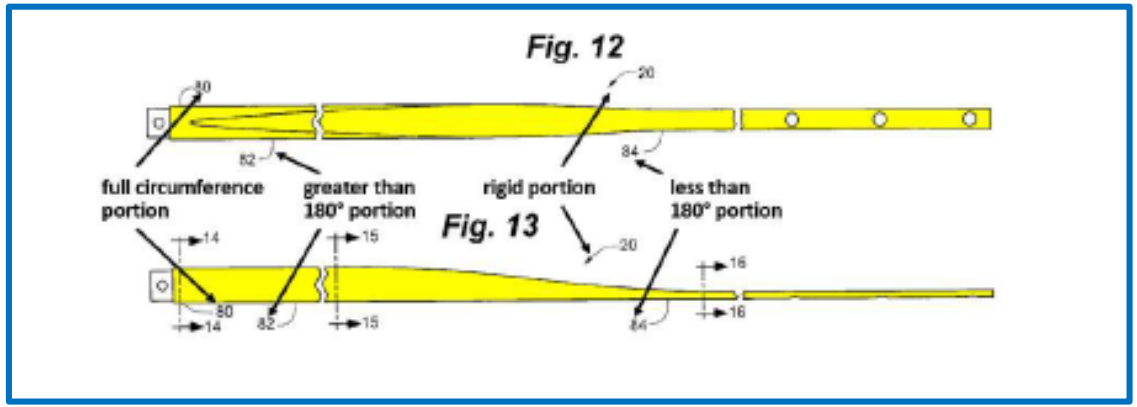
v.

TELEFLEX INNOVATIONS S.À.R.L.,
Patent Owner

Case No. IPR2020-00126
Case No. IPR2020-00127
U.S. Patent No. 8,048,032

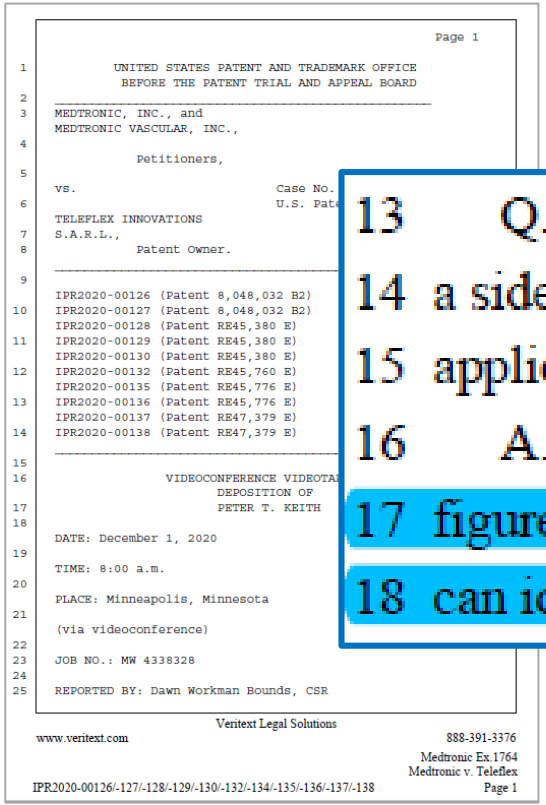
PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO AMEND





IPR2020-00126, Paper 102 at 3-4

Keith Agrees that Original Application Doesn't Describe a Side Opening



Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No.
U.S. Pat

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTA
DEPOSITION OF
PETER T. KEITH

DATE: December 1, 2020

TIME: 8:00 a.m.

PLACE: Minneapolis, Minnesota

(via videoconference)

JOB NO.: MW 4338328

REPORTED BY: Dawn Workman Bounds, CSR

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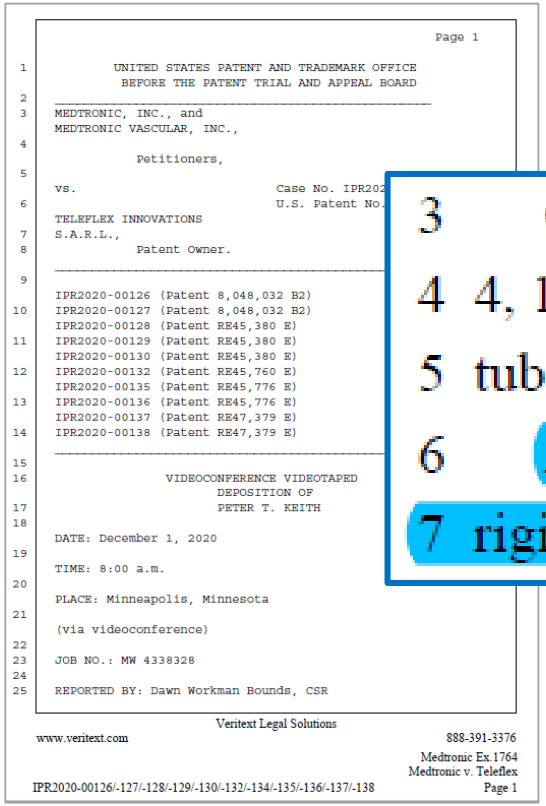
Medtronic Ex.1764
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

13 Q. Okay. But as you sit here, you can't identify
14 a side opening in the reinforced portion in the 629
15 application; is that right?
16 A. Well, when -- if you're saying a specific
17 figure, I don't know that in one specific figure that I
18 can identify that.

Ex-1764, 10:2-18 (Keith)

Keith Agrees that Original Application Doesn't Describe a Side Opening



Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR202
U.S. Patent No.

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
PETER T. KEITH

DATE: December 1, 2020

TIME: 8:00 a.m.

PLACE: Minneapolis, Minnesota

(via videoconference)

JOB NO.: MW 4338328

REPORTED BY: Dawn Workman Bounds, CSR

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Medtronic Ex.1764
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

3 Q. Right. The examples we've discussed in Figures
4 4, 10 and 11, and 12 through 16, those are cut into a
5 tube of substantially rigid material, correct?
6 A. The starting material would be substantially
7 rigid, yes.

Ex-1764, 24:3-7, 19-23 (Keith)

Keith Agrees that Original Application Doesn't Describe a Side Opening

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,

Petitioners,

vs.

TELEFLEX INNOVATIONS S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOTAPED DEPOSITION OF
PETER KEITH

DATE: February 17, 2021

TIME: 9:04 a.m. (Central Standard Time)

PLACE: Veritext Virtual Videoconference

REPORTED BY: PAULA K. RICHTER, RMR, CRR, CRC

So do you have any example or any suggestion in the spec where there's something different than that, something different than starting with one tube that you then cut to form rigid portion 20?

A. Right. So the examples that are described in the specification, that is the way they describe making that structure. Again, I think one of skill in the art would read this and understand that there are other ways that one could do that, but they are not specifically described in the specification.

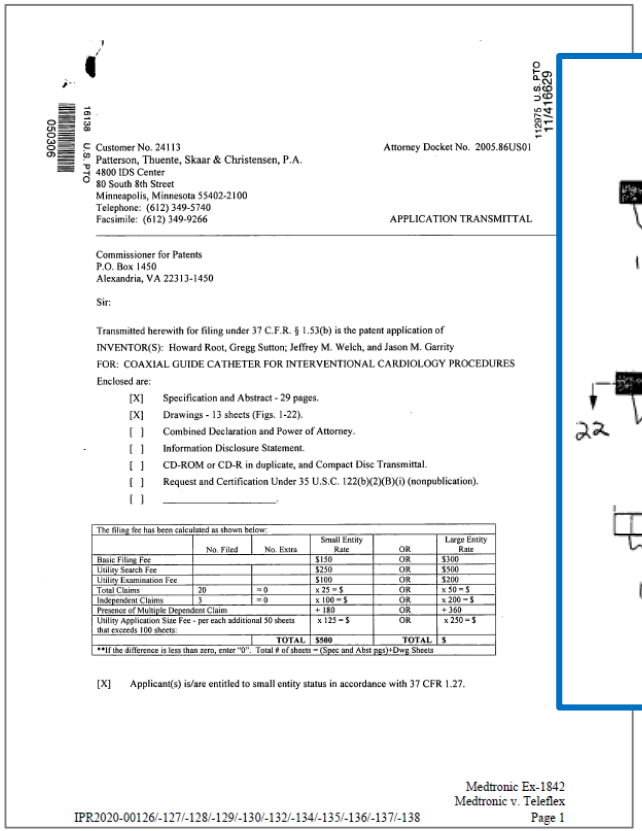
Ex-1922, 14:11-22 (Keith)

Patent Owner's Written Description Argument Lacks Merit

1. The priority application recites end openings that are not substantially rigid

2. The side opening can be made less rigid through relief cuts

Keith Admits No Disclosure of Side Opening



Customer No. 24113
Patterson, Thuente, Skaar & Christensen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: (612) 349-5740
Facsimile: (612) 349-9266

Attorney Docket No. 2005.86US01

APPLICATION TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith for filing under 37 C.F.R. § 1.53(b) is the patent application of
INVENTOR(S): Howard Root, Gregg Sutton; Jeffrey M. Welch, and Jason M. Garrity
FOR: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
Enclosed are:

[X] Specification and Abstract - 29 pages.
[X] Drawings - 13 sheets (Figs. 1-22).
[ ] Combined Declaration and Power of Attorney.
[ ] Information Disclosure Statement.
[ ] CD-ROM or CD-R in duplicate, and Compact Disc Transmittal.
[ ] Request and Certification Under 35 U.S.C. 122(b)(2)(B)(i) (nonpublication).
[ ] _____.

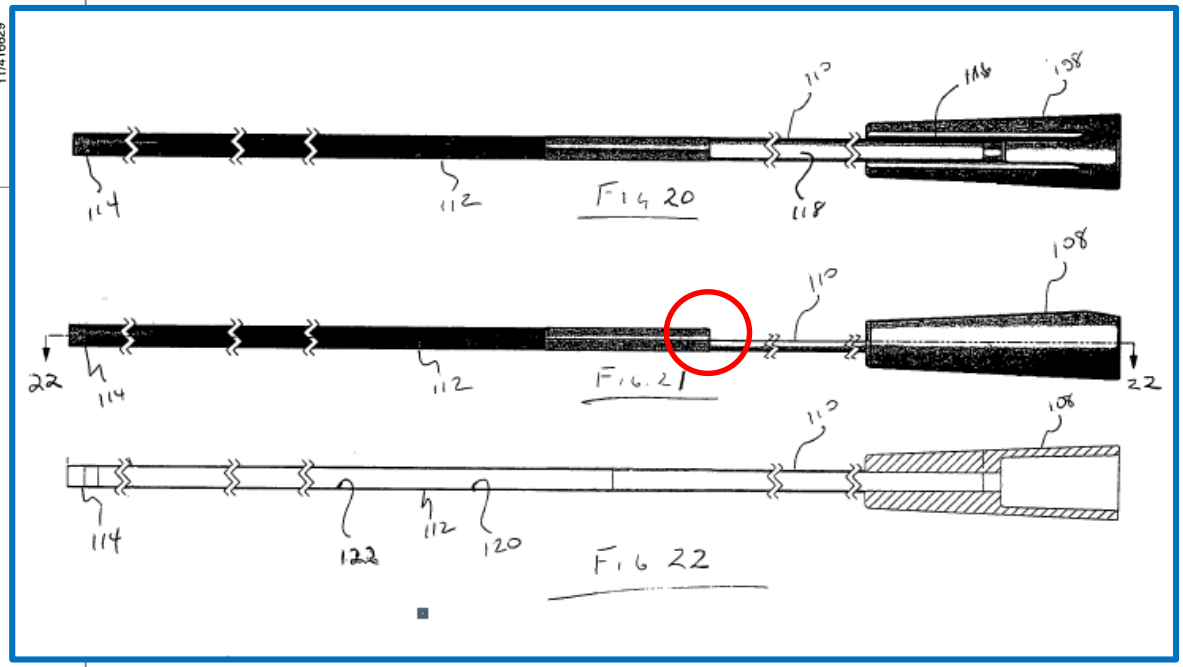
The filing fee has been calculated as shown below:

	No. Filed	No. Extra	Small Entity Rate		Large Entity Rate
Basic Filing Fee			$150	OR	$300
Utility Search Fee			$250	OR	$500
Utility Examination Fee			$100	OR	$200
Total Claims	20	= 0	x 25 = $	OR	x 50 = $
Independent Claims	3	= 0	x 100 = $	OR	x 200 = $
Presence of Multiple Dependent Claim			+ 180	OR	+ 360
Utility Application Size Fee - per each additional 50 sheets that exceeds 100 sheets:			x 125 = $	OR	x 250 = $
		TOTAL	$500	TOTAL	$

**If the difference is less than zero, enter "0". Total # of sheets = (Spec and Abst pgs)+Dwg Sheets

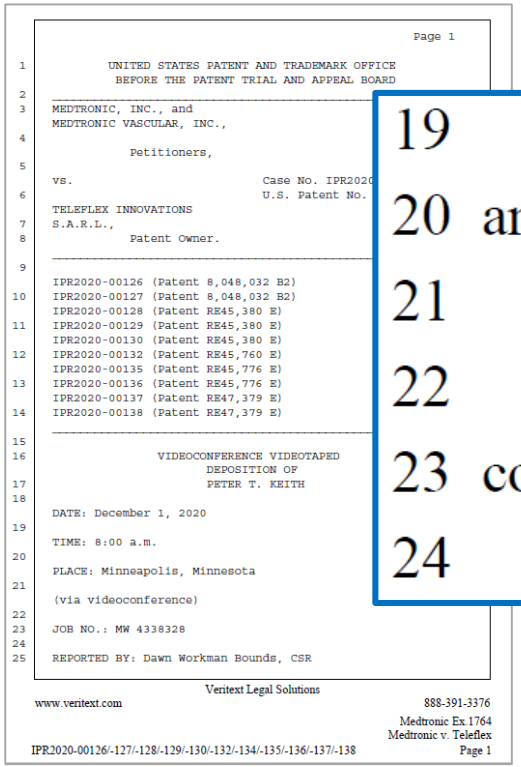
[X] Applicant(s) is/are entitled to small entity status in accordance with 37 CFR 1.27.

Medtronic Ex-1842
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1



Ex-1842 at 37

Keith Admits No Disclosure of Side Opening



Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR2020
U.S. Patent No.

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
PETER T. KEITH

DATE: December 1, 2020

TIME: 8:00 a.m.

PLACE: Minneapolis, Minnesota

(via videoconference)

JOB NO.: MW 4338328

REPORTED BY: Dawn Workman Bounds, CSR

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Medtronic Ex.1764
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

19 Q. Let's look at -- jump ahead to Figures 20, 21,
20 and 22, on page 44 of the exhibit.
21 A. Okay.
22 Q. These figures do not disclose a side opening,
23 correct?
24 A. I would agree with that.

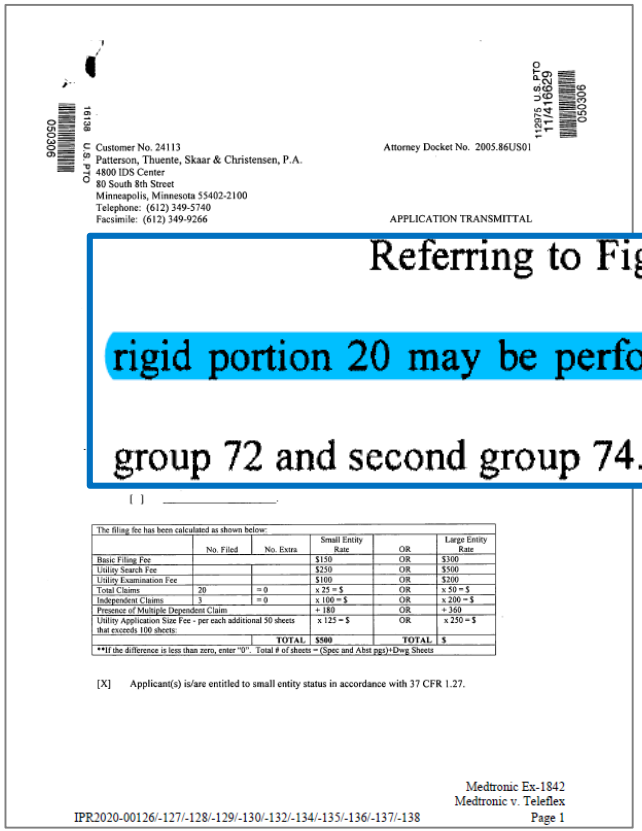
Ex-1764, 16:19-24 (Keith)

Patent Owner's Written Description Argument Lacks Merit

1. The priority application recites end openings that are not substantially rigid

2. The side opening can be made less rigid through relief cuts

Relief Cuts are in the Rigid Portion



Customer No. 24113
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80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: (612) 349-5740
Facsimile: (612) 349-9266

Attorney Docket No. 2005.86US01

APPLICATION TRANSMITTAL

The filing fee has been calculated as shown below:

	No. Filed	No. Extra	Small Entity Rate		Large Entity Rate
Basic Filing Fee			$150	OR	$300
Utility Search Fee			$250	OR	$500
Utility Examination Fee			$100	OR	$200
Total Claims	20	= 0	x 25 = $	OR	x 50 = $
Independent Claims	3	= 0	x 100 = $	OR	x 200 = $
Presence of Multiple Dependent Claim			+ 180	OR	+ 360
Utility Application Size Fee - per each additional 50 sheets that exceeds 100 sheets:			x 125 = $	OR	x 250 = $
		TOTAL	$500	TOTAL	$

**If the difference is less than zero, enter "0". Total # of sheets = (Spec and Abst pgs)+Dwg Sheets

[X] Applicant(s) is/are entitled to small entity status in accordance with 37 CFR 1.27.

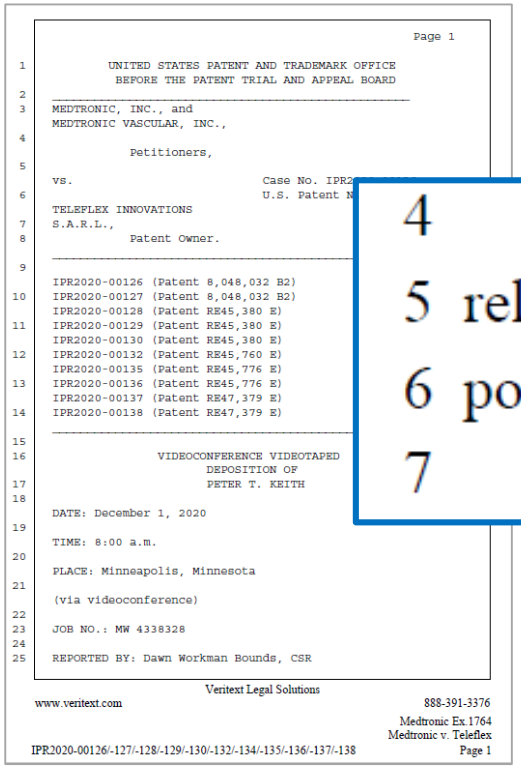
Medtronic Ex-1842
Medtronic v. Teleflex

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

Referring to Figs. 10 and 11, in some embodiments of coaxial guide catheter 12, rigid portion 20 may be perforated by relief cuts 70. Relief cuts 70 may be classed into first group 72 and second group 74.

Ex-1842 at 19

Keith Agrees that Relief Cuts are in the Rigid Portion



Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., and
MEDTRONIC VASCULAR, INC.,

Petitioners,

vs. Case No. IPR2
U.S. Patent N

TELEFLEX INNOVATIONS
S.A.R.L.,

Patent Owner.

IPR2020-00126 (Patent 8,048,032 B2)
IPR2020-00127 (Patent 8,048,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00129 (Patent RE45,380 E)
IPR2020-00130 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00136 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)
IPR2020-00138 (Patent RE47,379 E)

VIDEOCONFERENCE VIDEOTAPED
DEPOSITION OF
PETER T. KEITH

DATE: December 1, 2020

TIME: 8:00 a.m.

PLACE: Minneapolis, Minnesota

(via videoconference)

JOB NO.: MW 4338328

REPORTED BY: Dawn Workman Bounds, CSR

Veritext Legal Solutions
www.veritext.com 888-391-3376

Medtronic Ex.1764
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

4 Q. Sure. And as we already covered, all those
5 relief cuts are in what the specification calls rigid
6 portion 20, right?
7 A. Yes, in that -- from that paragraph, correct.

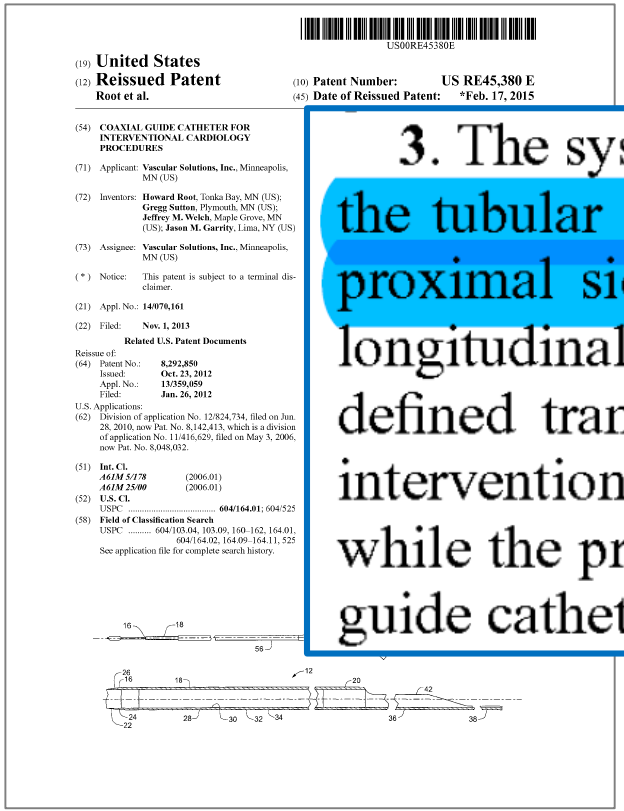
Ex-1764, 20:4-7 (Keith)

“First to invent” does not apply.

- Reissue patents include at least one claim reciting a side opening separate from the substantially rigid portion.

- AIA patent → Teleflex cannot swear behind Itou. AIA § 3(n)(1)(A); MPEP § 2159.02

’380 Patent: There is no Written Description Support for a Side Opening Outside the Substantially Rigid Portion



US00RE45380E

(19) **United States**
(12) **Reissued Patent**
Root et al.

(10) **Patent Number: US RE45,380 E**
(45) **Date of Reissued Patent: *Feb. 17, 2015**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(71) Applicant: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(72) Inventors: **Howard Root**, Tonka Bay, MN (US); **Gregg Sutton**, Plymouth, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Lima, NY (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/070,161**

(22) Filed: **Nov. 1, 2013**

Related U.S. Patent Documents

Reissue of:
(64) Patent No.: **8,292,850**
Issued: **Oct. 23, 2012**
Appl. No.: **13/359,059**
Filed: **Jan. 26, 2012**

U.S. Applications:
(62) Division of application No. 12/824,734, filed on Jun. 28, 2010, now Pat. No. 8,142,413, which is a division of application No. 11/416,629, filed on May 3, 2006, now Pat. No. 8,048,052.

(51) **Int. Cl.**
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)

(52) **U.S. Cl.**
USPC **604/164.01**; 604/525

(58) **Field of Classification Search**
USPC 604/103.04, 103.09, 160–162, 164.01, 604/164.02, 164.09–164.11, 525
See application file for complete search history.

3. The system of claim **2**, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

Ex-1001, claim 3 (’380 patent)

Patent Owner's Motions to Amend

1. The Amended Claims Lack Written Description Support
2. The Amended Claims are Indefinite
3. Patent Owner Broadens the Scope of the Amended Claims
4. The Amended Claims are Invalid Under §§ 102/103

“Total Length”: ’032 Patent Amended Claim 23 is Indefinite:

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.
Petitioners,

v.

TELEFLEX INNOVATIONS S.A.R.L.
Patent Owner.

Case IPR2020-00126
Case IPR2020-00127
Patent 8,048,032

APPENDIX A

APPENDIX TO PATENT OWNER’S CORRECTED CONTINGENT MOTION TO AMEND U.S. PATENT 8,048,032 UNDER 37 C.F.R. § 42.121

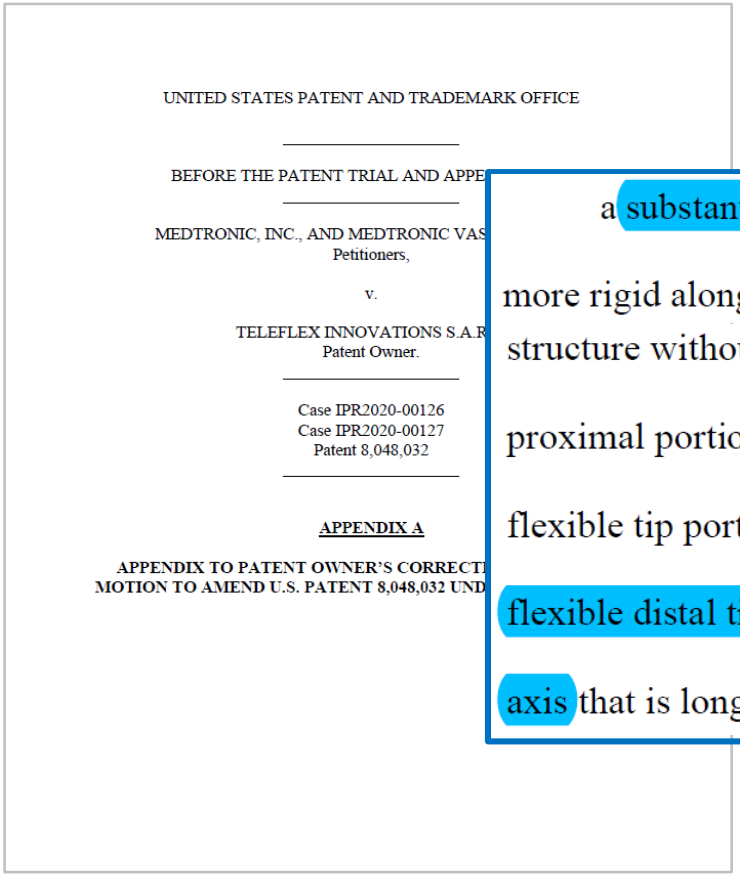
Claim 23 (replaces claim 1): A device for use with a standard 6 French guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising, in a distal-to-proximal direction:

a flexible tip portion defining a tubular structure having a circular cross-

a substantially rigid side opening that includes a first inclined region, a second inclined region, and a non-inclined concave track between the first and second inclined regions; and

IPR2020-00126, Paper 96 App’x A at 1 (’032 patent)

“Total Length”: ’032 Patent Amended Claim 23 is Indefinite



UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPE

MEDTRONIC, INC., AND MEDTRONIC VAS
Petitioners,

v.

TELEFLEX INNOVATIONS S.A.R
Patent Owner.

Case IPR2020-00126
Case IPR2020-00127
Patent 8,048,032

APPENDIX A

APPENDIX TO PATENT OWNER'S CORRECT
MOTION TO AMEND U.S. PATENT 8,048,032 UND

a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter,

IPR2020-00126, Paper 96 App’x A at 1-2 (’032 patent)

“Connected to”: ’032 Patent Amended Claim 24 is Indefinite

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.
Petitioners,

v.

TELEFLEX INNOVATIONS S.A.R.L.
Patent Owner.

Case IPR2020-00126
Case IPR2020-00127
Patent 8,048,032

APPENDIX A

**APPENDIX TO PATENT OWNER'S CORRECTED CONTINGEN
MOTION TO AMEND U.S. PATENT 8,048,032 UNDER 37 C.F.R. § 42**

Claim 24 (replaces claim 11):

an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter, the elongate structure including:

a flexible tip portion defining a tubular structure having a circular cross-

a reinforced portion having a uniform, fixed cross-sectional outer diameter proximal to the flexible tip portion; [and]

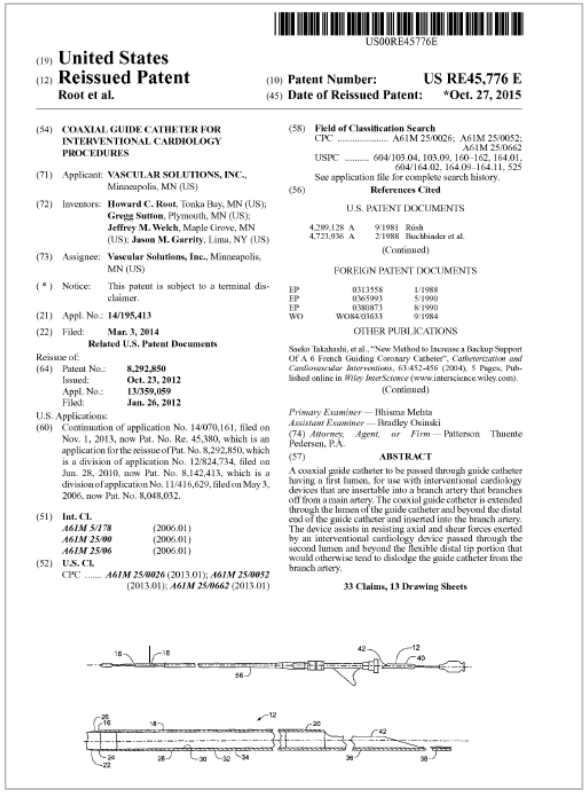
a substantially rigid portion proximal of and connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion,

IPR2020-00126, Paper 96 App’x A at 3 (’032 patent)

Patent Owner's Motions to Amend

1. The Amended Claims Lack Written Description
2. The Amended Claims are Indefinite
3. Patent Owner Broadens the Scope of the Amended Claims
4. The Amended Claims are Invalid Under §§ 102/103

Patent Owner's Amendments Improperly Broaden the Scope of the Claims



US00RE45776E

(19) **United States**
(12) **Reissued Patent**
Root et al.

(10) **Patent Number: US RE45,776 E**
(45) **Date of Reissued Patent: *Oct. 27, 2015**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

(71) Applicant: **VASCULAR SOLUTIONS, INC.**, Minneapolis, MN (US)

(72) Inventors: **Howard C. Root**, Tonka Bay, MN (US); **Gregg Sutton**, Plymouth, MN (US); **Jeffrey M. Welch**, Maple Grove, MN (US); **Jason M. Garrity**, Lima, NY (US)

(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/195,413**

(22) Filed: **Mar. 3, 2014**

Related U.S. Patent Documents

Reissue of:
(64) Patent No.: **8,292,850**
Issued: **Oct. 23, 2012**
Appl. No.: **13/359,059**
Filed: **Jan. 26, 2012**

U.S. Applications:
(60) Continuation of application No. 14/070,161, filed on Nov. 1, 2013, now Pat. No. Re. 45,380, which is an application for the reissue of Pat. No. 8,292,850, which is a division of application No. 12/824,734, filed on Jun. 28, 2010, now Pat. No. 8,142,413, which is a division of application No. 11/416,629, filed on May 3, 2006, now Pat. No. 8,048,032.

(51) **Int. Cl.**
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)
A61M 25/06 (2006.01)

(52) **U.S. Cl.**
CPC ***A61M 25/0026*** (2013.01); ***A61M 25/0052*** (2013.01); ***A61M 25/0662*** (2013.01)

(58) **Field of Classification Search**
CPC A61M 25/0026; A61M 25/0052; A61M 25/0662
USPC 604/103.04, 103.09, 160–162, 164.01, 604/164.02, 164.09–164.11, 525
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

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4,723,936 A 2/1988 Buchbinder et al.
(Continued)

FOREIGN PATENT DOCUMENTS

EP 0313558 1/1988
EP 0365993 5/1990
EP 0380873 8/1990
WO WO84/03033 9/1984

OTHER PUBLICATIONS

Sooko Takahashi, et al., "New Method to Increase a Backup Support Of A 6 French Guiding Coronary Catheter", *Catheterization and Cardiovascular Interventions*, 63:452-456 (2004), 5 Pages; Published online in *Wiley InterScience* (www.interscience.wiley.com).
(Continued)

Primary Examiner — Bhisma Mehta
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente Pedersen, P.A.

(57) **ABSTRACT**

A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

33 Claims, 13 Drawing Sheets

53. A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:

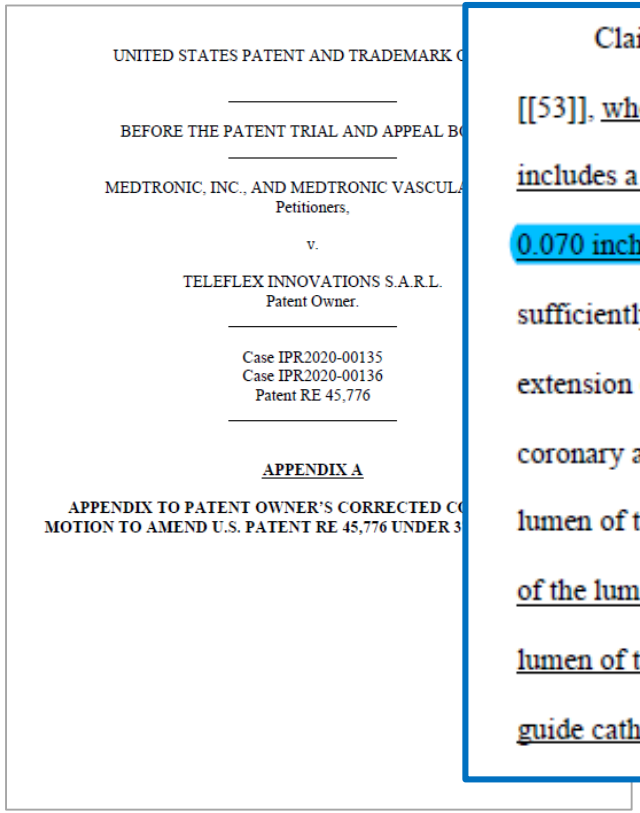
a substantially rigid segment;

a tubular structure defining a lumen and positioned distal to the substantially rigid segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and

a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter, a cross-section of the guide extension catheter at the proximal end of the tubular structure defining a single lumen;

wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.

’776 Patent: Patent Owner’s Amendments Improperly Broaden the Scope of the Claims



UNITED STATES PATENT AND TRADEMARK C

BEFORE THE PATENT TRIAL AND APPEAL B

MEDTRONIC, INC., AND MEDTRONIC VASCULA
Petitioners,

v.

TELEFLEX INNOVATIONS S.A.R.L.
Patent Owner.

Case IPR2020-00135
Case IPR2020-00136
Patent RE 45,776

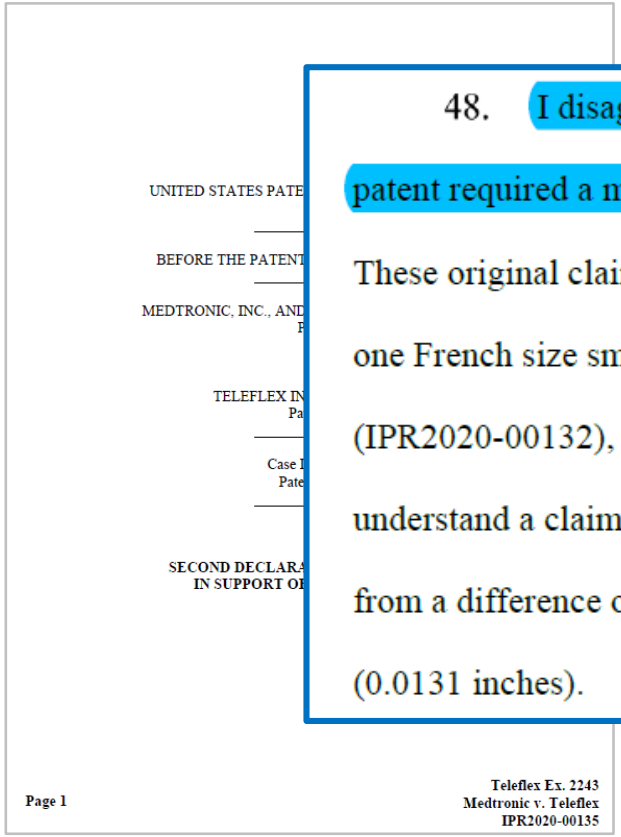
APPENDIX A

APPENDIX TO PATENT OWNER'S CORRECTED C
MOTION TO AMEND U.S. PATENT RE 45,776 UNDER 3

Claim 65 (replaces claim 56): The guide extension catheter of claim 52 [[53]], wherein the guide catheter is a standard 6 French guide catheter that includes a lumen having a cross-sectional inner diameter greater than or equal to 0.070 inches, wherein a cross-section of the substantially rigid segment is sufficiently sized and configured to permit the tubular structure of the guide extension catheter to be advanced partially through the guide catheter and into a coronary artery while preserving space of the cross-sectional inner diameter of the lumen of the guide catheter, and wherein a uniform cross-sectional inner diameter of the lumen of the tubular structure is greater than or equal to 0.056 inches and the lumen of the tubular structure is configured to be coaxial with the lumen of the guide catheter and to receive stents and balloon catheters when positioned therein.

IPR2020-00135, Paper 95, App’x A at 5 (’776 patent)

’776 Patent: Patent Owner’s Amendments Improperly Broaden the Scope of the Claims


UNITED STATES PATE

BEFORE THE PATENT

MEDTRONIC, INC., AND

TELEFLEX IN

Case I
Pate

SECOND DECLARA
IN SUPPORT OF

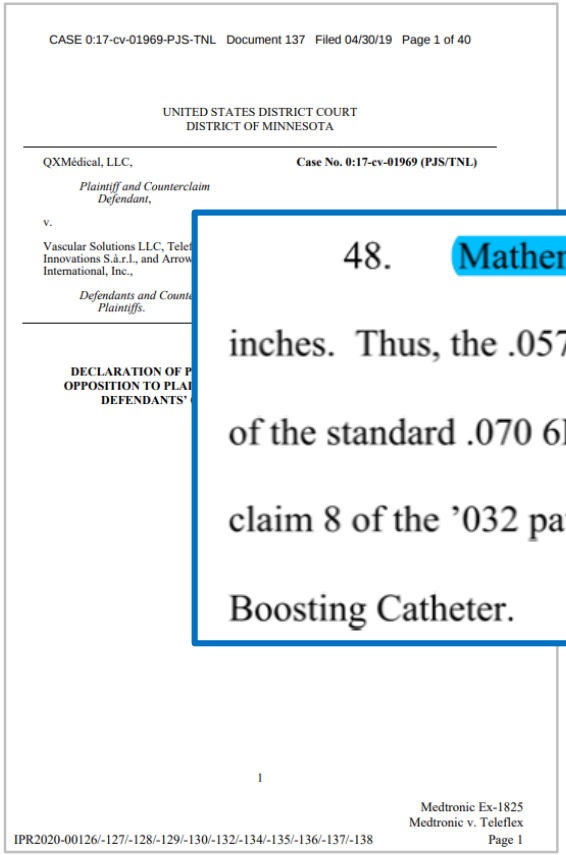
Page 1

Teleflex Ex. 2243
Medtronic v. Teleflex
IPR2020-00135

48. I disagree that original claims 51 of the ’760 patent and 53 of the ’776 patent required a mathematical difference of 1 French (1/3 mm, or 0.0131 inches). These original claims require that the guide catheter have a lumen not more than one French size smaller than the lumen of the guide catheter. *E.g.*, Ex-1001 (IPR2020-00132), 16:17-19 (original claim 51, emphasis added). As a POSITA, I understand a claim limitation that recites a one French ***size*** difference to be distinct from a difference of precisely the mathematical measurement of one French (0.0131 inches).

IPR2020-00135, Ex-2243, ¶ 48 (Keith)

’776 Patent: Patent Owner’s Amendments Improperly Broaden the Scope of the Claims



CASE 0:17-cv-01969-PJS-TNL Document 137 Filed 04/30/19 Page 1 of 40

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

QXMédical, LLC,

Plaintiff and Counterclaim Defendant,

v.

Vascular Solutions LLC, Teleflex Innovations S.à.r.l., and Arrow International, Inc.,

Defendants and Counterclaim Plaintiffs.

Case No. 0:17-cv-01969 (PJS/TNL)

DECLARATION OF P… OPPOSITION TO PLAI… DEFENDANTS’ …

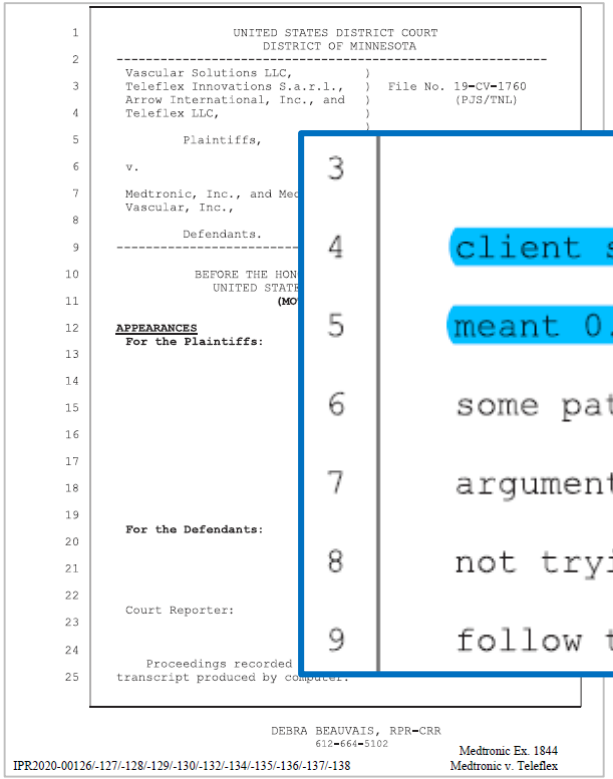
1

Medtronic Ex-1825
Medtronic v. Teleflex
IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138 Page 1

48. Mathematically, those of ordinary skill in the art define one French as .0131 inches. Thus, the .057-inch inner diameter of the 6F Boosting Catheter is within one French size of the standard .070 6F guide catheter. As such, it is my opinion that QXM directly infringes the claim 8 of the ’032 patent and claim 53 of the ’776 patent when it makes and sells its 6F Boosting Catheter.

IPR2020-00135, Ex-1825, ¶ 48 (Keith)

’776 Patent: Patent Owner’s Amendments Improperly Broaden the Scope of the Claims



UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Vascular Solutions LLC, Teleflex Innovations S.a.r.l., Arrow International, Inc., and Teleflex LLC,
Plaintiffs,
v.
Medtronic, Inc., and Medtronic Vascular, Inc.,
Defendants.

File No. 19-CV-1760 (PJS/TNL)

BEFORE THE HONORABLE
UNITED STATES
(MOTIONS HEARING)

APPEARANCES
For the Plaintiffs:

For the Defendants:

Court Reporter:

Proceedings recorded by mechanical stenography; transcript produced by computer.

DEBRA BEAUVAIS, RPR-CRR
612-664-5102

IPR2020-00126/-127/-128/-129/-130/-132/-134/-135/-136/-137/-138

Medtronic Ex. 1844
Medtronic v. Teleflex

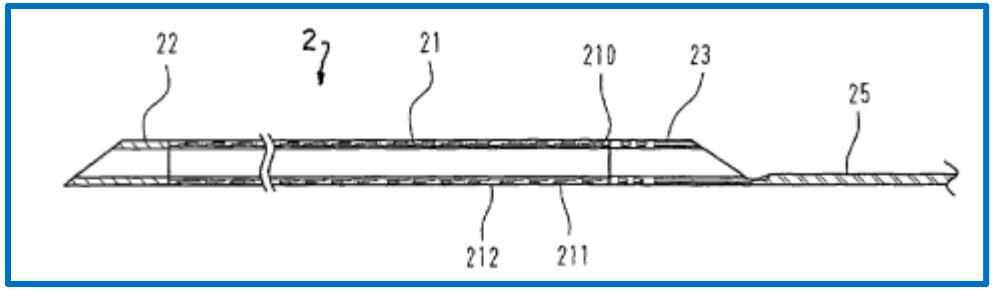
THE COURT: Your -- not you the attorney, but your client stood before me in *QX Medical* and told me one French meant 0.0131 inches. There was no it means something in some patents and it means something in other patents. Your argument is essentially an inch doesn't mean an inch. I'm not trying to be argumentative here. I honestly can't follow the argument.

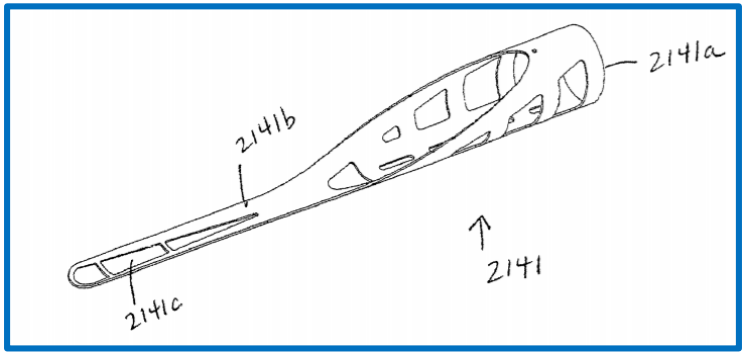
IPR2020-00135, Ex-1844, 27:3-9

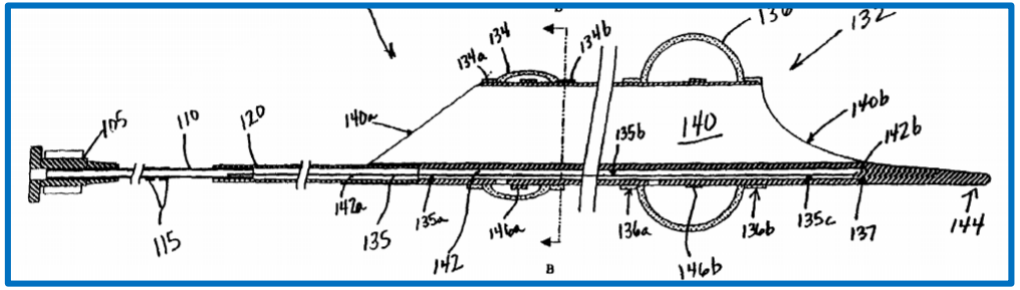
Patent Owner's Motions to Amend

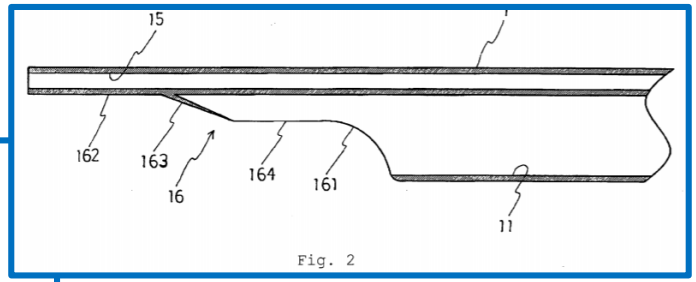
1. The Amended Claims Lack Written Description
2. The Amended Claims are Indefinite
3. Patent Owner Broadens the Scope of the Amended Claims
4. The Amended Claims are Invalid Under §§ 102/103

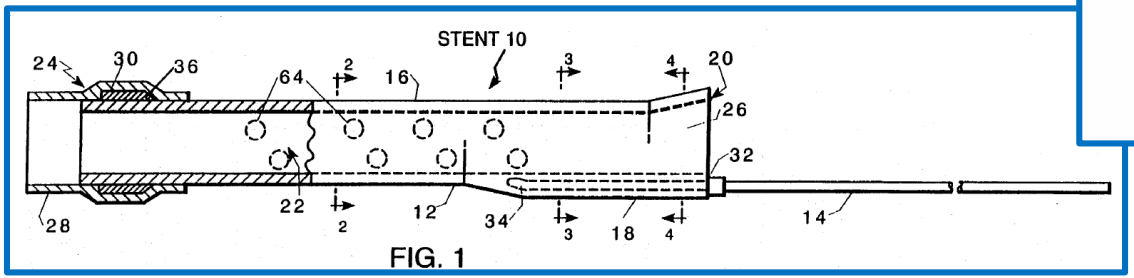
MTA – The Prior Art Discloses All Claim Elements











Ex-1007 (Itou); Ex-1008 (Ressemann)
Ex- 1009 (Kontos); Ex. 1025 (Kataishi)

MTA – Motivation to Combine

- "A person of ordinary skill is 'not an automaton,' limited to physically combining references."

  Univ. of Maryland Biotechnology Institute v. Presens Precision Sensing GmbH, 711 F. App'x 1007,1010 (Fed. Cir. 2017) (citations omitted) ("Even assuming that extra-vessel sensors are a "basic principle" of Weigl, that principle is independent of Weigl's pertinence to the Board's obviousness determination.")

- "Etter's assertions that Azure cannot be incorporated in Ambrosio are basically irrelevant, the criterion being not whether the references could be physically combined but whether the claimed inventions are rendered obvious by the teachings of the prior art as a whole."

  In re Etter, 756 F.2d 852, 859 (Fed. Cir. 1985) (en banc)

MTA – PO's Expert Testimony on Ressemann and Kataishi

8 Q. Okay. And the same question if we put the
9 push wire below the collar when we're making this
10 combination, it should be the same answer; there's
11 still a concave track?
12 A. I think I would give the same answer, yes.

Ex-1922 (Keith Dep. Tr.), 61:8-12

12 Q. Okay. And so setting aside the guidewire
13 lumen, the rest of that structure is concave and
14 would be a concave track, even in your opinion, if
15 the guidewire lumen was not there?
16 A. If the guidewire lumen was not there -- well,
17 again, it's -- if you're just talking about the
18 shape of it, is it concave? Without the guidewire
19 lumen, I think it probably is concave. I mean,
20 track implies some functionality about passing
21 devices through that, which it clearly doesn't
22 have, but just the shape would be concave if that
23 guidewire lumen were not present.

Ex-1922 (Keith Dep. Tr.), 65:12-23

MTA – PO's Expert Testimony on Kataishi

Q. Right, once you know the shape from Kataishi. And I know you're going to dispute motivation and whatnot, but I'm just saying, from an engineering standpoint, once you have the shape, can you make the Itou collar in that shape?
A. Well, I think you'd have to make it longer, for one, to really have room for that. So could you make it longer? I suppose you could make it longer.
Again, you're right; I will dispute that there's any motivation to do that. But I think one could say, I want to put a different shape. I think one could do that. Again, I don't think there's any motivation to do that, certainly not from this reference.

Ex-1922 (Keith Dep. Tr.), 66:6-20

I'm sorry to jump around, Mr. Keith, but if I could ask you one more question on Kataishi. Again, I know you disagree with the motivation, but if you simply formed that side wall shape for the Itou collar, in that scenario, if you did that, Itou would still have a concave track, right?
MR. WINKELS: Objection to form.
THE WITNESS: I think it probably would, assuming that the collar -- the modified collar of Itou doesn't have anything projecting up from the bottom of that concave surface.

Ex-1922 (Keith Dep. Tr.), 68:9-20