Medtronic, Inc. and Medtronic Vascular, Inc. v. Teleflex Innovations S.A.R.L.

Patent Owner's Hearing Demonstratives on CRTP

Outline

- Conception
- Corroboration of Reduction to Practice
  - Non-Inventor Testimonial Corroboration
  - Documentary Corroboration
  - Corroboration of Testing
- The Prototypes Practiced the Claimed Invention
- Patent Owner Was Diligent Through May 2006

Petitioner Bears the Burden of Persuasion on CRTP

Although the burden of production can be a shifting burden, we note that the burden of persuasion is on Petitioner to ultimately prove "unpatentability by a preponderance of the evidence," and that this burden never shifts to Patent Owner.

Motorola Mobility LLC v. Intellectual Ventures II LLC, IPR2014-00504, Paper 84 at 14-15 (PTAB Mar. 13, 2020); Sur-Reply at 2

THE COURT: Mr. Morton, the last point you said on the issue where Petitioner bears the burden, is it your understanding that you bear the burden on the conception and reduction to practice issue?

MR. MORTON: Yes, your Honor, once they've called into question, set it forth and made their case, the ultimate burden is on us.

Ex-1099, 12:18-25; Sur-Reply at 2

Rule of Reason

"In assessing corroboration of oral testimony, courts apply a rule of reason analysis. Under a rule of reason analysis, an evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the inventor's story may be reached."

Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578 (Fed. Cir. 1996); *e.g.* Response at 20-21, 25, 27

"But our case law does not require that evidence have a source independent of the inventors on every aspect of conception and reduction to practice; 'such a standard is the antithesis of the rule of reason.' Here, the law requires only that the corroborative evidence, including circumstantial evidence, support the credibility of the inventors' story."

E.I. du Pont de Nemours & Co. v. Unifrax I LLC, 921 F.3d 1060, 1077 (Fed. Cir. 2019) (internal citations omitted); Response at 22; Sur-Reply at 6, 8

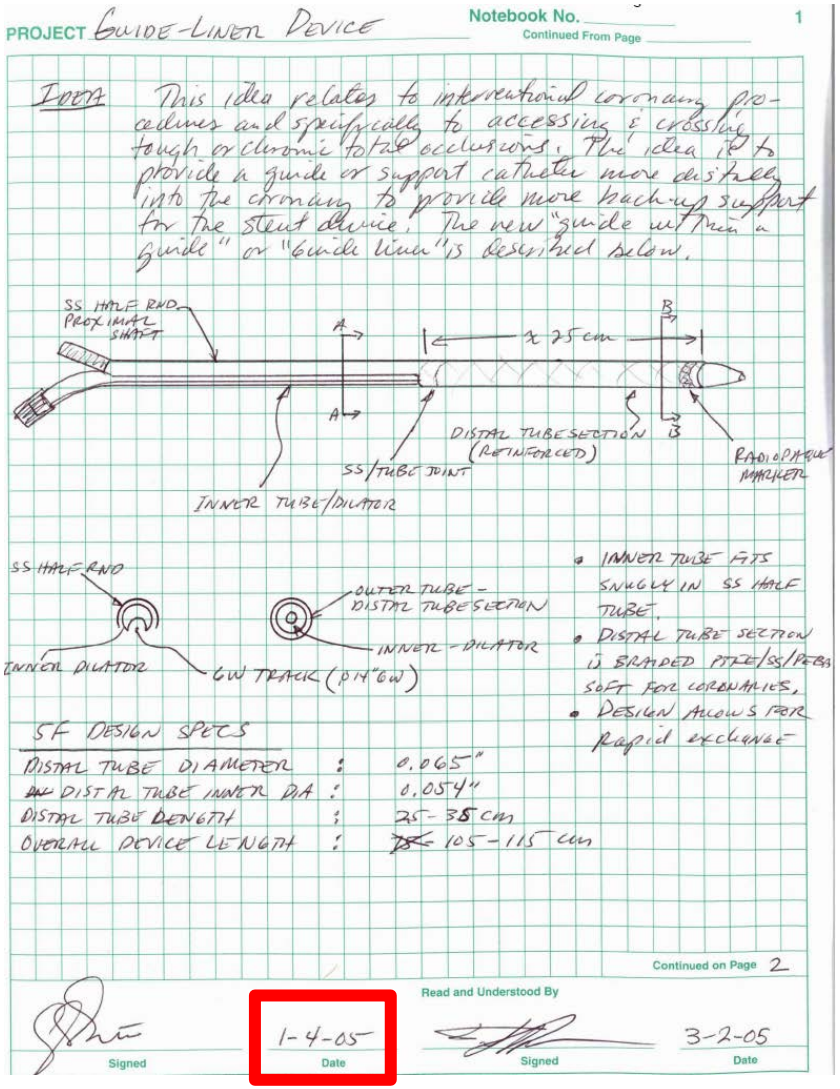
CONCEPTION

Conception Is Relevant Only If No Actual RTP Before the Critical Date

To antedate (or establish priority) of an invention, a party must show either an earlier reduction to practice, or an earlier conception followed by a diligent reduction to practice.

Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359, 1365 (Fed. Cir. 2001); Response at 19-20

Sutton Lab Notebook



PROJECT Guide-Liner Device — Notebook No. — Continued From Page — 1

IDEA This idea relates to interventional coronary procedures and specifically to accessing & crossing tough or chronic total occlusions. The idea is to provide a guide or support catheter more distally into the coronary to provide more back-up support for the stent device. The new "guide within a guide" or "guide liner" is described below.

- INNER TUBE FITS SNUGLY IN SS HALF TUBE.
- DISTAL TUBE SECTION IS BRAIDED PTFE/SS/PEBA SOFT FOR CORONARIES.
- DESIGN ALLOWS FOR Rapid exchange

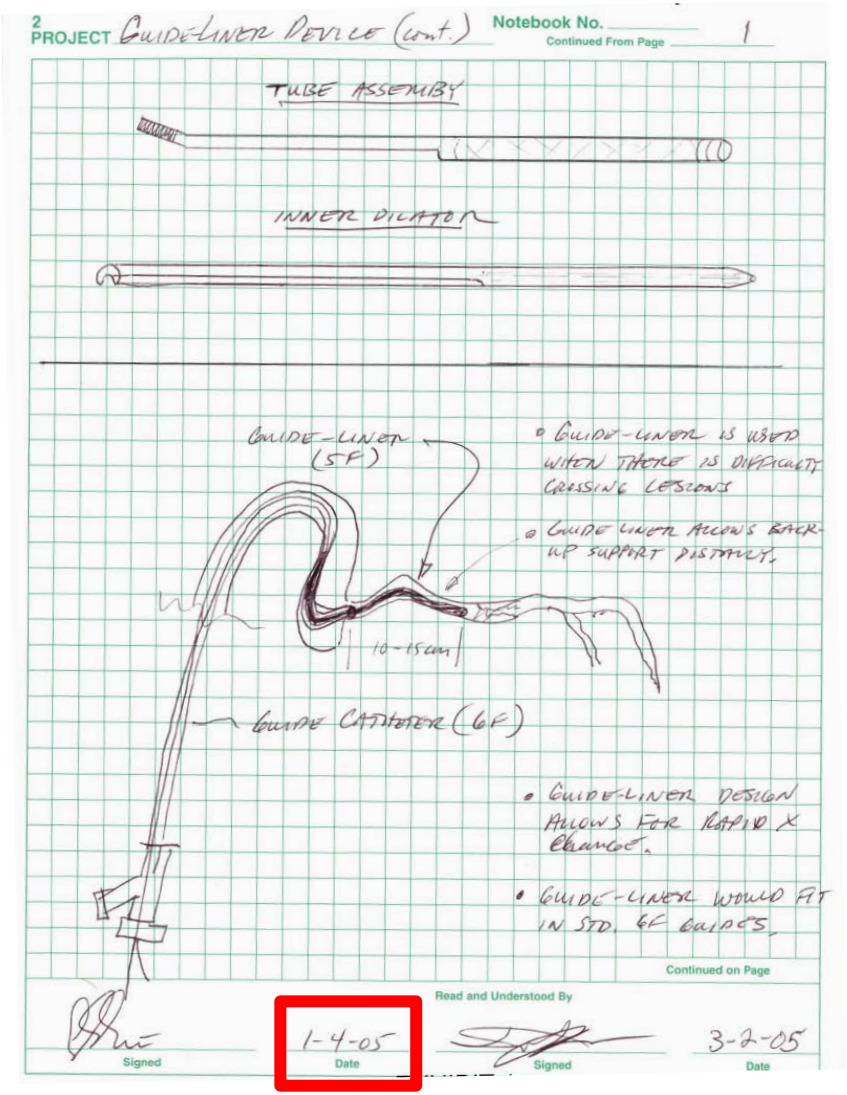
5F DESIGN SPECS

DISTAL TUBE DIAMETER	:	0.065"
~~DISTAL~~ TUBE INNER DIA	:	0.054"
DISTAL TUBE LENGTH	:	25-35 cm
OVERALL DEVICE LENGTH	:	~~125~~ 105-115 cm

Continued on Page 2

Read and Understood By

Signed — 1-4-05 Date — Signed — 3-2-05 Date



PROJECT Guideliner Device (cont.) — Notebook No. — Continued From Page — 1

TUBE ASSEMBLY

- Guide-liner is used when there is difficulty crossing lesions
- Guide liner allows back-up support distally.
- Guide-liner design allows for rapid x change.
- Guide-liner would fit in std. 6F guides.

Continued on Page

Read and Understood By

Signed — 1-4-05 Date — Signed — 3-2-05 Date

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

Ex-2002 at 8-9; *e.g.* Response at 4-6

Market Feasibility Memo (Feb. 2005)

Vascular Solutions, Inc.

Memo

From: Howard Root

To: GuideLiner DHF

Date: February 4, 2005

RE: **Market Feasibility for the GuideLiner catheters**

Background

As part of Phase I of the product development SOP 1043, a review of the market feasibility of the new product is required. The GuideLiner catheter is a new product idea of a "liner" to be delivered inside standard guide catheters to provide the ability to create a deep seating of the guide for added support in the interventional procedure. The GuideLiner catheter is designed to be used in interventional cardiology procedures. Three versions of the GuideLiner product are anticipated: a "5in6 GuideLiner", a "6in7 GuideLiner" and a "7in8 Guideliner".

Ex-2003 at 1; Ex-2127;
Response at 6;
Sur-Reply at 9

Business Records Need No Corroboration

This court does not require corroboration where a party seeks to prove conception through the use of physical exhibits. The trier of fact can conclude for itself what documents show, aided by testimony as to what the exhibit would mean to one skilled in the art.

Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578 (Fed. Cir. 1996);
Sur-Reply at 3

Root Notes and Patent

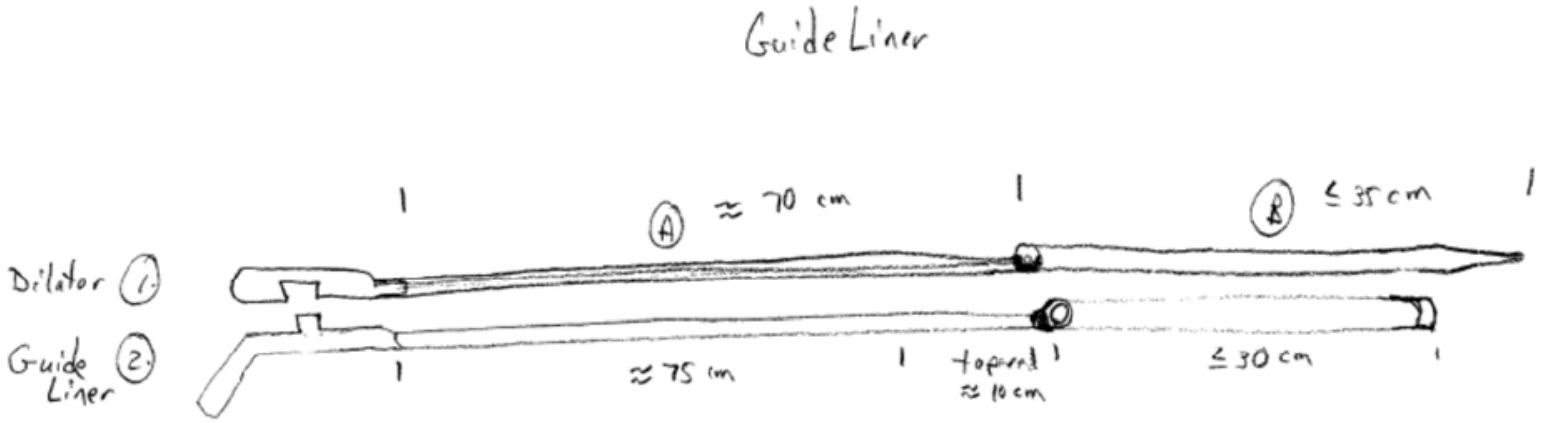
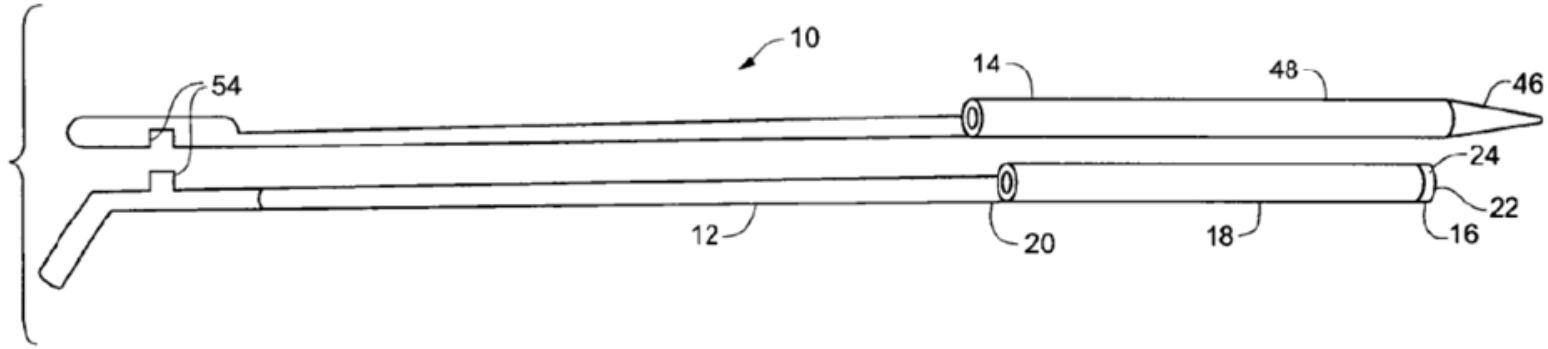
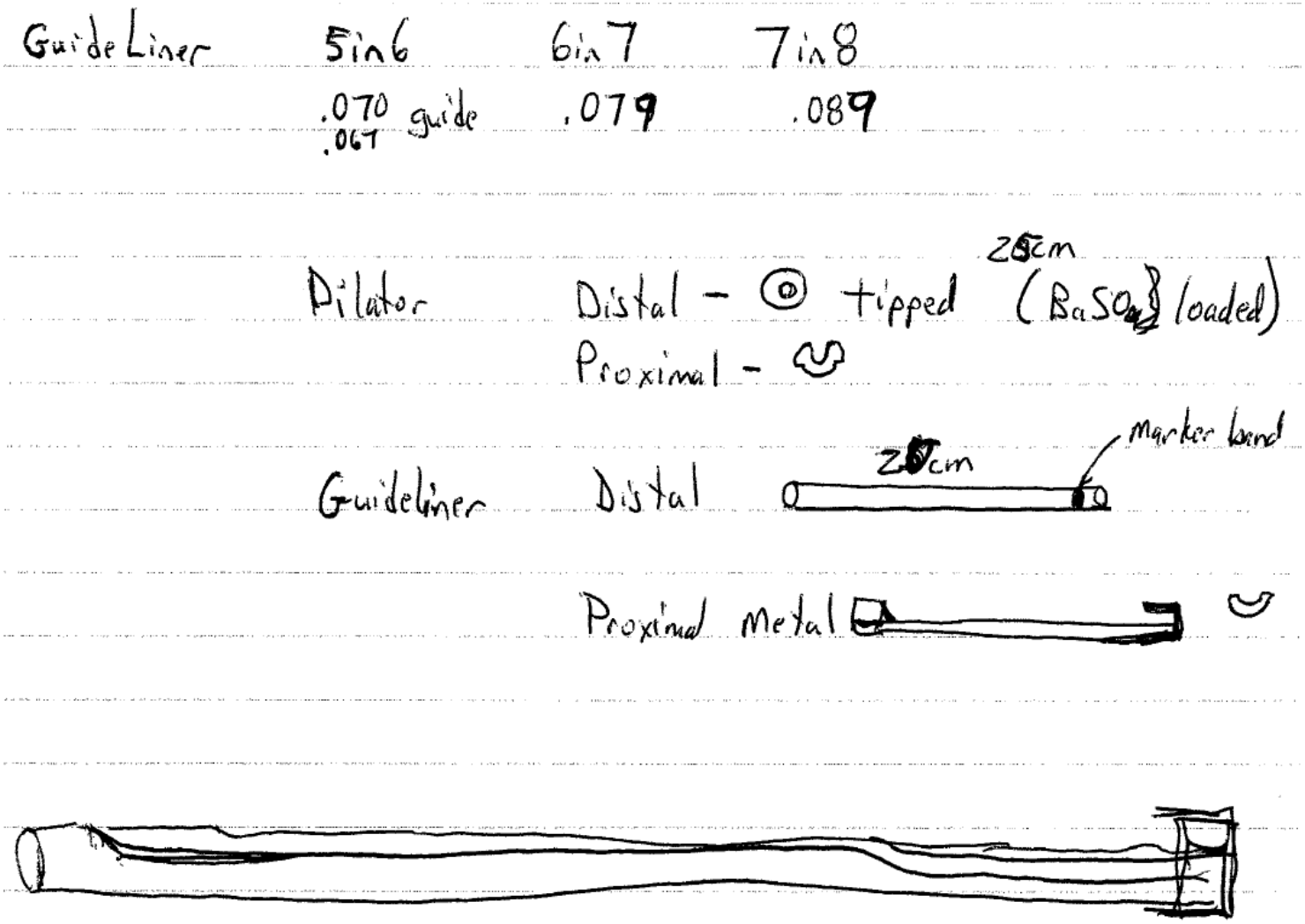


Fig. 1

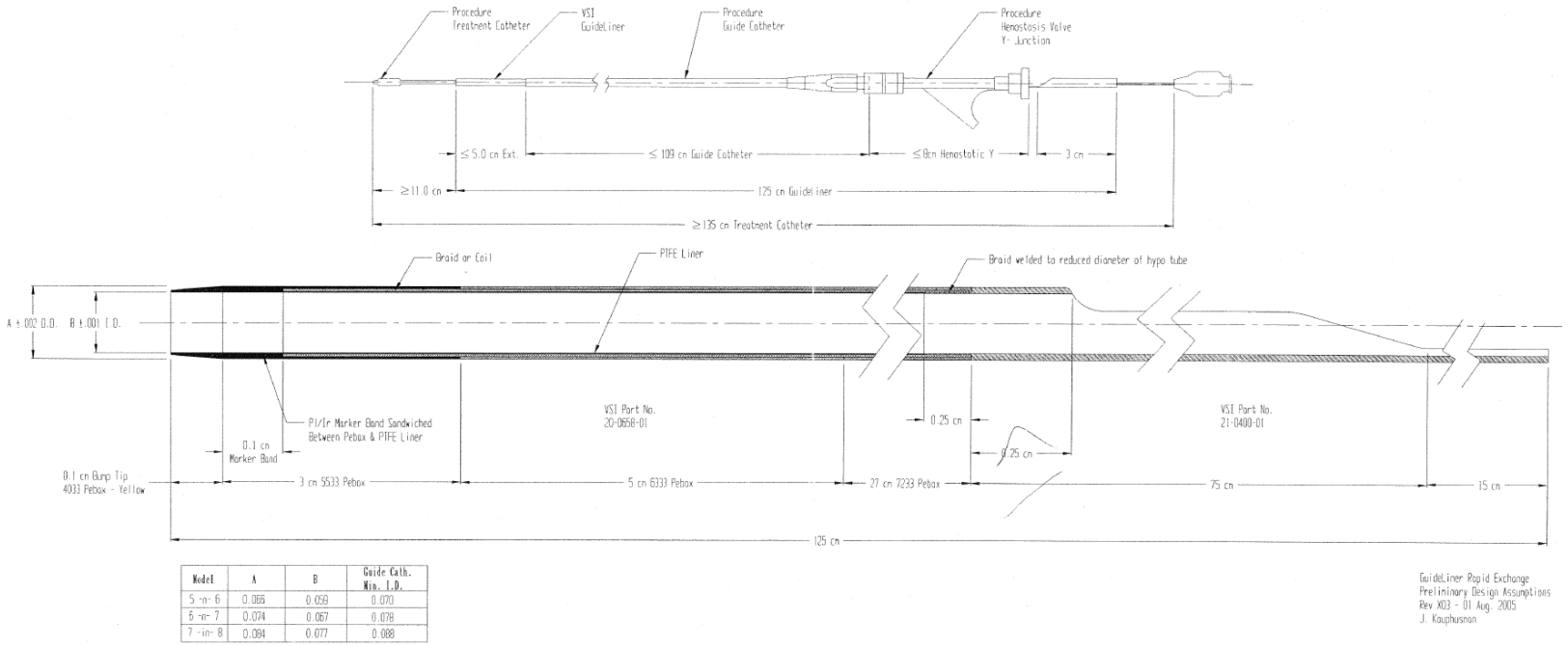


Ex-2004 at 1; Response at 6

Root Notes


Guide Liner
5in6
6in7
7in8
.070
.067
guide
.079
.089
Dilator
Distal - tipped
25cm
(BaSO4 loaded)
Proximal -
Guideliner
Distal
25cm
marker band
Proximal metal

August 2005 Computer Drawing



Zalesky Testimony

Q: So you would agree that Exhibit 2022 sets forth the concept for the rapid exchange GuideLiner, right? . . .

THE WITNESS: The concept, yes.

Ex-2022; Ex-2237 at 250:9-1, 250:13; Response at 16; Sur-Reply at 5

CORROBORATION OF REDUCTION TO PRACTICE – NON-INVENTOR TESTIMONY

Corroborating Witness #1 – Steve Erb

I, Steven Erb, declare as follows:

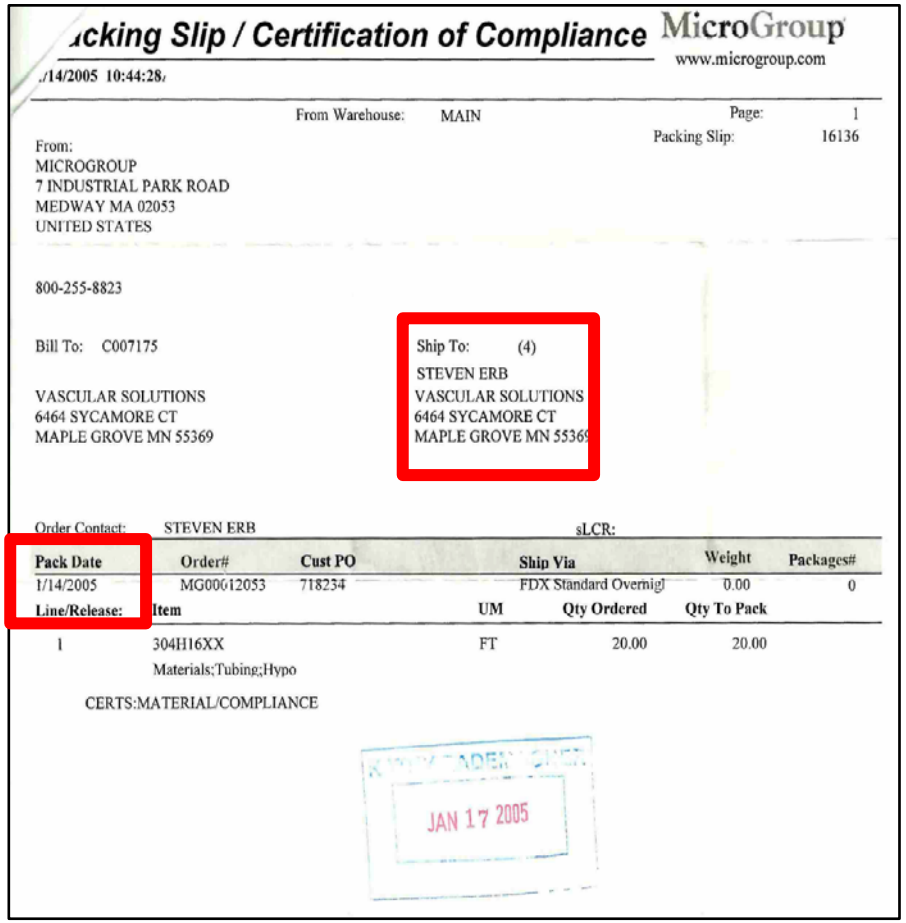
1. My name is Steven Erb. I began working for Vascular Solutions, Inc. ("Vascular Solutions") in 2005 as a Technician in the Research & Development ("R&D") group. I continue to work for the company today, which is now owned by Teleflex. My title today is Technologist in the R&D group for what is now known as the Interventional Business Unit of Teleflex. The Interventional Business Unit is where the former Vascular Solutions business resides at Teleflex.

Ex-2122 at ¶ 1; Sur-Reply at 10

Erb Testimony

7. Early in our development process for the GuideLiner, in 2005, we ordered stainless steel and nitinol hypotubes from various vendors to use in prototyping the device. For example, I have reviewed the documents found at **Exhibits 2110** and recognize those to be the invoice, packing slip, and proof of Vascular Solution's payment for an order I placed in early January 2005 with Microgroup for stainless steel hypotubes. As shown by the packing slip at the page marked VSIMDT00040846 of Exhibit 2110, that order was shipped overnight to my attention at Vascular Solutions on January 14, 2005. We used these hypotubes to build some of the first prototypes of the GuideLiner rapid exchange device.

Ex-2122 at ¶ 7;
Response at 7;
Sur-Reply at 10



…cking Slip / Certification of Compliance MicroGroup
www.microgroup.com

…/14/2005 10:44:28…

From Warehouse: MAIN
Page: 1
Packing Slip: 16136

From:
MICROGROUP
7 INDUSTRIAL PARK ROAD
MEDWAY MA 02053
UNITED STATES

800-255-8823

Bill To: C007175

VASCULAR SOLUTIONS
6464 SYCAMORE CT
MAPLE GROVE MN 55369

Ship To: (4)
STEVEN ERB
VASCULAR SOLUTIONS
6464 SYCAMORE CT
MAPLE GROVE MN 55369

Order Contact: STEVEN ERB
sLCR:

Pack Date	Order#	Cust PO	Ship Via	Weight	Packages#
1/14/2005	MG00012053	718234	FDX Standard Overnigl	0.00	0

Line/Release:	Item	UM	Qty Ordered	Qty To Pack
1	304H16XX	FT	20.00	20.00
	Materials;Tubing;Hypo			

CERTS:MATERIAL/COMPLIANCE

JAN 17 2005

Ex-2110 at 3;
Response at 7;
Sur-Reply at 10

Erb Testimony

8. As a machinist for the group, I worked on the early GuideLiner prototypes. Specifically, I machined-down the hypotubes that were used to form the proximal end of the early prototypes of that device. I personally made a special jig to hold the hypotubes and then used a vertical milling machine to cut the tubes along their length. I remember the process well because it is difficult to hold and cut small-diameter tubes like the hypotubes that we used to build the GuideLiner prototypes. Using that jig and the vertical milling machine we had in the R&D lab at Vascular Solutions, I cut-down these early hypotubes into a hemi-cylindrical shape along part of their length. This hemi-cylindrical shape extended all the way to the end of one side of the machined hypotube, while the other end remained in a fully cylindrical shape. The transition between the hemi-cylindrical portion and the full circumference portion had a gradual slope. Machining these parts was an iterative process, as we kept cutting-away portions of the circumference from the hypotubes to optimize the flexibility of this component of the device. These hypotubes were, in turn used to form the proximal end of the first rapid exchange GuideLiner prototypes in early 2005.

10. After I machined-down the hypotubes, they were attached to the polymer distal tubular portion of the device. For a couple of the earliest prototypes, we bonded the machined-down hypotube to the polymer tubular portion with an adhesive. Quickly, however, we began to attach the sections using heat shrink tubing and a reflow process. The attachment of the metal to the polymer sections was achievable with the adhesives and materials we had in-house at Vascular Solutions for purposes of these early prototypes.

Ex-2122 at ¶¶ 8, 10;
Response at 7, 22;
Sur-Reply at 8, 10

Erb Testimony

11. These prototypes were then tested, including for durability with basic pull-tests and for functionality in two-dimensional benchtop heart models to ensure that the device could get where it needed to go in the vasculature and to understand the forces involved in maneuvering the GuideLiner through the heart model. I personally was involved in some of these tests on the GuideLiner prototypes. I also was aware of, though was not personally involved in, tests of the GuideLiner prototypes involving the delivery of stents and balloons in a benchtop heart model. Whenever a prototype was constructed at Vascular Solutions, it was typical that testing immediately followed. I recall watching Howard Root and others working in R&D at Vascular Solutions test prototypes on multiple occasions.

12. Although we initially machined-down both the stainless steel and nitinol tubes in-house at Vascular Solutions, we soon moved to laser cutting these parts with outside vendors. We used both LSA and SPECTRAlytics for laser cutting hypotubes for the GuideLiner prototypes. I primarily was involved in making prototypes before we started outsourcing the laser cutting to LSA and SPECTRAlytics. However, I did help assemble some of the subsequent prototypes. Additional testing, including testing of the kind mentioned above, was performed on these subsequent prototypes. I recall watching Howard Root and others working in R&D test these subsequent prototypes, as well.

Ex-2122 at ¶¶ 11-12;
Response at 7-8, 11-12, 15, 22-23;
Sur-Reply at 8, 10

Erb Testimony

13. Although the GuideLiner rapid exchange was not commercialized until several years after these initial prototypes were constructed, we knew from our early testing of prototypes of the device that it would work. But because it was a first-of-kind product, we were continually working to optimize the design so it could be efficiently and effectively manufactured and reproduced for commercialization. We were able to make several prototypes that worked, but we needed to develop manufacturing processes that were reproducible and a refined design that was able to be commercialized. Work toward this end was consistent from the time of the earliest prototypes through commercialization.

Ex-2122 at ¶ 13;
Response at 7, 19, 22-23;
Sur-Reply at 11

Corroborating Witness #2 – Deborah Schmalz

I, Deborah Schmalz (formerly Deborah Neymark), hereby declare and state as follows:

Personal Background

1. I currently live and work in the Raleigh-Durham North Carolina area.

2. I joined Vascular Solutions, Inc. ("VSI") in September 2000 as Vice President of Regulatory and Clinical Affairs. I remained in this position until I left VSI in July 2008.

Ex-2039 at ¶¶ 1-2; Response at 2

Schmalz Testimony

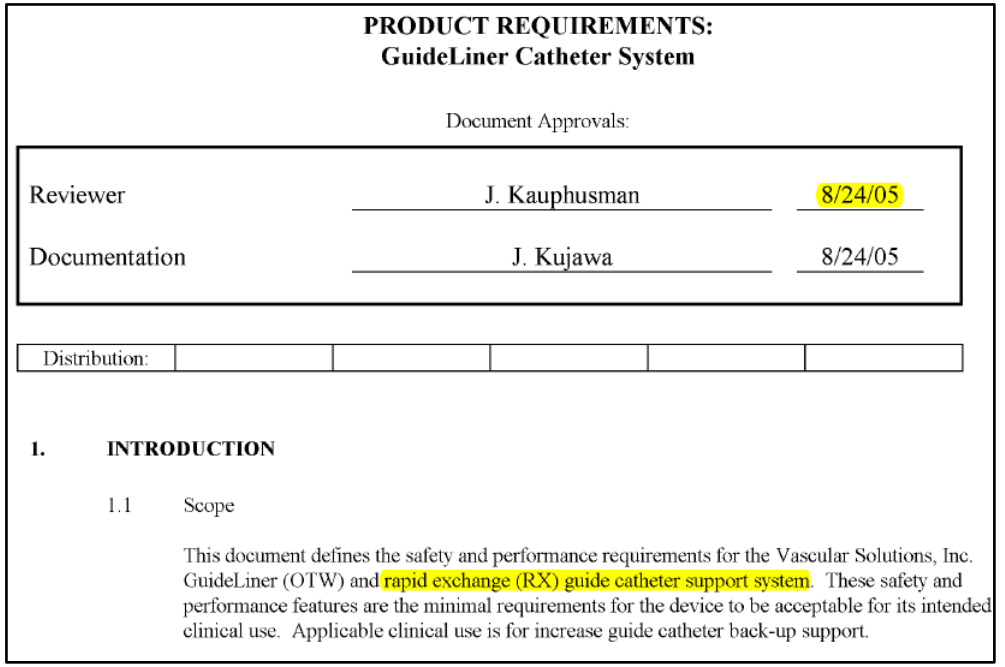
5. GuideLiner was a fast-moving, high-priority project for VSI. At the beginning, the project involved a rapid exchange version; an over-the-wire version was added a short time later and the two versions were worked on concurrently. I recall that the initial development period from the first time I saw a concept drawing to the time a working prototype of the rapid exchange version of GuideLiner was developed was very fast.

Ex-2039 at ¶ 5;
Response at 23;
Sur-Reply at 8, 10

Schmalz Testimony

6. Exhibit 2024 is a Product Requirements document for the GuideLiner Catheter System, dated August 24, 2005. Such a document was created for products at the end of the concept development phase. In practice, this meant that a product must have been prototyped, thoroughly tested, and shown to work for its intended purpose before a Product Requirements document was created. A Product Requirements document marked the start of the Regulatory department's formal quality process, which ensured regulatory compliance and quality control for products in the commercialization stage. VSI's quality process was a formal, meticulous, and time-consuming process. Once a Product Requirements document was created, any further changes made or testing performed on the product must be carefully tracked and documented. This quality process was not initiated until a design had been prototyped, tested, and shown to work for its intended purpose.

Ex-2039 at ¶ 6;
Response at 3, 17, 22-24;
Sur-Reply at 8, 10



PRODUCT REQUIREMENTS:
GuideLiner Catheter System

Document Approvals:

Reviewer	J. Kauphusman	8/24/05
Documentation	J. Kujawa	8/24/05

Distribution:					

1. INTRODUCTION

1.1 Scope

This document defines the safety and performance requirements for the Vascular Solutions, Inc. GuideLiner (OTW) and rapid exchange (RX) guide catheter support system. These safety and performance features are the minimal requirements for the device to be acceptable for its intended clinical use. Applicable clinical use is for increase guide catheter back-up support.

Ex-2024;
Response at 17;
Sur-Reply at 9-10

Schmalz Testimony

11. Exhibit 2041 is part of the materials presented to the Vascular Solutions Board of Directors in connection with its October 2005 meeting. This document contains a Marketing Update from October 2005 provided by VSI's CEO and one of the GuideLiner inventors, Howard Root, and another employee, Fred Reuning. The Marketing Update explains that the GuideLiner product "has received extremely favorable early concept reviews from our physician advisors." Ex. 2041 at 4. This demonstrates that GuideLiner had been prototyped, tested, and confirmed to work for its intended purpose before October 2005, which is consistent with my recollection of the GuideLiner development process. Indeed, given that we had received physician feedback by October 2005 is consistent with my recollection that GuideLiner had been prototyped, tested, and confirmed to work for its intended purpose months before that, and certainly before August 24, 2005, the date of the Products Requirement document of Exhibit 2024. Obtaining physician feedback took time because products had to be constructed, physician evaluators had to be engaged, the physicians had to evaluate the product, and then provide feedback to us on the product.

Ex-2039 at ¶ 11;
Response at 3, 23;
Sur-Reply at 8

Marketing Update- October 2005
Howard Root and Fred Reuning

2006 Products – Looking into 2006, we have worked with R&D on developing the new GuideLiner product, which has received extremely favorable early concept reviews from our physician advisors. The GuideLiner product provides a coaxial liner for use in any manufacturer's guide catheter to allow a safe version of "deep seating" the guide in the coronary artery and also provides better back-up support, particularly in chronic total occlusion cases.

Ex-2041 at 4;
Ex-2118 at ¶ 62;
Response at 2, 18-19

Schmalz Testimony

7. The August 24, 2005 Products Requirements document of Exhibit 2024 references both the rapid exchange and over-the-wire versions of GuideLiner. We would not have identified both versions if they had not both reached the point of being prototyped, tested, and shown to work for their intended purpose. Moreover, I specifically recall that a working prototype of the rapid exchange version of GuideLiner was created prior to creation of the August 24, 2005 Products Requirements document.

Ex-2039 at ¶ 7;
Response at 3, 22-24;
Sur-Reply at 8, 10

Zalesky Testimony (Medtronic Expert)

Q. You're not saying that Mr. Root is lying in his declaration, are you?

A. No, I'm not saying that.

Q. And you're not saying that Mr. Sutton is lying in his declaration, are you?

A. No.

Q. And you're not saying that Mr. Sutton lied in his deposition testimony, are you?

A. No.

Q. You're not saying Mr. Erb lied in his declaration, are you?

A. No.

Q. And you're not saying that Mr. Erb lied in his deposition testimony, are you?

A. No.

Q. And you're not saying that Ms. Schmalz lied in her declaration, are you?

A. No.

Q. And you're not saying that Ms. Schmalz lied in her deposition testimony, are you?

A. No.

Ex-2237 at 139:5-25, *see also* 225:8-11, 227:14-17;
Sur-Reply at 8

Zalesky Testimony (Medtronic Expert)

Q. So it's your testimony that there must be some tangible form of a written record for an electronic record in order for an inventor to show that his or her invention works for its intended purpose?

A. Essentially, yes. There needs to be some statement of what's driving what he's making.

Q. And that has to be written down in an electronic or paper record; is that right?

A. It needs to be recorded somewhere, otherwise third parties are clueless, yes.

Ex-2237 at 253:15-25;
Response at 24

Q. And in your opinion, the evidence that must accompany the testimony has to be in written form, correct?

A. It needs to be in recorded form. It could be photographic. It could be electronic, digital.

Ex-2237 at 140:15-18
Response at 24

Q. And so is it your opinion that because there isn't a photograph, et cetera, that reduction to practice of the GuideLiner rapid exchange did not, in fact, occur?

***

A. Yes, that's my opinion.

Ex-2237 at 142:20–143:1
Response at 24

Oral Testimony Is Sufficient for All Aspects of Reduction to Practice

Under the "rule of reason," the inventor's testimony must be sufficiently corroborated by independent evidence, but not necessarily documentary evidence. Rather, "the rule requires an evaluation of all pertinent evidence when determining the credibility of an inventor's testimony." Furthermore, it is not surprising that Loral has been unable to submit documents showing production test results, considering that the events at issue occurred almost 30 years ago.

Loral Fairchild Corp. v. Matsushita Elec. Indus.,266 F.3d 1358, 1364-65 (Fed. Cir. 2001); Response at 24; Sur-Reply at 10

Although no direct evidence supported Goldfarb's testimony that he measured fibril length and observed tissue ingrowth in July of 1973, we agree with the Board that circumstantial evidence provided sufficient corroboration. Goldfarb testified that he examined fibril length at the time of the successful implant. His testimony was corroborated by the testimony of Mendenhall and Green.

Cooper v. Goldfarb, 154 F.3d 1321, 1330 (Fed. Cir. 1998); Response at 24; Sur-Reply at 8

CORROBORATION OF REDUCTION TO PRACTICE – DOCUMENTARY CORROBORATION

Market Feasibility Memo (Feb. 2005)

Vascular Solutions, Inc.

Memo

From: Howard Root

To: GuideLiner DHF

Date: February 4, 2005

RE: **Market Feasibility for the GuideLiner catheters**

Background

As part of Phase I of the product development SOP 1043, a review of the market feasibility of the new product is required. The GuideLiner catheter is a new product idea of a "liner" to be delivered inside standard guide catheters to provide the ability to create a deep seating of the guide for added support in the interventional procedure. The GuideLiner catheter is designed to be used in interventional cardiology procedures. Three versions of the GuideLiner product are anticipated: a "5in6 GuideLiner", a "6in7 GuideLiner" and a "7in8 Guideliner".

Ex-2003 at 1;
Response at 7;
Sur-Reply at 9

Market Feasibility Memo (Feb. 2005)

To meet this market opportunity, our GuideLiner product should be deliverable through the standard guide catheters (J&J, BSX, Guidant and Medtronic) currently on the market. In addition, the GuideLiner product should be deliverable with a short (preferably app. 20cm) rail segment, thus allowing delivery using standard rapid exchange techniques. The GuideLiner should include a tapered dilator that runs over a standard .014" coronary guide wire to allow atraumatic placement within the coronary artery (and then removal of the dilator). Also, the GuideLiner should be able to be delivered through the existing hemostatic valve on the guide catheter without preventing injections through the existing Y-adapter. Finally, the GuideLiner should have an inner diameter that is acceptable for delivering standard coronary devices after it is placed in the vessel.

Three sizes of the GuideLiner product should be developed, corresponding to the 8F, 7F and 6F guide catheters that are used in interventional cardiology procedures. The minimum I.D.'s of the current guide catheters (J&J, Guidant, BSX, Medtronic) that would be used with the GuideLiner are as follows:

8F $\geq$ 0.088" I.D.
7F $\geq$ 0.078" I.D.
6F $\geq$ 0.070" I.D.

A crude evaluation of the space necessary between the O.D. of the GuideLiner and the I.D. of the guide catheter to allow acceptable movement and delivery was performed. From this evaluation, it is expected that a minimum of only 0.002" in space is necessary between the two tubes to allow for delivery of the GuideLiner.

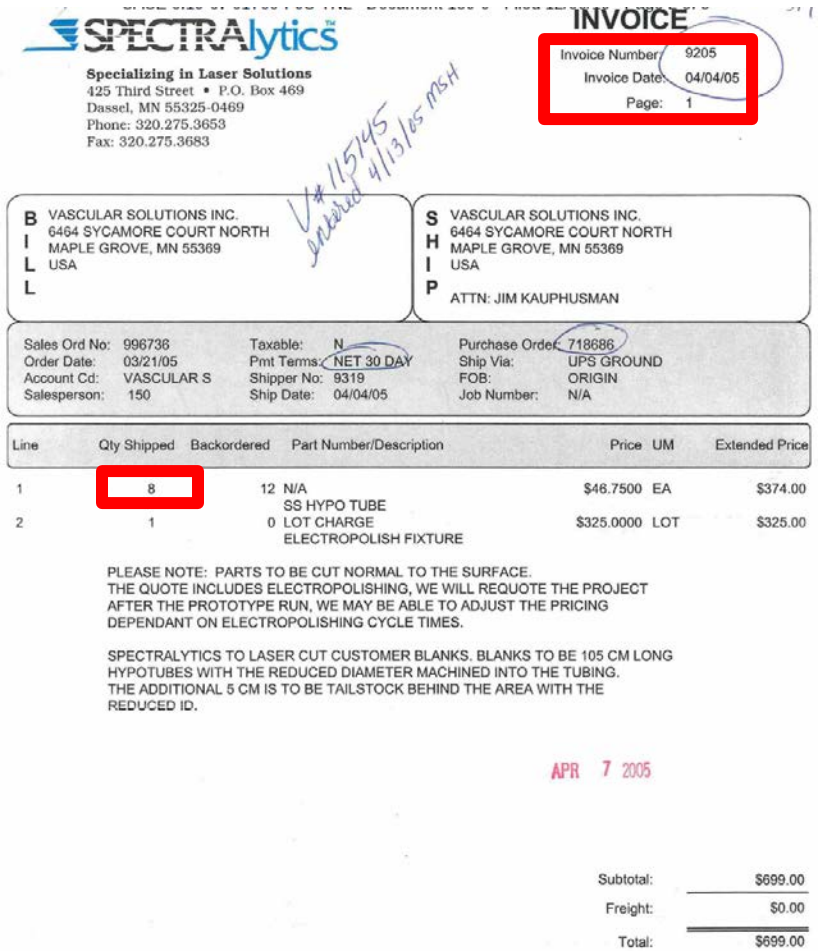
To meet user expectations, the effective I.D. of each size of our GuideLiner product should be equivalent to the next smaller guide catheter to allow the typical cardiology tools to be used. According to the published research, a 0.059" I.D. will allow all PTCA balloons and stents up to 4.0mm in size to be delivered. Thus, the maximum O.D. and the minimum effective I.D. of each size of the Guide Liner should be as follows:

Size	Min. I.D.	Max. O.D.
7in8 GuideLiner	$\geq$ 0.078"	$\leq$ 0.086"
6in7 GuideLiner	$\geq$ 0.068"	$\leq$ 0.076"
5in6 GuideLiner	$\geq$ 0.059"	$\leq$ 0.068"

Finally, the distal portion of the GuideLiner and the dilator should be radiopaque to indicate positioning during delivery, and a hydrophilic or other slippery coating should be applied to the distal potion of the GuideLiner.

Ex-2003 at 2;
Response at 7;
Sur-Reply at 9

April Prototypes – Proximal Section



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Invoice Date: 04/04/05
Page: 1

V# 115145 ordered 4/13/05 MSH

BILL: VASCULAR SOLUTIONS INC.
6464 SYCAMORE COURT NORTH
MAPLE GROVE, MN 55369
USA

SHIP: VASCULAR SOLUTIONS INC.
6464 SYCAMORE COURT NORTH
MAPLE GROVE, MN 55369
USA
ATTN: JIM KAUPHUSMAN

Sales Ord No:	996736	Taxable:	N	Purchase Order:	718686
Order Date:	03/21/05	Pmt Terms:	NET 30 DAY	Ship Via:	UPS GROUND
Account Cd:	VASCULAR S	Shipper No:	9319	FOB:	ORIGIN
Salesperson:	150	Ship Date:	04/04/05	Job Number:	N/A

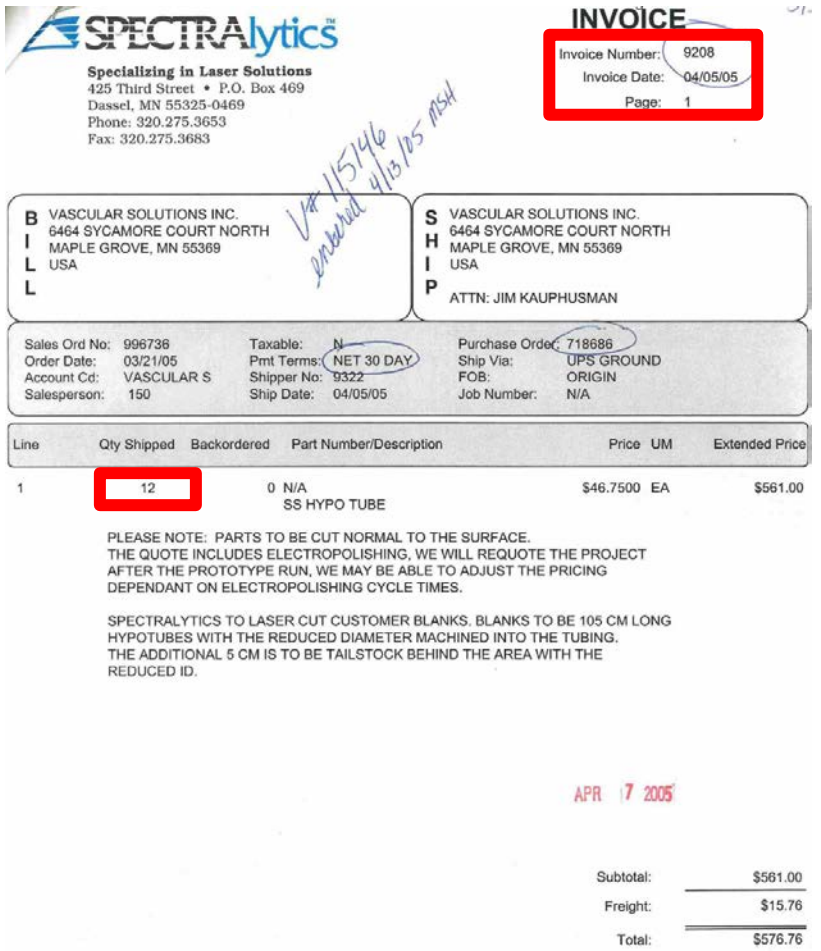
Line	Qty Shipped	Backordered	Part Number/Description	Price	UM	Extended Price
1	8	12	N/A SS HYPO TUBE	$46.7500	EA	$374.00
2	1	0	LOT CHARGE ELECTROPOLISH FIXTURE	$325.0000	LOT	$325.00

PLEASE NOTE: PARTS TO BE CUT NORMAL TO THE SURFACE.
THE QUOTE INCLUDES ELECTROPOLISHING, WE WILL REQUOTE THE PROJECT AFTER THE PROTOTYPE RUN, WE MAY BE ABLE TO ADJUST THE PRICING DEPENDANT ON ELECTROPOLISHING CYCLE TIMES.

SPECTRALYTICS TO LASER CUT CUSTOMER BLANKS. BLANKS TO BE 105 CM LONG HYPOTUBES WITH THE REDUCED DIAMETER MACHINED INTO THE TUBING. THE ADDITIONAL 5 CM IS TO BE TAILSTOCK BEHIND THE AREA WITH THE REDUCED ID.

APR 7 2005

Subtotal:	$699.00
Freight:	$0.00
Total:	$699.00



SPECTRAlytics™

Specializing in Laser Solutions
425 Third Street • P.O. Box 469
Dassel, MN 55325-0469
Phone: 320.275.3653
Fax: 320.275.3683

INVOICE

Invoice Number: 9208
Invoice Date: 04/05/05
Page: 1

V# 115146 ordered 4/13/05 MSH

BILL: VASCULAR SOLUTIONS INC.
6464 SYCAMORE COURT NORTH
MAPLE GROVE, MN 55369
USA

SHIP: VASCULAR SOLUTIONS INC.
6464 SYCAMORE COURT NORTH
MAPLE GROVE, MN 55369
USA
ATTN: JIM KAUPHUSMAN

Sales Ord No:	996736	Taxable:	N	Purchase Order:	718686
Order Date:	03/21/05	Pmt Terms:	NET 30 DAY	Ship Via:	UPS GROUND
Account Cd:	VASCULAR S	Shipper No:	9322	FOB:	ORIGIN
Salesperson:	150	Ship Date:	04/05/05	Job Number:	N/A

Line	Qty Shipped	Backordered	Part Number/Description	Price	UM	Extended Price
1	12	0	N/A SS HYPO TUBE	$46.7500	EA	$561.00

PLEASE NOTE: PARTS TO BE CUT NORMAL TO THE SURFACE.
THE QUOTE INCLUDES ELECTROPOLISHING, WE WILL REQUOTE THE PROJECT AFTER THE PROTOTYPE RUN, WE MAY BE ABLE TO ADJUST THE PRICING DEPENDANT ON ELECTROPOLISHING CYCLE TIMES.

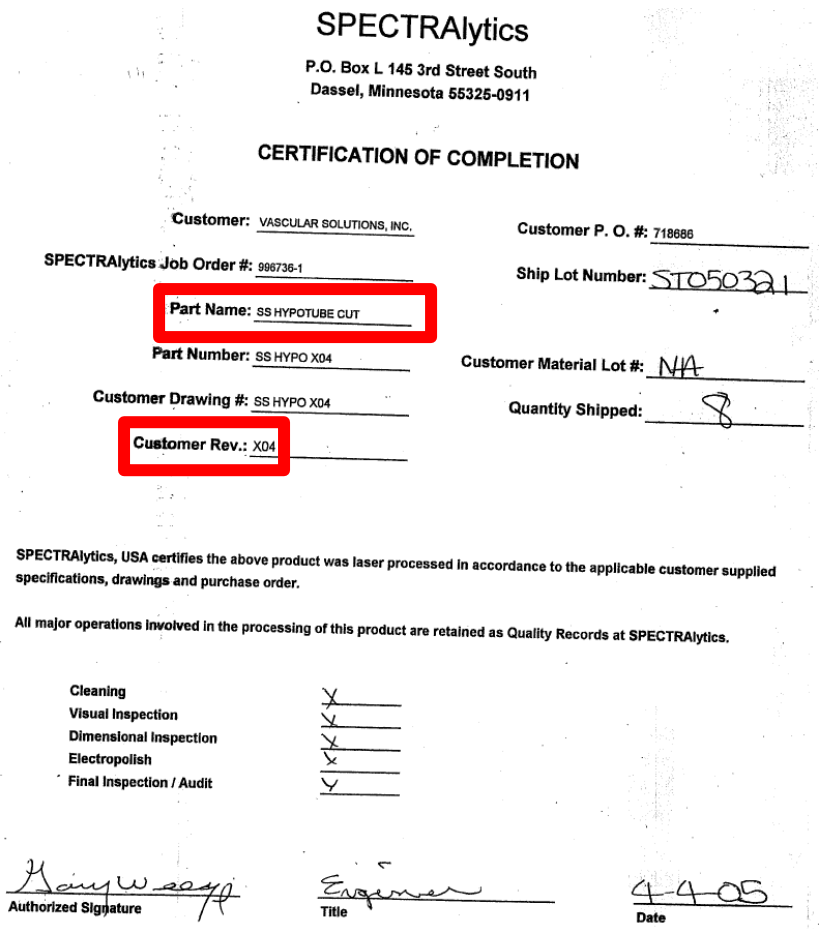
SPECTRALYTICS TO LASER CUT CUSTOMER BLANKS. BLANKS TO BE 105 CM LONG HYPOTUBES WITH THE REDUCED DIAMETER MACHINED INTO THE TUBING. THE ADDITIONAL 5 CM IS TO BE TAILSTOCK BEHIND THE AREA WITH THE REDUCED ID.

APR 7 2005

Subtotal:	$561.00
Freight:	$15.76
Total:	$576.76

Ex-2013;
Response at 7, 10

April Prototypes – Proximal Section



SPECTRAlytics

P.O. Box L 145 3rd Street South
Dassel, Minnesota 55325-0911

CERTIFICATION OF COMPLETION

Customer: VASCULAR SOLUTIONS, INC.

Customer P. O. #: 718686

SPECTRAlytics Job Order #: 996736-1

Ship Lot Number: ST050321

Part Name: SS HYPOTUBE CUT

Part Number: SS HYPO X04

Customer Material Lot #: NA

Customer Drawing #: SS HYPO X04

Quantity Shipped: 8

Customer Rev.: X04

SPECTRAlytics, USA certifies the above product was laser processed in accordance to the applicable customer supplied specifications, drawings and purchase order.

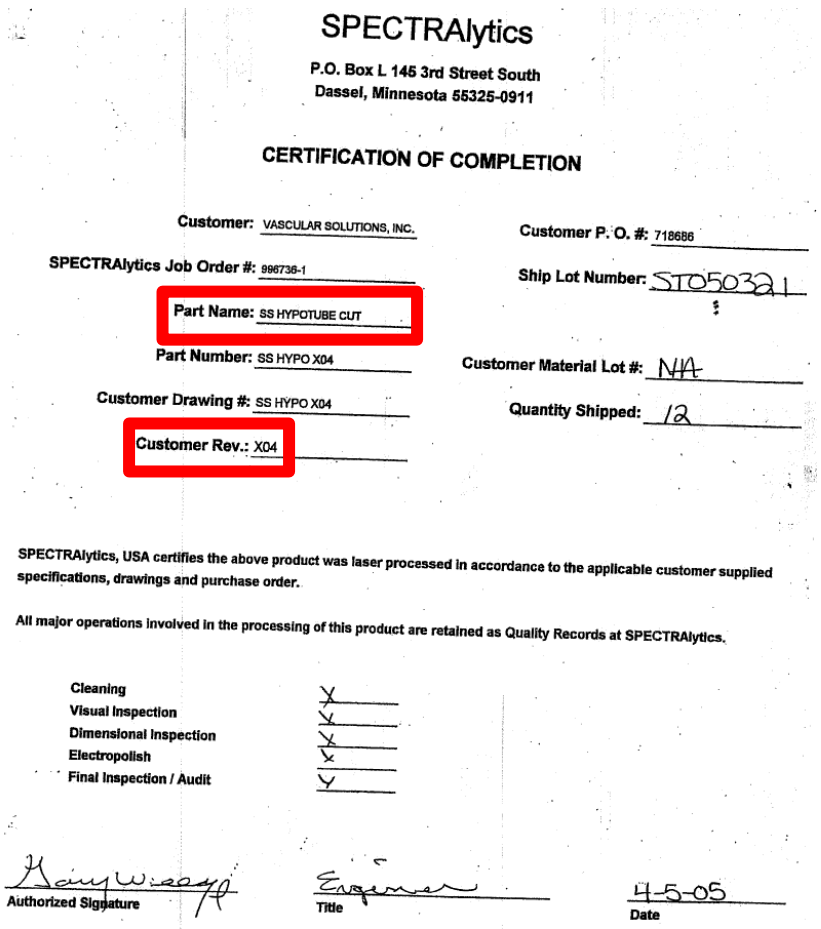
All major operations involved in the processing of this product are retained as Quality Records at SPECTRAlytics.

Cleaning	X
Visual Inspection	X
Dimensional Inspection	X
Electropolish	X
Final Inspection / Audit	X

Authorized Signature

Title

4-4-05
Date



SPECTRAlytics

P.O. Box L 145 3rd Street South
Dassel, Minnesota 55325-0911

CERTIFICATION OF COMPLETION

Customer: VASCULAR SOLUTIONS, INC.

Customer P. O. #: 718686

SPECTRAlytics Job Order #: 996736-1

Ship Lot Number: ST050321

Part Name: SS HYPOTUBE CUT

Part Number: SS HYPO X04

Customer Material Lot #: NA

Customer Drawing #: SS HYPO X04

Quantity Shipped: 12

Customer Rev.: X04

SPECTRAlytics, USA certifies the above product was laser processed in accordance to the applicable customer supplied specifications, drawings and purchase order.

All major operations involved in the processing of this product are retained as Quality Records at SPECTRAlytics.

Cleaning	X
Visual Inspection	X
Dimensional Inspection	X
Electropolish	X
Final Inspection / Audit	X

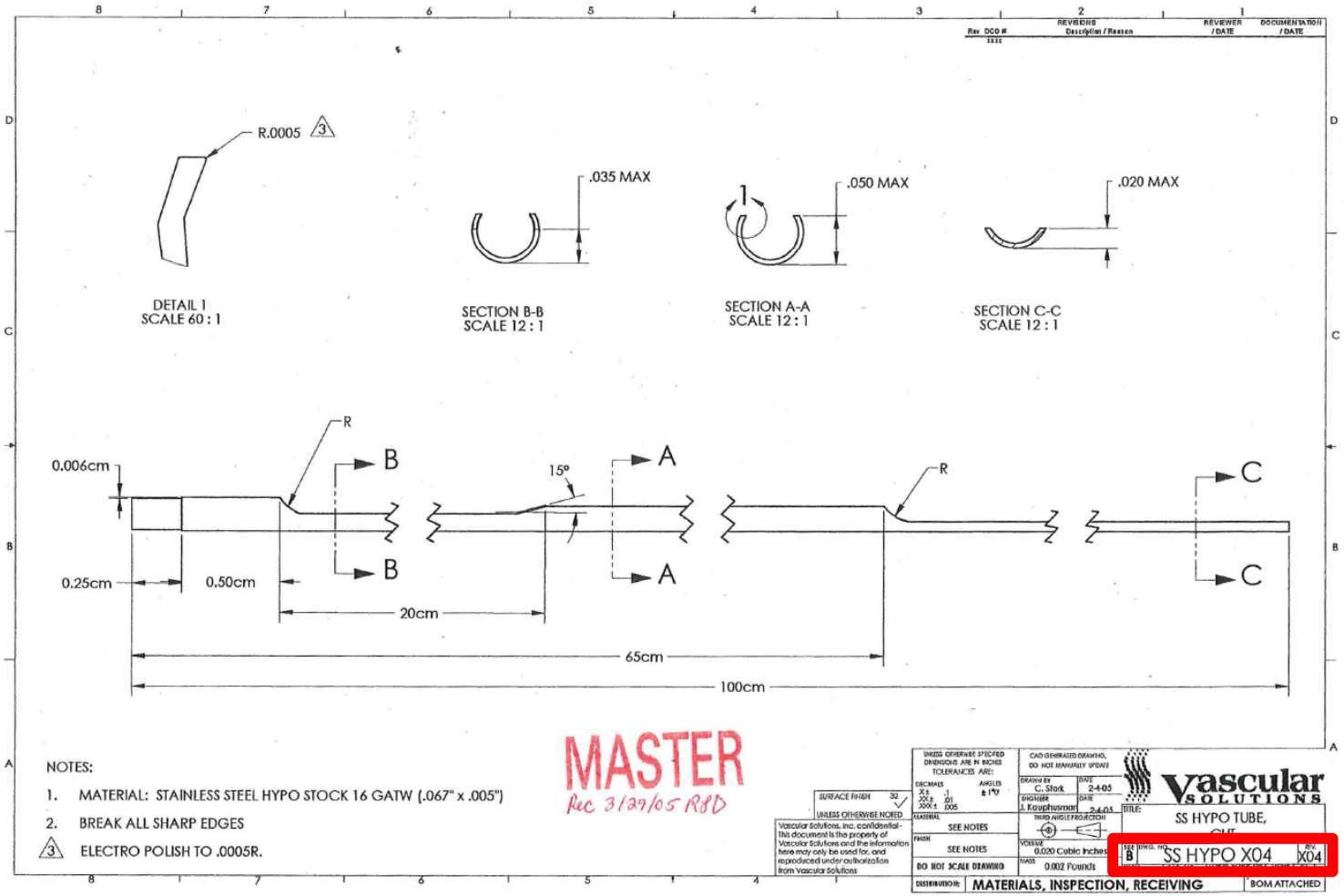
Authorized Signature

Title

4-5-05
Date

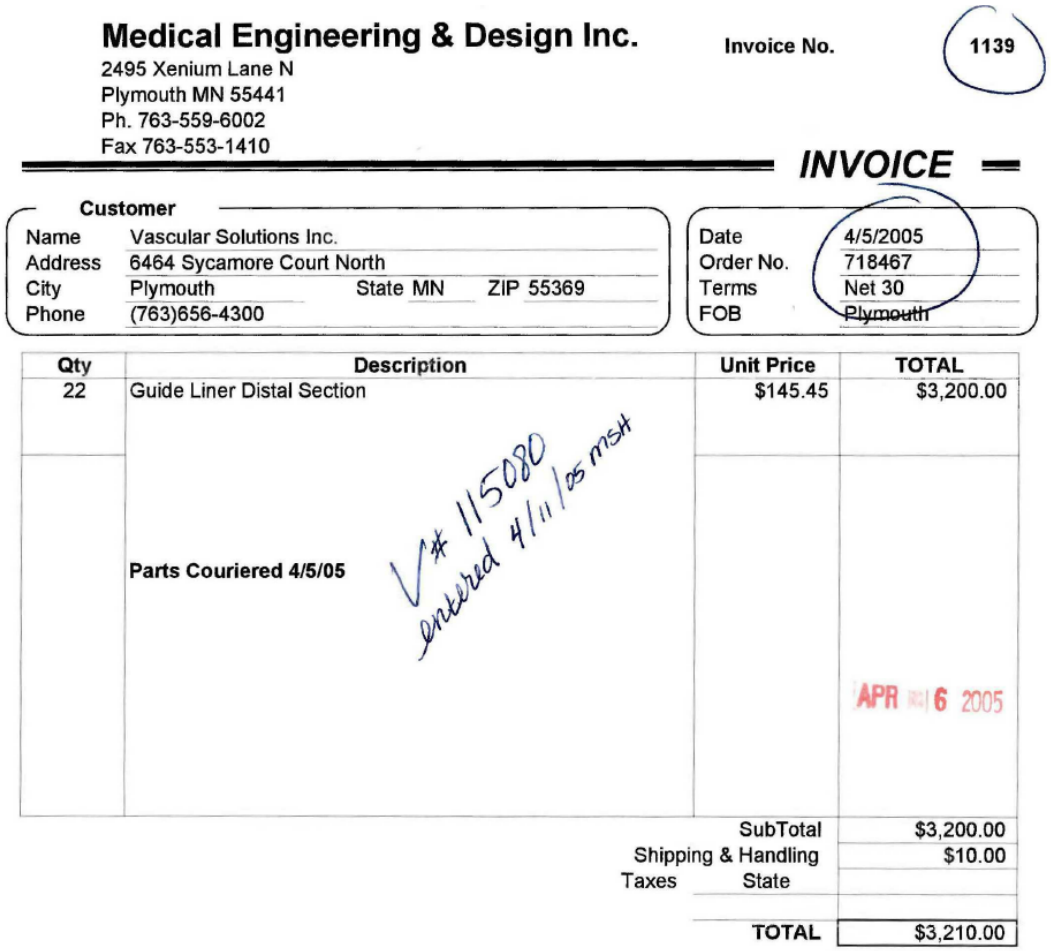
Ex-2095;
Response at 7, 10

April Prototypes – Proximal Section



Ex-2113 at 2;
Response at 8, 10-11;
Sur-Reply at 5-8, 13

April Prototypes – Distal Section



Medical Engineering & Design Inc.
2495 Xenium Lane N
Plymouth MN 55441
Ph. 763-559-6002
Fax 763-553-1410

Invoice No. 1139

INVOICE

Customer

Name	Vascular Solutions Inc.		
Address	6464 Sycamore Court North		
City	Plymouth	State MN	ZIP 55369
Phone	(763)656-4300		

Date	4/5/2005
Order No.	718467
Terms	Net 30
FOB	Plymouth

Qty	Description	Unit Price	TOTAL
22	Guide Liner Distal Section	$145.45	$3,200.00
	Parts Couriered 4/5/05		

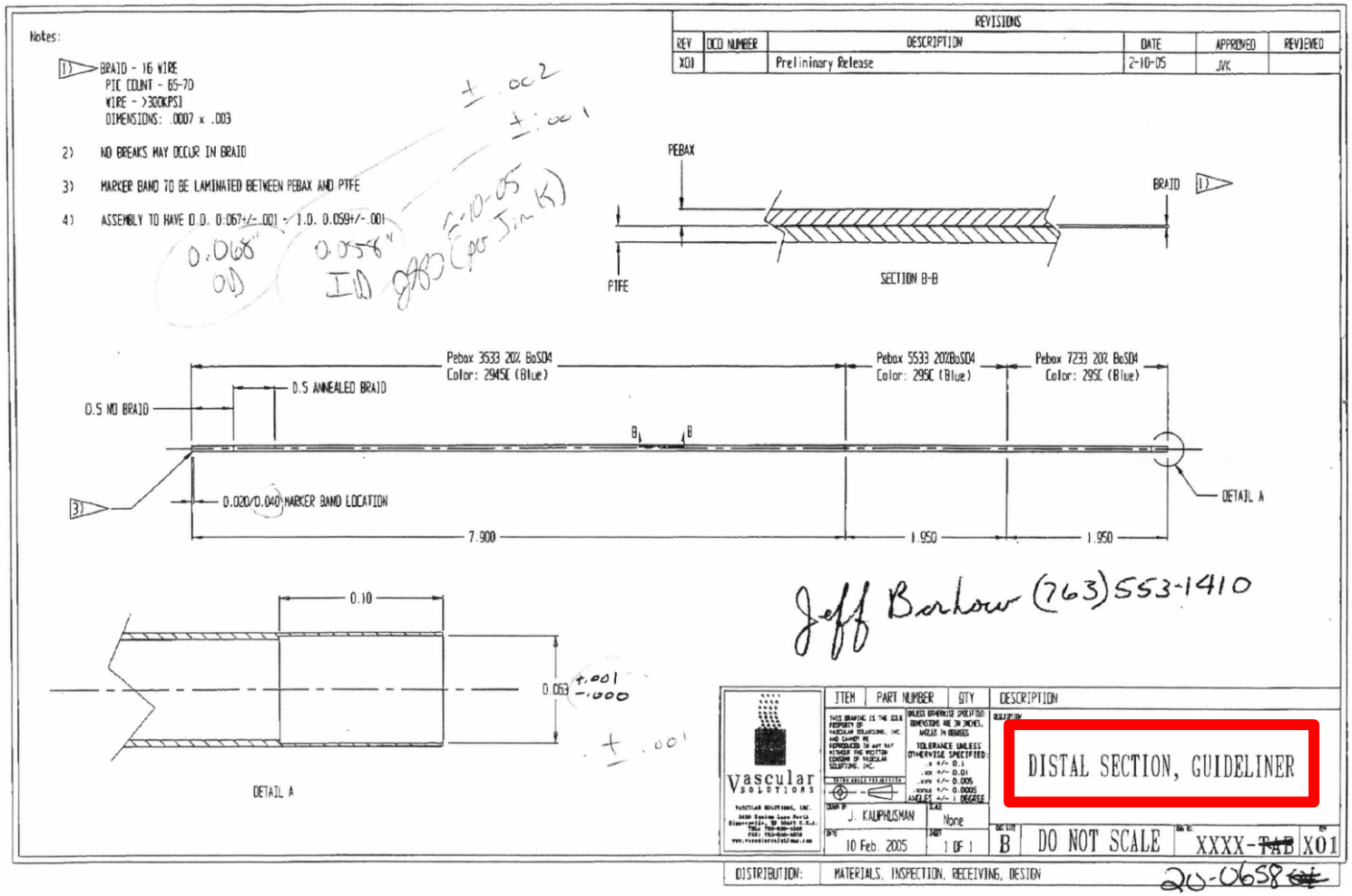
V# 115080 entered 4/11/05 msh

APR 6 2005

	SubTotal	$3,200.00
	Shipping & Handling	$10.00
Taxes	State	
	TOTAL	$3,210.00

Ex-2011 at 2;
Response at 7-8

April Prototypes – Distal Section



Ex-2089 at 8;
Response at 7-10, 10-11;
Sur-Reply at 7-8, 13

July Prototypes – Proximal Section

SPECTRAlytics

Specializing in Laser Solutions
425 Third Street • P.O. Box 469
Dassel, MN 55325-0469
Phone: 320.275.3653
Fax: 320.275.3683

INVOICE

Invoice Number: 9941
Invoice Date: 07/28/05
Page: 1

Vt#146789 entered 8/31/05 mst

BILL
VASCULAR SOLUTIONS INC.
6464 SYCAMORE COURT NORTH
MAPLE GROVE, MN 55369
USA

SHIP
VASCULAR SOLUTIONS INC.
6464 SYCAMORE COURT
MAPLE GROVE, MN 55369
USA
ATTN: JIM KAUPHUSMAN

Sales Ord No:	997021	Taxable:	N	Purchase Order:	719391
Order Date:	06/23/05	Pmt Terms:	NET 30 DAY	Ship Via:	DROP-OFF
Account Cd:	VASCULAR S	Shipper No:	[illegible]	FOB:	ORIGIN
Salesperson:	150	Ship Date:	07/28/05	Job Number:	N/A

Line	Qty Shipped	Backordered	Part Number/Description	Price	UM	Extended Price
1	20	0	N/A GUIDELINER NARROW SST REV.X01	$58.7500	EA	$1,175.00

SPECTRALYTICS TO LASER CUT CUSTOMER SUPPLIED TUBES. SPECTRALYTICS WILL MACHINE THE STEP IN THE OD. TUBES TO BE AT LEAST 42" LONG.

PLEASE NOTE ***PARTS TO BE CUT NORMAL TO THE SURFACE***

****INCLUDES ELECTROPOLISHING****

KATHY RADEMACHER
AUG 31 2005
AUG 1 2005

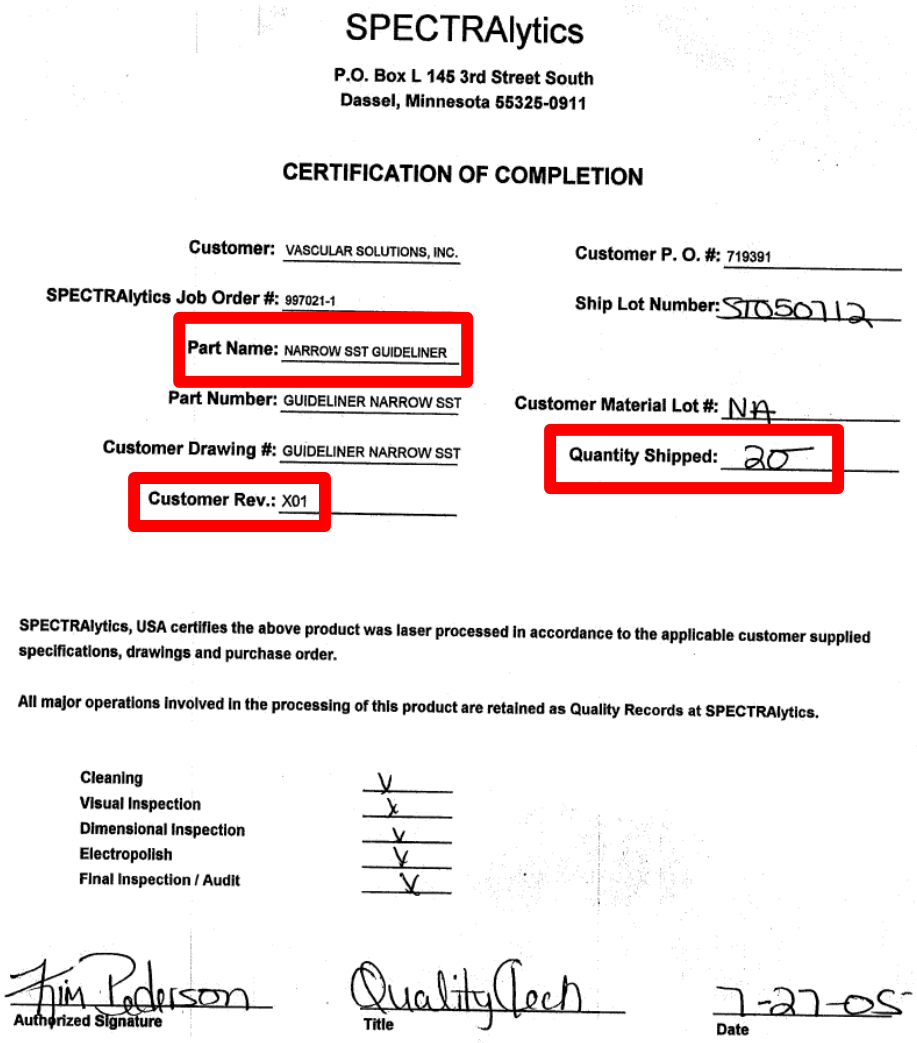
5008500 038

Subtotal:	$1,175.00
Freight:	$0.00
Total:	$1,175.00

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

Ex-2020 at 4;
Response at 7, 13

July Prototypes – Proximal Section



SPECTRAlytics

P.O. Box L 145 3rd Street South
Dassel, Minnesota 55325-0911

CERTIFICATION OF COMPLETION

Customer: VASCULAR SOLUTIONS, INC.

Customer P. O. #: 719391

SPECTRAlytics Job Order #: 997021-1

Ship Lot Number: STO50712

Part Name: NARROW SST GUIDELINER

Part Number: GUIDELINER NARROW SST

Customer Material Lot #: NA

Customer Drawing #: GUIDELINER NARROW SST

Quantity Shipped: 20

Customer Rev.: X01

SPECTRAlytics, USA certifies the above product was laser processed in accordance to the applicable customer supplied specifications, drawings and purchase order.

All major operations involved in the processing of this product are retained as Quality Records at SPECTRAlytics.

Cleaning	V
Visual Inspection	V
Dimensional Inspection	V
Electropolish	V
Final Inspection / Audit	V

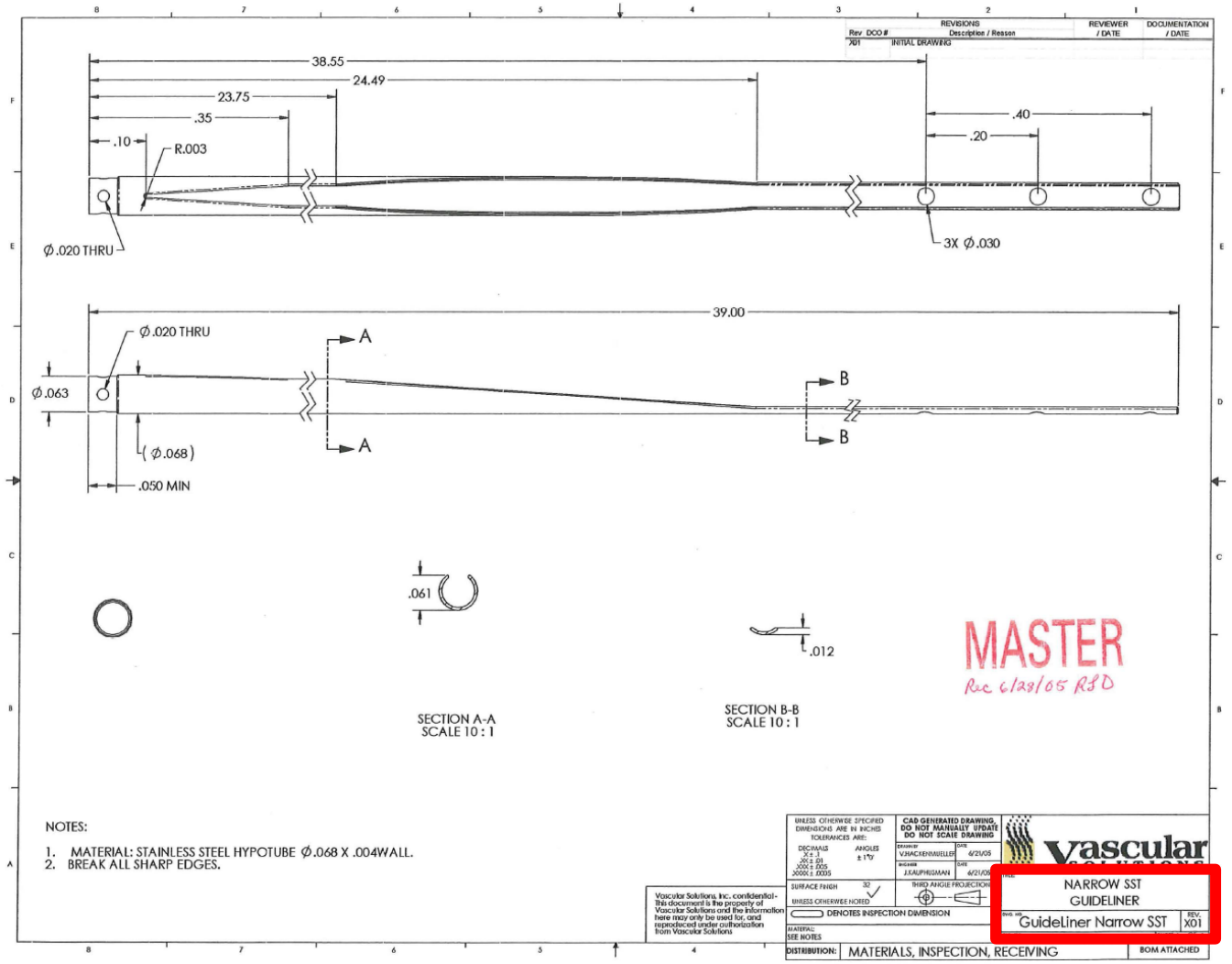
Jim Pederson — Authorized Signature

Quality Tech — Title

7-27-05 — Date

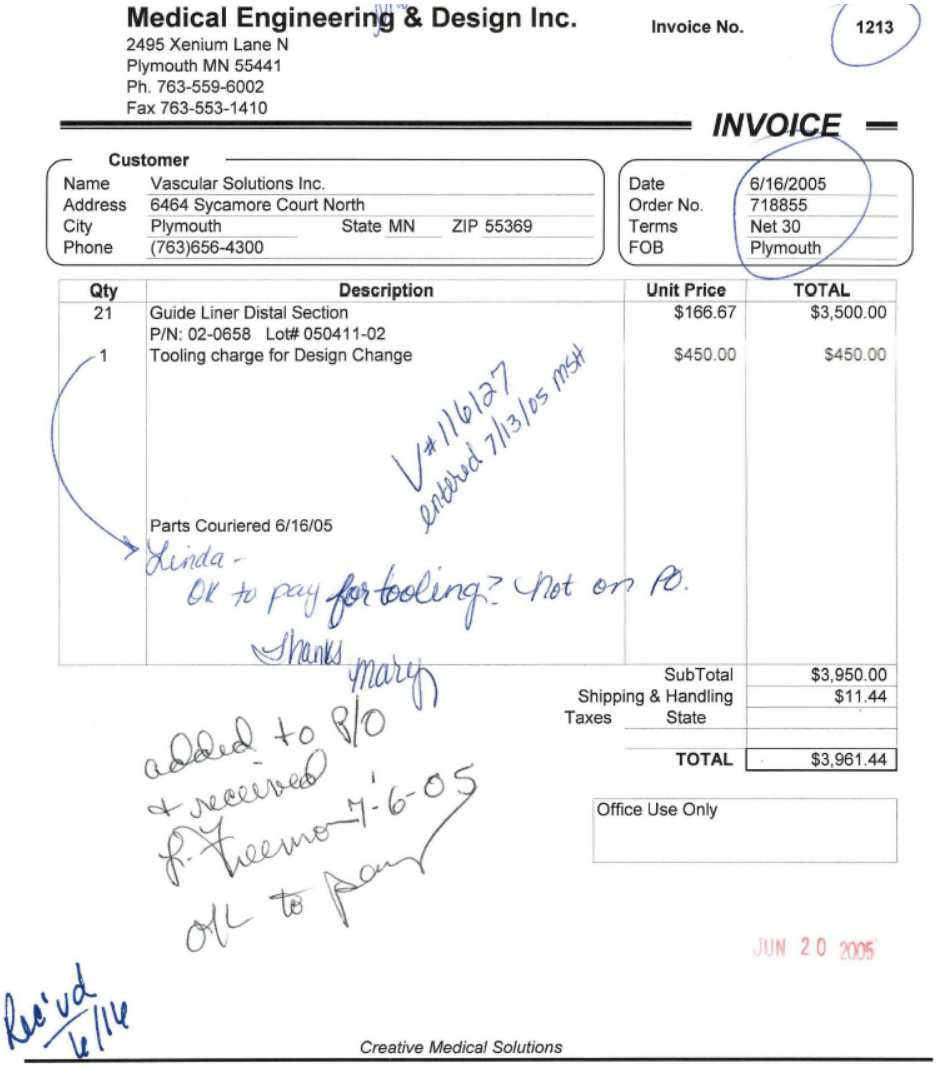
Ex-2095 at 1-2;
Response at 7, 10;

July Prototypes – Proximal Section



Ex-2114;
Response at 7-8, 13-14;

July Prototypes – Distal Section



Medical Engineering & Design Inc.
2495 Xenium Lane N
Plymouth MN 55441
Ph. 763-559-6002
Fax 763-553-1410

Invoice No. 1213

INVOICE

Customer

Name	Vascular Solutions Inc.
Address	6464 Sycamore Court North
City	Plymouth State MN ZIP 55369
Phone	(763)656-4300

Date	6/16/2005
Order No.	718855
Terms	Net 30
FOB	Plymouth

Qty	Description	Unit Price	TOTAL
21	Guide Liner Distal Section P/N: 02-0658 Lot# 050411-02	$166.67	$3,500.00
1	Tooling charge for Design Change	$450.00	$450.00

V# 116127 entered 7/13/05 mst

Parts Couriered 6/16/05

Linda -
OK to pay for tooling? Not on PO.
Thanks
Mary

added to P/O
+ received
J. Freeman 7-6-05
OK to Pay

	SubTotal	$3,950.00
Shipping & Handling		$11.44
Taxes	State	
	TOTAL	$3,961.44

Office Use Only

JUN 20 2005

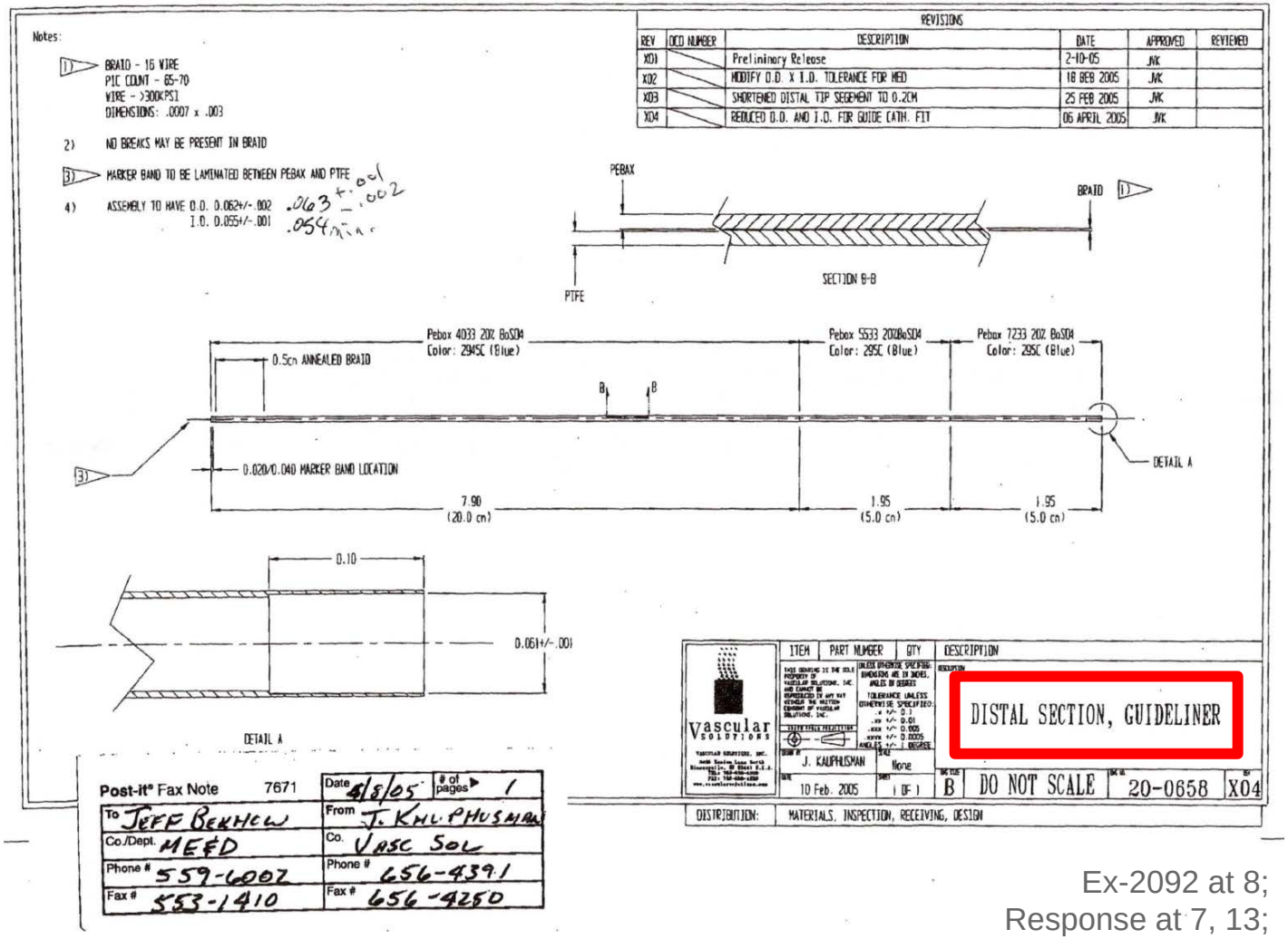
Rec'vd 6/14

Creative Medical Solutions

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

Ex-2021 at 2;
Response at 7, 13

July Prototypes – Distal Section



Ex-2092 at 8;
Response at 7, 13;
Sur-Reply at 7-8, 14

Zalesky Testimony (Medtronic Expert)

Q. But my question is: Would it be reasonable for VSI to spend thousands of dollars on customized parts like those shown in 2089, 2113, 2092, and 2114, would it be reasonable for VSI to not assemble those parts together?

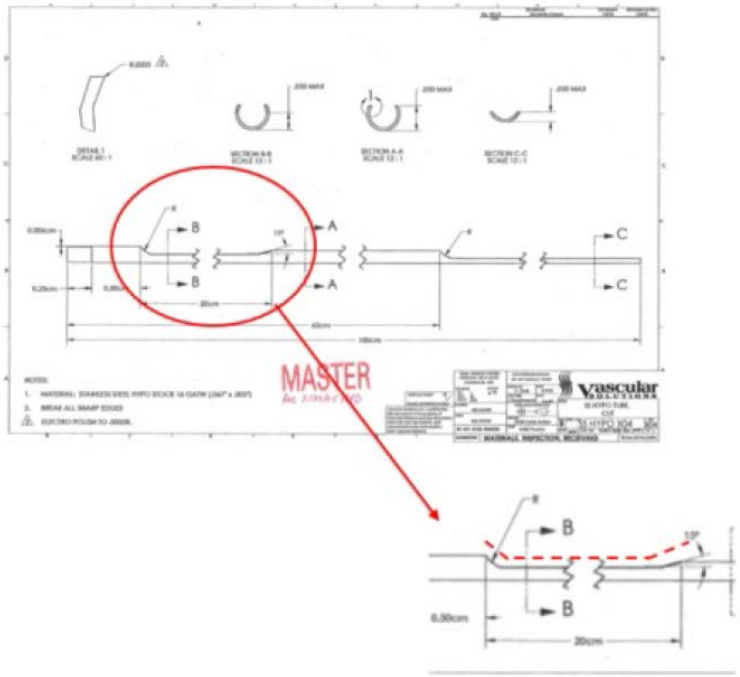
A. I agree that doesn't make a lot of sense, but I can certainly conceive of using those parts for other purposes, for other potential designs, through other exploratory concepts. I just don't have any evidence that indicates how they were used or that they were assembled into any prototype.

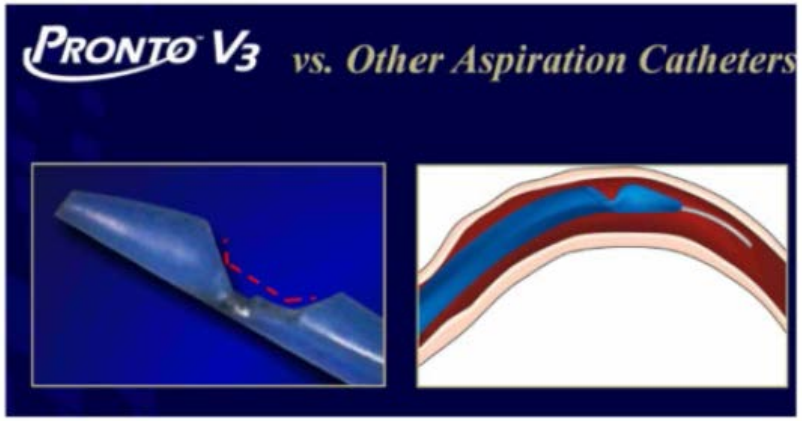
Q. And you don't have any evidence that those parts were, in fact, used for another purpose, do you?

A. I do not have that evidence.

Ex-2237 at 208:14-209:4;
Sur-Reply at 8, 15

Zalesky's Speculation





Q. So what you're displaying in paragraph 165 of your declaration is a 5-millimeter section, right?

A. Yes.

Q. And that is significantly smaller, is it not, than the 20-centimeter segment that is shown in Exhibit 2113?

A. Yes, it is.

Ex-1755 at ¶¶ 164-165; Ex-2237 at 172:19-25;
Reply at 16;
Sur-Reply at 7

Zalesky Testimony (Medtronic Expert)

A. I should point out that the exhibit we were looking at just prior, 1763, is, in fact, labeled OTW.

Q. That's right. And it's got a Pebax -- a series of Pebax tubing that is 43 inches, correct?

A. Right.

Q. But that's not the same part that's shown in Exhibit 2089 because the exhibit shown in 2089 is only 11.8 inches, right?

A. Right.

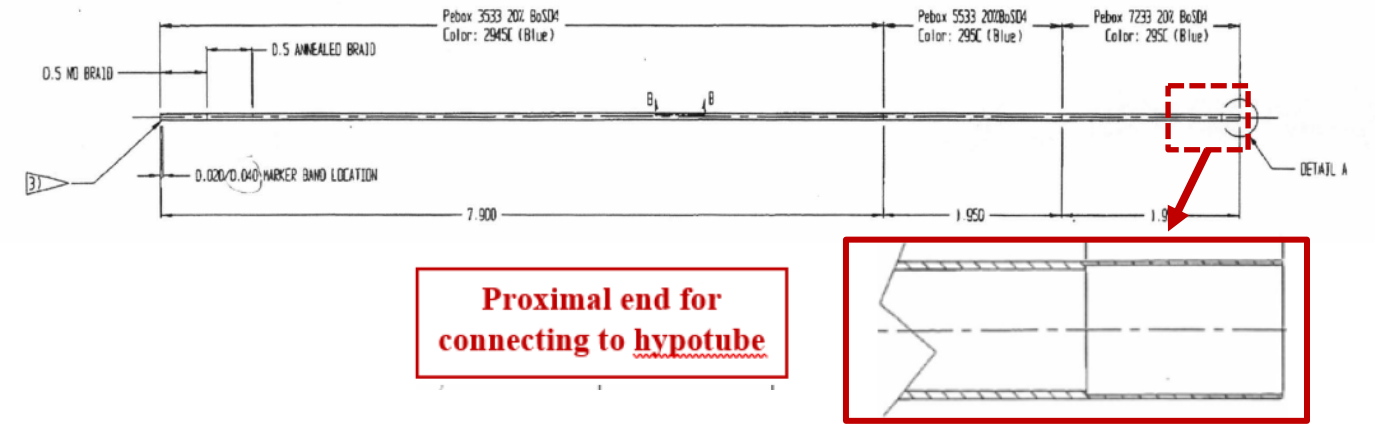
Q. So these are, in fact, two very different parts?

A. They probably are.

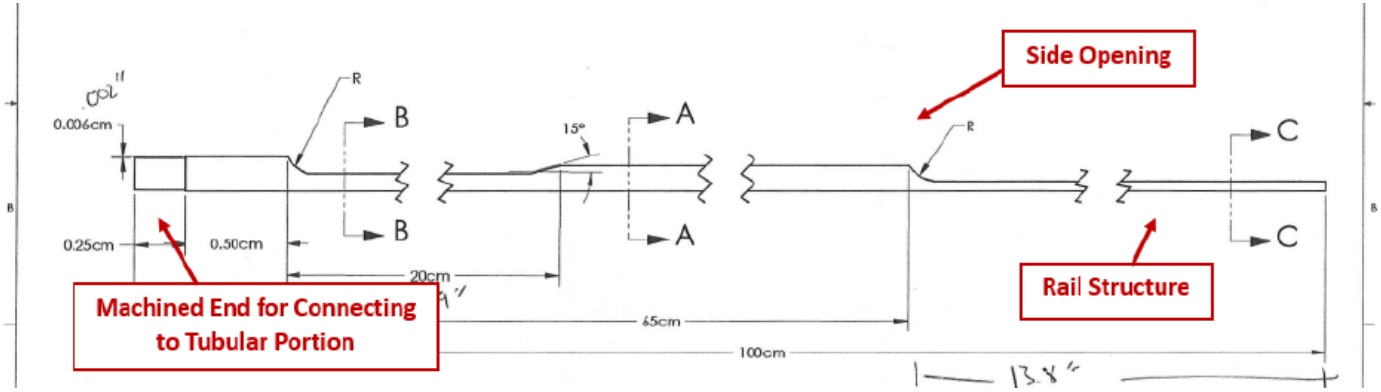
Ex-2237 at 167:7-19;
Sur-Reply at 6-7

Prototype Parts Are Designed to Mate

April Prototype – Distal Portion



April Prototype – Proximal Portion



Ex. 2089, Ex. 2113; Response at 9-11

CORROBORATION OF TESTING

Successful Testing Was Performed – Root Testimony

18. Testing of the GuideLiner prototypes consisted of simulating a procedure in which the GuideLiner would be used, including inserting a standard guide catheter into the coronary model, advancing the prototype into the guide catheter until the distal end of the prototype extended beyond the distal end of the standard guide catheter, and then delivering a stent or balloon catheter into the guide catheter, into and through the tubular portion of the GuideLiner prototype and out the distal end of the GuideLiner prototype. We also observed the forces involved in navigating the GuideLiner prototype through such a model, and performed pull tests to assess the durability of the prototype. Such testing, including testing the rapid exchange GuideLiner prototypes in a bench-top model such as this was sufficient to determine that the concept would work for its intended purpose, namely that a rapid exchange guide extension catheter could deliver interventional cardiology devices, such as a stent or balloon catheter, alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy.

Ex-2118 at ¶ 18;
Response at 7-8, 11-12, 15, 22, 25;
Sur-Reply at 10

Root Testimony

47. Vascular Solutions promptly tested the rapid exchange GuideLiner prototypes it assembled in a bench-top coronary model with test materials it already possessed and acquired. Among other things, Vascular Solutions already had coronary models and balloon catheters (see Exhibits 2018, 2129) and it already had purchased guide catheters into which the GuideLiner could be inserted (Exhibit 2016). Although I already had confidence that the rapid exchange GuideLiner would work for its intended purpose, these tests further confirmed that a rapid exchange GuideLiner including a substantially rigid proximal portion, a side opening having a non-inclined region between two inclined regions, and a tubular portion with a lumen distal of the proximal portion would work for its intended purpose, i.e., facilitate the delivery of balloon catheters and stents deep into coronary arteries while providing increased backup support.

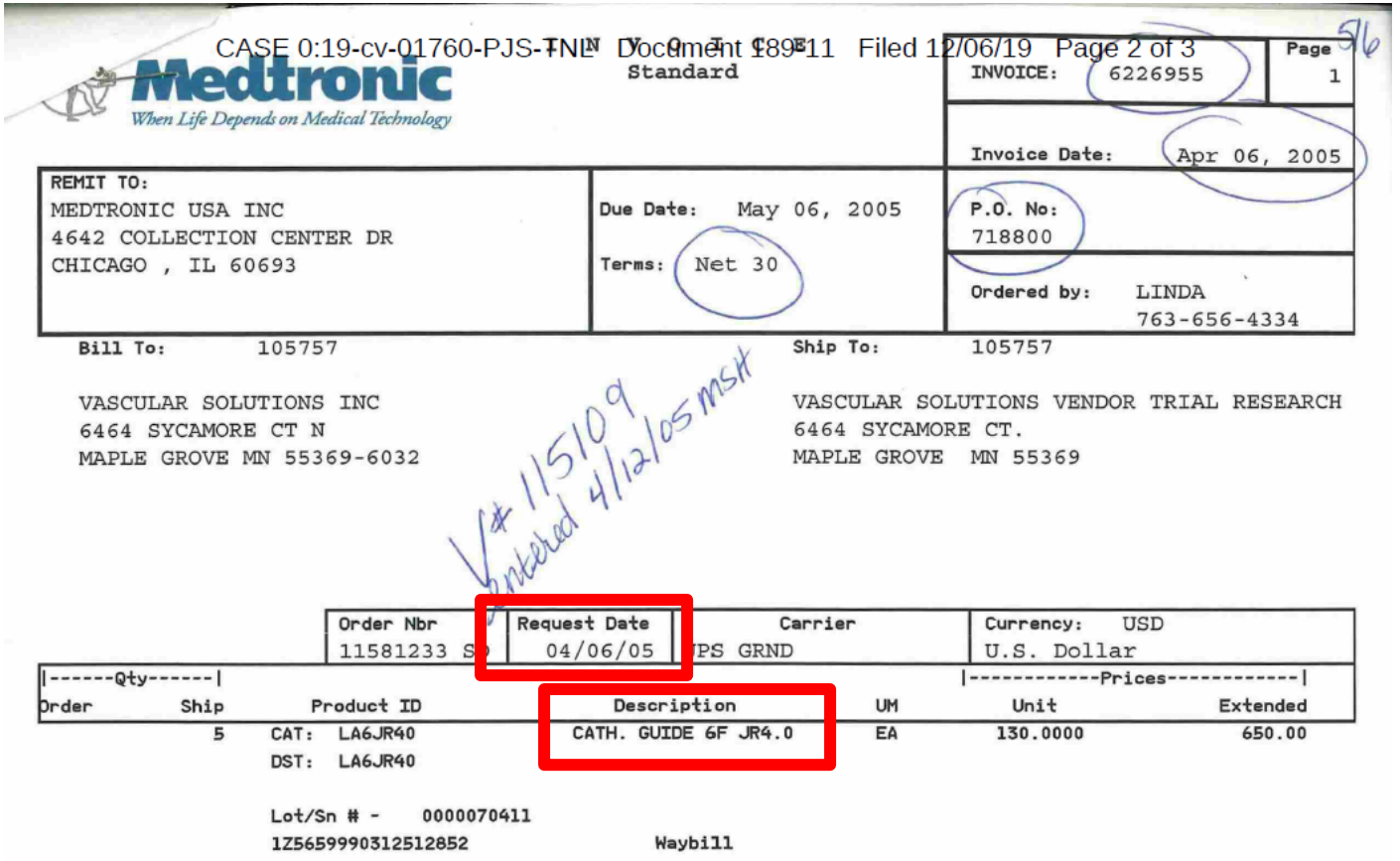
Ex-2118 at ¶ 47;
Response at 11-13, 15, 22, 25

Sutton Testimony

41. Multiple tests were performed on the early GuideLiner rapid exchange prototypes we built in early to mid-2005. We performed pull tests to determine their durability. We accurately measured their dimensions to ensure they could fit inside guide catheters. We used both two-dimensional acrylic heart models and three-dimensional glass heart models to simulate the use of the rapid exchange GuideLiner prototypes. Sometimes tests involving these models were performed in a heated water bath. Other times the tests were performed using dry models. For example, we inserted a standard guide catheter into the model, then inserted the rapid exchange GuideLiner and navigated it beyond the distal end of the guide catheter. We observed the forces involved in navigating the GuideLiner through the guide catheter and beyond to determine that it provided backup support. We also delivered stents and balloon catheters through the rapid exchange GuideLiner in these heart models to ensure such interventional cardiology devices could safely be delivered and would not snag or get caught on the device. This testing was more qualitative than quantitative but based on these tests there was no question in our minds that the prototypes we made would work to deliver interventional cardiology devices and provide additional backup support compared to the guide catheter alone. From that point on our work was on making a commercially appropriate version of the GuideLiner rapid exchange.

Ex-2119 at ¶ 41;
Response at 7, 11-12, 15, 22;
Sur-Reply at 10-11

April 2005 Purchase of 6F Guide Catheters



CASE 0:19-cv-01760-PJS-TNL Document 189-11 Filed 12/06/19 Page 2 of 3

Medtronic
When Life Depends on Medical Technology

Standard

INVOICE: 6226955 | Page 1

Invoice Date: Apr 06, 2005

REMIT TO:
MEDTRONIC USA INC
4642 COLLECTION CENTER DR
CHICAGO , IL 60693

Due Date: May 06, 2005
Terms: Net 30

P.O. No: 718800

Ordered by: LINDA
763-656-4334

Bill To: 105757

VASCULAR SOLUTIONS INC
6464 SYCAMORE CT N
MAPLE GROVE MN 55369-6032

Ship To: 105757

VASCULAR SOLUTIONS VENDOR TRIAL RESEARCH
6464 SYCAMORE CT.
MAPLE GROVE MN 55369

V# 115109 entered 4/12/05 mst

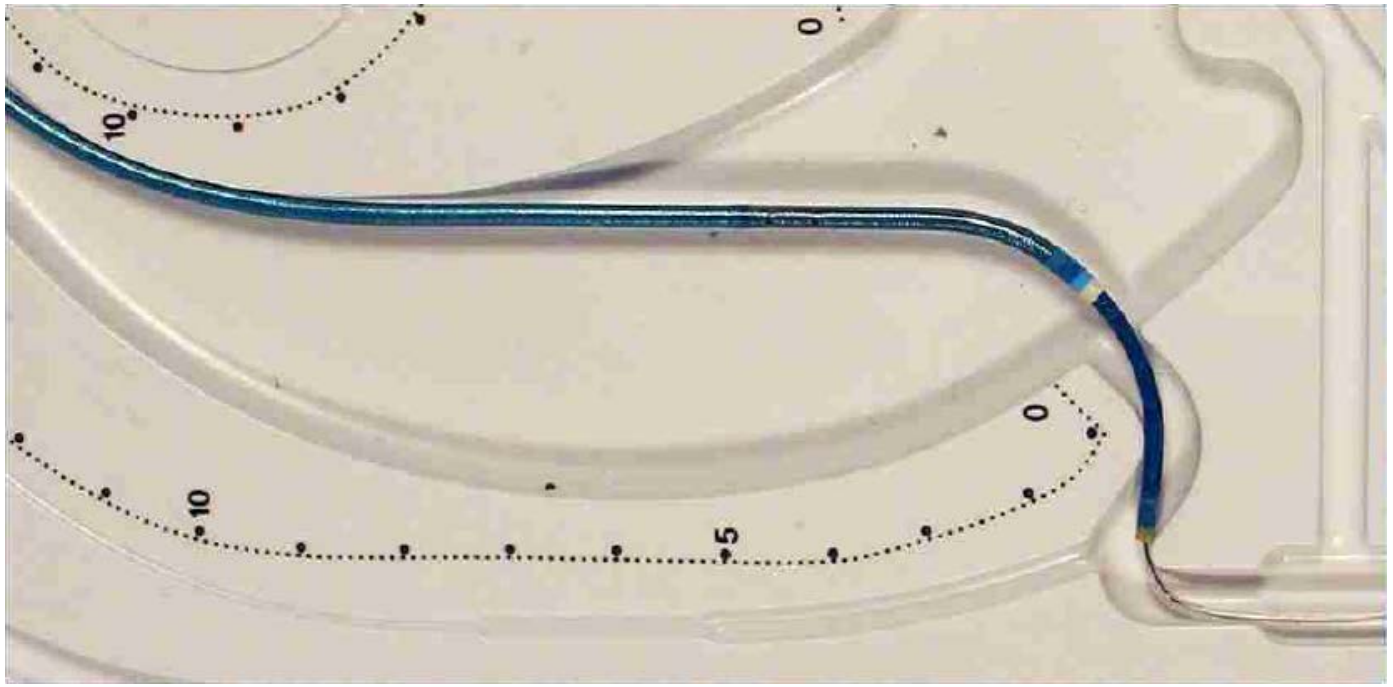
Order Nbr	Request Date	Carrier	Currency: USD
11581233 S0	04/06/05	UPS GRND	U.S. Dollar

Qty Order	Qty Ship	Product ID	Description	UM	Unit Price	Extended Price
	5	CAT: LA6JR40 DST: LA6JR40	CATH. GUIDE 6F JR4.0	EA	130.0000	650.00

Lot/Sn # - 0000070411
1Z5659990312512852 Waybill

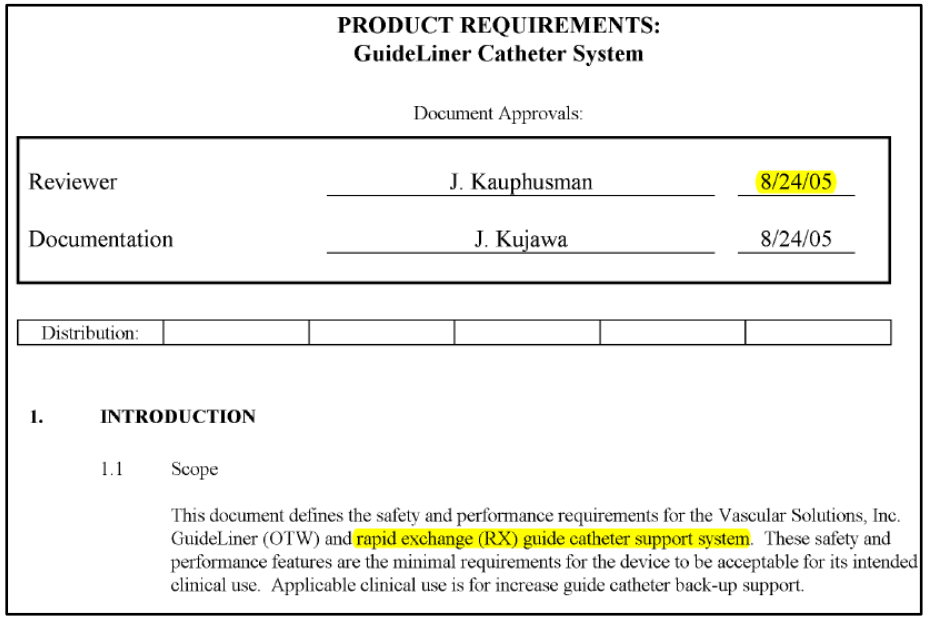
Ex-2016 at 2;
Response at 12;
Sur-Reply at 17-18

July 2005 “New Products” Powerpoint Shows OTW GuideLiner in Heart Model



Ex-2018 at 12;
Response at 11-12, 23

August 2005 Product Requirements (Schmalz)



PRODUCT REQUIREMENTS:
GuideLiner Catheter System

Document Approvals:

Reviewer	J. Kauphusman	8/24/05
Documentation	J. Kujawa	8/24/05

Distribution:					

1. INTRODUCTION

1.1 Scope

This document defines the safety and performance requirements for the Vascular Solutions, Inc. GuideLiner (OTW) and rapid exchange (RX) guide catheter support system. These safety and performance features are the minimal requirements for the device to be acceptable for its intended clinical use. Applicable clinical use is for increase guide catheter back-up support.

Ex-2024;
Response at 17;
Sur-Reply at 9-10

6. Exhibit 2024 is a Product Requirements document for the GuideLiner Catheter System, dated August 24, 2005. Such a document was created for products at the end of the concept development phase. In practice, this meant that a product must have been prototyped, thoroughly tested, and shown to work for its intended purpose before a Product Requirements document was created. A Product Requirements document marked the start of the Regulatory department's formal quality process, which ensured regulatory compliance and quality control for products in the commercialization stage. VSI's quality process was a formal, meticulous, and time-consuming process. Once a Product Requirements document was created, any further changes made or testing performed on the product must be carefully tracked and documented. This quality process was not initiated until a design had been prototyped, tested, and shown to work for its intended purpose.

Ex-2039 at ¶ 6;
Response at 3, 17, 22-24;
Sur-Reply at 8, 10

Zalesky Testimony (Medtronic Expert)

Q. Have you personally ever begun the process for regulatory approval before you knew the product would work for its intended purpose?

A. No, not the formal regulatory process.

Ex-2237 at 64:17-20;
Sur-Reply at 11

August 2005 Clinical Technical Report

Clinical Technical Report:

The Use of Catheters in a Coronary Application: A Clinical Literature Review

Sponsor Identification: Vascular Solutions, Inc
6464 Sycamore Ct. N
Minneapolis, MN 55369
(763) 656-4300
(763) 656-4250 Fax

Sponsor Contact: Gwen Gimmestad
Senior Clinical Research Associate
ggimmestad@vascularsolutions.com

Author Contact: Gwen Gimmestad
Senior Clinical Research Associate
ggimmestad@vascularsolutions.com

The GuideLiner Catheter Systems are designed for use in the coronary vasculature in conjunction with standard guide catheters. The GuideLiner Catheter System provides additional backup support for the existing guide catheter while maintaining access to the distal coronary vasculature. Further, it provides the physician additional guide catheter support without having to upsize the existing guide catheter.

* * *

The GuideLiner RX (Rapid Exchange) Catheter System is a single lumen catheter with an RX port, located in the 0.014" guidewire compatible dilator, which allows for insertion of the catheter over a short guidewire. The pre-loaded stiffening dilator incorporates an atraumatic tip for steerability, while maintaining guidecatheter position in coronary ostium. Once the dilator has been removed a treatment catheter or stent delivery device can be advanced more distally due to the additional backup provided by the device.

Ex-2025 at 1, 6;
Response at 17

August 2005 Clinical Technical Report (Schmalz)

9. Exhibit 2025 is a Clinical Technical Report dated August 26, 2005, which states that VSI "has developed, and is currently manufacturing four types of catheters" including GuideLiner. Ex. 2025 at 2-3. This Clinical Technical Report confirms that by this time, the rapid exchange version of GuideLiner had advanced beyond the concept development phase. These reports are meant to collect issues identified by the regulatory department that may need to be considered in the process of obtaining FDA approval for a product. This Clinical Technical Report is consistent with both the Product Requirements document and my recollection of the GuideLiner development process.

Ex-2039 at ¶ 11;
Response at 17, 22-23;
Sur-Reply at 8

Corroborating Testimony - Erb

Q. When you say you were personally involved, what was your role?

A. I would have been standing there next to whoever was testing. So that would have been my personal role. Assisting, I guess would be the term.

Q. You were standing there or you were assisting?

A. Well, it would have been both. Whatever was required of me being a technician. So sometimes I may not -- may not have a role, but I would still be there just in case we needed something or -- also, it was exciting. I would be there just to see how it worked.

Ex-1756 at 67:6-19;
Reply at 20

Corroborating Testimony - Erb

Page 94

Q. So if you look at the drawing, it's dated June 21st, 2005?
A. Correct.
Q. Is this a Vascular Solutions drawing?
A. Yes.
Q. And if you look at the drawing, you can see that there's a -- I guess, does the drawing look to you to be a cut-down hypotube?
A. Yes, it does.
Q. And do you recall seeing a prototype like this that was made in 2005?
A. I do not remember.
Q. And if you look at the bottom left on the notes of the drawing, it says, "Material: Stainless Steel Hypotube .068 by .004 Wall".
Do you see that?
A. Yes.
Q. Does that refresh your memory at all of whether this -- this -- a prototype was made using this part in 2005?
A. Yes, it does. Yeah. That's the same hypotube we -- we would have used.
Q. And so do you -- looking more at the document, do you recall seeing a prototype made using this part in 2005?

Page 95

A. Yes. I remember the turned-out end there, that 50-thousandths part to the left of the distal end.
Q. Okay. Now, you -- you testified on questioning from counsel that you witnessed testing of prototypes.
Do you recall that -- that questioning?
A. Correct.
Q. Was the prototype shown in Exhibit 2114 tested and -- and shown to work?
A. Yes.
Q. And what do you mean by it worked?
A. Well, it -- it functioned. It -- it did what we thought it would do. It could go inside of a vessel on the -- on the benchtop, and we could launch -- use it as a launching pad to further another catheter.
Q. Counsel asked you, Mr. Erb, questions regarding prototypes that you made in January of 2005.
Do you recall that questioning?
A. Yes.
Q. If you could go into the Exhibit Share folder and if you click the little black arrow back, it

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

Ex-1756 at 94-95

Corroborating Testimony – Schmalz

11. Exhibit 2041 is part of the materials presented to the Vascular Solutions Board of Directors in connection with its October 2005 meeting. This document contains a Marketing Update from October 2005 provided by VSI's CEO and one of the GuideLiner inventors, Howard Root, and another employee, Fred Reuning. The Marketing Update explains that the GuideLiner product "has received extremely favorable early concept reviews from our physician advisors." Ex. 2041 at 4. This demonstrates that GuideLiner had been prototyped, tested, and confirmed to work for its intended purpose before October 2005, which is consistent with my recollection of the GuideLiner development process. Indeed, given that we had received physician feedback by October 2005 is consistent with my recollection that GuideLiner had been prototyped, tested, and confirmed to work for its intended purpose months before that, and certainly before August 24, 2005, the date of the Products Requirement document of Exhibit 2024. Obtaining physician feedback took time because products had to be constructed, physician evaluators had to be engaged, the physicians had to evaluate the product, and then provide feedback to us on the product.

Ex-2039 at ¶ 11;
Response at 3, 23;
Sur-Reply at 8

No Testing Required When a POSITA Knows the Invention Will Work

"Less complicated inventions and problems do not demand stringent testing. In fact, some inventions are so simple and their purpose and efficacy so obvious that their complete construction is sufficient to demonstrate workability."

Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578 (Fed. Cir. 1996); Response at 21, 25

"[W]hen the problem to be solved does not present myriad variables, common sense similarly permits little or no testing to show the soundness of the principles of operation of the invention."

Scott v. Finney, 34 F.3d 1058, 1061-63 (Fed. Cir. 1994); Response at 21-22

Brecker Testimony (Medtronic Expert)

Q. Okay. In -- in fact, it's the opposite. Your opinion is that [Itou's suction catheter] inherently will work to deliver stents.

A. Yes. I don't see why it would not.

Q. Okay. Now -- and -- and that's not just your opinion, you know, as Dr. Brecker. You think one skilled in the art --

A. Yes.

Q. -- would -- would recognize that this thing would function to deliver stents inside an artery?

A. Yes. Yeah. I think if you showed that to a skilled cardiologist around the early to mid 2000s or even the late 1990s, they would say yes, that -- you could use that to deliver a stent.

Q. Okay. And -- and -- and they would say it will work.

A. They would expect it to work.

* * * *

Q. Okay. Okay. So -- so as long as the relative sizes were satisfactory, even in 2005, a person of skill in the art would believe that a suction catheter like shown in Itou would work to deliver stents?

A. Yes, I think so.

Q. Even without testing.

A. I think so.

Ex-2116 at 106:8-24, 109:2-9;
Response at 25-26

Brecker Testimony (Medtronic Expert)

Q. I really am trying to understand whether the -- the basis for your belief that the Itou device that one skilled in the art would -- would believe that it would work to provide backup support, and it sounds like the answer to that question is –

A. Yes.

Q. -- yes, one skilled in the art would believe that opinion?

A. Yes. One skilled in the art would definitely and firmly believe that putting an Itou suction catheter down the coronary artery would give you more support. It has to.

* * * *

Q. Even in 2005 you're saying somebody skilled in the art would have known that?

A. They would have known it because we did -- you know, we -- we used longer sheaths to give support to the guide catheter. Wherever you had something inside something else, it was more supportive, inherently so.

Ex-2116 at 113:2-24;
Response at 26;
Sur-Reply at 9, 16

Jones Testimony (Medtronic Expert)

Q. Okay. Same question with respect to the Itou device. Do you agree that a person of skill in the art would know that the Itou device would improve backup support?

A. Yes. Again, in the Itou device, they show a guide catheter with a suction catheter within it. And the combination would increase backup support.

Ex-2241 at 86:21-87:2;
Sur-Reply at 9, 16

Petitioner's Assertion of Inherency Obviates Need for Testing Evidence

"Petitioners further argue that Patent Owner's antedation evidence fails to establish that HuMAb4D5-5 and HuMAb4D5-8 would work for their intended purpose.... Although Patent Owner sufficiently documents the binding properties of HuMAb4D5-5 and HuMAb4D5-8 (see PO Resp. 39–40), Petitioners argue that Patent Owner fails to provide any evidence of immunogenicity testing.

* * * *

Petitioners' argument is also undercut by their assertion that 'immunogenicity compared to a non-human parent [is] an inherent aspect of the claimed humanized antibodies.' In light of Petitioners' admission, HuMAb4D5-5 and HuMAb4D5-8 would necessarily have such "reduced immunogenicity."

Pfizer, Inc. v. Genentech, Inc., IPR2017-01488, Paper 12 at 23-24 (PTAB, Nov. 29, 2018); Sur-Reply at 9, 16

Testing in a Heart Model Was Sufficient

"[T]ests performed outside the intended environment can be sufficient to show reduction to practice if the testing conditions are sufficiently similar to those of the intended environment."

DSL Dynamic Scis., Ltd. v. Union Switch & Signal, Inc., 928 F.2d 1122, 1125 (Fed. Cir. 1991); Response at 24-25; Sur-Reply at 11

"Dr. Mahurkar designed these tests to show the efficiency of his structure knowing that polyethylene catheters were too brittle for actual use with humans. But, he also knew that his invention would become suitable for its intended purpose by simple substitution of a soft, biocompatible material. Dr. Mahurkar adequately showed reduction to practice of his less complicated invention with tests which did not duplicate all of the conditions of actual use."

Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578 (Fed. Cir. 1996); Response at 21, 25

Keith Testimony (Teleflex Expert)

21. It was in 2005, and remains today, standard practice in the medical device industry to test new designs on bench models that simulate the native environment in which they would be used to determine whether those designs would work for their intended purpose. This was particularly true in 2005, and is still today, for catheter related designs in the interventional cardiology space.

* * * *

23. It is further my opinion that testing a prototype GuideLiner device in a bench model that simulates the native environment would be sufficient to show that the device works for its intended purpose. Such a test would be consistent with industry practice in 2005 (and even still today) to demonstrate that cardiac catheter devices work for their intended purpose.

Ex-2123 at ¶¶ 21, 23;
Response at 12, 25

Quantitative Test Results Are Not Required

Under the “rule of reason,” the inventor’s testimony must be sufficiently corroborated by independent evidence, but not necessarily documentary evidence.

Loral Fairchild Corp. v. Matsushita Elec. Indus., 266 F.3d 1358, 1364-65 (Fed. Cir. 2001);
Response at 24; Sur-Reply at 6, 10

Although no direct evidence supported Goldfarb’s testimony that he measured fibril length and observed tissue ingrowth in July of 1973, we agree with the Board that circumstantial evidence provided sufficient corroboration.

Cooper v. Goldfarb, 154 F.3d 1321, 1330 (Fed. Cir. 1998);
Response at 24; Sur-Replyat 8

Keith Testimony (Teleflex Expert)

22. Similarly, it is my opinion that, to the extent testing of a GuideLiner prototype were necessary at all, qualitative testing of a prototype would be more than sufficient to reduce the invention to practice if the testing showed that the prototype (a) could be delivered through a guide catheter so that the distal end of the tubular portion extended beyond the distal end of the guide catheter while being tracked over a winding path; and (b) allowed a stent delivery catheter or balloon catheter to pass into the tubular portion and out the far end of the tubular portion while located within the guide catheter.

Ex-2123 at ¶ 22;
Response at 12, 25

Zalesky Testimony (Medtronic Expert)

Q. Can you assess backup support qualitatively?

A. You can do it both qualitatively and quantitatively.

***

Q. Is quantitative data required to show intended purpose?

A. I don't think it's necessarily required.

Ex-2237 at 37:11-13, 39:7-9
Response at 12, 25

Time or Changes Prior To Commercialization Do Not Disprove RTP

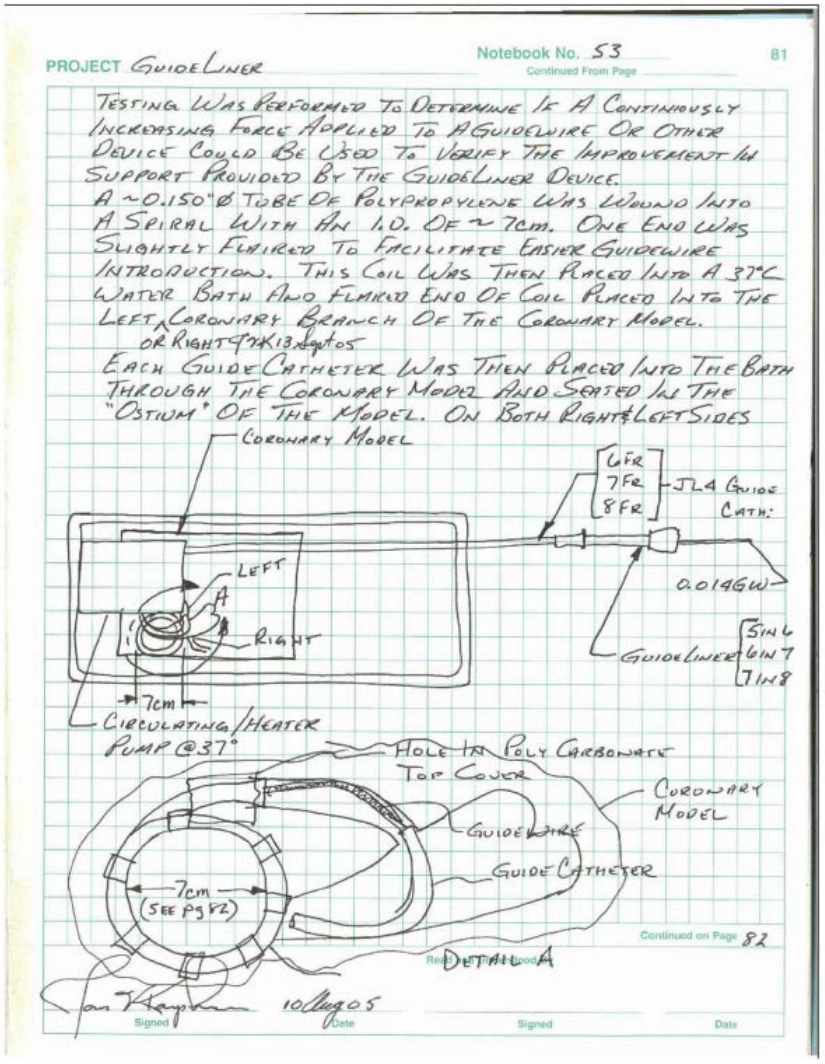
"Reduction to practice does not require that the invention, when tested, be in a commercially satisfactory stage of development. . . ."

Scott v. Finney, 34 F.3d 1058, 1061-63 (Fed. Cir. 1994); Response at 21-22

"Once the invention has been shown to work for its intended purpose, reduction to practice is complete. Further efforts to commercialize the invention are simply not relevant to determining whether a reference qualifies as prior art against the patented invention."

Loral Fairchild Corp. v. Matsushita Elec. Indus., 266 F.3d 1358, 1362-63 (Fed. Cir. 2001); Response at 27; Sur-Reply at 11

Formal Testing Followed Proof of Conception



PROJECT GuideLiner

Notebook No. 53

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Continued From Page

Testing Was Performed To Determine If A Continuously Increasing Force Applied To A Guidewire Or Other Device Could Be Used To Verify The Improvement In Support Provided By The GuideLiner Device.
A ~0.150"Ø Tube Of Polypropylene Was Wound Into A Spiral With An I.D. Of ~ 7cm. One End Was Slightly Flared To Facilitate Easier Guidewire Introduction. This Coil Was Then Placed Into A 37°C Water Bath And Flared End Of Coil Placed Into The Left Coronary Branch Of The Coronary Model.
OR Right ~~Trk 13~~ 10/05
Each Guide Catheter Was Then Placed Into The Bath Through The Coronary Model And Seated In The "Ostium" Of The Model. On Both Right & Left Sides

Coronary Model
6Fr
7Fr
8Fr
JL4 Guide Cath.
0.014GW
Left
A
Right
GuideLiner
Sin 6
6in 7
7in 8
7cm
Circulating/Heater Pump @37°
Hole In Poly Carbonate Top Cover
Coronary Model
Guidewire
Guide Catheter
7cm (See Pg 82)
Continued on Page 82
Detail A
10/19/05
Signed
Date
Signed
Date

Ex-1760, p. 86;
Reply at 10

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

Zalesky Testimony (Medtronic Expert)

Q. And is the testing that's required for a 510(k) the same testing that is required to show reduction to practice for patentability?

A. No, no, no, no, no. The testing requirement for regulatory submission such as a 510(k) is quite extensive. It requires detailed protocols. It requires statistical significance in most cases. It requires formal biocompatibility. It requires additional tests.

So it's a – it's a very significantly different level than that required to demonstrate reduction to practice.

* * * *

Q. In other words, there might be more specific FDA requirements, but you're talking in paragraph 55 about FDA testing, not the testing that occurs in the earlier phases, right?

A. Correct. This is much more rigidly controlled testing, where, for instance, you can't just use two or three prototypes. You need to construct a meaningful number that will satisfy statistical requirements.

Ex-2237 at 63:23-64:9, 115:21-116:4;
Sur-Reply at 5, 11

Root Testimony

90. In addition, for medical products it is not unusual for extensive specification and testing work, including engineering refinements, to be needed between the point that the idea is shown to work in prototype and FDA clearance and commercial introduction. There is a big difference between (a) building one (or even 20) medical device prototypes that work; and (b) cost effectively building thousands of products to close tolerances and in accordance with strict safety protocols as required by the FDA.

Ex-2118 at ¶ 90;
Response at 19, 27;
Sur-Reply at 11

Keith Testimony (Teleflex Expert)

25. I also note and understand that there is a difference between reducing an invention to practice (i.e., showing that it will work for its intended purpose) and refining a design such that the product can be made commercially in a sufficiently durable and profitable way. It is not uncommon for medical device products, and in particular catheter-related designs in the interventional cardiology space, to take many years from the point of proving that a design will work for its intended purpose to the point of having a commercially viable product ready for FDA approval.

Ex-2123 at ¶ 25;
Response at 19, 27

Zalesky Testimony (Medtronic Expert)

Q. Do you have any experience with an invention that you showed would work for its intended purpose, for the patentability sense, but then you later made design changes?

A. Oh, that's quite common, yes.

* * * *

[Q:] But if the declarants are speaking truthfully, as you have testified they are . . . and the prototypes were reduced to practice and tested and shown to work for their intended purpose, as they testified the GuideLiner rapid exchange prototypes were, it really didn't matter what VSI did or didn't do to the design after that point for purposes of patentability, did it?

Once it's reduced to practice, it's reduced to practice, right?

A. Right. If those things actually occurred, then what you just said is correct.

Ex-2237 at 43:22-44:1, 194:22-23, 195:1-11;
Sur-Reply at 11

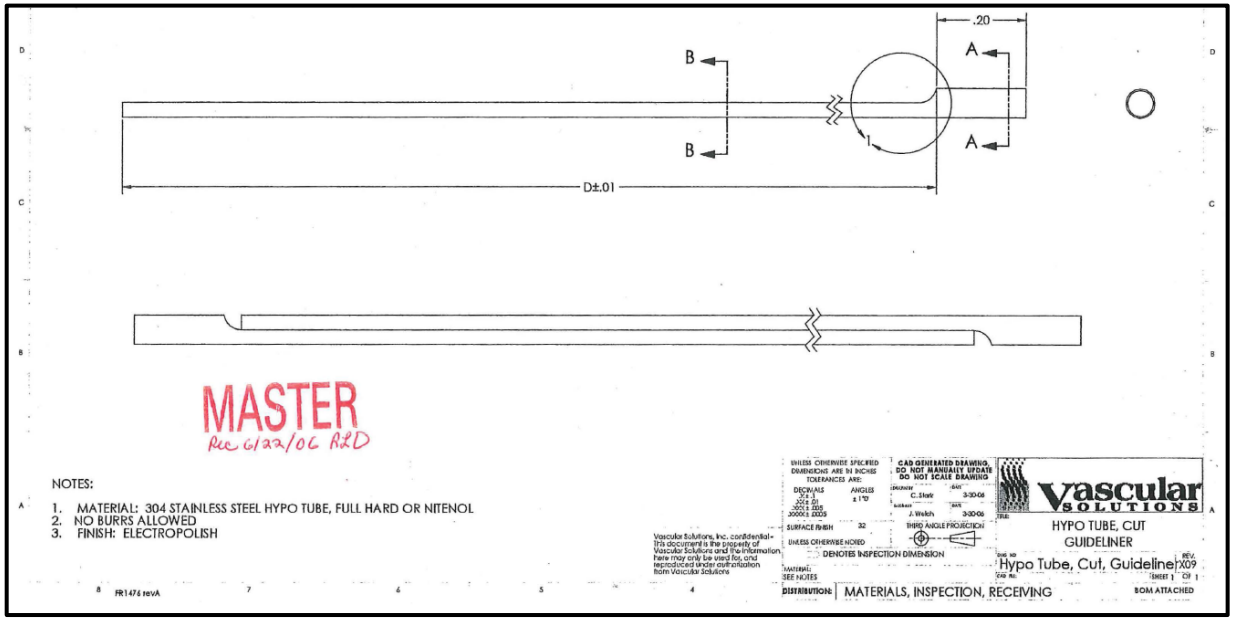
Root Testimony

65. **Exhibit 2100** is a true and correct copy of a Vascular Solutions, Inc. 2006 Strategic Objectives document, labeled as being drafted on December 1, 2005. Although VSI had produced working prototypes of the rapid exchange GuideLiner, we realized that additional work would be needed in order to make a commercial version of the product, for example one that could be produced at scale and at reasonable cost. Exhibit 2100 indicates that this work would continue through the end of 2006.

Ex-2118 at ¶ 65;
Response at 19;
Sur-Reply at 11

Post-Conception Work Was for Commercialization

70. Exhibit 2115 shows an additional engineering drawing drawn on March 30, 2006 and obtained from the files of SPECTRAlytics. The bottom figure of this drawing shows an attempt to cut two GuideLiner rapid exchange proximal portions out of a single hypotube in order to simply and reduce costs of manufacturing.



Ex-2118 at ¶ 70; Ex-2115;
Response at 7-8, 19; Sur-Reply at 11

Personnel Changes

Root Declaration

89. One reason why the rapid exchange GuideLiner was not commercialized until 2009 is that we had substantial turnover in R&D personnel at VSI in the 2006-08 timeframe, which delayed commercialization efforts for many of our new medical devices from our original projected launch dates.

Ex-2118 at ¶ 89;
Response at 19; Sur-Reply at 11

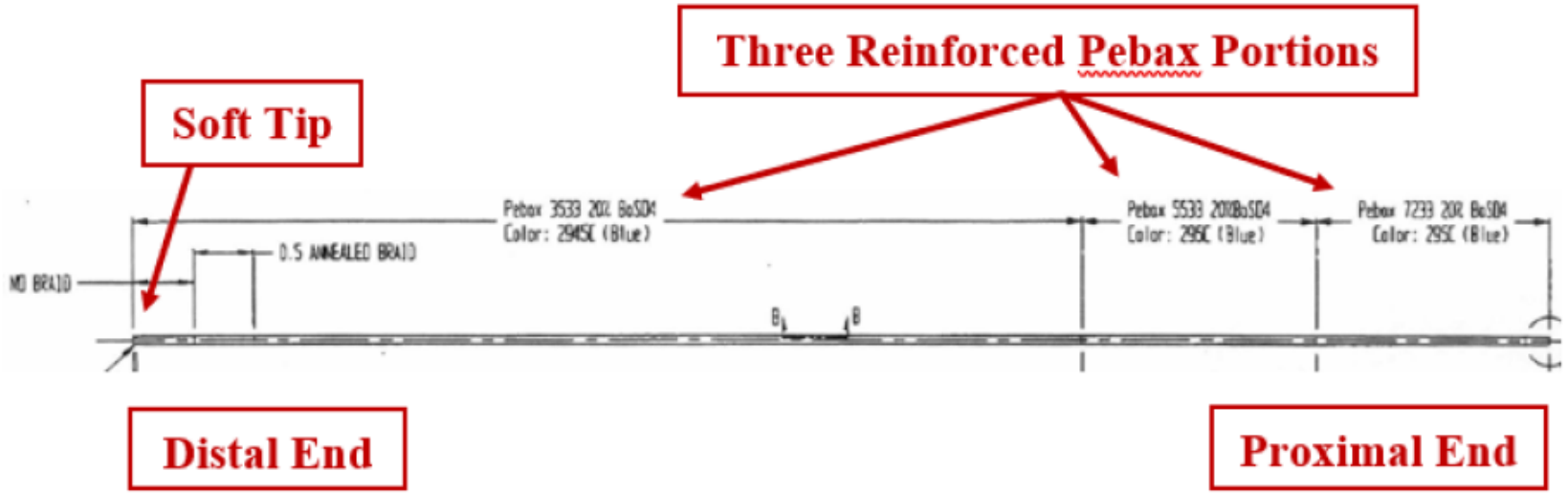
Sutton Declaration

2. I began working at Vascular Solutions, Inc. ("VSI") as Vice President, Research & Development in 2004, and I continued in a similar role until mid-2006. My role was to oversee development of new products for the company. Starting in late-2004 until I left VSI, I performed research and development work on what became the GuideLiner guide extension catheter.

Ex-2119 at ¶ 2;
Response at 2

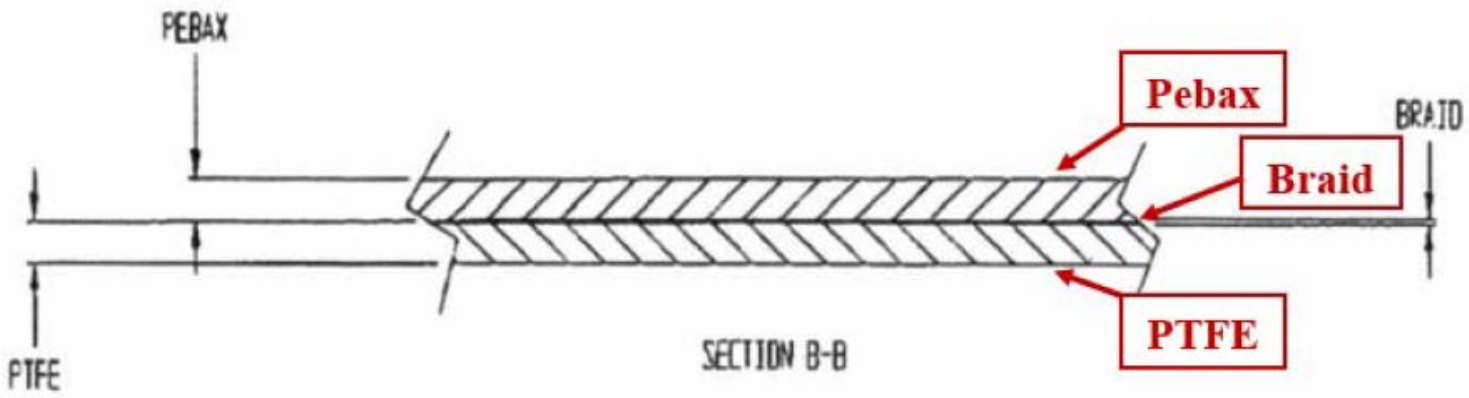
THE PROTOTYPES PRACTICED THE CLAIMED INVENTION

Annotated MED Drawing



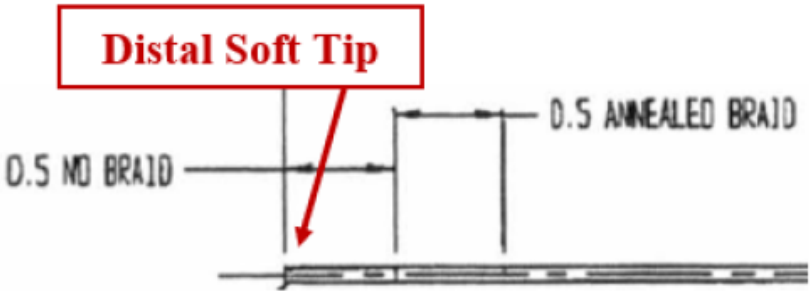
Response at 9

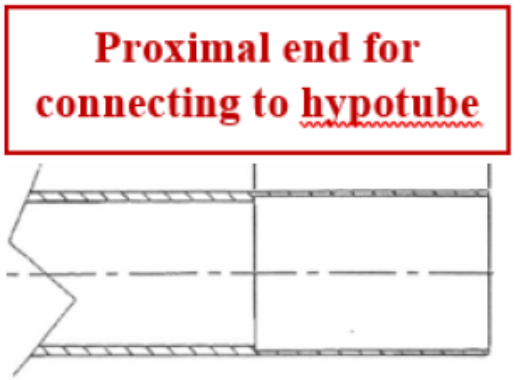
Annotated MED Drawing



Response at 9

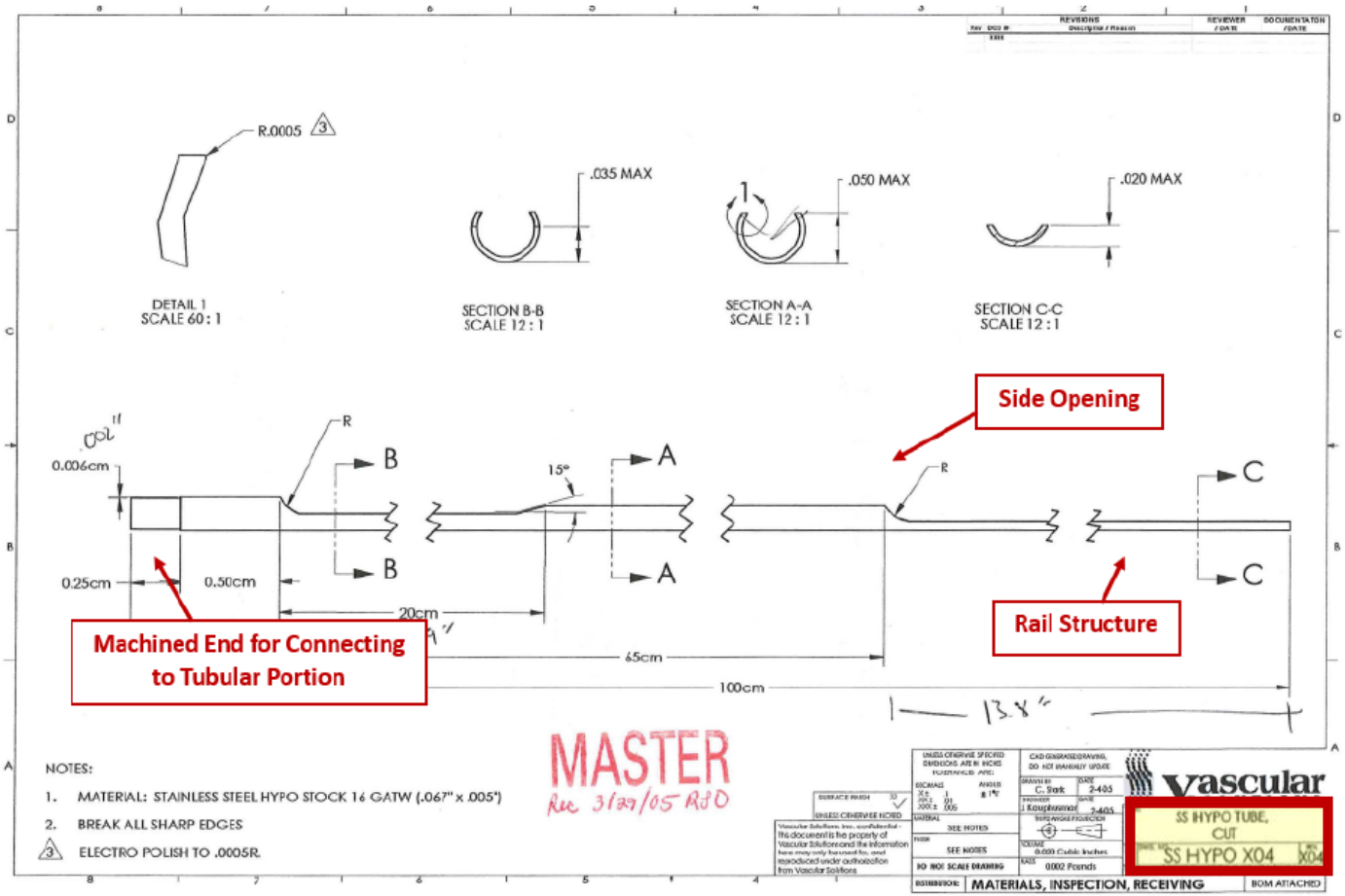
Annotated MED Drawing





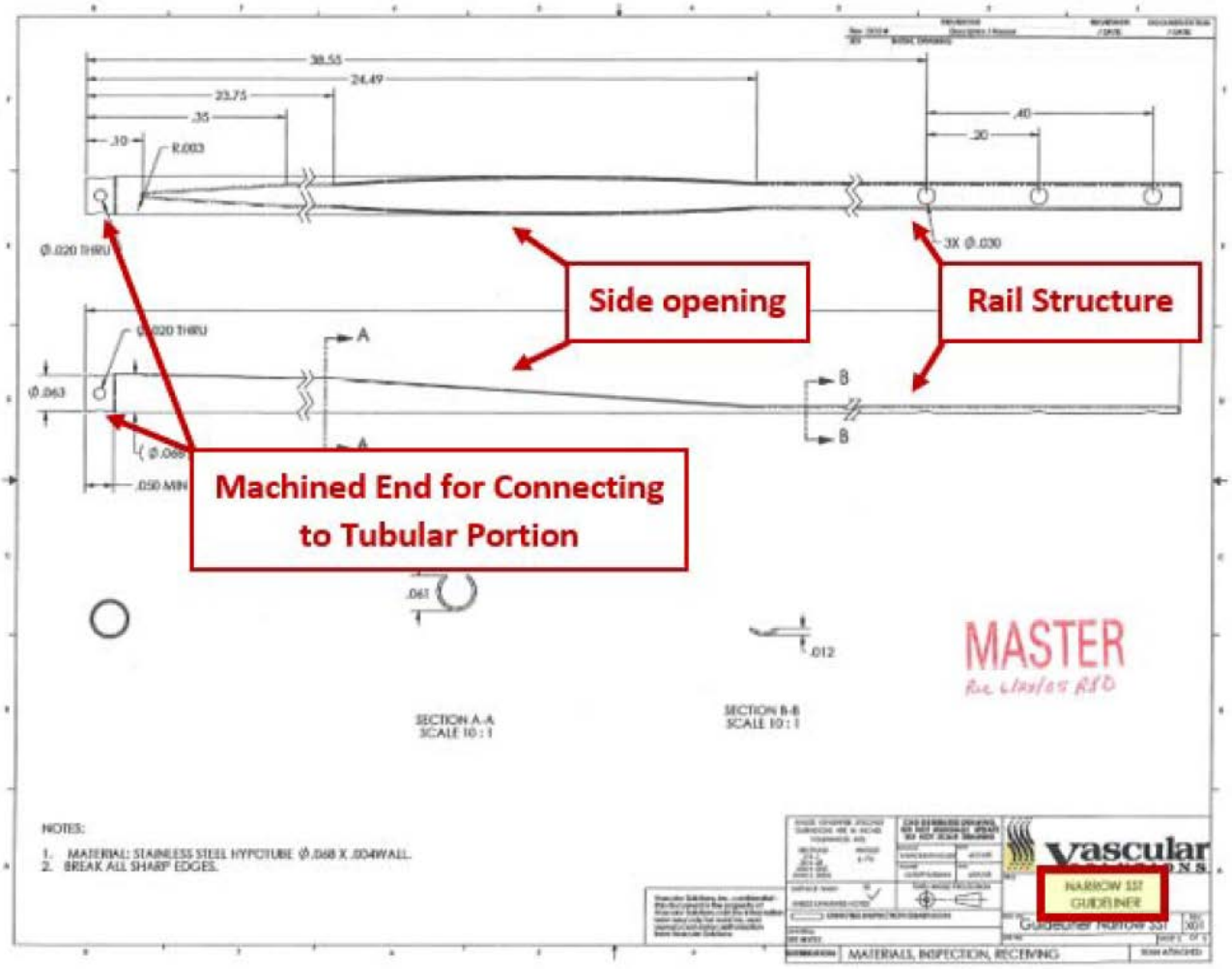
Response at 10

Annotated Spectralytics Drawing



Response at 11

Annotated Spectralytics Drawing



Response at 14

Patent Figures

Fig. 12

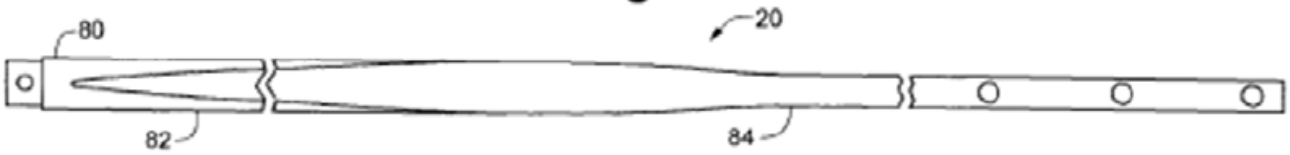


Fig. 13

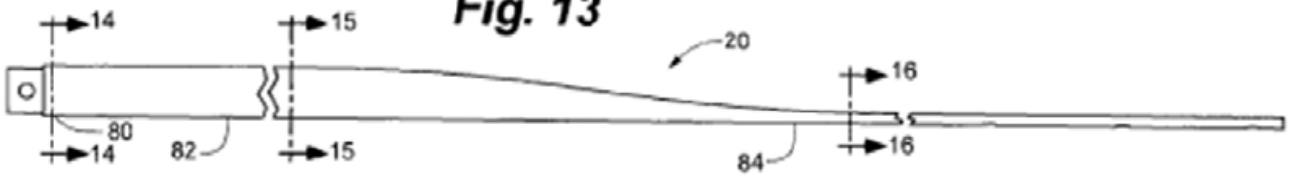


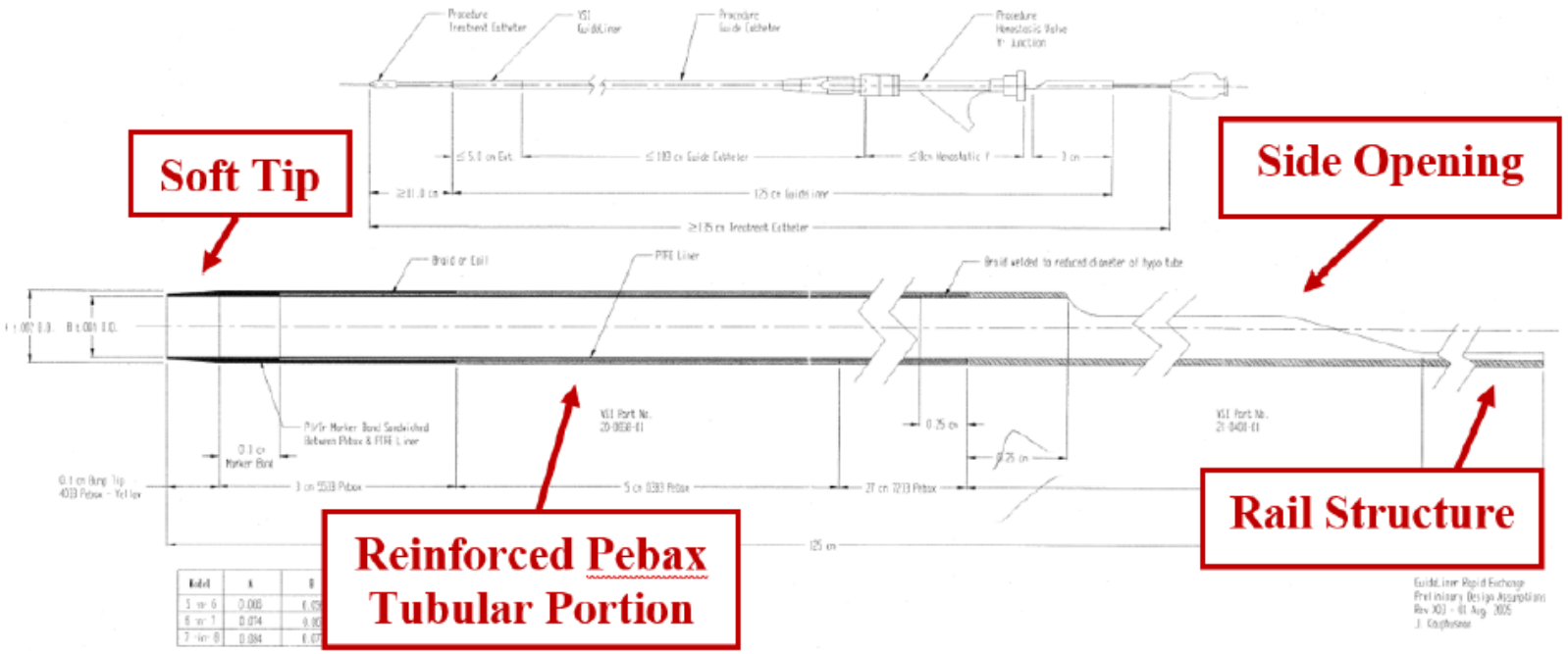
Fig. 14

Fig. 15

Fig. 16

Response at 15

August 2005 Annotated Drawing

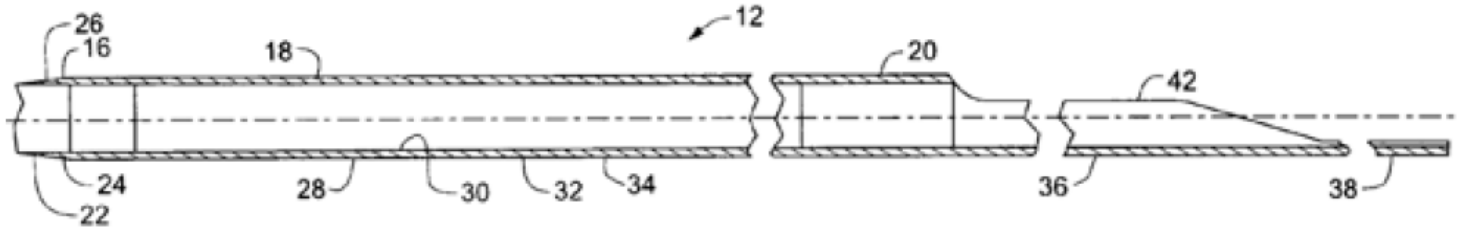


Sur-Reply at 5

Patent Figures

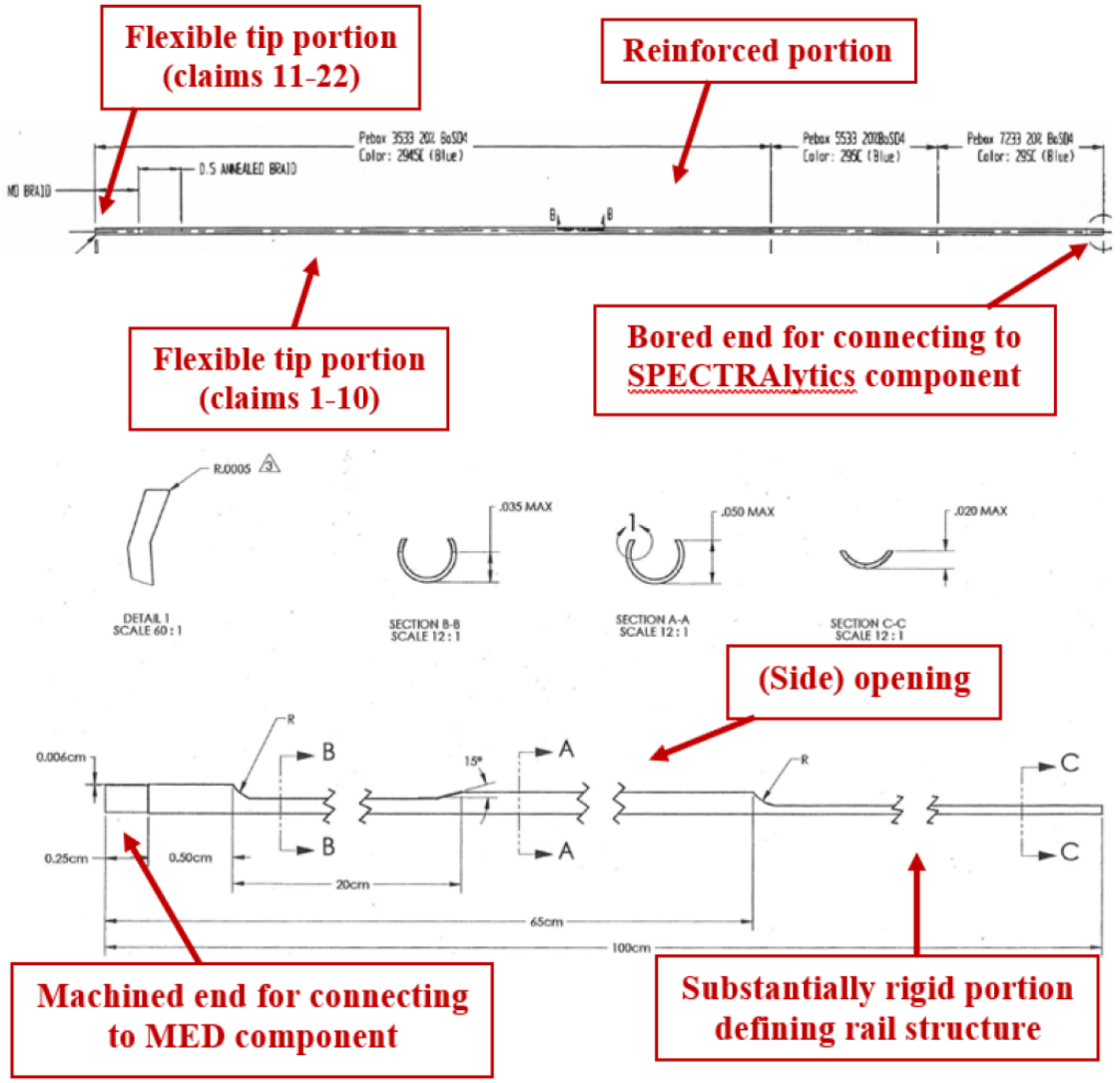
Fig. 3

Fig. 4

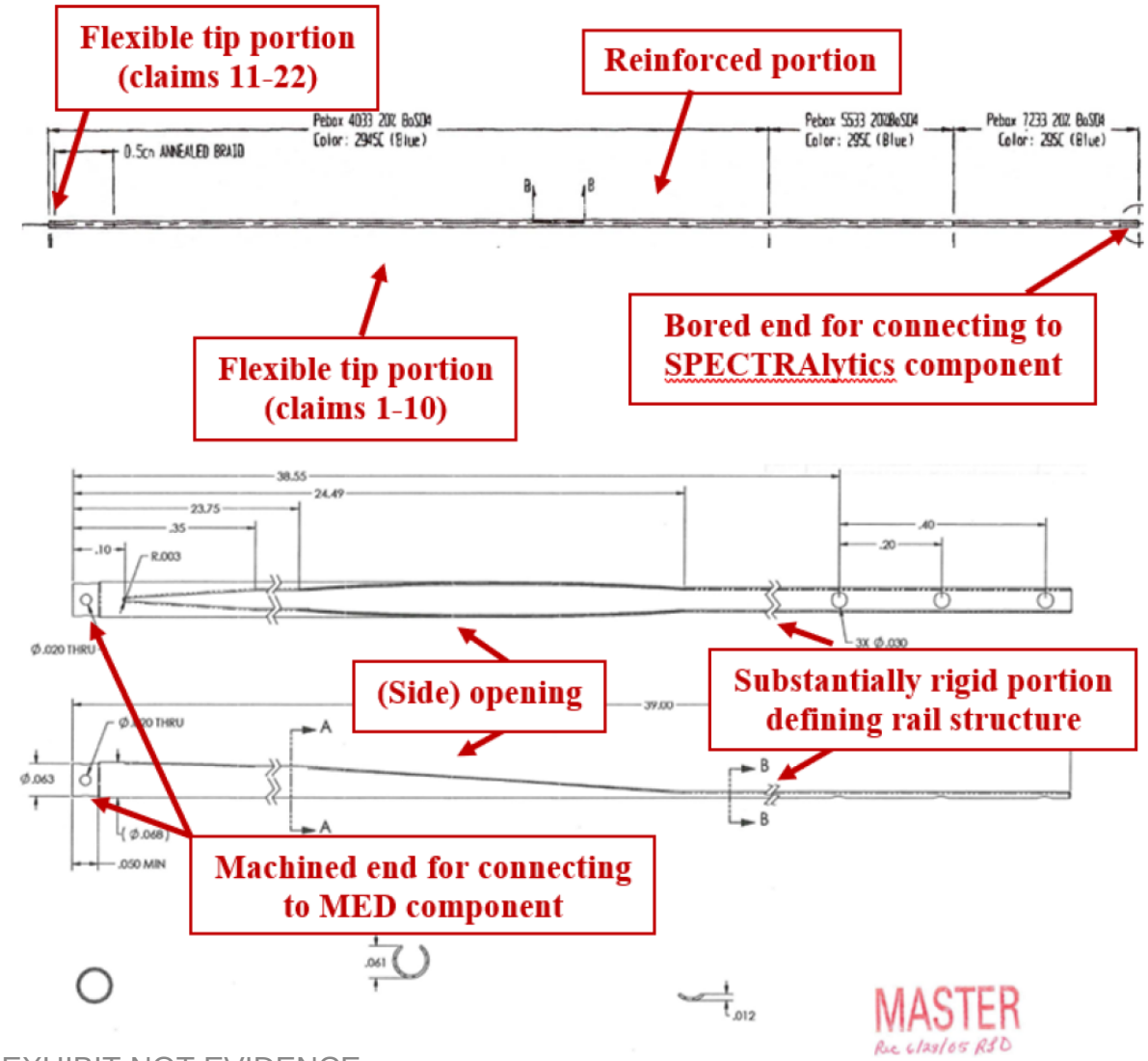


Response at 16

Annotated April Prototypes ('032 Patent)



Annotated July Prototypes ('032 Patent)

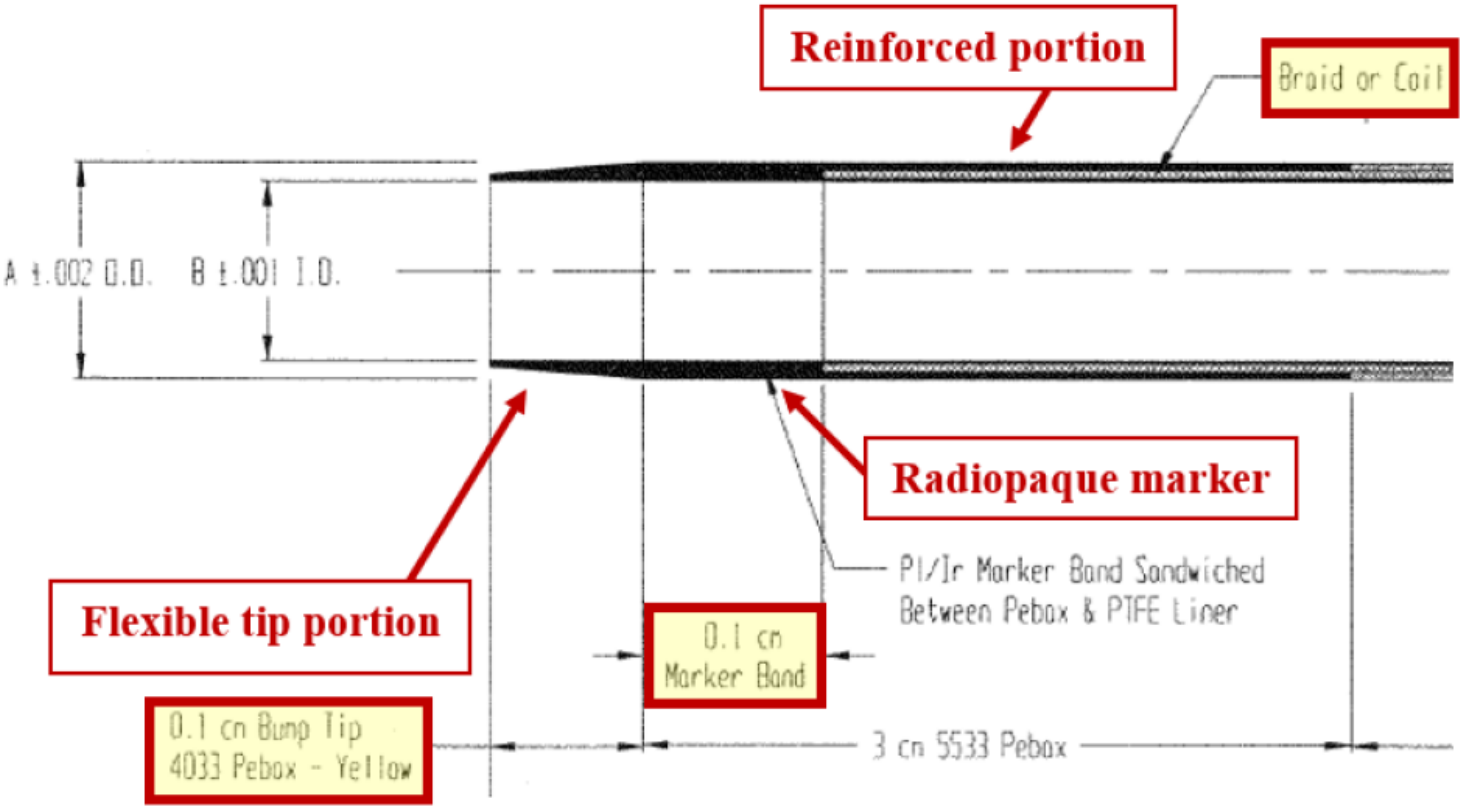


MASTER

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

Sur-Reply at 14

Annotated Computer Drawing



Sur-Reply at 16

Zalesky Testimony (Medtronic Expert)

Q. So with respect to your opinion on construction and reduction to practice, you have not formed an opinion about what the claim terms mean; is that correct?

A. That's correct.

Q. So when you say, for example, the prototype that Mr. Root speaks of didn't have a particular claim element, you're not basing that understanding -- or basing that opinion on any understanding of what the claim element means. You're just saying that Mr. Root hasn't corroborated his opinion.

Is that your -- is that what you've done with your report here? . . .

[A.] Yes, that's correct.

Ex-2237 at 216:8-12, 216:13-21, 216:24;
Sur-Reply at 12, 17

Zalesky Testimony (Medtronic Expert)

[A.] But all of my rebuttal comments are very specific to Mr. Root's assertions, and largely depend on my absence of evidence introduced regarding an actual prototype and actual testing of the prototype for its intended use.

Q. So you're not applying any understanding that you may have of the claim terms in forming --

A. That's correct.

Q. -- your opinions?

That's correct?

A. Yes.

Ex-2237 at 218:1-12;
Sur-Reply at 12, 17

Zalesky Testimony (Medtronic Expert)

Q. Okay. So then let's move to Exhibit 2092. And this is the MED distal section from the July GuideLiner prototype.

A. Okay.

* * * *

Q. And so there is .1 centimeter of a distal tip that's not a marker band and not annealed braid, right?

A. Okay.

Q. Do you agree with that?

A. Yes.

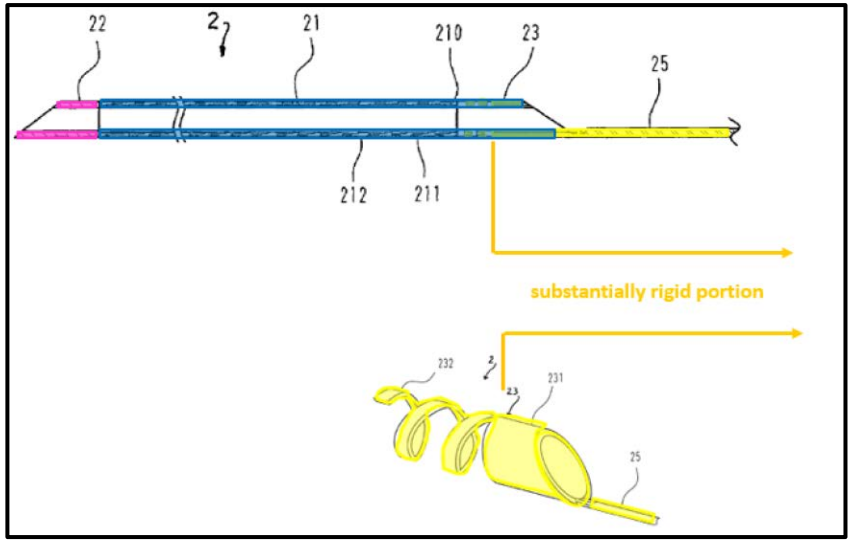
Ex-2237 at 176:10-13, 179:24-180:4;
Response at 15

Teleflex Need Not Show Any More Than Shown in Itou

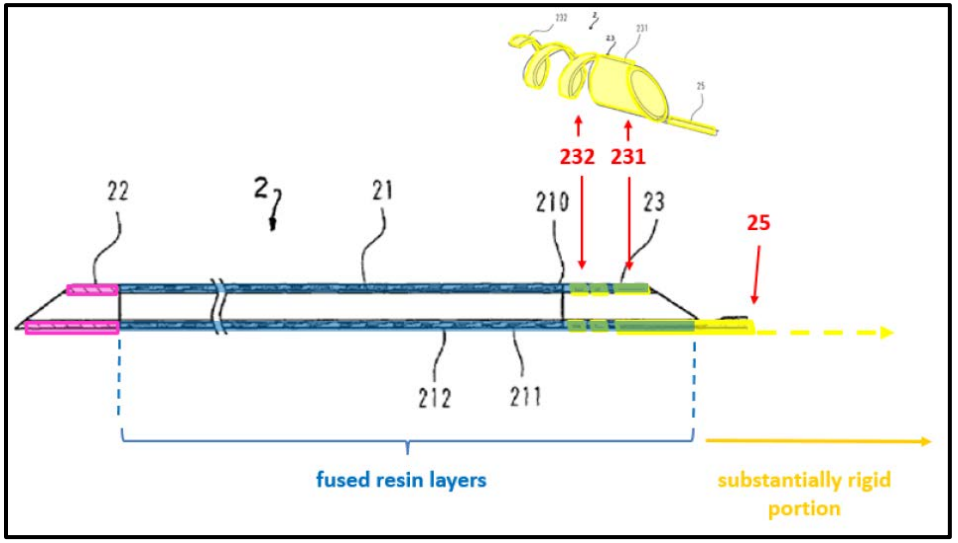
"Alternatively, to the extent Petitioners are incorrect about the inherency of reduced immunogenicity, neither Kurrle nor Queen 1990 provides evidence of immunogenicity testing, and Patent Owner has antedated as much of the claimed invention as shown in those references. *See In re Stempel*, 241 F.2d 755, 759 (1957) ("all the applicant can be required to show is priority with respect to so much of the claimed invention as the reference happens to show. When he has done that he has disposed of the reference"); *In re Stryker*, 435 F.2d 1340, 1341 (1971)."

Pfizer, Inc. v. Genentech, Inc., IPR2017-01488, Paper 12 at 24 (PTAB, Nov. 29, 2018); Sur-Reply at 9, 16

Brecker Claim Charts (Medtronic Expert)



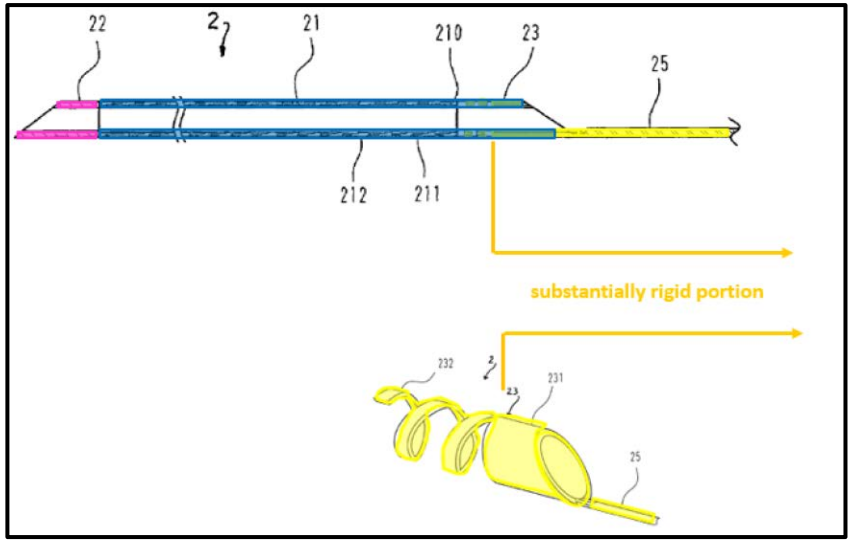
‘032 Patent, Claim 1



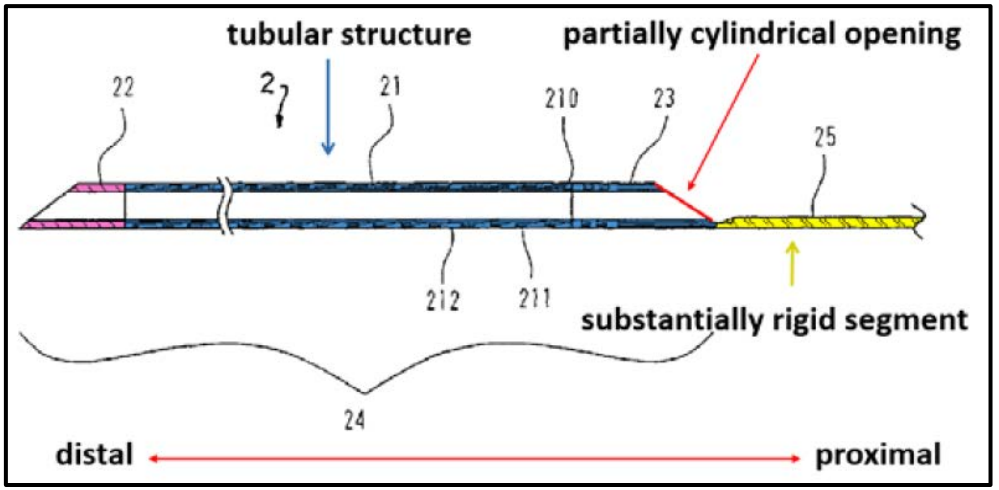
‘032 Patent, Claim 3

IPR2020-00126, Ex-1005, ¶¶ 170, 195;
e.g. Sur-Reply at 17

Brecker Claim Charts (Medtronic Expert)



‘032 Patent, Claim 1



‘776 Patent, Claim 25

IPR2020-00126, Ex-1005, ¶ 170; IPR2020-00135, Ex-1005, ¶ 158;
e.g. IPR2020-00126, Sur-Reply at 17

DILIGENCE FROM CRITICAL DATE TO PATENT FILING

Diligence Need only Be Reasonably Continuous, Showing Invention Was Not Abandoned

[D]iligence need not be perfectly continuous—only reasonably continuous. [P]eriods of inactivity within the critical period do not automatically vanquish a patent owner's claim of reasonable diligence. [T]he point of the diligence analysis is not to scour the patent owner's corroborating evidence in search of intervals of time where the patent owner has failed to substantiate some sort of activity. Rather, the adequacy of the reduction to practice is determined by whether, in light of the evidence as a whole, the invention was not abandoned or unreasonably delayed.

Arctic Cat Inc. v. GEP Power Prods., 919 F.3d 1320, 1331 (Fed. Cir. 2019); Response at 28

Evidence Shows Reasonable Diligence

Root Testimony

59. From September of 2005 forward, I and others at VSI continued to act diligently to bring the rapid exchange GuideLiner to market. The rapid exchange GuideLiner project was one of the primary development initiatives at VSI during this time and we continuously worked on this project through market launch.

Ex-2118 at ¶ 59;
Response at 19; Sur-Reply at 11

Schmalz Testimony

12. At no time between the start of the regulatory process for GuideLiner in August of 2005 and the filing of the patent application in May 2006 was the rapid exchange GuideLiner project abandoned or paused. The rapid exchange GuideLiner project was always a high priority project during my time at VSI.

Ex-2039 at ¶ 12;
Response at 19, 23

Evidence Shows Reasonable Diligence

Date	Corroborating Evidence Showing Diligence
August 2005	VSI patent counsel performs patent search related to GuideLiner (Ex-2096 at 8)
August 11, 2005	VSI patent counsel opens patent search for GuideLiner (Ex-2023 at 5)
September 14, 2005	VSI patent counsel reports results of patent search related to GuideLiner (Ex-2098 at 2)
October 2005	Report to the VSI Board on favorable physician feedback regarding GuideLiner, and plan for 510(k) regulatory submission for Rx version in 1st quarter 2006 (Ex-2133 at 4, 7)
October 10, 2005	VSI patent counsel opens patent prosecution matter for GuideLiner (Ex-2023 at 5)
November 1, 2005	GuideLiner Narrow SST-02 Flatt Pattern engineering drawing created (Ex-2019 at 2)
November 22, 2005	Gregg Sutton reported that for Rx GuideLiner VSI planned to complete design verification testing in June 2006 and to submit an FDA application in July 2006 (Ex-2099)

Evidence Shows Reasonable Diligence

Date	Corroborating Evidence Showing Diligence
December 2005	VSI patent counsel performs patent work related to GuideLiner (Ex-2117 at 20)
December 1, 2005	Gregg Sutton reports to VSI Board that additional engineering work would be done on Rx GuideLiner (Ex-2100 at 8-9)
January 2006	VSI patent counsel performs patent work related to GuideLiner (Ex-2101 at 7)
January 23, 2006	Gregg Sutton sends fax with GuideLiner sketches to VSI patent counsel (Ex-2102)
March 2006	VSI patent counsel performs patent work related to GuideLiner (Ex-2103 at 6)
March 15, 2006	Email exchange between Howard Root and patent counsel regarding GuideLiner patent application (Ex-2098 at 4)
March 21, 2006	Gregg Sutton sends rapid exchange GuideLiner component drawings to VSI patent counsel (Ex-2019)

Evidence Shows Reasonable Diligence

Date	Corroborating Evidence Showing Diligence
March 24, 2006	Vita Needle ships 600 feet of stainless steel tubing for GuideLiner project (Ex-2104, Ex-2005 at 5)
March 30, 2006	Hypo Tube, Cut GuideLiner engineering drawing created (Ex-2115)
April 2006	Budget to Actual Variances report shows significantly higher spend on GuideLiner compared to budget, most of which Mr. Root said was for Rx GuideLiner (Ex-2105 at 4-5; Ex-2118 at ¶ 71)
April 7, 2006	Shipping invoice from LSA for laser cut and electro-polished GuideLiner parts (Ex-2106 at 3)
April 18, 2006	Shipping invoice from MicroGroup to Steve Erb for hypotubing related to GuideLiner (Ex-2107)
April 19, 2006	Shipping invoice from LSA for cut GuideLiner hypotubes (Ex-2108 at 4-5)

Response at 2, 7-8, 18-19

Medtronic, Inc. and Medtronic Vascular, Inc. v. Teleflex Innovations S.A.R.L.

Patent Owner's Hearing Demonstratives (102/103)

Claims/Grounds Challenged If Itou is Prior Art

IPR	Separately-Challenged Claims	Grounds
IPR2020-00126	Independent claims 1, 11 Dependent claims 3, 6, 13, 14	Grounds 1-2
IPR2020-00128	Independent claims 1, 12 Dependent claims 3, 14, 15	Grounds 1-2
IPR2020-00129	Independent claim 25 Dependent claims 27, 33	Grounds 7, 9
IPR2020-00132	Dependent claims 32 and 39	Grounds 2-4
IPR2020-00134	None	None
IPR2020-00135	Independent claims 25, 52, 53 Dependent claims 32, 36, 37	Grounds 1-5
IPR2020-00137	Dependent claim 44	Grounds 2, 4-5

Petitioner's Reliance on Itou's Protective Catheter

'380 Patent, Claim 25:

"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…"

Also applies to:

'032 Patent, claims 3, 13, 14

'380 Patent, claims 3, 14, 15

Institution Decision:

As noted by Patent Owner, in Itou's disclosed embodiment, the suction catheter and interventional device (end protective catheter) are inserted into the guide catheter outside of the body and then the entire assembled structure is inserted into the patient. Prelim. Resp. 43–44 (citing Ex. 1207, 4:64–7:8; Ex. 2042 ¶ 37). Petitioner does not explain sufficiently why this disclosure teaches or suggests the limitations of claim 25. Nor does Petitioner persuasively explain why the suction catheter is inherently configured to receive the end protective catheter from an intermediate or distal portion of the guide catheter when it is disposed in a branch vessel. Ex. 1201, 13:47–51 (requiring receiving the interventional device from an intermediate or distal portion of the means for guiding and guiding the device "*deeper* into the branch vessel"). Accordingly, on this record, we are not persuaded that Petitioner has demonstrated a reasonable likelihood that claim 25 is anticipated by Itou. Claims 26, 28–30, 32–37, and 39 of the '380

IPR2020-00129, Paper 22 at 30

“through which interventional cardiology devices are insertable”

Independent claims 1 and 11
(126 IPR, ’032 patent):

[1/11]. A device for use with a standard guide catheter . . . 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;**
. . .

Independent claims 1 and 12
(128 IPR, ’380 patent):

[1/12]. A system for use with **interventional cardiology devices,** . . . the system comprising:
. . .
a device adapted for use with the guide catheter, including:
[. . .]
a flexible tip portion defining a tubular structure and 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**;
. . .

Ex-1001, 126 IPR
Ex-1001, 128 IPR

“through which interventional cardiology devices are insertable”

The specification defines “interventional cardiology devices”:

Interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. 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. In coronary artery disease the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions. These lesions may totally obstruct the lumen of the artery or may dramatically narrow the lumen of the artery. Narrowing is referred to as stenosis. In order to diagnose and treat obstructive coronary artery disease it is commonly necessary to pass a guidewire or other instruments through and beyond the occlusion or stenosis of the coronary artery.

IPR2020-00126 Ex-1001, 1:17-21; POR at 9-10

Zalesky Testimony (Medtronic Expert)

Q. Okay. Do you agree that the invention in this application has to be able to deliver guidewires?
A. Yes.
MS. TREMBLAY: Objection. Scope.
BY MR. WINKELS:
Q. Do you agree that the invention here has to be able to deliver balloon catheters?
MS. TREMBLAY: Objection. Scope.
A. As stated in this Background section, yes.
Q. Do you agree that the invention here has to be able to deliver stents?
MS. TREMBLAY: Objection. Scope.
A. Same answer, yes, as before.
Q. And do you agree that the invention here has to be able to deliver stent catheters?
MS. TREMBLAY: Objection. Scope.
A. Again, the same answer.

“interventional cardiology devices”

The system is deliverable using standard techniques utilizing currently available equipment. The present invention also allows atraumatic placement within the coronary artery. Further, the invention is deliverable through an existing hemostatic valve arrangement on a guide catheter without preventing injections through existing Y adapters. Finally, the invention has an inner diameter acceptable for delivering standard coronary devices after it is placed in the blood vessel.

IPR2020-00126 Ex-1001, 5:9-12; POR at 10

“interventional cardiology devices”

from the major blood vessel. The bump tip **22** of coaxial guide catheter **12** is inserted with tapered inner catheter tip **42** well into ostium **60** of coronary artery **62** or other blood vessel until bump tip **22** of coaxial guide catheter **12** achieves a deep seated position. Tapered inner catheter **14** is then withdrawn from the lumen of coaxial guide catheter **12**. An interventional cardiology treatment device such as a catheter bearing a stent or a balloon (not shown) is then inserted through the lumen of coaxial guide catheter **12** which remains inside guide catheter **56**.

IPR2020-00126 Ex-1001, 9:58-63; POR at 12-13, 22

“through which interventional cardiology devices are insertable”

‘032 Patent, claims 1, 11

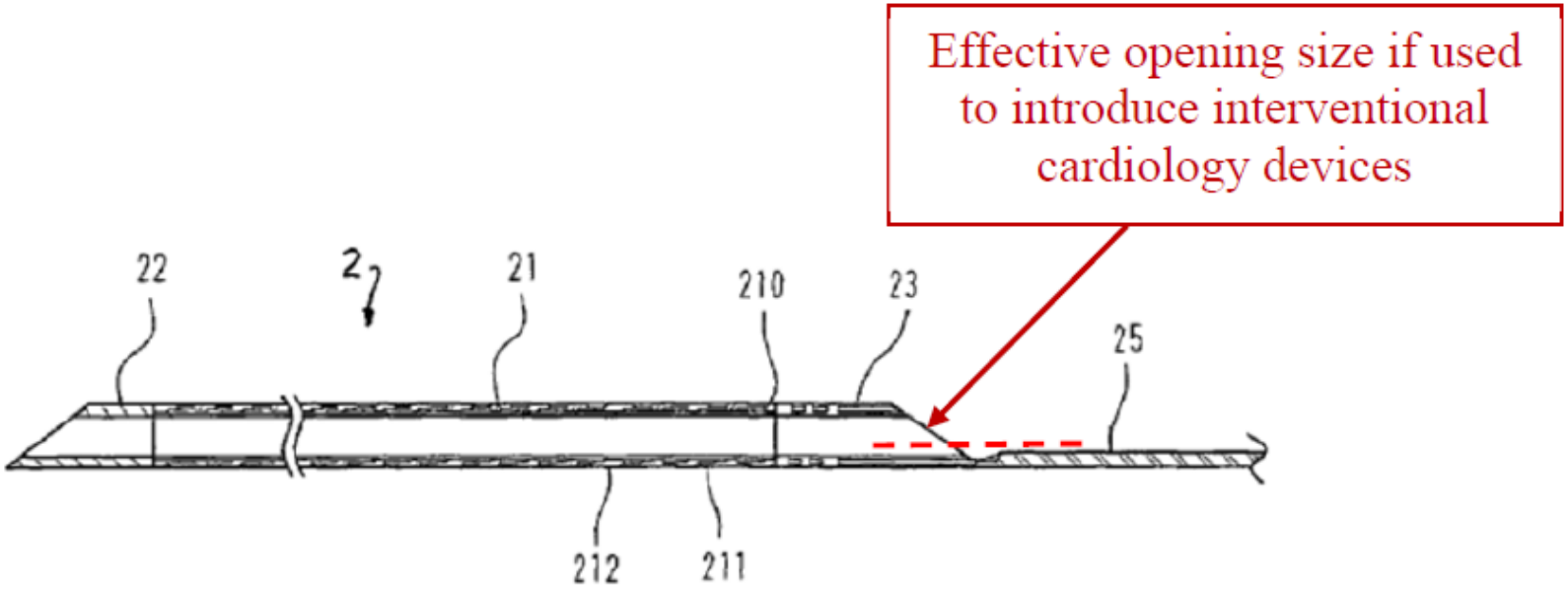
‘380 Patent, claim 1, 12

…defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable;

‘776 Patent, claim 25

configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter

Itou's Suction Catheter Is Not Configured to Receive Interventional Cardiology Devices, Including Stents



IPR2020-00126 Ex-1007, Fig. 3; Ex-2138, ¶¶128-129; POR at 21

“through which interventional cardiology devices are insertable”

Inherency is a high bar:

“[A]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must ***necessarily*** include the unstated limitation . . .”

Transclean Corp. v. Bridgewood Servs., 290 F.3d 1364, 1373 (Fed. Cir. 2002) (emphasis in the original)

No burden shifting for inherency:

“In an inter partes review, the burden of persuasion is on the petitioner . . . and that burden never shifts to the patentee. We have noted that ‘a burden-shifting framework makes sense in the prosecution context,’ where ‘[t]he prima facie case furnishes a 'procedural tool of patent examination, allocating the burdens of going forward as between examiner and applicant.’ [H]owever, **that burden-shifting framework does not apply in the adjudicatory context of an IPR.**”

In re Magnum Oil Tools Int'l, Ltd., 829 F.3d 1364, 1375 (Fed. Cir. 2016) (internal citations omitted)

IPR2020-00126 POR at 22-23; Sur Reply at 11.

Jones Testimony (Medtronic Expert)

Q. So is it your testimony, then, in no situations would a stent that can fit through the guide catheter that Itou teaches, that under no situations would that stent not be able to enter the Itou suction catheter in the perfectly straight configuration?

Is that your testimony?

MR. MORTON: Objection. Form.

A. Well, first off, I don't think I made that -- I don't think that was my testimony.

Further, I don't know that I could make a definitive statement like that without having tested a range of devices to either demonstrate that to prove or disprove that statement.

Q. Right. And you haven't tested Itou to try to prove or disprove that statement, right?

A. No, I have not.

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

IPR2020-00126 Ex-2239 at 67:5-21; Sur Reply at 10

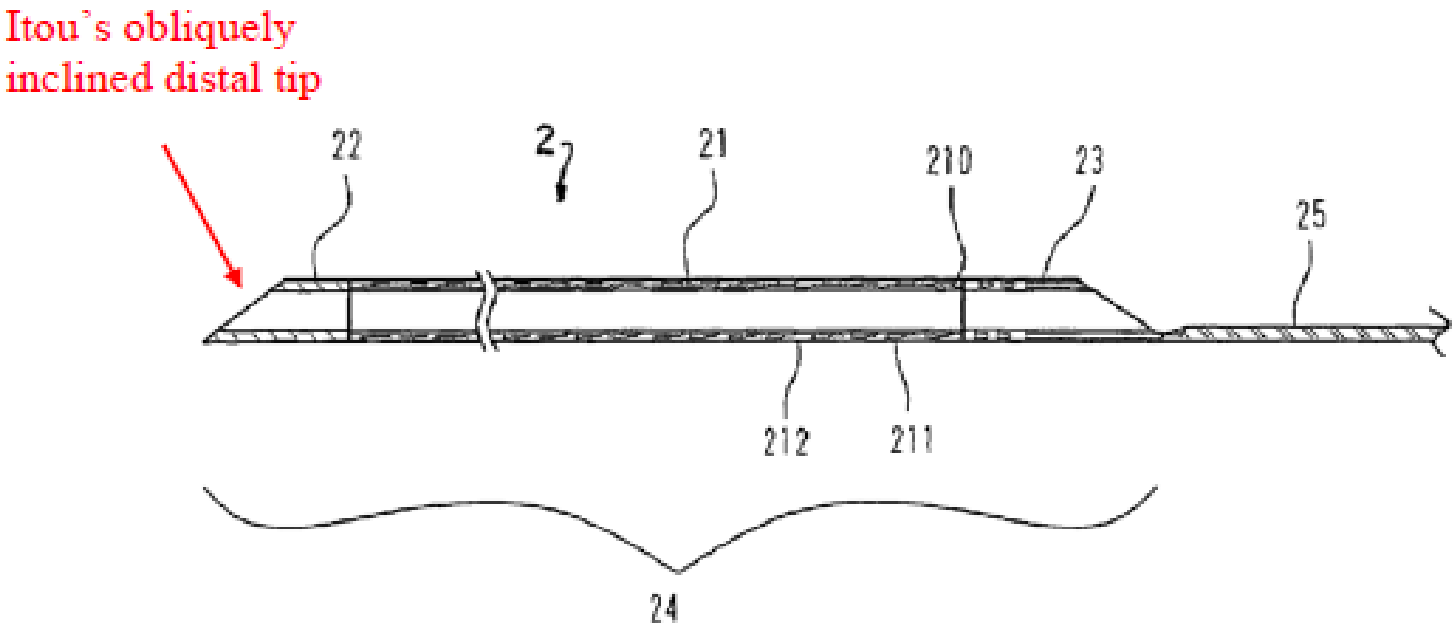
Keith Testimony (Teleflex Expert)

Q. Okay. You just told me that the conversion of 0.046 inches into French is 3.5 French, right?
A. Yes.
Q. Does a coronary catheter with a crossing profile of 3.2 French, that crossing profile is smaller than 3.5 French, isn't it?
A. Well, you're giving me two dimensions, and 3.2 is smaller than 3.5.
Q. And a coronary catheter with a crossing profile of 2.9 French, 2.9 French is smaller than 3.5 French, also, right?
A. Again, it's smaller.
It doesn't mean it necessarily mean it fits, you know, into a space of a catheter that's down inside of a guide catheter.

IPR2020-00126 Ex-1805 at 140:9-15; Sur Reply at 10

Itou Does Not Disclose a Flexible Cylindrical Distal Tip Portion

(126 IPR – '032 patent, claim 6; 128 IPR – '380 patent, claim 1)



IPR2020-00126 Ex-1007, Fig. 3; Ex-2138, ¶149; POR at 32

NO MOTIVATION TO REPLACE ITOU'S PROXIMAL OPENING WITH A COMPLEX SIDE OPENING

IPR2020-00129 (Ground 9); IPR2020-00132 (Grounds 2-4); IPR2020-00135 (Grounds 3-5); IPR2020-00137 (Grounds 2, 4-5)

Also Applies to: IPR2020-00126 (Ground 2); IPR2020-00128 (Ground 2)

Complex side opening claims
(135 IPR, ’776 patent)

52. A guide extension catheter . . . 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**

53. A guide extension catheter . . . 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; . . . 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**

36. The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening **includes at least one inclined region that tapers into a non-inclined region**.

Ex-1001 (135 IPR)

Complex side opening claims
(129 IPR, ’380 patent, 132 IPR, ‘760 patent, 137 IPR, ‘379 patent)

‘380 Patent, claim 27

The system of claim 26, wherein the side opening **includes at least two different inclined slopes**.

‘760 Patent, claim 32

The system of claim 25, wherein the segment defining the side opening **includes at least two inclined slopes**.

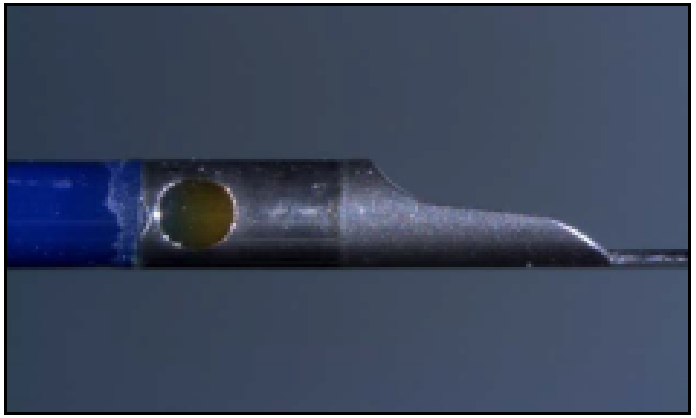
‘379 Patent, claim 44

“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 and the second inclined sidewall by a non-inclined region**.”
.

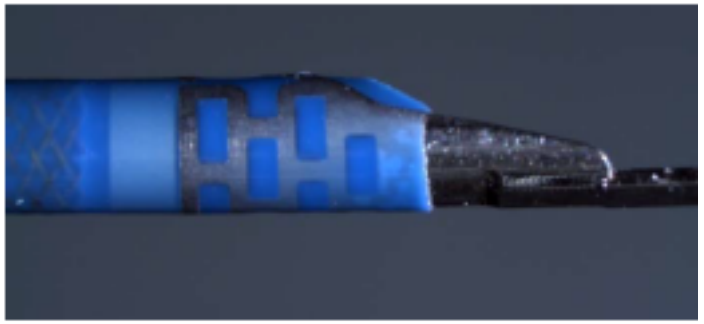
Ex-1201 (129 IPR); Ex-1001 (132 IPR); Ex-1001 (137 IPR)

Complex Side Opening is a Commercially Important Feature

GuideLiner V1 collar side view



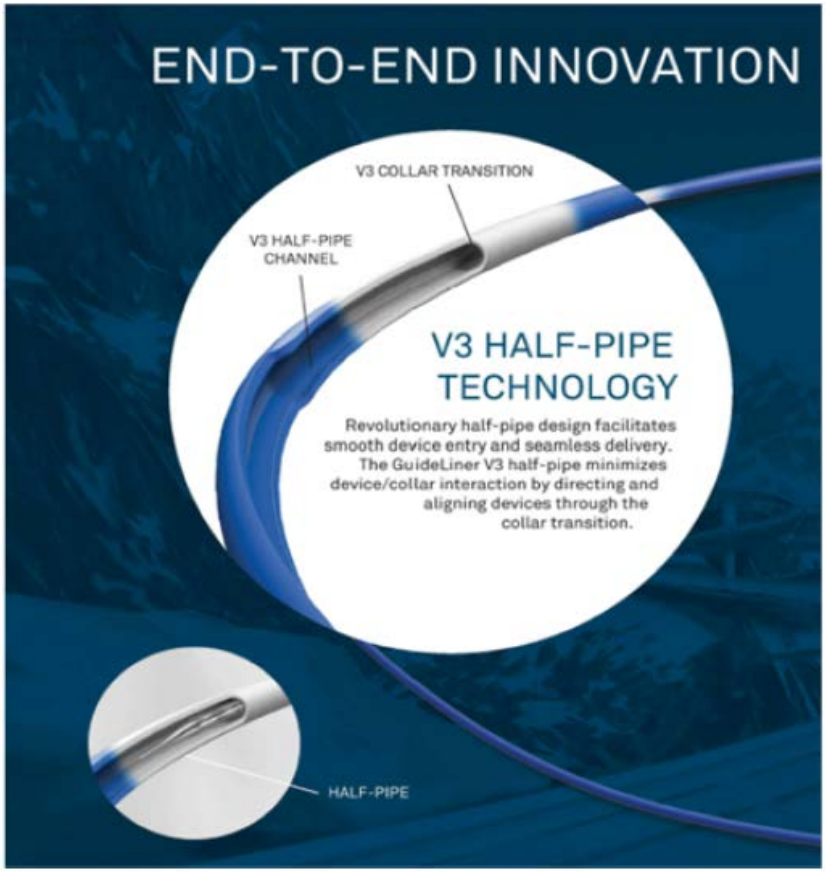
Guidezilla I Collar Side View



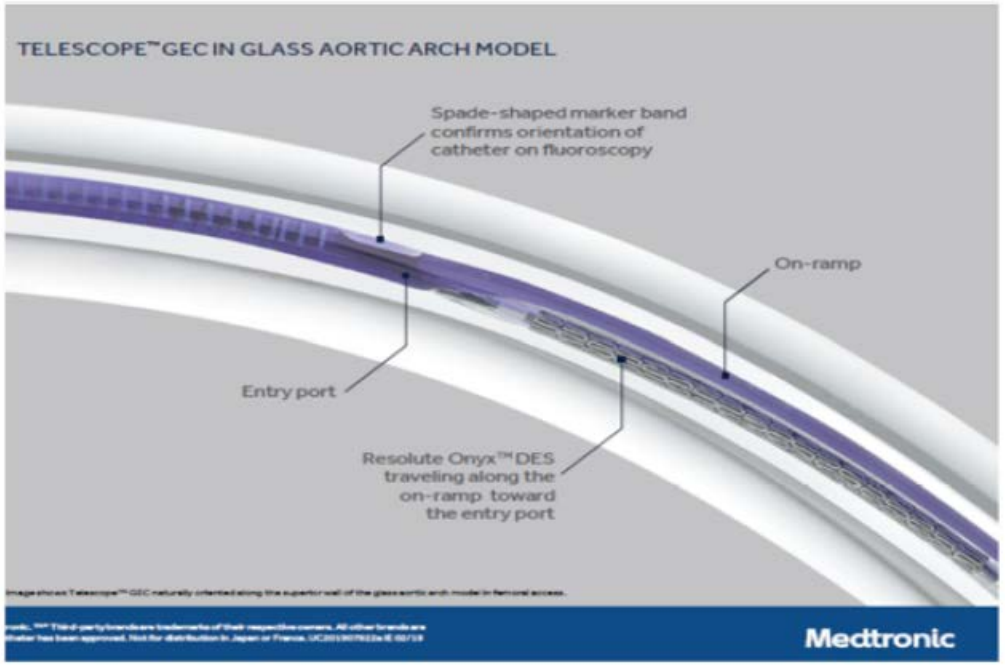
QXM Boosting Catheter:

IPR2020-00126 Ex-2138, ¶¶186, 199; POR at 52-53

Complex Side Opening is a Commercially Important Feature



GuideLiner V3



Telescope

IPR2020-00126, Ex-2138, ¶208; Ex-2063; Ex-2071 at 20; POR at 53-57

Complex Side Opening

Three Arguments Based on Three Secondary References:

1. Itou + Kataishi
2. Itou + Ressemann
3. Itou + Enger

NONE SHOW A DEVICE WITH A PROXIMAL COMPLEX SIDE OPENING

Itou + Kataishi

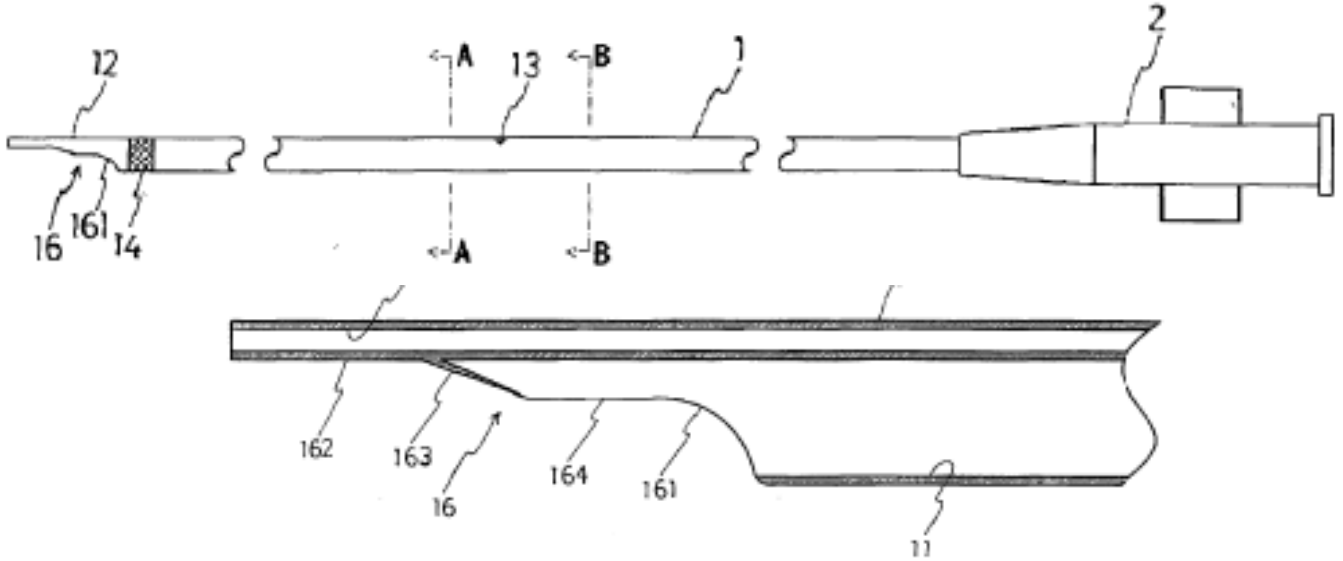


Figure 2

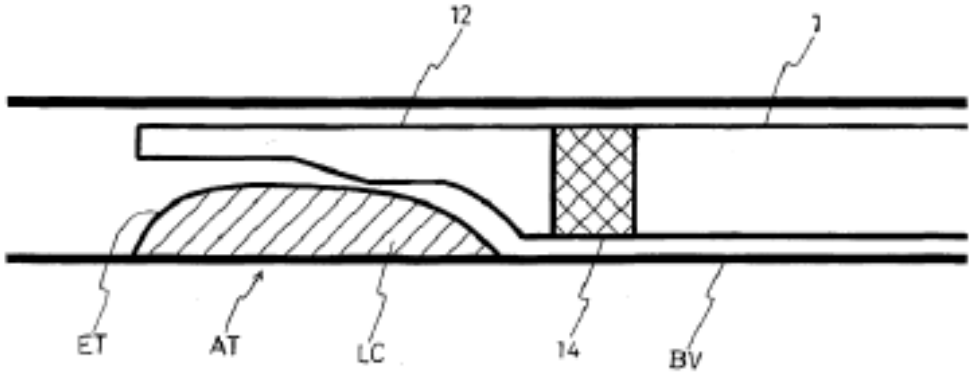
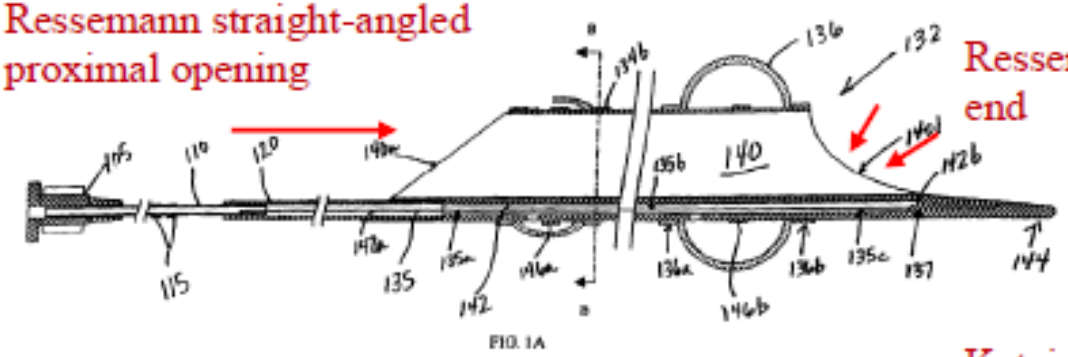


Figure 10

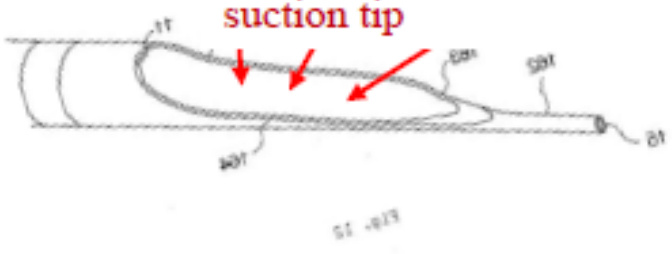
Itou + Kataishi + Ressemann: **NEW IN REPLY**

Ressemann straight-angled proximal opening



Ressemann curved distal end

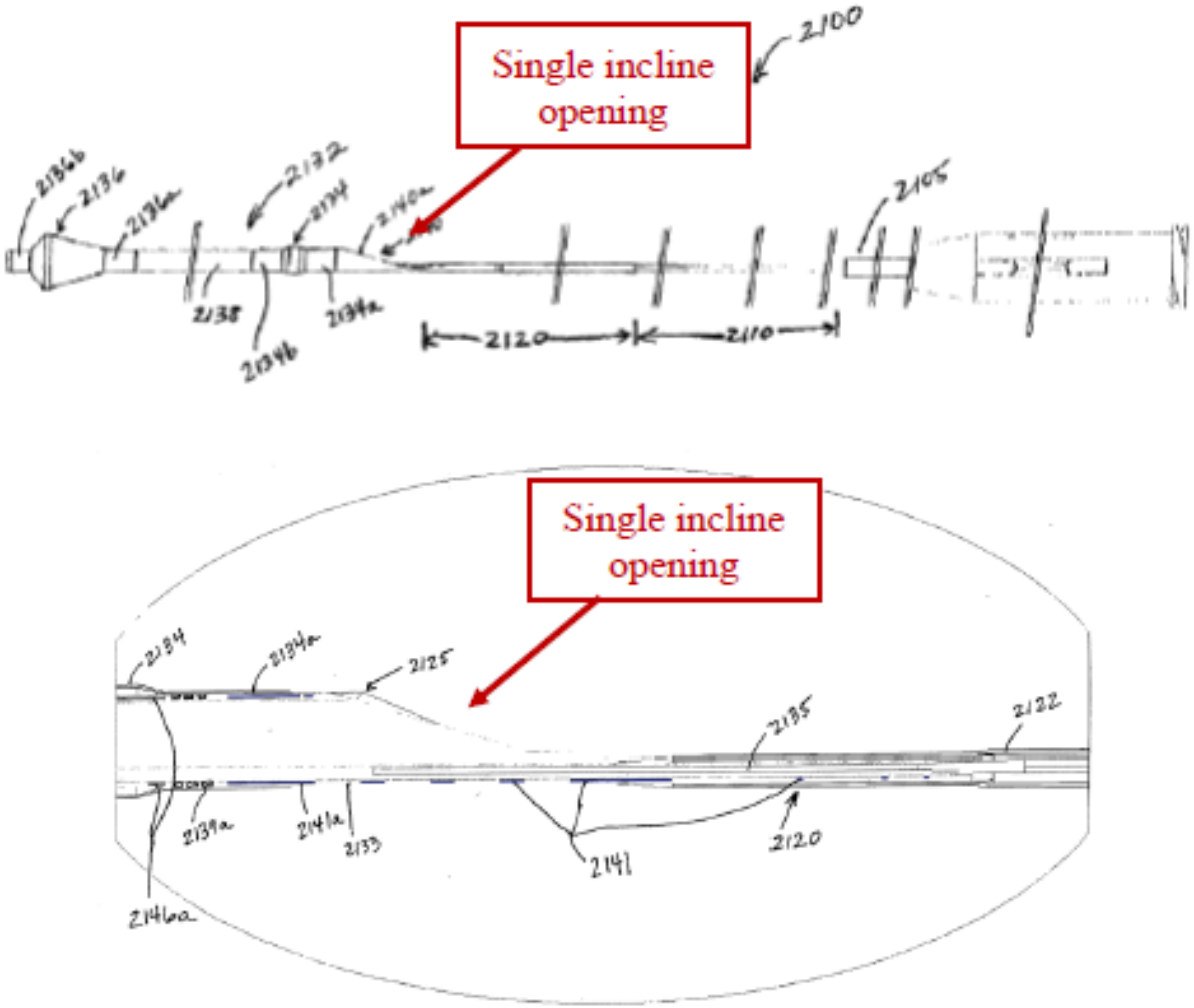
Kataishi curved distal suction tip



IPR2020-00132 Ex-1008, Fig. 1A; Ex-1025, Fig. 12; Sur-reply at 19-20

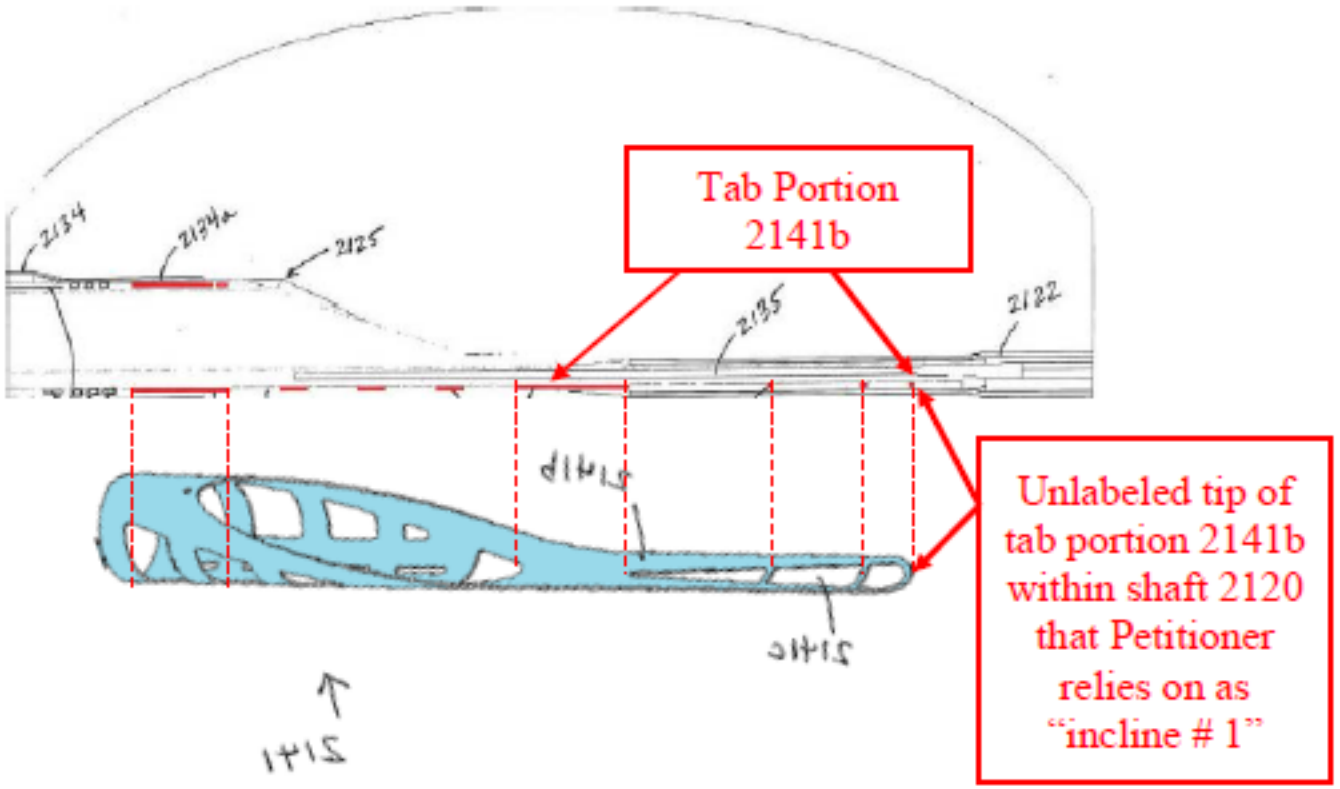
Itou + Ressemann

Ressemann teaches only a ***single incline*** proximal opening:



IPR2020-00132 Ex-1008, Fig. 16A (annotations added); Ex-2138, ¶ 112; Sur Reply at 3

Itou + Ressemann

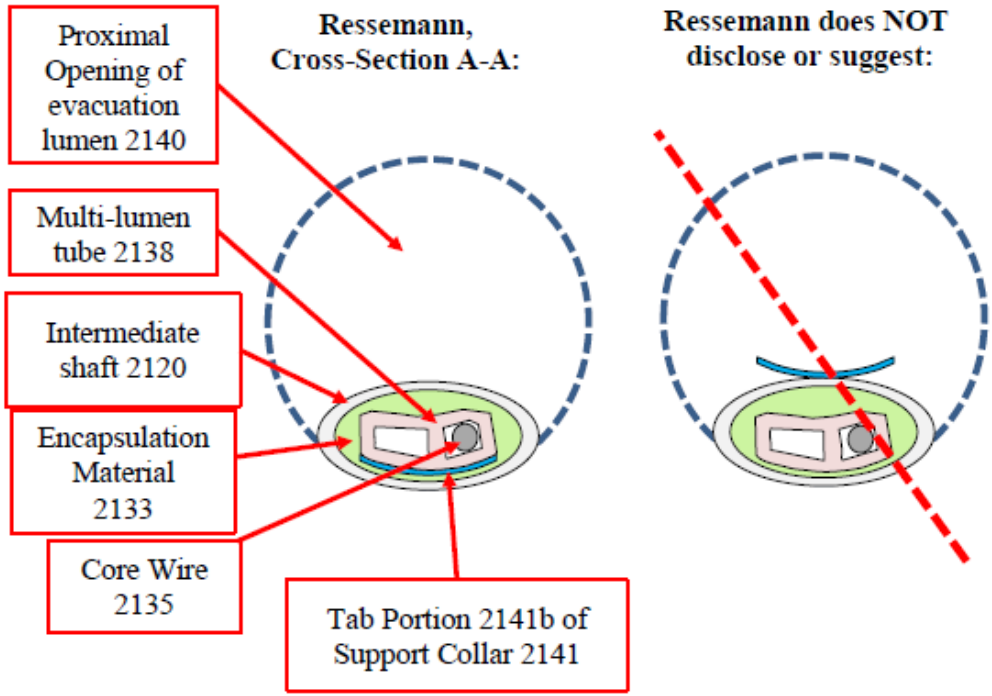


IPR2020-00132, Ex-2138, ¶115; POR at 15

Itou + Ressemann

Ressemann teaches tab portion ***inside*** shaft 2120 and ***underneath*** core wire:

> To facilitate attachment between the evacuation head 2132 and the intermediate shaft portion 2120, approximately 1 cm of a distal portion of polymer tube 2122 is flared and flattened by heating with an appropriately formed mandrel. This flared section is overlapped over the walls of the multi-lumen tube 2138, which define the core wire lumen 2143 and the inflation lumen 2142, **as well as over the tab portion 2141b of the support collar 2141**.



IPR2020-00132, Ex-1008, 27:59-67 (emphasis added); Ex-2138, ¶117; POR at 26-28

Hillstead Testimony (Medtronic Expert)

Q. Okay. So when you offered those opinions, did you have any opinion or understanding as to what the shape of the top portion of that shaft 2120 was?

Was it convex, concave, flat?

MR. PINAHS: Objection, form.

THE WITNESS: I'm not -- I don't have a -- a very firm opinion of what the shape of -- of that was.

Again, I want to use an element of the construct here, uh, to combine with others to -- to create a device and, no, I -- I don't think I -- unless you saw something where you think I'm opining on the shape of it right there, uh, it didn't -- it didn't really concern me that much.

Brecker Testimony (Medtronic Expert)

A. I hadn't used that detail in forming my opinion about how you might use Ressemann.
Q. Right. Okay.
A. How you might use the collar.
Q. So -- yeah. Okay. So in the opinions that you did form, the location of where that support collar is in the finished devices was not important to your analysis; is that correct?
A. Where it -- where it is in Ressemann is not -- is not directly transferrable to how I'm using it or how it could be used in Itou.

IPR2020-00132, Ex-2116 at 239:7-13; POR at 23

Jones Declaration (Medtronic's New Expert)

82. I am aware that Patent Owner discussed embodiment 2100 of Ressemann, and addressed its view of how collar 2141 is incorporated into embodiment 2100, shown in Fig. 16. I have not been asked to render an opinion on this issue.

IPR2020-00132, Ex-1807, ¶ 82; Sur Reply at 12

Hillstead Testimony (Medtronic Expert)

interventional cardiology procedure percutaneously is something that, um, I would look at and draw from, and I don't necessarily need to be totally wrapped up in -- in what the element that I choose to pick and choose from to use as -- to combine with something else, what it does in the current device. I'm more concerned about how I can use it in combination for what I want to do.

And in the Ressemann, uh, reference, the Ressemann collar is the element of interest.

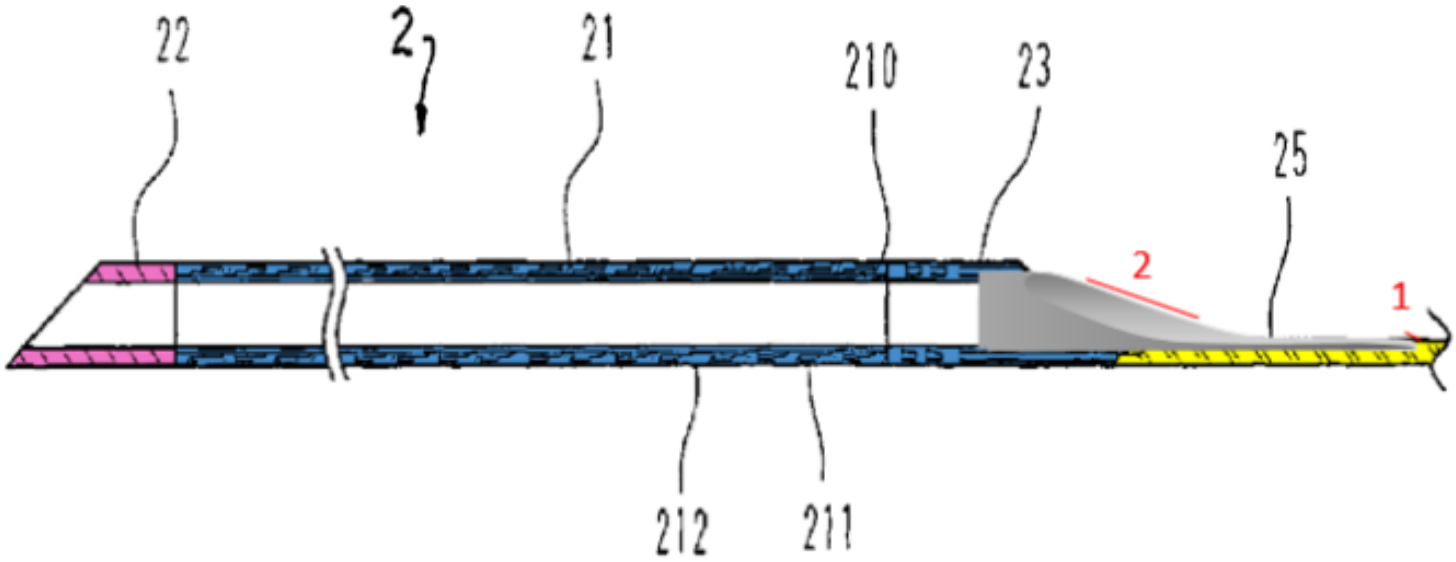
IPR2020-00132, Ex-2137 at 133:3-9; POR at 23

Brecker Testimony (Medtronic Expert)

A. But I was taking it as, if you will, a standalone adjunctive piece of the technology of Ressemann and seeing how that piece of technology which was designed as a support collar could be used to advantage in a piece of known prior art.

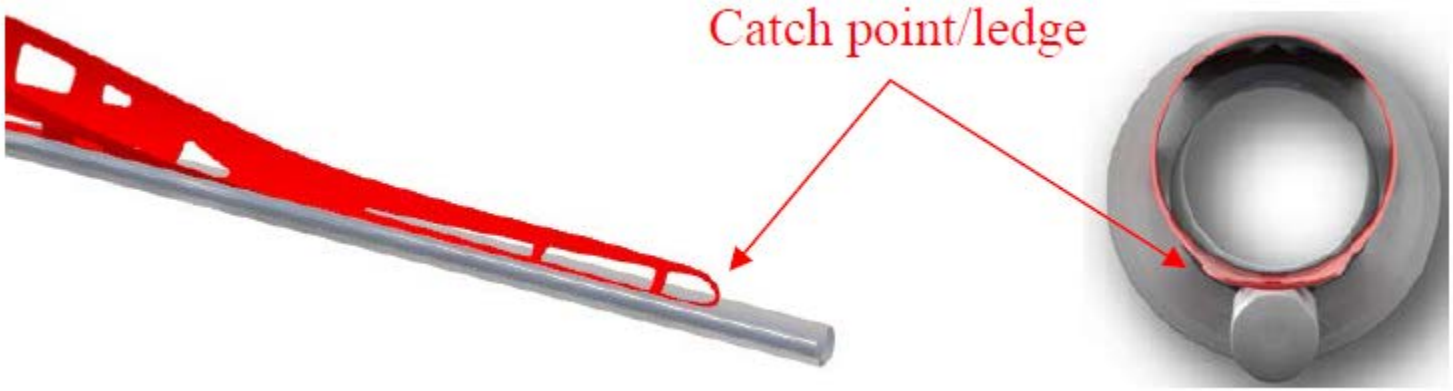
IPR2020-00132, Ex-2116 at 241:7-15; POR at 23

Itou + Ressemann as Combined in Petition



IPR2020-00132, Petition 67-68

Itou + Ressemann as Combined in Petition



IPR2020-00132, Ex-2138, ¶152; POR at 42

Itou + Ressemann – New “Encasement” Evidence

If “encased,” ***no evidence*** that tiny angle at tip of tab would be preserved:

Patent Owner’s expert Mr. Keith:

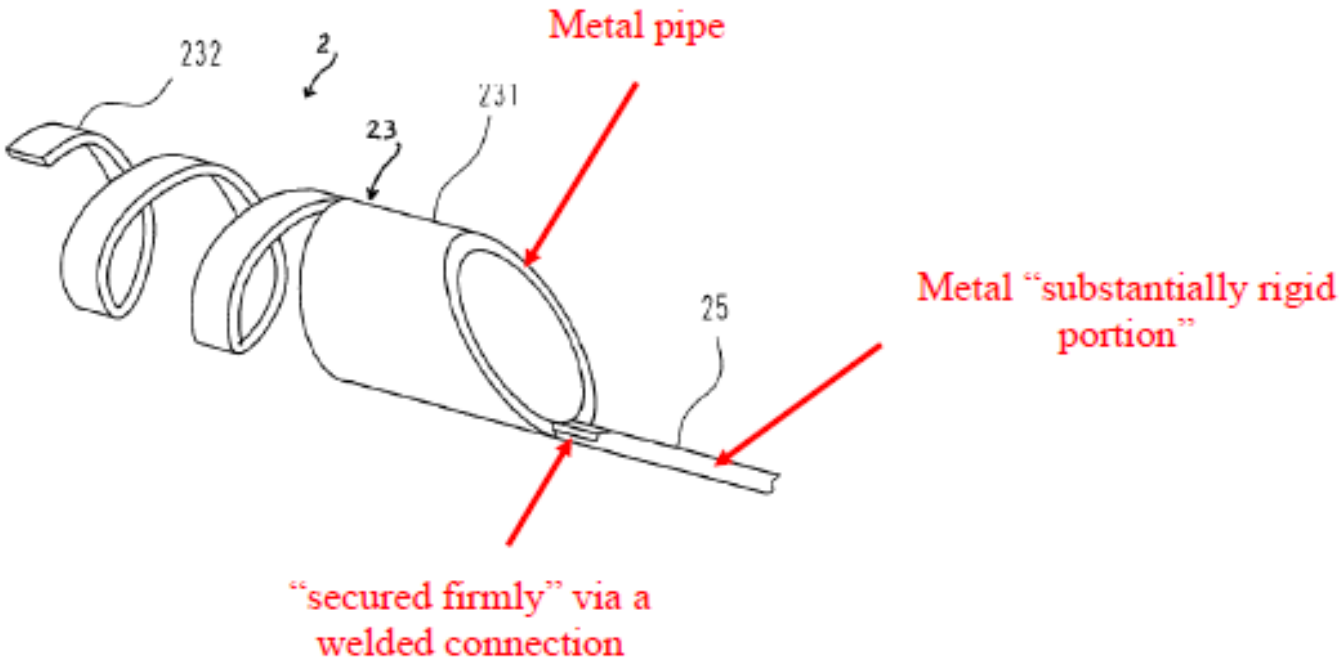
“[A] POSITA would expect that incline #1’ to be simply buried or ‘erased’ by the encapsulating polymer” (Ex-2138, ¶150)

Petitioner’s new expert Mr. Jones:

“I have not worked that out or provided an opinion on that” (Ex-2239, 116:19-24)

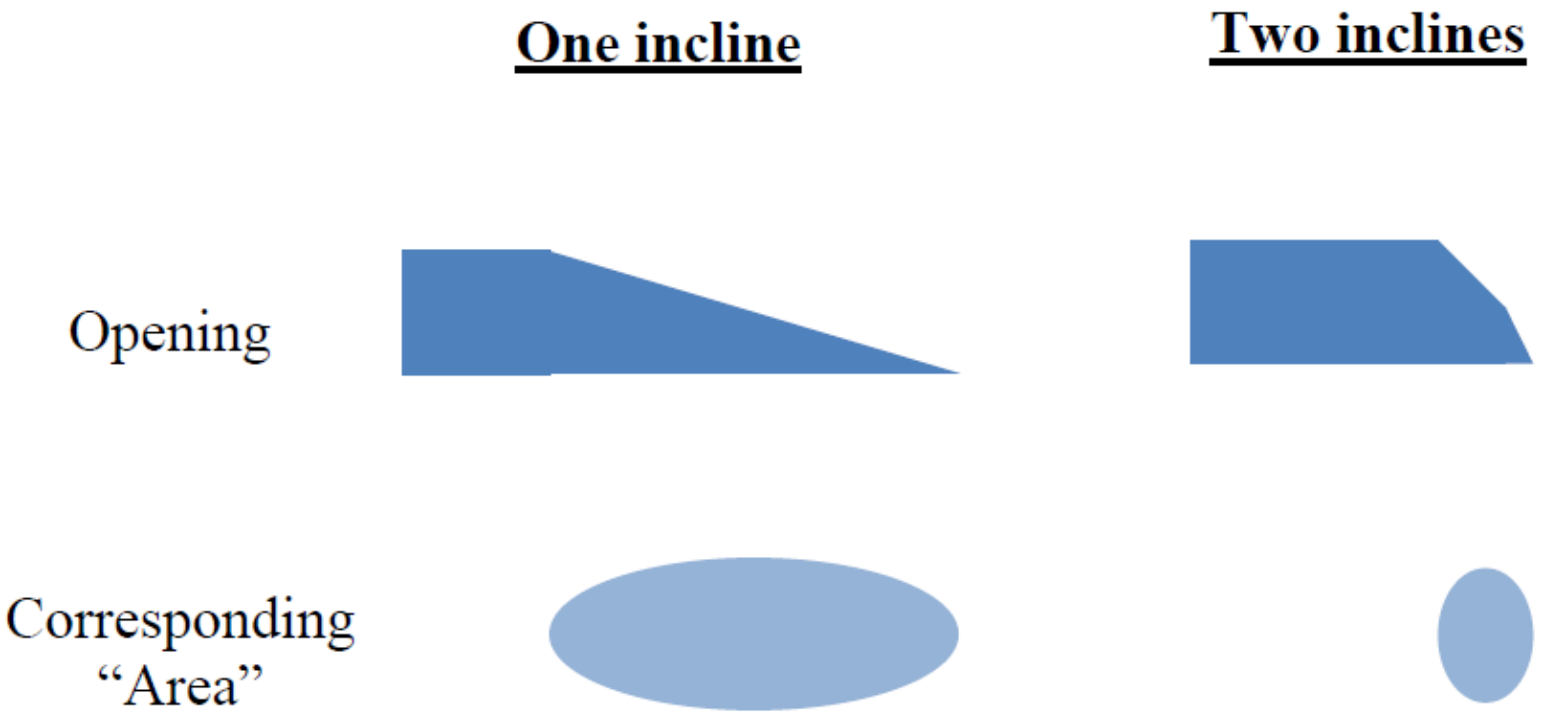
IPR2020-00132, POR at 40; Sur-reply at 13

Itou's Existing Structure



IPR2020-00132, Ex-2138, ¶145; POR at 37

Increasing Opening Area is Unrelated to Two Inclines



IPR2020-00132, Ex-2138, ¶142; POR at 32-33

Hillstead Testimony (Medtronic Expert)

Q. Okay. So you would agree that here in paragraph 112, what you're pointing out, that motivation does not have anything to do with going from one incline to two inclines, correct?

MR. PINAHS: Objection, form.

THE WITNESS: In this representation that we're looking at here, um, it does not, no. It shows the -- you're right. In this

Ex-2137 at 195:23-196:6; IPR2020-00132 Sur Reply at 10

Hillstead Testimony (Medtronic Expert)

Q. My question is: Do you agree that what you've labeled as incline number one in paragraph 103 does not actually serve as an on-ramp for interventional devices in the Ressemann device that's disclosed?

MR. PINAHS: Objection, form.

THE WITNESS: In -- in what we see of Ressemann, uh, I don't think that it is exposed as such in being an on-ramp, so it -- nothing comes in direct contact probably with that part in Ressemann.

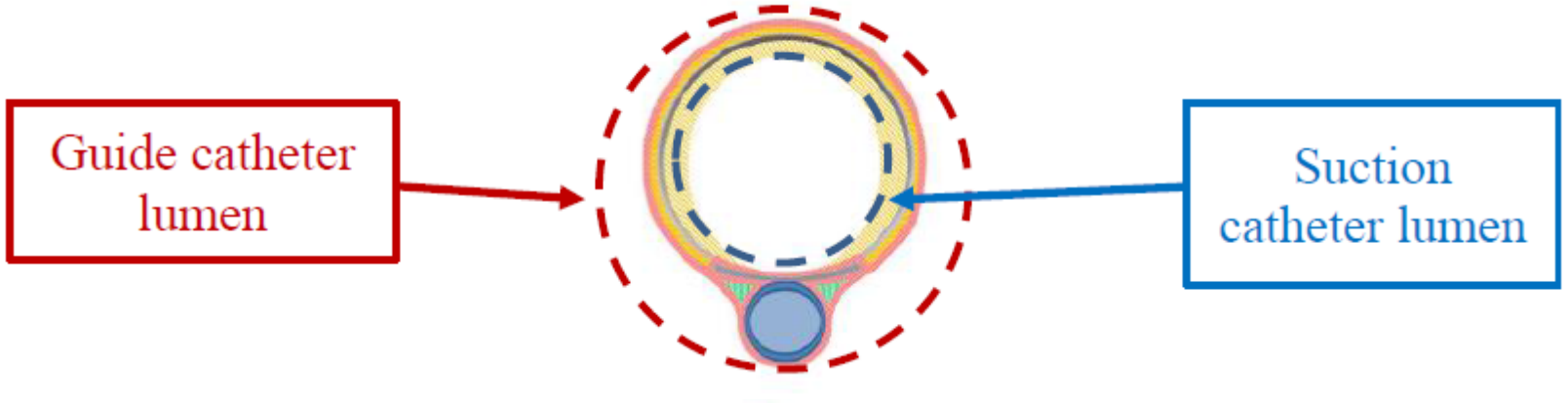
Ex-2137 at 162:5-15; IPR2020-00132 POR at 24-25

Itou + Ressemann

Petitioner failed to prove motivation/reasonable expectation of success for hindsight-driven tab-on-top combination:

Petition evidence for 'tab-on-top' combination	Patent Owner evidence showing no motivation/reasonable expectation of success for tab-on-top combination
Hillstead (incorrect) assertion that "*Ressemann explicitly instructs how to incorporate the support collar 2141 into the suction catheter (2). Ressemann instructs to . . . rest tab portion 2141b adjacent the exterior of wire-like portion 25*." *(Ex-1042, ¶101 (132 IPR))* Hillstead single conclusory assertion that tab would be "*encased in polymer as commonly known in the art*" *(Ex-1042, ¶96 (132 IPR))*	Undisputed Ressemann teaching that tab 2141b should be placed ***under*** reinforcing core wire 2135 and multilumen tube 2138 and *inside* the bottom of shaft 2120 *(Ex-1008, 27:51-67; Fig. 16D)* Hillstead admission that a tab-on-top combination "may not be the way that Ressemann would teach" (Ex-2137, 216:7-13) Keith testimony correctly understanding/explaining how Ressemann teaches to incorporate tab *(Ex-2138 ¶¶112-117, 137-140, 148 (132 IPR))* Keith testimony that a POSITA would not to be able to encase in polymer and still preserve tiny "incline #1" *(Ex-2138 ¶150 (132 IPR))* Jones (Petitioner's new expert) admission that, as to how the tiny incline would be preserved, he "[has] not worked that out or provided an opinion on that" (Ex-2239, 116:19-24) Keith testimony regarding expected peel-off/pop-off issues with tab 2141b *(Ex-2138 ¶151 (132 IPR))* Keith testimony that the tab-on-top would create a problematic ledge/catch points *(Ex-2138 ¶152 (132 IPR))* Keith testimony that adding Ressemann's collar in a tab-on-top manner would add obstruction to proximal opening of Itou *(Ex-2138 ¶153 (132 IPR))*

Itou + Ressemann



IPR2020-00132, Ex-1807, ¶130; Sur Reply at 5

Jones Testimony (Medtronic's New Expert)

Q. And if we compare the lumen of the guide catheter that that would fit into, which is 2.2 millimeters in diameter, with the interior lumen of Itou's suction catheter that you said is 1.5 millimeters, what is the difference between those lumen diameters?

A. Well, it's getting later in my day. I'm sure it's later than yours. So let me put on the calculator so I can report it correctly.

.7 millimeters. 0.7 millimeters.

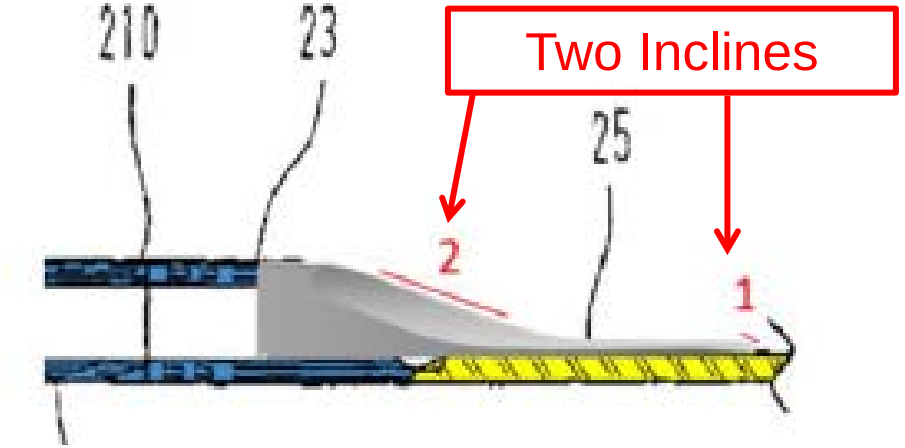
Q. And 0.7 millimeters is more than a 2 French difference between the diameter of the lumen of the bag catheter and the diameter of the lumen of the Itou suction catheter in your proposed combination, right?

A. I'd say it's nominally a 2 French difference.

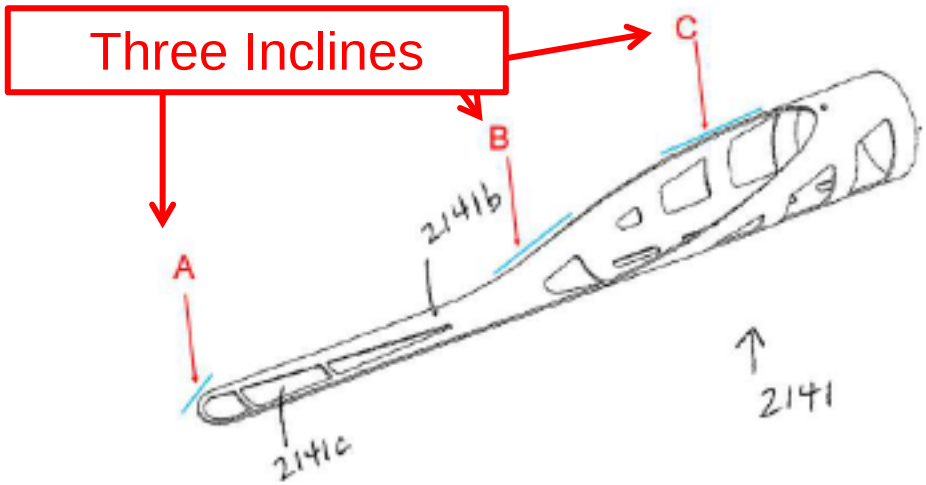
IPR2020-00132, Ex-2239, 170:14-174:9; Sur Reply at 4-5

Itou + Ressemann: **NEW IN REPLY**

Version 1 (Petition):



Version 2 (Reply):



IPR2020-00132, Ex-1042, ¶101; Ex-1806, ¶87; Ex-1807, ¶132; Sur Reply at 6-14

Itou + Enger

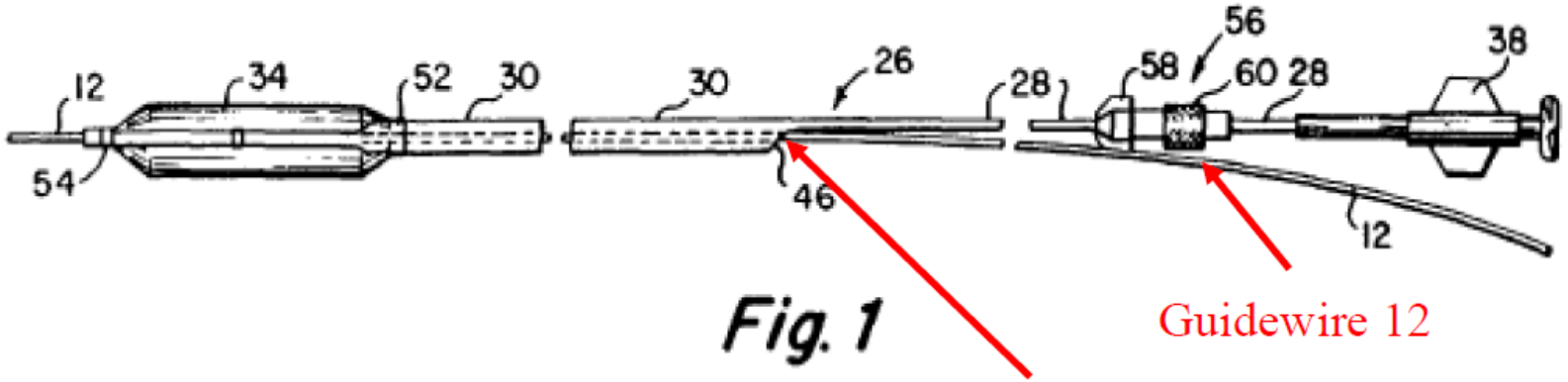


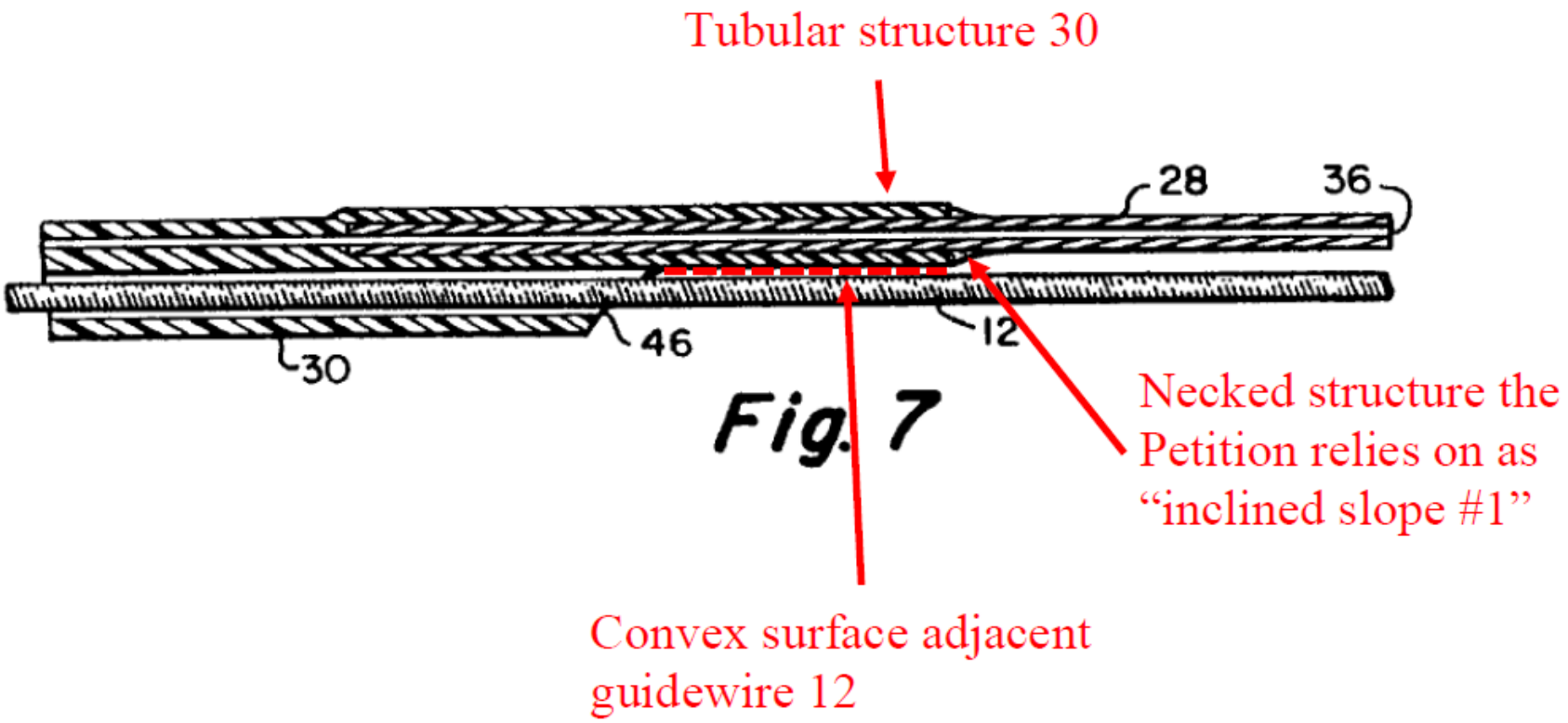
Fig. 1

Guidewire 12

Single-incline guidewire lumen opening 46

IPR2020-00132, Ex-1050, Fig. 1; Ex-2138, ¶¶124-125; POR at 54

Itou + Enger



IPR2020-00132, Ex-2138, ¶¶125-126; POR at 56

Hillstead Testimony (Medtronic Expert)

Q. Okay. And my question is: What is the shape of that structure above the guidewire between the -- uh, the opening 46 and then where that little lead line 12 is?

A. Oh, when you say "shape," are you talking three-dimensional shape or what we're looking at -- at here?

Q. Three-dimensional shape.

A. Uh, good question. I think it's substantially, um, tubular at about that --

Q. In other words, it would -- okay.

So it would have an exterior surface that would be, uh, convex at that point.

A. Uh, I guess so if you're talking -- if you're talking in on convex, a tube I believe has a convex outer surface and a concave inner surface, and that appears to be tubular, um, to the best of my recollection of this drawing, yes.

Hillstead Testimony (Medtronic Expert)

Q. Okay. You said a lot of things there, but I still don't think you answered the question.

Uh, the original question is: Is incline number one part of the side opening in Enger?

THE WITNESS: I'm just trying to think of how I can say what I've said and what I've described in a way that, um, it doesn't change what I'm saying and it satisfies what you're saying, but I don't -- I don't -- I don't think we can get there.

It is -- you know, it is -- incline one is not directly at the opening where incline two is, but it is formed of the material, the same material that is part of the base of incline number two or opening 46 rather.

Q. Okay. So the opinion that you're offering, it's not that Enger discloses a side opening with two inclined regions; instead, it's that Enger discloses a side opening with one inclined region, and then a second inclined region nearby; is that correct?

THE WITNESS: Yes. Enger shows a side opening 46 with inclined number one squarely over that side opening and then shortly beyond that, at a continuation of the same material that makes up the opening, is a second incline.

IPR2020-00132, Ex-2137 at 239:18-240:11, 244:8-21; POR at 55

Brecker Testimony (Aug. 11, 2020)

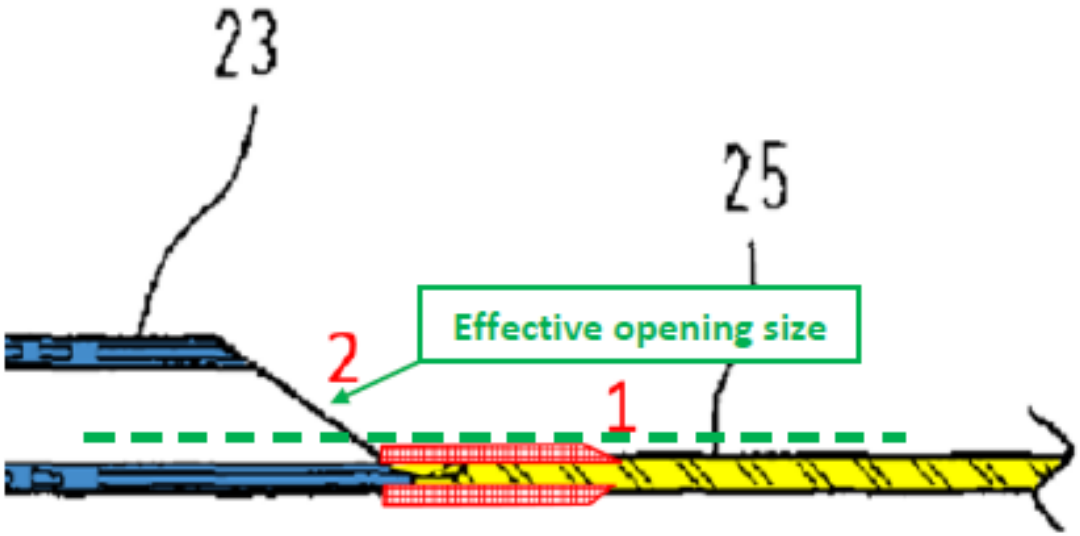
Q. And -- and is it correct that if the guidewire were to come out of a rapid exchange balloon catheter all the way proximal so it came out the proximal end of the monorail opening, it's -- it's quite challenging to reintroduce the wire at that point?

A. Yes, yes. Yeah, you would -- you -- you --

Q. Do you recall that ever happening during your procedures?

A. You -- you probably wouldn't -- you probably wouldn't even want to try because you -- you're in a guide catheter, and you've got no way of knowing where even the orifice of the -- of the monorail segment is entering. So if it came right back, the safest thing to do would be to put a new wire down and then readvance the wire -- sorry, readvance the balloon.

Itou + Enger as Combined in Petition



IPR2020-00132, POR at 60

Ressemann-Based Challenges

IPR2020-00129 (Grounds 1-6), IPR2020-00134 (Ground 4),
IPR2020-00138 (Grounds 1-5)

IPR2020-00129 (Grounds 1-6) – '380 Patent

Claim 25: "**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**…"

Claim 27: "wherein the side opening includes **at least two different inclined slopes**."

Claim 32: "wherein a uniform inner diameter of a lumen of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is **not more than one French smaller** than a second inner diameter of the lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel."

Claim 25: Means-Plus-Function

Three Issues:

1. Has Petitioner overcome the presumption that 112[6] applies?
2. What is the “corresponding structure” disclosed in the specification?
3. Has Petitioner proved that Ressemann discloses the same or equivalent structure for performing the claimed function?

“Means for Receiving and Guiding”

To overcome the means plus function presumption a petitioner must show that “the claim recites sufficient structure for performing the described functions in their entirety.”

“Sufficient structure exists when the claim language specifies the exact structure that performs the functions in question in without need to resort to other portions of the specification or extrinsic evidence.”

TriMed, Inc. v. Stryker Corp., 514 F.3d 1256, 1259-60 (Fed. Cir. 2008); POR at 8-10

Brecker Testimony (Medtronic Expert)

A. If you're asking me about a specific description of a tip of a device, then I would need you to take me specifically to exactly what we're talking about.

Q. I think you've hit on what I was, you know, interested in, is, of course, that is a term that's used in some of the claims of some of the patents at issue.

But outside the context of the specification of the patents at issue, does the word "tip portion" describe a specific thing?

MS. ROBERG-PEREZ: Objection; scope. Objection; asked and answered.

THE WITNESS: So I would find it very difficult to answer what -- you would need to be much more specific.

Q. I'm asking you to describe generally, in the interventional cardiology space in general, can you describe for me the structure of a reinforced portion?

MS. ROBERG-PEREZ: Objection; scope.

THE WITNESS: I don't think any cardiologist could describe to you the structure of a reinforced portion as a generic single entity.

Ex-2116 at 304:8-23, 306:2-10; IPR2020-00129 POR at 9

Board's Institution Decision

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. Thus, insofar as we have preliminarily construed the "means for receiving . . . and guiding" in claim 25 as a means-plus-function claim limitation, we determine that the corresponding structure for this claim limitation would be understood to be a "coaxial guide catheter" and equivalents thereof.

IPR2020-00129 Paper 22 at 19-20

Corresponding Structure: "**the** coaxial guide catheters" Disclosed in the Specification

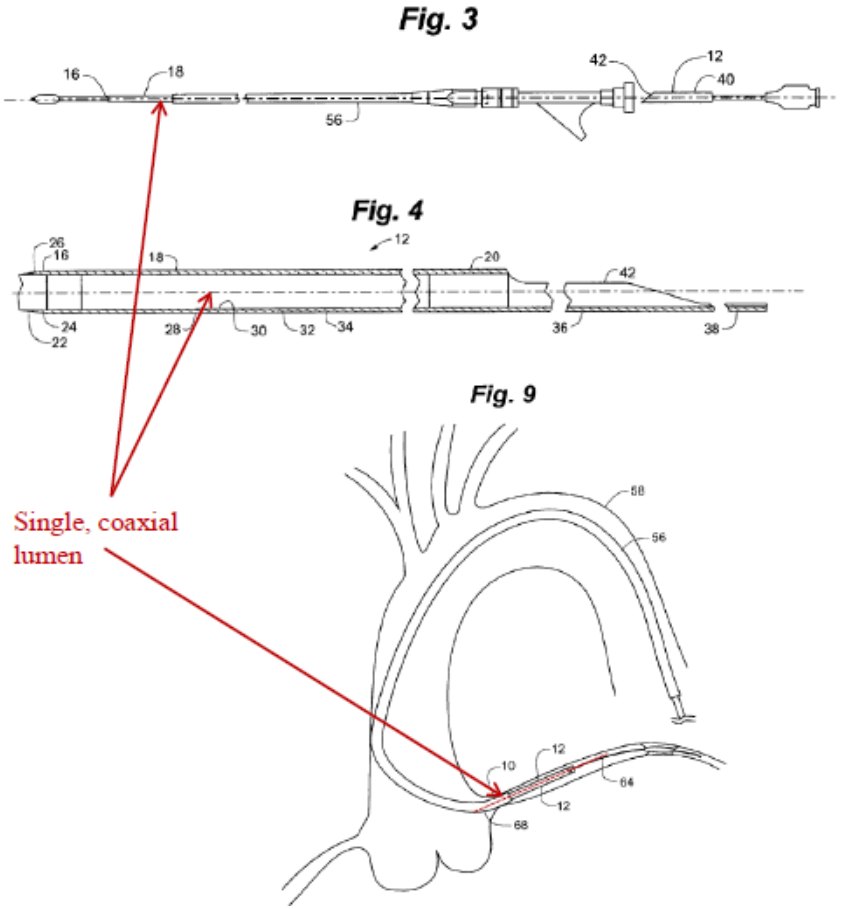
"[S]tructure disclosed in the specification qualifies as 'corresponding structure' if the specification or prosecution history clearly links or associates that structure to the function recited in the claim."

B. Braun Med., Inc. v. Abbott Labs., 124 F.3d 1419, (Fed. Cir. 1997)

"Medtronic argues that even if the limitation is a means-plus-function limitation linked to the disclosed polyaxial structure, the claim nonetheless should be construed to include alternative structures like monoaxial screws. However, because there is only one embodiment described in the specification to secure the anchor to the bone--a polyaxial screw and anchor structure—there is no basis on which to extend the limitation to cover alternative, non-disclosed structure not shown to be structurally equivalent."

Cross Med. Prods. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 13045, 1308 (Fed. Cir. 2005); POR at 10

Corresponding Structure: "**the** coaxial guide catheters" Disclosed in the Specification



IPR2020-00129 POR at 13

Corresponding Structure: "**the** coaxial guide catheters" Disclosed in the Specification

Reinforced portion **18** includes braid or coil reinforcement **32**. Braid or coil reinforcement **32** may be formed of metal, plastic, graphite, or composite structures known to the art. Reinforced portion **18** may be lined on the interior by PTFE liner **30** and covered on the exterior by Pebax® material **28**. Tip portion **16** and reinforced portion **18** together form a substantially cylindrical structure. Braid or coil reinforcement **32** may extend approximately 20 to 30 cm. In one exemplary embodiment, braid or coiled portion has a length of approximately 32 to 36 cm.

seated position. Tapered inner catheter **14** is then withdrawn from the lumen of coaxial guide catheter **12**. An interventional cardiology treatment device such as a catheter bearing a stent or a balloon (not shown) is then inserted through the lumen of coaxial guide catheter **12** which remains inside guide catheter **56**

Ex-1201, 6:53-55, 10:16-25; IPR2020-00129 POR at 12, 14-15, 22

Ressemann Does Not Disclose A Coaxial Guide Catheter

Fig. 6C

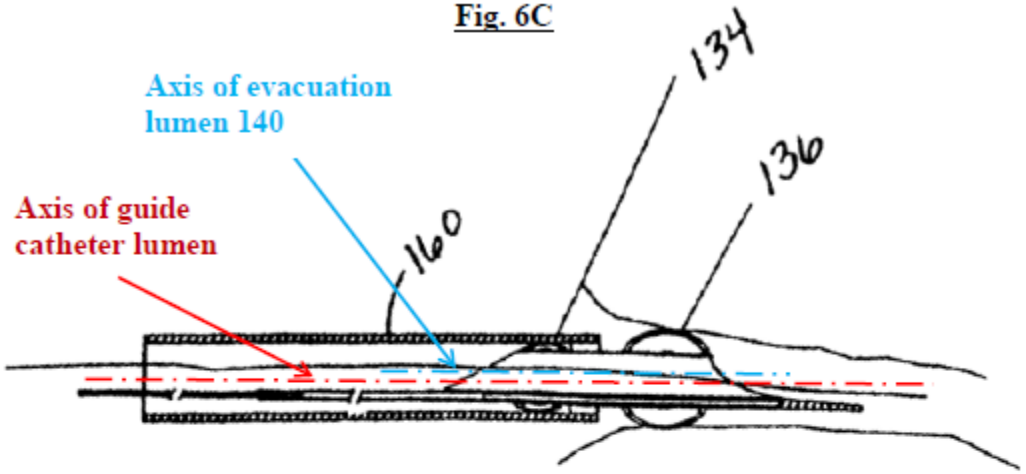
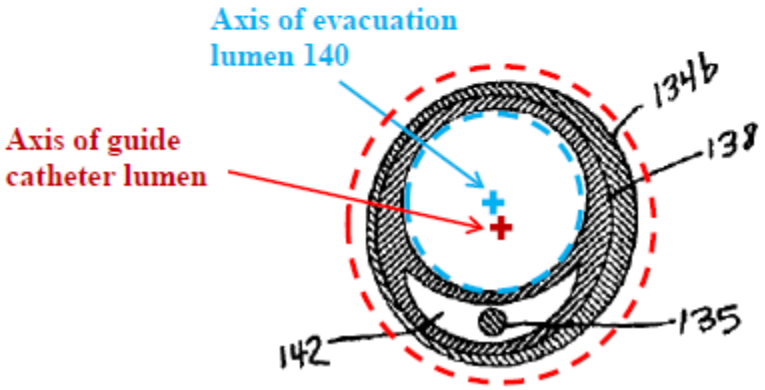


Fig. 1B
(cross-section of multi-lumen evacuation sheath 100 of Fig. 6C)



Ex-2138, ¶125; IPR2020-00129 POR at 18-20

Board's Institution Decision – IPR2020-00133

Having considered the parties positions and evidence of record, summarized above, we are persuaded by Patent Owner's arguments that the Petition fails to sufficiently establish that Ressemann discloses "a tubular structure defining a lumen coaxial . . . with the lumen of the guide catheter" as required recited by claim 25 and dependent claims thereto. In particular, we are persuaded that Ressemann discloses that evacuation lumen 140 is offset from that of the guide catheter 160, and thus the lumen of the evacuation lumen 140 is not disclosed as being coaxial to the lumen of the guide catheter 160. The Petition fails to sufficiently account for that difference identified by Patent Owner.

IPR2020-00133 Paper 20 at 15

The Claimed "Guiding" Function is Achieved Through Backup Support

(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

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.

Summary of Invention

Once the tapered inner catheter is removed a cardiac treatment device, such as a guidewire, balloon or stent, may be passed through the coaxial guide catheter within the guide catheter and into the coronary artery. As described below, the presence of the coaxial guide catheter provides additional backup support to make it less likely that the coaxial guide catheter guide catheter combination will be dislodged from the ostium of the coronary artery while directing the coronary therapeutic device past a tough lesion such as a stenosis or a chronic arterial occlusion.

Ex-1201, Abstract, 4:53-62; IPR2020-00129 POR at 12-15, 22

The Claimed "Guiding" Function is Achieved Through Backup Support

(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

Detailed Description

Coaxial guide catheter **12** is now ready to accept a treatment catheter such as a stent or balloon catheter. Referring to FIG. **9**, 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. In addition, the improved back up support assists in the positioning of a treating catheter that may include a stent or balloon.

seated position. Tapered inner catheter **14** is then withdrawn from the lumen of coaxial guide catheter **12**. An interventional cardiology treatment device such as a catheter bearing a stent or a balloon (not shown) is then inserted through the lumen of coaxial guide catheter **12** which remains inside guide catheter **56**

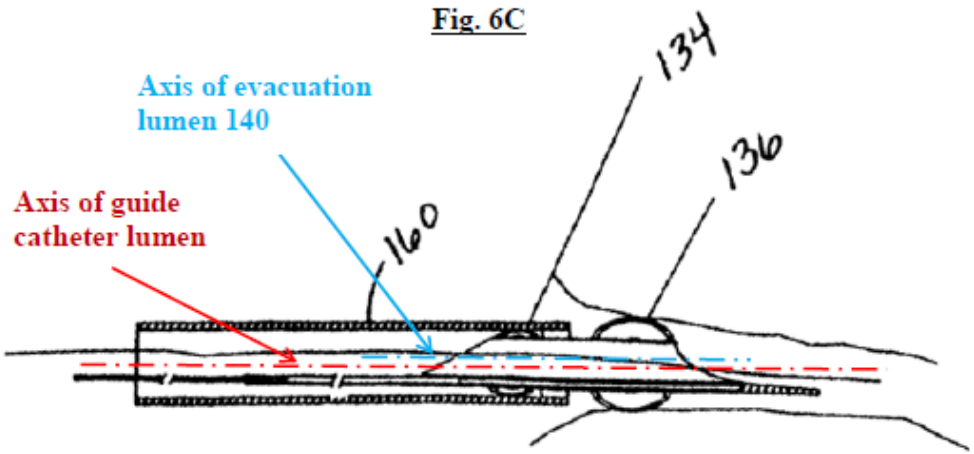
Ex-1201, 8:18-32, 10:16-20; IPR2020-00129 POR at 12-15, 22

Keith Declaration (Teleflex Expert)

155. Concerning the claimed function of "guiding an interventional device deeper into a branch vessel," I note that this function is not simply about having a lumen through which interventional devices can pass. The primary purpose and benefit of the "coaxial guide catheter" disclosed in the '380 patent is its ability to guide interventional devices deeper into the vasculature *after the device has extended beyond the distal end of the coaxial guide catheter*. The '380 patent's coaxial guide catheter accomplishes this purpose and provides this benefit by resisting reactive and shear forces that are created when an interventional device is passed "beyond the flexible distal tip portion" of the coaxial guide catheter. Ex-1201, Abstract.

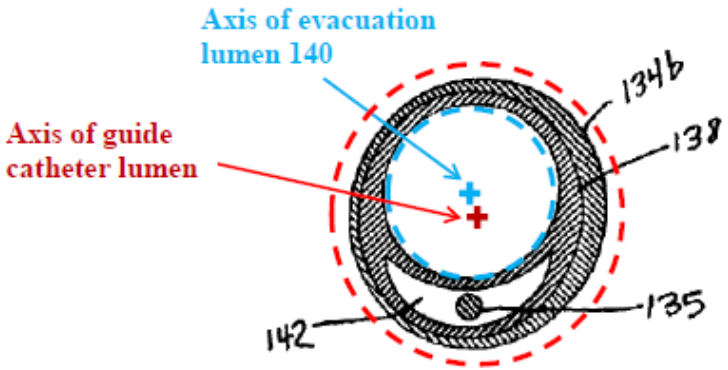
IPR2020-00129 Ex-2138, ¶155; POR at 22-24

Ressemann's Structure is Not Equivalent to the Disclosed Coaxial Guide Catheter



In use, the distal balloon **136** is intended to be positioned distal of the distal tip of a guiding catheter **160** and inflated against the inside surface of the blood vessel **150** causing a fluid tight seal between the blood vessel **150** and the balloon **136**. The proximal balloon **134** is intended to be positioned proximal of the distal end of the guiding catheter **160** and inflated against the guiding catheter **160** causing a fluid tight seal.

Ex-1208, 9:44-51; Sur Reply at 9



After any dislodged material has been removed, and after normal antegrade blood flow has been allowed, if so desired, all seals are again established. With all seals in place, a therapeutic device such as a stent delivery system **193** is advanced across the stenosis **180** with antegrade flow stopped, as shown in FIG. 6E. The touhy borst valve **184** attached to the guide

Ex-1208, 13:55-60; POR 24

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

IPR2020-00129 Ex-2138, ¶125; POR at 18-20

Brecker Testimony (Medtronic Expert)

Q. If Ressemann's device were put in place as it's describing in columns 12 through 14 and the balloons are inflated, if a large forward pressure is put on, for example, a stent delivery catheter such that there is a reactive force coming back at the device, part of that reactive force is going to be transmitted by the balloons to the vessel wall, correct?

A. Yes.

Q. This may get to the same point, but I wanted to ask you if you'd turn to paragraph 136 of your report. You're talking about Ressemann and you say, "Whilst the inflated balloons may offer some resistance to back forces, a physician would not rely on the balloons to provide such support."

And my question is: Why would a physician not do that?

A. So you would know that there would be a risk of damage to the vessel if you relied on the balloons in that way because if the device were pushed out of the vessel, it could traumatize inside because the balloons would still be inflated when they were pushed out.

Ex-2238, 133:4-134:4; Sur Reply at 10

Risks Associated With the Use of Balloons During Delivery Shows Non-Equivalence

"Moreover, there is a genuine issue of material fact as to whether the set screw accomplishes the claimed function in substantially the same way as the external nut. Medtronic has cited the testimony of Dr. Puno stating that he considered using a set screw in 1990 to hold the rod in place but decided against the set screw because of splaying concerns. Dr. Puno stated that having the side walls of the anchor seat spread apart when the screw was tightened down would be 'a bad thing' and 'could end up loosening the connection on the rod.'"

Cross Med. Prods. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1316-17 (Fed. Cir. 2005) (citations omitted); POR at 10

Ressemann's Structure is Not Equivalent to the Disclosed Coaxial Guide Catheter

Evidence of No Structural Equivalency	Evidence of Structural Equivalency
• Keith Declaration Ex-2138, ¶¶155-163. • Brecker Testimony, Ex-2238, 133:4-134:4.	• Petitioner's Opening Papers: **None** • Petitioner's Reply Papers: Brecker Supp. Decl. Ex-1806, ¶¶132-137 ▪ Ignores Ressemann's balloons ▪ Wrongly claims that Ressemann teaches to provide backforce

IPR2020-00129 POR at 22-25; Sur Reply at 9-10

Claim 27: Proximal Side Opening With Two Inclined Slopes

Similar Arguments as With Itou:

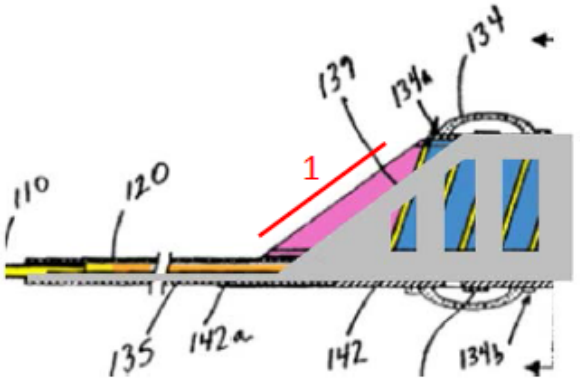
1. Ressemann + Kataishi (Ground 3)
2. Ressemann Fig. 1 + Ressemann Fig. 16 (Ground 2)
3. Ressemann + Enger (Ground 4)

NONE SHOW A DEVICE WITH A PROXIMAL COMPLEX SIDE OPENING

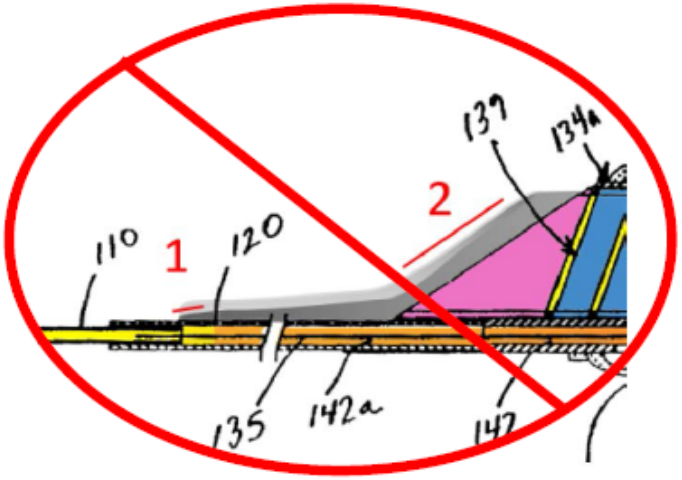
Ressemann + Knowledge of a POSITA

IPR2020-00129 (Ground 2); IPR2020-00138 (Ground 2)

If a POSITA could "envisage" combining support collar 2141 with the embodiment of Figure 1, pursuant to what Ressemann teaches:



Petitioner's incorrect "combination":

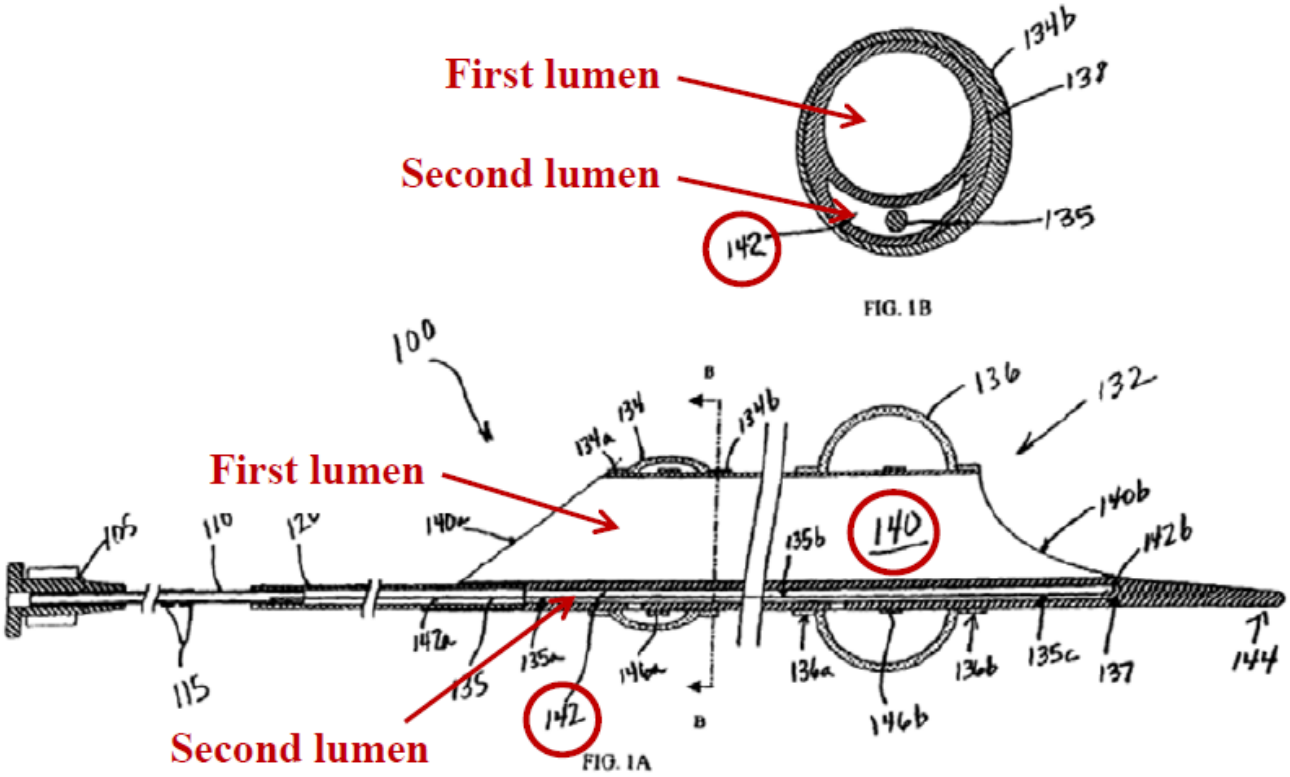


IPR2020-00129 Ex-2138, ¶¶176-78; POR at 34-35

Claim 32: "Not More Than One French Smaller"

"We question whether Petitioner has adequately supported such sweeping changes to Ressemann's system, and this is an issue the parties may address during trial."

Paper 22 (Institution Decision) at 33



DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

IPR2020-00129 Ex-2138, ¶ 124; POR at 18-20

Ressemann *is* an Embolic Protection Device

(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

EP	0 427 429	A2	5/1991

FIELD OF THE INVENTION

The present invention relates to apparatus and methods used to prevent the introduction of emboli into the blood-stream during and after surgery performed to reduce or remove blockage in blood vessels.

SUMMARY OF THE INVENTION

In accordance with the invention, methods and apparatuses for reducing or removing a blockage within a vessel without permitting embolization of particulate matter are provided. The methods and apparatuses occlude blood flow for a mini-mal amount of time and capture particulate matter created during each step of the surgical process.

Ex-1208; IPR2020-00129 POR at 43, 54-55

Brecker Testimony (Medtronic Expert)

Q. Okay. The balloons are a necessary part of stopping blood flow, correct?
A. Yes.
Q. And so in the context of Ressemann, those balloons are necessary to the embolic protection function of that?
A. The balloons and the retrograde flow and evacuation, yes.
Q. And the balloons and the retrograde flow are also necessary for the suctioning aspect of Ressemann, correct?
A. Yeah. That is all part of how it would work as an embolic protection device.

Ex-2116 at 396:21-397:20; IPR2020-00129 POR at 55

IPR2020-00134 (Ground 4) – '760 Patent

Claim 48, 51 and 53:

> "the guide extension catheter including… a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter; the lumen of the tubular structure… 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…
>
> Ex-1601

Ressemann's Evacuation Lumen is Not Coaxial With the Guide Catheter

Fig. 6C

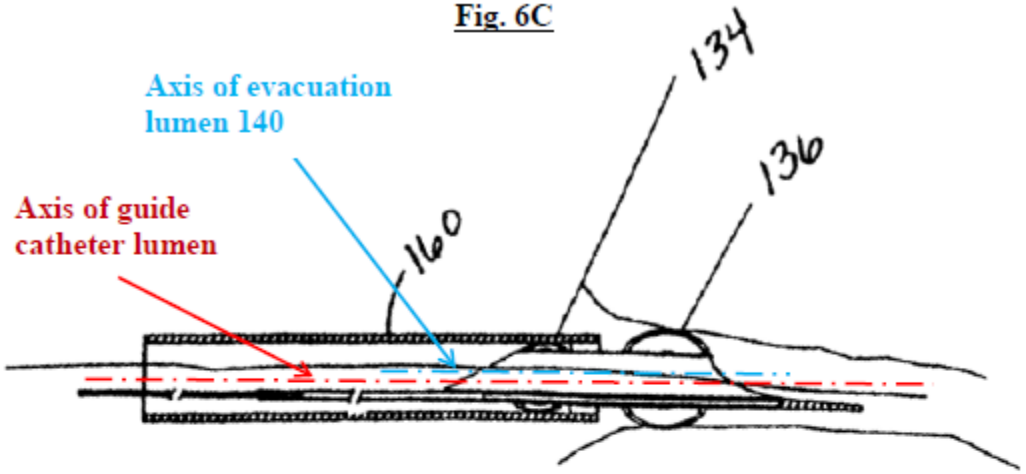
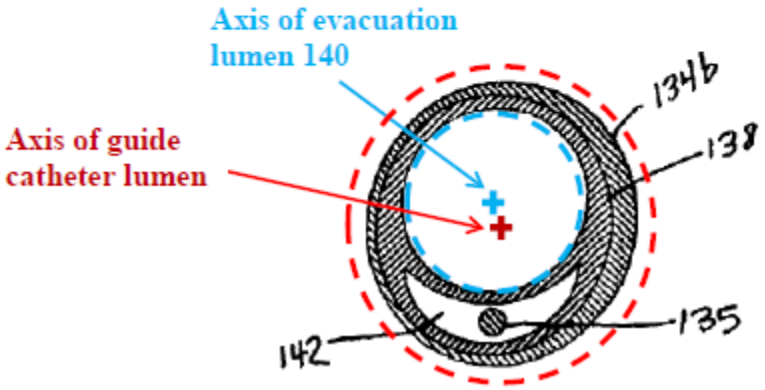


Fig. 1B
(cross-section of multi-lumen evacuation sheath 100 of Fig. 6C)



Petition's NEW CONSTRUCTION IN REPLY

"'Coaxial means 'aligned in the same direction as the axis of the lumen of the guide catheter'"

Reply at 1-9

In other words, "coaxial means parallel"???

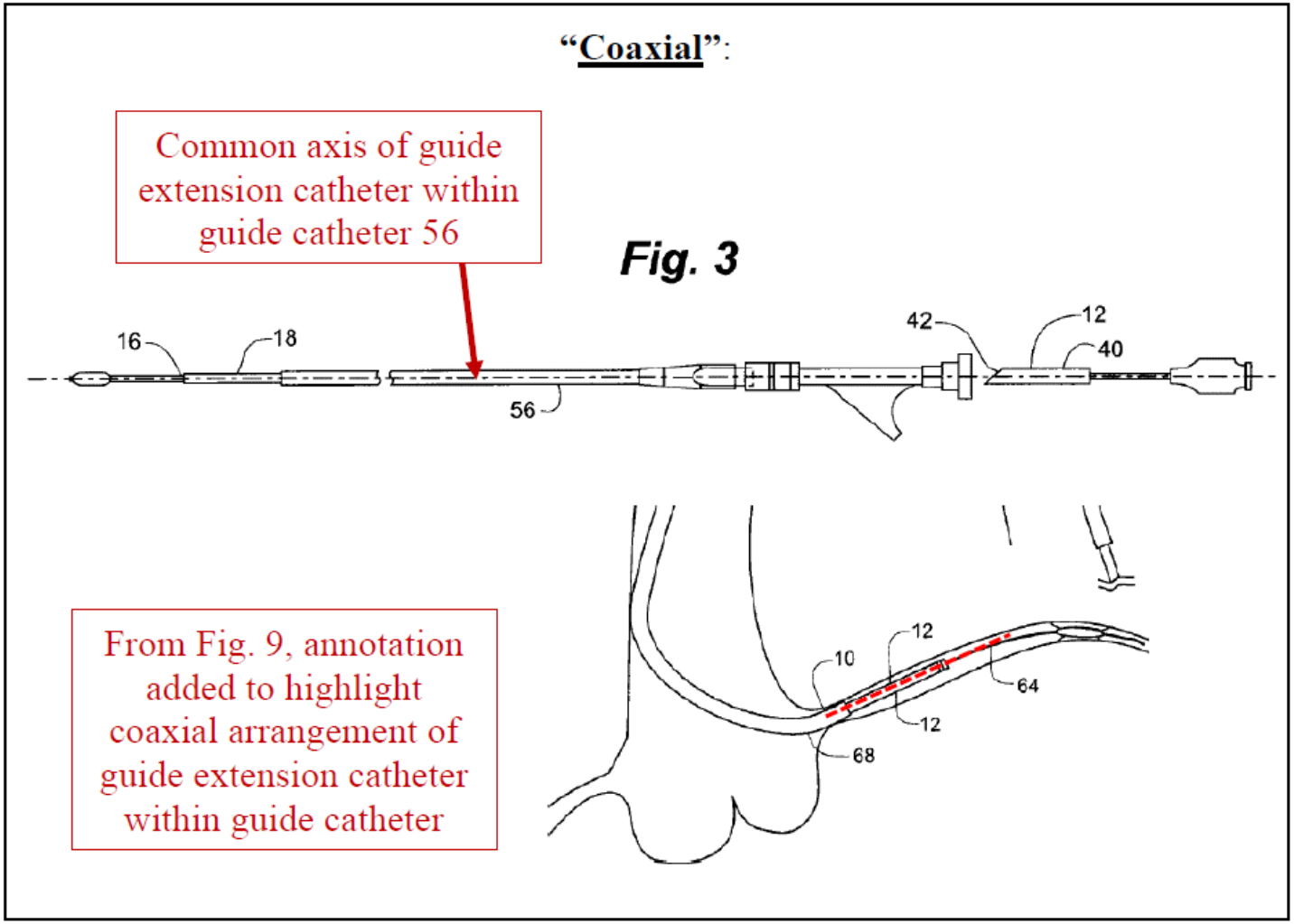
IPR2020-00134 Sur Reply at 4

Brecker Testimony (Medtronic)

Q. So you formed an opinion regarding what the term "coaxial" means in the claims of the five Teleflex patents at issue, correct?
A. I have.
Q. And is that definition set forth in paragraph 26 of Exhibit 1806?
A. Yes.
Q. Is that based on a definition contained in the specification of the five Teleflex patents?
A. No. I don't believe there is a definition of what coaxial is in the specification of the Teleflex patents.

Ex-2238, 28:10-14; IPR2020-00134 Sur Reply at 7

“Coaxial” – Intrinsic Evidence



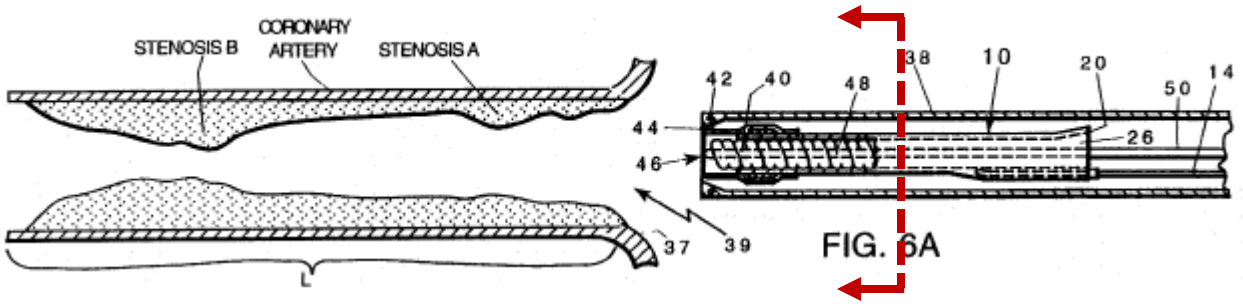
Ex-1601, Figs. 3, 4, 8, 9; IPR2020-00134 Sur Reply at 5

Brecker Opening Reports (Medtronic Expert)

Brecker Declaration (IPR2020-00130, Ex-1405, ¶171)

The tubular structure defines a coaxial lumen because, as shown in Figure 2, tube 16 of body 12 has a continuous lumen 22, which is coaxial with the outer surface of tube 16. (Ex-1409, 3:56-59, 4:48-50, Fig. 2.) Alternatively, if the extension catheter must be coaxial to the guide catheter, this is also achieved. Indeed, a vertical cross section of Kontos's Figure 6A show that the tubular structure 16 and guide catheter 38 are coaxial.

Kontos (Ex-1409, Fig. 6A)



Sur Reply at 7-8

Zalesky Testimony (Medtronic Expert)

Q. And in basic terms, I believe you described the mother-and-child as the child being a smaller catheter that nests inside the larger mother catheter; is that right?
A. Yes.
Q. And you mentioned those two catheters are coaxial.
Do you remember that?
A. Yes.
Q. And by "coaxial," do you mean that those two catheters share the same axis?
scope.
THE WITNESS: Yes.

Ex-2237, 130:13-22; IPR2-2-=00134 Sur Reply at 7-8

“Coaxial” - Kontos

Kontos’s full-length OTW embodiment has “coaxial” lumen:

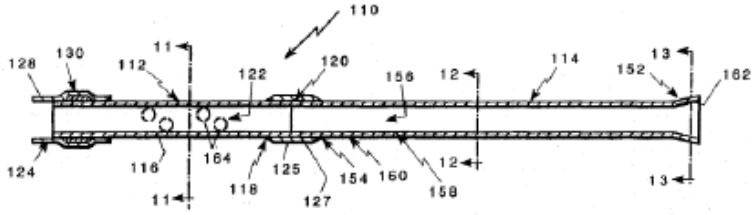


FIG. 10

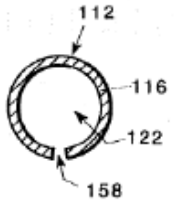


FIG. 12

*“[T]ube 116 and lumen 122 are generally cylindrical and **coaxial** along the length of body 112 . . . Body tube 116 is dissimilar to tube 16 of the prior embodiment in that . . . base portion 118 is symmetrical about its axis, **not eccentric**.” Ex-1409, 8:31-37.*

Portion of Kontos embodiment Petitioner relies on, without funnel, has “eccentric” lumen:

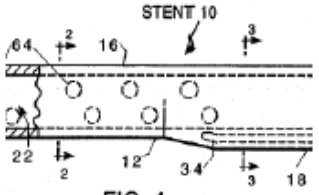


FIG. 1

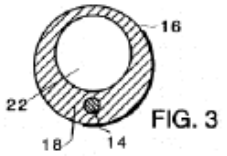


FIG. 3

*“[T]ube 16 has an **eccentric** cross-section at base portion 18. . . .” Ex-1409, 4:35-36.*

Ex-1609, Figs. 1, 3, 10, 12, 4:35-38, 8:34-42; Sur Reply at 7

“Coaxial”

US005156594A

United States Patent [19]

Keith

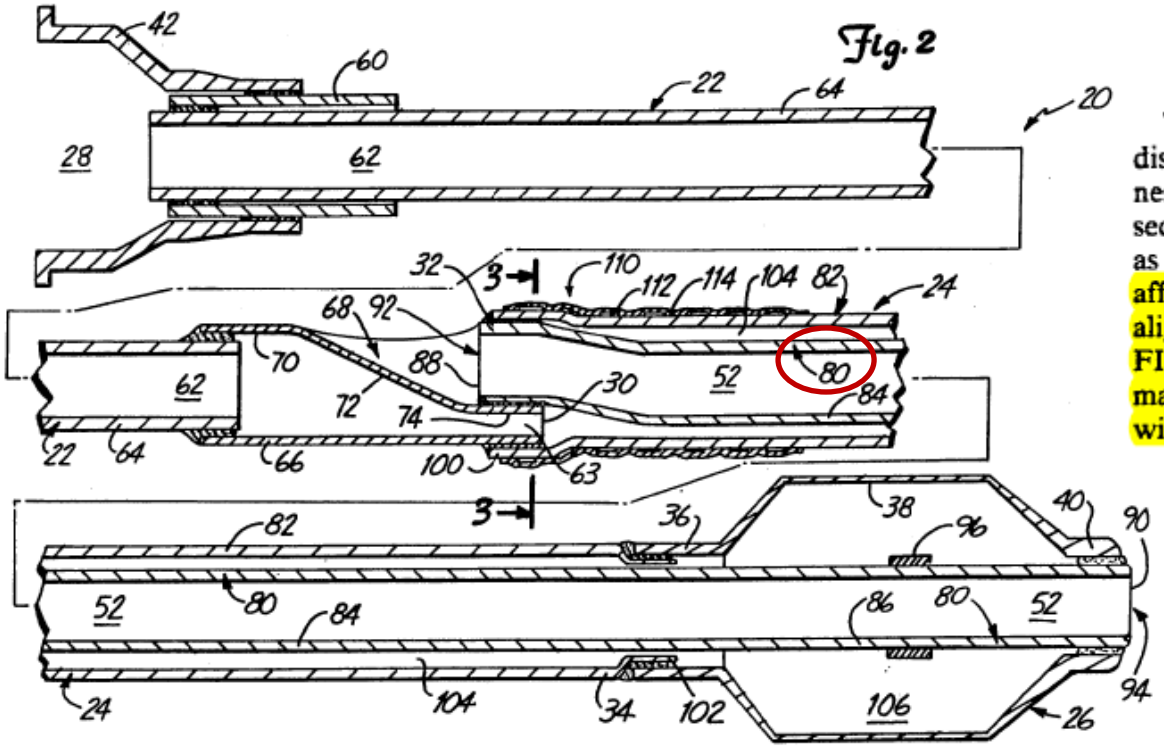
[11] **Patent Number: 5,156,594**

[45] **Date of Patent: Oct. 20, 1992**

[54] **BALLOON CATHETER WITH DISTAL GUIDE WIRE LUMEN**

OTHER PUBLICATIONS

“USCI Lo Profile II Balloon Dilatation Catheters,” C.



The inner core tube **80** has a proximal end **88** and a distal end **90**. At its proximal end **88**, the core tube **80** is nested within the bonding region **74** of the distal shaft section **66** and bonded thereto by suitable means, such as epoxy or cyanoacrylate. The core tube **80** is thus affixed to the main shaft section **22** in an “off-axis” alignment at the bonding region **74**. However, as seen in FIG. **2**, as the core tube **80** extends distally from the main shaft section **22**, it is aligned generally coaxially with the shaft section **22**.

“Coaxial”

FIG. **6** is a cross-sectional view of a portion of balloon catheter **100** taken along line B-B of FIG. **2**, and illustrates a coaxial dual lumen arrangement as discussed with reference to FIG. **3**. As apparent in FIG. **6**, inflation lumen **108** is formed between outer surface **308** of guidewire shaft **110** and inner surface **302** of inflation shaft **102** to allow inflation media to flow into balloon **118**. FIG. **6** shows a guidewire **602** within guidewire lumen **116**.

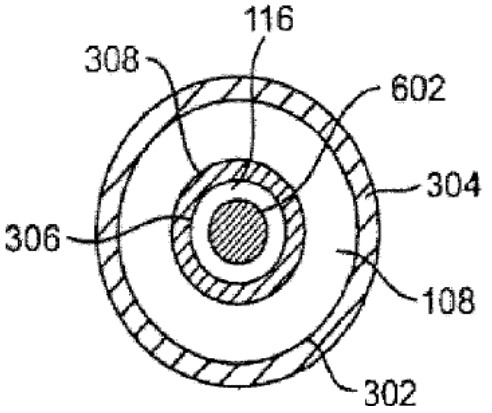


FIG. 6

FIG. **7** is an alternate embodiment of balloon catheter **100** taken along line B-B of FIG. **2**, and illustrates a non-coaxial arrangement of guidewire lumen **416** and inflation lumen **408** as discussed with reference to FIG. **4**. Guidewire **602** is shown within guidewire shaft **410**.

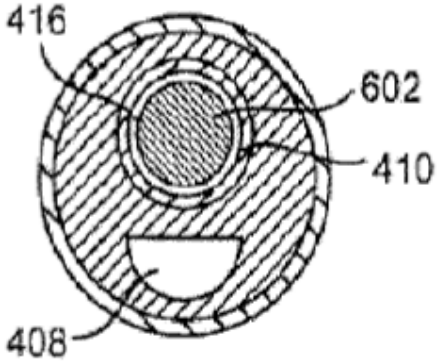


FIG. 7

Keith Testimony (Teleflex Expert)

Q. Okay. You see your opinion that a coaxial guide catheter must be perfectly concentric with a guide catheter in order to be coaxial?

A. No, I don't think it would have to be perfect. You know, in the real world things typically aren't perfect in any regard that way.

Q. Okay. So how do you know, I would suggest, how imperfect the prototypes were with respect to a standard guide catheter?

A. I'd rely on my understanding of what coaxial means. And if you've got a -- something like a guide extension catheter that's in relatively close proximity to a guide catheter that it's designed for, that's coaxial.

Ex-1764 at 90:2-91:18; IPR2020-00134 Sur Reply at 6

IPR2020-00138 (Grounds 1-5) – '379 Patent

Claim 44 (complex side opening claim):

> "*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 and the second inclined sidewall by a non-inclined region.*"

Ex-1201

Kontos-Based Challenges

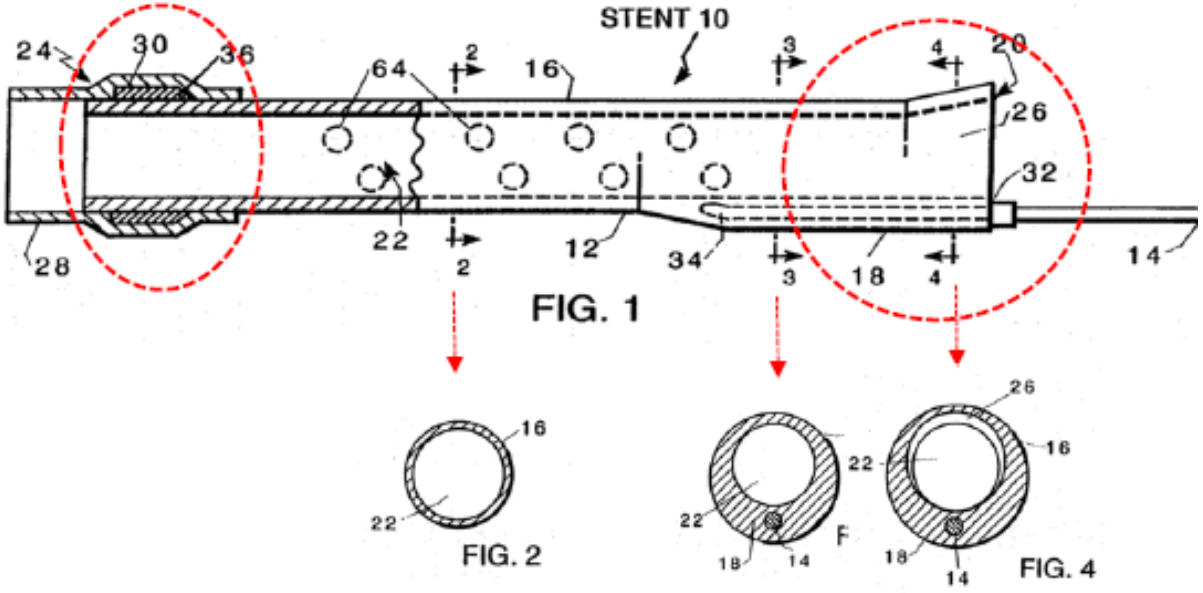
- **IPR2020-00127 (’032 patent)**
- **IPR2020-00130 (’380 patent)**
- **IPR2020-00136 (’776 patent)**

Kontos

(127/130/136 IPRs)

Tip/marker band structure

Base portion 18 for pushrod (wire 14) attachment



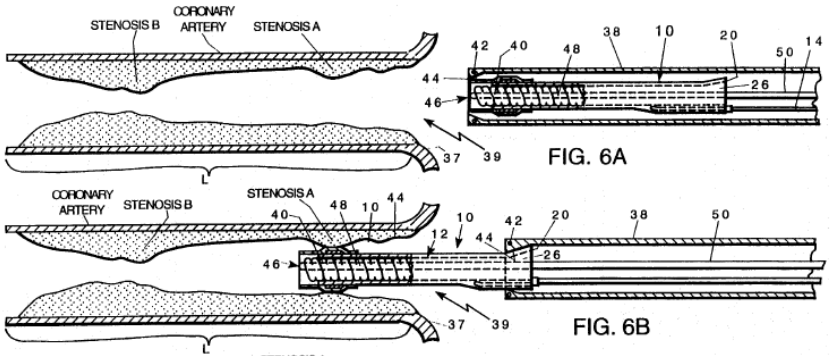
DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

Ex-1401, Figs. 1-4
Ex-2138, ¶118 (127 IPR)

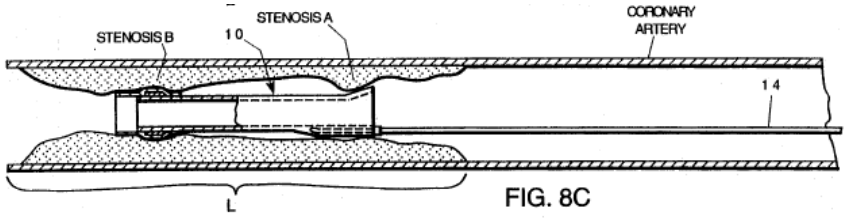
Kontos
(127/130/136 IPRs)

Summary of the Invention: "[A] support catheter, which can also function as a stent, connected to means such as a wire handle" (Ex-1409, 2:13-15)

- "support" and "protect" the "fragile" PTCA catheter that is "readily susceptible to kinking" (*e.g., Ex-1409, 5:20-24, 1:34-35)*



- Narrow enough to serve as a temporary stent itself (*e.g., Ex-1409, 6:59-7:5*):



Ex-1401, Figs. 6A, 6B, 8C

Kontos
(127/130/136 IPRs)

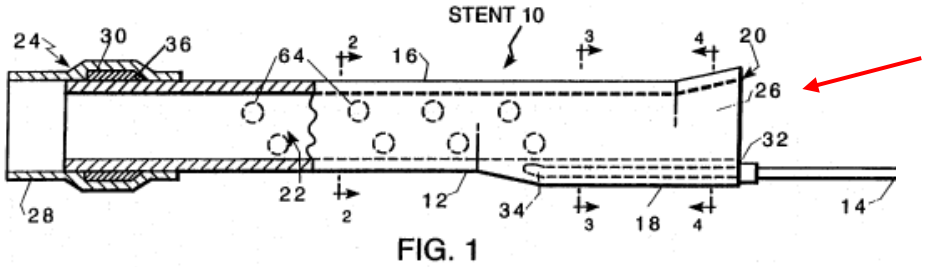


FIG. 1

Kontos's proximal "funnel portion 26":

- "funnel portion 26 facilitates passage of the PTCA catheter 40 from the guide catheter 38 into the lumen 22 of body 12" (Ex-1409, 7:49-52)
- "[t]he conical opening of lumen 22 at funnel portion 26 facilitates insertion of a PTCA catheter or the like therethrough" (Ex-1409, 3:66-68)
- "Because of flared funnel portion 26, the second catheter can negotiate the transition from guide catheter 38 into body 12." (Ex-1409 at 7:20-22).

Ex-1401, Figs. 1-4
Paper 40, 26-27(127 IPR)
Paper 39, 29 (130 IPR)
Paper 39, 17-18 (136 IPR)

Kontos-Based Challenges

***Kontos plus Adams combinations*:**

- IPR2020-00127, all Grounds (’032 patent)
- IPR2020-00130, all Grounds (’380 patent)

Outline of the Arguments:
-00127 and -00130 IPRs (’032 and ’380 patents)

127 IPR: Independent claims 1 and 11 130 IPR: Independent claims 1 and 12	“through which interventional cardiology devices are insertable”
127 IPR: dependent claims 2 and 12 130 IPR: dependent claims 2 and 13	“assists in resisting axial and shear forces . . . that would otherwise tend to dislodge the guide catheter from the branch artery”
127 IPR: dependent claim 6 130 IPR: Independent claim 1	“cylindrical reinforced portion”
127 IPR: dependent claims 3, 4, 9, 13, 18 130 IPR: dependent claims 3, 4, 9, 14, 19	Side opening claims
127 IPR: dependent claims 8 and 17 130 IPR: dependent claims 8 and 18	“One French” claims

Outline of the Arguments:
-00127 and -00130 IPRs (’032 and ’380 patents)

127 IPR: Independent claims 1 and 11 **130 IPR: Independent claims 1 and 12**	**“through which interventional cardiology devices are insertable”**
127 IPR: dependent claims 2 and 12 130 IPR: dependent claims 2 and 13	“assists in resisting axial and shear forces . . . that would otherwise tend to dislodge the guide catheter from the branch artery”
127 IPR: dependent claim 6 130 IPR: Independent claim 1	“cylindrical reinforced portion”
127 IPR: dependent claims 3, 4, 9, 13, 18 130 IPR: dependent claims 3, 4, 9, 14, 19	Side opening claims
127 IPR: dependent claims 8 and 17 130 IPR: dependent claims 8 and 18	“One French” claims

“through which interventional cardiology devices are insertable” (127/130 IPRs)

Independent claims 1 and 11, ’032 patent (127 IPR):

[1/11]. A device for use with a standard guide catheter . . . 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;**
. . .

Independent claims 1 and 12, ’380 patent (130 IPR):

[1/12]. A system **for use with interventional cardiology devices,** . . . the system comprising:
. . .
a device adapted for use with the guide catheter, including:
[. . .]
a flexible tip portion defining a tubular structure and 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**;
. . .

Ex-1401, 127 IPR
Ex-1401, 130 IPR

“through which interventional cardiology devices are insertable” (127/130 IPRs)

The specification defines “interventional cardiology devices”:

Interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. 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. In coronary artery disease the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions. These lesions may totally obstruct the lumen of the artery or may dramatically narrow the lumen of the artery. Narrowing is referred to as stenosis. In order to diagnose and treat obstructive coronary artery disease it is commonly necessary to pass a guidewire or other instruments through and beyond the occlusion or stenosis of the coronary artery.

Ex-1401, 1:17-21 (127 IPR)
Paper 40, 9-11, 18-19 (127 IPR)
Paper 39, 9-11, 19-20 (130 IPR)

“through which interventional cardiology devices are insertable” (127/130 IPRs)

Kontos does not teach cross-sectional diameter through which *stents* or *stent catheters* are insertable:

- No express or inherent disclosure of use with a stent
- Teaches narrow 0.045” inner diameter embodiment, designed to be close-fitting with the narrow PTCA balloon catheter (*Ex-1409, 4:48-50*)

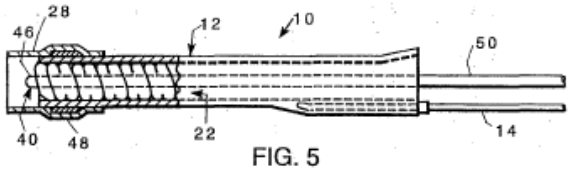


FIG. 5

- Teaches use of support catheter *itself* as a stent (*Ex-1409, 1:13-16, 2:13-14, 6:59-7:5*)

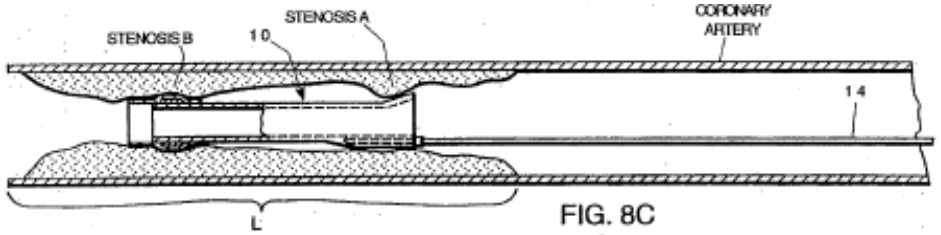


FIG. 8C

“through which interventional cardiology devices are insertable” (127/130 IPRs)

Undisputed that PTCA catheter is a **single** interventional cardiology device :

> “*The ‘PTCA catheter 40 with balloon 48’ that Dr. Brecker points to (Ex-1405, ¶171), is only one such ‘interventional cardiology device’ . . . POSITA would consider the stent and stent catheter to be two separate devices, while a balloon catheter would be considered one device*.”

Ex-2138 (127/130 IPR), ¶141

Outline of the Arguments:
-00127 and -00130 IPRs (’032 and ’380 patents)

127 IPR: Independent claims 1 and 11 130 IPR: Independent claims 1 and 12	“through which interventional cardiology devices are insertable”
127 IPR: dependent claims 2 and 12 **130 IPR: dependent claims 2 and 13**	**“assists in resisting axial and shear forces . . . that would otherwise tend to dislodge the guide catheter from the branch artery”**
127 IPR: dependent claim 6 130 IPR: Independent claim 1	“cylindrical reinforced portion”
127 IPR: dependent claims 3, 4, 9, 13, 18 130 IPR: dependent claims 3, 4, 9, 14, 19	Side opening claims
127 IPR: dependent claims 8 and 17 130 IPR: dependent claims 8 and 18	“One French” claims

“assists in resisting axial and shear forces . . . ”
(127/130 IPRs)

Dependent claim 2, ’032 patent (127 IPR)
Dependent claim 2, ’380 patent (130 IPR):

2. The [device/system] 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.**

Dependent claim 12, ’032 patent (127 IPR)
Dependent claim 13, ’380 patent (130 IPR):

[12/13]. The [device/system] of claim [11/12] wherein, when the distal portion of the flexible tip portion is insertable through the continuous lumen of the guide catheter and beyond the distal end of the guide catheter, the **device assists in resisting axial and shear forces** exerted by an interventional cardiology device passed through and beyond the coaxial lumen **that would otherwise tend to dislodge the guide catheter from the branch artery.**

“assists in resisting axial and shear forces . . . ”
(127/130 IPRs)

No burden shifting, even for inherency:

> “In an inter partes review, the burden of persuasion is on the petitioner . . . and that burden never shifts to the patentee. We have noted that ‘a burden-shifting framework makes sense in the prosecution context,’ where ‘[t]he prima facie case furnishes a 'procedural tool of patent examination, allocating the burdens of going forward as between examiner and applicant.’ [H]owever, ***that burden-shifting framework does not apply in the adjudicatory context of an IPR.***”
>
> *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016) (internal citations omitted, emphasis added)

Paper 86, 9-10 (127 IPR)
Paper 84, 10-11 (130 IPR)

“assists in resisting axial and shear forces . . . ”
(127/130 IPRs)

Inherency is a high bar:

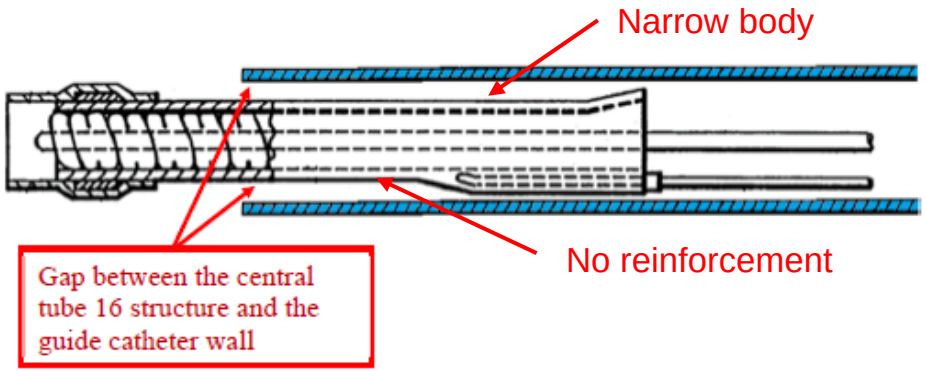
> “[A]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must ***necessarily*** include the unstated limitation . . .”
>
> *Transclean Corp. v. Bridgewood Servs*., 290 F.3d 1364, 1373 (Fed. Cir. 2002) (emphasis in the original)

“assists in resisting axial and shear forces . . . ”
(127/130 IPRs)

Petitioner has not proven inherency:

- Petition: conclusory assertion that Kontos contains “same teachings” as ’032/’380 patents (*Petition at 40 (127 IPR); Petition at 45 (130 IPR)*)

➡ **Not** “same teachings”:



- Kontos’s device **not designed or intended** to “assist[] in resisting axial and shear forces . . . that would otherwise tend to dislodge the guide catheter from the branch artery,” as required by the claims

- “**Pliable**” material (*Kontos, Ex-1009, 4:1-4*)

> Tube **16** may be composed of any pliable material suitable for percutaneous medical procedures, but preferably is composed of a molded plastic material, such as polyethylene.

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

Paper 40, 21-25 (127 IPR)
Paper 39, 24-28 (130 IPR)
Ex-1009, Fig. 1 and 4:1-4; Ex-2138, ¶¶144-149 (127 IPR)

Outline of the Arguments:
-00127 and -00130 IPRs (’032 and ’380 patents)

127 IPR: Independent claims 1 and 11 130 IPR: Independent claims 1 and 12	“through which interventional cardiology devices are insertable”
127 IPR: dependent claims 2 and 12 130 IPR: dependent claims 2 and 13	“assists in resisting axial and shear forces . . . that would otherwise tend to dislodge the guide catheter from the branch artery”
127 IPR: dependent claim 6 **130 IPR: Independent claim 1**	**“cylindrical reinforced portion”**
127 IPR: dependent claims 3, 4, 9, 13, 18 130 IPR: dependent claims 3, 4, 9, 14, 19	Side opening claims
127 IPR: dependent claims 8 and 17 130 IPR: dependent claims 8 and 18	“One French” claims

“cylindrical reinforced portion”

(127/130 IPRs)

Dependent claim 6, ’032 patent (127 IPR):

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.

Independent claim 1, ’380 patent (130 IPR):

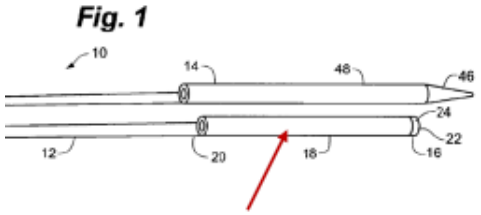
1. . . . wherein the tubular structure includes a flexible cylindrical distal tip portion and a **flexible cylindrical reinforced portion** proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion.

Ex-1401, 127 IPR
Ex-1401, 130 IPR

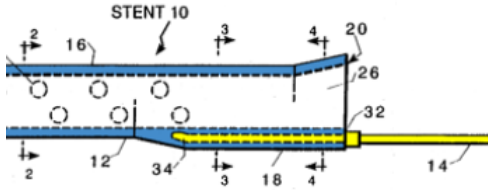
“cylindrical reinforced portion”

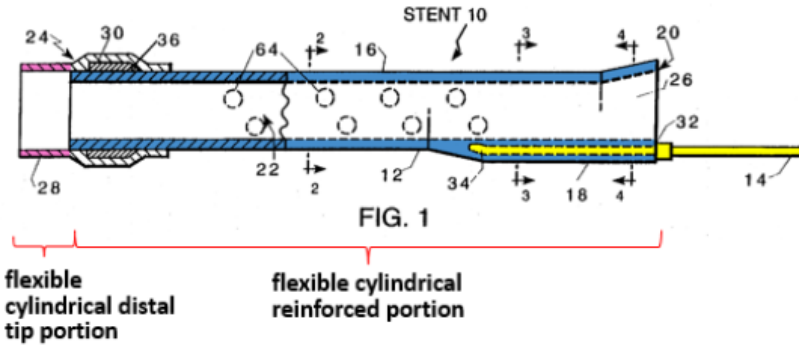
(127/130 IPRs)

“Cylindrical” structure claimed by the ’032 and ’380 patents:



The portions of Kontos the Petition pointed to are not “cylindrical”:



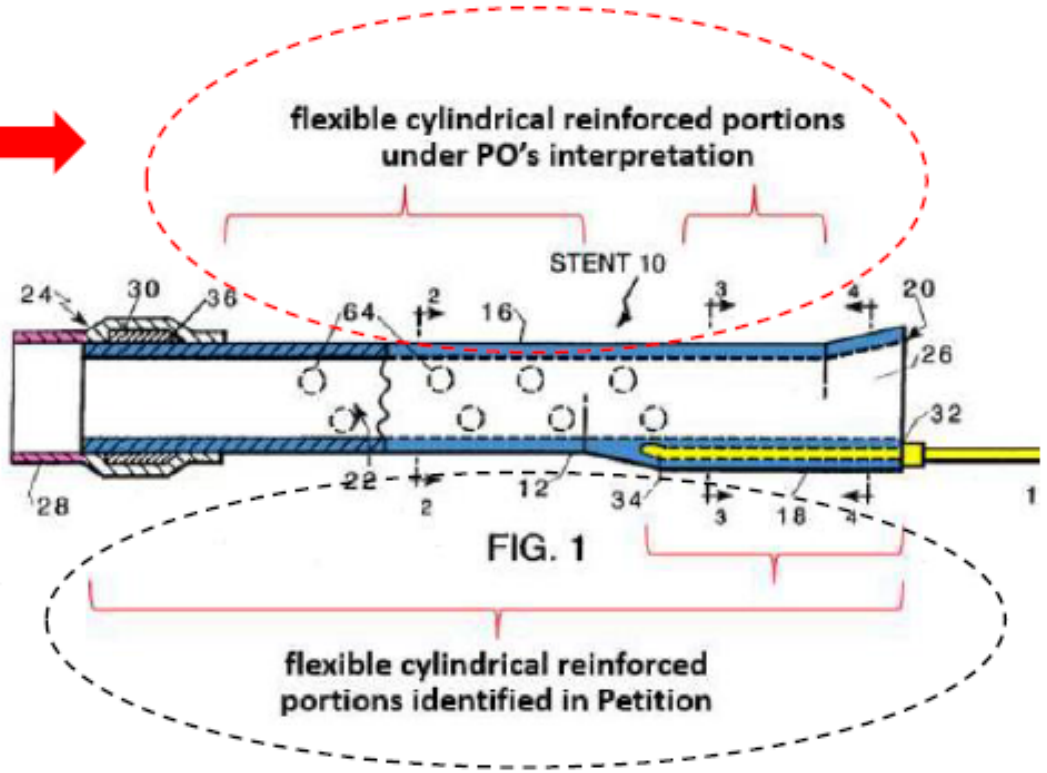


Ex-1405, ¶¶ 206, 217 (127 IPR)
Petition at 49; Paper 40, 41-42 (127 IPR)
Petition at 40-41; Paper 39, 22-24 (127 IPR)

“cylindrical reinforced portion”
(127/130 IPRs)

Petitioner pivots to a ***new mapping*** in Reply:

New argument using a new mapping in Reply



Argument in Petition

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

Paper 86, 22-23 (127 IPR)
Paper 84, 9-10 (130 IPR)
Ex-1009, Fig. 1; Ex-2138, ¶147 (127 IPR)

KONTOS-BASED CHALLENGES

NEW "*six additional modifications*"
Reply Theory

- **IPR2020-00127 ('032 patent)**
- **IPR2020-00130 ('380 patent)**
- **IPR2020-00136 ('776 patent)**

New Reply theory: ***six additional modifications*** to Kontos

127/130 IPR ('032 and '380 patents):

Kontos (as modified in Petition):

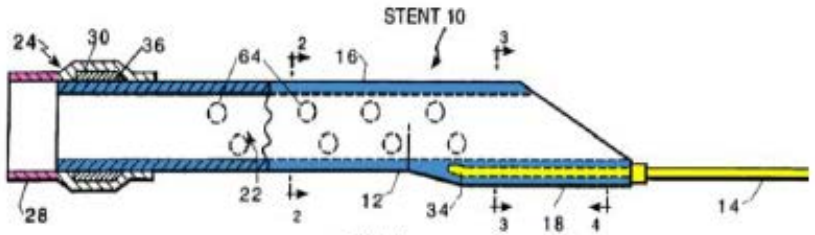


FIG. 1

Kontos (as completely redesigned in Reply):

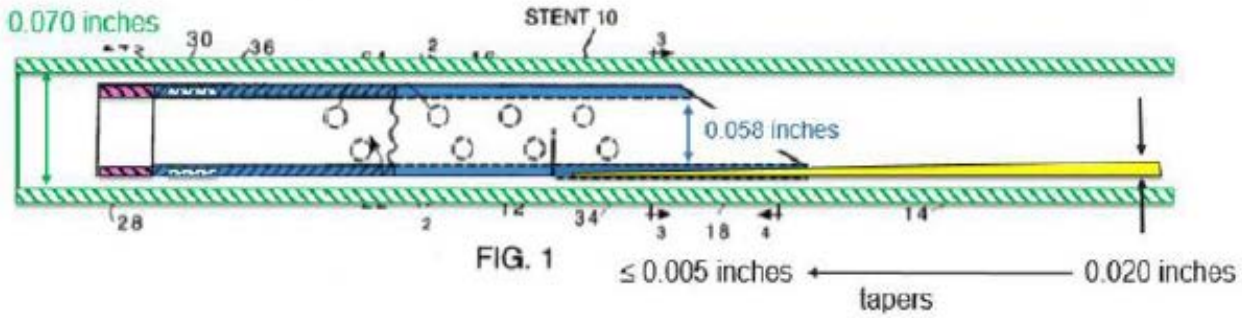
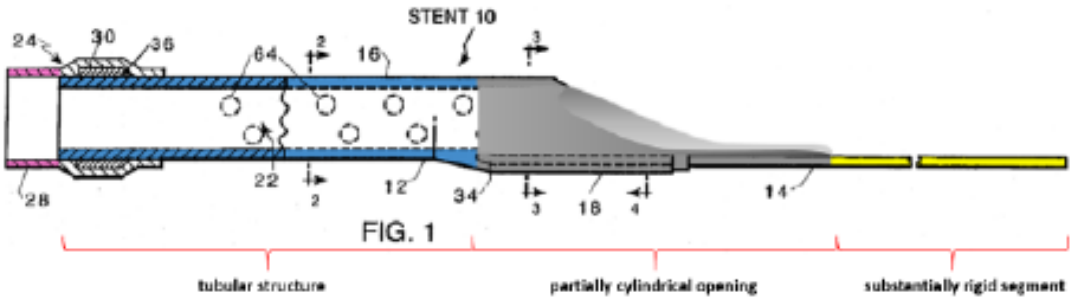


FIG. 1

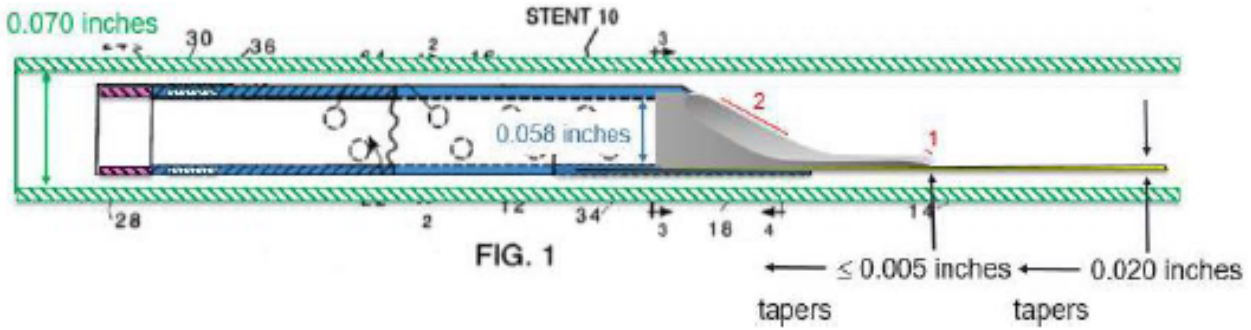
New Reply theory: ***six additional modifications*** to Kontos

136 IPR
('776 patent):

Kontos, as modified in Petition:



Kontos, as completely redesigned in Reply:



New Reply theory: ***six additional modifications*** to Kontos

Petitioner's new expert Jones admitted the new theory requires at least ***six additional changes***:

Q. A fifth modification you show in your combination is to align the distal soft tip with the tube, right?
A. That's correct.
Q. A sixth modification you show in your proposed combination is you taper the Kontos push wire, right?
A. That's correct.

(Ex-2241, 124:13-126:20)

Kontos (as modified in Petition):

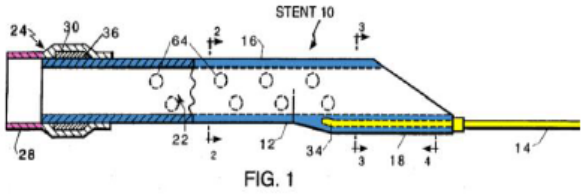


FIG. 1

Kontos (as completely redesigned in Reply):

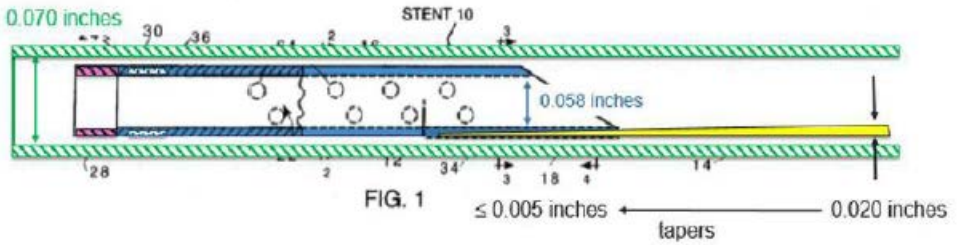


FIG. 1

Paper 86, 3-7 (127 IPR)
Paper 84, 3-7 (130 IPR)
Paper 85, 3-7 (136 IPR)

New Reply theory: ***six additional modifications*** to Kontos

Petitioner relies on the new "six additional change" theory for many challenged claims:

Claims	Petitioner Reply	Type
3, 4, 9, 13, 18 of '032 patent (127 IPR)	Paper 71 at 13-14 and n.4, 18-19	Side opening claims
3, 4, 9, 14, 19 of '380 patent (130 IPR)	Paper 69 at 14-15 and n.4, 19-20	Side opening claims
8, 17 of '032 patent (127 IPR)	Paper 71 at 21-22	"one French" claims
8, 18 of '380 patent (130 IPR)	Paper 69 at 21-22	"one French" claims
25, 52, 53 of the '776 patent (136 IPR)	Paper 69 at 8, 13-15	Side opening and complex side opening claims
30-31, 53-56 of the '776 patent (136 IPR)	Paper 69 at 20-21	"one French size" claims

New Reply theory: ***six additional modifications*** to Kontos

Petitioner's new Reply theory is unsupported: eccentric base portion 18 "provides leverage"

will readily occur to those skilled in the art. It will be appreciated that this configuration, wherein tube **16** has an eccentric cross-section at base portion **18** and wire **14** is affixed thereto, provides leverage for facilitating manipulation of body **12**.

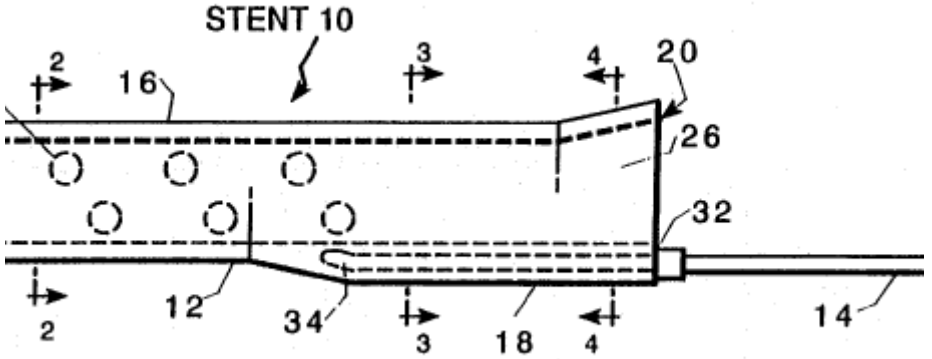


FIG. 1

Ex-1409, 3:67-68, 4:25-38; Fig. 1
Paper 86 at 6 (127 IPR)
Paper 84 at 6 (130 IPR)
Paper 85, 5-6 (136 IPR)

New Reply theory: ***six additional modifications*** to Kontos

Petitioner's new Reply theory is unsupported: Deposition testimony of Petitioner's new engineering expert Jones

- Petitioner's expert **not aware of any prior art showing wire tapered to less than 0.005"**

So the question specific -- the question specifically to the wire being tapered, I don't know the ultimate smallest diameter that a

Page 49

guidewire can be tapered down to.
Q. Okay. You haven't identified any prior art where a wire is tapered down to .005 inches, right?
A. I believe that's correct. I have not identified prior art with the wire tapered below .005 inches.

- 'Tapered' pushwire would result in a **256X *decrease*** in polar moment of inertia

A. The ratio of polar moment of inertia for an .020 wire is 256 times larger than the polar moment of inertia for a .005 wire.

- POSITA **would have to "bolster" base portion** of tube wall (Ex-2241, 138:3-11)

Q. Are you saying that the -- in your proposed combination, that the Kontos device would not have a constant wall thickness?
A. I'm saying it can -- it can be created so that it does not have a constant wall thickness.
Q. And I'm asking you: What are you saying one of skill in the art would do in this case?
A. In this case, one would bolster the wall to provide a better bonding.

Paper 86 at 6 (127 IPR); Paper 84 at 6 (130 IPR); Paper 85, 5-6 (136 IPR)

Outline of the Arguments:
-00127 and -00130 IPRs (’032 and ’380 patents)

127 IPR: Independent claims 1 and 11 130 IPR: Independent claims 1 and 12	“through which interventional cardiology devices are insertable”
127 IPR: dependent claims 2 and 12 130 IPR: dependent claims 2 and 13	“assists in resisting axial and shear forces . . . that would otherwise tend to dislodge the guide catheter from the branch artery”
127 IPR: dependent claim 6 130 IPR: Independent claim 1	“cylindrical reinforced portion”
127 IPR: dependent claims 3, 4, 9, 13, 18 **130 IPR: dependent claims 3, 4, 9, 14, 19**	**Side opening claims**
127 IPR: dependent claims 8 and 17 130 IPR: dependent claims 8 and 18	“One French” claims

Side opening claims
(127/130 IPRs)

127 IPR, Ground 1 (’032 patent)
130 IPR, Ground 1 (’380 patent):

3. The [device/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 . . .

9. The [device/system] of claim 1 wherein the substantially rigid portion includes from distal to proximal direction, a cross-sectional shape having **a full circumference portion, a hemicylindrical portion and an arcuate portion**.

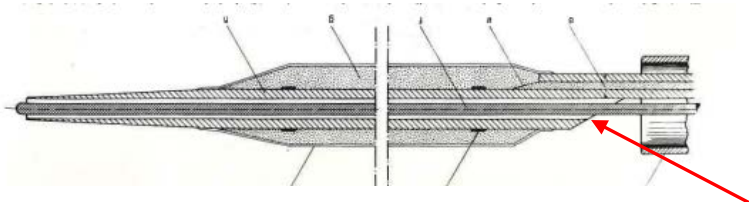
[13/14]. The [device/system] of claim [11/12] wherein the substantially rigid portion further includes a **partially cylindrical portion defining an opening extending for a distance along a side thereof** defined transverse to a longitudinal axis . . . the opening extending substantially along at least a portion of a length of the substantially rigid portion.

[18/19]. The [device/system] of claim [11/12] wherein the substantially rigid portion includes, [starting at a] from distal to proximal [direction], **a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion**.

Side opening claims
(127/130 IPRs)

Proximal side openings to receive interventional devices while inside the guide catheter were ***not*** "well-known in the art" *(see Petition at 42 (127 IPR); Petition at 47 (130 IPR))*

- Bonzel (*Ex-1432*):



- Enger (*Ex-1450, Fig. 7*):

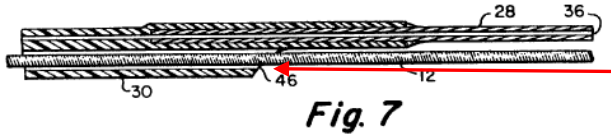
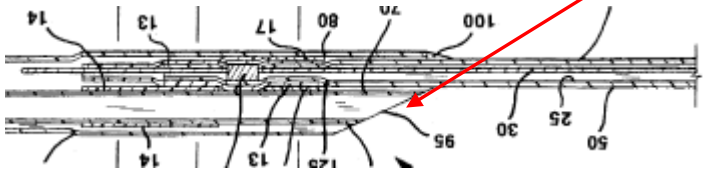


Fig. 7

- Verbeek (*Ex-1461, Fig. 1B*):

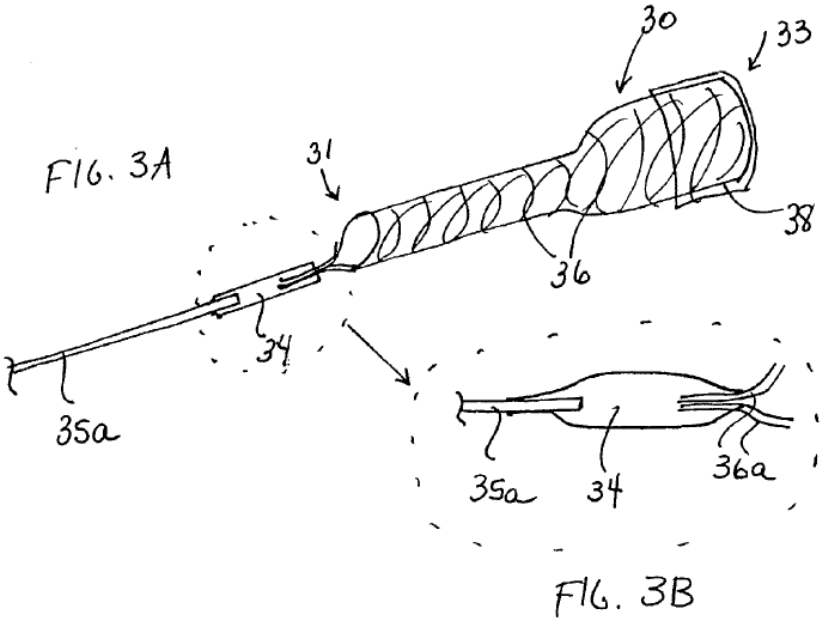


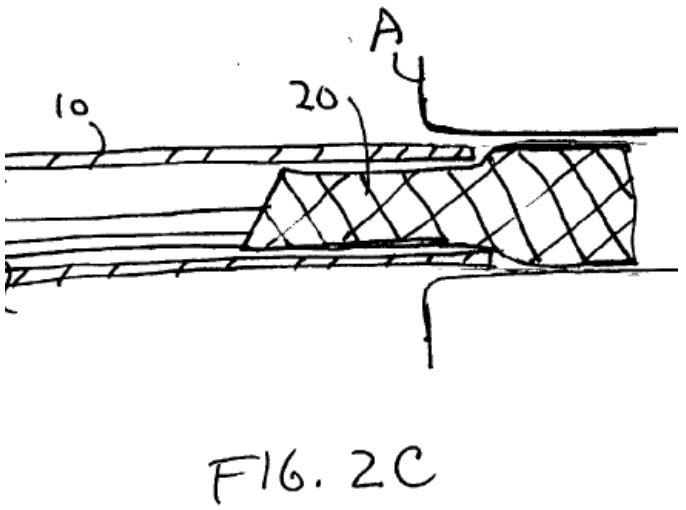
Guidewire ***exit*** port

Paper 40, 32-33 (127 IPR)
Paper 39, 36 (130 IPR)
Ex-2138 (127 IPR), ¶¶ 166-172
Ex-2145, ¶¶ 107-109

Adams (127/130 IPRs)

Adams (Ex-1435) teaches an expandable mesh guide seal:





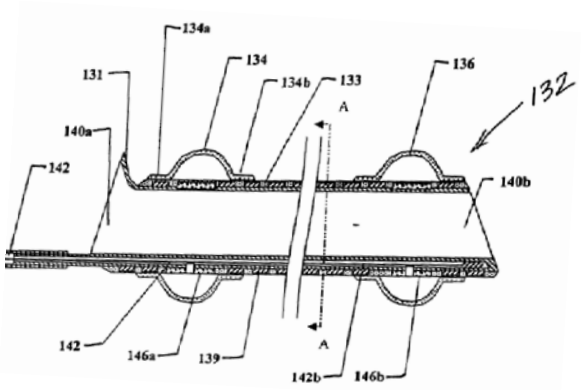
Ex-2138, ¶ 163-164; Ex-2145, ¶ 159, 163-165, 218
Ex-1435, Figs. 2C, 3A, 3B, [0066], [0067]

Side opening claims
(127/130 IPRs)

Ressemann teaches away from replacing a funnel with a bare side opening:

- Funnel = no catching/hang-up issues

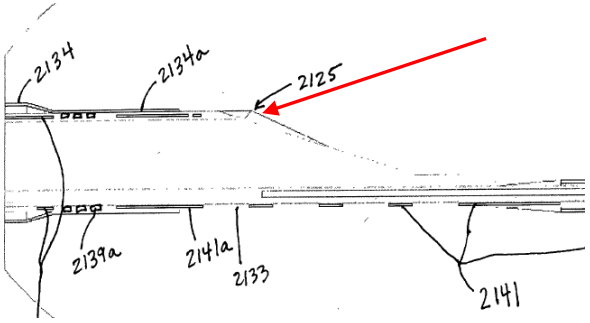
The evacuation head **132** also contains a flare **131** on the proximal end **140***a* of the evacuation lumen **140**. This flare **131** is intended to allow for easier passage of devices through the proximal end **140***a* of the evacuation lumen **140**. The flare **131** can also create a clearance seal that prevents the passage of fluid between the evacuation head **132** and the guide catheter **160**. This provides a sliding seal when the proximal and distal sealing balloons **134** and **136** are deflated.



Ex-1408, 7:40-46 and Fig. 11A

- Bare side opening = ***creates*** catching/hang-up issues

The reverse bevel **2125** preferably is formed at an angle of between about 30 and 60 degrees from perpendicular and further serves to minimize hanging-up or catching of intravascular devices on the proximal end of the evacuation head **2132**. Stent delivery catheters, for example, are particularly subject to hanging-up on the proximal end of the evacuation head **2132** without reverse bevel **2125**.



Ex-1408, 25:23-29 and Fig. 16D

Paper 40, 28-29; Paper 86, 11-12, 15-16 (127 IPR)
Paper 39, 31; Paper 84, 13, 16-17 (130 IPR)

Kontos
(127/130/136 IPRs)

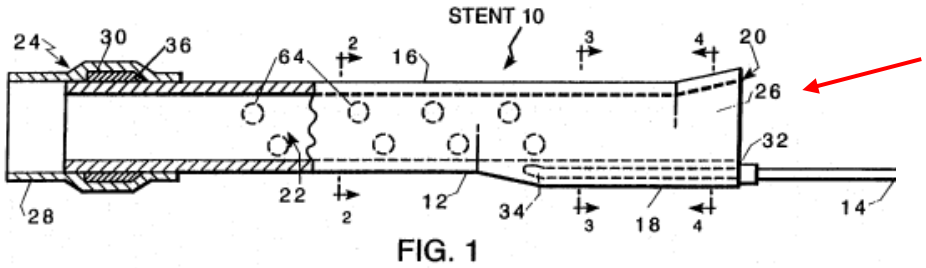


FIG. 1

Kontos's proximal "funnel portion 26":

- "funnel portion 26 facilitates passage of the PTCA catheter 40 from the guide catheter 38 into the lumen 22 of body 12" (Ex-1409, 7:49-52)
- "[t]he conical opening of lumen 22 at funnel portion 26 facilitates insertion of a PTCA catheter or the like therethrough" (Ex-1409, 3:66-68)
- "Because of flared funnel portion 26, the second catheter can negotiate the transition from guide catheter 38 into body 12." (Ex-1409 at 7:20-22).

Ex-1401, Figs. 1-4
Paper 40, 26-27(127 IPR)
Paper 39, 29 (130 IPR)
Paper 39, 17-18 (136 IPR)

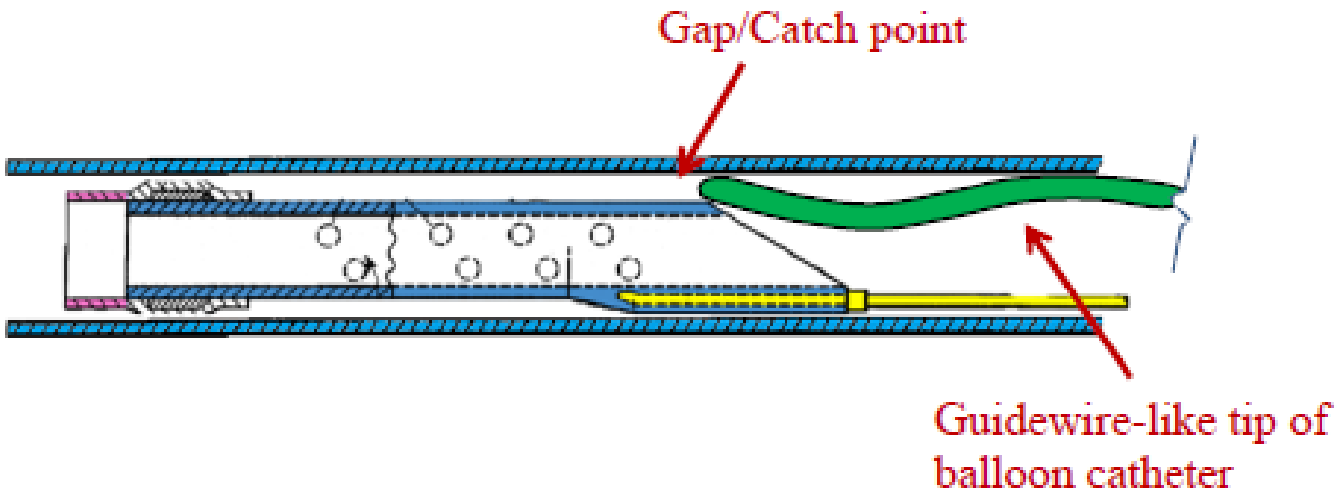
Side opening claims
(127/130 IPRs)

Petitioner relies on shifting and unsupported 'motivations'

Petition 'motivation'	Reply 'motivation'
First, "permit a reduction of the outer diameter of the catheter assembly without resulting in a commensurate reduction in the area of the point of entry" *(Paper 3 at 43-47 (127 IPR); Paper 1 at 48-52 (130 IPR))*	Petitioner ***does not dispute*** that Kontos as disclosed would fit in a 6 *French (e.g., Paper 71, 16-17(127 IPR))* Petitioner ***admits*** would need the new "six additional modifications" Reply theory to fit into 5 French guide catheter *(e.g., Paper 71, 13 n.4 (127 IPR))*
--	**NEW in Reply:** "maximizes the usable real estate within the catheter assembly" *(Paper 71, 11-14 (127 IPR); Paper 69, 12-15 (130 IPR))*
--	**NEW in Reply:** "increasing the diameter of the extension catheter" *(Paper 71, 13-14 (127 IPR); Paper 69, 14-15 (130 IPR))*
Second, "facilitates 'smoother' reception of the 'interventional cardiology device as it enters the lumen" *(Paper 3 at 43-47 (127 IPR); Paper 1 at 48-52 (130 IPR))*	Reply addresses briefly
Third, "promotes 'smoother passage' of the catheter assembly as it navigates the tortuous vasculature" *(Paper 3 at 43-47 (127 IPR); Paper 1 at 48-52 (130 IPR))*	Reply addresses briefly
Fourth, "permitted smooth re-entry" of the proximal end into the GC "if the proximal end of the extension catheter was extended beyond the distal end of the GC" *(Paper 3 at 43-47 (127 IPR); Paper 1 at 48-52 (130 IPR))*	Reply addresses briefly

Side opening claims
(127/130 IPRs)

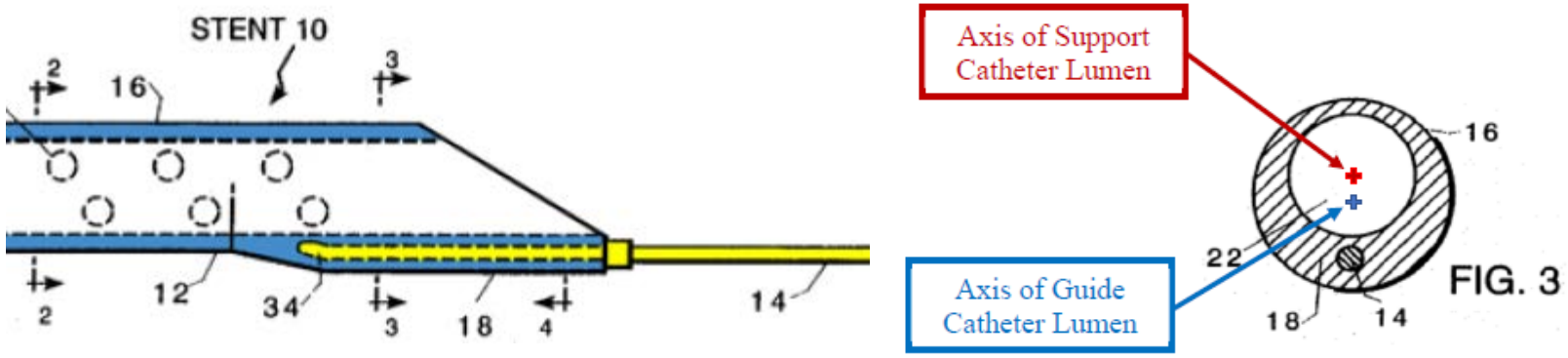
Modification expected to create problems where none existed before:



Paper 40, 27-28; Paper 86, 17-18 (127 IPR)
Paper 39, 30-31; Paper 84, 18-19 (130 IPR)
Ex-2138, ¶158 (127 IPR)

Side opening, claims 3 and 9
(127/130 IPRs)

For claims 3 and 9 of ’032 and ’380 patents, Kontos as modified by Petitioner not “coaxial”:



Paper 40, 39-40 and n.7; Paper 86, 19-22 (127 IPR)
Paper 39, 42-43 and n.8; Paper 84, 20-23 (130 IPR)

Side opening, claims 3 and 9
(127/130 IPRs)

For claims 3 and 9 of ’032 and ’380 patents, Kontos as modified by Petitioner not “coaxial”:

Kontos’s full-length, OTW embodiment:

“Coaxial”:

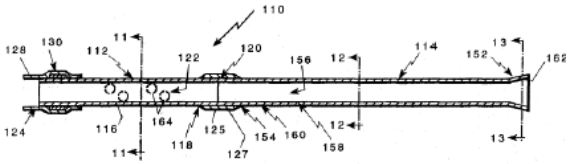


FIG. 10

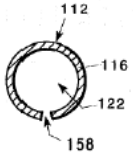


FIG. 12

*“[T]ube 116 and lumen 122 are generally cylindrical and **coaxial** along the length of body 112 . . . Body tube 116 is dissimilar to tube 16 of the prior embodiment in that . . . base portion 118 is symmetrical about its axis, **not eccentric**.” Ex-1409, 8:31-37*

Kontos embodiment Petition relies on:

“Eccentric”:

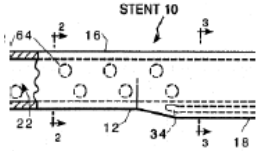


FIG. 1

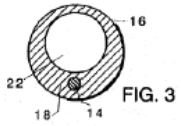


FIG. 3

*“[T]ube 16 has an **eccentric** cross-section at base potion 18. . . .” Ex-1409, 4:35-36.*

Outline of the Arguments:
-00127 and -00130 IPRs (’032 and ’380 patents)

127 IPR: Independent claims 1 and 11 130 IPR: Independent claims 1 and 12	“through which interventional cardiology devices are insertable”
127 IPR: dependent claims 2 and 12 130 IPR: dependent claims 2 and 13	“assists in resisting axial and shear forces . . . that would otherwise tend to dislodge the guide catheter from the branch artery”
127 IPR: dependent claim 6 130 IPR: Independent claim 1	“cylindrical reinforced portion”
127 IPR: dependent claims 3, 4, 9, 13, 18 130 IPR: dependent claims 3, 4, 9, 14, 19	Side opening claims
127 IPR: dependent claims 8 and 17 **130 IPR: dependent claims 8 and 18**	**“One French” claims**

“one French” claims
(127/130 IPRs)

Claims 8 and 17, ’032 patent
(127 IPR, Ground 2):

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.

17. The device of claim 11 wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion is **not more than one French smaller** than the cross-sectional inner diameter of the guide catheter.

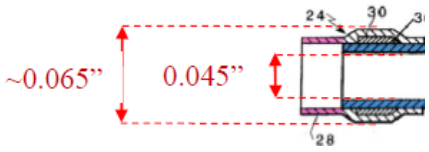
Claims 8 and 18, ’380 patent
(130 IPR, Ground 2):

8. The system 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.

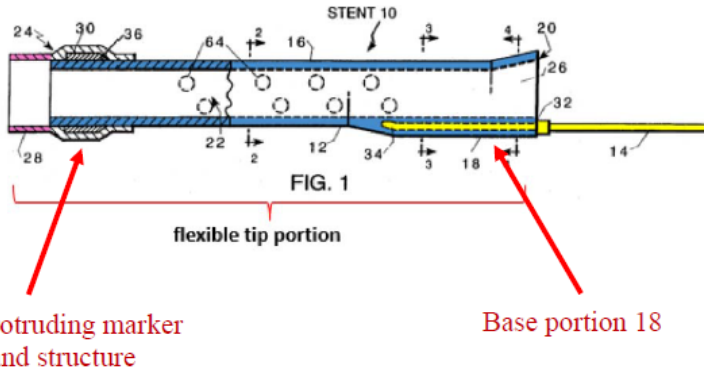
18. The system of claim 12, wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion is **not more than one French smaller** than the cross-sectional inner diameter of the guide catheter.

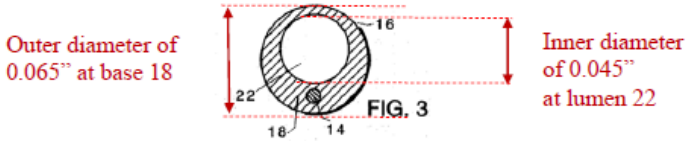
“one French” claims
(127/130 IPRs)

- Modification proposed by the Petition (removing the proximal funnel) would not result in the claimed “one French” limitation:



0.020” > “one French”





0.020” > “one French”

- The Board should **reject** Petitioner’s new “six additional modifications” theory *(see Reply, Paper 71 at 21-22 (127 IPR) and Paper 69 at 21-22 (130 IPR))*

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

Ex-2138, ¶199-201 (127 IPR)
Paper 40, 44-47 (127 IPR)
Paper 39, 46-48 (130 IPR)

Takahashi (Ex-1410)

Teaches mother-in-child technique:

"The concept of a mother-and-child catheter system dates back to at least 1991, when U.S. Patent No. 5,120,323 was filed by Shockey et al. (Ex-1454.)"

- Petitioner's expert Dr. Brecker (Ex-1405, ¶ 71)

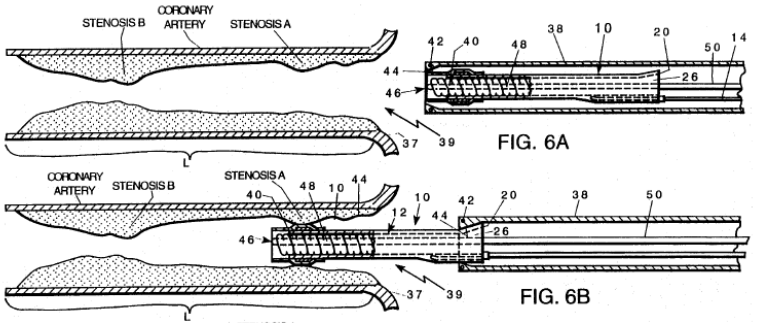
'032/'380 patents expressly discuss and distinguish Takahashi:

A fourth technique includes the placement of a smaller guide catheter within a larger guide catheter in order to provide added support for the crossing of lesions or for the distal delivery of balloons and stents. This technique has been described in an article by Takahashi entitled "New Method to Increase a Backup Support of Six French Guiding Coronary Catheter," published in Catheterization and Cardiovascular Interventions, 63:452-456 (2004). This technique is used in order to provide a method of deep seating the guide catheter within the ostium of the coronary artery. Deep seating refers to inserting the catheter more deeply into the ostium of the coronary artery than typically has been done before. Unfortunately, deep seating by this technique with a commonly available guide catheter creates the risk that the relatively stiff, fixed curve, guide catheter will damage the coronary artery. This damage may lead to dissection of the coronary artery when the catheter is advanced past the ostium.

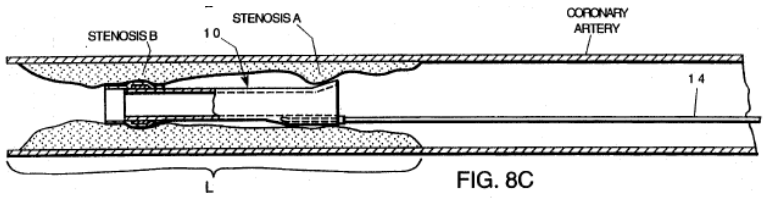
Several other problems arise when using a standard guide catheter in this catheter-in-a-catheter fashion. First, the inner catheters must be substantially longer than the one hundred centimeter guide catheter. Second, a new hemostasis valve must be placed on the inner guide catheter which prevents the larger guide catheter from being used for contrast injections or pressure measurements. Third, the smaller guide catheter still must be inserted into the coronary vessel with great care since the smaller guide catheter has no tapered transition or dilator at its tip and does not run over a standard 0.014 inch guidewire.

“one French” claims
(127/130 IPRs)

- Requires removing Kontos’s proximal funnel – no motivation
- No motivation to “maximize inner diameter” of Kontos
  - Kontos intended to “support” and “protect” the “fragile” PTCA catheter that is “readily susceptible to kinking” (*e.g., Ex-1409, 5:20-24, 1:34-35*):



  - Kontos intended to serve as a temporary stent itself (*e.g., Ex-1409, 6:59-7:5*):



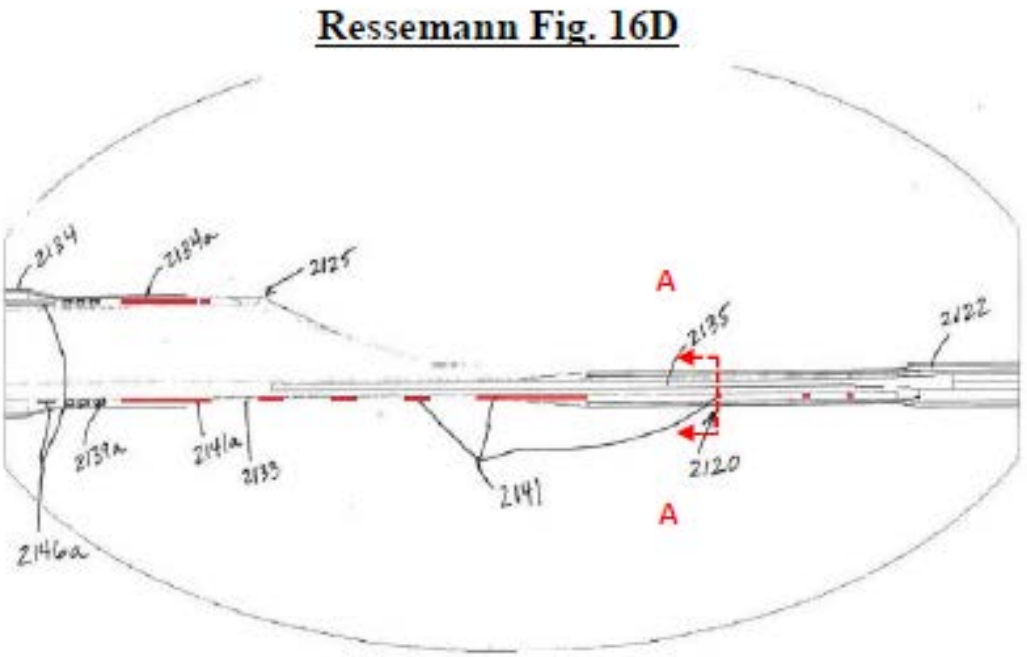
Paper 40, 43-44; Paper 86, 23-24 (127 IPR)
Paper 39, 44-46; Paper 84, 23 (130 IPR)

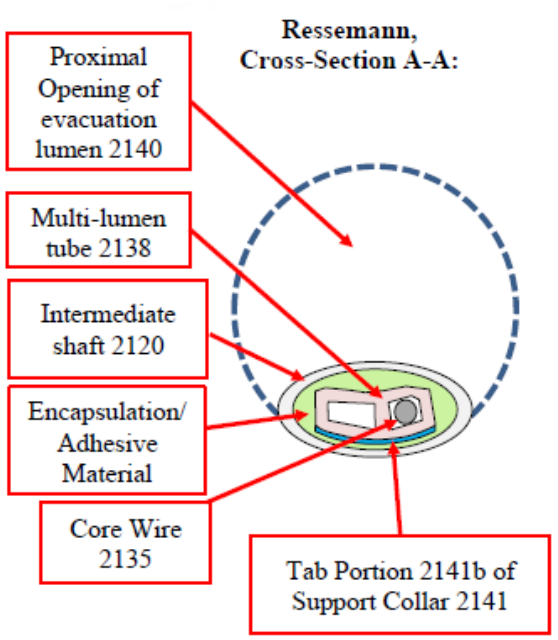
Kontos-Based Challenges

***Kontos plus Ressemann/Kataishi combinations*:**

- IPR2020-00136, all Grounds (’776 patent)

“a segment defining a partially cylindrical opening”
(136 IPR, claim 25)





Paper 39, 35-36 (136 IPR)
Ex-2138, ¶ 128 (136 IPR)

Outline of the Arguments:
-00136 IPR ('776 patent)

Independent claim 25 (Ground 1) *[Kontos + Ressemann]*	**"segment defining a partially cylindrical opening . . . having an angled proximal end"**
Independent claim 52 (Ground 1) Independent claim 53 (Ground 2) Dependent claim 36 (Ground 1) *[Kontos + Ressemann]*	complex side opening claims
Independent claim 52 (Ground 3) Independent claim 53 (Ground 4) *[Kontos + Ressemann + Kataishi]*	complex side opening claims
Independent claim 53 (Ground 2) *[Kontos, Ressemann, Takahashi]* Independent claim 53 (Ground 4) *[Kontos, Ressemann, Takahashi, Kataishi]* Dependent claims 30-32 (Ground 2)	"One French size" claims
Dependent claim 49 (Ground 1) *[Kontos + Ressemann]*	"resist axial and shear forces . . . that would otherwise tend to dislodge the distal portion"

“a segment defining a partially cylindrical opening”
(136 IPR, claim 25)

25. 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

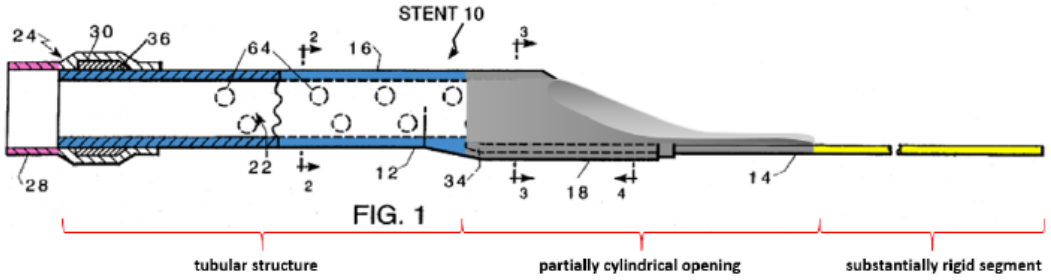
a **segment defining a partially cylindrical opening** positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, **the segment defining the partially cylindrical opening having an angled proximal end**, formed from a material more rigid than a material 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.

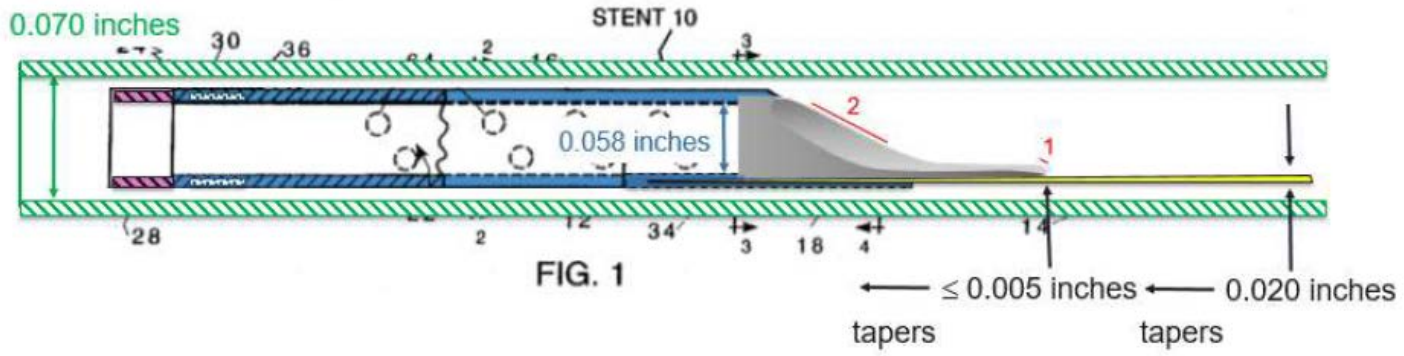
“a segment defining a partially cylindrical opening”

(136 IPR, independent claims 25, 52, 53)

Combination proposed by the Petition:



New theory in Reply:



DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

Petition, 28-29; Paper 69, 8, 14-15, 20-21 (136 IPR)

“a segment defining a partially cylindrical opening”

(136 IPR, independent claims 25, 52, 53)

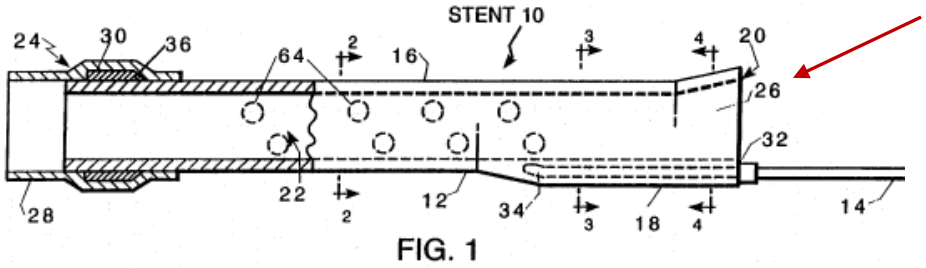


FIG. 1

Kontos’s proximal “funnel portion 26”:

- “funnel portion 26 facilitates passage of the PTCA catheter 40 from the guide catheter 38 into the lumen 22 of body 12” (Ex-1409, 7:49-52)
- “[t]he conical opening of lumen 22 at funnel portion 26 facilitates insertion of a PTCA catheter or the like therethrough” (Ex-1409, 3:66-68)
- “Because of flared funnel portion 26, the second catheter can negotiate the transition from guide catheter 38 into body 12.” (Ex-1409 at 7:20-22).

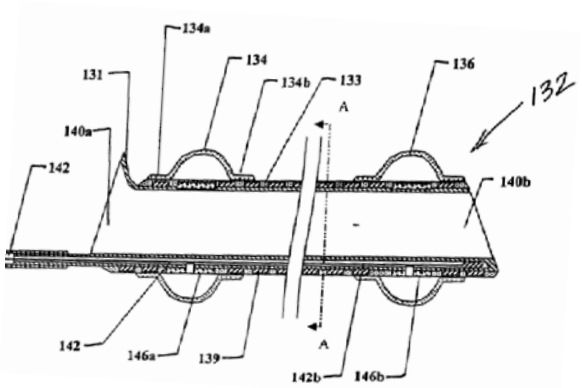
Ex-1401, Figs. 1-4
Paper 39, 17-18 (136 IPR)

“a segment defining a partially cylindrical opening”
(136 IPR, independent claims 25, 52, 53)

Ressemann teaches away from replacing a funnel with a bare side opening:

- Funnel = no catching/hang-up issues

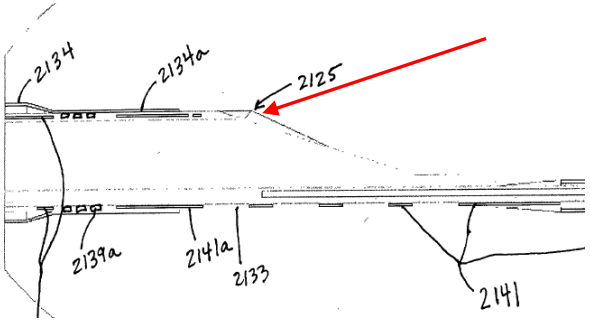
The evacuation head **132** also contains a flare **131** on the proximal end **140***a* of the evacuation lumen **140**. This flare **131** is intended to allow for easier passage of devices through the proximal end **140***a* of the evacuation lumen **140**. The flare **131** can also create a clearance seal that prevents the passage of fluid between the evacuation head **132** and the guide catheter **160**. This provides a sliding seal when the proximal and distal sealing balloons **134** and **136** are deflated.



Ex-1408, 7:40-46 and Fig. 11A

- Bare side opening = ***creates*** catching/hang-up issues

The reverse bevel **2125** preferably is formed at an angle of between about 30 and 60 degrees from perpendicular and further serves to minimize hanging-up or catching of intravascular devices on the proximal end of the evacuation head **2132**. Stent delivery catheters, for example, are particularly subject to hanging-up on the proximal end of the evacuation head **2132** without reverse bevel **2125**.



Ex-1408, 25:23-29 and Fig. 16D

Paper 39, 20; Paper 85, 13 (136 IPR)
Ex-2138 (136 IPR), ¶¶148-149; Ex-2145, ¶216

“a segment defining a partially cylindrical opening”

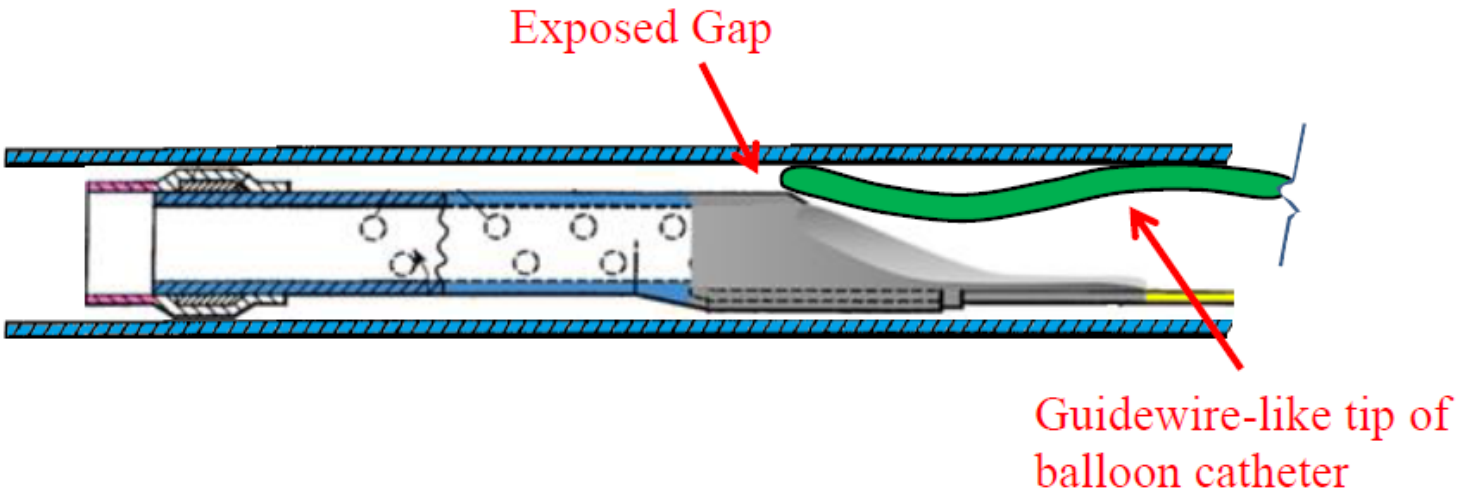
(136 IPR, independent claims 25, 52, 53)

Petitioner relies on shifting and unsupported ‘motivations’

Petition ‘motivation’	Reply ‘motivation’
First, “permit a reduction of the outer diameter of the catheter assembly without resulting in a commensurate reduction in the area of the point of entry” *(Paper 3 at 29-31 (136 IPR))*	Petitioner ***does not dispute*** that Kontos as disclosed would fit in a 6 *French (Paper 69, 11 (136 IPR))* Petitioner ***admits*** would need the new “six additional modifications Reply theory to fit into 5 French guide catheter *(Paper 69, 7 n.2 (136 IPR)*
--	**NEW in Reply:** “maximizes the usable area in the catheter assembly” *(Paper 69, 5-8 (136 IPR))*
--	**NEW in Reply**: “increasing the diameter of the extension catheter” *(Paper 69, 7-8 (136 IPR))*
--	**NEW in Reply:** “increase the area of entry—by more than five-fold—into the side opening” *(Paper 69, 9 (136 IPR))*
Second, “facilitates ‘smoother’ reception of the ‘interventional cardiology device as it enters the lumen” *(Paper 3 at 31 (136 IPR))*	Reply addresses briefly
Third, “promotes ‘smoother passage’ of the catheter assembly as it navigates the tortuous vasculature” *(Paper 3 at 32 (136 IPR))*	Reply addresses briefly
Fourth, “permitted smooth re-entry” of the proximal end into the GC “if the proximal end of the extension catheter was extended beyond the distal end of the GC” *(Paper 3 at 32 (136 IPR))*	Reply addresses briefly

“a segment defining a partially cylindrical opening”
(136 IPR, independent claims 25, 52, 53)

Modification expected to create problems where none existed before:



Paper 39 at 18-20; Paper 85 at 14-16 (136 IPR)
Ex-2145, ¶¶233-235; Ex-2138, ¶¶145-149 (136 IPR)

Outline of the Arguments:
-00136 IPR ('776 patent)

Independent claim 25 (Ground 1)	"a segment defining a partially cylindrical opening . . . having an angled proximal end"
Independent claim 52 (Ground 1) **Independent claim 53 (Ground 2)** **Dependent claim 36 (Ground 1)** ***[Kontos + Ressemann combinations]***	**complex side opening claims**
Independent claim 52 (Ground 3) **Independent claim 53 (Ground 4)** ***[Kontos + Kataishi combinations]***	**complex side opening claims**
Independent claim 53 (Grounds 2, 4) Dependent claims 30-32 (Ground 2)	"One French size" claims
Dependent claim 49 (Ground 1)	"resist axial and shear forces . . . that would otherwise tend to dislodge the distal portion"

Complex side opening claims
(136 IPR, ’776 patent)

52. A guide extension catheter . . . 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**

53. A guide extension catheter . . . 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; . . . 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**

36. The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening **includes at least one inclined region that tapers into a non-inclined region**.

Complex side opening claims
(136 IPR, ’776 patent)

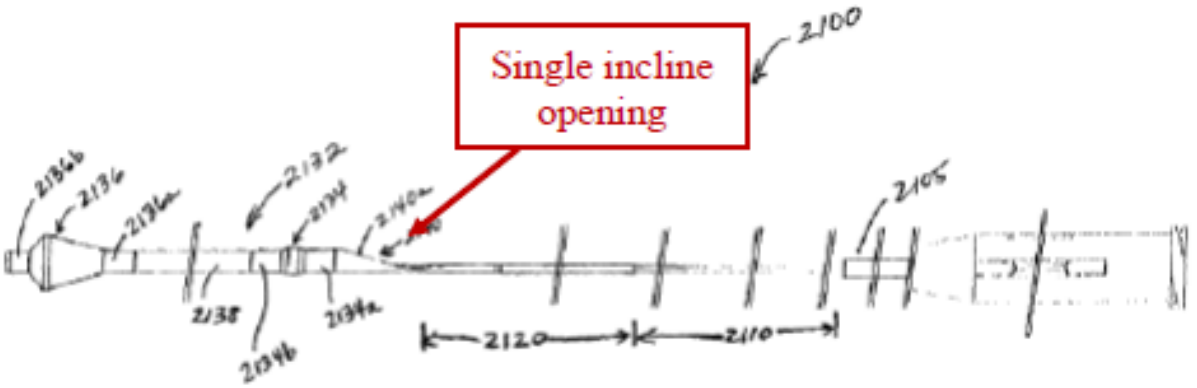
Two Arguments Based on Two Secondary References:

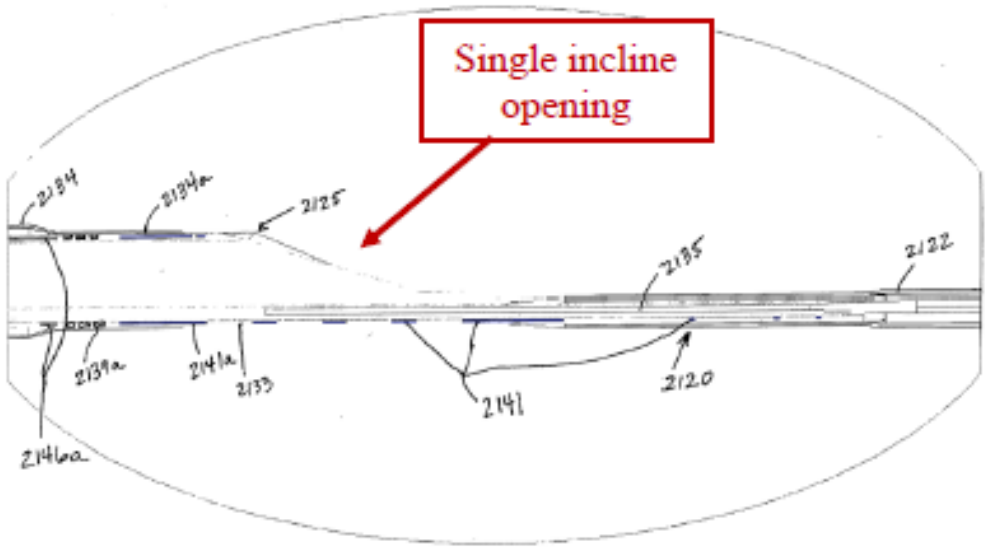
1. **Kontos + Ressemann**
   - Claims 52, 36 (Ground 1)
   - Claims 53-56 (Ground 2)
2. Kontos + Kataishi
   - Claim 52 (Ground 3)
   - Claims 53-56 (Ground 4)

NONE SHOWS A DEVICE WITH A PROXIMAL COMPLEX SIDE OPENING

Complex side opening claims – **Kontos + Ressemann**
(136 IPR, ’776 patent)

Ressemann teaches only a ***single incline*** proximal opening:





Ex-1408, Figs. 16A, 16D
Paper 39, 32-33 (136 IPR)
Ex-2138 (136 IPR), ¶¶ 184-86; Ex-2145, ¶ 140-42

Complex side opening claims – **Kontos + Ressemann**
(136 IPR, ’776 patent)

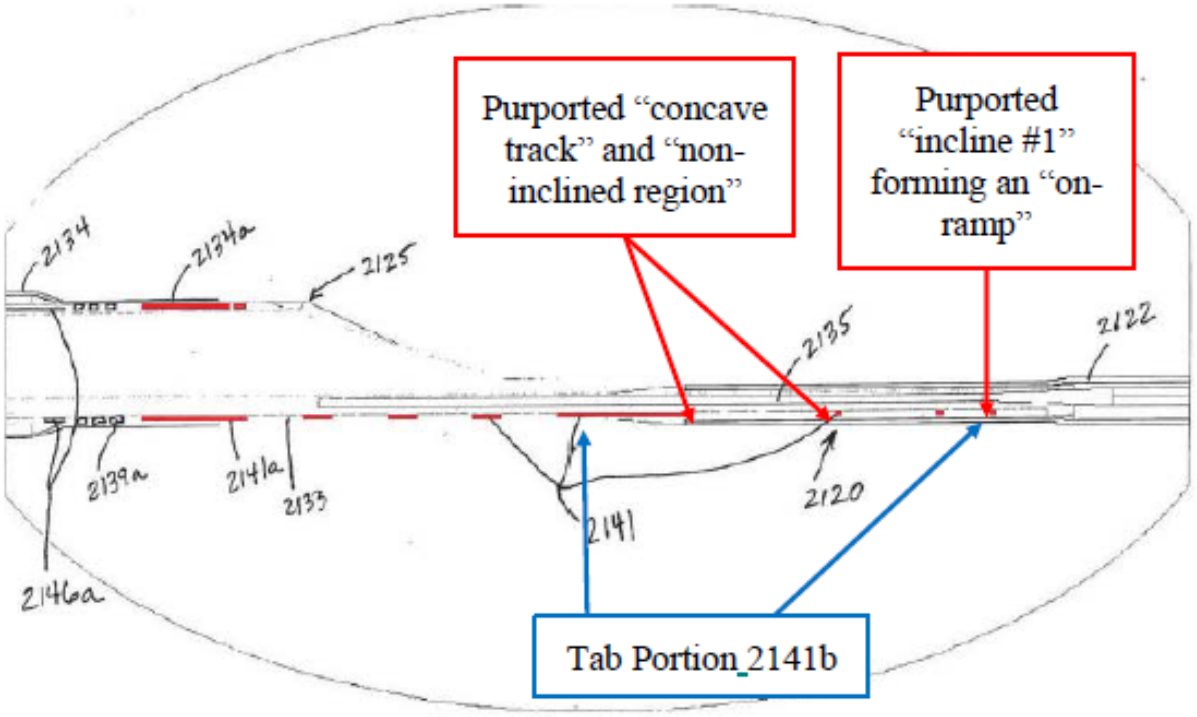


Fig. 16D

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

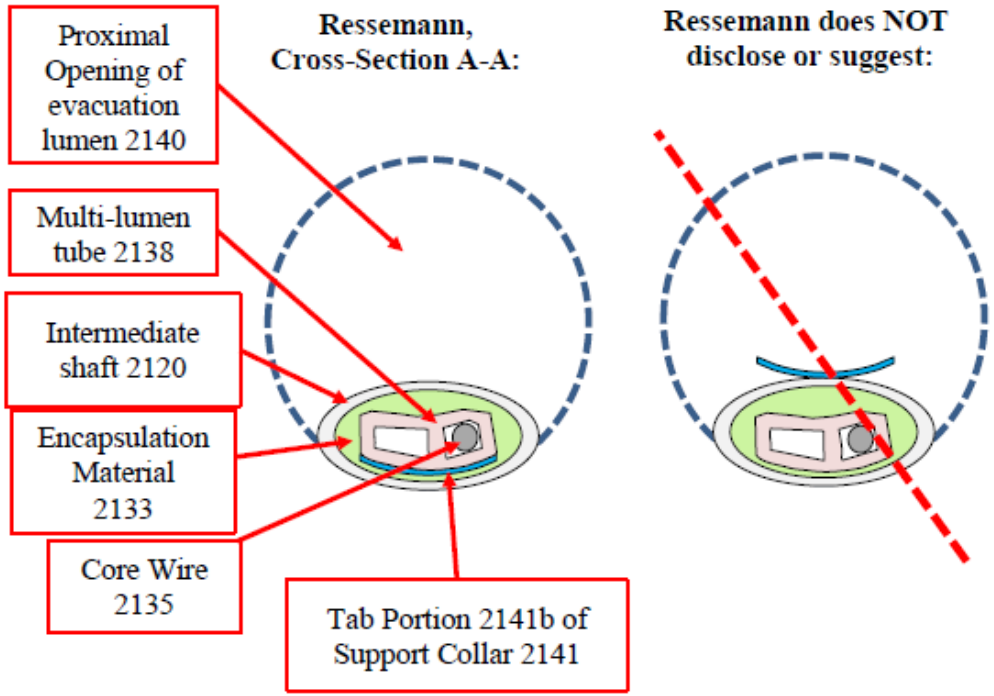
Ex-1408, Figs. 16D, 16J
Paper 39, 33-34 (136 IPR)
Ex-2138 (136 IPR), ¶¶ 126-128, 184

Complex side opening claims – **Kontos + Ressemann**
(136 IPR, ’776 patent)

Ressemann teaches tab portion ***inside*** shaft 2120 and ***underneath*** core wire:

> To facilitate attachment between the evacuation head 2132 and the intermediate shaft portion 2120, approximately 1 cm of a distal portion of polymer tube 2122 is flared and flattened by heating with an appropriately formed mandrel. This flared section is overlapped over the walls of the multi-lumen tube 2138, which define the core wire lumen 2143 and the inflation lumen 2142, **as well as over the tab portion 2141b of the support collar 2141**.

Ex-1408, 27:51-67



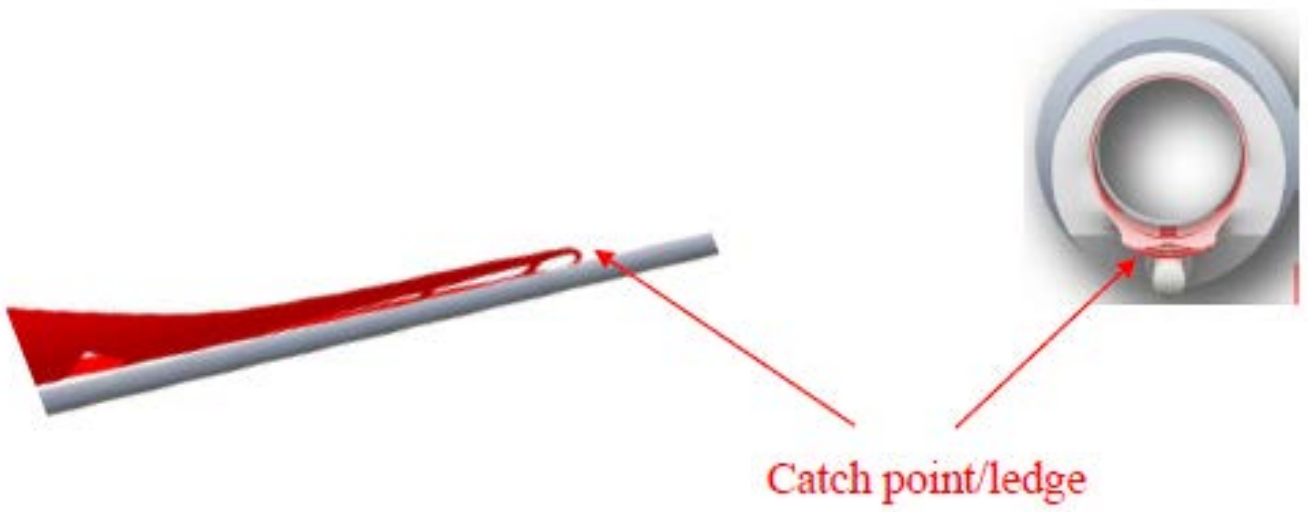
Paper 39, 35-36 (136 IPR)
Ex-2138 (136 IPR), ¶¶ 128, 186

Complex side opening claims – **Kontos + Ressemann**
(136 IPR, ’776 patent)

Petitioner failed to prove motivation/reasonable expectation of success:

Petition evidence for ‘tab-on-top’ combination	Patent Owner evidence showing no motivation/reasonable expectation of success for tab-on-top combination
Hillstead assertion that Ressemann teaches that collar tab 2141b would be “adjacent” pushwire 14 *(Ex-1442, ¶89)* Hillstead single conclusory assertion that tab would be “encased in polymer as commonly known in the art” *(Ex-1442, ¶89)*	Undisputed Ressemann teaching that tab 2141b should be placed ***under*** reinforcing core wire 2135 and multilumen tube 2138 and *inside* the bottom of shaft 2120 *(Ex-1408, 27:51-67 and Fig. 16D)* Hillstead admission that a tab-on-top combination “may not be the way that Ressemann would teach” (Ex-2137, 216:7-13) Keith testimony correctly understanding/explaining how Ressemann teaches to incorporate tab *(Ex-2138 ¶¶125-128, 192-193)* Keith testimony that a POSITA would not to be able to encase in polymer and still preserve tiny “incline #1” *(Ex-2138 ¶194)* Jones (Petitioner’s new expert) admission that, as to how the tiny incline would be preserved, he “[has] not worked that out or provided an opinion on that” (Ex-2239, 116:19-24) Keith testimony regarding expected peel-off/pop-off issues with tab 2141b *(Ex-2138 ¶195)* Keith testimony that the tab-on-top would create a problematic ledge/catch points *(Ex-2138 ¶196)*

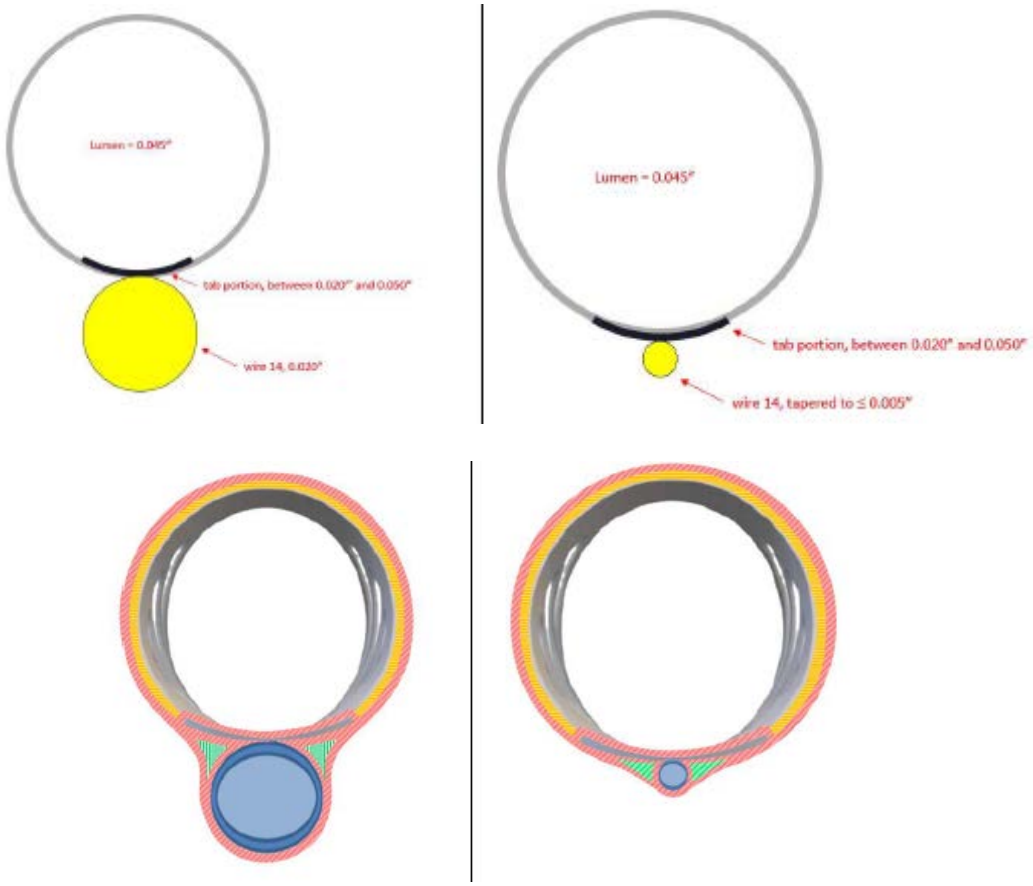
Complex side opening claims – **Kontos + Ressemann**
(136 IPR, ’776 patent)



Paper 39, 40-42 (136 IPR)
Ex-2138 (136 IPR), ¶196

Complex side opening claims – **Kontos + Ressemann**
(136 IPR, ’776 patent)

New theory in Reply:



Complex side opening claims – **Kontos + Ressemann**
(136 IPR, ’776 patent)

If “encased,” ***no evidence*** that tiny angle at tip of tab would be preserved:

Patent Owner’s expert Mr. Keith:

“[A] POSITA would expect that incline #1’ to be simply buried or ‘erased’ by the encapsulating polymer” (Ex-2138, ¶194)

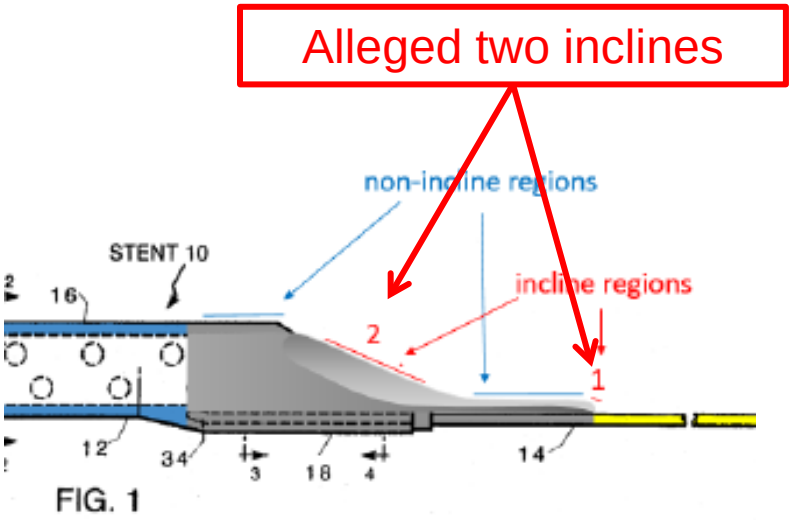
Petitioner’s new expert Mr. Jones:

“I have not worked that out or provided an opinion on that” (Ex-2239, 116:19-24)

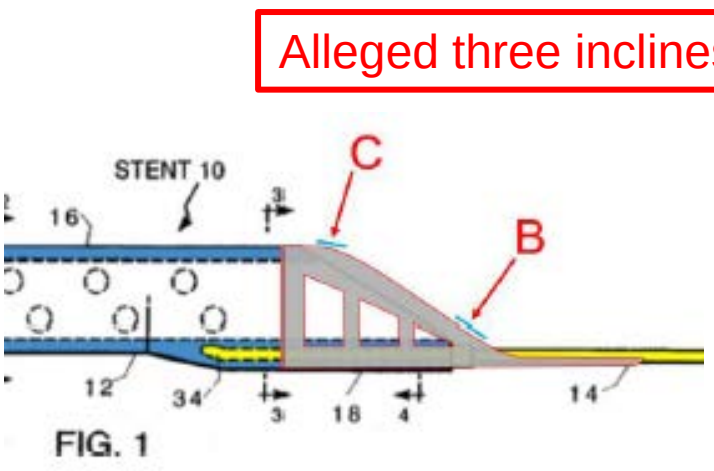
Paper 39, 40-42 (136 IPR)
Ex-2138 (136 IPR), ¶¶ 196

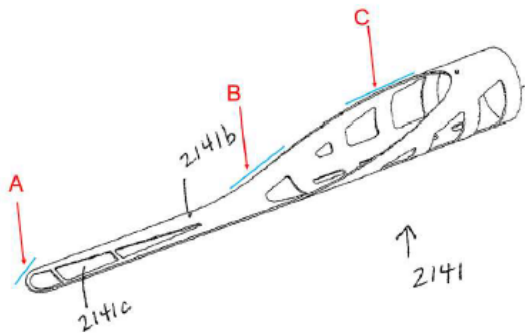
Complex side opening claims – **Kontos + Ressemann**
(136 IPR, ’776 patent)

Version 1 (Petition):



*Version 2 (**NEW** in Reply):*





DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

Paper 3 (Petition) at 43; Paper 69 (Reply), 15-18 (136 IPR)

Complex side opening claims
(136 IPR, ’776 patent)

Two Arguments Based on Two Secondary References:

1. Kontos + Ressemann
   - Claims 52, 36-37 (Ground 1)
   - Claims 53-56 (Ground 2)
2. **Kontos + Kataishi**
   - Claim 52 (Ground 3)
   - Claims 53-56 (Ground 4)

NONE SHOWS A DEVICE WITH A PROXIMAL COMPLEX SIDE OPENING

Complex side opening claims – **Kontos + Kataishi**

(136 IPR, ’776 patent)

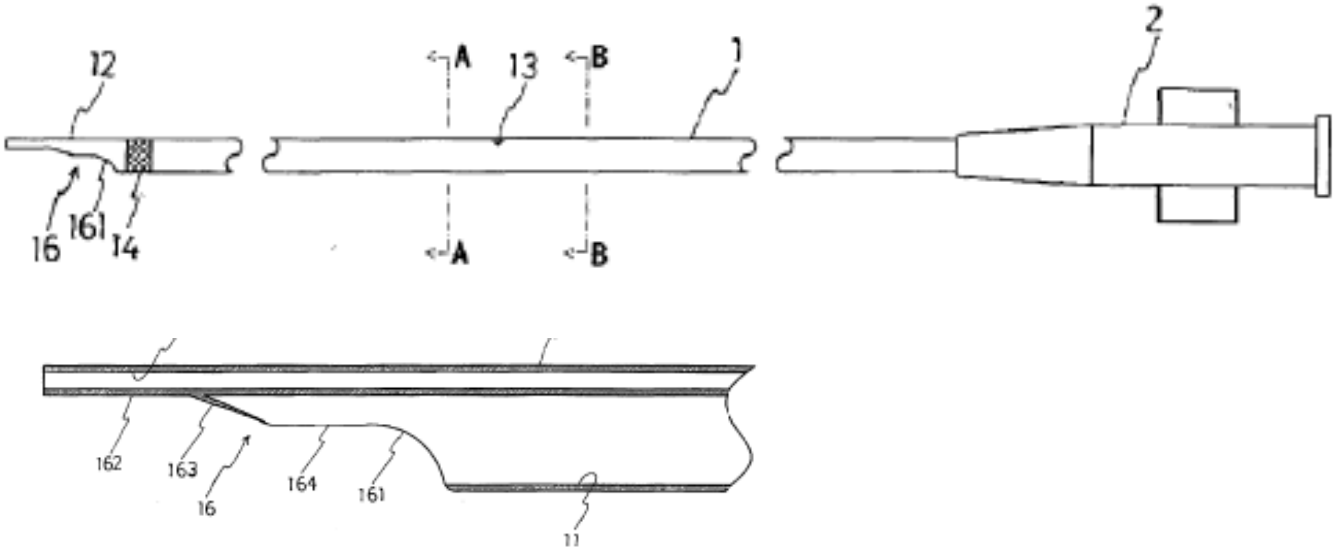


Figure 2

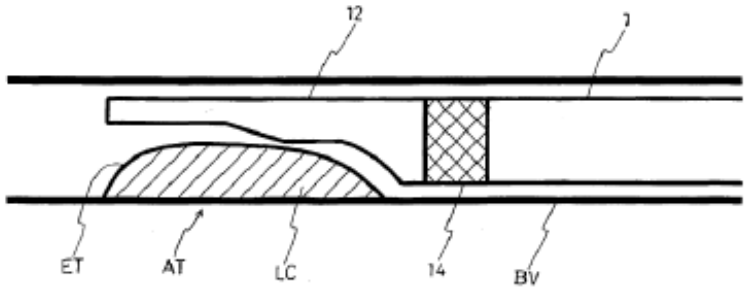


Figure 10

Ex-1425, Figs. 1, 10

Outline of the Arguments:
-00136 IPR ('776 patent)

Independent claim 25 (Ground 1)	"a segment defining a partially cylindrical opening . . . having an angled proximal end"
Independent claim 52 (Ground 1) Independent claim 53 (Ground 2) Dependent claims 36 (Ground 1)	complex side opening claims, Kontos + Ressemann combination
Independent claim 52 (Ground 3) Independent claim 53 (Ground 4)	complex side opening claims, Kontos + Kataishi combination
Independent claim 53 (Grounds 2, 4) **Dependent claims 30-32 (Ground 2)** ***[Takahashi combinations]***	**"One French size" claims,**
Dependent claim 49 (Ground 1)	"resist axial and shear forces . . . that would otherwise tend to dislodge the distal portion"

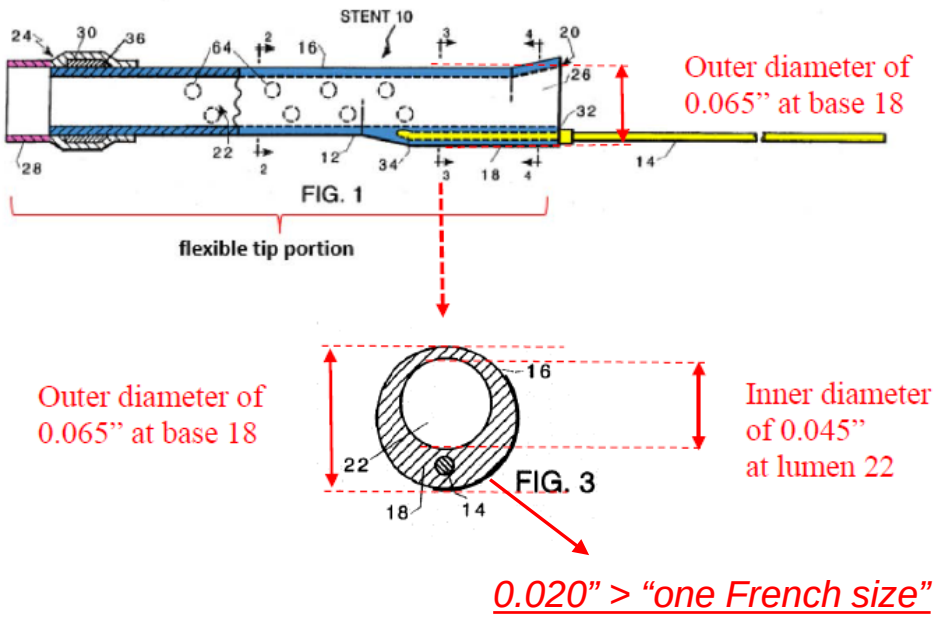
“One French size” claims
(136 IPR, ’776 patent)

53. A guide extension catheter . . . 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; . . . 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

30. The guide extension catheter of claim 25, wherein the guide catheter includes **a lumen having a cross-sectional inner diameter of six French, seven French or eight French and** 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

“One French size” claims
(136 IPR, ’776 patent)

- Modification proposed by the Petition (removing the proximal funnel) would not result in the claimed “one French size” limitation:



- The Board should **reject** Petitioner’s new “six additional modifications” theory (*see* Reply, Paper 71 at 21-22 (127 IPR) and Paper 69 at 21-22 (130 IPR))

Ex-2138, ¶¶202-207 (136 IPR)
Paper 39 at 44-47; Paper 85 at 22-23 (136 IPR)

Outline of the Arguments:
-00136 IPR ('776 patent)

Independent claim 25 (Ground 1)	"a segment defining a partially cylindrical opening . . . having an angled proximal end"
Independent claim 52 (Ground 1) Independent claim 53 (Ground 2) Dependent claim 36 (Ground 1)	complex side opening claims, Kontos + Ressemann combination
Independent claim 52 (Ground 3) Independent claim 53 (Ground 4)	complex side opening claims, Kontos + Kataishi combination
Independent claim 53 (Grounds 2, 4) Dependent claims 30-32 (Ground 2)	"One French size" claims,
Dependent claim 49 (Ground 1)	**"resist axial and shear forces . . . that would otherwise tend to dislodge the distal portion"**

“Resist axial and shear force” – claim 49

(136 IPR, ’776 patent)

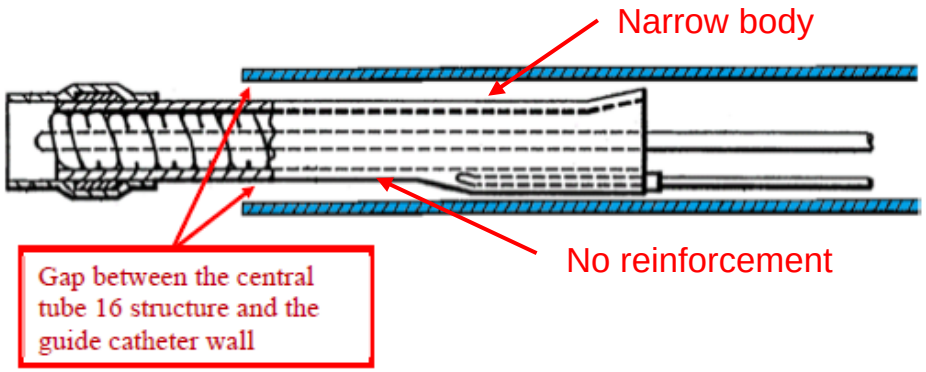
49. The guide extension catheter of claim 25, wherein a distal portion of the tubular structure is configured to anchor within an ostium of a coronary vessel **and resist axial and shear forces** exerted by the received one or more interventional cardiology devices **that would otherwise tend to dislodge the distal portion.**

“Resist axial and shear force” – claim 49
(136 IPR, ’776 patent)

Petitioner has not proven inherency:

- Petition: conclusory assertion that Kontos contains “same teachings” as ’776 patent (*Petition at 52)*

➡ **Not** “same teachings”:



- Kontos’s device **not designed or intended** to “assist[] in resisting axial and shear forces . . . that would otherwise tend to dislodge the guide catheter from the branch artery,” as required by the claims

- “**Pliable**” material (*Kontos, Ex-1009, 4:1-4*)

> **Tube 16** may be composed of any pliable material suitable for percutaneous medical procedures, but preferably is composed of a molded plastic material, such as polyethylene.

Paper 39 at 43 (136 IPR)
Ex-1409, Fig. 1 and 4:1-4
Ex-2138, ¶¶100-121, 197-201 (136 IPR)

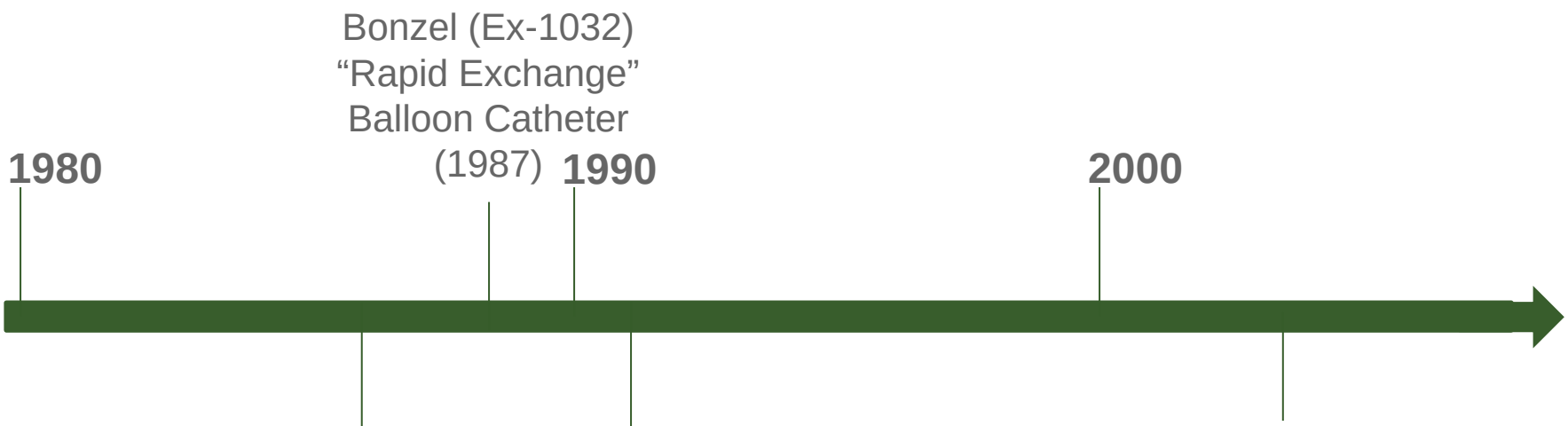
Medtronic, Inc. and Medtronic Vascular, Inc. v. Teleflex Innovations S.A.R.L.

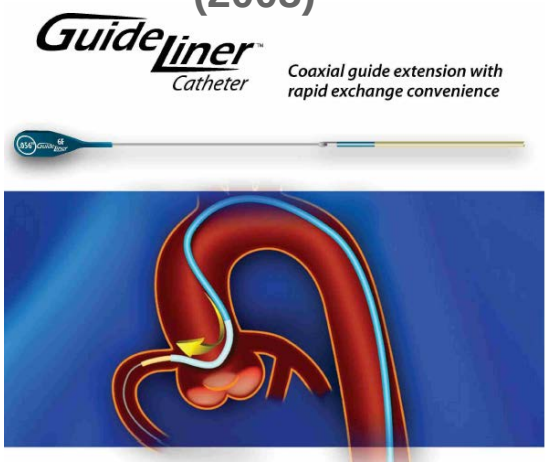
Patent Owner's Hearing Demonstratives (Objective Evidence)

Summary of the Argument

Patent	IPR	Objective Evidence Claims	Objective Evidence Asserted	Grounds Affected
032 Patent	126	3, 13	Long-felt need, Industry Praise, Commercial Success, Licensing, Copying	1, 2
	127	3, 9, 13, 18	Long-felt need, Industry Praise, Commercial Success, Licensing, Copying	1
380 Patent	128	3, 14	Long-felt need, Industry Praise, Commercial Success, Licensing, Copying	1, 2
	129	27	Copying	1-4, 9
	130	3, 9, 14, 19	Long-felt need, Industry Praise, Commercial Success, Licensing, Copying	1
760 Patent	132	32	Copying	2-4
	134	48, 51, 53	Long-felt need, Industry Praise, Commercial Success, Licensing, Copying	4
776 Patent	135	36, 52, 53	Copying	1, 3-5
	136	25, 52, 53	Long-felt need, Industry Praise, Commercial Success, Licensing, Copying	1-4
379 Patent	137	44	Copying	2, 4-5
	138	33, 44	Long-felt need, Industry Praise, Commercial Success, Licensing, Copying	1-5

State of the Art Before GuideLiner





DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

IPR2020-126, POR at 3; IPR 2020-00126, Ex-2138, ¶¶ 58-72; Ex-2155

Undisputed that GuideLiner Satisfied a Long-Felt Need

“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.”

IPR2020-00126, POR at 58-59 (citing Ex-2138, ¶218; Ex-2145, ¶¶67-82, 238-56; Ex-2215, ¶¶21-25; Ex-2151)

GuideLiner Created the Guide Extension Catheter Market

Undisputed that GuideLiner Satisfied a Long-Felt Need

So I was aware that there was a need to overcome the issue of a lack of backup support, you know, certainly in the -- even in the late '90s, early 2000, you know, in that

[. . . .]

Q. So when you first encountered the GuideLiner product, do you recall thinking that it was innovative?

A. I think I recall thinking it's about time that something got out here in the marketplace. Um --

[. . . .]

THE WITNESS: Yeah. Yeah. Um, yes. Again, this is a problem that's been around for a while and I thought, you know, when I saw that, well, there's -- that's cool. There's a -- uh, a product that addresses the issue.

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

IPR2020-00126, POR at 40 (citing Ex-2137 at 51:17-20, 53:42-54:17 (Hillstead Testimony (Sept. 11, 2020))

Undisputed that GuideLiner Received Substantial Industry Praise

- "The GuideLiner has become an ***indispensable*** part of my tool kit for complex PCI. Simply put, ***it's a game changer***." (Ex-2066, 3)
- "The GuideLiner allows me to ***successfully complete previously unimaginable interventions***." (Ex-2066, 5)
- "[The GuideLiner] ***can really save you*** one day!" (Ex-2066, 4)
- "[GuideLiner] does not add complexity to the intervention and provides extraordinary backup support for complex interventions" (Ex-2167, 182)
- "The [GuideLiner] provides an ***elegant*** method to overcome this challenge [severe vessel angulation and tortuosity], and represents one of the most common indications for its use." (Ex-2194, 142)

Undisputed that GuideLiner Received Substantial Industry Praise

- "***These cases could not have been completed successfully if the GuideLiner catheter would not have been used***, as other techniques (buddy wire, anchoring, incremental dilations) failed." (Ex-2176, 460)
- "In this case, ***stent delivery was impossible despite the use of a highly supportive guiding catheter***. ***By using the GuideLiner, the stent was deployed easily and successfully because of the extra back up support and deep intubation*** without any displacement of the guide catheter or the wire or any vessel trauma." (Ex-2066, 5)
- "GuideLiner was considered ***key to the success of the intervention*** . . . ." (Ex-2170, 484)

Undisputed that GuideLiner Received Substantial Industry Praise

Medtronic

Print Page Close Window

PRESS RELEASE

Medtronic Launches Telescope(TM) Guide Extension Catheter to Support Complex Coronary Cases

Medtronic

FDA Cleared and CE Marked, Telescope Enters Global Market with Design Innovations to Enable Smooth Delivery of Coronary Stents and Balloons

DUBLIN - May 16, 2019 - Medtronic plc (NYSE:MDT), a global leader in percutaneous coronary intervention (PCI) innovation, today announced its entrance into the guide extension catheter market with the global launch of the Telescope(TM) Guide Extension Catheter, a newly designed catheter used to provide additional backup support and access to distal lesions. Guide extension catheters help deliver coronary stents, balloons and other interventional devices during angioplasty procedures that help to restore blood flow through the coronary and peripheral arteries.

Developed alongside interventional cardiologists, many of whom are increasingly challenged with complex cases - such as patients with tortuous anatomies, calcified vessels, and distal lesions - the Telescope guide extension catheter provides operators with superior deliverability[1] and is designed to enable smooth delivery of interventional devices in more challenging cases.

"It is not an exaggeration to say that guide extension technologies have greatly impacted the ability to deliver devices to the distal coronary vasculature, especially for cases where traditional guide support may be limited," said Ajay Kirtane, M.D., S.M., director of the NewYork-Presbyterian Hospital/Columbia University

IPR2020-00126, POR at 50 (citing Ex-22041 at 1)

Undisputed Evidence of Long-Felt Need and Industry Praise

Evidence of Industry Praise and Long-Felt Need	Petitioner	Patent Owner
Cardiologist Testimony	None	Ex-2145 (Dr. Graham) Ex-2151 (Dr. Azzalini) Ex-2215 (Dr. Thompson)
Industry Publications	None	Ex-2176; Ex-2194; Ex-2170; Ex-2180; Ex-2176; Ex-2179; Ex-2194; Ex-2168; Ex-2204
Scientific Literature	None	Ex-2135; Ex-2166; Ex-2168; Ex-2169; Ex-2170; Ex-2171; Ex-2172; Ex-2173; Ex-2174; Ex-2175; Ex-2176; Ex-2177; Ex-2178; Ex-2180; Ex-2194; Ex-2136; Ex-2181; Ex-2182; Ex-2183; Ex-2184; Ex-2185; Ex-2186; Ex-2187; Ex-2188; Ex-2189; Ex-2190; Ex-2191; Ex-2192; Ex-2193

Undisputed that GuideLiner Has Been Highly Commercially Successful

Undisputed that GuideLiner Has Been Highly Commercially Successful

Nexus is Undisputed

- Rapid Exchange Functionality
- Ability to Receive and Deliver the Full Suite of Interventional Cardiology Devices Deep into the Vasculature
- Markedly Improved Backup Support

IPR2020-00126, POR at 58-59 (citing Ex-2138, ¶ 218; Ex-2145, ¶¶ 67-82, 238-56; Ex-2215, ¶¶ 21-25; Ex-2151 ¶¶ 9-17)

Legal Standard-Objective Evidence

“[T]he fact that an isolated feature may be present in the prior art may not render irrelevant objective evidence of non-obviousness of that feature in the claimed combination.”

WBIP, LLC v. Kohler Co., 829 F.3d 1317, 1330-31 (Fed. Cir. 2016)

Legal Standard-Objective Evidence

Objective evidence provides a "built-in protection [that] can help to place a scientific advance in the proper temporal and technical perspective when tested years later for obviousness against charges of making only a minor incremental improvement."

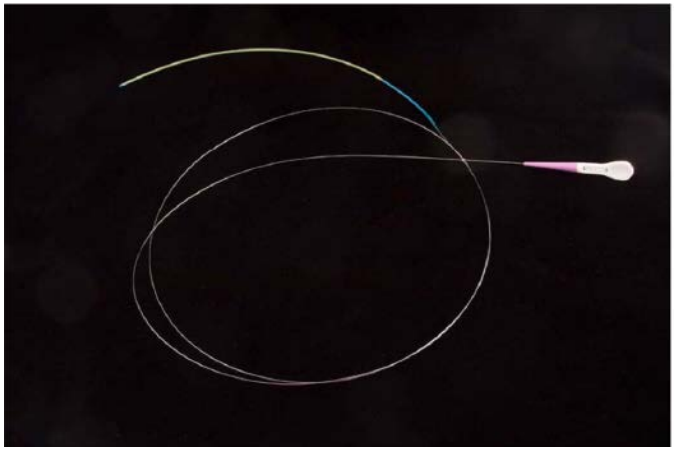
Mintz v. Dietz & Watson, Inc., 679 F.3d 1372, 1378 (Fed. Cir. 2011)

GuideLiner Was Copied by All U.S. Competitors

GuideLiner

Guidezilla

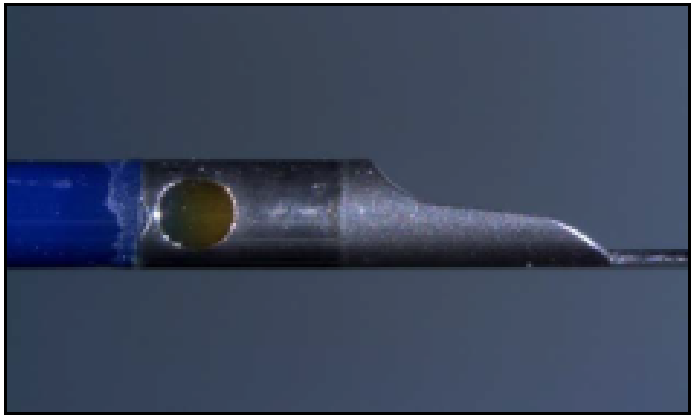
Telescope



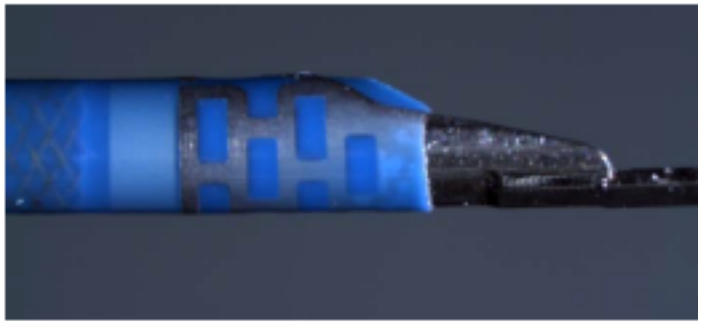
Boosting Catheter

Undisputed that Boston Scientific and QXM Copied GuideLiner

GuideLiner V1 collar side view



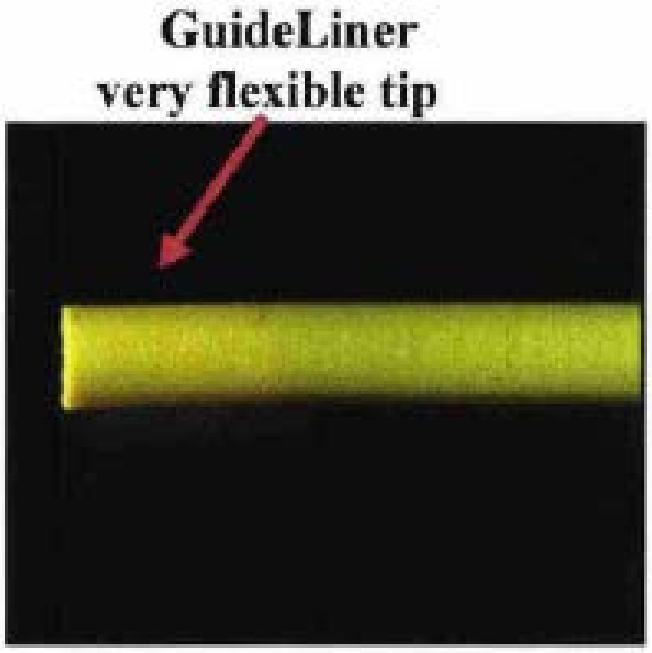
Guidezilla I Collar Side View

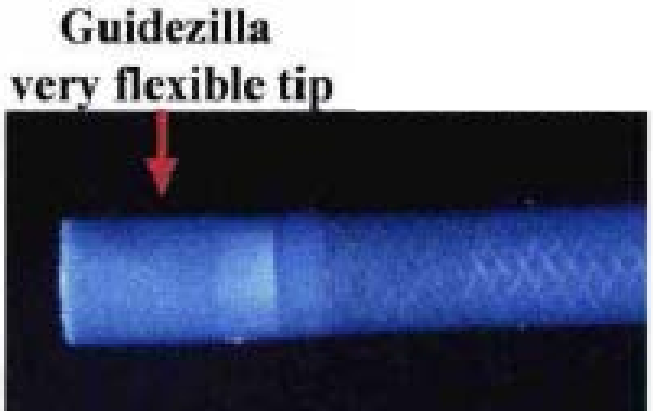


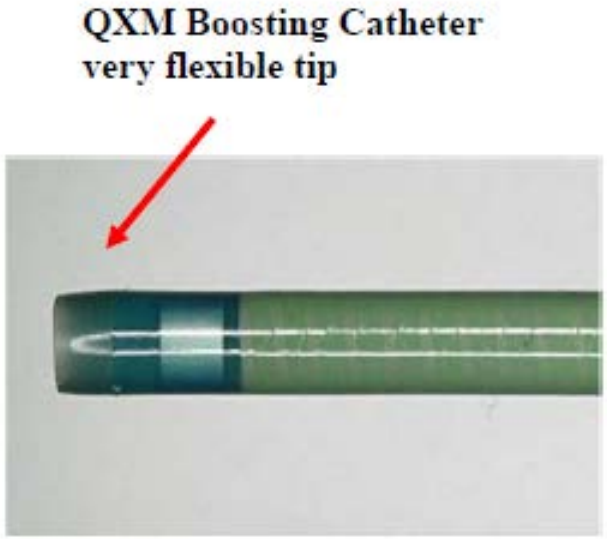
QXM Boosting Catheter:

IPR2020-00126, POR at 51-53 (citing Ex-2138, ¶¶186, 199)

Undisputed that Boston Scientific and QXM Copied GuideLiner







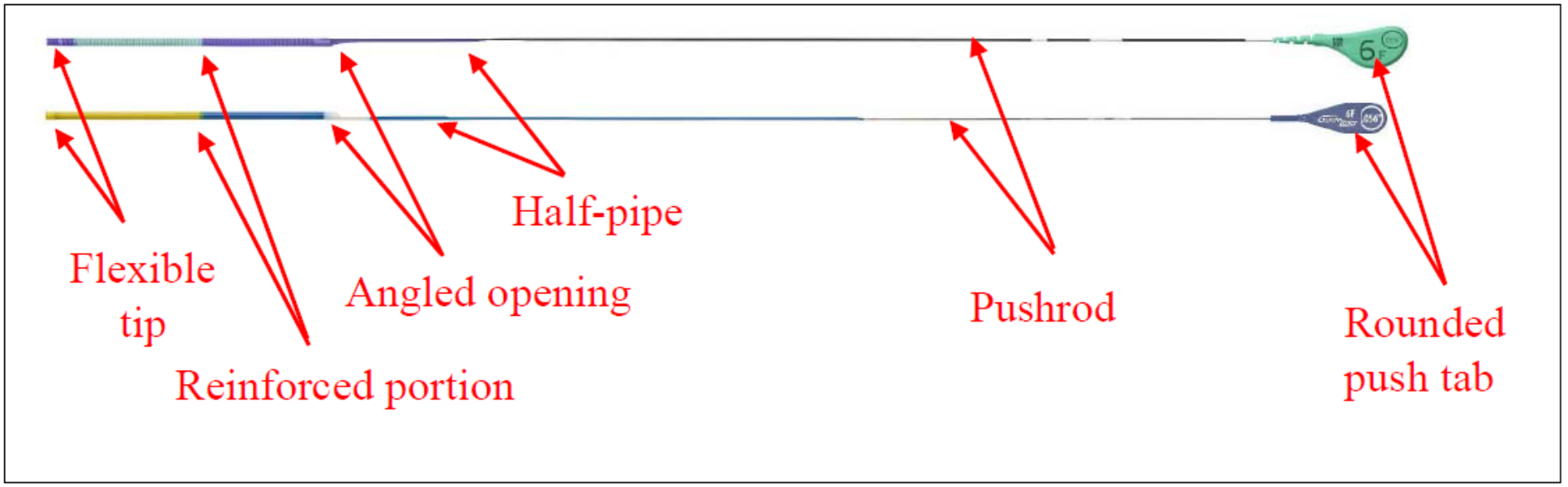
IPR2020-00126, POR at 51-53 (citing Ex-2138, ¶¶188, 197)

Legal Standard-Copying

"[C]opying requires the replication of a specific product. This may be demonstrated [] through . . . access to, and substantial similarity to, the patented product (as opposed to the patent)"

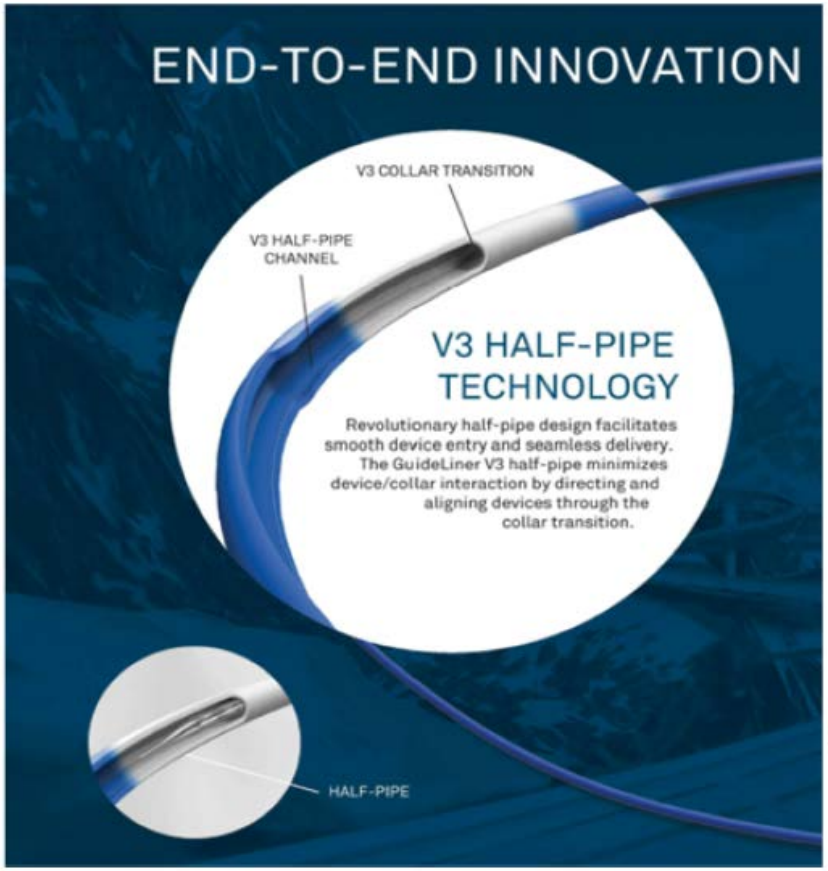
Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1325 (Fed. Cir. 2004)

Telescope is a Copy of GuideLiner

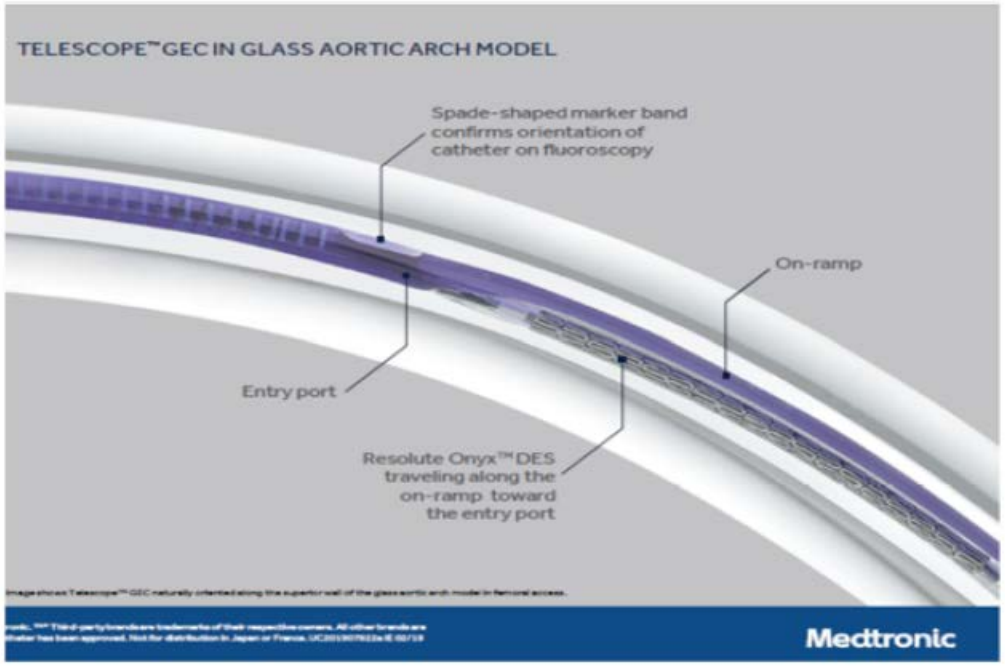


POR at 54 (Telescope (top) and GuideLiner (bottom))

Telescope is a Copy of GuideLiner



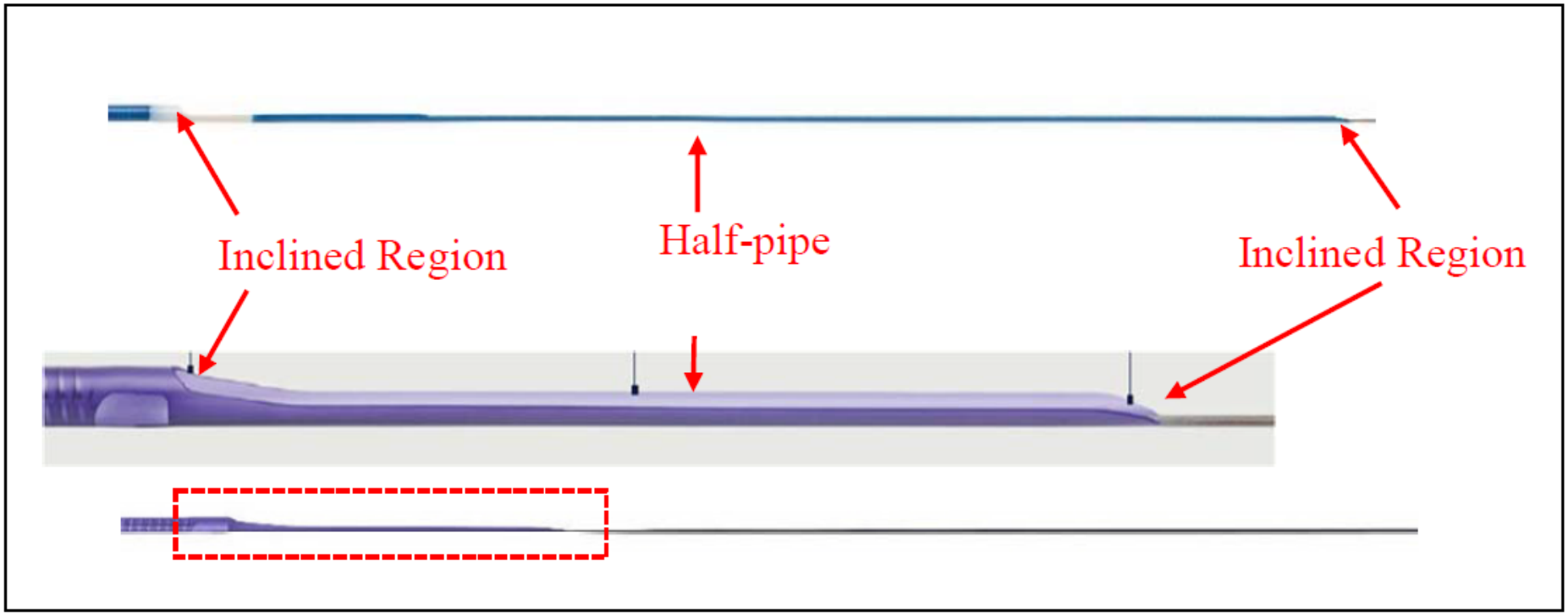
GuideLiner



Telescope

IPR2020-00126, POR at 54 (citing Ex-2138, ¶ 208)

Telescope is a Copy of GuideLiner



POR at 54 (GuideLiner (top) and Telescope (bottom)

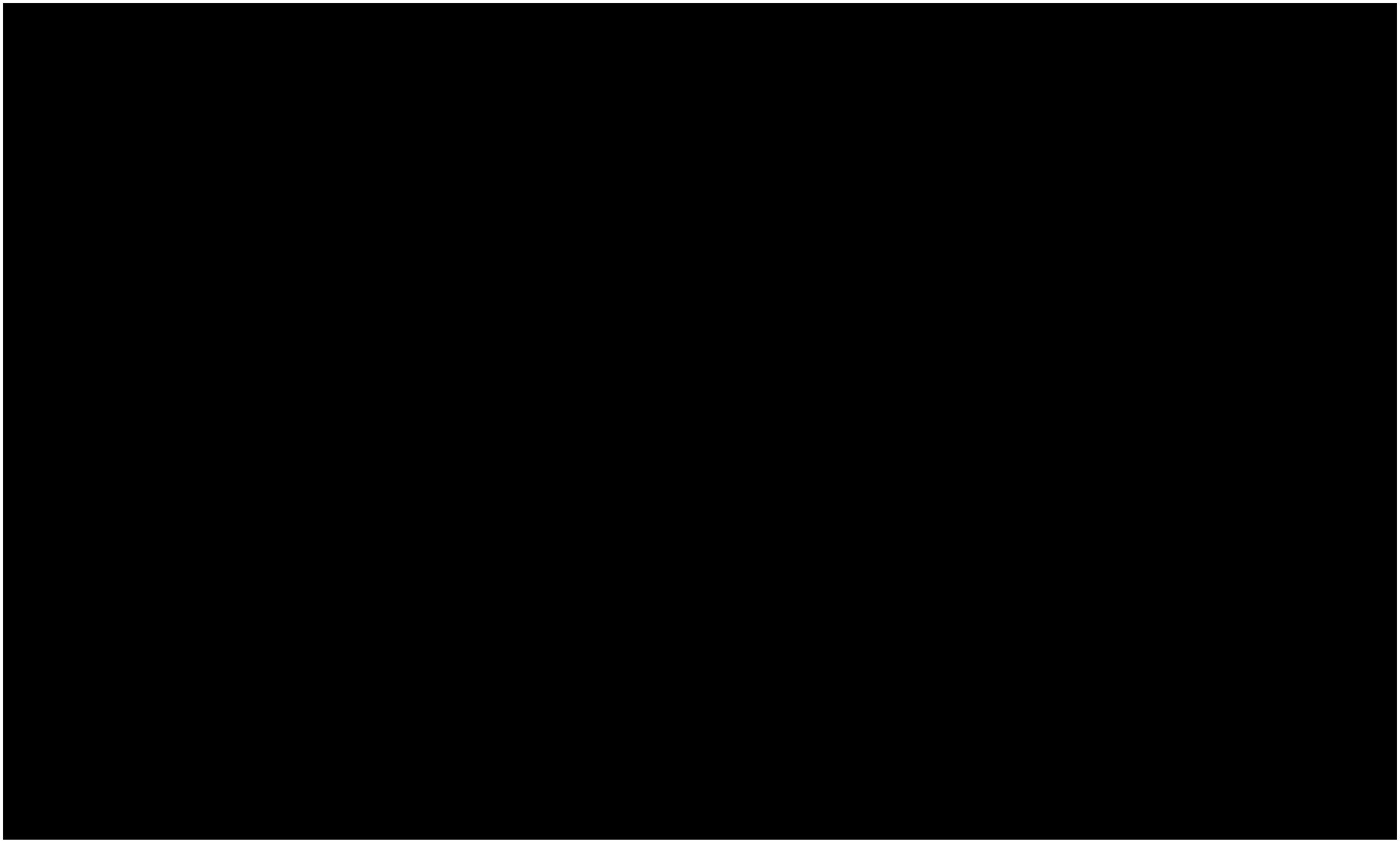
Telescope is a Copy of GuideLiner

Zalesky Decl. (Ex-1830)

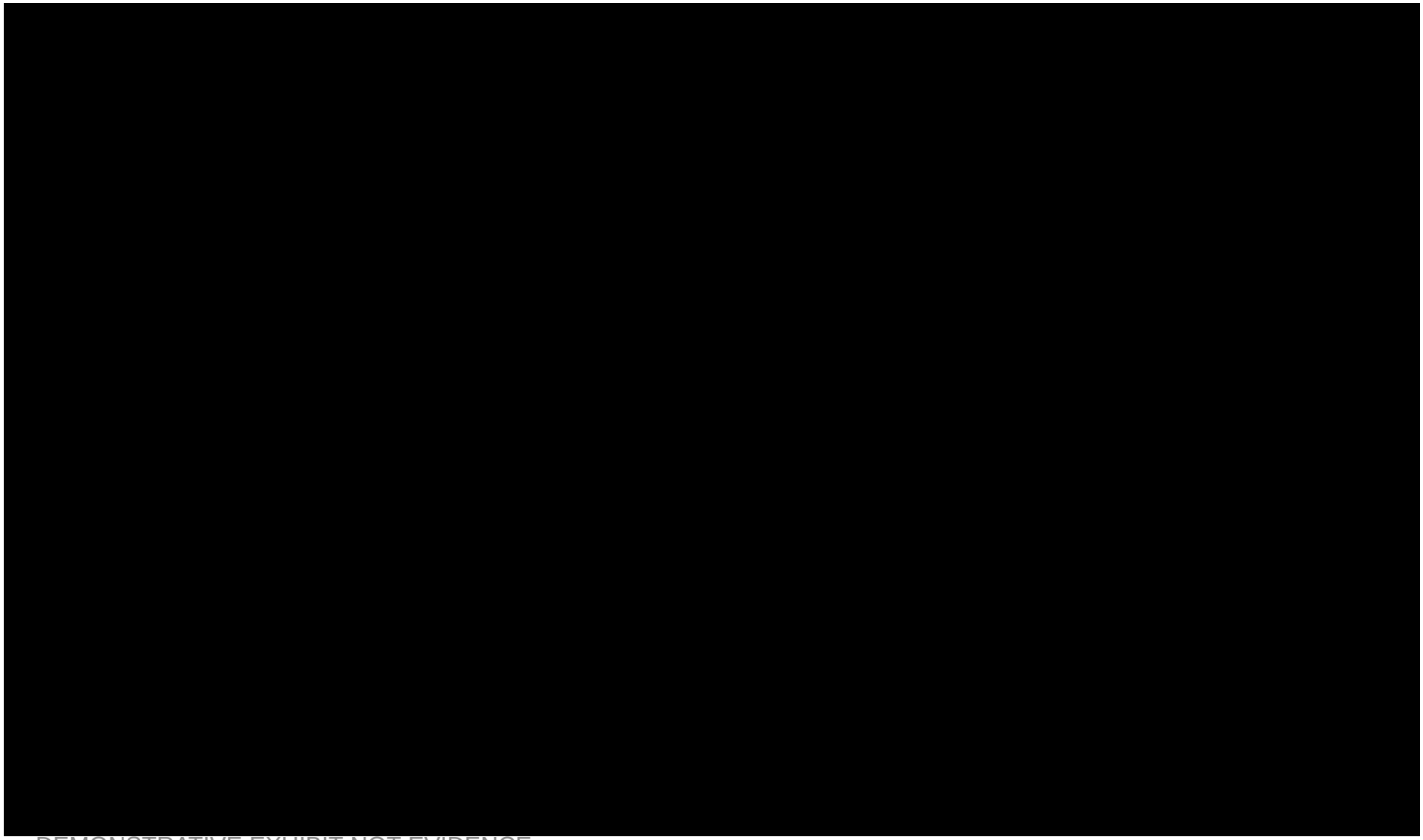
features." Ex-1821, 53:19-54:11. Telescope employs a significantly different pushwire design—it consists of a solid, round wire that is tapered along its length from a full circle proximally to a semicircle mid length to a tapered semicircle at its termination. Its full length is 125 cm and its termination, via a weld to a spade-shaped R/O marker band, occurs in close proximity to a sculpted entry port in the catheter body. The GuideLiner Version 3 pushwire, by contrast, is 108 cm long in the finished product (Ex-2161 at 3) and tapers—from a relatively proximal location—from 0.010 inches (Ex-2141 at 30) proximally to .0035 inches (*id.*).

IPR2020-00127, Pet. Reply at 28-29 (citing Ex-1830, ¶18)

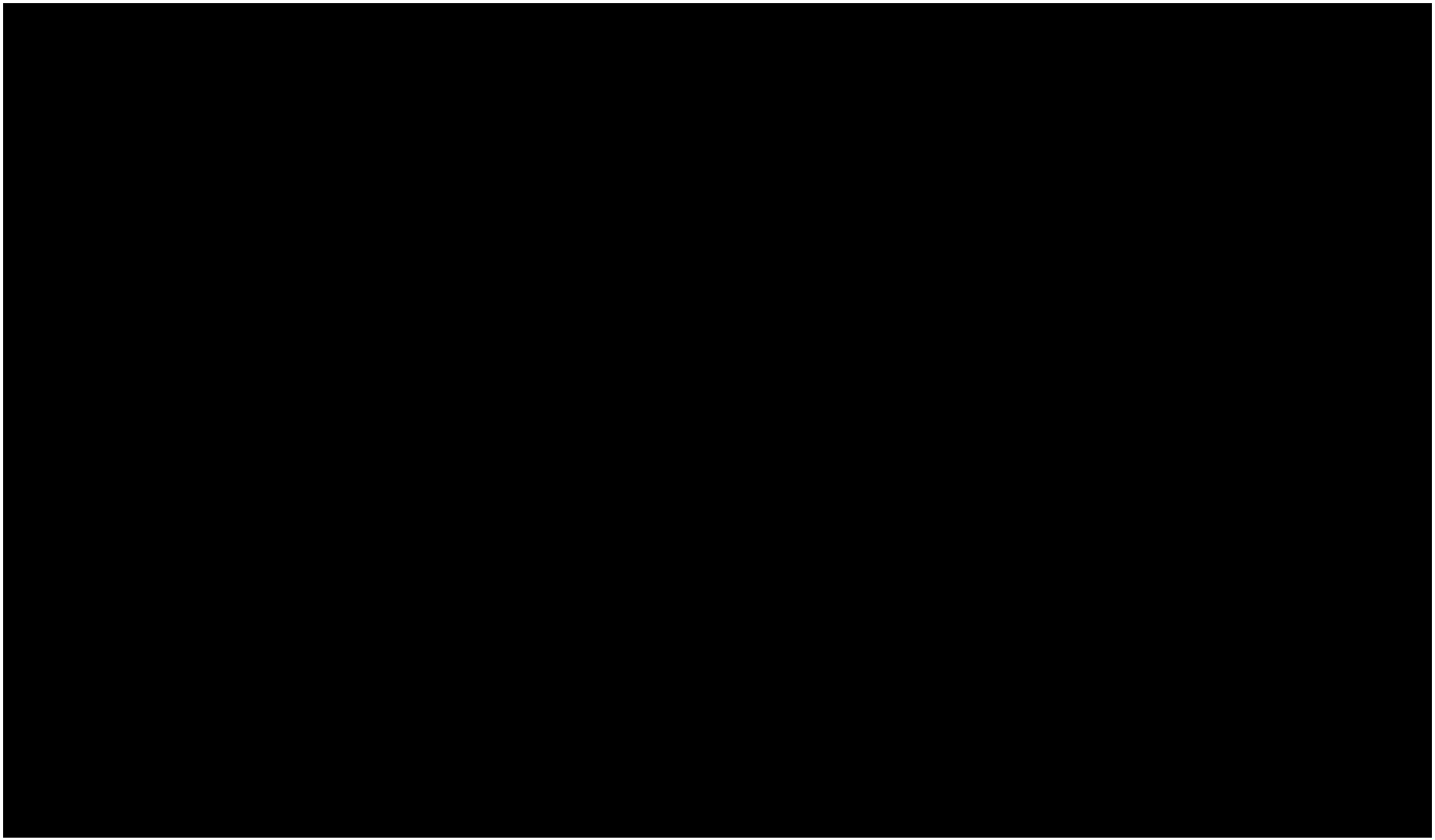
Zalesky Testimony (Jan. 25, 2021)



Telescope is a Copy of GuideLiner

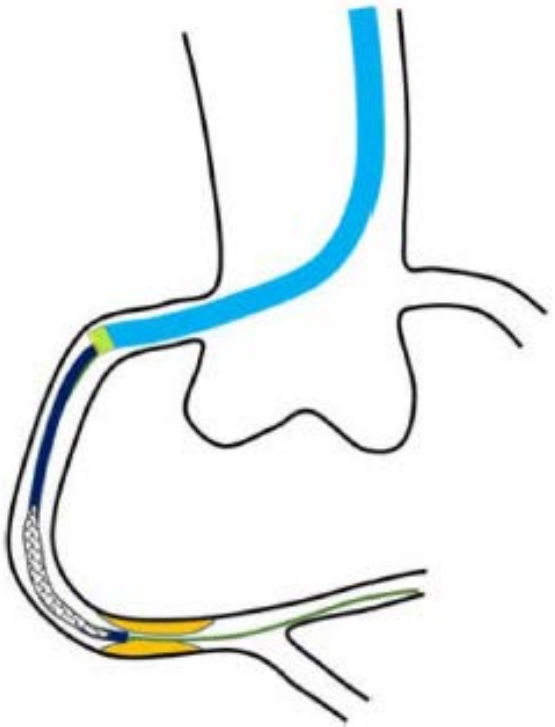


Zalesky Testimony (Jan. 25, 2021)

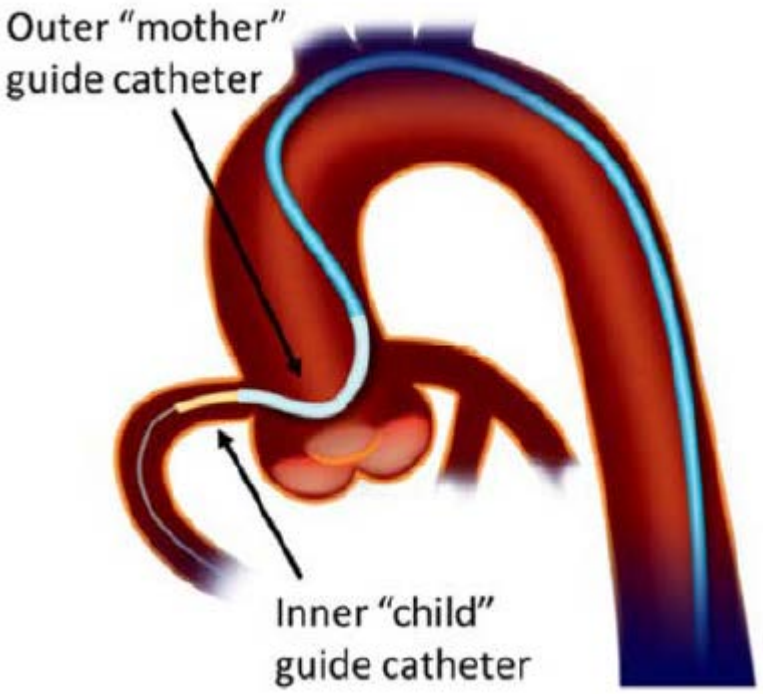


State of the Art Before GuideLiner

Insufficient Back-Up Support



“Deep Seating”

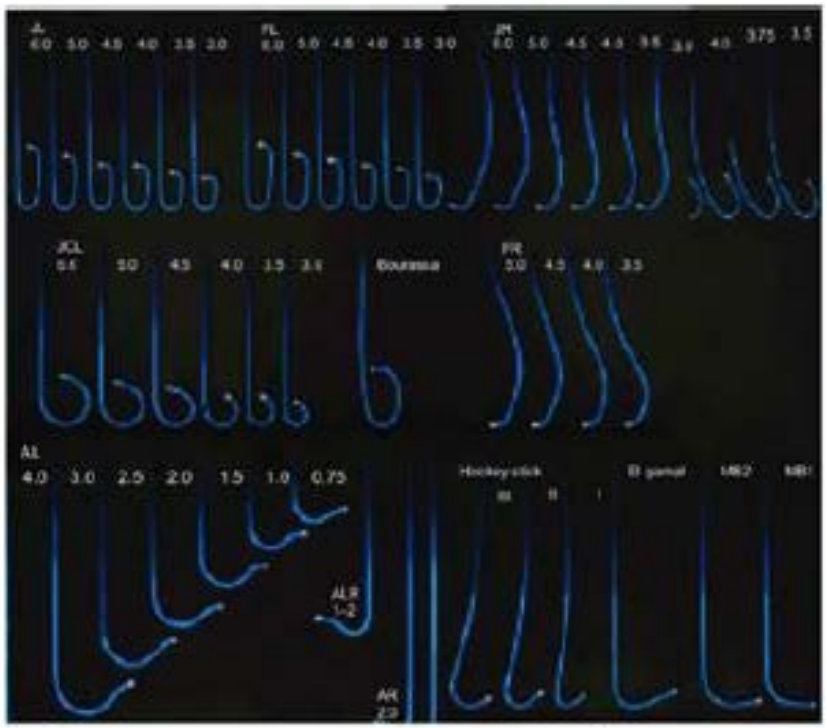


The “Mother and Child” Approach

IPR2020-126, POR at 3
IPR 2020-00126, Ex-2138, ¶¶ 61-62

State of the Art Before GuideLiner

Insufficient Back-Up Support



Upsizing/Changing Guide Catheter Configuration

58. **Using a "buddy" wire.** Another technique that cardiologists tried in an effort to address the backup support problem was through use of a "buddy wire." This technique involved threading an additional guidewire, called a "buddy" wire, through the guide catheter alongside the first guidewire. The idea was that by doing this, one could maybe get slightly more support as one tried to push an interventional cardiology device such as a stent catheter down the now doubled-up guidewire. This technique had fewer risks than the other available techniques. However, while of some use in overcoming tortuosity, it was not very effective for increasing backup support in calcified lesions. Additionally, inserting an additional guidewire into the vessel carried additional risk. First, there is a risk of "wire wrap," which is where the guidewires and equipment inside the guide catheter or vessel become entangled with one another. Second, devices take up space within the vessel lumen, and each additional device that is inserted decreases blood flow, which in turn increases the risk of clotting. Third, blood clots are prone to forming on the surface of devices themselves. Thus, it is not optimal to insert more devices than are necessary.

The "Buddy Wire" Technique

IPR2020-126, POR at 3
Ex-2145, ¶¶ 54, 58

Side Opening in Combination with Other Features Provides Benefits

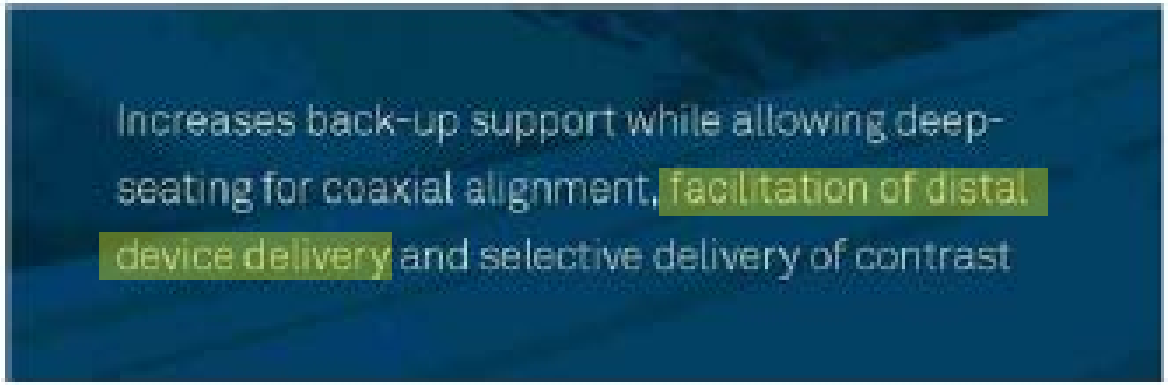
"In this case, ***stent delivery was impossible despite the use of a highly supportive guiding catheter***. ***By using the GuideLiner, the stent was deployed easily and successfully because of the extra back up support and deep intubation*** without any displacement of the guide catheter or the wire or any vessel trauma."

IPR2020-00126, POR at 49 (citing Ex-2066, 5)

Side Opening in Combination with Other Features Provides Benefits

GuideLiner™ Catheter

The GuideLiner catheters are intended to be used in conjunction with guide catheters to access discreet regions of the coronary and/or peripheral vasculature, and to facilitate placement and exchange of guidewires and other interventional devices.



IPR2020-00126, POR at 61-62 (citing Ex-2155; Ex-2162)

Medtronic, Inc. and Medtronic Vascular, Inc. v. Teleflex Innovations S.A.R.L.

Patent Owner's Hearing Demonstratives (Motion to Amend)

WRITTEN DESCRIPTION

Substitute Claim 43 of the ’380 Patent

Claim 43 (replaces claim 1): A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

a standard 6 French 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 the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter of at least 0.070 inches and sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and

a device adapted for use with the guide catheter, including:

a flexible tip portion defining a tubular structure and 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 uniform, fixed 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, including stent catheters, are insertable while the tubular structure is located within the guide catheter; 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 structure without a lumen 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, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter;

wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion; and

wherein the device is configured such that, when the flexible tip portion extends into the branch artery, the flexible tip portion and substantially rigid portion assist in resisting forces exerted by the interventional cardiology devices passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the artery.

Zalesky Testimony (Jan. 25, 2021)

And just for your reference, I want you to confirm that you don't have any opinions in Exhibit 1919 that Claim 43 of the '380 patent has a written description problem.

A. I don't believe I do.

[...]

I'm not seeing any reference to a side opening in this claim.

Q. Okay. And that's why you did not allege a written description problem, right? Because this claim doesn't claim an angled or side opening, right?

MS. TREMBLAY: Objection. Form.

A. That's my understanding.

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

IPR2020-00126, Ex-2242 at 46:23-48:10; Paper 106 at 5

Substitute Claim 44 of the ’380 Patent

wherein the device further includes a substantially rigid partially cylindrical portion proximal to a distal end of the substantially rigid portion, the partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to the longitudinal axis of the device that is adapted to receive the interventional cardiology devices passed through the continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, wherein the opening in the partially cylindrical portion includes a first inclined sidewall that is separated from a second inclined sidewall in the partially cylindrical portion by a non-inclined concave track; and

wherein the flexible tip portion is more flexible than the reinforced portion.

IPR2020-00128, Paper 38, Appx A, 4-5

Substitute Claim 57 of the ’760 Patent

the guide extension catheter including, in a proximal to distal direction, a first substantially rigid segment, said first substantially rigid segment defining a rail structure without a lumen, a second substantially rigid segment, said second substantially rigid segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than [[the]] a cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the second substantially rigid segment [defining the side opening] and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the second substantially rigid segment [defining the side opening] and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;

Substitute Claim 63 of the ’776 Patent

Claim 63 (replaces claim 45): A guide extension catheter for use with a standard 6 French guide catheter, comprising:

a first substantially rigid segment, said first substantially rigid segment defining a rail structure without a lumen;

a tubular structure with a uniform, fixed outer diameter that defines a lum and positioned distal to the first substantially rigid segment, the lumen of the tubular structure configured to be coaxial with the lumen of the guide catheter when positioned therein, the lumen having a uniform cross-sectional inner diameter of at least 0.056 inches, the tubular structure comprising a cylindrical distal tip portion distal to a reinforced portion; and

a second substantially rigid segment, said second substantially rigid segment defining a partially cylindrical opening positioned between a distal end of the first substantially rigid segment and a proximal end of the tubular structure, the second substantially rigid segment defining the partially cylindrical opening having an angled proximal end and configured to receive stent catheters 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 each of the first and second substantially rigid segments is formed from a material more rigid along a longitudinal axis of the guide extension catheter than a material or material combination forming the tubular structure

[The guide extension catheter of claim 25], wherein the tubular structure includes a reinforcing braid or coil extending along a portion of a length of the tubular structure and surrounded by one or more polymer materials.

IPR2020-00135, Paper 95, Appx A, 3-4

Substitute Claims 58-59 of the ’776 Patent (Depend from Claim 25)

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.

IPR2020-00135, Ex-1001, claim 25

Substitute Claims 58-59 of the ’776 Patent (Depend from Claim 25)

25. A guide extension catheter for use with a guide catheter, comprising:

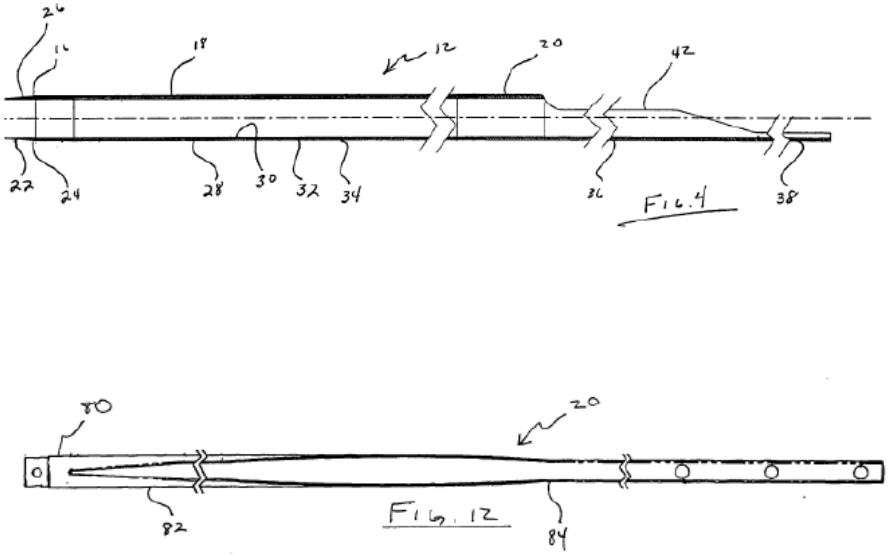
a substantially rigid segment;

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,

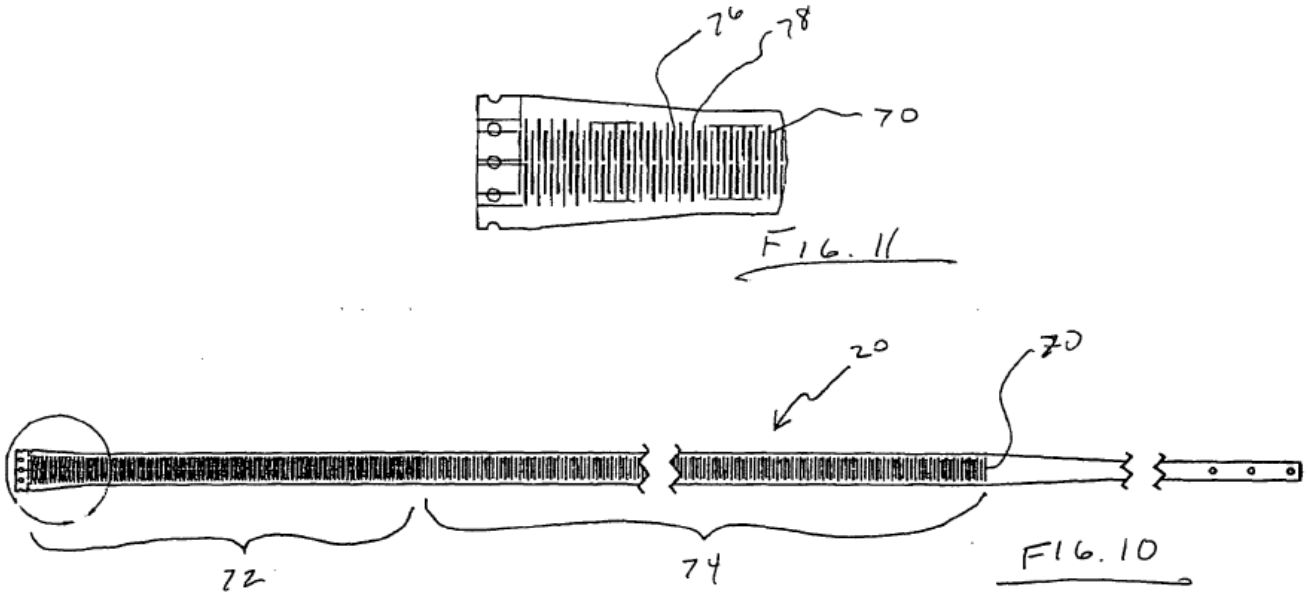
wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.

IPR2020-00135, Ex-1001, claim 25



IPR2020-00126, Ex-1003 at 35, 41

The ’629 Application



IPR2020-00126, Ex-1003 at 40

Substitute Claims 58-59 of the ’776 Patent (Depend from Claim 25)

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.

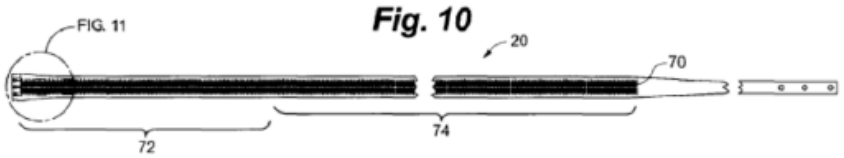


Fig. 10

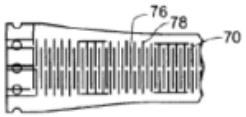


Fig. 11

Zalesky Testimony (Jan. 25, 2021)

Q. And you agree that Figures 10 and 11 show relief cuts, right?

A. Yes, that's my understanding, as described in the body of the patent application.

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

IPR2020-00126, Ex-2242 at 54:7-10; Paper 106 at 6

Zalesky Testimony (Jan. 25, 2021)

If you look at the patent as a whole, do you agree that the patent as a whole is teaching that relief cuts can be put in the side opening to make the side opening more flexible?

A. I'm saying that the content of the patent is that relief cuts can be put in the rigid portion of the continuous metal tube to make it more flexible. And per other figures and statements, the side opening can be made in that rigid structure.

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

IPR2020-00126, Ex-2242 at 57:1-10;
Paper 106 at 6

First Keith Decl

36. The specification also conveys to a POSITA that the side opening can be made flexible. The substantially rigid portion can be made of Nitinol, *id.*, at 8:17-18; 15:4-5; 17:2, which a POSITA would recognize could be flexible, especially if the Nitinol is thin. Further, "[t]he rigid portion may include a plurality of radially oriented slits or other cuts in its distal portion to increase and control the flexibility of the rigid portion." *Id.* at 9:6-7. Figures 10 and 11 show an embodiment where regions of the so-called rigid portion with the side opening are "perforated by relief cuts" that increase the flexibility of those regions.

IPR2020-00126, Ex-2124, ¶36; Paper 96 at 4

First Keith Decl

37. The specification would convey to a POSITA that the device generally increases in flexibility in a proximal-to-distal direction. *Id.* at 15:4-5, 16:8-17:2. A POSITA would know that cuts through the wall thickness can render an otherwise rigid structure dramatically more flexible. A POSITA further would understand that the patentee added rigidity comparisons to the claims where that was desired. For example, issued claim 1 of the '032 patent recites that the "substantially rigid portion [is] more rigid along a longitudinal axis than . . . the

IPR2020-00126, Ex-2124, ¶37;
Paper 96 at 4

Second Keith Decl

40. Further, the proximal portion of a polymer tubular structure (or the reinforced portion) could be more rigid than even a metal side opening, for example, where the side opening is made of flexible Nitinol and/or has relief cuts. Where the proximal portion of the reinforced portion is more rigid than a metal side opening, it could be called "substantially rigid," in which case it does not seem to me to make sense to require that the side opening must be in the "substantially rigid" portion—because that would mean it could be in either the distal portion of the metal (if the substantially rigid portion is metal) or in the proximal portion of the tubular section. For these reasons, I disagree that a POSITA would understand the disclosure of the '629 application to be limited to a side opening that is formed in the substantially rigid portion, as Dr. Zalesky opines. Ex-1919. ¶¶71-73.

IPR2020-00126, Ex-2243, ¶40; Paper 106 at 5

Legal Standard

"[T]he district court erroneously inferred that the examiner considered all of the claims to be limited to a lockout mechanism located on the staple cartridge. In doing so, the district court confused a claim not supported by the specification, which is not allowable, with a broad claim, which is. Claim 1 was properly rejected because it **recited** ***an element not supported by [patentee's] disclosure, i.e., a lockout 'on the stapler.' It does not follow, however, that [patentee's] disclosure could not support claims sufficiently broad to read on a lockout off of the cartridge. . . . [If the inventor] did not consider the precise location of the lockout to be an element of his invention, he was free to draft claim 24 broadly…to exclude the lockout's exact location as a limitation of the claimed invention…. Such a claim would not be unsupported by the specification even though it would be literally infringed by undisclosed embodiments."***

Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 93 F.3d 1572, 1582 n.7 (Fed. Cir. 1996) (internal citations omitted)

Legal Standard

***"[E]xceptions to the general rule"*:**

"[I]f the art is unpredictable, then disclosure of more species is necessary to adequately show possession of the entire genus."

"Instead of suggesting that the [patent] encompasses additional [embodiments], the specification specifically distinguishes the prior art as inferior and touts the advantages of the [disclosed embodiment]"

Bilstad v. Wakalopulos, 386 F.3d 1116, 1125 (Fed. Cir. 2004) (citation omitted)

Legal Standard

"In addition to predictability, we have held that the criticality or importance of an unclaimed limitation to the invention can be relevant to the written description inquiry."

In re Global IP Holdings LLC, 927 F.3d 1373, 1377 (Fed. Cir. 2019)

Legal Standard

"It is a familiar principle of patent law that a claim need not be limited to a preferred embodiment. The specification also includes references to half-shells without the modifier 'identical' or 'identically shaped,' indicating that identical half-shells are not critical to the invention. Although the patent drawings show only identical half-shells, that does not compel the conclusion that the written description . . .is so narrowly tailored as to preclude [Patent Owner] from claiming non-identical half-shells. . . . The drawings in the patent are merely a 'practical example' of the invention."

Lampi Corp. v. Am. Power Prods., Inc., 228 F.3d 1365, 1377-78 (Fed. Cir. 2000) (internal citations omitted)

Zalesky Testimony (Jan. 25, 2021)

Q. Right. And that's the point I'm making. The specification says you can have a reinforced portion and the reinforced portion could be made with a braid or a coil, right?

A. Right.

Q. And there's no written description problem if a claim simply recites a reinforced portion but doesn't also say that that reinforced portion is made with a braid or a coil, right?

MS. TREMBLAY: Objection. Form. Scope.

A. I think that's okay.

IPR2020-00126, Ex-2242 at 137:2-138:14; Paper 106 at 5 (citing Ex-2243, at ¶31)

The ’629 Application

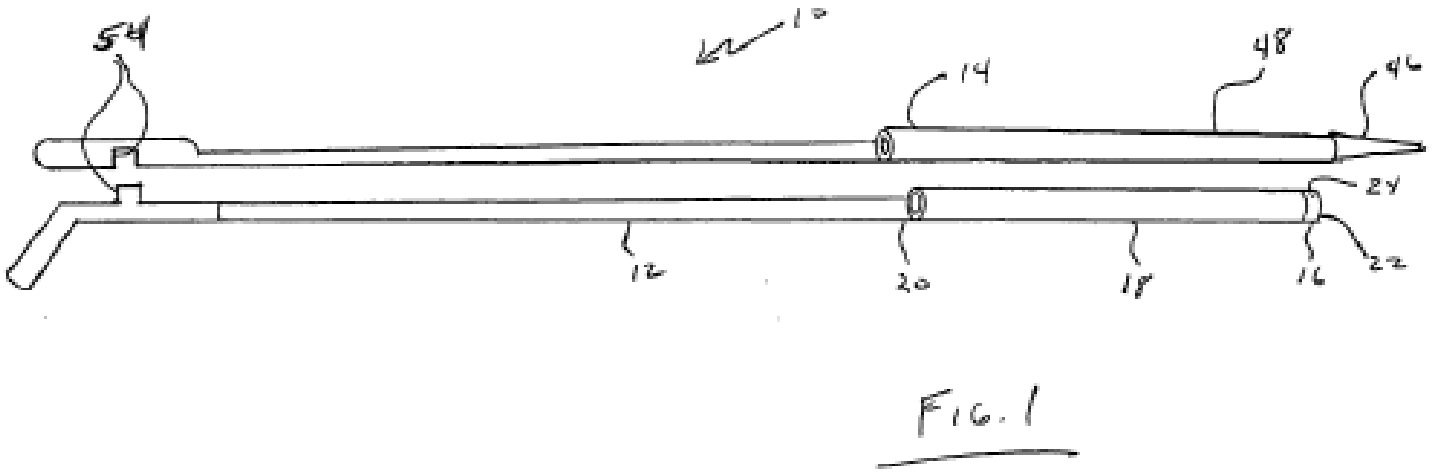
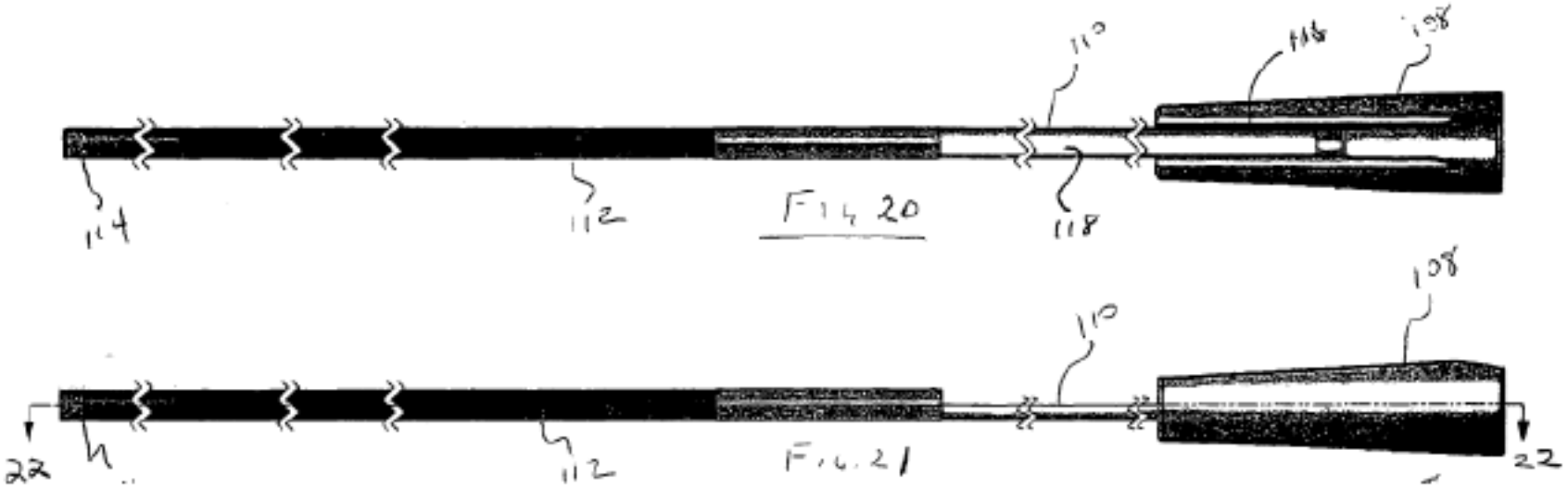


FIG. 1

IPR2020-00126, Ex-2243, ¶33; Ex-1003 at 32; Paper 106 at 5

The ’629 Application



IPR2020-00126, Ex-2243, ¶28; Ex-1003 at 44; Paper 106 at 5

Zalesky Testimony (Jan. 25, 2021)

Q. Okay. Now, with respect to Figures 20 and 21, the patent application is teaching that the full circumference portion is part of a tubular portion made of polymer, right?

A. Yes, that's my understanding.

IPR2020-00126, Ex-2242, 42:3-7;
Paper 106 at 5

Zalesky Declaration

25. The '032 patent also describes an embodiment in which the opening is vertical, or perpendicular, to the hemi-tube portion 110. In this embodiment, the rigid portion 110 is described as a "hemi-tube" along its entire length. There is no portion of the rigid portion 110 that includes a full circumference portion. *See id.*, 9:5-41.

Fig. 20

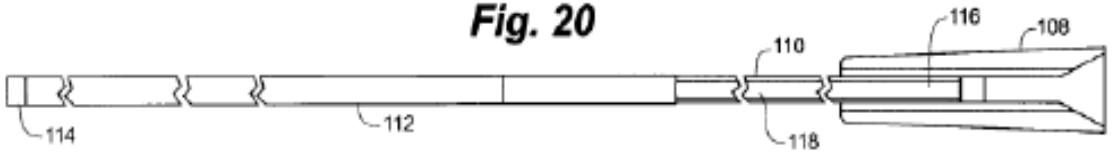
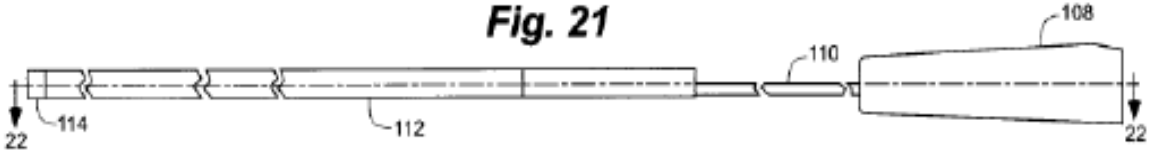


Fig. 21



IPR2020-00126, Ex-1919, ¶25; Paper 106 at 5

Second Keith Declaration

33. As set forth in my opening declaration, the specification provides support for an opening located outside of the substantially rigid portion. For example, Figures 20 and 21 of the '629 application teach that the proximal opening is part of a tubular portion made of polymer, not the substantially rigid portion. Petitioner's expert, Dr. Zalesky, agrees. Ex-2242, 41:15-42:7; Ex-1919, ¶25. Figure 1 also shows an opening that is located in the reinforced portion 18, which is made of polymer and may include a braid or coil. Ex-1003, 14:17-20. Figure 1 is shown below:

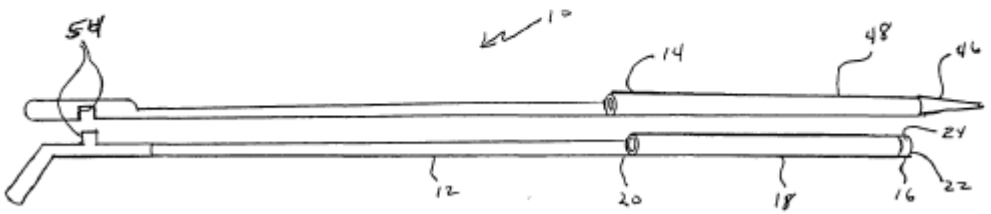


FIG. 1

IPR2020-00126, Ex-2243, ¶33; Paper 106 at 5

The ’629 Application

Reinforced portion 18 includes braid or coil reinforcement 32. Braid or coil reinforcement 32 may be formed of metal, plastic, graphite, or composite structures known to the art. Reinforced portion 18 may be lined on the interior by PTFE liner 30 and covered on the exterior by Pebax® material 28. Tip portion 16 and reinforced portion 18 together form a substantially cylindrical structure. Braid or coil reinforcement 32 may extend approximately 20 to 30 cm. In one exemplary embodiment, braid or coiled portion has a length of approximately 32 to 36 cm.

IPR2020-00126, Ex-2243, ¶33; Ex-1003 at 14:17-20; Paper 106 at 5

Zalesky Testimony (Jan. 25, 2021)

Q. And the only point I'm making is: The inventor is disclosing both options, an end opening and a side opening, and nowhere does the inventor say, "The side opening is critical to my invention."

Right?

A. The inventor never states that the side opening is critical to the invention, yes.

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

IPR2020-00126, Ex-2242 at 80:19-81:1; Paper 106 at 5-6

The ’629 Application

Rigid portion 20 may be secured to braid or coil reinforcement by, for example, welding or bonding. Rigid portion 20 may be formed from a hypotube or a section of stainless steel or Nitinol tubing. Other substantially rigid materials may be used as well. Rigid portion 20 includes first full circumference portion 34, hemicylindrical portion 36, arcuate portion 38, and second full circumference portion 40.

[. . .]

distal portion of braid or coil reinforcement 32. Next may come an approximately five cm portion of 6333 Pebax® which encloses part of braid or coil reinforcement 32 followed by an approximately twenty seven cm portion of 7233 Pebax® covering the most proximal portion of braid or coil reinforcement 32. Braid or coil reinforcement 32 is bonded to rigid portion 20 which may be formed from stainless steel or a similar biocompatible material. Rigid portion 20

IPR2020-00126, Ex-1003 at 15:4-5, 16:18-19; Paper 106 at 6

Zalesky Testimony (Jan. 25, 2021)

Q. Okay. So you agree that the '629 application is teaching that the substantially rigid portion can be made out of other substantially rigid materials such as biocompatible materials, right?

A. That's what's stated here, yes.

Q. You agree that one of skill in the art would understand that various polymers could be substantially rigid, right?

MS. TREMBLAY: Objection. Scope.

A. I agree that's a possibility. Some materials do come to mind that are substantially rigid, as polymers, yes.

Q. And what would be some of those materials that come to your mind that would be polymers that would be substantially rigid?

A. Polyimide is probably the most likely suspect.

IPR2020-00126, Ex-2242 at 59:25-60:17; Paper 106 at 5-6 (citing Ex-2243, ¶36)

Zalesky Testimony (Jan. 25, 2021)

Q. And in 2005, would one of ordinary skill in the art have known how to make the side opening more flexible even if it was made out of stainless steel?

MS. TREMBLAY: Objection. Scope.

A. I believe that's generally true. And, you know, we made one reference to the modified metal tubing, for instance, that would, you know, produce increased flexibility along the length, yes.

Q. And the modified -- the modification you were talking about there are those relief cuts; is that right?

A. Yes.

IPR2020-00126, Ex-2242 at 62:6-18; Paper 106 at 4, 6-7

Zalesky Testimony (Jan. 25, 2021)

Q. Okay. And in 2005, would one of ordinary skill in the art have known how to make the side opening more rigid even if it was made out of a polymer?

MS. TREMBLAY: Objection. Scope.

A. There are probably ways of introducing a secondary material, such as a ring of some sort, at the side opening, if such a side opening were made in something like polyimide.

Q. And alternatively, one of ordinary skill in the art in 2005 would have known that they could use a thicker polyimide to make the side opening more rigid, right?

A. Yes, I think that's generally true.

Q. Generally, you agree that in 2005 a person of ordinary skill in the art would have known that a structural property of a device could be changed by changing the material, itself, or the thickness of the material or adding some kind of relief cuts, right?

MS. TREMBLAY: Objection. Form. Scope.

A. In general, yes.

IPR2020-00126, Ex-2242 at 62:19-63:16; Paper 106 at 4, 6-7

Jones Testimony (Jan. 20, 2021)

Q. Okay. In 2005, would one of ordinary skill in the art have appreciated that the angled opening could have been made out of metal or polymer?

A. Yes, I believe so.

Q. In 2005, would one of ordinary skill in the art have known how to make an angled opening flexible, even if that angled opening was made out of stainless steel?

MR. PINAHS: Objection. Form.

A. So as demonstrated by Ressemann's collar and the various perforations and cuts in it, it should be a flexible or transitional stiffness member.

So my answer -- so my answer is yes.

Q. Okay. And that's just what I wanted to confirm with you, Mr. Jones.

As shown in Ressemann, in 2005, one of the ways one of skill in the art would have known to make a part made out of stainless steel more flexible would be to provide some relief cuts in that angled opening, right?

A. That's correct.

IPR2020-00126, Ex-2241 at 150:3-24; Paper 106 at 4, 6-7

Jones Testimony (Jan. 20, 2021)

Q. Right. So my question is: You said a person of ordinary skill in the art in 2005 would have appreciated that an angled opening could have been made out of polymer, right?

A. Yes. A person of ordinary skill in the art could understand the angled opening to be metal or polymer.

Q. And in 2005, would a person of skill in the art have known that if they wanted to make that polymer-angled opening more rigid, they could employ a more rigid polymer?

A. Absolutely.

IPR2020-00126, Ex-2241 at 152:21-153:7; Paper 106 at 4, 6-7

Jones Testimony (Jan. 20, 2021)

Q. Is it your opinion that one of ordinary skill in the art in 2005 would have known that a structural property of a device could be changed by changing the material that is used for that device?

A. An engineer -- so let's get to the engineering side of this. An engineer would appreciate that polymers come in all sorts of -- in a various range of mechanical properties, typically reflected by their flexural modulus. And one can create -- use those properties.

So if we used the Ressemann collar as an example, that the Ressemann collar, when made in a soft polyurethane, would be more flexible than the Ressemann collar if made of polyimide. And both of those would be more flexible than the Ressemann collar made of stainless steel.

So in 2005, that would have been known to an engineer skilled in the art.

IPR2020-00126, Ex-2241 at 153:23-154:15; Paper 106 at 4, 6-7

Second Keith Declaration

37. Regardless of whether the side opening was formed out of the exact substantially rigid materials described in the specification or other materials that are compatible with the intended purpose of the proximal opening, a POSITA would understand that the principal function of the side opening—facilitating the entry of interventional cardiology devices into the proximal portion of the tubular structure while the guide extension catheter is disposed within the guide catheter—would still be served. A POSITA reading Teleflex's disclosure in 2005 would have known that the side opening could be made out of metal or polymer, that relief cuts could be used to increase flexibility, and/or that different types of material and thickness of the material could be used. Petitioner's experts, Dr. Zalesky and Mr. Jones both agree. Ex-2242, 62:6-63:16, 89:23-90:3; Ex-2241, 150:3-155:1. Moreover, assigning clear rigidity-based demarcations to the invention would be inconsistent with the understanding of a POSITA, particularly when the '629 application discloses a variety of suitable materials for any given portion. Ex-2124, ¶33.

IPR2020-00126, Ex-2243, ¶37; Paper 106 at 5-7

The ’629 Application

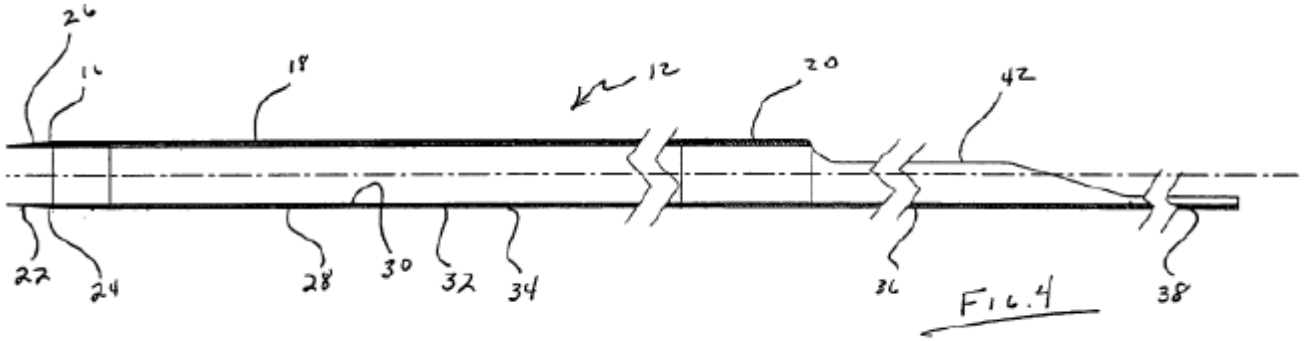


FIG. 4

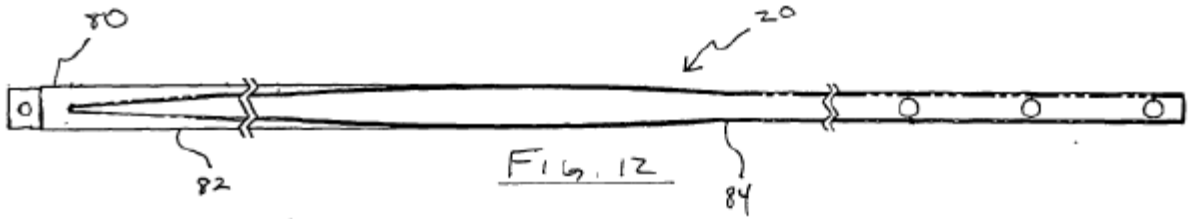


FIG. 12

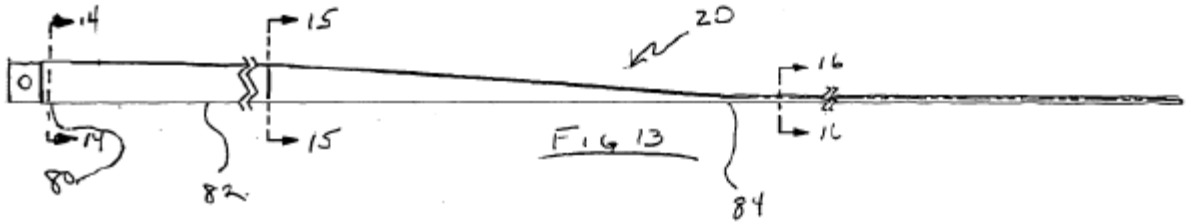


FIG 13

IPR2020-00126, Ex-2243, ¶29; Ex-1003 at 35, 41; Paper 106 at 5

The ’629 Application

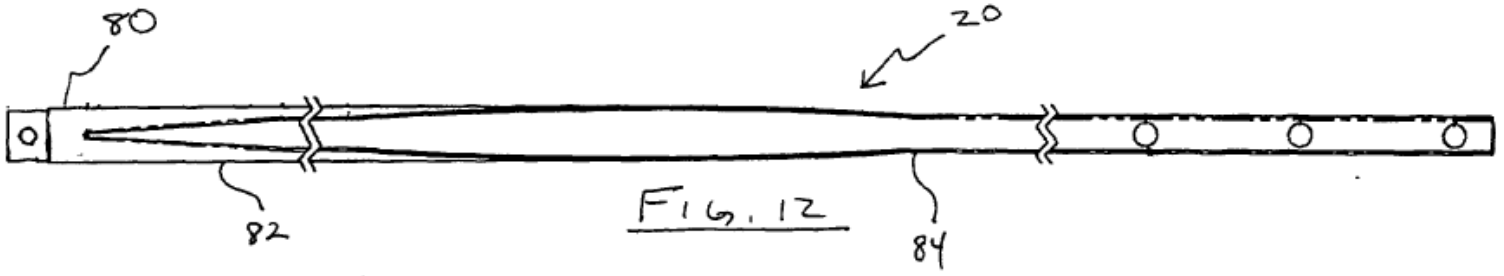


FIG. 12

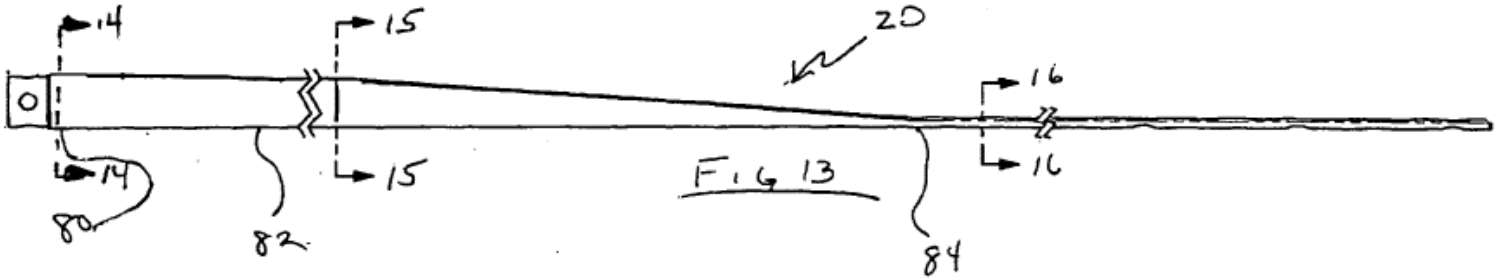


FIG 13

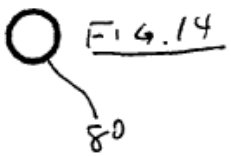


FIG. 14

FIG. 15

FIG. 16

IPR2020-00126, Ex-2243, ¶29; Ex-1003 at 41; Paper 106 at 5

The ’629 Application

Preferably, the rigid portion may be advantageously formed from a stainless steel or Nitinol tube. The rigid portion may be joined to the braid or coil portion by welding. The rigid portion may include a cutout portion and a full circumference portion. For example, the cutout portion may include a section where about 45% of the circumference of the cylindrical tubular structure has been removed. The cutout portion may also include a section where 75-90% of the circumference of the tubular structure has been removed. In one exemplary embodiment, the portion having approximately 45% removed may extend for approximately 75 cm and the portion having 75-90% of the structure removed extends for about 15 cm. The full circumference portion of the rigid portion is typically located at the most proximal end of the coaxial guide catheter.

IPR2020-00126, Ex-1003 at 8:17-9:5; Paper 106 at 5

Zalesky Testimony (Jan. 25, 2021)

Q. Okay. Would you agree that that location or specification is not -- well, strike that.

Do you agree that that locat- -- there is nowhere in that location a specification that says that the specific structure he's describing is critical to the invention?

A. I'm agreeing that he's not stating that this particular configuration is a must, but he is reciting the specification content here about the geometry and the rigid portion.

IPR2020-00126, Ex-2242 at 83:1-10; Paper 106 at 5-6

Legal Standard

"Nor do we agree that the disclosed tip configuration was critical. No prior art was distinguished from and no rejection was overcome on the basis of the tip shape. Most importantly, one skilled in the art would readily understand that in practicing the invention it is unimportant whether the tips are tapered, and the board erred in determining the contrary."

In re Peters, 723 F.2d 891, 893 (Fed. Cir. 1983)

File History of the ’379 Patent

Regarding claims 26 and 38, the new claim language of “a segment having/defining a side opening” does not have support in the specification of the '850 patent or the '059 application resulting in the patent. The ‘850 patent is very clear that the side opening, i.e. the opening in the catheter wall made from “first full circumference portion 34, hemicylindrical portion 36 and arcuate portion 38” is part of rigid portion 20 and not its own segment apart from rigid portion. See the ‘850 patent col. 6, ll. 50-65. Claim 26 further places the newly claimed “segment” “proximal of the proximal end portion of the reinforced segment.” However, the substantially rigid segment is located proximal of the proximal end portion of the reinforced segment. Claim 38 identifies the segment defining the side opening as a completely different structure from the rigid portion which is contrary to the ‘850 patent specification. Appropriate correction is required.

IPR2020-00126, Ex-2124, ¶37; Paper 106 at 7-8; IPR2020-00137, Ex-1003, 163, 174-175 (OA dated 07/20/2017)

File History of the ’379 Patent

38. A method of forming a device adapted for use with a standard guide catheter having a continuous lumen extending for a predefined length, the method comprising:

providing a flexible tip segment having a lumen therethrough;

providing a reinforced segment including one or more metallic elements covered with a polymer and having a lumen for coaxial alignment with the lumen of the flexible tip ~~portion~~ segment;

providing a substantially rigid segment extending from a proximal end portion to a distal end portion, wherein the substantially rigid segment is more rigid along a longitudinal axis than the flexible tip segment;

~~providing a segment~~ defining a side opening portion, including forming, in a proximal to distal direction, an arcuate cross-sectional shape and a hemicylindrical cross-sectional shape, the side opening portion extending for a distance along a longitudinal axis of the device[[and]] such that the side opening portion is accessible from a longitudinal side, defined transverse to the longitudinal axis, to receive a balloon catheter[[or]] and stent; and

arranging, in a proximal to distal direction, the substantially rigid segment, ~~the segment defining~~ the side opening portion, the reinforced segment, and the flexible tip segment such that when the flexible tip segment is extended distally of a distal end of the guide catheter, the proximal end portion of the substantially rigid segment extends proximally of a proximal end of the guide catheter and the side opening portion is positioned within the continuous lumen of the guide catheter.

IPR2020-00137, Ex-1003 at 232-33;
IPR2020-00126, Paper 106 at 7

Zalesky Testimony (Jan. 25, 2021)

Q. And so all this work that you're referring to designing catheters with multi-hardness bodies and multi-flexibility properties and different materials, that was all being done in the '95 to the 2005 time frame?

A. Yes. I think it actually started well before that. Certainly in the latter '80s and through the '90s, but certainly through that time frame as well.

Q. Okay. So by 2005, am I correct that the catheter field was pretty mature at that point?

A. I would say very mature.

IPR2020-00126, Ex-2242 at 18:9-21:15; Paper 106 at 4

Zalesky Testimony (Jan. 25, 2021)

Q. Based on what you said about catheter design kind of starting in the 1980s, as we move forward 20 years to the 2005 time period, catheter design wasn't a new field in 2005, right?

A. That's correct.

Q. And there was a lot of prior work that had been done with catheter design that allowed engineers to predict how a certain catheter design may function, right?

MS. TREMBLAY: Objection. Form.

A. I would say that's true in general, but with exceptions, in the sense that especially when you're playing with a different geometry of a device or looking for lower profile, you really had to evaluate prototypes to see if they, in fact, would function as you hoped.

IPR2020-00126, Ex-2242 at 21:13-22:17; Paper 106 at 4

Substitute Claims 58-59 of the ’776 Patent (Depend from Claim 25)

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.

Substitute Claims 54-56 of the ’760 Patent (Depend from Claim 25)

25. A system, comprising:

a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and

a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,

the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and 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, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;

wherein a material forming the segment defining the side opening is more rigid than the tubular structure.

Zalesky Testimony (Jan. 25, 2021)

Q. Okay. The '629 teaches that the substantially rigid section can be made of nitinol, right? That's one piece of material that it says it can be made of?

A. Yes.

Q. Nitinol can be flexible, right?

A. Yes.

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

IPR2020-00126, Ex-2242 at 58:1-7; Paper 106 at 6

Second Keith Declaration

40. Further, the proximal portion of a polymer tubular structure (or the reinforced portion) could be more rigid than even a metal side opening, for example, where the side opening is made of flexible Nitinol and/or has relief cuts. Where the proximal portion of the reinforced portion is more rigid than a metal side opening, it could be called "substantially rigid," in which case it does not seem to me to make sense to require that the side opening must be in the "substantially rigid" portion—because that would mean it could be in either the distal portion of the metal (if the substantially rigid portion is metal) or in the proximal portion of the tubular section. For these reasons, I disagree that a POSITA would understand the disclosure of the '629 application to be limited to a side opening that is formed in the substantially rigid portion, as Dr. Zalesky opines. Ex-1919, ¶¶71-73.

IPR2020-00126, Ex-2243, ¶40; Paper 106 at 6

INDEFINITENESS

Substitute Claim 23 of 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 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-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;

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 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,

such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

Zalesky Testimony (Jan. 25, 2021)

well, the second-to-last clause in the claim, am I correct that the claim recites that the flexible tip portion and the substantially rigid portion, together, have a length that defines a total length of the device?

A. That's what it states, yes.

Q. Okay. And so there are just two separate portions in this claim, right?

A. That's my understanding.

Q. And is it accurate to say that the portion of the device that includes the side opening must be part of the substantially rigid portion?

MS. TREMBLAY: Objection. Form.

A. That's my understanding.

IPR2020-00126, Ex-2242 at 135:1-14; Paper 106 at 8

Substitute Claim 24 of the ’032 Patent

Claim 24 (replaces claim 11): 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-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:

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-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the flexible tip portion being sized 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;

a reinforced portion having a uniform, fixed cross-sectional outer diameter proximal to the flexible tip portion; [and]

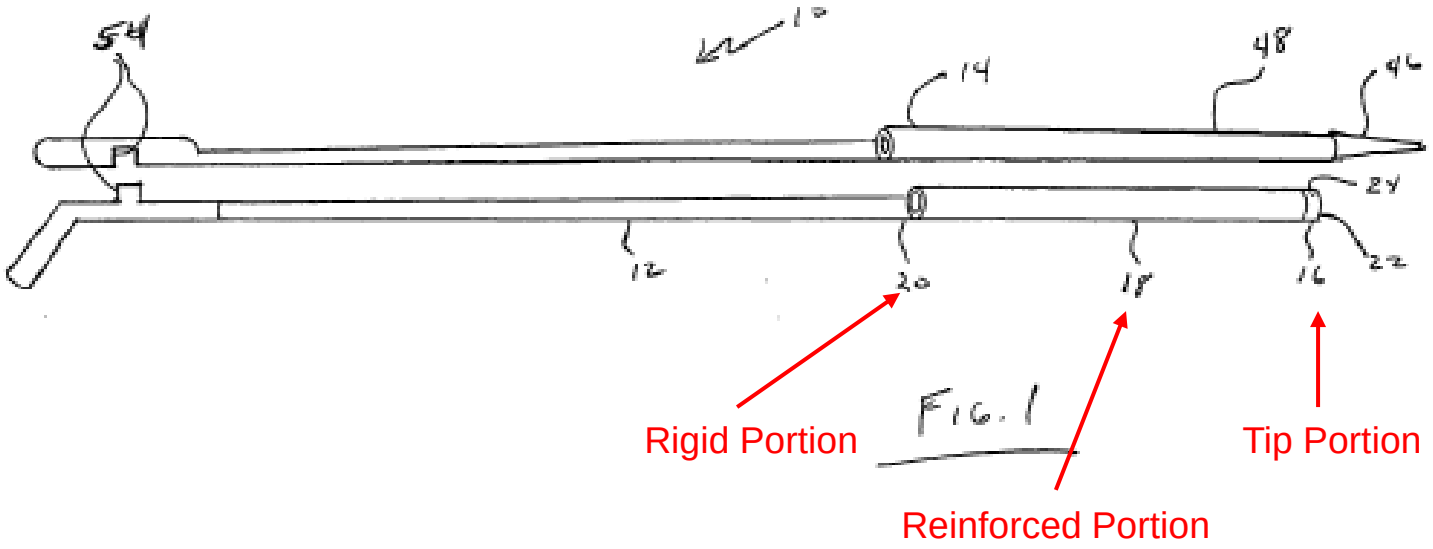
a substantially rigid portion proximal of and connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion,

such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the 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 hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter; and

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;

wherein the device is configured so that, when the reinforced portion extends into the branch artery, the reinforced portion and the substantially rigid portion assist in resisting forces exerted by the interventional cardiology devices passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the artery.

The ’629 Application



IPR2020-00126; Ex-1003 at 32 (annotations added); Paper 106 at 8-9; Paper 96 at 4

Substitute Claim 44 of the ’380 Patent

Claim 44 (replaces claim 12): A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

a standard 6 French guide catheter having a continuous lumen with an internal diameter greater than or equal to 0.070 inches extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that the interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and

a device adapted for use with the guide catheter, including:

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, in a distal-to-proximal direction:

a cylindrical flexible tip portion and a reinforced portion proximal to the flexible tip portion together defining a tubular structure with a single lumen and having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the flexible tip portion 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 with the guide catheter and with the tubular structure having a cross-sectional inner diameter of at least 0.056 inches through which the interventional cardiology devices are insertable; and

[a reinforced portion proximal to the flexible tip portion; and]

a substantially rigid portion proximal of, connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the 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 hemostatic valve in common with the interventional cardiology devices that are insertable into the guide catheter; [[and]]

wherein the device further includes a substantially rigid partially cylindrical portion proximal to a distal end of the substantially rigid portion, the partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to the longitudinal axis of the device that is adapted to receive the interventional cardiology devices passed through the continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, wherein the opening in the partially cylindrical portion includes a first inclined sidewall that is separated from a second inclined sidewall in the partially cylindrical portion by a non-inclined concave track; and

wherein the flexible tip portion is more flexible than the reinforced portion.

SCOPE OF THE ORIGINAL CLAIMS

Substitute Claim 58 of the ’760 Patent

Claim 58 (replaces claim 51): A system, comprising:

a standard 6 French guide catheter with an internal diameter greater than or equal to 0.070 inches configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and

a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,

the guide extension catheter including, in a proximal to distal direction, a substantially rigid rail structure segment, a segment defining a side opening, and a tubular structure comprising a reinforced portion and a cylindrical distal tip portion distal to the reinforced portion, the tubular structure having a uniform, fixed outer diameter and defining a single lumen that is coaxial and in fluid communication with the lumen of the guide catheter when positioned therein, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is greater than or equal to 0.056 inches so as to be not more than one French size smaller than the cross-sectional inner diameter of the lumen of the standard 6 French guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;

wherein the segment defining the side opening includes a first inclined sidewall proximate to a non-inclined region that is proximate to a second inclined sidewall;

wherein the segment defining the side opening and the rail structure segment are more rigid than the tubular structure;

wherein the reinforced portion is more rigid than the tip portion;

wherein a distal portion of the tubular structure is configured to extend past the ostium of a vessel and anchor within the vessel so that the reinforced portion and the substantially rigid rail structure segment are configured to resist forces exerted by received stent and balloon catheters that would otherwise tend to dislodge the guide catheter from the ostium;

wherein the tip portion includes an atraumatic bumper formed from a flexible material and having a lumen continuous with the lumen of the tubular structure; and

wherein the reinforced portion [tubular structure] includes a reinforcing braid or coil, and wherein the tip portion includes a marker band positioned distal to the distal end of the reinforcing braid or coil.

Substitute Claim 65 of the ’776 Patent

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.

Substitute Claim 65 of the ’776 Patent (Originally Depends from Claim 53)

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.

IPR2020-00135, Ex-1001, claim 53; Paper 95, Appx A at 5

The ’629 Application

In one embodiment, the coaxial guide catheter is made in at least three sizes corresponding to the internal capacity of 8 French, 7 French, and 6 French guide catheters that are commonly used in interventional cardiology procedures. An 8 French catheter has an internal diameter greater than or equal to 0.088 inches. A 7 French catheter has an internal diameter greater than or equal to 0.078 inches. A 6 French guide catheter has an internal diameter greater than or equal to 0.070 inches. Thus, for three exemplary sizes the effective internal diameter of the coaxial guide catheter may be as follows. For a 7 French in 8 French coaxial guide catheter the internal diameter should be greater than or equal to 0.078 inches. For a 6 French in 7 French coaxial guide catheter the internal diameter should be greater than or equal to 0.070 inches. For a 5 French in 6 French coaxial guide catheter the internal diameter should be greater than or equal to 0.056 inches.

IPR2020-00135, Ex-1003 at 7:8-18, Paper 105, 7-8

Second Keith Decl

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;
Paper 105 at 7-8

Second Keith Decl

50. The specification of the GuideLiner patents is consistent with the widely held understanding in the art during the 2006 timeframe and beyond. The disclosure does not define one French size in its strict mathematical sense. Ex-1003, 7:8-18. For example, the disclosure states that, for a "5 French in 6 French" configuration, the internal diameter of a 6 French guide catheter is 0.070, and the internal diameter of the guide extension catheter should be "greater than or equal to 0.056 inches." *Id.* at 3:45-51. Thus, according to the specification a guide extension catheter is used with a guide catheter that is one French size different, with respect to the inner diameters, even when the difference is 0.014 inches. This is consistent with how a one French size difference would have been understood by a POSITA.

IPR2020-00135, Ex-2243, ¶50; Paper 105 at 7-8

Hillstead Testimony (Sept. 15, 2020)

a 6 French. So is what you're saying, if I have a 5 French size guide catheter in a 6 French size guide catheter, the difference in that -- in their inner diameters could be, for example, more than .0131?

MR. PINAHS: Objection; form.

THE WITNESS: Well, you chose that number, but it could be different than whatever the spec is. If it says it's a 5 French catheter, it could be slightly larger or slightly smaller.

DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

IPR2020-00135, Ex-2137 at 371:25-372:9; Paper 105 at 8

Jones Testimony (Jan. 18, 2021)

Q. You can answer, Mr. Jones.

A. Okay. So the -- the way I was going to answer that is the ID rating on a catheter is a published number by the manufacturer. They may or may not conform to that ID.

So I think you have to have a set of -- there's a lot of wiggle room in how catheters are specified for ID and OD; therefore, you'd have to have some allowance or variation for what's possible between them.

So 1 French is not 13 -- 1 French is .013, but the variation across two catheters that are rated at 1 French difference between them on their ID could be substantially more than that.

IPR2020-00135, Ex-2239 at 156:10-18; Paper 105 at 7-8

Petitioner's Sur-reply to '760 MTA

IV. PROPOSED CLAIM 58 IS A BROADENING AMENDMENT

PO does not dispute that proposed claim 58 permits the distance between the inner diameter of the tubular structure and the inner diameter of the guide catheter to be 0.014 inches. (MTA Reply, 7-8.) Nor does PO dispute that original claim 51 required a "1 French" differential, which, as measured "mathematical[ly, is a] difference of . . . 0.0131 inches." (*See, e.g.*, Ex. 2243, ¶ 48.) As previously briefed, PO's argument—that 1 Fr means something other than 1 Fr—should be rejected, and the Board should find that proposed claim 58 is a broadening amendment.

Comparison between MTA Surreply and Second Keith Decl

IV. PROPOSED CLAIM 58 IS A BROADENING AMENDMENT

PO does not dispute that proposed claim 58 permits the distance between the inner diameter of the tubular structure and the inner diameter of the guide catheter to be 0.014 inches. (MTA Reply, 7-8.) Nor does PO dispute that original claim 51 required a "1 French" differential, which, as measured "mathematical[ly, is a] difference of . . . 0.0131 inches." (*See, e.g.*, Ex. 2243, ¶ 48.) As previously briefed, PO's argument—that 1 Fr means something other than 1 Fr—should be rejected, and the Board should find that proposed claim 58 is a broadening amendment.

IPR2020-00134, Paper 109 at 15

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).

IPR2020-00134, Ex-2243, ¶48; Paper 101 at 7-8

Petitioner's Sur-reply to '776 MTA

IV. PROPOSED CLAIM 65 IS A BROADENING AMENDMENT

PO does not dispute that proposed claim 65 permits the distance between the inner diameter of the tubular structure and the inner diameter of the guide catheter to be 0.014 inches. (MTA Reply, 7-8.) Nor does PO dispute that original claim 56 required a "1 French" differential, which, as measured "mathematical[ly, is a] difference of . . . 0.0131 inches." (*See, e.g.*, Ex. 2243, ¶ 48.) As previously briefed, PO's argument—that 1 Fr means something other than 1 Fr—should be rejected, and the Board should find that proposed claim 65 is a broadening amendment.

Comparison between MTA Surreply and Second Keith Decl

IV. PROPOSED CLAIM 65 IS A BROADENING AMENDMENT

PO does not dispute that proposed claim 65 permits the distance between the inner diameter of the tubular structure and the inner diameter of the guide catheter to be 0.014 inches. (MTA Reply, 7-8.) Nor does PO dispute that original claim 56 required a "1 French" differential, which, as measured "mathematical[ly, is a] difference of . . . 0.0131 inches." (*See, e.g.*, Ex. 2243, ¶ 48.) As previously briefed, PO's argument—that 1 Fr means something other than 1 Fr—should be rejected, and the Board should find that proposed claim 65 is a broadening amendment.

IPR2020-00135, Paper 113 at 15

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).

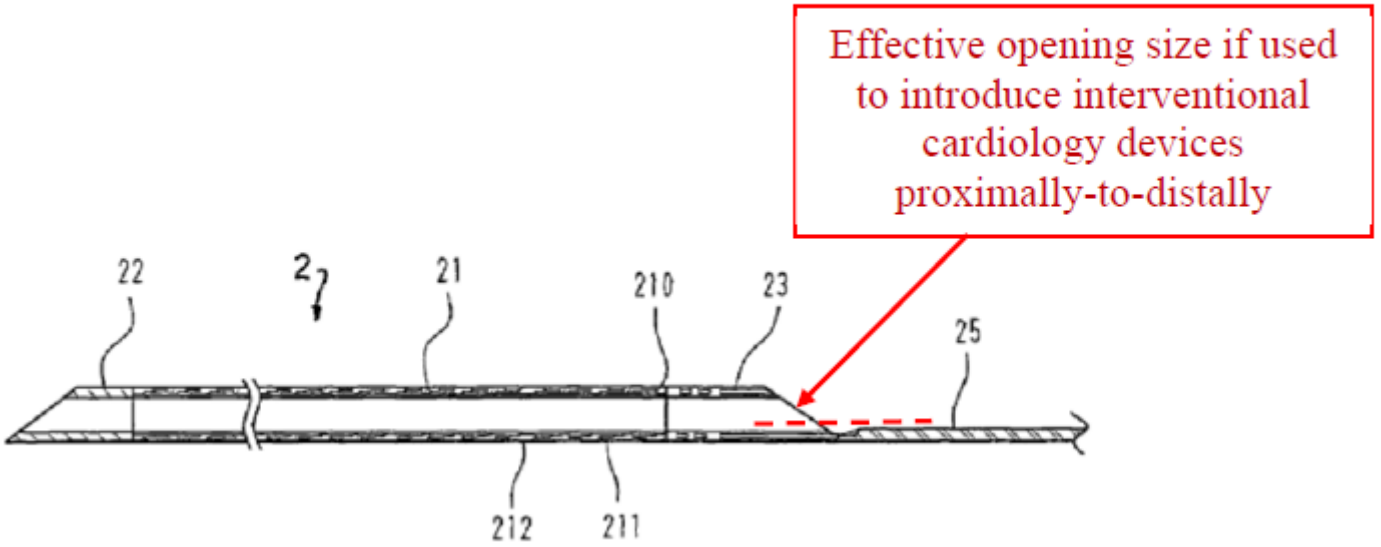
IPR2020-00135, Ex-2243, ¶48; Paper 105 at 7-8

NOVELTY AND NONOBVIOUSNESS

A Structure Through Which "Interventional Cardiology Devices," "Stents," or "Stent Catheters" are Insertable

All substitute claims
except claim 57 of the '760 patent
and claims 58-62 of the '776 patent

Itou Fig. 3



IPR2020-00126, Ex-1007, Fig. 3 (annotation added); Ex-2138, ¶128; Paper 43 at 21

Kontos

A PTCA catheter is a single balloon device:

The physician then slides a PTCA catheter **40** through **L5** the body **12** until the distal tip **46** of the catheter reaches soft tip **28**. (See, e.g., FIG. **5**.) The balloon **48** of PTCA catheter **40** will then be captured within the confines of body **12**. In this arrangement, the relatively fragile PTCA catheter balloon **48** will be safely surrounded by the more durable body **12** during insertion and maneuvering through the guide catheter **38** and vascular system.

A PTCA catheter does not include a stent:

Kontos also explains that the "distal end of a PTCA catheter is made to be extremely soft and flexible" and is therefore "susceptible to kinking and bending." . . . [C]atheters with a stent would not be "soft and flexible" and therefore "susceptible to kinking and bending." Therefore, a POSITA would not understand Kontos to teach the use of a stent catheter.

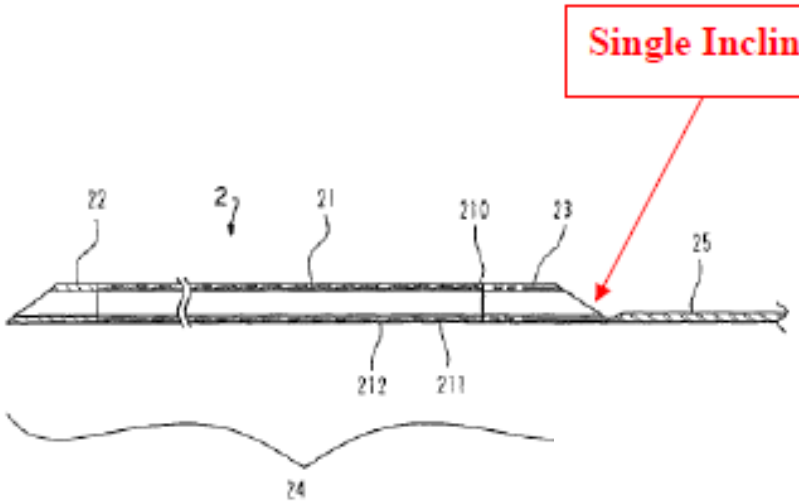
IPR2020-00126, Ex-1009 at 5:16-24; Ex-2243, ¶85; Paper 106 at 19-20

Complex Side Opening

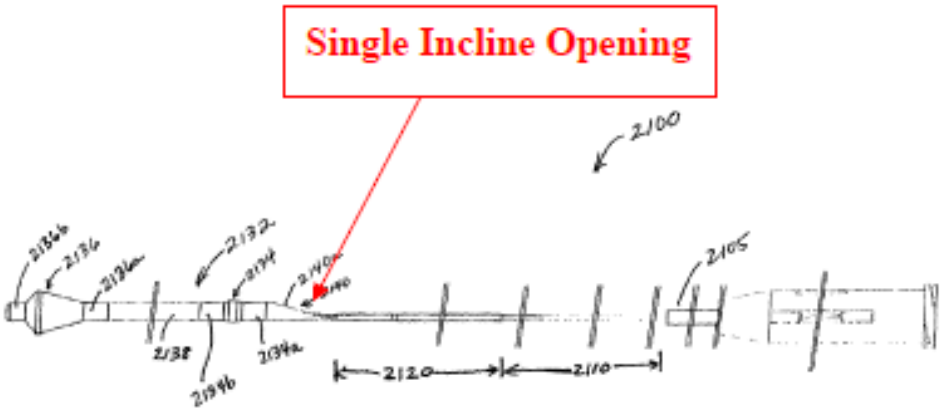
Substitute claims 23-25 of the ’032 patent, 44 of the ’380 patent, 56-58 of the ’760 patent, 58-65 of the ’776 patent, and 46-48 and 50-51 of the ’379 patent

Itou Fig. 3 and Ressemann Fig. 16A

FIG.3



Ex-1007 (Itou), Fig. 3



Ex-1008 (Ressemann), Fig. 16A

IPR2020-00126, Ex-1007, Fig. 3 & Ex-1008, Fig. 16A (annotations added); Ex-2243, ¶58; Paper 106 at 12.

Ressemann Fig. 16J

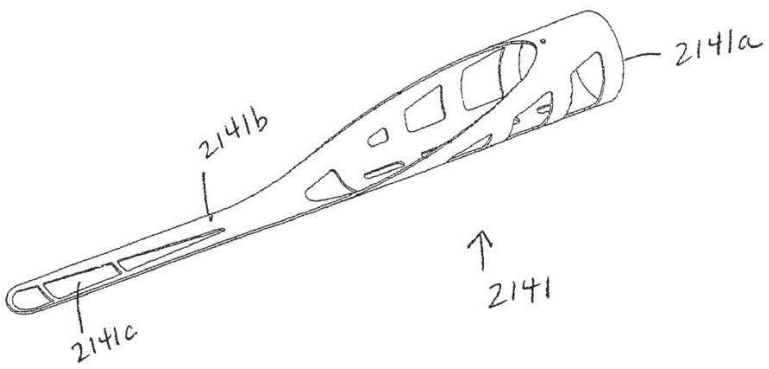


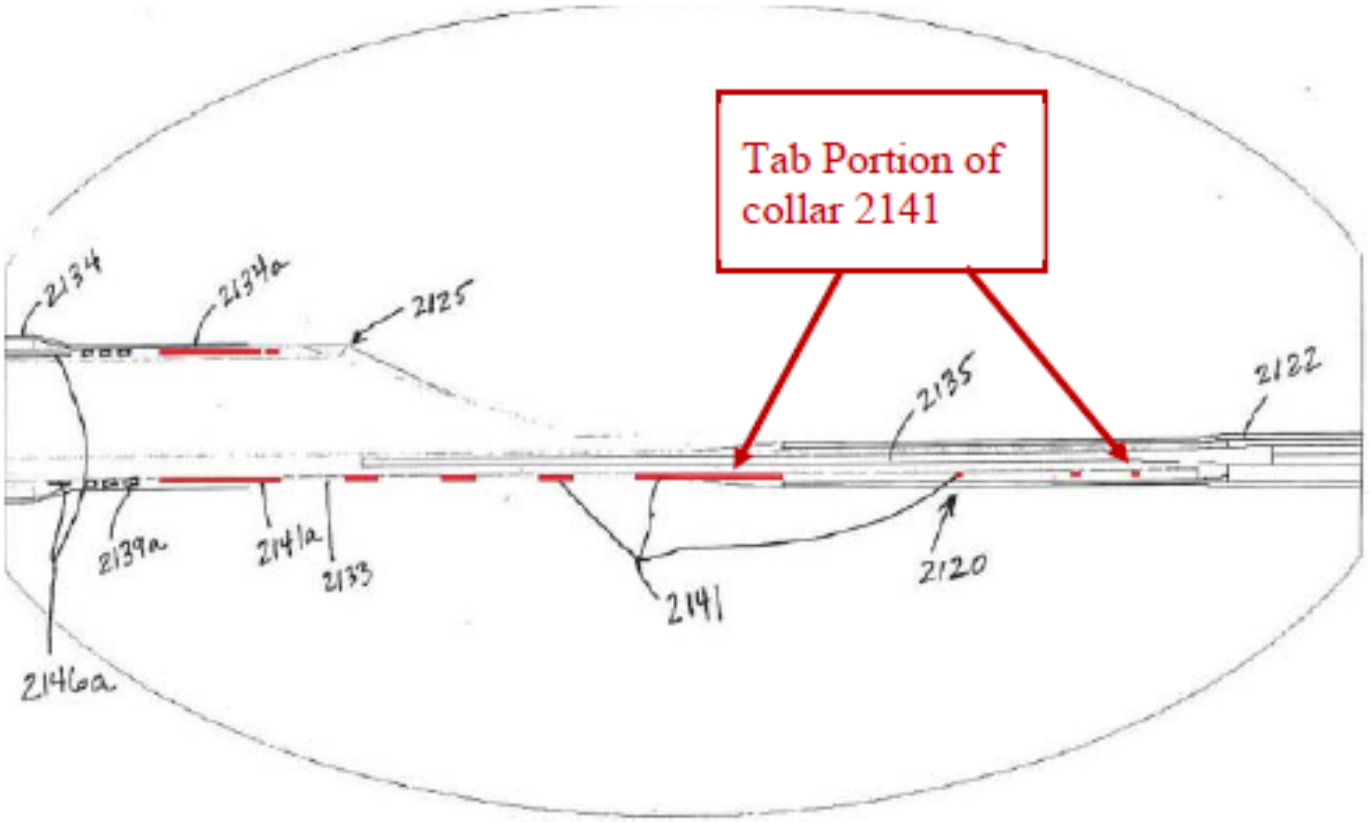
Fig. 16J

- "The windows 2141c allow for some flexibility and also allow for better adhesion or the encapsulation material 2133, which covers the support collar 2141...." IPR2020-00126, Ex. 1008, 25:4-6.

"In a preferred embodiment, the support collar 2141 has a wall thickness of approximately 0.002 inches, although it may vary between 0.001 and 0.004 inches." *Id.*, 25:8-11.

IPR2020-00126, Ex-1008, Fig. 16J; Paper 106 at 10-15 (citing Ex-2243, ¶66).

Ressemann Fig. 16D



IPR2020-00126, Ex-1008, Fig. 16D (annotations added); Ex-2138, ¶155; Paper 43 at 35-36.

Ressemann's Stent Teaching

- "The encapsulation 2133 formed over the exterior of the multi-lumen tube 2138 is formed with a reverse bevel 2125 at its extent over the proximal opening of the evacuation lumen, as shown in FIG. 16D.... **Stent delivery catheters**, for example, **are particularly subject to hanging-up on the proximal end of the evacuation head 2132 without reverse bevel 2125**."

IPR2020-00126, Ex-1008 at 25:17-29 (emphasis added);
Paper 106 at 12, 19, 21

Hillstead Testimony (Sept. 11, 2020)

interventional cardiology procedure percutaneously is something that, um, I would look at and draw from, and I don't necessarily need to be totally wrapped up in -- in what the element that I choose to pick and choose from to use as -- to combine with something else, what it does in the current device. I'm more concerned about how I can use it in combination for what I want to do.

IPR2020-00126, Ex-2137 at 133:3-9;
Paper 106 at 13

Brecker Testimony (Aug. 11, 2020)

A. I hadn't used that detail in forming my opinion about how you might use Ressemann.
Q. Right. Okay.
A. How you might use the collar.
Q. So -- yeah. Okay. So in the opinions that you did form, the location of where that support collar is in the finished devices was not important to your analysis; is that correct?
A. Where it -- where it is in Ressemann is not -- is not directly transferrable to how I'm using it or how it could be used in Itou.

IPR2020-00126, Ex-2116 at 239:7-13;
Paper 106 at 13

Jones Testimony (Jan. 18, 2021)

Q. And let me just re-ask it, so I make sure that the record is clear what you're saying there.

To the extent you have an opinion regarding motivations to use Ressemann's collar in the Figure 1 embodiment, those opinions are not based on how Ressemann is using the collar in the Figure 16 embodiment, right?

A. I believe -- correct.

IPR2020-00126, Ex-2239 at 105:7-24;
Paper 106 at 13

Jones Testimony (Jan. 18, 2021)

25 Q. Now, do you agree that the way you propose

1 adding Ressemann's collar to the Figure 1

2 embodiment is different than the way Ressemann,

3 itself, teaches to situate the tab portion of the

4 collar relative to the tube?

5 A. Yes, I do.

IPR2020-00126, Ex-2239 at 105:25-106:5;
Paper 106 at 13

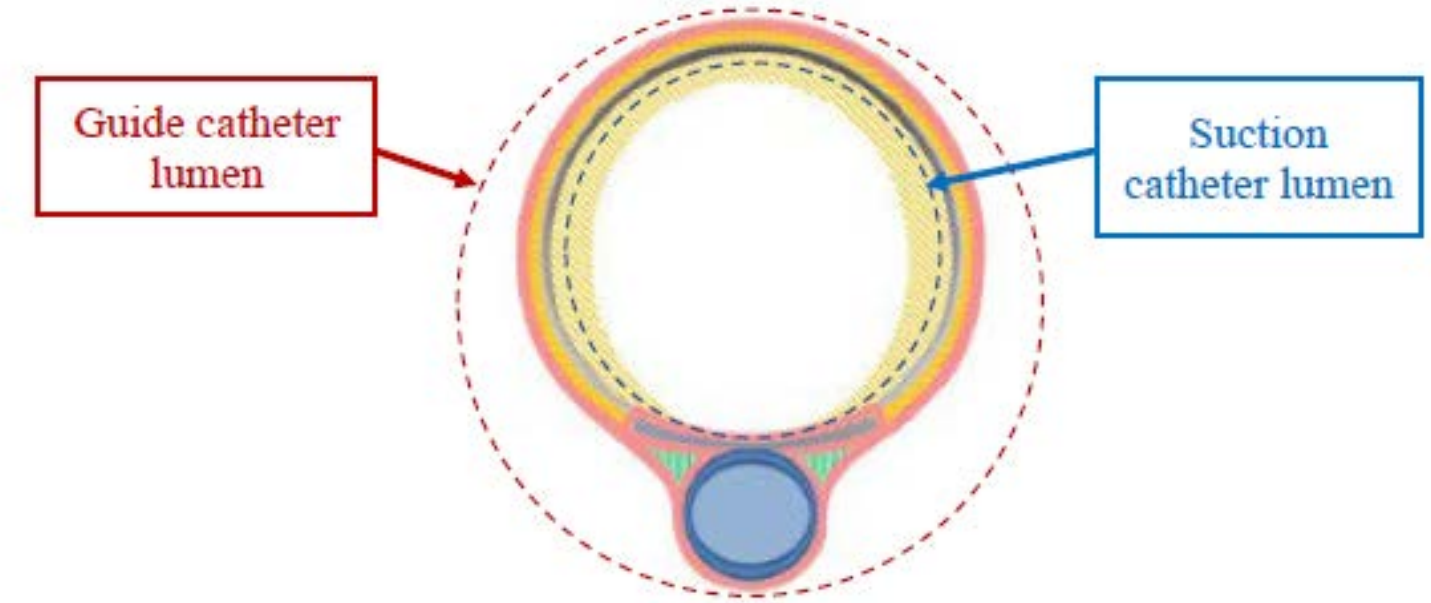
Second Keith Declaration

62. I understand that Dr. Jones agreed that adding Ressemann's collar to Itou's proximal opening would require at least these modifications:

- Removing Itou's collar;
- Extracting Ressemann's collar from inside the structure of Ressemann and adding it to Itou's proximal opening;
- Tapering Itou's pushwire down to less than 0.005 inches;
- Adhering the Itou and Ressemann structures together with adhesive;
- Adding a polymer coating to the assembly; and
- Altering the position of Itou's pushwire so that it is placed below the bottom of Itou's tubular structure.

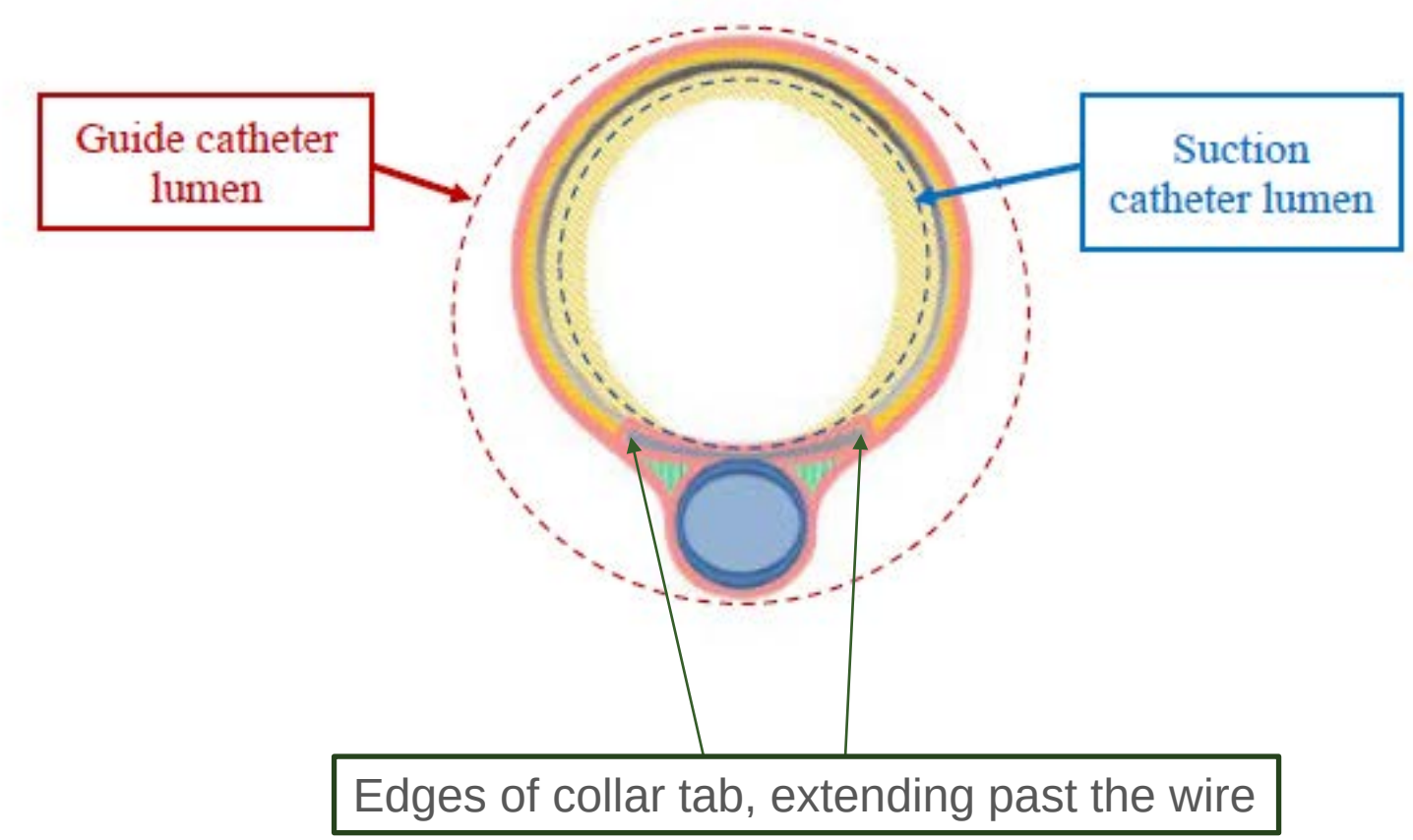
IPR2020-00126, Ex-2243, ¶62 (citing Ex-2241 at 51:23-53:1, 43:21-52:1 (Dr. Jones)); Paper 106 at 13

Itou + Ressemann Device



IPR2020-00126, Ex-2228; Paper 106 at 18

Itou + Ressemann Device



IPR2020-00126, Ex-2228; Paper 106 at 18

Itou + Ressemann Device

Q. Would a person of skill in the art in 2005 be motivated to mount the Ressemann collar on top of a push wire in that way?

A. No, I don't think so.

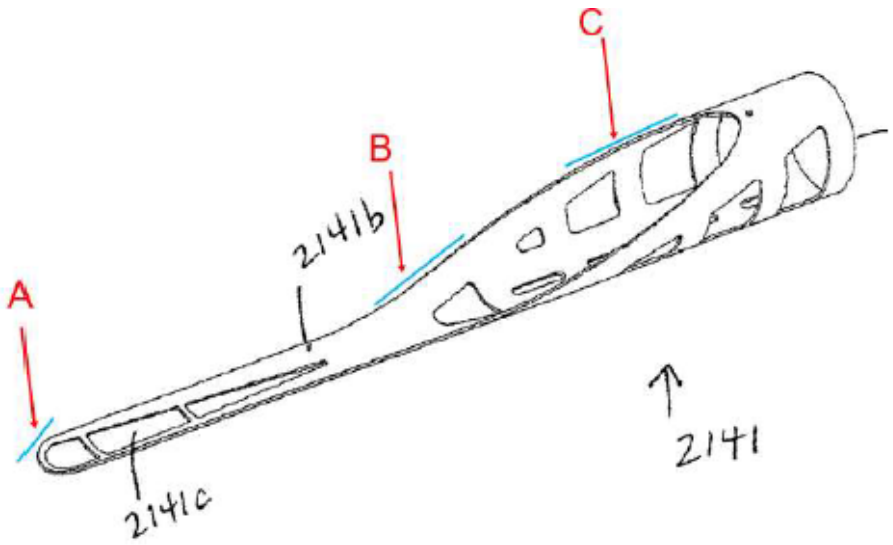
Q. And why not?

A. Well, first off, the way the Ressemann collar is utilized in Ressemann and the way it's taught is that it actually sits below that structure and not above that structure.

And the second reason is, if you did place that above that structure, then I think you've got those -- the sides of those, the tabs sort of projected up into the space of the guide catheter, and I think those are catch points for a stent catheter, say, that you're trying to advance into the distal part of that catheter.

IPR2020-00126, Ex-1922 at 77:22-78:12; Ex-2243, ¶107; Paper 106 at 19.

Itou + Ressemann Device



Petitioner's expert:

"If the collar were placed beneath pushrod wire 25, . . . 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 . . ."

IPR2020-00126, Ex-1807, ¶132; Paper 83 at 16

Brecker Testimony (Jan. 14, 2021)

Q. And you can achieve that design intent just as easily with a single angle as you can with a double angle, correct?

MS. ROBERG-PEREZ: Objection; form.

THE WITNESS: So you can achieve that element of the intent, i.e., increasing the area of entry, but there are other features that I mentioned.

Ex-2238 at 144:22-145:3; Paper 106 at 13-14 (citing Ex-2243, ¶65)

Brecker Testimony (Jan. 19, 2021)

Q. So is it accurate to say that if you wanted to increase the area of entry for Itou, you could simply make the angle shallower, as we talked about earlier?

MS. ROBERG-PEREZ: Objection. Scope.

A. So I've set out in my declaration a number of reasons why a POSITA would want to use the Ressemann collar. If the only thing you wanted to do was increase the area of entry, you could make it more shallow, but that might, in itself, give some other consequences of just making it more shallow.

IPR2020-00126, Ex-2240 at 163:13-22;
Paper 106 at 14

Itou's Pushwire Needs No Reinforcement

- Itou has "a metal tubular portion attached via a rigid weld to a metal pushwire" that itself is 0.017 inches thick. Ex-2243, ¶66; Ex-1007, Table 1 (0.45mm diameter).
- Itou's design is torqueable. Ex-2243, ¶66.
- Replacing Itou's "rigid structures . . . with Ressemann's far more flexible collar and tab structure would be counter to" Itou's purposes. *Id.*

IPR2020-00126, Ex-2243, ¶66; Paper 106 at 14

Kontos + Ressemann: Continued Evolution

Original: Kontos Figure 1 (IPR 2020-00126, Ex-1009, Fig. 1):

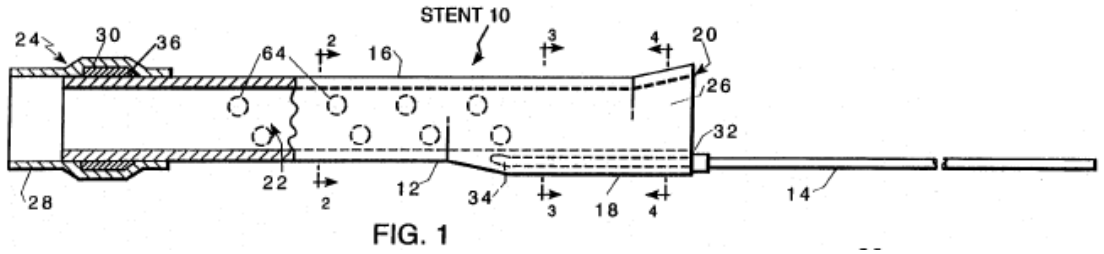
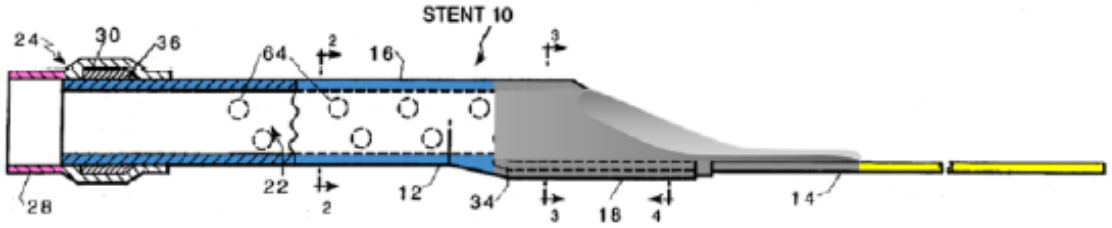
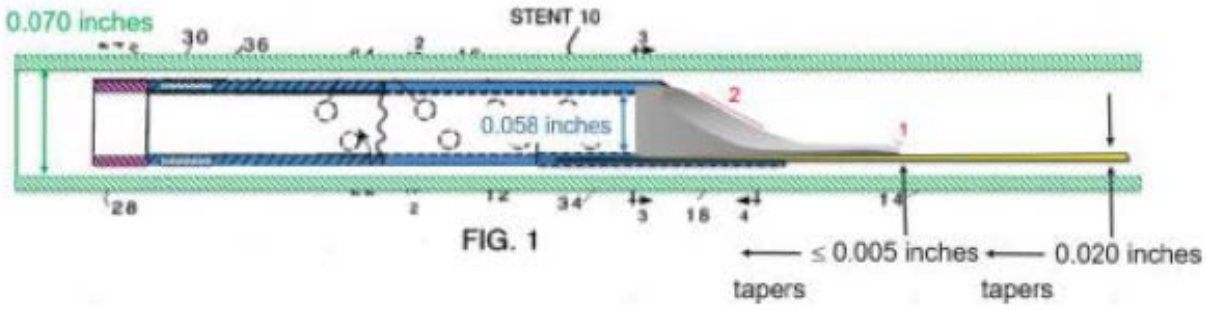


FIG. 1

Version 2: IPR2020-00136, Petition at 29



Version 3: MTA Oppositions (IPR2020-00126, Paper 102 at 30)



Second Keith Declaration

91. Specifically, Dr. Brecker testified that at least ten changes had to be made to Kontos to make Petitioner's new Kontos-Ressemann device:

- Reconfiguring the distal soft tip 28 of the Kontos catheter so that it is flush with and no longer overlaps Kontos's tube 16, Ex-2240, 130:19-131:2;
- Resizing the distal marker band and recessing the marker band into the sidewall of the Kontos device, *id.*, 131:3-6;
- Increasing the inner diameter of Kontos's tube 16 so that its new *inner* diameter (which is increased from 0.045 inches to 0.058 inches) now is larger than its original *outer* diameter (0.055 inches), *id.*, 135:1-3, 139:20-24;
- Removing Kontos's base portion 18, *id.*, 134:24-25, 94:14-18;
- Removing Kontos's proximal funnel, *id.*, 134:11-15;
- Adding Ressemann's support collar 2141 to Kontos's proximal opening, *id.*, 134:21-23, 136:16-18;
- Securing Ressemann's support collar tab 2141b on top of Kontos's pushwire, *id.*, 148:5-9;
- Tapering Kontos's pushwire down to a thickness of 0.005 inches or less, *id.*, 136:4-6;
- Covering the holes or "windows" in Ressemann's collar 2141, *id.*, 137:5-13, 39:1-18; and
- Reinforcing Kontos's tube 16 with braiding, *id.*, 156:4-6.

IPR2020-00126, Ex-2243, ¶91 (citing Dr. Brecker); Paper 106 at 22

Jones Testimony (Jan. 20, 2021)

A. Again, I don't know what Dr. Hillstead was asked to do. I'm -- I was asked to come up with all things that could be done to produce basically what is shown in paragraph 179. I'm not privy to what Dr. Hillstead's work instructions were.

179. By adding Ressemann's support collar 2141 to Kontos, the resulting combination would result in, a segment defining a side opening positioned proximal to the flexible tip portion, as demonstrated in the modified figure below.

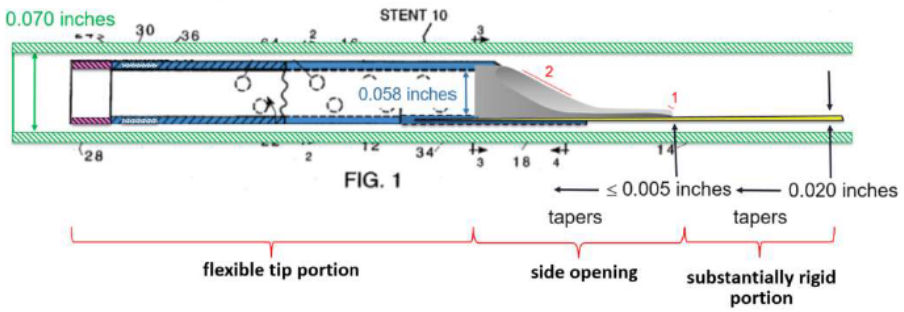


FIG. 1

Ex. 1009, Fig. 1 (modified by Petitioner).

IPR2020-00126, Ex-2241, 141:18-21; Ex-1900, ¶ 179 (Brecker); Paper 106 at 22-23

Brecker Testimony (Jan. 19, 2021)

Q. So it's spaced apart from the wall of the guide catheter by at least the thickness of the wire underneath the tab portion of the collar, right?

A. Yes.

Q. And it's also spaced away by the wall thickness of the tube, right?

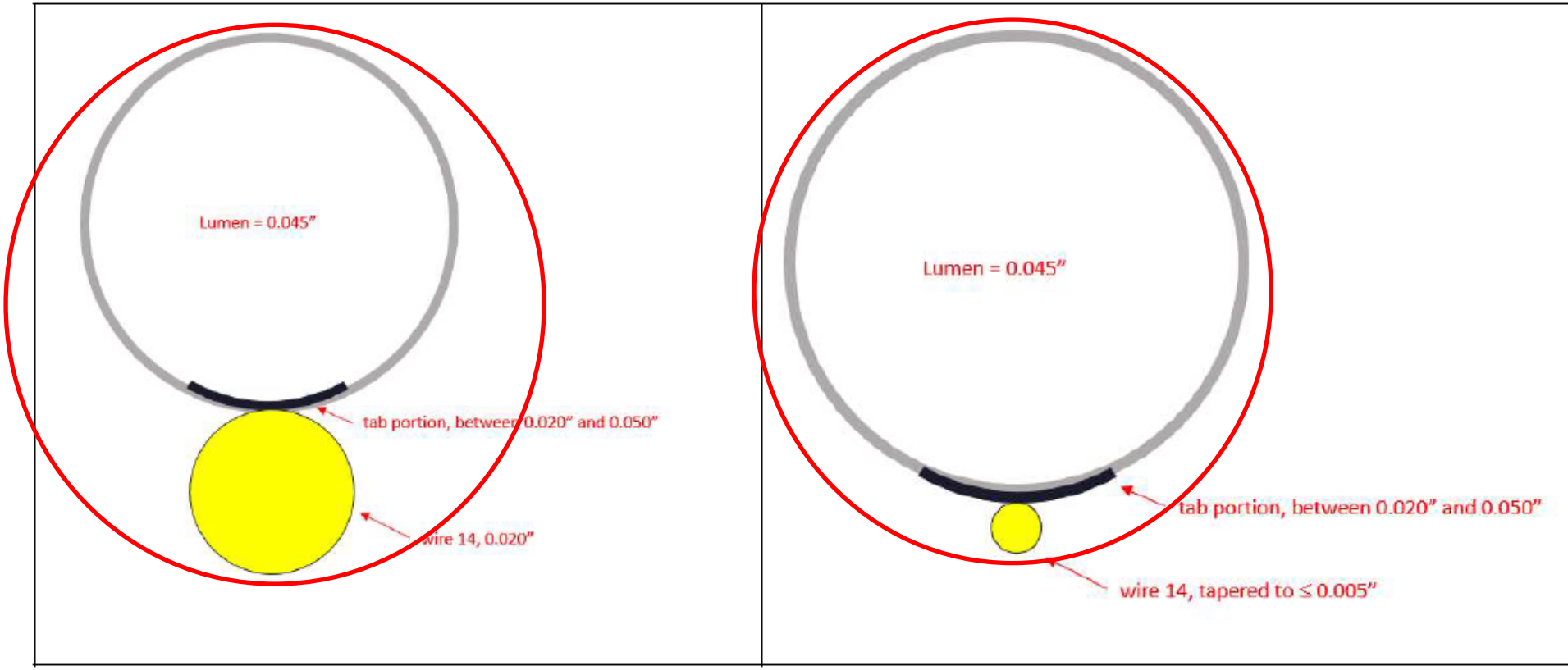
A. Yes.

Q. And it's spaced away -- if the Kontos tube is at the top of the guide catheter, then it's spaced away also by the gap between the outer diameter of the tube and the inner diameter of the guide catheter, correct?

A. Yes.

IPR2020-00126, Ex-2240 at 148:5-18;
Paper 106 at 19

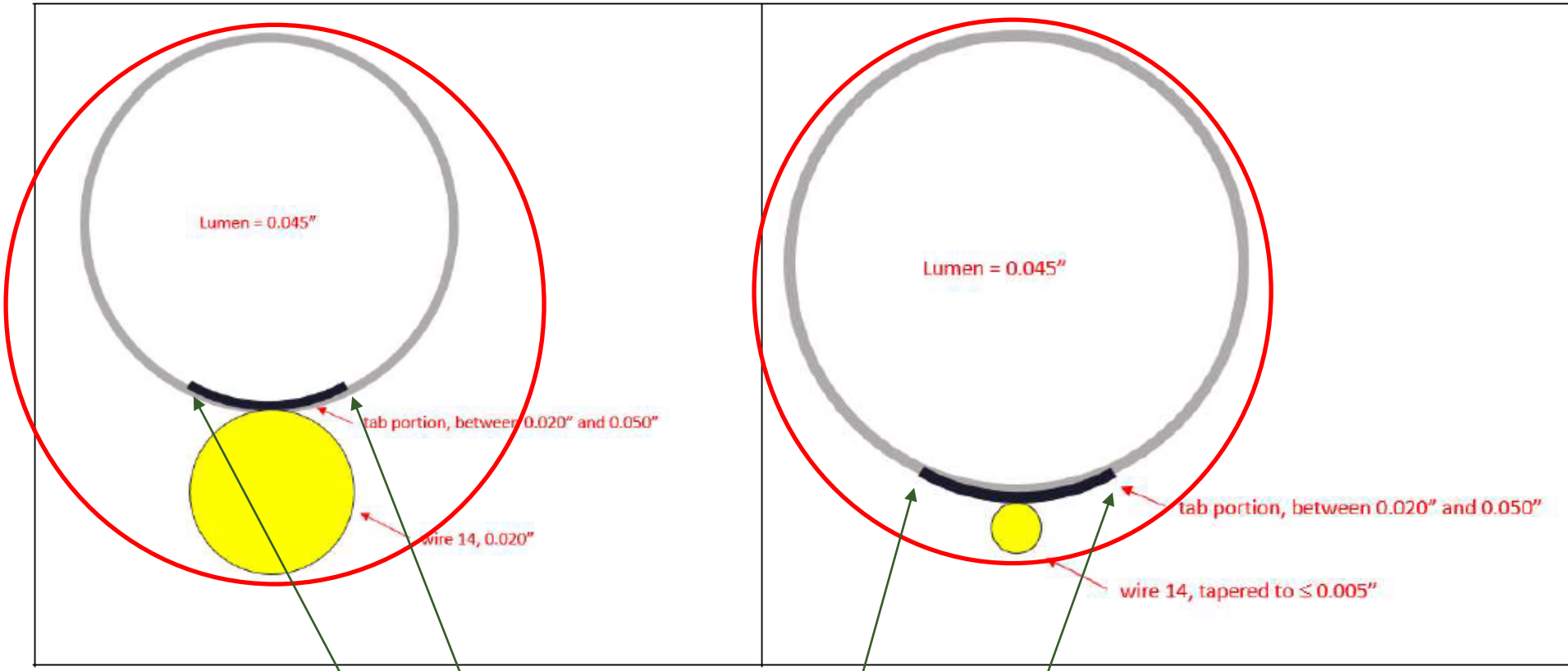
Jones Declaration



DEMONSTRATIVE EXHIBIT-NOT EVIDENCE

Ex-1807, ¶189 (Red Circles for Guide Catheter added)

Jones Declaration



Edges of collar tab, extending past the wire

Ex-1807, ¶189 (Red circles for guide catheter inner wall added)

Jones Testimony (Jan. 20, 2021)

Q. Okay. You haven't identified any prior art where a wire is tapered down to .005 inches, right?

A. I believe that's correct. I have not identified prior art with the wire tapered below .005 inches.

IPR2020-00126, Ex-2241, 49:2-6;
Paper 106 at 23

Brecker Testimony (Jan. 19, 2021)

Q. Is it fair to say that the stronger the push wire, the more ability the device has to be advanced across a tougher lesion?

MS. ROBERG-PEREZ: Objection. Form. Scope.

A. No. I haven't -- I honestly have not considered that aspect of the design of Kontos. It needs to be rigid enough for it to be advanced -- to be able to advance it.

So the push wire can't be flimsy. But, you know, there are aspects to the body of Kontos that you would be -- and the push wire is only one of the whole design features.

IPR2020-00126, Ex-2240, 85:6-15;
Paper 106 at 23

Kataishi's Distal Tip Has a Guidewire Lumen

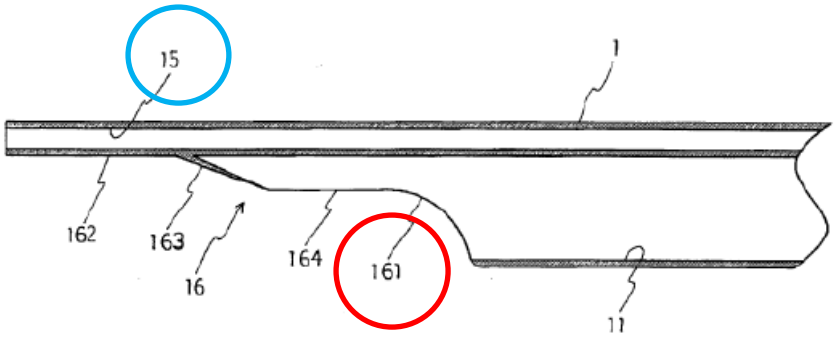


Fig. 2

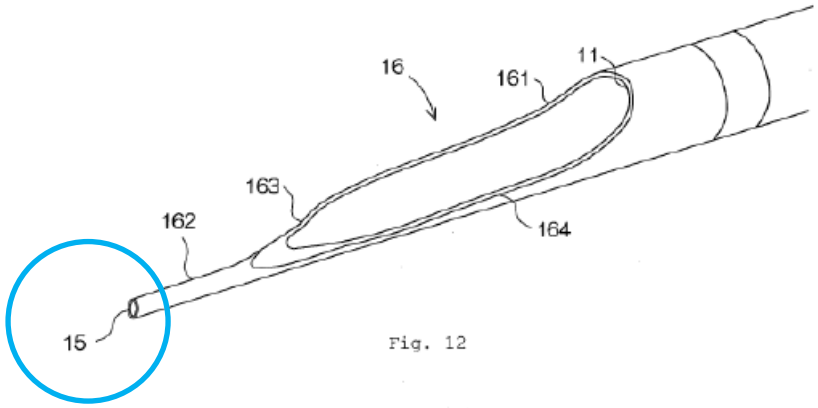


Fig. 12

IPR2020-00126, Ex-1025, Figs. 2, 12; Paper 96 at 8; Paper 106 at 15

Kataishi Lacks a Complex Side Opening

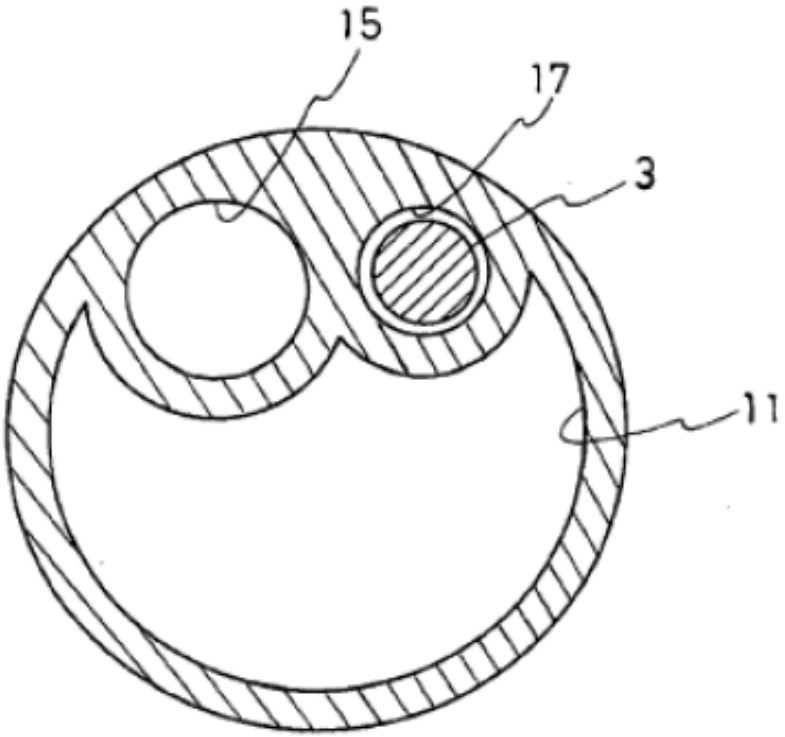
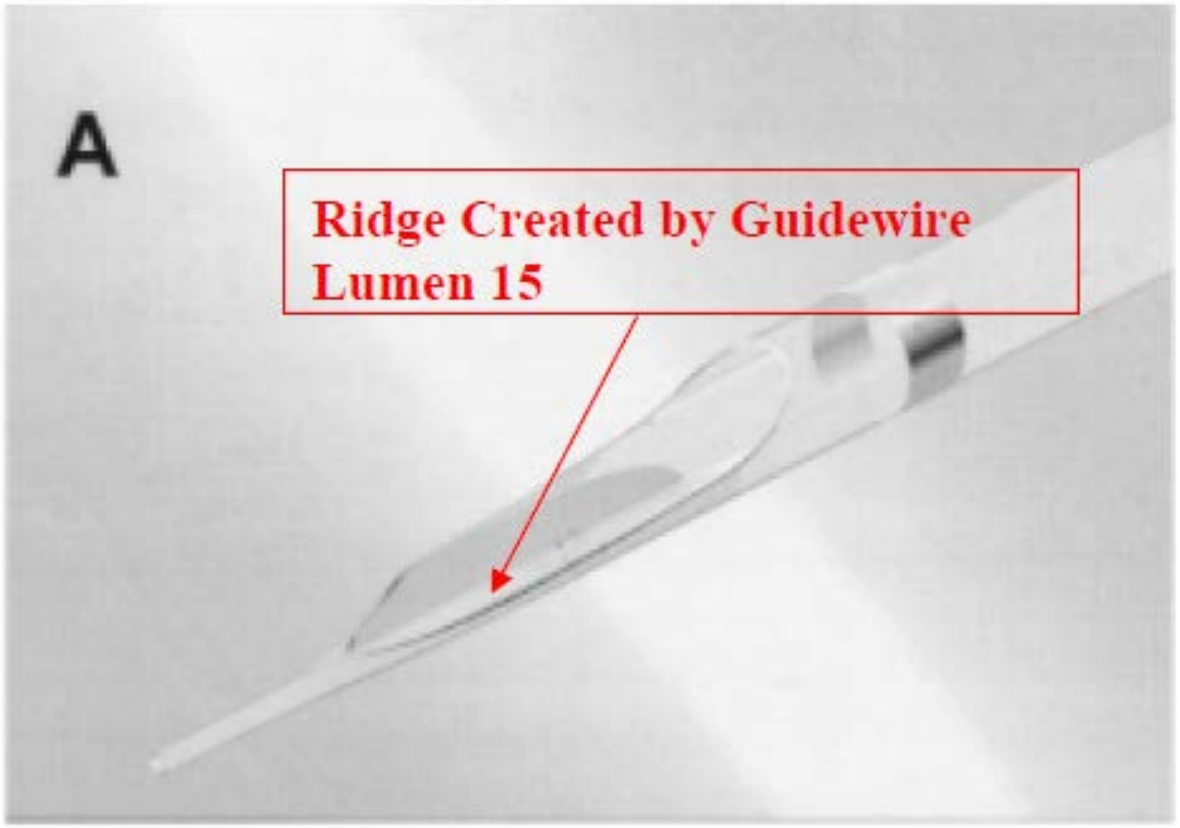


Fig. 4

IPR2020-00126, Ex-1025, Fig. 4; Paper 96 at 8

Sakurada Fig. A



IPR2020-00126, Ex-1055, 300 (Fig. 1A) (annotation added); Ex-2243, ¶69; Paper 106 at 15

Kataishi

shape (including the shape of an asymptote) in the angled direction as shown in **FIG. 2**. The concave portion **161** is a means for improving flexibility of the catheter distal end and enabling the cut surface **16** to adsorb an expanded atheroma AT by suction, when the atheroma AT as shown in **FIG. 10** is covered with the distal end opening **12** and is aspirated with a suction pump (**6** in **FIG. 7**). This remarkably enhances suction (the suction pressure becomes substantially 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 be provided entirely on the proximal end side of the cut surface **16** (i.e., without cut surface **163** and ledge surface **164**) or partially on the proximal end side (as shown, for example, in **FIG. 2**), considering the shape of atheroma.

IPR2020-00126, Ex-1025, ¶27;
Paper 106 at 16-17

Brecker Testimony (Jan. 19, 2021)

Q. Is it fair to say that Kataishi teaches enhancing suction by reducing the gap to better cover the atheroma with the distal end of the suction catheter?

A. Yeah. It teaches that this design is able to advance more effectively to and over the lesion, minimizing the gap between the catheter, the entrance, and the lesion, and then suction can be applied.

IPR2020-00126, Ex-2240 at 103:2-6;
Paper 106 at 16

Brecker Testimony (Jan. 19, 2021)

Q. And to be clear: Do you understand that to mean, then, that the improved flexibility helps with the suction?

A. Well, not directly. Improved flexibility means the catheter can get and cover the lesion. What enhances suction is one step away from that, which is the opening is directly over the catheter and -- sorry, directly over the atheroma and covering it. So it's penetrated into it.

IPR2020-00126, Ex-2240 at 105:24-106:7;
Paper 106 at 17

Kataishi's Flexibility Teaches Away

131. ***Fifth***, Kataishi teaches away from using its distal tip structure on the proximal end of a guide extension catheter. Kataishi's distal tip is intentionally designed to be highly flexible, which allows the catheter to get to and cover the lesion so that suction is enhanced. Ex-1025, Abstract, ¶[0027]. Dr. Brecker agrees. Ex-2240, 105:24-106:7. While increased flexibility at the distal end provides increased suction, flexibility at the proximal opening of the catheter would increase the risk of kinking. Ex-2138 (IPR2020-00136), ¶217.

IPR2020-00126, Ex-2243, ¶131;
Paper 106 at 25

Kataishi Lacks a Complex Side Opening

- Petitioner seemingly concedes that Kataishi has no concave track: "PO's argument that Kataishi does not disclose a concave track because of Kataishi's guidewire lumen is irrelevant—Itou's primary embodiment does not have a guidewire lumen." (IPR2020-00126, Paper 114 at 5.)

- Kataishi uses "concave" to refer to the curve in the *side* profile: "The **concave portion 161** is a means **for improving flexibility** of the catheter distal end . . . ." (IPR2020-00126, Ex-1025, ¶27; Paper 106 at 16-17.)

“Coaxial,” Size, and “French Size” Limitations

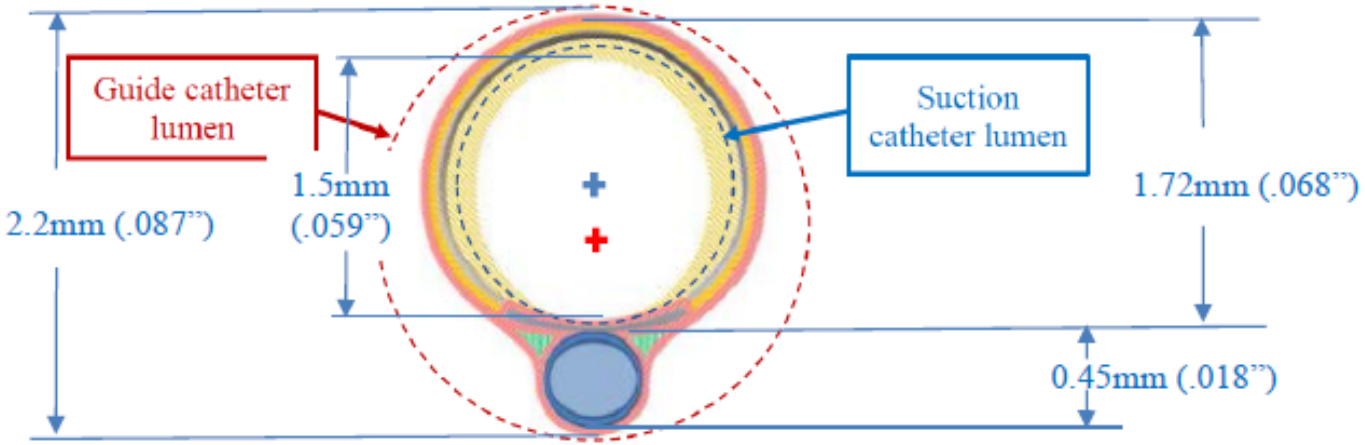
“Coaxial”: All substitute claims of ’032, ’380, ’760, and ’379 patents and claims 63-65 of the ’776 patent

“.056” Tubular Portion for 6 French Guide Catheter: Claims 23 and 25 of the ’032 patent; all substitute claims of the ’380 patent; claim 58 of the ’760 patent; claims 63-65 of the ’776 patent; and claims 46-48 of the ’379 patent

“One French Size”: Claims 54-57 of the ’760 patent and claims 49-51 of the ’379 patent

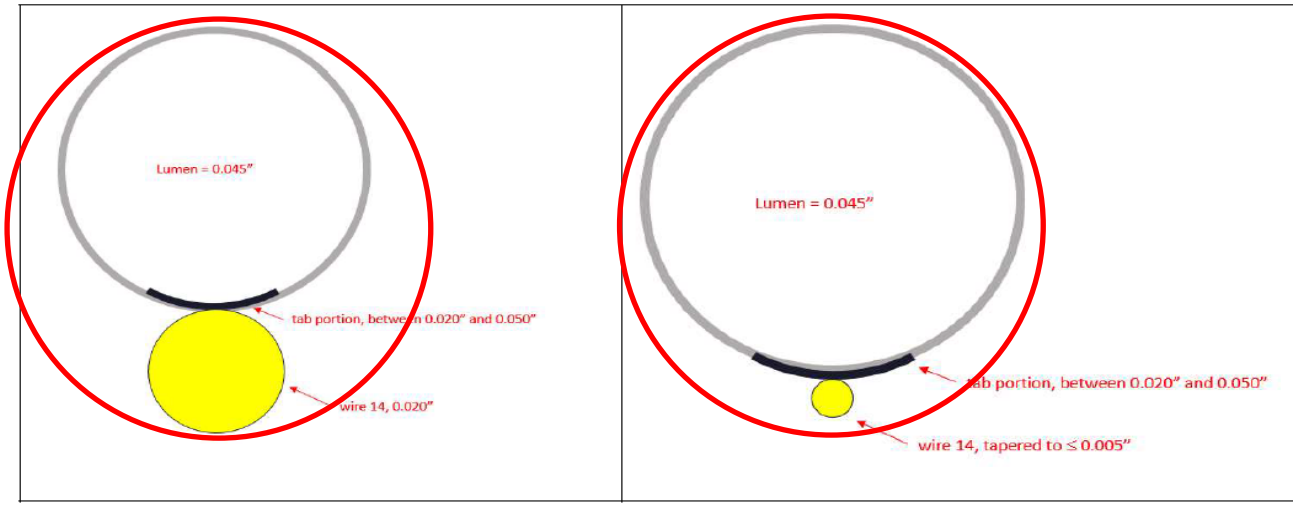
Itou/Kontos + Ressemann's collar

Itou:



IPR2020-00126, Ex-2228 (dimensions from Ex-2239, 170:12-173:17); Paper 106 at 18

Kontos:



Ex-1807, ¶189 (Red circles for guide catheter inner wall added)

Petitioner's Tapered Pushwire

- Neither Mr. Jones nor Mr. Keith is aware of any prior device where the pushwire has been tapered to less than 0.005 inches, (IPR2020-00126, Ex-2241, 49:2-6; Ex-2243, ¶105; Paper 106 at 23)
- "[S]uch a small taper could make this critical portion of the pushwire too flimsy to advance the support catheter," (IPR2020-00126, Ex-2243, ¶105; Paper 106 at 23-24)
- Ressemann's collar tab's has "windows" that "minimize the amount of metal in the tab (particularly at the tab's proximal end)," *id.*
- While Petitioner "proposes this extreme tapering of the pushwire, [it] also would increase the diameter and rigidity of Kontos's tube," *id.*

Takahashi, Ex-1010

- The Takahashi authors were aware of rapid exchange devices
  - Takahashi discloses that “a rapid-exchange balloon catheter (Ryujin 2.5 X 20 mm; Terumo) was pushed into the artery model,” IPR2020-00126, Ex-1010 at 5-6; Paper 96 at 8
  - One of the Takahashi authors was Takenari Itoh of Terumo Corporation, likely the same Takenari Itou of the Itou reference, IPR2020-00126, Ex-1007; Paper 96 at 8

- Yet none of the Takahashi authors came up with Teleflex’s invention

- Creating a rapid exchange device with a suitable side opening and connection was an inventive step not met by Petitioner’s modifications to Itou or Kontos