

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRONT LINE MEDICAL TECHNOLOGIES, INC.
Petitioner

v.

PRYTIME MEDICAL DEVICES, INC.
Patent Owner

Patent No. 11,857,737

Post Grant Review No. PGR2024-00028

DECLARATION OF DR. SCOTT A. RESNICK, M.D.
IN SUPPORT OF PETITION FOR POST GRANT REVIEW OF
U.S. PATENT NO. 11,857,737

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001.

Dated: May 6, 2024

By: Scott Resnick, MD, FSIR

Scott Resnick, MD, FSIR

LIST OF EXHIBITS

Ex-1001	U.S. Patent No. 11,857,737 (“the ’737 Patent”)
Ex-1002	Prosecution history of U.S. Patent No. 11,857,737
Ex-1004	U.S. Patent Number 3,467,101 (“Fogarty”)
Ex-1005	S. Chengod, MD. et al., <i>Selective Left Bronchial Intubation and Left-Lung Isolation in Infants and Toddlers: Analysis of a New Technique</i> , Department of Anesthesiology and Intensive Care, Division of Cardiothoracic and Vascular Anesthesiology and Intensive Care, Amrita Institute of Medical Sciences and Research Center, Kerala, India. (2005) (“Chengod”)
Ex-1006	Mark A. Saab, <i>Applications of High-Pressure Balloons in the Medical Device Industry</i> , Medical Device & Diagnostic Industry Magazine (September 2000) (“Saab”)
Ex-1007	U.S. Patent No. 10,004,622 (“Sanati”)
Ex-1008	Dr. David H. Deaton, <i>Image-Guided Thrombectomy in Vascular Surgery</i> , , Endovascular Today (July 2005) (“Deaton”)
Ex-1009	U.S. Patent Number 9,131,874 (“Eliason”)
Ex-1010	Daniel J. Scott, et al., <i>A novel fluoroscopy-free, resuscitative endovascular aortic balloon occlusion system in a model of hemorrhagic shock</i> , The Journal of Trauma and Acute Care Surgery, Vol. 75, Issue 1 (July 2013) (“Scott”)
Ex-1011	U.S. Publication Number 2015/0133892 (“Joe”)
Ex-1012	International Application Number PCT/US2011/033368 (“Eliason PCT Application”)
Ex-1013	U.S. Patent Pub. No. 2013/0060316 (“Sanati Publication”)
Ex-1014	X. Gu et al., <i>A New Technique for Sizing of Atrial Septal Defects</i> , Catheterization and Cardiovascular Interventions (1999) (“Gu”)
Ex-1015	Handbook of Endovascular Peripheral Interventions (C.D. Owens &

	Y. Yeghiazarians eds., Springer 2012)
Ex-1016	PCT publication number WO 2014/036530 to Bagaoisan ("Bagaoisan")
Ex-1017	U.S. Patent No. 8,088,121 to Nishide ("Nishide")
Ex-1018	U.S. Patent No. 5,607,394 to Anderson ("Anderson")
Ex-1019	U.S. Patent No. 5,779,731 to Leavitt ("Leavitt")
Ex-1020	U.S. Patent Publication No. 2008/0188803 by Jang ("Jang")
Ex-1021	John M. Mathis, et. al, <i>Physical Characteristics of Balloon Catheter Systems Used in Temporary Cerebral Artery Occlusion</i> , American Society of Neuroradiology (November 1994) ("Mathis")
Ex-1022	U.S. Patent No. 4,846,174 to Willard et al. ("Willard")
Ex-1023	Patent Owner's Infringement Claim Charts filed in <i>Prytime Medical Devs., Inc. v. Front Line Med. Techs., Inc.</i> , Case No. 6:24-cv-00001, Dkt. No. 1-3 (W.D. Tex. Jan. 2, 2004)
Ex-1024	E.P. Gerstenfeld & J. Michele, <i>Pulmonary vein isolation using a compliant endoscopic laser balloon ablation system in a swine model</i> , Springer Science+Business Media, LLC (2010) ("Gerstenfeld")
Ex-1025	U.S. Patent No. 5,087,246 to Smith ("Smith")

LIST OF APPENDICES

Appendix A	Curriculum Vitae of Scott Resnick, MD, FSIR
Appendix B	Comparison of Sanati and Sanati Publication
Appendix C	Comparison of Eliason and Eliason PCT Application
Appendix D	List of Materials Considered

I. Introduction

1. I make this Declaration in support of the above-captioned Petition for Post Grant Review (PGR) of U.S. Patent No. 11,857,737 (the '737 Patent). I have reviewed the '737 Patent to assess its patentability. The following is my report regarding my assessment.

2. I have been retained by Forsgren Fisher McCalmont DeMarea Tysver LLC on behalf of the Petitioner, Front Line Medical Technologies, Inc.

3. I am being compensated at a rate of \$750 per hour for my work in this proceeding. My compensation is in no way contingent on the nature of my findings, the presentation of my findings in testimony, or the outcome of this proceeding. I have no other interest in this proceeding.

4. I have been asked to provide my technical review, analysis, insights, and opinions regarding the prior art references that form the basis for the grounds of rejection set forth in the PGR petition.

5. Appendix I is a list of documents and other information that I have considered in forming my opinions. Should additional information become available to me that affects the conclusions or opinions herein, I may supplement or amend this declaration as appropriate.

6. All of my opinions stated in this declaration are based on my own personal knowledge and professional judgment. In forming my opinions, I have

relied on my knowledge and experience in the area of Vascular and Interventional Radiology.

II. Professional Qualifications

7. I am a physician who is dual board certified in both Diagnostic Radiology and in Vascular and Interventional Radiology.

8. Following completion of undergraduate education at University of Michigan with highest honors, I completed a medical degree at Northwestern University Feinberg School of Medicine and was awarded AOA designation, signifying highest honors. I subsequently completed a transitional medical/surgical internship, undertook a Diagnostic Radiology residency at Northwestern University where I was selected as Chief Resident, and followed with a fellowship in Vascular and Interventional Radiology, also at Northwestern University.

9. During my initial post-graduate years, I was employed in a vascular-oriented combined Interventional Cardiology/Interventional Radiology practice. I returned to Northwestern University in 2000. I am currently a Full Professor in both the Departments of Radiology (Interventional) and Surgery (Vascular) at Northwestern University, where I have worked for the past 24 years.

10. During this time, I have served on various vascular intervention quality care and education committees at both the local and national level. I served as the Director of Interventional Radiology fellowship training at Northwestern University for many years as well as Vice President and subsequently President of

the national Interventional Radiology Program Director society. I have served as an examiner for both Diagnostic Radiology and Interventional Radiology national certification boards many times and I act as a reviewer for numerous national and international medical journals.

11. Throughout my career I have maintained an academic and clinical focus in vascular disease as evidenced by my current Dual Appointment in both the Interventional Radiology and Vascular Surgical divisions. As such, I have extensive experience performing vascular-specific interventional procedures. These include procedures such as angiography, angioplasty, stent placement, atherectomy, thrombectomy, thrombolysis and others.

12. In this capacity, I have broad experience utilizing various interventional tools including catheters, balloons, stents, and other endovascular devices. These devices utilize a variety of valves, hubs, markers, lumen, wires, balloons, syringes, inflation devices and other detailed components regularly found in minimally invasive medical systems.

13. More specifically, I have extensive experience using both off-the-shelf and purpose-built devices for vascular occlusion in a variety of situations including balloon occlusion devices in patient temporization / stabilization for hemorrhage prior to definitive therapy administration. This experience includes Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) devices in the setting of both traumatic and non-traumatic massive hemorrhage.

14. I have maintained an active Illinois State medical license and a national Controlled Substance Certification throughout my medical career.

15. My detailed resume is attached to this Declaration as Appendix II.

III. Person Having Ordinary Skill in the Art

16. I have been advised that whether a claim of a patent is obvious is controlled by the Patent Act, 35 U.S.C. § 103, which states in part, “A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.”

17. I understand that obviousness is to be judged by a person having ordinary skill in the art (or “PHOSITA”) in the context of the ’737 Patent at the time the earliest application that led to the ’737 Patent was filed, i.e., March 19, 2015. I understand that there are several factors relevant to determining the level of ordinary skill in the art. These factors include the educational level of workers in the field, the sophistication of the technology, and the nature of common problems and solutions within the industry at the time of the alleged invention.

18. Given these factors, and upon my review of the ’737 Patent (Ex-1001) and its prosecution history (Ex-1002), a person having ordinary skill in the

art must possess a medical degree and sufficient experience with interventional procedures, specifically with endovascular procedures including extensive use of both angioplasty balloons and occlusion devices. A busy interventionalist could conceivably acquire an adequate level of experience having a minimum of ten years of post-graduate experience in fields such as interventional radiology, vascular surgery, or interventional cardiology, or have other extensive experience as an endovascular interventionist. Such a person would be familiar with various occlusion balloon catheters and their use in performing vascular occlusion procedures throughout the vascular system, including occlusion procedures within the aorta.

19. I understand the capabilities of a person of ordinary skill in the relevant field, and believe I had the capabilities of at least a PHOSITA at the relevant time. I have worked with many such persons over the course of my career. I undertook Interventional Radiology training at a busy major medical institution where various endovascular balloon technologies were in active use beginning as early as 1978. I received extensive training in the use of these balloon technologies during both resident and fellowship years. I have subsequently trained hundreds of residents and well over 100 Interventional Radiology fellows in the use of these balloon technologies. I have served as an examiner for the Interventional Radiology board certification exam for more than a decade and have examined hundreds of prospective examinees in vascular interventions. I served as the President of the

Interventional Radiology Training Program Directors national society. My opinion on the level of ordinary skill in the art is based on my experience and my observations while training others in the use of balloon technologies at the relevant time, understanding the capabilities needed to understand the technology and procedures used in vascular intervention and the sophistication of the technology at that time.

IV. Legal Standards for Obviousness, and Written Description

20. I have been advised and understand that a patent claim can be considered to have been obvious to a person of ordinary skill in the art at the time the application was filed. This means that, even if all of the requirements of a claim are not found in a single prior art reference, the claim is not patentable if the differences between the subject matter in the prior art and the subject matter in the claim would have been obvious to a person of ordinary skill in the art at the time the application was filed.

21. I have been advised and understand that a determination of whether a claim would have been obvious should be based upon several factors, including, among others: (1) the level of ordinary skill in the art at the time the application was filed; (2) the scope and content of the prior art; and (3) what differences, if any, existed between the claimed invention and the prior art.

22. I have been informed and understand that the teachings of two or more references may be combined in the same way as disclosed in the claims, if

such a combination would have been obvious to one having ordinary skill in the art.

In determining whether a combination based on either a single reference or multiple references would have been obvious, it is appropriate to consider, among other factors:

- whether the teachings of the prior art references disclose known concepts combined in familiar ways, which, when combined, would yield predictable results;
- whether a person of ordinary skill in the art could implement a predictable variation, and would see the benefit of doing so;
- whether the claimed elements represent one of a limited number of known design choices, and would have a reasonable expectation of success by those skilled in the art;
- whether a person of ordinary skill would have recognized a reason to combine known elements in the manner described in the claim;
- whether there is some teaching or suggestion in the prior art to make the modification or combination of elements claimed in the patent; and
- whether the claim applies a known technique that had been used to improve a similar device or method in a similar way.

23. I am advised and understand that a motivation to combine prior art references may be found explicitly or implicitly in market forces; design incentives; the interrelated teachings of multiple patents; any need or problem known in the field of endeavor at the time of invention and addressed by the patent; and the background knowledge, creativity, and common sense of the person of ordinary skill.

24. I understand that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the patent being considered.

V. Claim Construction

25. I have been advised and understand that claim construction is a matter of law and that the final claim construction will ultimately be determined by the Patent Trial and Appeal Board. For the purposes of my analysis in this proceeding and with respect to the prior art, I have been advised and understand that a claim of a patent, or a claim proposed in a motion to amend, is construed by the Patent Trial and Appeal Board in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.

26. I have been advised and understand that the patentee can serve as their own lexicographer. As such, if a claim term is provided with a specific

definition in the specification, I should use a claim construction of that claim term in light of the particular definition provided by the patentee.

27. I have reviewed the '737 Patent and its file history and considered each of the documents cited herein, in light of general knowledge in the art. In formulating my opinions, I relied upon my experience in the relevant art and considered the viewpoint of a PHOSITA as of March 19, 2015, the priority date of the '737 Patent.

28. My opinions are based on the following claim constructions:

29. "proximal": I understand the '737 Patent expressly defines the term "proximal" and that I should use the express definition given (in bold below):

In the following description, when reference is made to the terms "**proximal**" or "proximally" it is intended to mean **a portion or component of the preferred vascular occlusion catheter system that is oriented away from the body into which the system is or is intended to be placed.**

'737 Patent, 21:52-56 (emphasis added) (Ex-1001).

30. "distal": I understand the '737 Patent expressly defines the term "distal" and that I should use the express definition given (in bold below):

In the following description, ... when reference is made to the terms "**distal**" or "distally" it is intended to mean **a portion or component of the preferred balloon catheter system that is oriented toward the body into which the system is or is intended to be placed.**

'737 Patent, 21:52-60 (emphasis added) (Ex-1001).

31. For all other claim terms, I use their ordinary and customary meaning as understood by a PHOSITA.

VI. Description of the Relevant Field and the Relevant Timeframe

32. Based upon my review of the above materials, I believe that the relevant field for purposes of the '737 Patent is balloon catheters for use in interventional procedures.

33. I have been told to treat the effective filing date of the '737 Patent to be March 19, 2015. I will consider this date as the relevant date for purposes of my analysis, including for evaluating the PHOSITA and the PHOSITA's knowledge. Thus, my references to the "date" or "time" or "timeframe" of the '737 Patent should be understood to refer to March 19, 2015.

VII. General Knowledge of a PHOSITA

A. Occlusion Balloon Catheters

34. At the time of the '737 Patent, balloon catheters, including occlusion balloon catheters, were well known in the medical profession and to the PHOSITA. An occlusion balloon catheter is a balloon device meant to provide body lumen or vessel occlusion, i.e., to block or obstruct a body lumen or vessel. As disclosed in the references cited herein, balloon catheters have been in use for decades and have been used for various procedures including, but not limited to, intravascular and intrabronchial occlusion. Although portions of my declaration discuss balloon catheters in the context of radiology, these portions are merely exemplary and are not intended to restrict the relevant field for purposes of the '737 Patent, which includes all balloon catheters, regardless of their intended use.

35. In radiology, different balloon catheters may be used for different procedures. For example, as opposed to an angioplasty balloon, which is typically semi-compliant or noncompliant in nature, an occlusion balloon is not intended to provide vessel dilation. Thus, occlusion balloons are typically compliant in nature such that the inflated balloon will conform to the vascular channel and fill the space surrounding the balloon, resulting in an occlusive configuration (e.g., blocking the channel so that blood flow is stopped or mostly stopped). This temporary vessel occlusion can have a number of different therapeutic values depending upon the purpose in question. Deflation of the balloon will resolve the occlusive configuration and allow return of blood flow. I was first instructed in the use of balloon catheters for vascular occlusion in 1992 during a medical school rotation through the Interventional Radiology service at Northwestern University. During this rotation I encountered a number of patients with severe bleeding of both traumatic and nontraumatic origins. In these situations, the Interventional Radiology service would on occasion utilize balloon occlusion of major arteries to staunch bleeding prior to definitive therapy. These patients presented with a variety of clinical scenarios, including trauma (gunshot, stabbing, or other penetrating injury, motor vehicle accident, fall from height, iatrogenic vessel disruption, etc.) and nontraumatic (post-partum hemorrhage, placental ingrowth abnormalities, etc.) in origin. In these cases, inflow artery balloon occlusion would routinely be undertaken prior to definitive endovascular or surgical treatment. In

this setting, a variety of devices would be used to obtain vessel occlusion. These would include compliant occlusion balloons or standard (semi-compliant and noncompliant) angioplasty balloons of various size and configuration. While my exposure to and performance of such procedures began in medical school, such experience continued throughout my residency and fellowship interventional training 1993 – 1998, and subsequently continued during my years in active clinical interventional practice (1998 – present)

36. Each of these catheters (i.e., those including compliant occlusion balloons and standard (semi-compliant and noncompliant) angioplasty balloons) included a balloon for occluding blood flow in the vasculature of the patient. The catheters included a lumen through which an inflation fluid would pass to inflate the balloon.

37. I have had personal experience with the Fogarty occlusion balloon catheter prior to 2015. In particular, I have been involved with using the Fogarty occlusion balloon in an artery for the purpose of limiting downstream flow in the setting of acute hemorrhage, beginning in 1992. In the intervening 32 years I have used the Fogarty occlusion balloon on a regular basis for a variety of clinical tasks. In addition to regular use of the Fogarty occlusion balloon in the setting of acute hemorrhage, I have also participated in using the Fogarty catheter by inflating the balloon in an artery for the purpose of controlling embolic material delivery and/or dwell time. I also have been involved where a Fogarty occlusion balloon was

inflated in an artery, vein, or graft for the purpose of vessel occlusion and intraluminal thrombus manipulation. A PHOSITA understands that each of these distinct procedures, wherein vessel occlusion is performed, utilizes a Fogarty device of the size appropriate for the vessel caliber in question. Specifically, smaller diameter (typically 4 French) devices would most often be used for vessel occlusion with intraluminal thrombus manipulation, whereas larger catheters (5 Fr or 6 Fr) would be used for embolic delivery manipulation and/or hemorrhage temporization prior to definitive therapy.

38. I first became familiar with the REBOA-type procedure in approximately 1992. As indicated in the '737 Patent, "REBOA" is an acronym for "Resuscitative Endovascular Balloon Occlusion of the Aorta." The basic REBOA procedure can be used with a variety of different balloon catheters. Prior to the date of the '737 Patent, I had participated in REBOA-type and similar procedures utilizing large diameter balloon angioplasty catheters wherein the balloon diameter approximated that of the aorta. At the time, such procedures were widely known and routinely performed when the appropriate clinical indication presented itself. That said, the acronym moniker of 'REBOA' was not in use at the time and the procedure was simply referred to as aortic balloon occlusion. Furthermore, given that interventionalists routinely performed aortic balloon angioplasty for stenotic atherosclerotic lesions, as early as the late 1970s, and that a potential outcome of such angioplasty was acute balloon-induced aortic rupture, every interventionalist

needed to be familiar with the concept of aortic balloon occlusion. While modern interventionalists have a variety of devices available to rapidly manage such acute situations in the interventional suite (graft-covered stents/aortic stent grafts), earlier interventionalists did not have the luxury of such device availability. Prior to the first US aortic stent graft implantation in 1992, and subsequent first aortic stent graft commercial US approval in 1999, the interventional treatment for angioplasty-induced aortic rupture was immediate aortic balloon occlusion followed by definitive surgical repair. Long before the time of the '737 Patent, from the late 1970s when aortic balloon angioplasty was routinely performed without the potential for covered stent bailout in the setting of balloon-induced aortic rupture, until the late 1990s, when aortic stent grafts became commercially available, every interventionalist performing aortic balloon angioplasty was well aware of these facts and methods.

B. Use of Stainless Steel

39. Care must be taken in the selection of materials that will be used for intravascular catheters. The various available construction materials impart specific performance and reliability characteristics to the device in question. Throughout the history of endovascular devices, a variety of metallurgy has been explored and utilized. This includes stainless steel, nitinol (a nickel-titanium alloy with temperature-determined shape and stiffness memory characteristics), cobalt chromium, titanium, and others. Stainless steel has a long history of use in medical

devices due its strength and corrosion resistance. Device performance characteristics imparted by stainless steel elements are readily manipulable by changing the anatomic configuration of the metal element utilized (diameter, taper, solid configuration, wound configuration etc.). When used in catheter construction, stainless steel imparts substantial strength to the device when compared to similar devices without steel incorporation. Wire windings, incorporated wire elements, and wire stylets are all examples of stainless-steel use in catheter construction. In particular, a PHOSITA at the time of the '737 Patent would be well-aware that a wire stylet for use within a catheter to add longitudinal and rotational stiffness to the catheter could advantageously be constructed of stainless steel.

40. Evidence of this knowledge is found in the literature. For example, in PCT publication number WO 2014/036530 to Bagaoisan (filed 2013, published March 6, 2014), "FIGS. 1A-1B depict plan and cross sectional views of a first exemplary embodiment of a balloon catheter 100." Bagaoisan ¶ [0094] (Ex-1016).

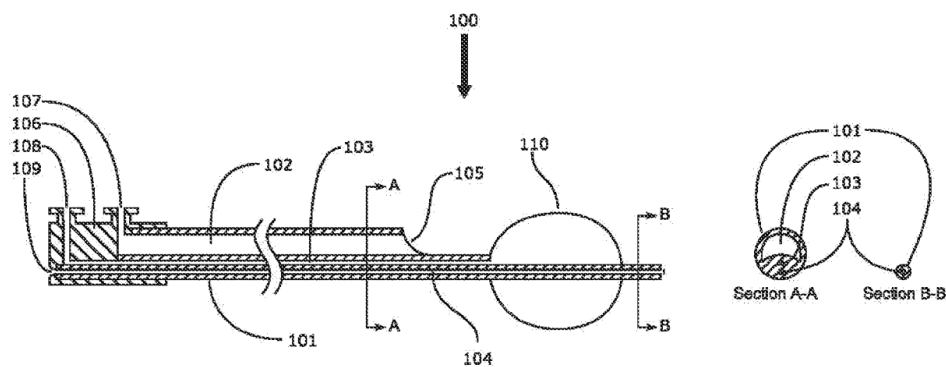


FIGURE 1A

41. Bagaoisan discloses “The elongate member 101 may be fabricated from materials known in the art including, but not limited to Pebax, nylon, urethane, polyester, polyethylene, polyimide, Teflon, Delrin, PEEK, polycarbonate, polypropylene and combinations thereof. **Furthermore, the elongate member 101 may be reinforced with additional materials such as braids, meshes, mandrels, liners, and the like fabricated from materials known in the art including**, but not limited to nitinol, **stainless steel**, titanium, combinations thereof, and the like.” Bagaoisan, ¶ [0095] (emphasis added) (Ex-1016). A PHOSITA understands Bagaoisan’s description of reinforcing elongate member 101 with stainless steel mandrels (i.e., a cylindrical rods or wires) would increase the longitudinal and rotational stiffness of the catheter.

42. Another example is U.S. Patent No. 8,088,121 to Nishide (filed 2005, issued 2012) (Ex-1017). Nishide discloses “a rapid exchange catheter” that takes “a balloon catheter as the primary example.” Nishide, 6:49-59 (Ex-1017). Nishide’s balloon catheter includes a core wire where “[t]he roles of the core wire are to improve the convenience of operation in inserting the catheter into the body along the guide wire, transmit the force applied to the catheter and prevent kink (bend) of the catheter.” Nishide, 10:30-35 (Ex-1017). Nishide discloses that “[t]he material for the core wire ... is preferably stainless steel....” Nishide, 11:48-53 (Ex-1017).

43. Another example is U.S. Patent No. 5,607,394 to Anderson (filed 1995, issued 1997) (Ex-1018). Anderson discloses “a catheter having a stylet that increases columnar strength and axial force transmission (‘pushability’) of the catheter shaft.” Anderson, Abstract (Ex-1018). In the balloon catheter of Figure 1, “The stylet is tapered, as shown in FIG. 2, and is preferably made from metal or metal alloy (e.g., **stainless steel** or Nitinol).” Anderson, 3:8-10 (emphasis added) (Ex-1018).

C. Radiopaque Markers

44. I am personally aware of many occlusion balloon catheters prior to the time of the '737 Patent that utilized radiopaque markers. A person having ordinary skill in the art would have intimate knowledge of the fact that balloon catheters (including occlusion balloon catheters) use radiopaque markers to indicate the location of the two sides of a balloon. In fact, I have never encountered either an occlusion balloon or an angioplasty balloon, either during my training or throughout my career which was intended to be used in a clinical setting that did not contain radiopaque markers to denote the balloon location. At the present time, most such devices include two radiopaque markers, one at the proximal end of the balloon and another at the distal end of the balloon. Given that both occlusion balloons and angioplasty balloons are therapeutic in their function, and that said function can only occur effectively if the occlusion balloon or angioplasty balloon is

positioned at the treatment site in question, it follows that appropriate identification of balloon positioning is critical to an effective therapy in this setting.

45. If an occlusion balloon or an angioplasty balloon failed to have radiopaque markers that allow for ready fluoroscopic visualization of the balloon position, the device would be of lesser value for use with image-guided therapy (which is the essence of interventional therapies). Safe performance of interventional therapies requires operator knowledge of device positioning relative to target lesion location and a device without radiopaque markers allowing for confident device positioning relative to the target lesion therefore would be of lesser interest to interventional practitioners. This is in contrast to other balloon-type catheters wherein exact device positioning is not critical for therapeutic effect, such as a balloon retention urinary drainage catheter, or a balloon retention intestinal tube (gastrostomy, jejunostomy, etc.). Thus, a PHOSITA would expect an angioplasty or occlusion balloon catheter that could be used in a clinical setting to indicate the balloon location with one or more radiopaque markers. Given the significant potential complications that can occur with balloon inflation in an incorrect location (vessel injury, including overt vessel rupture), exact balloon location identification prior to balloon inflation is critical for safe procedure performance. As such, while not every intravascular balloon will be identified with one such marker indicating the proximal end of the balloon and a second such marketer indicating the distal end of the balloon, such a configuration affords the most accurate balloon positioning

during procedure performance and as such nearly every intravascular balloon is configured in such a manner.

46. Evidence of a PHOSITA's knowledge that two radiopaque markers can be used to indicate the location of the two sides of a balloon in a balloon catheter is found in the literature. For example, "Image-Guided Thrombectomy in Vascular Surgery" by Dr. David H. Deaton (2005) discloses a Fogarty balloon catheter that included "[s]tainless steel bushings located at the proximal and distal ends of the balloon [to] enable accurate visualization under fluoroscopy." Deaton, p. 32 (Ex-1008). Radiopacity is a basic tenet of x-rays. Since the initial discovery of x-rays by Wilhelm Rontgen in 1895 it has been well understood that various materials are more or less visible when radiographically imaged. Basic and known radiopacities include air, soft tissue, fat, bone, metal. Accordingly, a PHOSITA understands Deaton's stainless steel bushings are an example of radiopaque markers on either side of the balloon.

47. Another example is U.S. Patent No. 5,779,731 to Leavitt (filed 1996, issued 1998) (Ex-1019). Leavitt discloses "An intravascular balloon catheter has a balloon near the distal end of a catheter shaft and a pair of radiopaque markers positioned within the balloon interior. The distal marker is disposed on an inner shaft member and the proximal marker is disposed at the distal end of an outer shaft member. The markers may be positioned to indicate under fluoroscopy the position and working length of the balloon." Leavitt, Abstract (Ex-1019).

48. Another example is U.S. Patent Publication No. 2008/0188803 by Jang (published 2008) (Ex-1020). Jang's application "relates [] generally to balloon catheters." Jang ¶ [0003] (Ex-1020). Jang's Figure 1 includes "radiopaque markers 124 and 126 [that] can be positioned at a proximal end of the balloon 100 and at a distal end of the balloon 100, respectively." Jang ¶ [0034] (Ex-1020).

D. Asymmetrical Balloon Shapes

49. In general, the balloon types used in balloon catheters can be divided between compliant, low-pressure balloons and semi-compliant or non-compliant high-pressure balloons. Low-pressure balloons are typically used for occlusion, while high-pressure balloons are typically used for angioplasty.

50. Most low-pressure balloons are configured to be inflated symmetrically around the axis of the catheter shaft. However, some low-pressure balloons are designed to be asymmetrical. The use of asymmetrical inflation in low-pressure, compliant balloons has been known for many decades and would be known to a PHOSITA.

51. This was described, for example, in an article by John M. Mathis, et. al, by the American Society of Neuroradiology, entitled "Physical Characteristics of Balloon Catheter Systems Used in Temporary Cerebral Artery Occlusion" and published in November 1994 (Ex-1021). This article compared four different low-pressure balloons used for arterial occlusion, and highlight the difference between symmetrical and asymmetrical balloons:

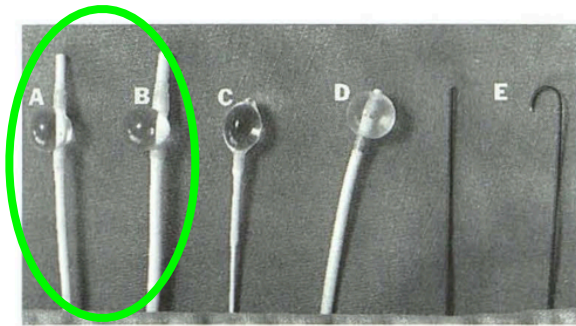


Fig 1. A, 5.0-F Meditech; B, 7.0-F Meditech; C, ITC-NDSB (1509); D, 5.0-F Swan-Ganz; and E, straight and J-tip exchange wires. All balloons are inflated to 5-mm diameter, which approximates working volume for internal carotid occlusion. Note the asymmetric balloon inflation of Meditech systems (A and B) relative to the catheter shaft.

Ex-1021-3.

Note that the green circle above, or other green elements found on the images in this Declaration, have been added for purpose of bringing attention to a relevant aspect of the image or drawing.

52. On the other hand, semi-compliant and non-compliant balloons, are consistently mounted in-line with the catheter shaft as balloon inflation parallel to the long axis of the vessel is critical to a safe angioplasty result.

53. A PHOSITA would be well aware that a compliant, low-pressure balloon used for arterial occlusion could be configured to inflate asymmetrically. Evidence of this knowledge is found in the literature including the Mathis article.

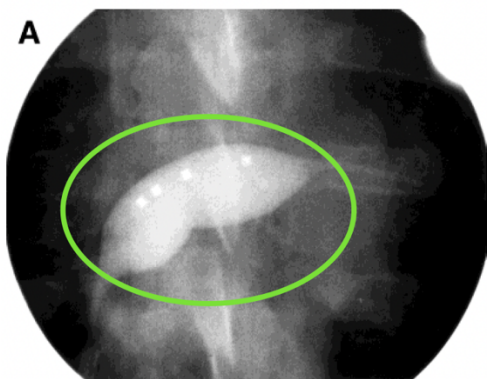
54. Another example is “Applications of High-Pressure Balloons in the Medical Device Industry” by Mark A. Saab, published in *Medical Device & Diagnostic Industry Magazine* on September 1, 2000. Saab confirms the PHOSITA’s knowledge: “an elastomeric [compliant] balloon (right) will often expand

asymmetrically compared with a high-pressure, thin-walled balloon (left).” Saab, 17 & Fig. 6 (below).



Saab, p. 90 (Ex-1006-11).

55. Further, a PHOSITA understands that compliant balloons are often used in occlusion catheters because the balloon can inflate asymmetrically when inside the patient. For example, during occlusion procedures, the balloons are used to completely fill the cavity, which often is asymmetrical in shape, resulting in an inflated balloon that is also asymmetrical. For example, X. Gu et al., *A New Technique for Sizing of Atrial Septal Defects*, CATHETERIZATION AND CARDIOVASCULAR INTERVENTIONS (1999) (“Gu”) confirms the PHOSITA’s knowledge that compliant balloon catheters were often asymmetrical. Gu’s catheter includes a “balloon [that] is compliant and made from a very thin stretchable polyurethane membrane.” Gu, p. 51 (Ex-1014). Figure 6 depicts a “deployed balloon catheter within the surgically created atrial septal defect” (Gu, p. 54 (Ex-1014)) that is asymmetrical:



E. Other Compliant Balloon Shapes

56. A PHOSITA understands that compliant balloons are typically used in occlusion procedures because the compliance allows the balloon to fill (and thus occlude) the cavity into which it is placed. In practice (as discussed above), this results in compliant balloons that, when inflated inside the cavity (e.g., intravascular, intrabronchial, etc.), are asymmetrical because those cavities typically have asymmetrical shapes.

57. Nevertheless, due to the way balloon catheters with compliant balloons are typically manufactured (e.g., since the Fogarty catheter was introduced in the 1960s), these compliant balloons have certain shape characteristics (when inflated outside the patient, i.e., not in regular use) that are well-known to a PHOSITA.

58. The first such well-known shape includes a “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion.” This shape characteristic is found throughout the literature, including:

- U.S. Patent No. 10,004,622 to Sanati et al. (“Sanati”) (Ex-1007): As discussed in detail below for Ground 3, Sanati is prior art to the ’737 Patent and discloses a balloon catheter that contains two different balloons (inner balloon 22a and outer balloon 22b) made of compliant material. Sanati, 7:35-47 & Fig. 1B (Ex-1007). Sanati’s inner balloon 22a has the “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion,” as depicted in annotated Figure 1B:

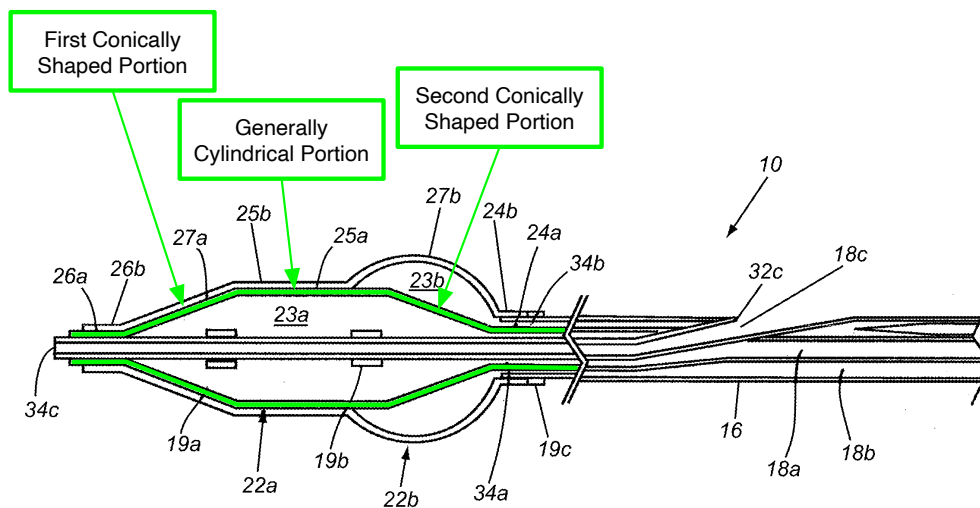


FIG. 1B

- U.S. Patent Number 9,131,874 to Eliason et al. (“Eliason”) (Ex-1009): As discussed in detail below for Ground 5, Eliason is prior art to the ’737 Patent and discloses a balloon catheter with a balloon made of a compliant material. Eliason, 4:54-61 & Fig. 10 (Ex-1009). Eliason’s balloon 14 has the “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion,” as depicted in annotated Figure 10:

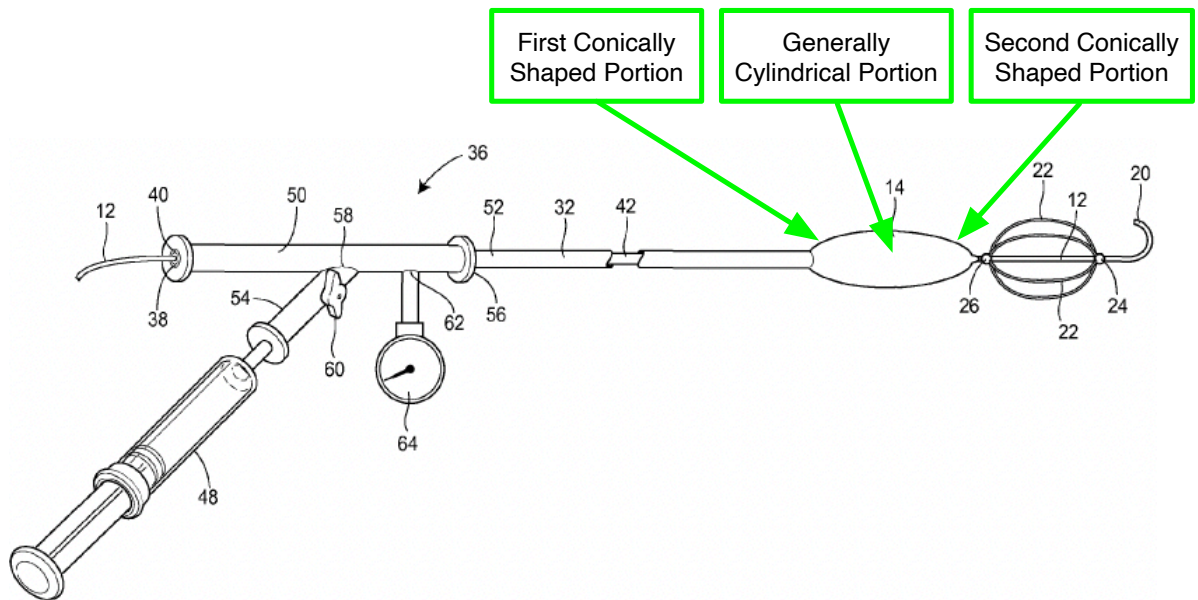
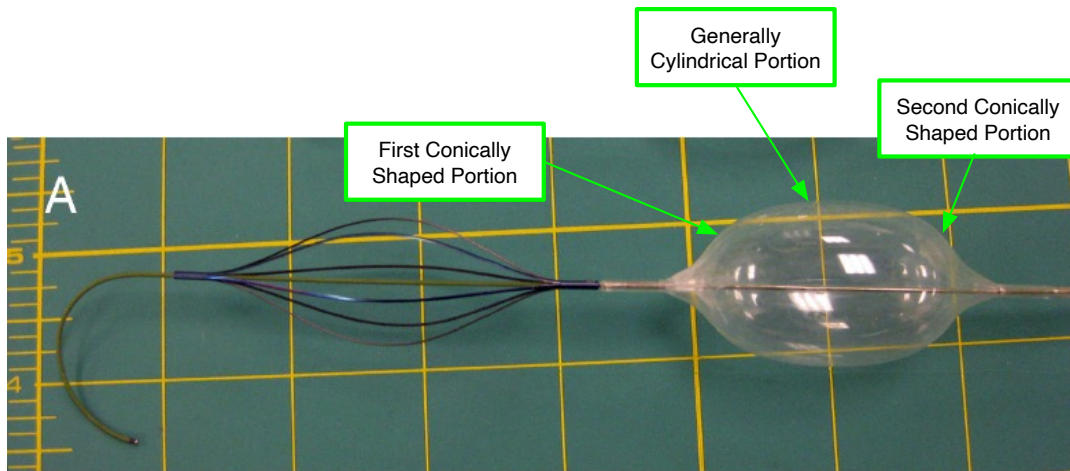
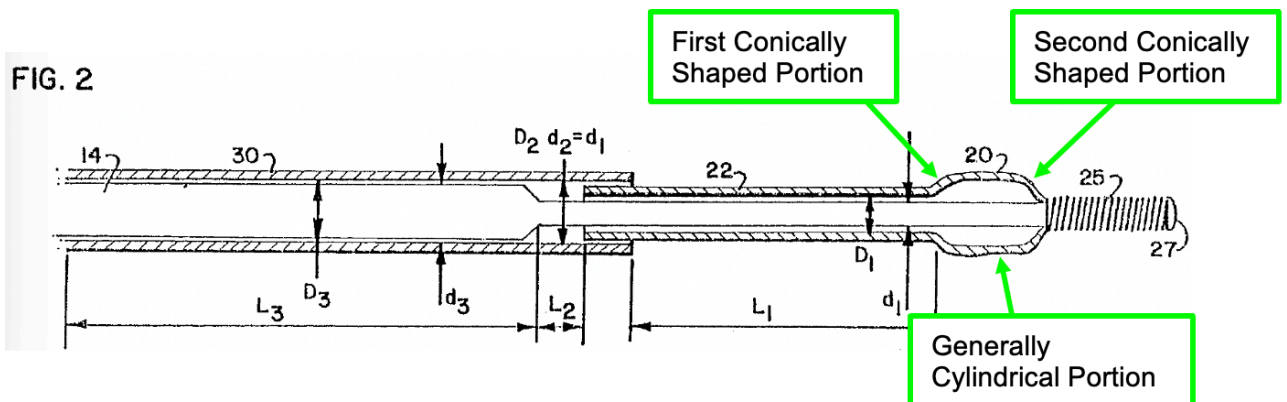


FIG. 10

- “A novel fluoroscopy-free, resuscitative endovascular aortic balloon occlusion system in a model of hemorrhagic shock,” by Daniel J. Scott et al., published in The Journal of Trauma and Acute Care Surgery, Vol. 75, Issue 1, July 2013. (“Scott”) (Ex-1010). As discussed in detail below for Ground 5, Scott is prior art to the ’737 Patent and discloses a balloon catheter with a balloon made of a compliant material. Scott, p. 123 & Fig. 1A (Ex-1010). Scott’s balloon has the “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion,” as depicted in annotated Figure 1A:

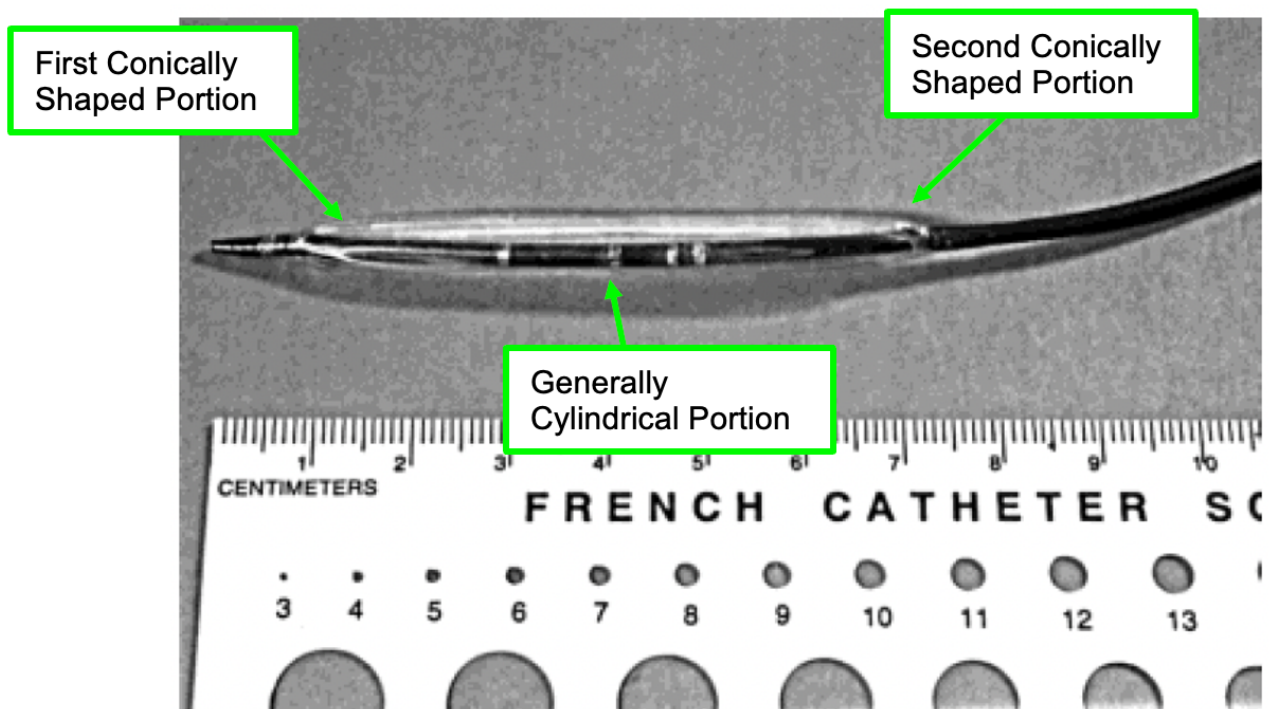


- U.S. Patent No. 4,846,174 to Willard et al. ("Willard") (Ex-1022). I understand Willard is prior art to the '737 Patent because it issued in 1989. Willard, cover page. Willard discloses a balloon catheter with a balloon 20 made of a compliant material, i.e., polyolefin. Willard, 5:9-11 (Ex-1022). Willard's balloon 20 has the "first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion," as depicted in annotated Figure 2:



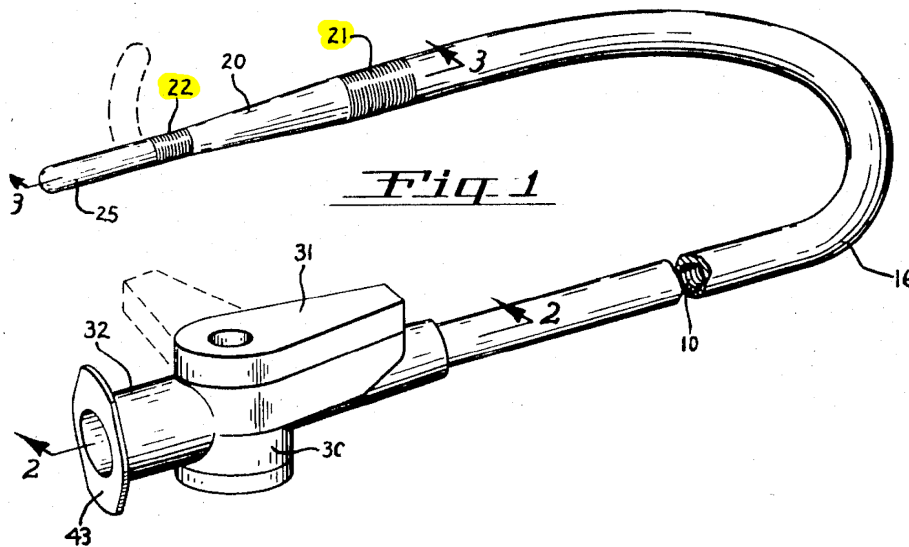
- X. Gu et al., *A New Technique for Sizing of Atrial Septal Defects*, CATHETERIZATION AND CARDIOVASCULAR INTERVENTIONS (1999) ("Gu") (Ex-1014).

I understand Gu is prior art to the '737 Patent because it issued in was published in 1999. Gu, p. 51 (Ex-1014). Gu discloses a balloon catheter with a balloon made of a compliant material: "The balloon is compliant and made from a very thin stretchable polyurethane membrane..." Gu, p. 51 & Fig. 1B (Ex-1014). Gu's balloon has the "first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion," as depicted in annotated Figure 1B:



59. The above literature confirms that complaint balloons with a "first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion" were well known to a PHOSITA in 2015. Indeed, a PHOSITA understands that this shape results from the way the balloon is attached to

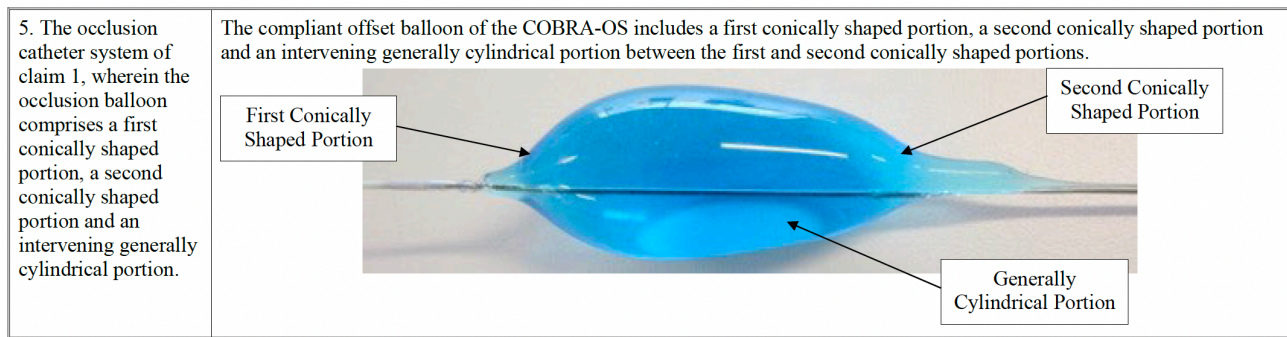
the underlying catheter body. For example, the balloon can be secured to the catheter body by windings around both distal and proximal ends of the balloon, as described in the Fogarty reference, U.S. Patent No. 3,467,101 (issued 1965) at 2:71-3:6 (describing balloon 20 is secured to tube 16 by windings 21 at the distal end and by windings 22 and the proximal end) & Figure 1 (windings highlighted) (Ex-1004):



60. A PHOSITA understands that compliant balloons attached in this way will inflate outside the body into a shape that includes a “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion.” This is because the center of the compliant balloon can stretch to a larger circumference whereas the portions of the balloon near the windings will tend to taper due to the restriction at the attachment point.

61. I understand the owner of the '737 Patent (Prytime) filed a complaint alleging that Petitioner Front Line infringes all claims of the '737 Patent. I further understand that Prytime alleges that the well-known compliant balloon

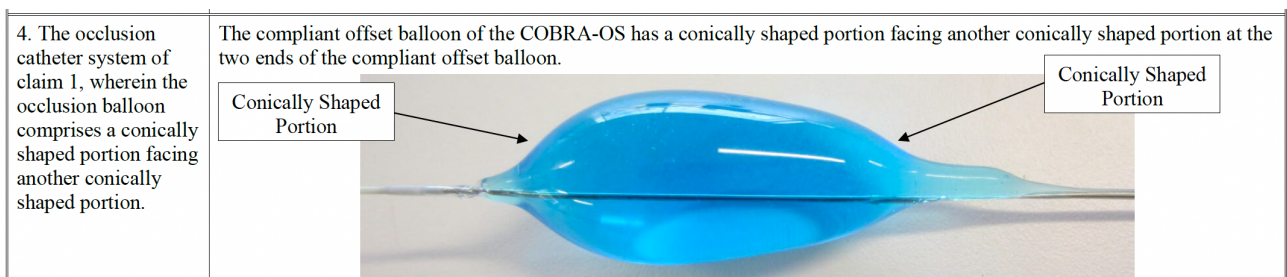
catheter configuration disclosed in Fogarty and the other references above satisfies claim language that requires a “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion.” Specifically, for claim 5, Prytime alleges:



Ex-1023, p. 14.

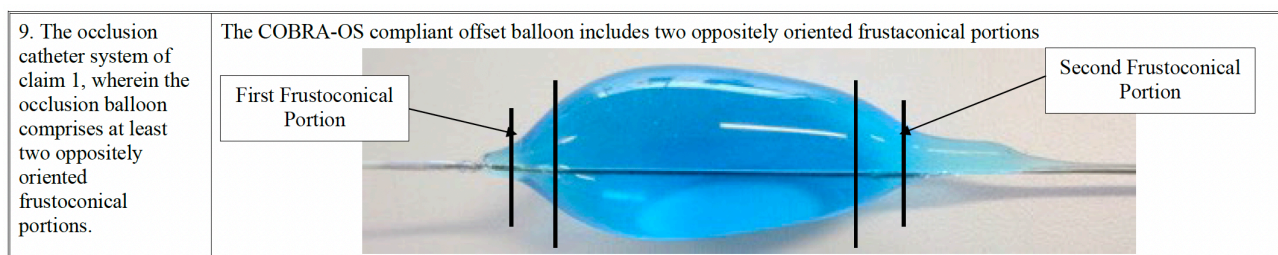
62. A PHOSITA further understands that a balloon having this “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion” also has “a conically shaped portion facing another conically shaped portion.” In particular, the “first conically shaped portion” in the above references faces the “second conically shaped portion.” Thus, “a conically shaped portion facing another conically shaped portion,” is also taught by the above references and was well known to a PHOSITA at the time of the ’737 Patent.

Prytime’s allegations are consistent with this understanding:



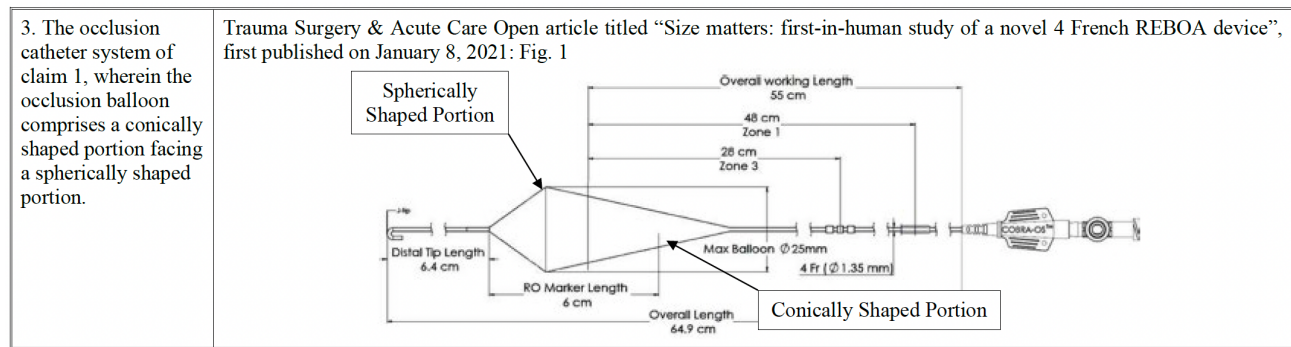
Ex-1023, p. 13.

63. A PHOSITA further understands that a balloon having this “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion” also has “at least two oppositely oriented frustoconical portions.” The term “frustoconical” is not a term of art in the medical profession (nor to a PHOSITA). I understand the term frustoconical describes a conical shape that stops short of reaching a single apex point (i.e., it is truncated before the apex of the cone). In the well-known balloon that has a “first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion,” the conical sections are actually frustoconical because the catheter running through the ends of the balloon results in truncation of the cone (i.e., there is no apex). Accordingly, a PHOSITA in 2015 was well aware that the “first conically shaped portion” and “second conically shaped portion” in the above references are “two oppositely oriented frustoconical portions.” Prytime’s allegations are consistent with this understanding:



Ex-1023, p. 17.

64. In its infringement allegations, Prytime alleges a conical balloon section satisfies the limitation in claim 3 of the '737 Patent that requires a “spherically shaped portion”:

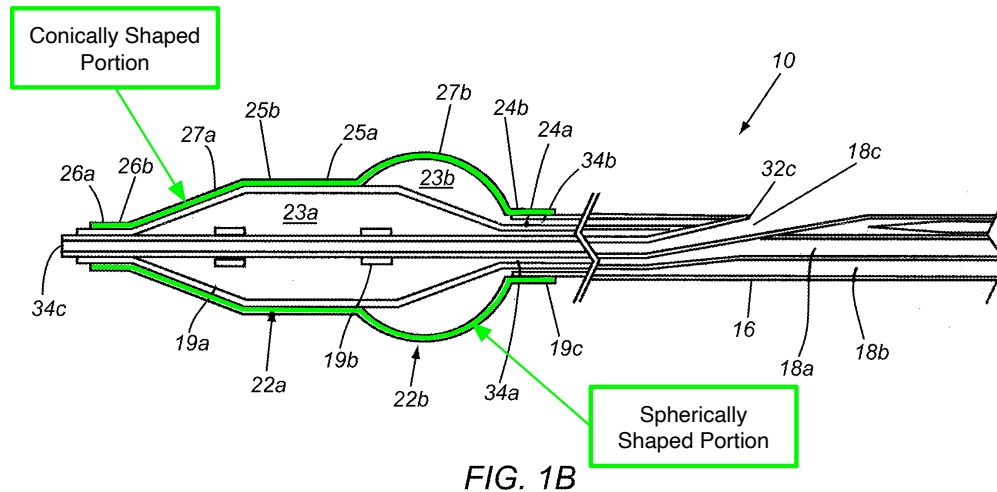


Ex-1023, p. 13.

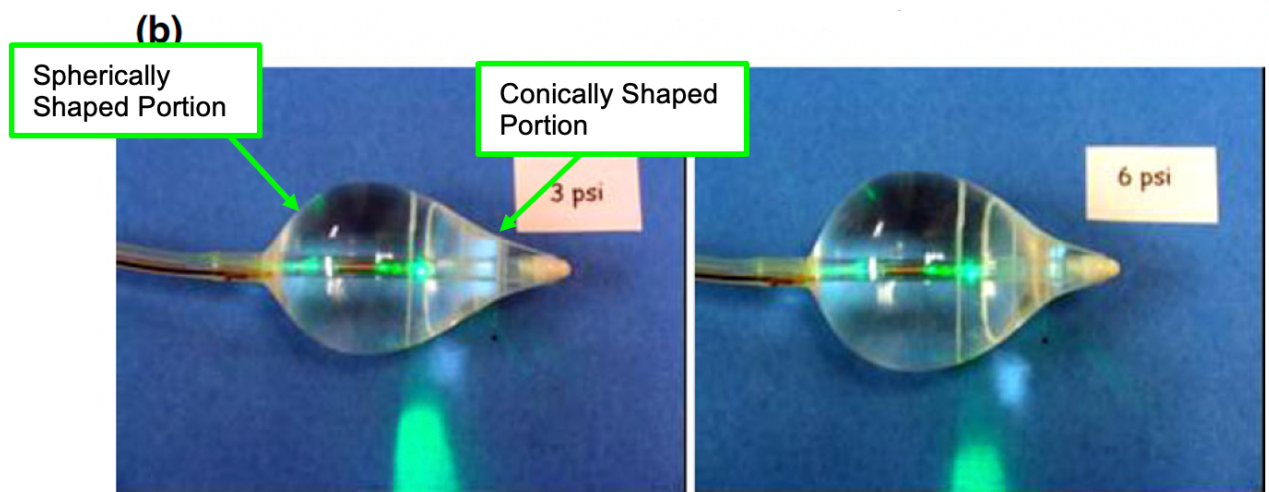
65. To the extent Prytime is correct that a conical portion of a balloon catheter qualifies as “spherical,” that shape is similarly found in each of the references discussed above and, thus, would have been well known to a PHOSITA in 2015.

66. Of course, other literature confirms that well-known compliant balloon shapes include a “conically shaped portion facing a spherically shaped portion.” This shape characteristic is found in:

- Sanati: Sanati discloses a balloon catheter that contains two different balloons (inner balloon 22a and outer balloon 22b) made of compliant material. Sanati, 7:35-47 & Fig. 1B (Ex-1007). Sanati’s outer balloon 22b has “a conically shaped portion facing a spherically shaped portion,” as depicted in annotated Figure 1B:



- “Pulmonary vein isolation using a compliant endoscopic laser balloon ablation system in a swine model,” E.P. Gerstenfeld & J. Michele, published by Springer Science+Business Media, LLC (2010) (“Gerstenfeld”) (Ex-1024): Gerstenfeld discloses a balloon catheter with a balloon made of a compliant material: “Fig. 2 ... (b) Photographs of the compliant balloon...” Gerstenfeld, p. 3 & Fig. 2b (Ex-1024). Gerstenfeld’s balloon has a “conically shaped portion facing a spherically shaped portion,” as depicted in annotated Figure 2b:



67. The above literature confirms that complaint balloons with a “conically shaped portion facing a spherically shaped portion” were well known to a PHOSITA in 2015.

VIII. Invalidity Ground 1: Claims 1- 10 are Obvious in View of the Fogarty and Chengod References and the PHOSITA’s Knowledge

68. For the reasons discussed below, it is my opinion that claims 1-10 of the ’737 Patent are obvious in view of the Fogarty and Chengod references and a PHOSITA’s knowledge.

A. Description of the Fogarty Reference (Ex-1004)

69. The Fogarty reference, U.S. Patent No. 3,467,101, describes what is commonly known as the Fogarty catheter. The Fogarty catheter was one of the first balloon catheters that could be used for vascular occlusion. This patent was issued on September 16, 1969, based on a patent application filed on September 30, 1965. Ex-1004.

70. Fogarty catheters have long been used in Interventional Radiology for a variety of purposes. While initial iterations of the catheter were designed without a guidewire lumen, later variations were of the “over-the wire” variety to accommodate a movable guidewire, which greatly expanded device utility. Both versions have been and are routinely used to manipulate intravascular materials, most commonly thrombus (i.e., a blood clot), as well as for balloon occlusion in a broad range of clinical scenarios. The devices are manufactured with

a broad range of catheter lengths/diameters and balloon sizes. Fogarty catheters, such as that described in the Fogarty reference, have been routinely used in Interventional Radiology procedures for decades, including for purposes such as dialysis access graft or fistula declotting, lumen targeting during occlusion recanalization or other “location-to location” type procedures, intravascular device repositioning, arterial and venous balloon occlusion for the management of hemorrhage as well as for balloon occlusion during the performance of embolization/occlusion procedures as a mechanism for flow control and embolic delivery management and others. It would not be an overstatement to suggest that without the Fogarty type balloon catheter, many routine interventional procedures could not have been performed safely or effectively.

B. Description of the Chengod Reference (Ex-1005)

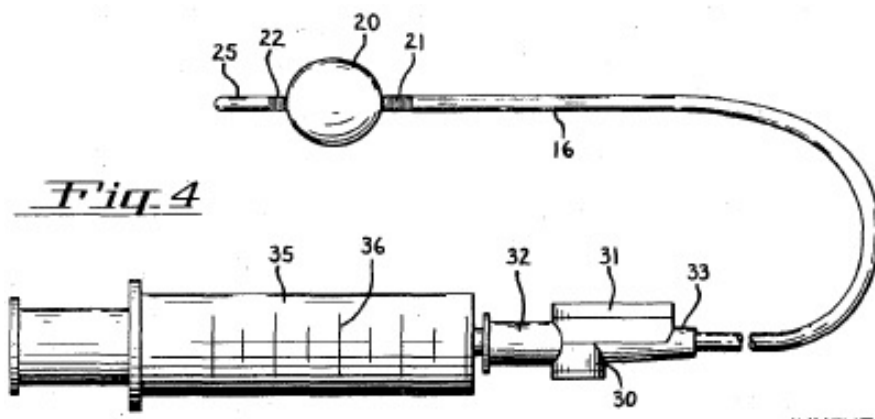
71. Chengod describes the use of a Fogarty catheter as a bronchial blocker in children. As explained above, the Fogarty catheter had broad use in a variety of medical specialties, and has routinely been used for arterial occlusion.

C. Claim 1

72. Independent claim 1 of the '737 Patent is presented below divided into separate elements. Each element is quoted from claim 1 in bolded italics.

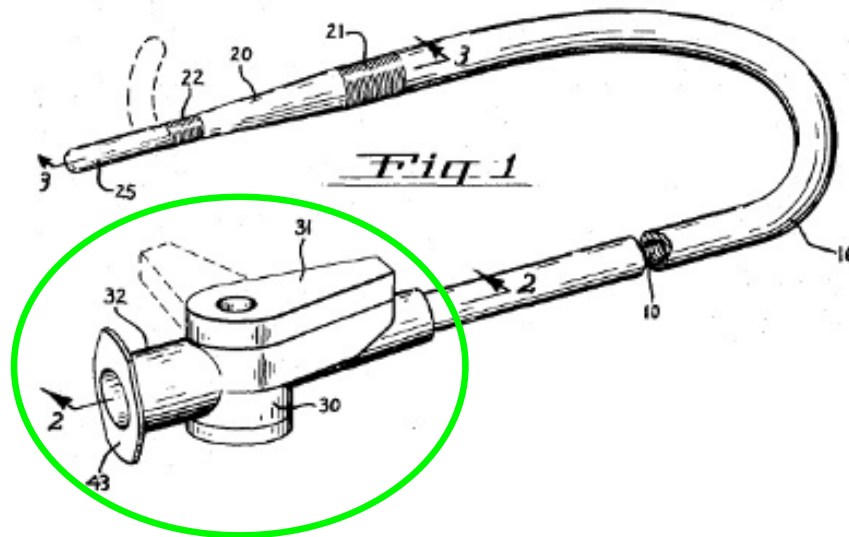
1. An occlusion catheter system comprising:

73. Fogarty discloses this element. The Fogarty reference describes an occlusion catheter system. The reference explains that this balloon catheter was designed for a variety of purposes, including for use in the human vascular system. Fogarty, 2:33-39 (Ex-1004). Figure 4 of the Fogarty reference shows an entire catheter system, including a proximal end (at figure number 16) and distal end (at figure number 25) of the catheter, an occlusion balloon (20), and a syringe (35):



a proximal hub;

74. Fogarty discloses this element. In Figure 1, the Fogarty reference shows and describes a hub in the form of the shut off valve 30, rotatable valve member 31, syringe fitting 32, and hub flange elements 43:

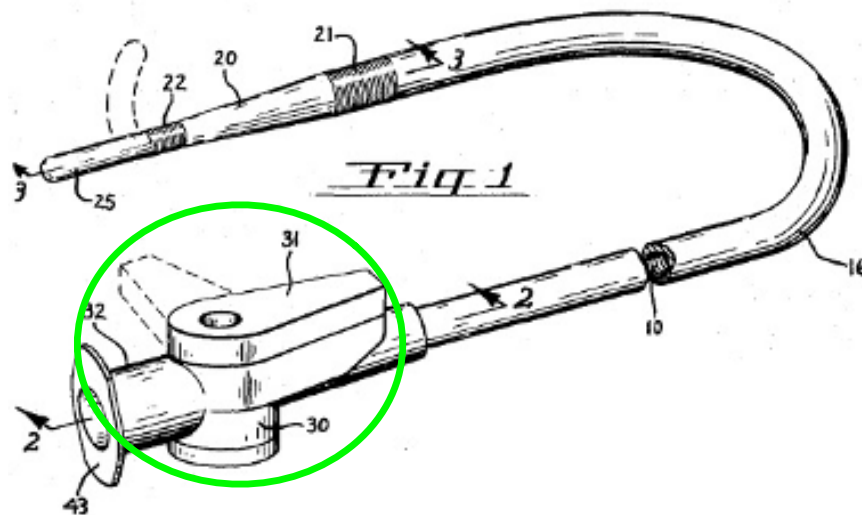


The Fogarty reference describes the flanges (43) on the syringe fitting (32) as “hub flange elements.” Fogarty, 3:60-63 (Ex-1004). A PHOSITA reviewing the Fogarty reference would recognize that the elements 30, 31, 32, and 43 comprise a hub that is on the proximal (away from the patient’s body) end of the catheter. ’737 Patent, 21:52-64 (Ex-1001). A PHOSITA understands these elements are a “hub” because these elements are designed to remain outside the body during use and are used to physically connect an inflation device (e.g., syringe (35)) to the inflation lumen of the catheter.

a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device

75. Fogarty discloses this element. The Fogarty reference explains that the “proximal end of the catheter tube is secured to a shut-off valve 30 having a rotatable valve member 31.” Fogarty, 3:38-39 (Ex-1004). The shut-off valve is equipped with a fitting (32) to receive a syringe (35) (i.e., an inflation device) for

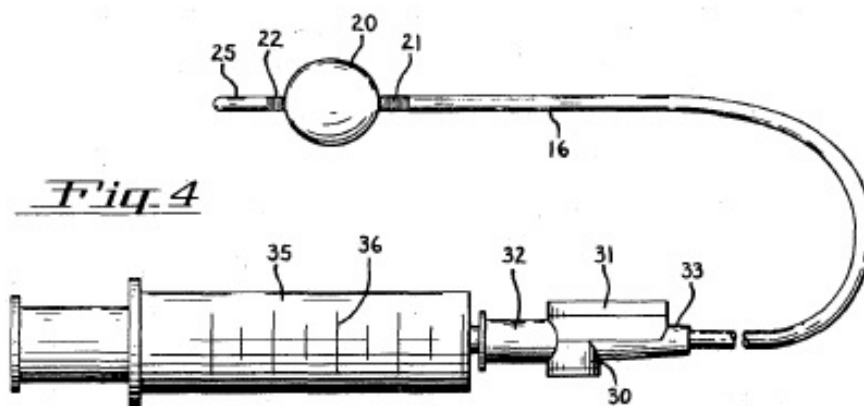
inflating the balloon. Fogarty, 3:40-42 (Ex-1004). Fogarty explains that a syringe may act as an inflation device and fluidly communicate with the proximal hub in order to inflate the balloon: “Preferably, an incompressible fluid such as liquid is used and the transparent body of the syringe contains markings 36 so that the amount of liquid displaced into the balloon may be known but air may be used if desired.” Fogarty, 3:42-46 (Ex-1004). Fogarty explains that the integral shut-off valve is used to maintain or “hold” the inflation of the balloon. Fogarty, 1:51-64 and 3:46-48 (Ex-1004). In other words, when the desired amount of fluid has been delivered from the syringe into the balloon to inflate it, the shut-off valve can be closed so that the balloon maintains the desired inflation.



Thus, valve 30 in Fogarty is being used to “selectively fluidly communicate: the proximal hub with an inflation device” (the syringe).

a proximal catheter section in fluid communication with the proximal hub;

76. Fogarty discloses this element. The Fogarty reference explains that the proximal end of the catheter tube (16) is secured to the shut-off valve 30 of the hub. Fogarty, 3:38-39 (Ex-1004). A PHOSITA reviewing the Fogarty reference would recognize that section 16 of the catheter is the proximal (away from the patient's body) end of the catheter. '737 Patent, 21:52-64 (Ex-1001). The inflation fluid in Fogarty passes from the syringe (35) through the hub, the hub's valve (30), and the proximal section of the catheter tube (16) in order to inflate the balloon (20) (as seen in Figure 4). Fogarty 3:42-46 (Ex-1004).

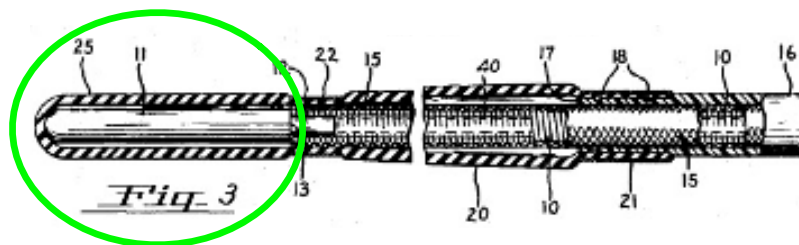


Thus, we know that the proximal catheter section is in fluid communication with the proximal hub.

A distal catheter section distally terminating with an atraumatic tip;

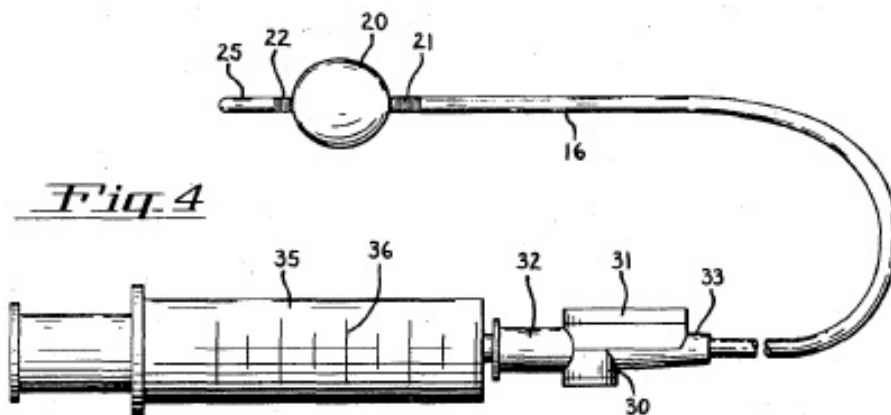
77. Fogarty discloses this element. The Fogarty reference uses a “soft rubber plug 11” as its atraumatic tip. See Fogarty, 2:43-49 (Ex-1004). This portion of Fogarty explains that the plug forms a “flexible tip” that will readily bend back on itself, as shown by the broken lines in Figure 1. The soft, flexible nature of

this plug (11) makes the tip of the Fogarty catheter atraumatic. Figures 1 and 4 both show that the distal catheter section includes the portion that includes winding 22 and terminates at its distal end at this atraumatic tip. A PHOSITA reviewing the Fogarty reference would recognize that the end of the catheter that includes the soft rubber plug 11 is the distal (oriented toward the patient's body) end of the catheter. '737 Patent, 21:52-64 (Ex-1001). The location of this atraumatic tip is also shown in Figure 3 of Fogarty (Ex-1004):



an intervening occlusion balloon connecting the proximal catheter section with the distal catheter section, the occlusion balloon being compliant;

78. Fogarty discloses this element. The Fogarty reference describes a balloon catheter, and its balloon is shown as element (20) in both Figures 1 and 4 (Ex-1004).



79. The balloon is described as being made of “a strong, elastic material such as latex rubber or a plastic elastomer whereby it will expand to a spherical shape when unconfined and inflated as shown in FIGURE 4.” Fogarty, 3:16-19 (Ex-1004). The fact that the balloon is made of elastic materials such as latex rubber or a plastic elastomer means that the balloon is compliant. For example, the *Handbook of Endovascular Peripheral Interventions* explains that “Balloons can be compliant, non-compliant, or semi-compliant” and “[c]ompliant balloon[s] will increase their diameter with increasing pressure. They are typically made of silicone and **thermoplastic elastomers**, polyethylene, or polyolefin polymers.” *Handbook of Endovascular Peripheral Interventions*, 81 (C.D. Owens & Y. Yeghiazarians eds., Springer 2012). Figure 4 (Ex-1004) clearly shows the inflated, compliant balloon (20) extending from the distal section of the catheter (at the closed-end portion of the balloon 25) to the proximal section of the catheter 16, thus connecting the two catheter sections.

At least one length marking on an exterior of the proximal catheter section to indicate an insertion depth of the occlusion catheter system;

80. Chengod discloses this element. The Fogarty reference doesn’t show length markings, but the Chengod reference describes using a Fogarty catheter that has length markings. On page 637, Chengod states that “[t]hree markings were made on the Fogarty catheter to aid accurate placement in the left mainstem bronchus.” Ex-1005. The article explains that the first mark was “the carinal

distance as measured from the tip of the catheter,” the second mark was the “carinal distance measured from the proximal joint of the balloon,” and the third mark was made one centimeter from the second mark. Chengod, p. 637 (Ex-1005). Figure 1 in Chengod shows these markings on an exterior of the proximal catheter section (i.e., in between the hub and the balloon):

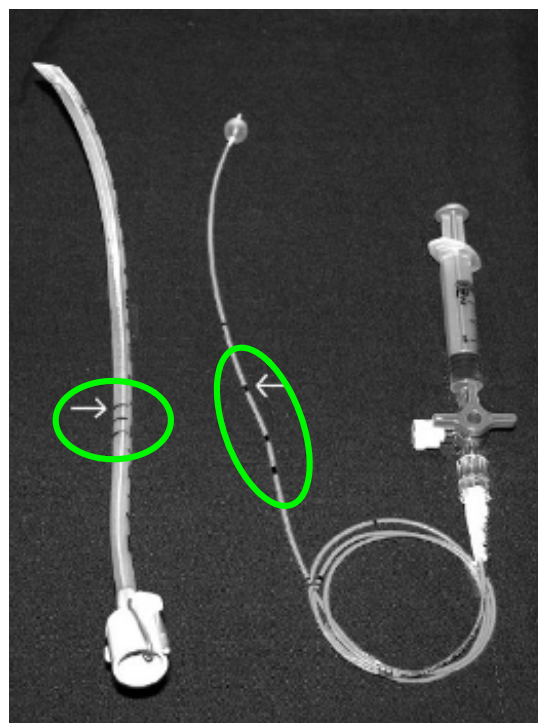


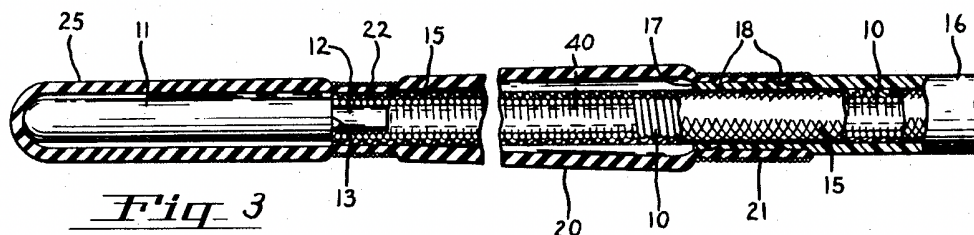
Fig 1. Endotracheal tube modified to resemble a left-sided double-lumen tube with the help of a stylet. Note the bevel of the tube facing toward the right side. Carinal distance is marked on the tube and the catheter as measured from the tip (Arrows). The second and third markings on the catheter, from below upwards, are the carinal distance from the proximal joint of the balloon and 1 cm from the second mark, respectively.

81. The Chengod article goes on to explain that these length markings are used to measure the insertion depth of the Fogarty occlusion catheter. In particular, the Fogarty catheter was first positioned so that “the most proximal mark made on the catheter (the first mark seen while pulling out) came to the level of the incisor or the gum of the upper jaw.” Positioning the catheter in this position

ensures that the Fogarty catheter is properly positioned with “the proximal joint of the balloon 1 cm beyond the carina into the left mainstem bronchus.” Chengod, p. 637 (Ex-1005).

a lumen extending from the proximal hub through the proximal catheter section and into fluid communication with the occlusion balloon;

82. Fogarty discloses this element. A PHOSITA understands that a “lumen” in the context of the claimed occlusion catheter refers to a hollow portion of the catheter through which the fluid (or gas) used to inflate the balloon travels. The Fogarty reference explains that the catheter body is built on a core 10 made of a coil of wire wound so that adjacent turns are in contact with one another.” Fogarty, 1:40-43 (Ex-1004). As shown in Figure 3, the coil (10) is covered with a braid (15) that is braided directly onto the body coil. Fogarty, 1:57-60 (Ex-1004). This braid (15) is then covered with an outer plastic tube (16) made of a suitable, shrinkable plastic, which is then heat shrunk onto the braid (15) and the underlying coil (10). Fogarty, 1:61-68 (Ex-1004). This creates a catheter body having a “hollow inner core.” Fogarty, 1:66-67 (Ex-1004).



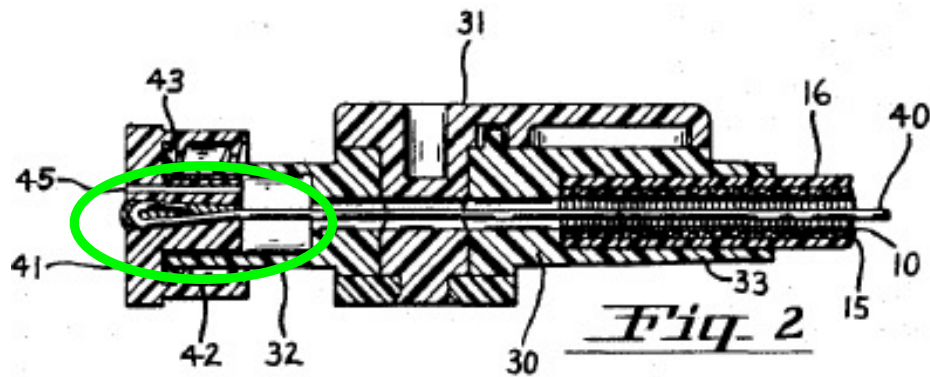
83. As shown in Figures 1 and 4 (Ex-1004), the catheter body (proximal catheter section 16) is connected to the proximal hub. Fluid flows from

the proximal hub (“fluid communication”), through the “hollow inner core” of the proximal catheter section 16, and into the occlusion balloon 20. Fogarty explains that “[i]n order to inflate and deflate the balloon, a number of turns of the coil 10 are very slightly separated from each other in the interval between the windings 21 and 22 whereby an inflating fluid introduced into the proximal end of the lumen of coil 10 will pass freely through the separated turns and inflate this portion of the balloon as shown.” Fogarty, 3:19-25 (Ex-1004).

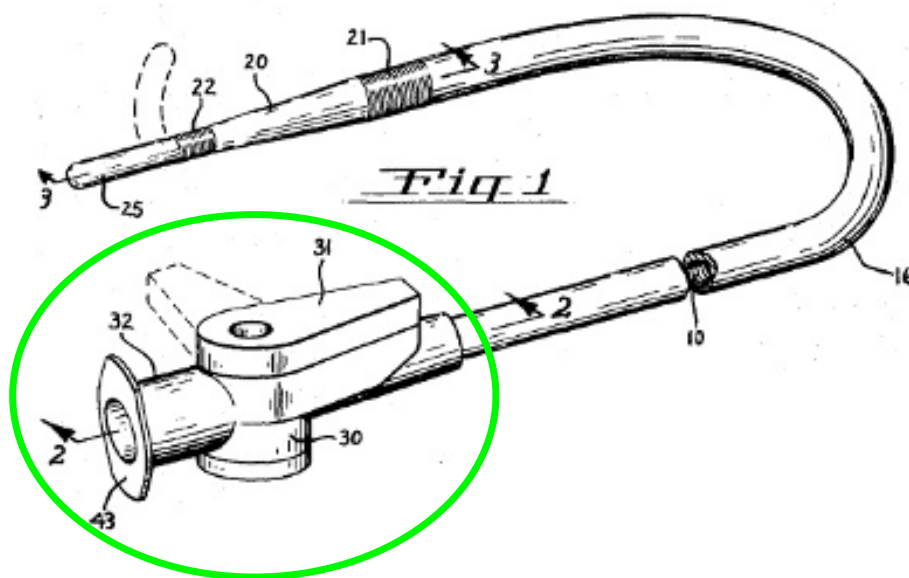
a solid wire, secured at a proximal-most end thereof within the proximal hub, and extending within the proximal catheter section, the occlusion balloon and into the distal catheter section; and

84. Fogarty discloses and teaches this element. The Fogarty reference explains that the Fogarty catheter uses a metal wire stylet 40 “to facilitate the insertion of the catheter into a luminal structure within the body.” Fogarty, 3:48-54 (Ex-1004). The metal wire stylet (40) facilitates insertion by providing longitudinal column strength to the catheter shaft such that the manually advanced catheter will move forward as a unit, rather than bend or kink along the catheter column.

85. The metal wire stylet (40) is secured inside the hub by being secured to a cap (41) which is threaded into the flange elements (43) on the hub. This is shown most clearly in Figure 2 (Ex-1004):



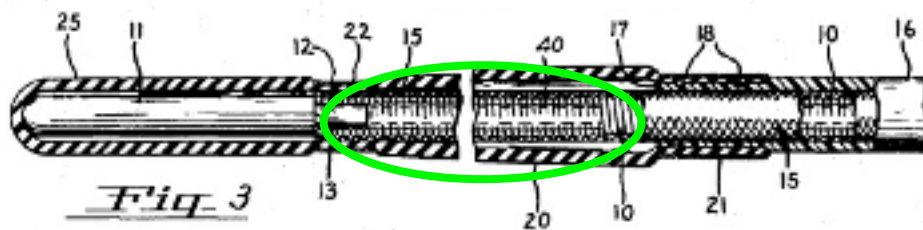
As can be seen in this figure, it is the proximal-most end of this metal wire (40) (the end that is away from the patient's body when the catheter is in use) that is secured into cap (41), which is threaded to flange element (43), which forms part of the hub as shown in Figure 1:



86. The wire stylet (40) is attached within proximal hub, and this attachment allows the wire and the catheter to withstand normal operating conditions and perform the preferred functions of the catheter. Thus, the Fogarty reference teaches that the metal wire stylet is secured within the hub (30, 31, 32),

and this securing occurs at the wire's proximal-most end. This prevents movement of the wire stylet (40) relative to the rest of the catheter and provides stiffening to the catheter so that it can perform its preferred functions.

87. The wire stylet (40) extends from this position in the proximal hub "to the proximal end of the reduced portion 12 of the plug 11." Fogarty, 3:48-54 (Ex-1004). This distal end of the wire (40) extending through the balloon and to the distal catheter section containing the soft rubber atraumatic tip (11) is shown in Figure 3:



88. Thus, the Fogarty reference teaches a wire (40), that is secured at a proximal-most end (within flange element 43) thereof within the proximal hub and extends within the proximal catheter section (16) through the occlusion balloon (20), and into the distal catheter section at the soft rubber tip (11).

89. While Fogarty does not explicitly state that the wire stylet (40) is solid, a PHOSITA understands that a metal wire stylet designed to facilitate the insertion of the catheter into a patient would be solid and not hollow, as a solid wire provides more stability. For example, the Bagaoisan, Nishide, and Anderson references disclose solid metal stylets and mandrels. (I discussed those references above when discussing the PHOSITA's knowledge of the use of stainless steel for the

solid wire.) A PHOSITA understands those metal stylets and metal mandrels to be the same as a wire. U.S. Patent No. 5,087,246 to Smith issued in 1992 and includes “elongate wire 34” that is secured to the hub (called the “proximal fitting”) and extends to the “distal tip 38” of the balloon catheter. Smith, 4:17-23 (Ex-1025). A PHOSITA understands Smith’s disclosure to be a solid metal wire, as depicted in Figure 3. Thus, Smith is additional evidence that a PHOSITA was well aware (decades before the ’737 Patent) of the use of solid metal wires in balloon catheters. Moreover, the use of a hollow wire (i.e., a “tube with a lumen, as distinguished in the ’737 Patent (30:61-64 (Ex-1001))) is counter to basic medical device manufacture goals as it would create a larger profile, thus unnecessarily forcing the creation of a larger medical device. Furthermore, a hollow stylet creates an opportunity for the stylet to kink or collapse upon itself not afforded by a similar device of solid construction.

the proximal catheter section, the occlusion balloon and the distal catheter section having a greatest outer diameter of less than 6 Fr in an uninflated configuration.

90. Chengod discloses this element and it was known to a PHOSITA. Fogarty does not indicate a size of the disclosed catheter. However, as explained above, the Fogarty catheter has long been available in sizes with an outer diameter smaller than six French (6 Fr) in an uninflated configuration. This was personally known to me prior to the date of invention and was well-known to a PHOSITA.

Furthermore, the Chengod article discloses that the authors used Fogarty catheters that were as small as four French (4 Fr). Chengod, p. 637 (Ex-1005). Additional evidence that a PHOSITA had knowledge of occlusion balloon catheters smaller than 6 Fr include the Deaton article. Deaton discloses the “Fogarty Thru-Lumen Embolectomy Catheter is manufactured in sizes of 3 F to 7 F.” Deaton, p. 32 (Ex-1008).

91. Further, a PHOSITA would find it obvious to size a Fogarty catheter less than 6 Fr in diameter (in an uninflated configuration) because a 6 Fr size for an occlusion catheter is simply one of a limited number of known design choices, and a PHOSITA would have a reasonable expectation of success in making and using a 6 Fr (or less) sized Fogarty occlusion catheter in 2015. Again, Chengod expressly discloses four French (4F) and five French (5F) catheters as design choices for an occlusion catheter, where smaller diameter catheters are used for younger patients. Chengod, p. 637 (Ex-1005). Chengod’s disclosure also confirms that there is no question whether a Fogarty catheter with size less than 6 Fr would work. It did. The same is true of Deaton’s Fogarty catheter which was available in sizes of 3 F to 7 F.

92. A PHOSITA understands that a basic tenet of endovascular procedures is that the smallest device available that can adequately complete the job is the one that should be used. This is because endovascular procedures require devices to be inserted into the blood vessel (artery or vein) thereby creating a hole

in that vessel. The larger the device utilized, the larger the hole created. The larger the hole created, the greater the risk for an access site complication (bleeding, pseudoaneurysm formation, arteriovenous fistula formation) to occur. So, practitioners use smaller devices when available because they're generally safer.

D. Claim 2

2. The occlusion catheter system of claim 1, wherein the occlusion balloon is asymmetrical.

93. A PHOSITA had knowledge of this claim. Claim 2 depends from claim 1 which is obvious in view of the Fogarty and Chengod references and the PHOSITA's knowledge. As explained above in Section VII.D, a PHOSITA is well aware that compliant balloons such as the type used in the Fogarty catheters as described in the Fogarty and Chengod references could be designed to inflate asymmetrically.

E. Claims 3-5

3. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion.

4. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing another conically shaped portion.

5. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion.

94. A PHOSITA had knowledge of these claims. Claims 3-5 depend from claim 1 which is obvious in view of the Fogarty and Chengod references and the PHOSITA's knowledge. As explained above in Section VII.E, a PHOSITA is well aware that compliant balloons such as the type used in the Fogarty catheters as described in the Fogarty and Chengod references could be designed with the claimed shapes.

F. Claim 6

6. The occlusion catheter system of claim 1, wherein the solid wire is constructed of a metal.

95. Fogarty discloses this claim. Claim 6 depends from claim 1, which is obvious in view of the Fogarty and Chengod references and the PHOSITA's knowledge.

96. The Fogarty reference describes element (40) as a “metal wire stylet” (Fogarty, 3:48-59 (Ex-1004)), and therefore teaches that the wire is constructed of metal.

G. Claim 7

7. The occlusion catheter system of claim 1, wherein the solid wire is constructed of a stainless steel.

97. Fogarty teaches this element which was also well known to a PHOSITA. Claim 7 depends from claim 1, which is obvious in view of the Fogarty and Chengod references and a PHOSITA’s knowledge.

98. Claim 7 adds that the solid wire is constructed of stainless steel. The Fogarty reference itself explains that the wire stylet (40) is constructed of metal. Fogarty, 3:48-59 (Ex-1004). As explained above in Section VII.B, a PHOSITA is well aware that metal components used in balloon catheters (including occlusion catheters) can be made from stainless steel. Thus, for those same reasons, it would be obvious to construct the metal wire stylet of Fogarty out of stainless steel.

H. Claim 8

8. The occlusion catheter system of claim 1, further comprising a proximal radio opaque marker proximate a proximal end of the occlusion balloon and a distal radio opaque marker proximate a distal end of the occlusion balloon.

99. A PHOSITA had knowledge of this claim. Claim 8 depends from claim 1, which is obvious in view of the Fogarty and Chengod references and the PHOSITA's knowledge.

100. Claim 8 adds two radio opaque markers, one at the proximal end of the occlusion balloon and one at the distal end of the occlusion balloon. As explained above in Section VII.C, a PHOSITA is well aware that radio opaque markers are routinely used in balloon catheters, and the position of those markers at either end of the balloon is commonly used to identify the location of the balloon under fluoroscopy. Thus, a PHOSITA would find it obvious based on this knowledge to further modify the Fogarty catheter of claim 1 with radio opaque markers as claimed.

I. Claim 9

9. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises at least two oppositely oriented frustoconical portions.

101. A PHOSITA had knowledge of this claim. Claim 9 depends from claim 1 which is obvious in view of the Fogarty and Chengod references and the PHOSITA's knowledge. As explained above in Section VII.E, a PHOSITA is well aware

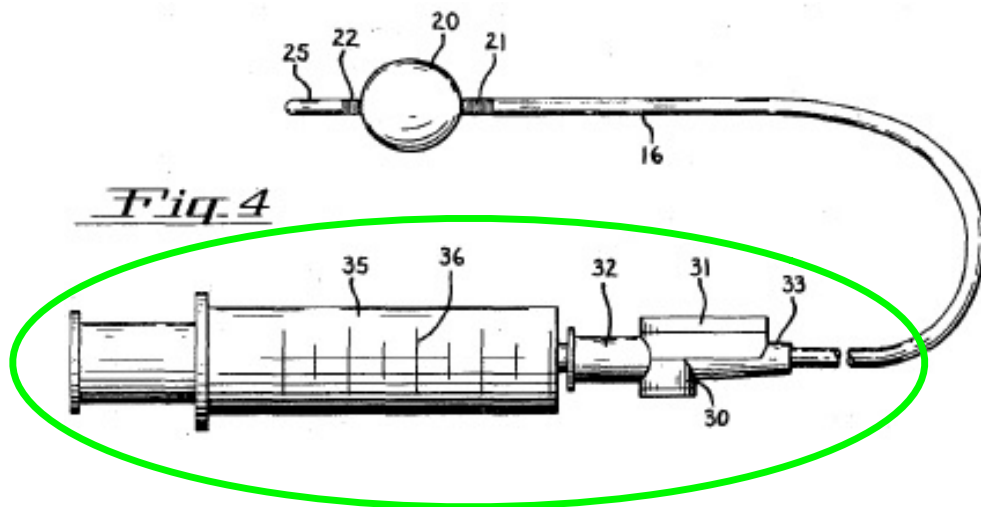
that compliant balloons such as the type used in the Fogarty catheters as described in the Fogarty and Chengod references could be designed with the claimed shape.

J. Claim 10

10. An inflation control system kit comprising: the occlusion catheter system of claim 1; and a syringe containing a fluid, the syringe being configured to fluidly connect with an inlet of the proximal hub.

102. Fogarty discloses this claim. Claim 10 depends from claim 1, which is obvious in view of the Fogarty and Chengod references and the PHOSITA's knowledge.

103. As explained above, the Fogarty and Chengod references together teach the occlusion catheter system of claim 1. The Fogarty reference explains that the valve (30) found at the hub has a conventional fitting (32) that can receive a syringe (35). Fogarty, 3:40-46 (Ex-1004). This section of Fogarty explains that the syringe can contain an incompressible fluid, can be fluidly connected to the valve input of the hub using the fitting (32), and can be used for inflating the balloon. This is shown in Figure 4 (Ex-1004):



104. Thus, Fogarty and Chengod teach a kit that includes the occlusion catheter system of claim 1, and a syringe (35) containing a fluid that is configured to fluidly connect with an inlet (32) of the proximal hub (30, 31, 32).

K. Motivation to Combine the Fogarty and Chengod References

105. Chengod provides express motivation to combine its markings and size (less than 6 Fr) with the Fogarty patent because Chengod discloses a Fogarty catheter with the markings and size required by Claim 1 of the '737 Patent. The Fogarty reference is a patent issued on the catheter design of Thomas Fogarty, based on a patent application filed in 1965. As explained above, the Fogarty catheter was a very early balloon catheter that could be used for vascular occlusion. In spite of the fact that the invention described in the Fogarty reference is almost sixty years old, the Fogarty catheter was successfully used for occlusion procedures for many decades, and is still used today. The Chengod reference describes the use of the Fogarty catheter in 2005. As explained above, the Fogarty catheter has long been

available in small sizes, and Chengod provides proof that the Fogarty catheter design shown in the Fogarty patent was available in a size of six French and smaller. Furthermore, the Chengod reference shows that a Fogarty catheter was actually modified by adding at least one length marking to the exterior of the proximal catheter section.

106. Even if Chengod had not used an actual Fogarty catheter, it would have been obvious to combine the teachings of Chengod and Fogarty. The Fogarty reference describes an early occlusion balloon catheter. Chengod teaches that such catheters can be made in sizes as small as four French (4 Fr), and that external depth insertion markings can be advantageously used on an occlusion balloon catheter. A PHOSITA would have been motivated by this teaching to make a catheter of the disclosed size and to add depth insertion markings on the catheter described in the Fogarty patent. The PHOSITA would have added depth insertion markings as disclosed in Chengod in order “to aid accurate placement” of the occlusion catheter. Chengod, p. 637 (Ex-1005). A PHOSITA understands that more accurate placement leads to fewer complications and higher success rates for the intervention procedure. The PHOSITA would have made a Fogarty catheter smaller than 6 Fr because smaller devices are safer (e.g., reduced risk of access site complications).

IX. Invalidity Ground 2: Claim 2 is Obvious in View of the Fogarty, Chengod, and Saab References and the PHOSITA's Knowledge

107. For the reasons discussed below, it is my opinion that claim 2 of the '737 Patent is obvious in view of the Fogarty, Chengod, and Saab references and a PHOSITA's knowledge.

A. Description of the Saab Reference (Ex-1006)

108. Mark A. Saab wrote an article entitled "Applications of High-Pressure Balloons in the Medical Device Industry," in *Medical Device & Diagnostic Industry Magazine*, which was published on September 1, 2000. Ex-1006-7. The article explained that balloon technology in the year 2000 was sufficiently advanced that "endless design possibilities" were available when designing balloon catheters. Saab, p. 86 (Ex-1006-7).

109. Saab explained that there were two basic balloon types, namely high-pressure balloons used to apply force, and low-pressure elastomeric balloons, usually used for occlusion. Saab, p. 86 (Ex-1006-7). Saab further explained that high pressure balloons typically used noncompliant or low-compliant materials that retain their size and shape, while low-pressure balloons "are typically dip molded in a tubular shape." Saab, p. 87 (Ex-1006-8).

110. Saab then explains that high-pressure balloons are known to exist in variety of shapes, and shows "[e]xamples of high-pressure balloon shapes" in Figure 2:

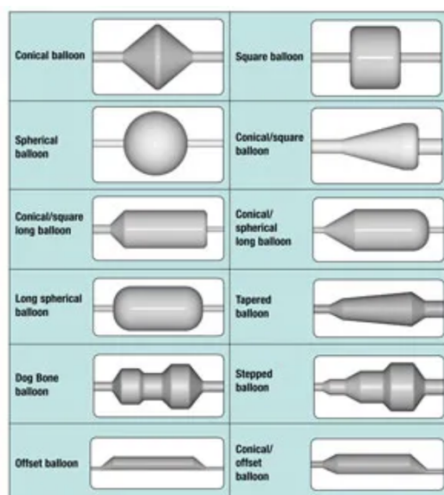


Figure 2. Examples of high-pressure balloon shapes. A specific shape may be demanded by the particularities of the anatomical site, the requirements of the treatment process, or both. (The designs shown here can be formed in different diameters and lengths.)

Saab, p. 88 (Ex-1006-9).

111. Saab also describes the fact that low-pressure elastomeric balloons can be made of latex or silicone. Saab, p. 86 (Ex-1006-7). These balloons can stretch from 100% to 600% of their size when inflated. Saab, p. 87 (Ex-1006-8).

112. A PHOSITA would recognize that Saab is explaining that balloons that are used in balloon catheters can be made in a variety of shapes.

B. Claim 2

2. The occlusion catheter system of claim 1, wherein the occlusion balloon is asymmetrical.

113. Saab discloses this claim. Claim 2 depends from claim 1, which is obvious in view of the Fogarty and Chengod references.

114. Claim 2 adds the requirement that the occlusion balloon is asymmetrical. Saab explains that low-pressure elastomeric balloons (i.e., compliant balloons) can be designed to expand in an asymmetrical manner. In fact, Saab includes an image of such a balloon in Figure 6:

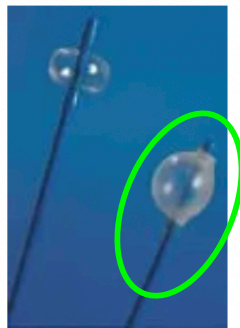


Figure 6. Offering less precision, an elastomeric balloon (right) will often expand asymmetrically compared with a high-pressure, thin-walled balloon (left).

Saab, p. 90 (Ex-1006-11).

115. Thus, a PHOSITA would have learned from Saab that the compliant balloon in the catheters described by either or both of the Fogarty and

Chengod references could be configured to expand asymmetrically. The '737 Patent does not describe an asymmetrical balloon *at all* in the specification, but rather first discusses this possible balloon configuration in claim 2. Thus, a PHOSITA could not recognize anything special in the asymmetry called for by claim 2 and would consider the addition of this feature (asymmetrical balloon inflation) to the Fogarty catheter (as modified by Chengod) to be obvious in light of the Saab reference.

C. Motivation to Combine Fogarty, Chengod, and Saab

116. The motivation to combine the Fogarty reference with Chengod's teaching of the Fogarty catheter was described above in connection Ground 1. Both of these references describe the Fogarty catheter, which, as explained above, includes a compliant balloon that has been used for occlusion procedures for many decades. The Saab reference is a 2000 journal article on the "endless design possibilities" that were available when designing balloon catheters, focusing almost exclusively on balloon shapes. Saab, p. 86 (Ex-1006-7). Saab explains that elastomeric (compliant) balloons "often expand asymmetrically." Saab, p. 90 (Ex-1006-11).

117. A PHOSITA reading Saab understands that compliant balloons may expand asymmetrically. In this case, Saab is explaining a behavior that is found in compliant balloons. Alternatively, a PHOSITA would read Saab to suggest that asymmetrical compliant balloons are a design choice that could be implemented on catheters such as the Fogarty catheter. Either way, a PHOSITA reading Saab would

understand that asymmetrical inflation of the compliant balloon in the Fogarty catheters is obvious.

118. Indeed, a PHOSITA understands that human anatomy is variable, and changes in that anatomy can occur secondary to disease processes (such as atherosclerosis, aneurysms, malignancies, and others). This variation in anatomy shape, size, and course leads to an understanding that in order to occlude a vessel various balloon sizes and shapes would be required. It's not a "one shape fits all" scenario. Thus, a compliant balloon capability to expand asymmetrically is not only known, but desired in many intervention procedures that would be performed with a Fogarty catheter.

X. Invalidity Ground 3: Claims 3-5 and 9 are Obvious in View of the Fogarty.

Chengod, and Sanati References and a PHOSITA's Knowledge

119. For the reasons discussed below, it is my opinion that claims 3-5 and 9 of the '737 Patent are obvious in view of the Fogarty, Chengod, and Sanati references and a PHOSITA's knowledge.

A. Description of the Sanati Reference (Ex-1007)

120. The Sanati reference is U.S. Patent No. 10,004,622, which issued on June 26, 2018, and was filed on May 18, 2015 (Ex-1007). This patent was a continuation of Serial No. 13/602,074, which was filed on August 31, 2012. I have been informed that the Sanati reference is prior art to the '737 Patent.

121. Sanati describes a balloon catheter that contains two different balloons. In particular, the Sanati reference has an outer balloon (22b) that starts with a tapered, distal end, and then converts to a spherical portion at its proximal end. Sanati, Figure 1B (Ex-1007).

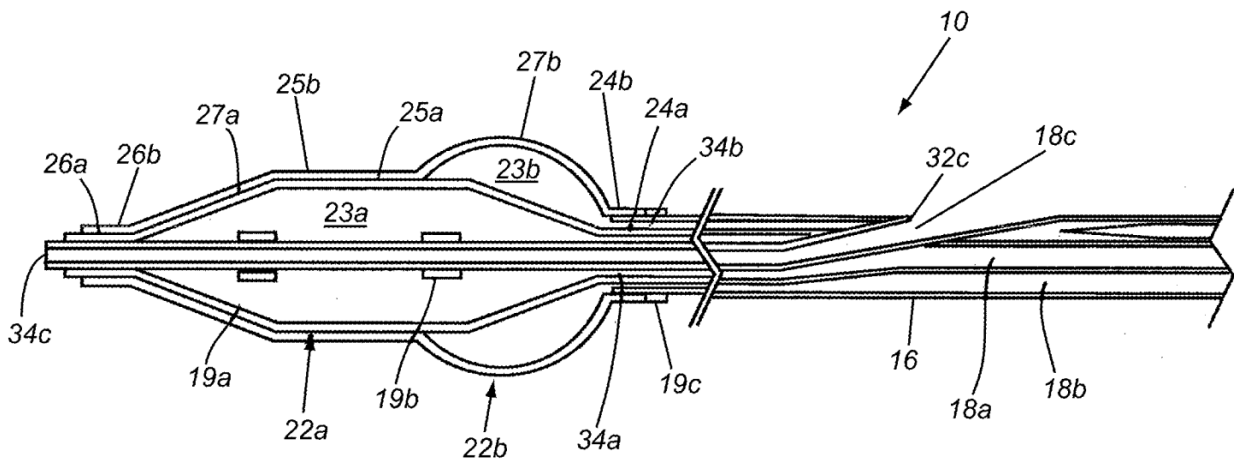


FIG. 1B

122. The Sanati reference also has an inner balloon (22a) that tapers at both ends and is cylindrical in the middle. Sanati, Figure 1B. The Sanati reference explains that both of these balloons can be constructed of a substantially elastic material, such as silicone. Sanati, 7:35-47 (Ex-1007). As I discussed previously, a PHOSITA understands that silicon balloons are compliant. See *Handbook of Endovascular Peripheral Interventions*, 81 (C.D. Owens & Y. Yeghiazarians eds., Springer 2012) (“[c]ompliant balloon[s] will increase their diameter with increasing pressure. They are typically made of silicone and thermoplastic elastomers, polyethylene, or polyolefin polymers.”) (Ex-1015-101). Furthermore, Sanati

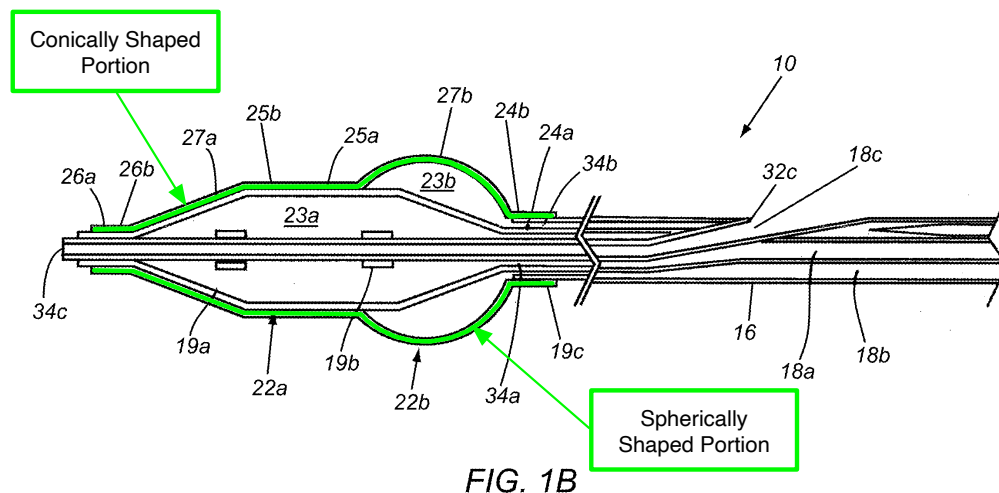
explains that this balloon configuration can be advantageously used to deliver therapeutic agents to a patient. Sanati, 9:1-8 (Ex-1007).

B. Claim 3

3. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion.

123. Sanati discloses this claim. Claim 3 depends from claim 1, which is obvious in view of the Fogarty and Chengod references.

124. Claim 3 adds the requirement that the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion. Sanati teaches a balloon having this configuration in Figure 1B (Ex-1007):



I have highlighted balloon 22b to clarify where this balloon is shown in Figure 1B.

Sanati refers to this as the “outer balloon 22b” and explains that it has a “substantially spherical” shape for the proximal section 27b and a “substantially uniform, smaller diameter shape” for the distal section 25b. Sanati, 7:54-65 (Ex-

1007). As shown in the figure, the most distal portion of the outer balloon 22b follows the shape of transition portion section 27a of the inner balloon 22a, which is described as being “tapered.” Sanati, 8:55-57 (Ex-1007).

125. A PHOSITA would recognize that the outer balloon 22b has a tapered portion which will form a three-dimensional conical shaped distal end. This conically shaped portion is facing the “substantially spherical” shaped portion 27b of the same balloon. As such, this outer balloon 22b teaches all elements added by claim 3. Furthermore, Sanati explains that this shape can be achieved in a balloon constructed of a substantially elastic material, such as silicone (e.g., a compliant material). Sanati, 7:35-47 (Ex-1007).

C. Claim 4

4. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing another conically shaped portion.

126. Sanati discloses this claim. Claim 4 depends from claim 1, which is obvious in view of the Fogarty and Chengod references.

127. Claim 4 adds the requirement that the occlusion balloon comprises a conically shaped portion facing another conically shaped portion. The Sanati reference discloses an inner balloon 22a of this same shape and further describes it as a “standard balloon” (Ex-1007).

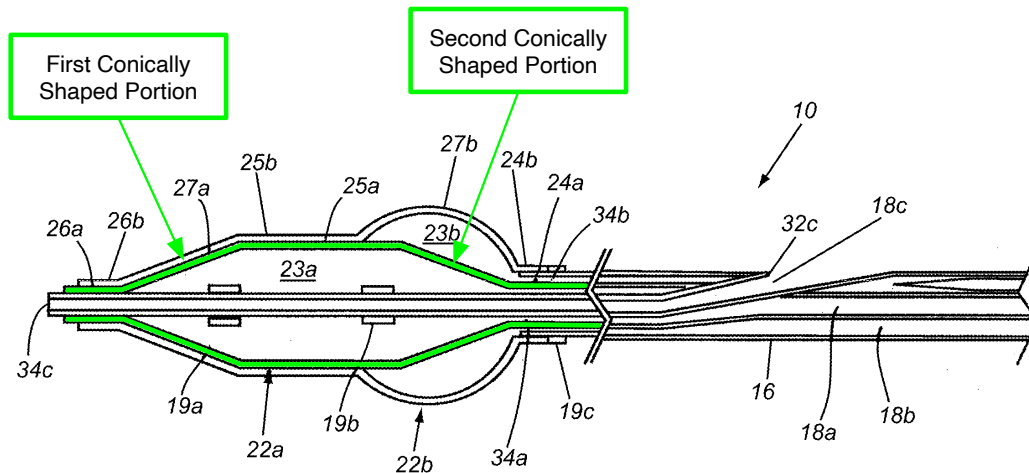


FIG. 1B

I have highlighted balloon 22a to clarify where this balloon is shown in Figure 1B.

128. This inner balloon 22a has the tapered portion 27a at its distal end that will form a first conically shaped portion. The proximal end of this inner balloon 22a is shown with another taper, and a PHOSITA would recognize that this would form a second conically shaped portion facing the first. Thus, the inner balloon 22a forms a balloon having the same configuration as that claimed in claim 4 of the '737 Patent. As was the case with the outer balloon 22b, the inner balloon 22a of Sanati is described as capable of being constructed out of a substantially elastic material, such as silicone (e.g., a compliant material). Sanati, 7:35-47 (Ex-1007).

D. Claim 5

5. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion.

129. Sanati discloses this claim. Claim 5 depends from claim 1, which is obvious in view of the Fogarty and Chengod references. Claim 5 is similar to claim 4, but it adds an intervening generally cylindrical portion to the two conically shaped portions. This again is the same configuration as the inner balloon 22a of Sanati (Ex-1007):

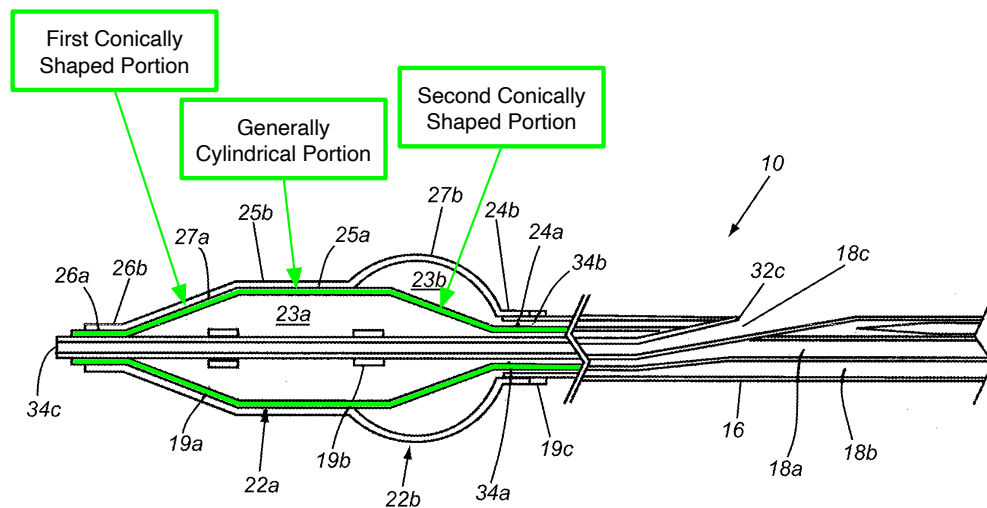


FIG. 1B

130. As explained above, the inner balloon 22a has a first conically shaped portion facing a second conically shaped portion. In between these two portions is a “main section 25a” that has “a substantially uniform diameter.” Sanati, 8:50-53 (Ex-1007). This uniformity is shown in Figure 1B, and a PHOSITA would

recognize that this drawing is showing a generally cylindrical portion. Sanati confirms that this is an accurate understanding of Figure 1B, as he describes this inner balloon as having “a substantially cylindrical shape”. Sanati, 8:44-49 (Ex-1007). Thus, the inner balloon 22a forms a balloon with a first conically shaped portion, a second conically shaped portion, and an intervening generally cylindrical portion, which is the same configuration claimed in claim 5 of the '737 Patent.

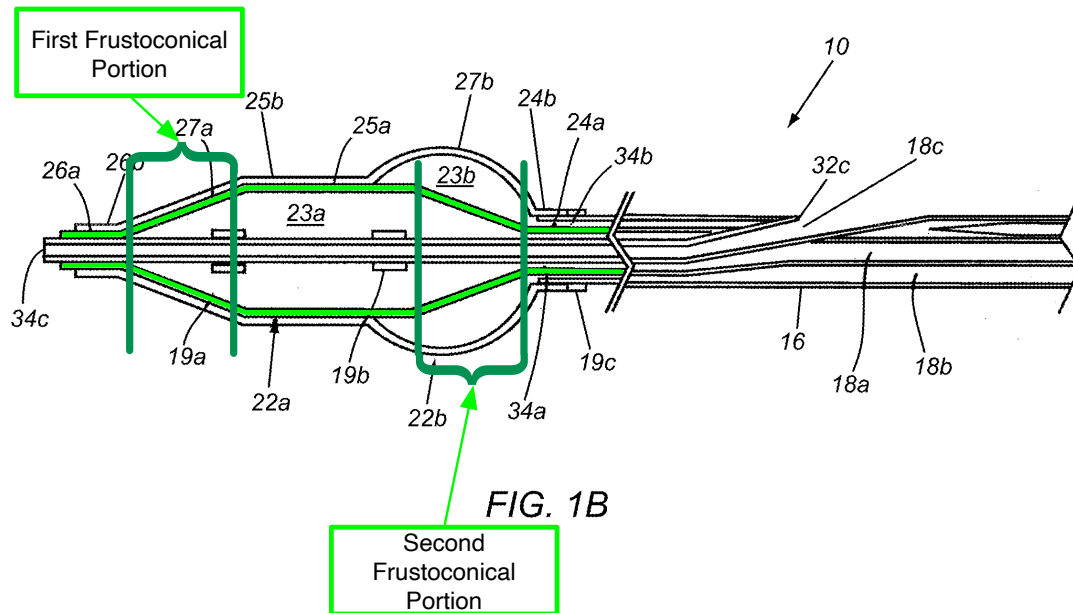
E. Claim 9

9. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises at least two oppositely oriented frustoconical portions.

131. Sanati discloses this claim. Claim 9 depends from claim 1, which is obvious in view of the Fogarty and Chengod references.

132. Claim 9 is similar to claim 4, except that while claim 4 requires two “conically shaped” portions facing each other, claim 9 requires two oppositely oriented “frustoconical portions.” The term “frustoconical” is not a term of art in the medical profession (nor to a PHOSITA). I understand the term frustoconical describes a conical shape that stops short of reaching a single apex point (i.e., it is truncated before the apex of the cone). As a pure conical portion is impractical for a balloon since it would require the conical portion to come to a single point in geometric space (the apex of the cone), balloon portions described as conical but that actually stop short of reaching a single apex point would qualify as frustoconical. Thus, the inner balloon 22a of Figure 1B of Sanati teaches two

oppositely oriented frustoconical portions. The conical sections are actually frustoconical because the catheter running through the ends of the balloon results in truncation of the cone (i.e., there is no apex) (Ex-1007):



F. Motivation to Combine Sanati with Fogarty and Chengod

133. The motivation to combine the Fogarty reference with Chengod's teaching of the Fogarty catheter was described above in connection with Ground 1. Both of these references describe the Fogarty catheter, which, as explained above, is a compliant balloon has been used for occlusion procedures for many decades. The Sanati reference describes a particular configuration for another compliant balloon catheter. Sanati, 7:39-47 ("[O]ne or both balloons 22, e.g., outer balloon 22b, may be formed from substantially elastic material, e.g., silicone, polyurethane, or polyethylene, such that the balloon 22 may be expanded to a variety of sizes depending upon the volume and/or pressure of fluid within the interior.") (Ex-

1007). A PHOSITA would recognize that both the Fogarty catheter (described in the Fogarty and Chengod references) and the catheter of the Sanati reference utilize compliant balloons that can be used for occlusion catheters, e.g., for blood flow occlusion of the lumens of the vascular system.

134. A PHOSITA with knowledge of the Sanati and Fogarty references would know to use the shape of the balloons shown in Sanati as one of the possible shapes for the balloon used in the Fogarty reference (as modified by Chengod and the PHOSITA's knowledge). As I discuss above, the variation in human anatomy shape, size, and course leads to a PHOSITA's understanding that in order to occlude a vessel, various balloon shapes and sizes will be required. Sanati is another iteration of an asymmetric balloon using a different mechanism of creating asymmetry a PHOSITA may use for balloon inflation. Sanati's balloon configuration was a known technique that had been used to improve balloon catheters at the time of the '737 Patent. While Sanati does not call its catheter a "Fogarty catheter," a PHOSITA would consider it to be a similar device. Thus, claims 3-5 and 9 of the '737 Patent simply apply a known technique (Sanati's compliant balloon shapes) that had been used to improve a similar device to the Fogarty balloon catheter in a similar way. Furthermore, Sanati teaches that using the disclosed double balloon configuration and shapes allows the operator to "substantially anchor the distal end" of the catheter during the procedure. Sanati, 13:6-10 (Ex-1007). Thus, a PHOSITA would have recognized that anchoring the distal end of the balloon

catheter was a reason to apply the teaching of Sanati to the Fogarty catheter described in Fogarty and Chengod. Moreover, a PHOSITA would have a reasonable expectation of success in using Sanati's balloon configuration at least because Sanati discloses its balloon is used for a 1.7mm catheter, which is about a 5.1 French size. (A basic French/mm conversion is that 3 French = 1 mm.) Hence, claims 3-5 and 9 would be obvious to one of ordinary skill.

XI. Invalidity Ground 4: Claim 8 is Obvious in View of the Fogarty, Chengod, and Deaton References and a PHOSITA's Knowledge.

135. For the reasons discussed below, it is my opinion that claim 8 of the '737 Patent is obvious in view of the Fogarty, Chengod, and Deaton references and a PHOSITA's knowledge.

A. Description of the Deaton Reference (Ex-1008)

136. The Deaton Reference is publication that appeared as an insert to Endovascular Today in July of 2005. The insert is an article entitled "Image-Guided Thrombectomy in Vascular Surgery," and was written by Dr. David H. Deaton (Ex-1008). This article describes the "Fogarty Thru-Lumen Embolectomy Catheter." The article explains that the standard Fogarty balloon catheter has become a standard since 1963. The development of "over-the-wire-based" catheter techniques led to the development of this new, over-the-wire version of the Fogarty balloon catheter. Deaton explains that this catheter utilizes "[s]tainless steel bushings

located at the proximal and distal ends of the balloon enable accurate visualization under fluoroscopy.” Deaton, p. 32 (Ex-1008).

B. Claim 8

8. The occlusion catheter system of claim 1, further comprising a proximal radio opaque marker proximate a proximal end of the occlusion balloon and a distal radio opaque marker proximate a distal end of the occlusion balloon.

137. Deaton discloses this claim. Claim 8 depends from claim 1, which is obvious in view of the Fogarty and Chengod references.

138. Claim 8 adds that the presence of two radio opaque markers, one at the proximal end of the occlusion balloon and one at the distal end of the occlusion balloon. Deaton teaches that, at least as early as July 2005, the version of the Fogarty catheter was commercially available that included “[s]tainless steel bushings located at the proximal and distal ends of the balloon [to] enable accurate visualization under fluoroscopy.” Deaton, p. 32 (Ex-1008). As discussed above in Section VII.C, a PHOSITA would recognize that stainless steel bushings are a form of radio opaque markers, which is why they enable visualization under fluoroscopy. Thus, the Deaton reference shows a proximal radio opaque marker proximate a proximal end of an occlusion balloon and a distal radio opaque marker proximate a distal end of an occlusion balloon.

C. Motivation to Combine Deaton with Fogarty and Chengod

139. The motivation to combine the Fogarty reference with Chengod's teaching of the Fogarty catheter was described above in connection with Ground 1.

140. Deaton provides express motivation to combine its markers with the Fogarty patent because Deaton discloses a Fogarty catheter with the markings required by Claim 8 of the '737 Patent. The Fogarty reference is one of the first patents issued on the catheter design of Thomas Fogarty, based on a patent application filed in 1965. As explained above, the Fogarty catheter was a very early balloon catheter that could be used for vascular occlusion. Nonetheless, the Fogarty catheter was used for occlusion procedures for many decades thereafter, and is still used today. The Deaton reference specifically mentions this history and explains that the catheter described in this article is the "latest iteration" of the Fogarty balloon catheter. Deaton, p. 32 (Ex-1008). Thus, the Deaton reference itself explains that the changes made are merely a new iteration of the catheter described in the Fogarty reference. In other words, not only is there a motivation to combine the elements, but Deaton also shows an actual real-life combination in the form of a new iteration of the Fogarty catheter.

141. Even if Deaton were not describing the latest iteration of the Fogarty catheter, it would have been obvious to combine the teachings of Deaton and Fogarty. The catheter in the Deaton reference is described as incorporating "the same compliant, concentric balloon technology and catheter as the standard Fogarty

Catheter.” Deaton, p. 32. Thus, Deaton explicitly states that it is using the same basic compliant balloon technology that is being used in the Fogarty and Chengod reference. Adding the radiopaque markers of Deaton to the Fogarty catheter described in the Fogarty and Chengod references would increase the usability of those catheters when attempting to locate the balloon under fluoroscopy, as Deaton explains. Thus, Deaton expressly recognized a reason to combine known elements (a Fogarty catheter as in Fogarty and Chengod with the radiopaque markers of Deaton) in the manner described in the claim 8 of the ’737 Patent. As explained above in Section VII.D, a PHOSTIA would require the presence of such markers in a balloon catheter if it was ever to be used in an image-guided clinical setting. Thus, the addition of the markers of Deaton to the catheter of the Fogarty reference (as modified by Chengod and a PHOSITA’s knowledge) would allow the catheter to be used in an image-guided clinical setting.

XII. Invalidity Ground 5: Claims 1-10 are Obvious in View of the Eliason Reference and a PHOSITA’s Knowledge

142. For the reasons discussed below, it is my opinion that claims 1-10 of the ’737 Patent is obvious in view of the Fogarty, Chengod, and Deaton references and a PHOSITA’s knowledge.

A. Description of the Eliason Reference (Ex-1009)

143. The Eliason reference is U.S. Patent No. 9,131,874, issued to Jonathan L. Eliason and Todd E. Rasmussen on September 15, 2015 (Ex-1009). The

Eliason reference was based on a PCT application, namely PCT/US2011/033368, which was filed on April 21, 2011. I understand the Eliason patent is prior art to the '737 Patent.

144. The Eliason reference describes a new “Fluoroscopy-independent, endovascular aortic occlusion system.” Based on the Field of the Disclosure in the Eliason reference, it is clear that this reference is describing an occlusion balloon catheter that is specially designed for performing REBOA. This occlusion catheter is designed to be fixed to a wire (12) that provides rigidity to the catheter. Eliason, 9:43-49 (Ex-1009). The wire (12) passes from the distal end of the catheter distal to the balloon (14), through the shaft (32) and into the hub, where it is secured by diaphragm (40). The wire and the rest of the balloon catheter are to be inserted as a single unit or device. Eliason, 6:5-7 (Ex-1009). The catheter described in the Eliason patent differs from the catheter described in the '737 Patent in the addition of self-expanding wire struts (element 22 in Figure 10, below) in the Eliason patent. These struts are located distal to the balloon, and are designed to keep the catheter centered in the vasculature.

B. Claim 1

1. An occlusion catheter system comprising:

145. Eliason discloses this element. The title of the Eliason reference, “Fluoroscopy-independent, endovascular aortic occlusion system,” shows that the

reference discloses an occlusion catheter system. Eliason, cover page. This is also seen in Figure 10 (Ex-1009):

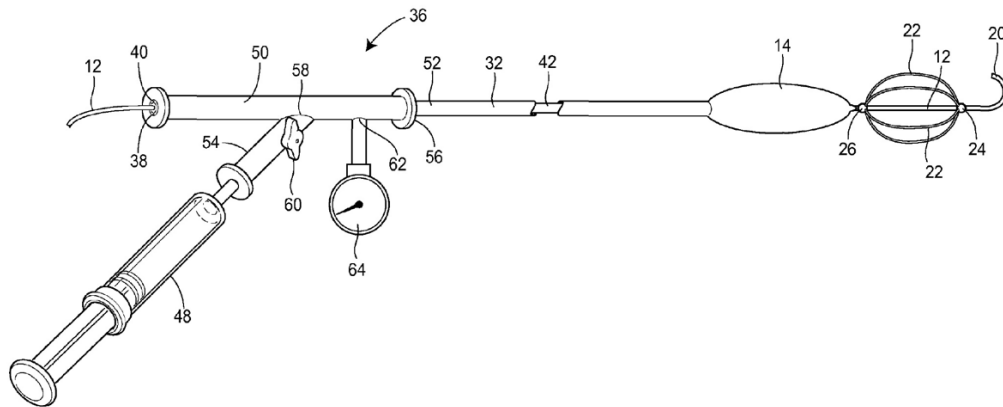


FIG. 10

a proximal hub;

146. Eliason discloses this element. The proximal hub in the Eliason catheter is shown in Figure 10 as element 36, which Eliason calls the “multi-port and valve assembly.” Eliason, 10:7-9 (Ex-1009). This assembly remains outside the body during use and is used to physically connect the inflation device (syringe) to the inflation lumen of the catheter.

a flow valve configured to selectively fluidly communicate the proximal hub with an inflation device

147. Eliason discloses this element. The inflation device in the Eliason reference is the syringe (48) that is attached to the hub (36). Eliason, 10:33-36 (Ex-1009). Eliason utilizes a valve (60) that is “actuatable between an open condition...and a closed position” to permit or prevent the passage of inflation fluid.

Eliason, 10:36-40. The syringe (48) and the valve (60) can be seen in Figure 10 (Ex-1009).

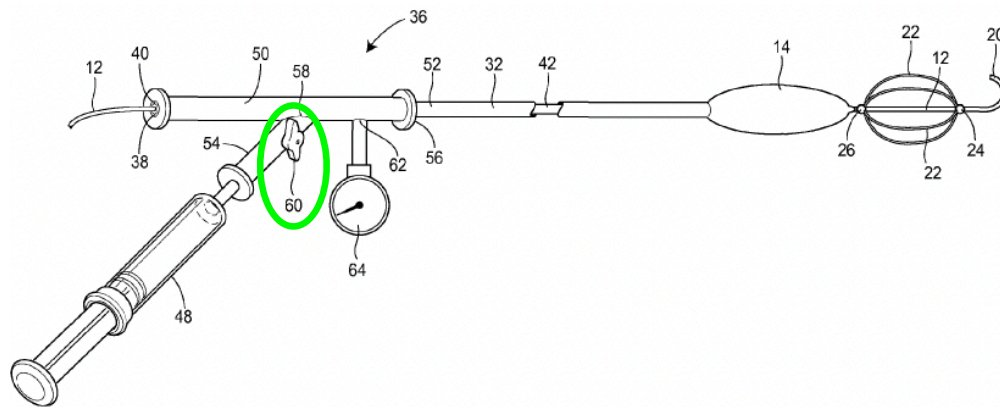


FIG. 10

Since the valve (60) moves between the open condition and the closed position, it is configured to selectively fluidly communicate the proximal hub with the inflation device.

a proximal catheter section in fluid communication with the proximal hub;

148. Eliason discloses this element. The proximal end (52) of the balloon shaft (32) is attached to the hub (36), as shown in Figure 10 and described at Eliason, 10:17-20 (Ex-1009). Eliason explains that the hub (36) is “in fluid communication” with both the proximal end of the balloon shaft (32) (proximal catheter section) and the syringe (48). Eliason, 11:33-36 (Ex-1009).

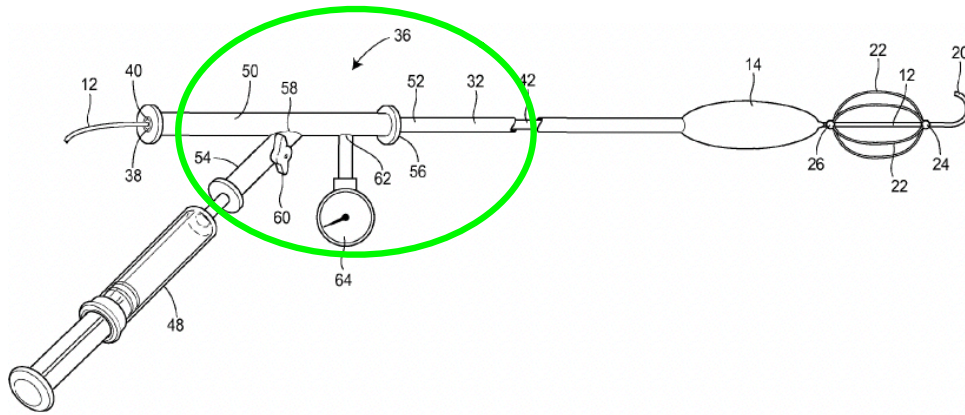


FIG. 10

a distal catheter section distally terminating with an atraumatic tip;

149. Eliason discloses this element. The distal end of the catheter terminates with a “J tip” (20), which is “used to minimize trauma to or perforation of the arterial vessels” during use of the catheter. Eliason, 8:47-49 (Ex-1009). Thus, the catheter has a distal section (including the portions with the J tip and the wire struts) terminating with an atraumatic tip. This is best seen in both Figure 10 above and Figure 6 (Ex-1009):

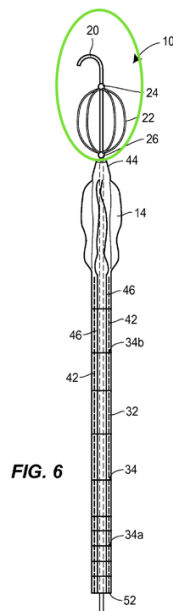


FIG. 6

an intervening occlusion balloon connecting the proximal catheter section with the distal catheter section, the occlusion balloon being compliant;

150. Eliason discloses this element. The Eliason reference describes its balloon as an “aortic occlusion balloon” (14). Eliason, 9:31-33 (Ex-1009). As can be seen in both Figures 6 and 10, this balloon (14) connects the proximal section (32) of the catheter with the distal section of the catheter.

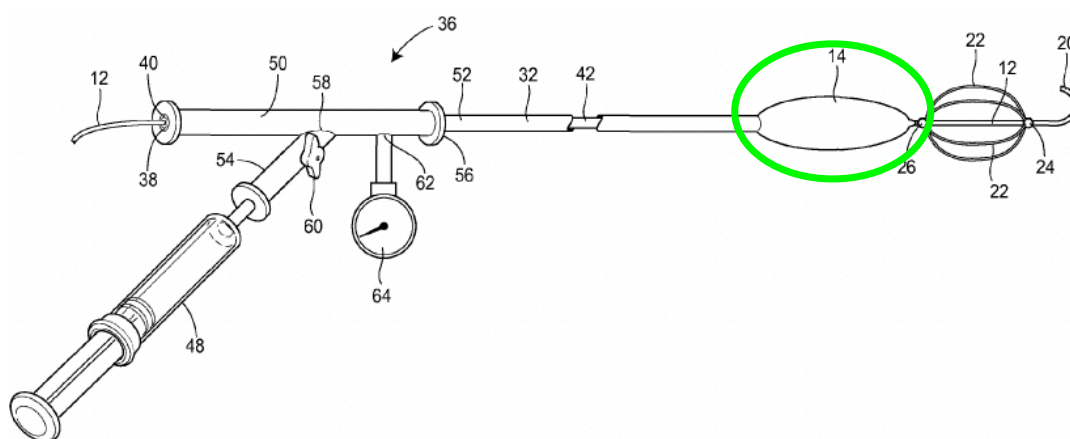


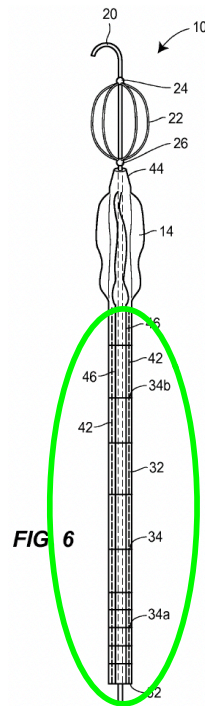
FIG. 10

Furthermore, Eliason describes this balloon (14) as “sufficiently compliant.” Eliason, 4:54-61 (Ex-1009). Thus, Eliason teaches this element of claim 1.

at least one length marking on an exterior of the proximal catheter section to indicate an insertion depth of the occlusion catheter system;

151. Eliason discloses this element. The length markings on the Eliason catheter are described as “pre-calibrated length indicia,” and they include both “minor length markers” (34a) and “major length markers” (34b) in 5-centimeter increments. Eliason, 9:31-35 (Ex-1009). These markers are found on the

exterior of the proximal section of the balloon shaft (32), as is best shown in Figure 6 (Ex-1009):



With these length markers, a physician can use a correlation chart or “nomogram” in order to properly position the aortic occlusion balloon at the desired location within the thoracic aorta. Eliason, 10:53-64 (Ex-1009). Thus, Eliason expressly discloses the length markers as indicating insertion depth of the catheter.

a lumen extending from the proximal hub through the proximal catheter section and into fluid communication with the occlusion balloon;

152. Eliason discloses this element. The Eliason reference teaches that a lumen is used to expand and deflate the balloon, and this lumen extends from the fluid source, namely the syringe (48), to the balloon (14). Eliason, 5:64-6:1 (Ex-

1009). To extend from the syringe to the balloon, this lumen must extend through the hub (36) and the proximal catheter section.

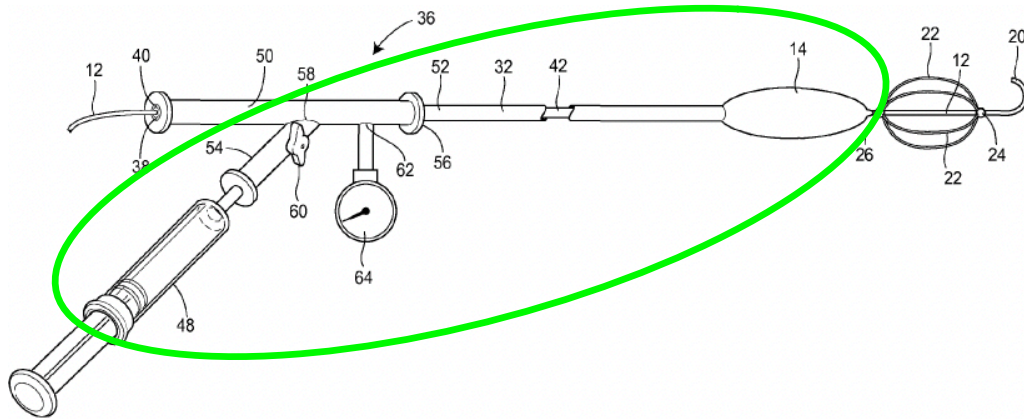


FIG. 10

a solid wire, secured at a proximal-most end thereof within the proximal hub, and extending within the proximal catheter section, the occlusion balloon and into the distal catheter section; and

153. Eliason teaches this element. The Eliason catheter uses an “endovascular wire” (12) that extends from the proximal hub (50), through the proximal catheter section (32), the occlusion balloon, and the distal catheter section. This is best seen in Figure 10 (Ex-1009):

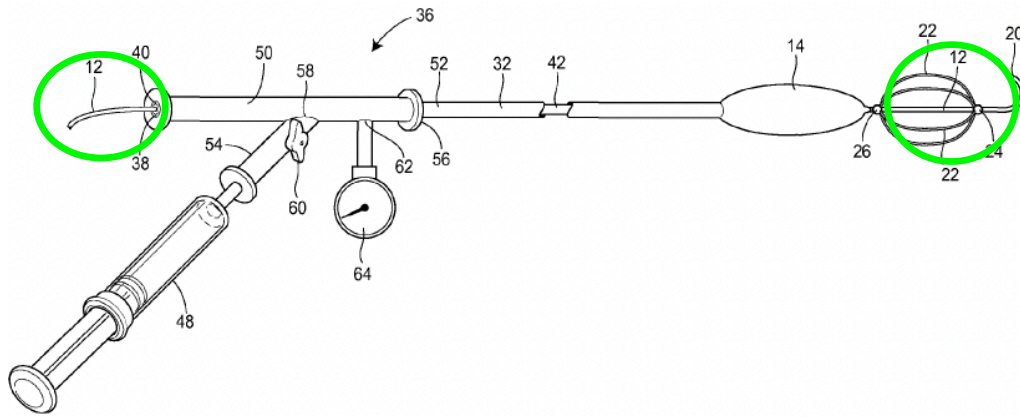


FIG. 10

The wire (12) provides rigidity to the catheter. Eliason, 9:43-49 (“The balloon shaft 32 will remain over the self-centering endovascular wire 12 during occlusion balloon inflation to provide a rigidity that is sufficient to permit the balloon to be manually maintained at a desired location within the thoracic aorta 47 (FIG. 1), resisting distal or caudal migration, such as might otherwise result from aortic pulsation”) (Ex-1009). Even though Eliason does not explicitly state that the wire (12) is solid, a PHOSITA understands that a wire that provides rigidity to the catheter would be solid and not hollow. I discussed this PHOSITA’s knowledge (solid wire) in Ground 1 above (i.e., for the same element of claim 1).

154. In some embodiments, the endovascular wire can move separately from the remainder of the catheter through a lumen. In other embodiments (“pre-securing embodiments”), however, “[t]he self-centering wire and the occlusion balloon may be inserted as a single unit or device.” Eliason, 6:5-7 (Ex-1009). In these embodiments, the wire 12 is secured to the remainder of the

catheter in two locations. One of these locations is at the trailing securement bead, which is shown as element 26 in Figure 10 (Ex-1009).

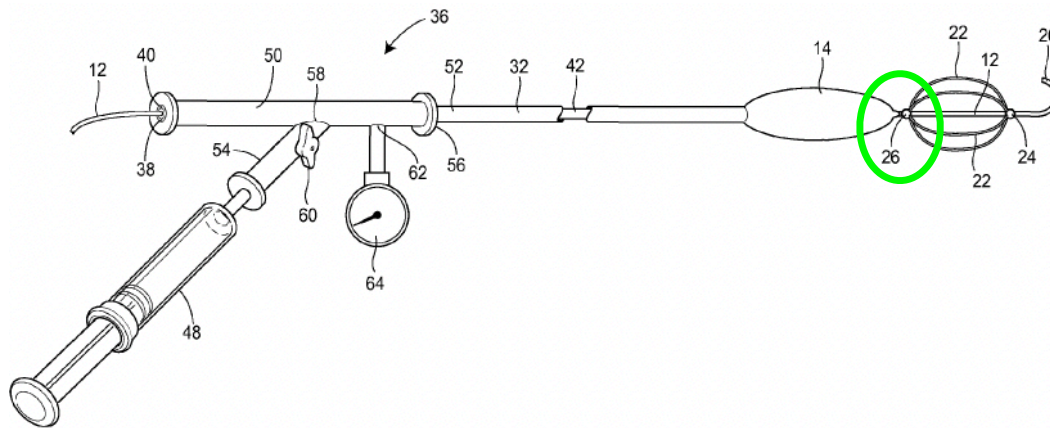


FIG. 10

As explained in claim 6 of Eliason, a method of use can include “pre-securing the balloon shaft to the endovascular wire proximate a trailing securement bead, allowing the balloon shaft and endovascular wire to be inserted in the patient and delivered as a single unit.” Eliason, 16:41-45 (claim 6) (Ex-1009). Eliason claim 6 depends from claim 4, which indicates the “pre-securing” method may be performed when “selectively inflating a thoracic aortic balloon” by comparing a pre-measured “distance between the at least two external anatomical landmarks of the patient to a prediction model and calculating a length to which a calibrated endovascular wire and a balloon shaft of the thoracic occlusion system are to be inserted in the patient.” Eliason, 16:18-38 (claim 4) (Ex-1009). According to this method, the catheter can be inserted “independent of fluoroscopy.” Eliason, 16:18-38 (claim 4) (Ex-1009). This “pre-securing” method was described in the published version of the PCT application (PCT/US2011/033368), which was published on October 27,

2011. Eliason PCT Application, cover page (Ex-1012). In particular, the “pre-securing” method was described in published claims 8, 56, and 57 (Ex-1012).

155. The endovascular wire (12) is also secured at the hub (36) at diaphragm (40), which ensures a “fluid-tight” connection between the hub (36) and the aortic balloon (14) (Ex-1009).

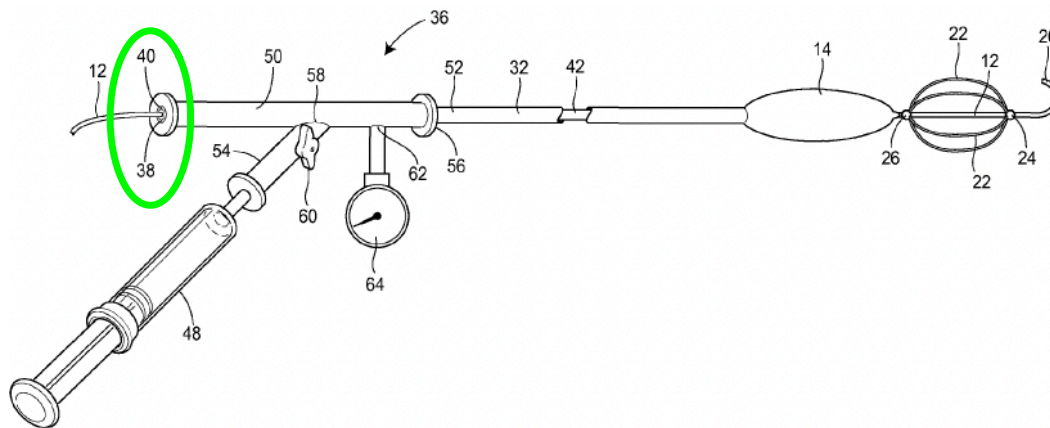


FIG. 10

Eliason, 10:12-17 (Ex-1009). Although the endovascular wire 12 can “extend” through the diaphragm 40, a PHOSITA understands that there is no need for the wire (12) to extend any significant distance beyond the diaphragm (40). This is possible because the diaphragm maintains that “fluid-tight connection, thereby avoiding leakage of bodily fluid through the first port 38.” Eliason, 12:29-32 (Ex-1009). Furthermore, where the wire (12) is secured at the hub (36) through diaphragm (40) and secured at the trailing securement bead (26), the wire (12) does not move with respect to the rest of the catheter. It is, in the words of Eliason, used as a “single unit or device.” Eliason, 6:5-7 (Ex-1009).

156. The “connection” (as described by Eliason at 10:29-32 (Ex-1009)) made by the diaphragm (40) and the wire (12) secures the proximal-most end (the end furthest from the patient when in use) within the interior of the hub (36). A PHOSITA understands the solid wire is “secured” to the proximal hub when it is attached so that it can withstand normal operating conditions and perform the preferred functions of the catheter. Eliason, 6:5-7 (Ex-1009). One such preferred function is “provid[ing] a rigidity ... [that] resists distal or caudal migration...” Eliason, 9:43-49 (Ex-1009). Figure 10 shows the diaphragm (40) securing the endovascular wire (12) at the proximal most end of the wire within the proximal hub (36), and therefore Eliason shows these elements of claim 1.

157. To the extent Patent Owner argues the connection between the diaphragm and the wire does not secure the proximal-most end of the wire to the proximal hub, a PHOSITA would have found it obvious to modify Eliason’s balloon catheter to arrive at this element of the claim. In particular, for the pre-securing embodiments, a PHOSITA understands that there is no need for the wire (12) to extend beyond the proximal hub (multi-port and valve assembly (36)) because the entire balloon catheter is fixed in position on wire 12 so that it can be “inserted as a single unit or device.” Eliason, 6:5-7 (Ex-1009). In contrast, the diaphragm is necessary in other embodiments (i.e., not the pre-securing embodiments) where the wire is first inserted into the patient, and the balloon shaft is later inserted over the wire until it reaches the trailing securement bead (26). Eliason, 9:38-41 (“The

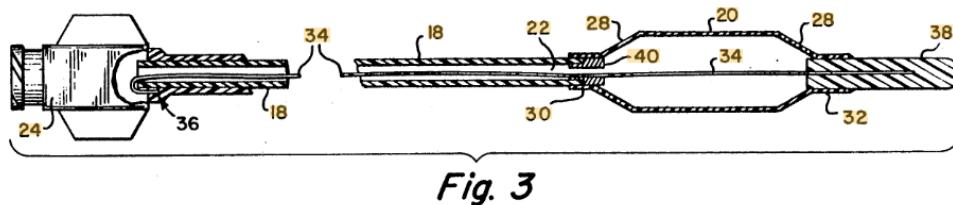
balloon shaft 32 includes a lumen 42 (see also Figs. 10 and 11), permitting the balloon shaft 32 to pass over the endovascular wire 12. A tapered distal end portion 44 of the balloon shaft 32 prevents the balloon shaft 32 from being inserted past the trailing securement bead 26.”) (Ex-1009); Eliason, 11:20-23 (“The kit may further include the occlusion balloon 14 that may be disposed proximally on the balloon shaft 32, and advanced over the endovascular wire 12 until it reaches the trailing securement bead 26.”) (Ex-1009). A PHOSITA understands there will be some amount of wire extending beyond the diaphragm in these other embodiments because the interventionist holds onto the wire while passing the balloon shaft over it. Because there is no need for the extra wire length in the pre-securing embodiments, a PHOSITA would have found it obvious to modify those embodiments to secure the wire to the proximal hub so that the wire does not extend beyond the hub.

158. A PHOSITA would have been motivated to modify Eliason’s pre-securing embodiments in this way because this modification represents known concepts combined in familiar ways, which, when combined, would yield predictable results. Eliason teaches the concept of securing the wire so that it is fixed in place with respect to the proximal hub so that the entire balloon catheter can be “inserted as a single unit or device.” Eliason, 6:5-7 (Ex-1009). By 2015, a PHOSITA was well aware of the concept that the proximal-most end of a wire (e.g., a

stylet or mandrel) could be secured within the proximal hub for a balloon catheter.

This knowledge is documented in the literature, including:

- The Fogarty reference (Ex-1004), as described above for Ground 1, claim 1.
- U.S. Patent No. 5,087,246 to Smith, which issued in 1992 (Ex-1025). Smith includes “elongate wire 34” that is secured by its proximal-most end to the hub (called the “proximal fitting”): “[E]longate wire 34 extends through the lumen 22 of the catheter. The proximal end of the wire 34 is encapsulated within the proximal fitting 24 as indicated somewhat diagrammatically at 36.” Smith, 4:17-23 & Fig. 3 (Ex-1025).



- U.S. Patent No. 8,088,121 to Nishide (filed 2005, issued 2012) (Ex-1017). In its discussion of the prior art, Nishide discloses “a dilation catheter having a stylet allowing improvement in the compression strength of the catheter shaft and the transmission (insertion) efficiency of the force in the axial direction. In this prior art, presence of the stylet leads to improvement in force transmission (insertion) in the axial direction and also in the convenience of operation when the catheter is inserted into the body along the guide wire from outside; but **the catheter has a structure in which the proximal terminal of the stylet terminates at the hub unit** including the proximal

terminal region of catheter shaft[.]”. Nishide, 3:5-14 (emphasis added) (Ex-1017).

159. Consequently, a PHOSITA would have been motivated to modify Eliason’s pre-securing embodiments to secure the proximal-most end of a wire to the hub because this modification represents known concepts (i.e., Eliason’s securing the wire so that it is fixed in place with respect to the hub and the PHOSITA’s knowledge that the proximal-most end of the wire could be secured within the proximal hub) combined in familiar ways (i.e., according to Fogarty, Smith, or Nishide), which, when combined, would yield predictable results (i.e., allowing the catheter to be inserted as a single unit or device). For the same reasons, a PHOSITA would understand that the claim applies a known technique (securing a proximal-most end of a wire within the hub) that had been used to improve similar devices (Fogarty, Smith, and Nishide balloon catheters) in a similar way (to allow insertion of the wire and the balloon shaft at the same time).

160. Additionally, a PHOSITA would find it obvious to modify Eliason’s balloon catheter to arrive at this element of the claim because a PHOSITA could implement a predictable variation (i.e., the variation taught in Fogarty, Smith, and Nishide), and would see the benefit of doing so. As for benefits, a PHOSITA would understand that implementing this variation (i.e., modifying Eliason) would likely result in a less costly device due to (1) requiring less metal (i.e., the metal wire would no longer extend past the hub) and (2) no longer requiring the diaphragm. An

additional benefit would likely be the simplification of manufacturing the device since Eliason's "fluid-tight" diaphragm connection would no longer be necessary. Eliason, 12:29-32 (Ex-1009). Additionally, a PHOSITA would understand that securing the proximal-most end of the wire within the hub as described in Fogarty, Smith, and Nishide would result in a balloon catheter design with the desired rigidity but without the excess wire hanging from the proximal end of the hub. Eliason, 9:43-49 ("The balloon shaft 32 will remain over the self-centering endovascular wire 12 during occlusion balloon inflation to provide a rigidity ... [that] resists distal or caudal migration...") (Ex-1009).

the proximal catheter section, the occlusion balloon and the distal catheter section having a greatest outer diameter of less than 6 Fr in an uninflated configuration.

161. Eliason discloses this element. Eliason explains that the various elements of the catheter, including the leading securement bead (24), the trailing securement bead (26), and the unexpanded occlusion balloon (14) are all of sufficiently small cross-sectional dimensions to pass through a sheath (28), which is preferably a six French sheath. Eliason, 9:12-27 (Ex-1009). Because the unexpanded occlusion balloon must advance through the sheath along with the balloon shaft (32), a PHOSITA would recognize that all of these elements have an outer diameter of less than six French if they are to pass through the sheath (28).

C. Claim 2

2. The occlusion catheter system of claim 1, wherein the occlusion balloon is asymmetrical.

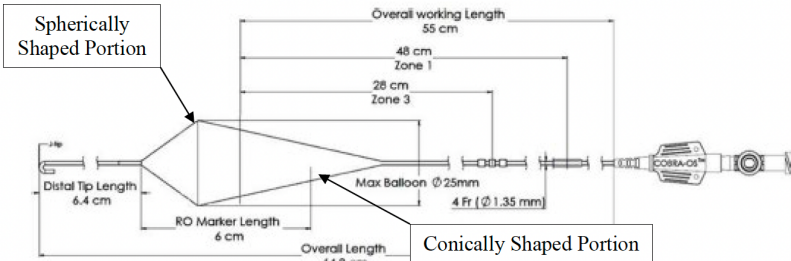
162. Eliason teaches this claim which is known to a PHOSITA. Claim 2 depends from claim 1, which is obvious in view of the Eliason reference and the PHOSITA's knowledge. As explained above in Section VII.D, a PHOSITA is well aware that compliant balloons such as the type described in Eliason could be designed to inflate asymmetrically. Since this is the only additional element added by claim 2, this claim is also obvious in view of Eliason and the PHOSITA's knowledge.

D. Claim 3

3. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion.

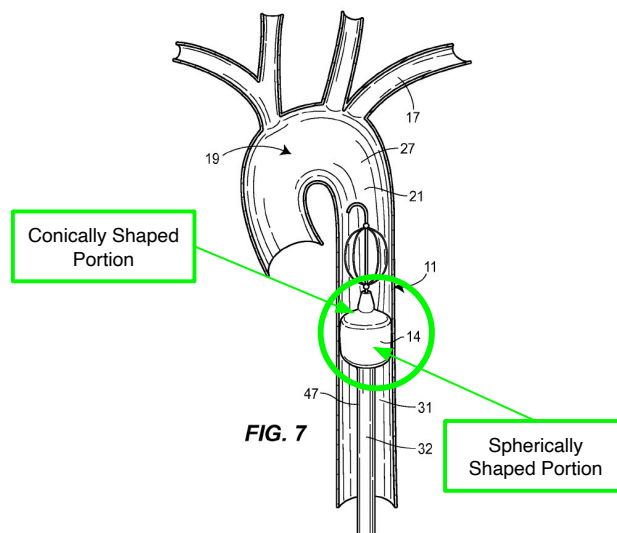
163. Eliason discloses and teaches this claim which is known to a PHOSITA. Claim 3 depends from claim 1, which is obvious in view of the Eliason reference and the PHOSITA's knowledge. Claim 3 adds the requirement that the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion.

164. As discussed above, Prytime alleges that a conical balloon with a circular cross section satisfies the limitation in claim 3 of the '737 Patent that requires a "spherically shaped portion":

<p>3. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion.</p>	<p>Trauma Surgery & Acute Care Open article titled “Size matters: first-in-human study of a novel 4 French REBOA device”, first published on January 8, 2021: Fig. 1</p>  <p>The drawing shows a catheter with a distal tip, a conically shaped portion, and a spherically shaped portion. Dimensions include: Distal Tip Length 6.4 cm, Overall Length 64.9 cm, Overall working Length 55 cm, Zone 1 48 cm, Zone 3 28 cm, RO Marker Length 6 cm, Max Balloon ϕ 25mm, and 4 Fr (ϕ 1.35 mm). Labels point to the Spherically Shaped Portion and the Conically Shaped Portion.</p>
---	--

Ex-1023, p. 13.

165. Based on the patent owner’s apparent understanding of the claim, Figures 7 and 11 of Eliason show the elements of claim 3, namely a conically shaped portion facing a spherically shaped portion. For example, Figure 7 of Eliason shows a particular shape for balloon (14) (Ex-1009):



166. In this figure, the top of the balloon (14) is shown as a conical shape. The center of the balloon has a circular cross section, similar to what Prytime identifies as a “spherically shaped portion.” The remainder of the balloon (14) is partially hidden because of the perspective of the drawing, but Figure 11 suggests a

similar profile to what Prytime identifies as “a conically shaped portion facing a spherically shaped portion”:

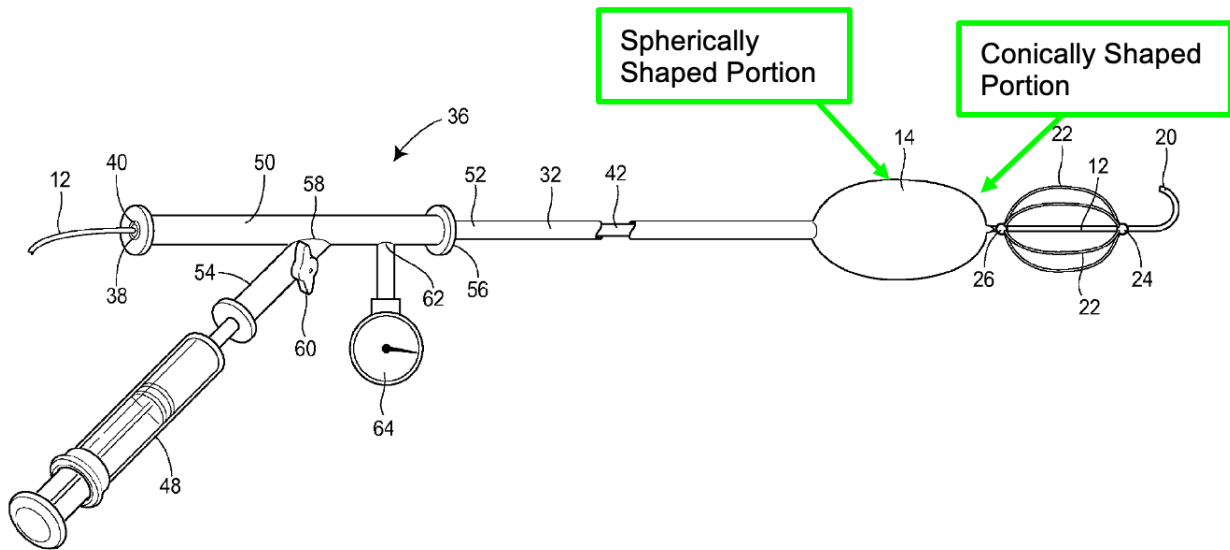


FIG. 11

167. To the extent it is argued Eliason does not disclose the balloon shape of claim 3, it is obvious based on the PHOSITA’s knowledge. As explained above in Section VII.E, a PHOSITA is well aware that compliant balloons such as the type described in Eliason could be designed to inflate with the shape of claim 3. Since this is the only additional element added by claim 3, this claim is also obvious in view of Eliason and the PHOSITA’s knowledge.

E. Claim 4

4. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing another conically shaped portion.

168. Eliason discloses and teaches this claim. Alternatively, a PHOSITA had knowledge of balloons having this shape. Claim 4 depends from claim 1, which is obvious in view of the Eliason reference and a PHOSITA's knowledge. Claim 4 adds the requirement that the occlusion balloon comprises a conically shaped portion facing another conically shaped portion. As explained in connection with claim 3, Figure 7 of Eliason shows that the top of the balloon (14) has a generally conical shape. A PHOSITA would examine this figure and conclude that the balloon (14) is symmetrical, and the bottom of balloon (14) must therefore also have a similar conical shape. Thus, Eliason shows an occlusion balloon having a conically shaped portion (the top in Figure 7) facing another conically shaped portion (the bottom in Figure 7). This can also be seen in Figures 10 and 11 (Ex-1009):

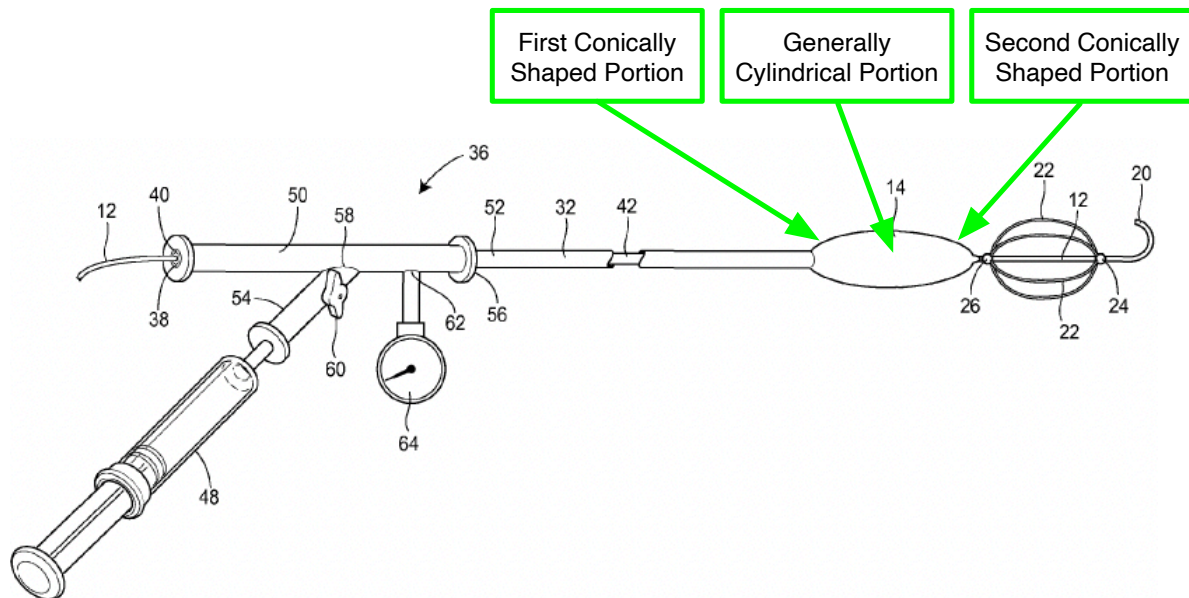


FIG. 10

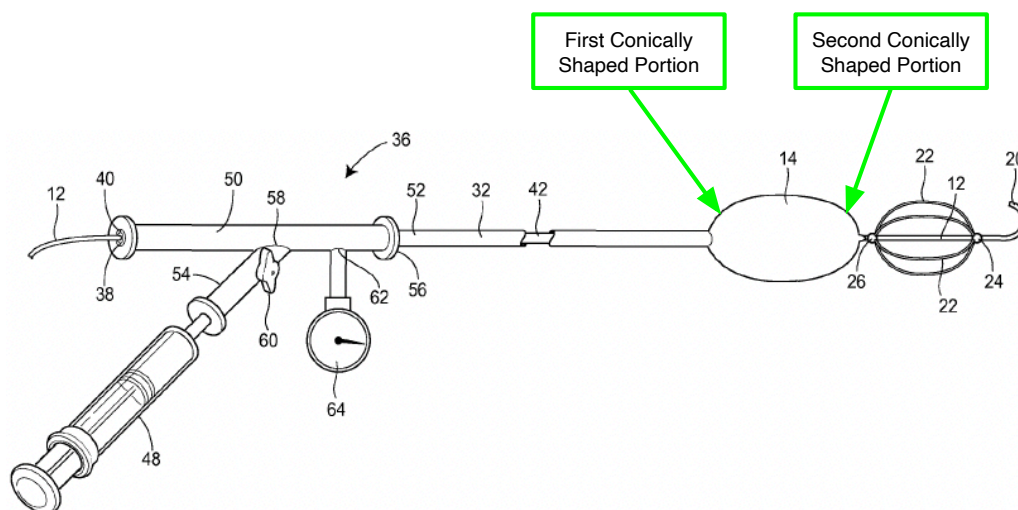


FIG. 11

Figures 7 and 10-11 of Eliason therefore show the elements of claim 4, namely a first conically shaped portion facing another conically shaped portion.

169. To the extent it is argued Eliason does not disclose the balloon shape of claim 4, it is obvious based on the PHOSITA's knowledge. As explained above in Section VII.E, a PHOSITA is well aware that compliant balloons such as the

type described in Eliason could be designed to inflate with the shape of claim 4.

Since this is the only additional element added by claim 4, this claim is also obvious in view of Eliason and the PHOSITA's knowledge.

F. Claim 5

5. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion.

170. Eliason discloses and teaches this claim. Alternatively, a PHOSITA had knowledge of balloons having this shape. Claim 5 depends from claim 1, which is obvious in view of the Eliason reference and the PHOSITA's knowledge. As explained in connection with Claim 4, Eliason also shows two conically shaped portions facing one another. Figure 10 shows that between these two portions of the balloon (14) rests an intervening cylindrical portion (Ex-1009).

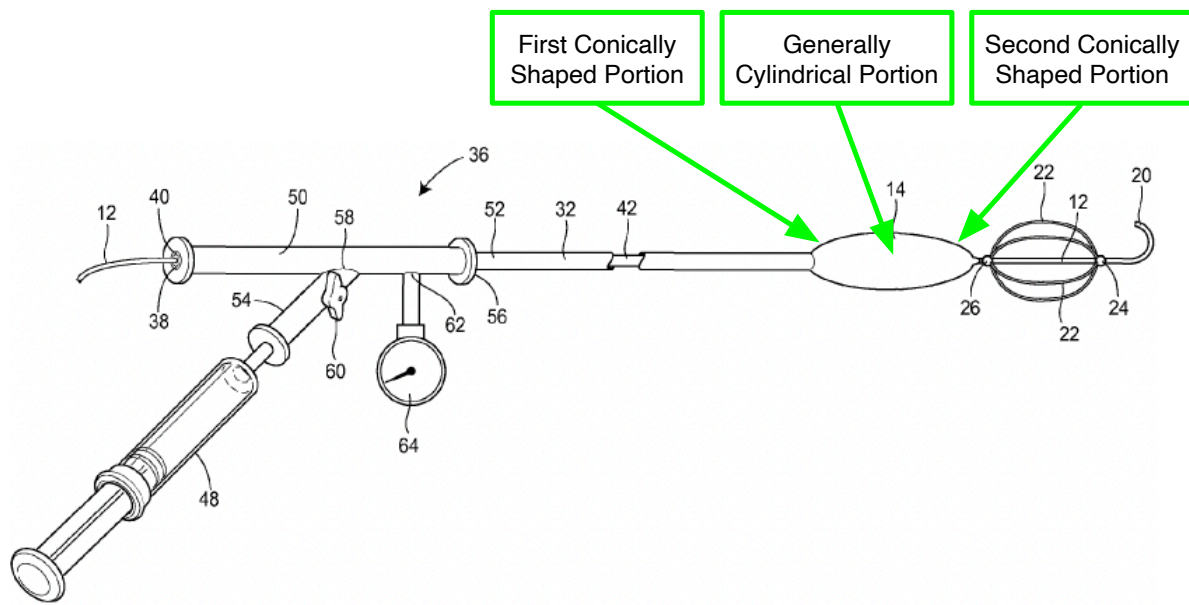


FIG. 10

Figure 10 shows the balloon (14) less inflated than in Figure 11. Thus, the spherically shaped portion shown in Figure 11 is more cylindrically shaped in Figure 10 (although both are cylindrical). Claim 5 specifically requires only a “generally” cylindrical shape. A PHOSITA would recognize that shape of the balloon (14) in Figures 10 and 11 as having a generally cylindrical shape between the two conically shaped portions.

171. To the extent it is argued Eliason does not disclose the balloon shape of claim 5, it is obvious based on the PHOSITA’s knowledge. As explained above in Section VII.E, a PHOSITA is well aware that compliant balloons such as the type described in Eliason could be designed to inflate with the shape of claim 5. Since this is the only additional element added by claim 5, this claim is also obvious in view of Eliason and the PHOSITA’s knowledge.

a. Claims 6 and 7

6. The occlusion catheter system of claim 1, wherein the solid wire is constructed of a metal.

7. The occlusion catheter system of claim 1, wherein the solid wire is constructed of a stainless steel.

172. Eliason teaches these claims. Both claim 6 and claim 7 depend from claim 1 which is obvious in view of the Eliason reference and the PHOSITA’s knowledge. Claim 6 adds that the solid wire is made of a metal, while claim 7 adds that the solid wire is constructed of stainless steel. As explained above, a PHOSITA is

well aware that metal components used in occlusion catheters can be made from stainless steel. In particular, the wire used for rigidity in a balloon catheter can be made from stainless steel. Thus, it would be obvious to construct the endovascular wire (12) of Eliason out of stainless steel.

b. Claim 8

8. The occlusion catheter system of claim 1, further comprising a proximal radio opaque marker proximate a proximal end of the occlusion balloon and a distal radio opaque marker proximate a distal end of the occlusion balloon.

173. A PHOSITA has knowledge of this claim. Claim 8 depends from claim 1, which is obvious in view of the Eliason reference and a PHOSITA's knowledge.

174. Claim 8 adds two radio opaque markers, one at the proximal end of the occlusion balloon and one at the distal end of the occlusion balloon. As explained above in Section VII.C, a PHOSITA is well aware that radio opaque markers are routinely used in balloon catheters, and the position of those markers at either end of the balloon is commonly used to identify the location of the balloon under fluoroscopy. While Eliason is generally designed for fluoroscopy-free procedures, Figure 12 explicitly describes that in "narrow margin procedures," fluoroscopy is required. Eliason, Fig. 12 & 11:50-51 (Ex-1009).

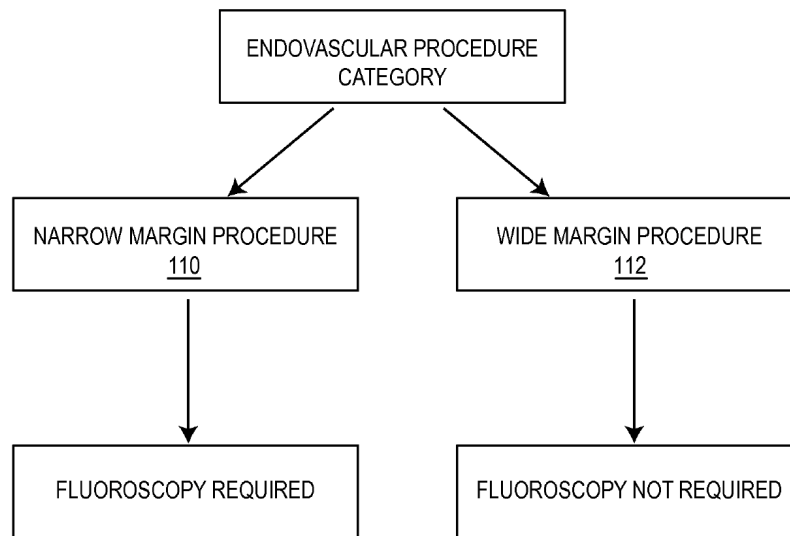


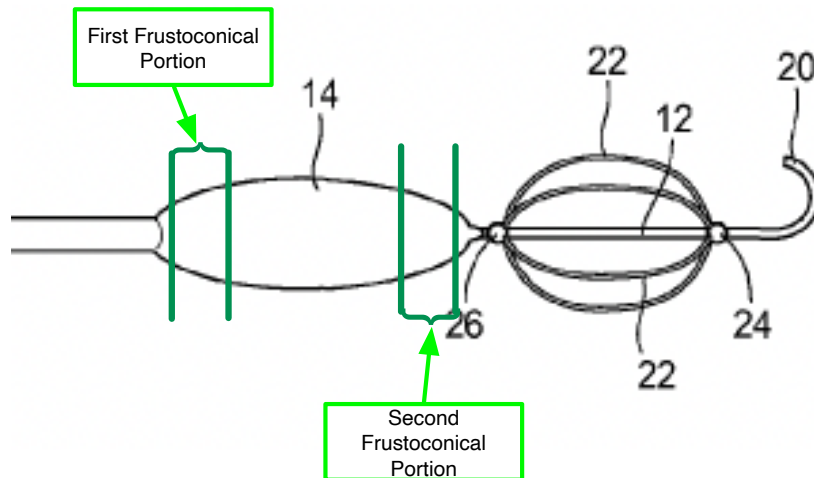
FIG. 12

175. Such narrow margin procedures include endovascular procedures in large axial vessels of the human torso. Eliason, 11:43-61 (Ex-1009). Thus, the addition of the radiopaque markers as well known to a PHOSITA would add the capability to use the device of Eliason in “narrow margin procedures.” A PHOSITA would find it obvious based on this knowledge to further modify the Eliason catheter (as modified based on the PHOSITA’s knowledge) with radio opaque markers as claimed. A PHOSITA understands that including the radio opaque markers would provide a more versatile balloon catheter that could be used for both narrow and wide margin procedures. A PHOSITA further understands that inclusion of the radio opaque markers does not interfere with the effective use of the balloon catheter in the fluoroscopy-free (wide margin procedure) setting.

G. Claim 9

9. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises at least two oppositely oriented frustoconical portions.

176. Eliason discloses and teaches this claim. Alternatively, a PHOSITA had knowledge of balloons having this shape. Claim 9 depends from claim 1, which is obvious in view of the Eliason reference and the PHOSITA's knowledge. Claim 9 is similar to claim 4, except that while claim 4 requires two "conically shaped" portions facing each other, claim 9 requires two oppositely oriented "frustoconical portions." As previously discussed, the term frustoconical describes a conical shape that stops short of reaching a single apex point (i.e., it is truncated before the apex of the cone). As a pure conical portion is impractical for a balloon since it would require the conical portion to come to a single point in geometric space (the apex of the cone), all balloon portions that are described as conical but that actually stop short of reaching a single apex point can also be described as frustoconical. Thus, Figure 10 of Eliason shows two oppositely oriented frustoconical portions. This can be more easily seen in this enlarged portion of Figure 10 (Ex-1009):



177. To the extent it is argued Eliason does not disclose the balloon shape of claim 9, it is obvious based on the PHOSITA's knowledge. As explained above in Section VII.E, a PHOSITA is well aware that compliant balloons such as the type described in Eliason could be designed to inflate with the shape of claim 9. Since this is the only additional element added by claim 9, this claim is also obvious in view of Eliason and the PHOSITA's knowledge.

H. Claim 10

10. An inflation control system kit comprising: the occlusion catheter system of claim 1; and a syringe containing a fluid, the syringe being configured to fluidly connect with an inlet of the proximal hub.

178. Eliason discloses this claim. Claim 10 depends from claim 1, which is obvious in view of the Eliason reference and the PHOSITA's knowledge. As explained above, the Eliason reference teaches the occlusion catheter system of claim 1. The Eliason reference in fact specifically explains that it may be "provided to users in the form of a kit." Eliason, 11:8-14 (Ex-1009). Figure 10 (below) shows that

the balloon catheter of Eliason coupled to a syringe, and Eliason explains that the syringe (48) is connected to the hub (36) through the side port (58) and branch (54) of the hub (36). Eliason, 10:33-36 (Ex-1009).

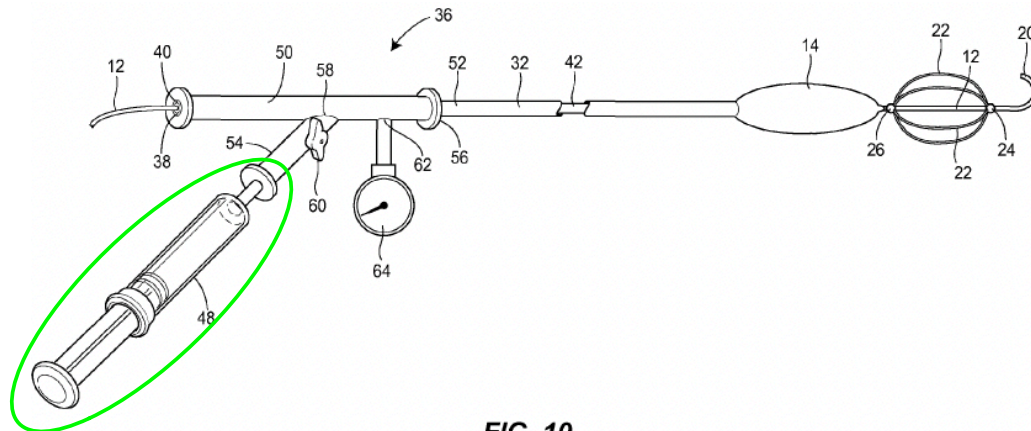


FIG. 10

179. The syringe (48) is filled with inflation fluid that is then introduced into the hub (36). Eliason, 9:67-7:3 (Ex-1009). Thus, Eliason shows all of the elements of claim 10.

XV. Invalidity Ground 6: Claims 1-10 are Obvious in View of the Eliason and Fogarty References and a PHOSITA's Knowledge

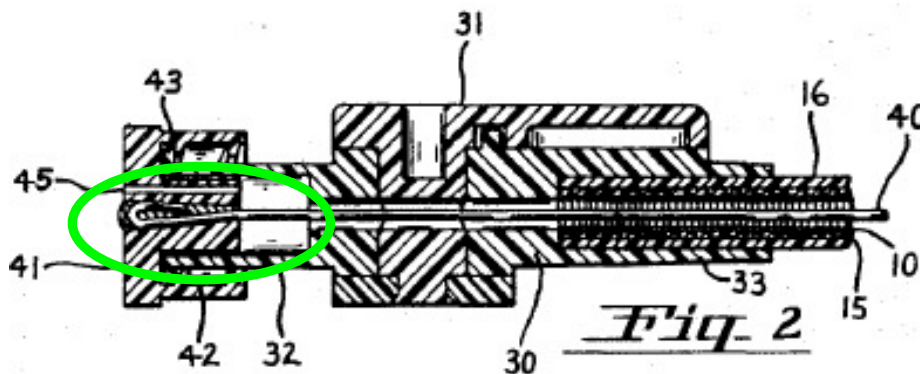
180. For the reasons discussed below, it is my opinion that claims 1-10 of the '737 Patent are obvious in view of the Eliason and Fogarty references and a PHOSITA's knowledge.

A. Claims 1- 10

181. As shown in invalidity Ground 5, claims 1-10 are obvious in view of the Eliason reference and the PHOSITA's knowledge. To the extent that the

Eliason reference and the PHOSITA's knowledge are deemed to not teach that the solid wire (12) is "secured at a proximal-most end thereof within the proximal hub" as recited in claim 1, this arrangement is taught by Fogarty, and each of these claims are therefore obvious in view of a combination of the Eliason and Fogarty references and the PHOSITA's knowledge.

182. As explained above, the Fogarty reference describes a metal wire stylet 40 "to facilitate the insertion of the catheter into a luminal structure within the body." Fogarty, 3:48-54 (Ex-1004). The metal wire stylet (40) is secured inside the hub to a cap (41) which is threaded into the flange elements (43), as is shown in Figure 2 (Ex-1004):



The "hub flange elements" (43) form part of the proximal hub (elements 30, 31, 32, and 43). The wire (40) is therefore attached within proximal hub, and this attachment allows the wire and the catheter to withstand normal operating conditions and perform the preferred functions of the catheter. Thus, the Fogarty reference teaches that the metal wire stylet is secured within the hub (30, 31, 32), and this securing occurs at the wire's proximal-most end. As further discussed

above, Fogarty teaches its wire is solid, not hollow, and this would be known to a PHOSITA.

B. Motivation to Combine the Eliason and Fogarty References

183. Both the Eliason reference and the Fogarty reference describe compliant balloon catheters that are used for vascular occlusion. Furthermore, both references are designed to use a configuration where the wire does not move with respect to the rest of the balloon catheter, as discussed above. (Eliason's "pre-securing embodiments" are also described in "A novel fluoroscopy-free, resuscitative endovascular aortic balloon occlusion system in a model of hemorrhagic shock," The Journal of Trauma and Acute Care Surgery, Vol. 75, Issue 1, by D.J. Scott et al., published in July 2013 ("Scott"). The Scott reference called it a "fused wire and balloon catheter scheme" that allows for a "one-pass" method without the need for fluoroscopy. Scott, p. 123 (Ex-1010).)

184. The Eliason reference claims pre-securing the wire (12) to the balloon shaft to allow "the balloon shaft and endovascular wire to be inserted in the patient and delivered as a single unit." Eliason, Claim 6 (Ex-1009); Eliason PCT Application, claims 8, 56 & 57 (Ex-1012). Eliason further describes this ability to insert the self-centering wire and occlusion balloon as a single device at col. 6, lines 5-7 (Ex-1009). Similarly, the Fogarty reference allows the wire to be secured to the proximal hub of the balloon shaft, with the metal wire stylet helping to "facilitate the insertion of the catheter into a luminal structure within the body." Fogarty, 3:49-54

(Ex-1004). Thus, both references describe balloon catheters that can be used for occlusion in the vascular system, and both references use an internal wire that is secured to the catheter body to assist with the insertion of the catheter into the body.

185. Fogarty teaches that this wire stylet can be secured in a cap that is attached to an internal thread of the proximal hub. Eliason would be motivated to use this mechanism as an alternative or improved method to attach the stylet to the balloon shaft for the reasons discussed above for Ground 5.

XVI. Invalidity Ground 7: Claim 2 is Obvious in View of the Eliason and Saab

References and a PHOSITA's Knowledge

186. For the reasons discussed below, it is my opinion that claim 2 of the '737 Patent is obvious in view of the Eliason and Saab references and a PHOSITA's knowledge.

a. Claim 2

2. The occlusion catheter system of claim 1, wherein the occlusion balloon is asymmetrical.

187. Saab discloses this claim. Claim 2 depends from claim 1, which is obvious in view of the Eliason reference and the PHOSITA's knowledge.

188. Claim 2 adds the requirement that the occlusion balloon is asymmetrical. Saab explains that low-pressure elastomeric balloons can be designed to expand in an asymmetrical manner. In fact, Saab includes an image of such a balloon in Figure 6 (Saab, p. 90 (Ex-1006-11)):

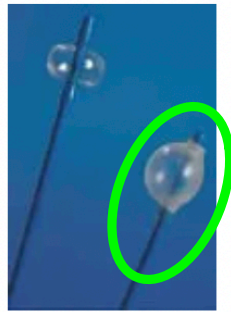


Figure 6. Offering less precision, an elastomeric balloon (right) will often expand asymmetrically compared with a high-pressure, thin-walled balloon (left).

189. Thus, a PHOSITA would have learned from Saab that the compliant balloon in the catheters described by the Eliason reference could be configured to expand asymmetrically. The '737 Patent does not describe an asymmetrical balloon *at all* in the specification, but rather first discusses this possible balloon configuration in claim 2. Thus, a PHOSITA could not recognize anything special in the asymmetry called for by claim 2 and would consider the addition of this feature (asymmetrical balloon inflation) to the Eliason catheter (as

modified in view of the PHOSITA's knowledge) to be obvious in light of the Saab reference.

b. Motivation to Combine Eliason and Saab

190. Much like the Fogarty catheters described in the Fogarty and Chengod references, the Eliason reference describes an elastic, compliant balloon that can be used for vascular occlusion. The Saab reference is a 2000 journal article on the “endless design possibilities” that were available when designing balloon catheters, focusing almost exclusively on balloon shapes. Saab explains that elastomeric (compliant) balloons “often expand asymmetrically.” Saab, p. 90 (Ex-1006-11).

191. As explained above in connection with the motivation to combine Saab with Fogarty and Chengod, Saab understands that compliant balloons may expand asymmetrically. In this case, Saab is explaining a behavior that is found Alternatively, a PHOSITA would read Saab to suggest that asymmetrical compliant balloons are a design choice that could be implemented on the catheter described in the Eliason reference. Either way, a PHOSITA reading Saab would understand that asymmetrical inflation of the compliant balloon in the Eliason catheter is obvious.

XVII. Invalidity Ground 8: Claims 3-5 and 9 are Obvious in View of the Eliason and Scott References and the PHOSITA's Knowledge

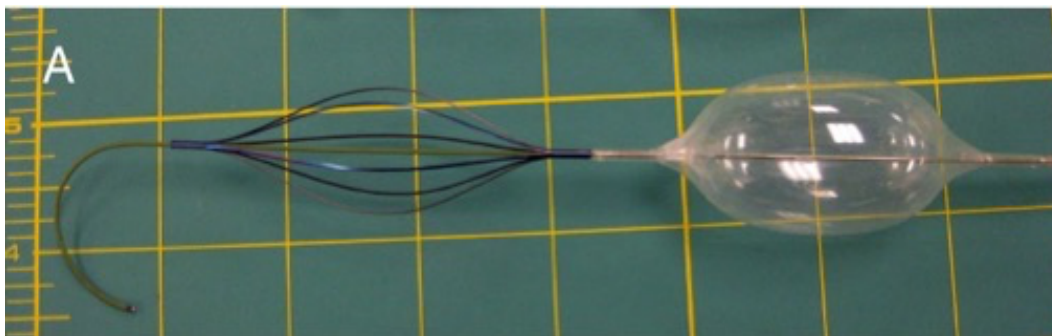
192. For the reasons discussed below, it is my opinion that claims 3-5 and 9 of the '737 Patent are obvious in view of the Eliason and Scott references and a PHOSITA's knowledge.

a. Description of the Scott Reference (Ex-1010)

193. The Scott reference is a "Poster Paper" presented at the 26th Annual Scientific Assembly of the Eastern Association for the Surgery of Trauma. That assembly took place between January 15th and January 19th of 2013. Scott, p. 122 (Ex-1010). The document was also published as an article entitled "A novel fluoroscopy-free, resuscitative endovascular aortic balloon occlusion system in a model of hemorrhagic shock" in The Journal of Trauma and Acute Care Surgery, Vol. 75, Issue 1, published on July 2013. Scott, p. 122 (Ex-1010). I am informed that this article is prior art to the '737 Patent.

194. The authors of this paper are Daniel J. Scott, Jonathan L. Eliason, and others. Mr. Eliason is the inventor of the Eliason reference. Mr. Eliason's co-inventor on the Eliason reference is Mr. Todd E. Rasmussen, who is also an author on the Scott reference (Ex-1010).

195. The Scott reference describes various tests of a "new, low-profile REBOA system." Scott, p. 123 (Ex-1010). The Scott reference describes this device as a "fused wire and balloon catheter" scheme, and shows a portion of it in Figure 1A:



Scott, p. 123 (Ex-1010).

196. This figure clearly shows a device that is similar (or identical) to the device described in the Eliason patent, as shown in Figure 10:

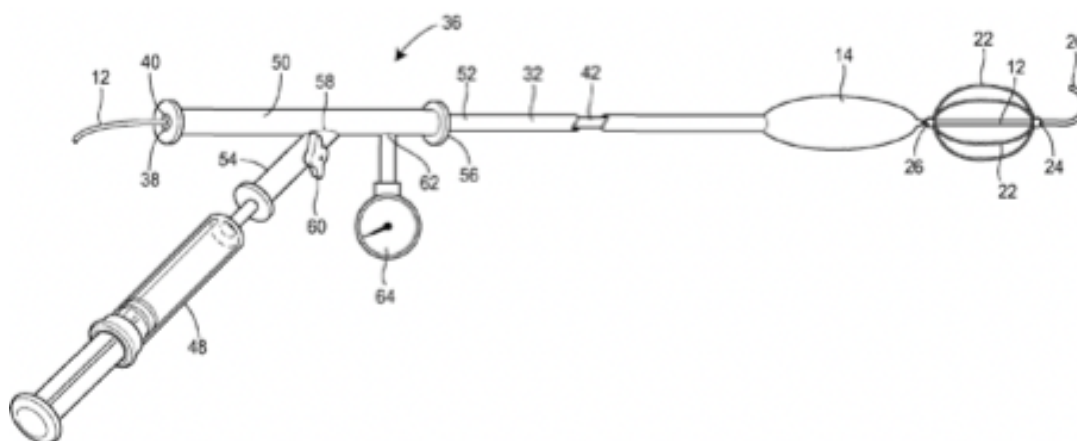
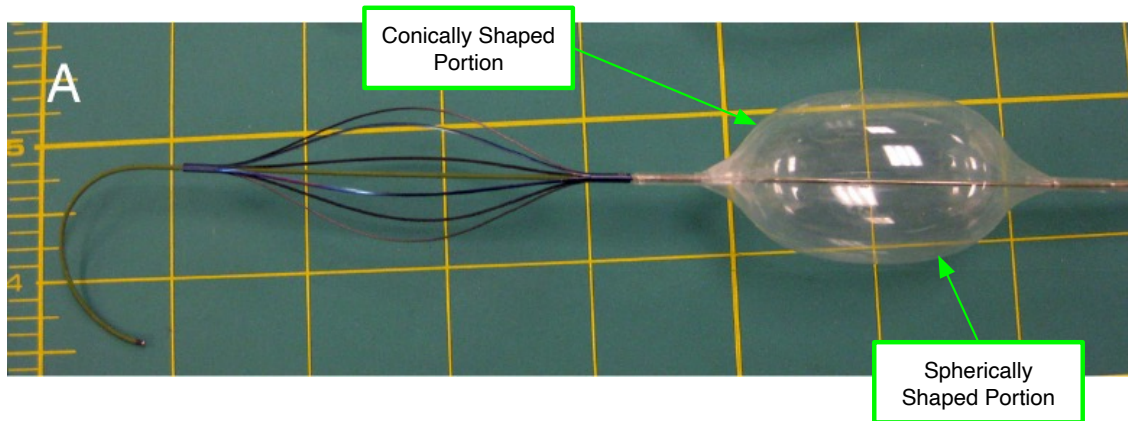


FIG. 10

b. Claim 3

3. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion.

197. Scott discloses and teaches this claim. Claim 3 depends from claim 1, and adds the requirement that the occlusion balloon comprises a conically shaped portion facing a spherically shaped portion. The Scott reference teaches a balloon having this configuration in Figure 1A:



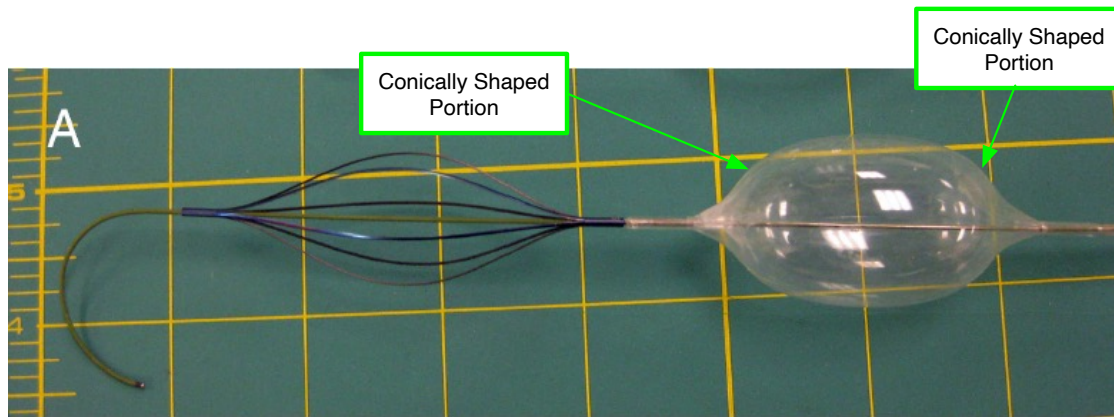
Scott, p. 123 (Ex-1010).

198. One can see that actual, inflated balloon in the Scott reference includes a conically shaped portion facing a spherically shaped portion, as required by claim 3.

c. Claim 4

4. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a conically shaped portion facing another conically shaped portion.

199. Scott discloses and teaches this claim. Claim 4 depends from claim 1, and adds the requirement that the occlusion balloon comprises a conically shaped portion facing another conically shaped portion. Once again, the Scott references teaches a balloon having this configuration in Figure 1A:



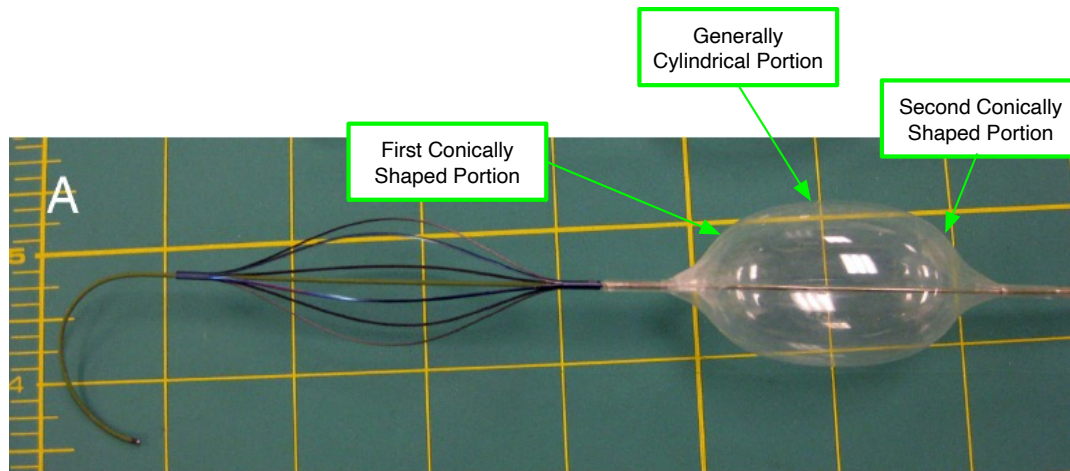
Scott, p. 123 (Ex-1010).

This shows that the inflated balloon from the Scott reference teaches all of the elements added by claim 4.

d. Claim 5

5. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises a first conically shaped portion, a second conically shaped portion and an intervening generally cylindrical portion.

200. Scott discloses and teaches this claim. Claim 5 is similar to claim 4, but it adds an intervening generally cylindrical portion to the two conically shaped portions. Figure 1A of the Scott reference shows all of the elements of this claim:

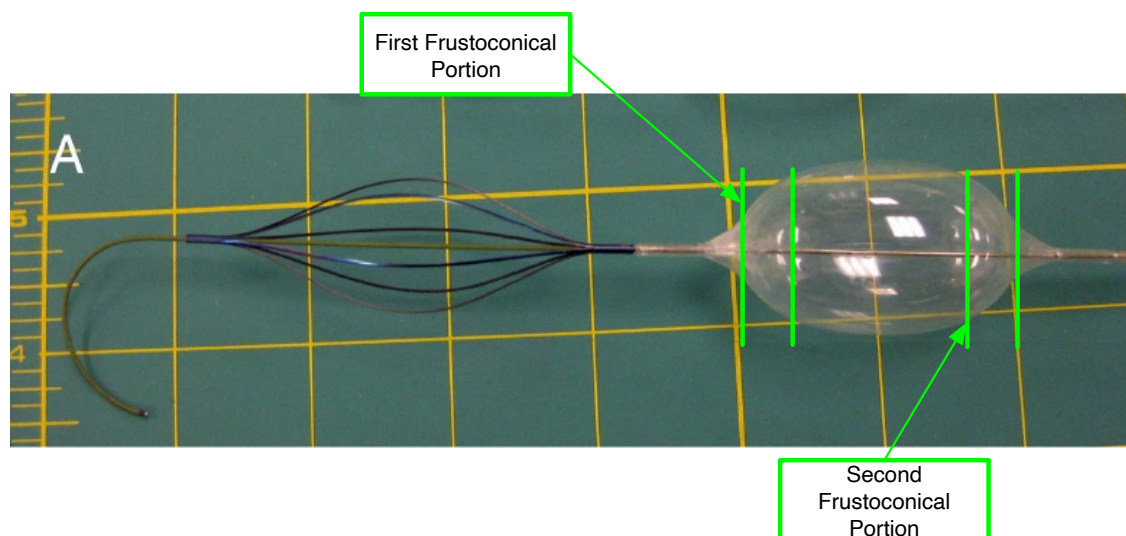


Scott, p. 123 (Ex-1010).

e. Claim 9

9. The occlusion catheter system of claim 1, wherein the occlusion balloon comprises at least two oppositely oriented frustoconical portions.

201. Scott discloses and teaches this claim. Claim 9 is similar to claim 4, except that while claim 4 requires two “conically shaped” portions facing each other, claim 9 requires two oppositely oriented “frustoconical portions.” This illustration of Figure 1A from the Scott reference shows that all of the elements of claim 9 can be found in this inflated balloon:



Scott, p. 123 (Ex-1010).

f. Motivation to Combine Scott with Eliason

202. As explained above in the description of the Scott reference, the inventors of the Eliason reference are co-authors of the Scott reference.

Furthermore, the image of the device described in the Scott reference very closely matches the invention set forth in the Eliason reference. Thus, it is likely that the two references are discussing the same basic catheter. As such, it would be obvious to combine their teachings as they are both describing and/or showing the same physical device. In other words, the nearly identical features in Scott and Eliason suggest combining the balloon shapes from Scott with Eliason's balloon catheter (as modified based on the PHOSITA's knowledge) to arrive at the shapes claimed in the '737 Patent. In fact, Scott suggests that the combination was actually made as early as January 2013, more than two years before the '737 Patent's March 19, 2015, claimed priority date.

203. Even if the Scott reference and the Eliason reference were not describing the same physical device, a PHOSITA with knowledge of both references would see the numerous similarities between the devices. Both devices include a compliant balloon and a self-centering rail system on a balloon catheter used for the occlusion of the aorta during REBOA like procedures. It would have been obvious to a PHOSITA that the shape of the balloon shown in the Scott reference could have been used on the device described in the Eliason reference. Because claims 3-5 and 9 relate to the shape of the compliant balloon, the claims simply apply a known technique (the balloon shapes disclosed in Scott) that had been used to improve a similar device (REBOA balloon catheters having a compliant balloon and a self-centering rail system) in a similar way.

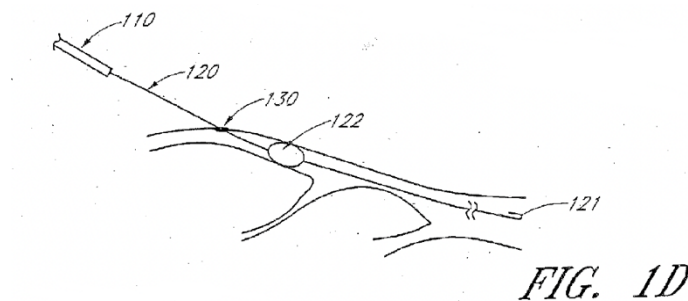
XVIII. Invalidity Ground 9: Claim 8 is Obvious in View of the Eliason and Joe References and a PHOSITA's Knowledge.

204. For the reasons discussed below, it is my opinion that claim 8 of the '737 Patent is obvious in view of the Eliason and Joe references and a PHOSITA's knowledge.

a. Description of the Joe Reference (Ex-1011)

205. The Joe reference is U.S. Publication No. 2015/0133892, published on May 14, 2015. Joe, cover (Ex-1011). Joe was filed as a continuation-in-part application, which was filed on November 11, 2014. Joe, cover (Ex-1011). As

this filing date was prior to the priority date of the '737 Patent, I am informed that Joe is prior art against the '737 Patent. The title of the Joe reference identifies that it is describing a “low-profile occlusion balloon catheter.” Joe, cover (Ex-1011). Joe specifies that it uses a soft, compliant balloon. Joe, ¶ [0088] (Ex-1011). The catheter in Joe has a balloon (122) that is positioned and inflated at a desired occlusion site to occlude blood flow. Joe, ¶ [0070] & Fig. 1D (Ex-1011).



b. Claim 8

8. The occlusion catheter system of claim 1, further comprising a proximal radio opaque marker proximate a proximal end of the occlusion balloon and a distal radio opaque marker proximate a distal end of the occlusion balloon.

206. Joe teaches this claim. Claim 8 depends from claim 1, which is obvious in view of the Eliason reference and a PHOSITA's knowledge. Claim 8 adds the presence of two radio-opaque markers: one at the proximal end and one at the distal end of the occlusion balloon. The Joe reference indicates that even with low profile occlusion catheters, it is helpful to include radiopaque markers:

In some embodiments, the balloon 220 and/or portions of the device 202 immediately proximal and distal to the balloon 220 may include

one or more radiopaque markers, to facilitate visualization of the balloon outside a patient's body using radiographic imaging techniques and thus facilitate placement of the balloon 220 in a desired location.

Joe ¶ [0133] (Ex-1011).

c. Motivation to Combine the Eliason and Joe References

207. The Eliason reference describes an occlusion balloon catheter that uses a compliant balloon for occluding blood flow in the arterial system. Similarly, the Joe reference describes a compliant balloon catheter designed for arterial blood flow occlusion. Both devices can be deployed in the aorta. Joe explains that the utilization of radiopaque markers assists in the visualization of the balloon using radiographic imaging techniques. While Eliason is generally designed for fluoroscopy-free procedures, Figure 12 explicitly describes that in “narrow margin procedures,” fluoroscopy is required. Eliason, Figure 12 & 11:50-51 (Ex-1009).

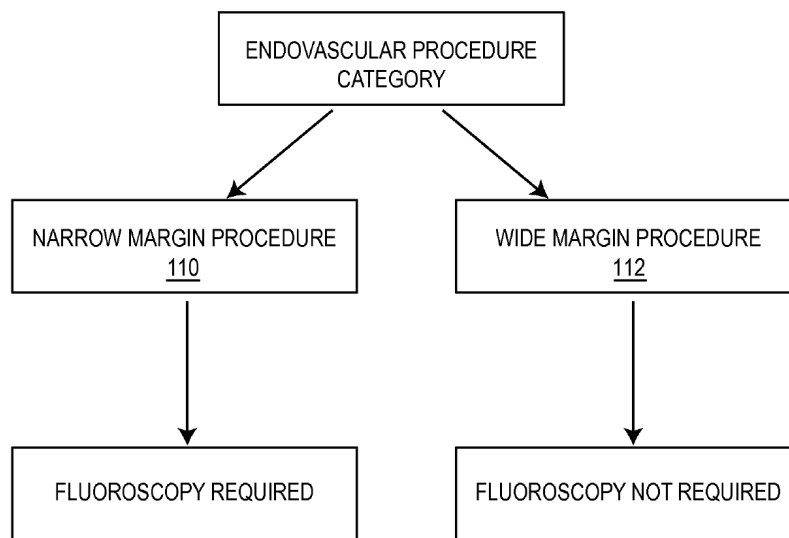


FIG. 12

208. Such narrow margin procedures include endovascular procedures in large axial vessels of the human torso. Eliason, 11:43-61 (Ex-1009). Thus, the addition of the radiopaque markers described in the Joe reference would add the capability to use the device of Eliason in “narrow margin procedures.” Accordingly, a PHOSITA would find it obvious based on Joe to further modify the Eliason catheter (as modified based on the PHOSITA’s knowledge) with radio opaque markers as claimed. A PHOSITA understands that including the radio opaque markers would provide a more versatile balloon catheter that could be used for both narrow and wide margin procedures. A PHOSITA further understands that inclusion of the radio opaque markers does not interfere with the effective use of the balloon catheter in the fluoroscopy-free (wide margin procedure) setting.

XIX. COMPARISON OF PRIORITY DOCUMENTS

209. Counsel informs me that Sanati (Ex-1007) qualifies as prior art because it was effectively filed on August 31, 2012. Counsel informs me that, under 35 U.S.C. § 102(d)(2), Sanati was effectively filed on August 31, 2012, based on the prior-filed parent application (No. 13/602,074) that published March 7, 2013 (“Sanati Application”) (Ex-1013). I also understand that in order to claim the benefit of the Sanati Application, the subject matter relied upon in Sanati (Ex-1007) must have been described in the Sanati Application (Ex-1013). Accordingly, I have been asked to provide a table comparing the disclosures of Sanati (Ex-1007) that are relied on in this declaration (and in the Petition) with the corresponding disclosures of the Sanati Application, as published (Ex-1013). This table is included as Appendix B to my declaration, which includes a side-by-side comparison of the passages and figures relied upon in this declaration, showing that the same disclosure exists in the Sanati Application. Because the disclosures in Sanati that I (and Petitioner) rely on were previously described in the Sanati Application, I understand that Sanati is entitled to claim the benefit of the filing date of the Sanati Application (August 31, 2012) and qualifies as prior art.

210. Counsel informs me that Eliason (Ex-1009) qualifies as prior art because it was effectively filed on April 21, 2011. Counsel informs me that, under 35 U.S.C. § 102(d)(2), Eliason was effectively filed on April 21, 2011, based on PCT/US2011/033368 (“Eliason PCT Application”) (Ex-1012). I also understand that

in order to claim the benefit of the Eliason PCT Application, the subject matter relied upon in Eliason (Ex-1009) must have been described in the Eliason PCT Application (Ex-1012). Accordingly, I have been asked to provide a table comparing the disclosures of Eliason (Ex-1009) that are relied on in this declaration (and in the Petition) with the corresponding disclosures of the Eliason PCT Application, as published (Ex-1012). This table is included as Appendix C to my declaration, which includes a side-by-side comparison of the passages and figures relied upon in this declaration, showing that the same disclosure exists in the Eliason PCT Application. Because the disclosures in Eliason that I (and Petitioner) rely on were previously described in the Eliason PCT Application, I understand that Eliason is entitled to claim the benefit of the filing date of the Eliason PCT Application (April 21, 2011) and qualifies as prior art.

XX. AVAILABILITY FOR CROSS-EXAMINATION

211. In signing this Declaration, I recognize that this declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in this proceeding and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination.

XXI. RIGHT TO SUPPLEMENT

212. I reserve the right to supplement my opinions in the future to respond to any arguments that the Patent Owner or others raise, and to take into account new information as it becomes available to me.

XXII. CONCLUSION

213. In summary it is my opinion that claims 1-10 of the '737 Patent are obvious in view of the prior art Grounds presented above.

APPENDIX A

Updated 1/10/24

Scott A. Resnick, M.D., FSIR

1520 West Nelson Street
Chicago, Illinois 60657
(773) 485-8523 (mobile)

Northwestern Memorial Hospital
Department of Radiology
251 East Huron Street
Feinberg 4-710X
Chicago, IL 60611
sresnick@northwestern.edu

US Citizen

Detroit, MI

03/11/66

EDUCATION

Undergraduate
6/84 - 6/88

University of Michigan
Ann Arbor, MI
BS, College of Literature, Sciences, and the Arts

Medical
9/88 - 6/92

Northwestern University Medical
Chicago, IL
MD

Internship
7/92 – 6/93

Northwestern University
Evanston Hospital
Transitional medical-surgical
Evanston, IL

Residency
7/93 – 6/97

Diagnostic Radiology
Northwestern University
Chicago, IL

Fellowship
7/97 – 6/98

Vascular and Interventional Radiology
Northwestern University
Chicago, IL

Hospital Staff Appointments

Attending Staff

Midwest Heart Specialists

07/98 - 09/00	Elmhurst Hospital Elmhurst , IL Department of Cardiology
07/98 - 09/00	Edward Hospital Naperville, IL Department of Cardiology
07/98 - 09/00	Central Dupage Hospital Winfield, IL Department of Cardiology
04/11 – 2016	Section of Interventional Radiology Department of Radiology Saint Joseph Hospital
Active Staff 10/00 - Present	Division of Interventional Radiology Department of Radiology Northwestern Memorial Hospital
08/09 – Present	Section of Interventional Radiology Department of Radiology Jesse Brown Veterans Administration Hospital
04/11 – Present	Section of Interventional Radiology Department of Radiology Northwestern Lake Forest Hospital
09/13 – Present	Section of Interventional Radiology Department of Radiology Elmhurst Memorial Hospital
06-18 – Present	Section of Interventional Radiology Department of Radiology Lurie Children's Hospital

ACADEMIC APPOINTMENTS

Instructor 10/00 - 08/04	Section of Vascular and Interventional Radiology Department of Radiology Northwestern Memorial Hospital
Assistant Professor 08/04 – 08/09	Section of Vascular and Interventional Radiology Department of Radiology Northwestern Memorial Hospital
Assistant Professor 08/04 – 08/09	Division of Vascular Surgery Department of Surgery Northwestern Memorial Hospital
Associate Professor 09/09 – 05/18	Section of Vascular and Interventional Radiology Department of Radiology Northwestern Memorial Hospital

Associate Professor
09/09 – 05/18

Division of Vascular Surgery
Department of Surgery
Northwestern Memorial Hospital

Professor
05/18 – present

Section of Vascular and Interventional Radiology
Department of Radiology
Northwestern Memorial Hospital

Professor
05/18 – present

Division of Vascular Surgery
Department of Surgery
Northwestern Memorial Hospital

ADMINISTRATIVE APPOINTMENTS

**Northwestern Interventional Radiology
Fellowship Director**
2001- 2015

Section of Vascular and Interventional Radiology
Department of Radiology
Northwestern University

Director, Northwestern Vein Center
11/04 – Present

Section of Interventional Radiology
Department of Radiology
Northwestern University

Co-Director, Northwestern Endovascular Service
2004 – 2012

Section of Interventional Radiology and
Division of Vascular Surgery
Northwestern Memorial Hospital

Director, Interventional Radiology
2020 – 2023

Section of Interventional Radiology
Department of Radiology
Northwestern Medicine North Region
Northwestern University

Academic Community Service

6/04 – 6/08

Facilities Committee
Northwestern Memorial Hospital

6/03 – 6/08

Endovascular QA/QM Committee
Northwestern Memorial Hospital

10/09 – present

ABR subspecialty oral examiner for Vascular
and Interventional CAQ

10/09 – present

ABR Maintenance of Certification (MOC)
Cognitive Exam Committee

10/10 – 01/14

Surgical Services Executive Committee
Northwestern Memorial Hospital

10/10 – 01/14	Bluhm Cardiovascular Institute Planning and Operations Committee Northwestern Memorial Hospital
10/10 – 01/14	Bluhm Cardiovascular Center Invasive Services Committee Northwestern Memorial Hospital
12/10 – 01/14	Clinical Operations Committee Northwestern Medical Faculty Foundation
08/13 – 01/15	Ambulatory Medical Director Group Northwestern Medical Group
03/21 - present	Radiology Clinical Services Committee Northwestern Medicine
Fall 2011	ABR CAQ recertification exam Panel Chair
Fall 2022	ABR Certification exam Panel Chair
2011 - present	SIR MOC Committee
2011 - present	SIR GME committee
2002 –present	JVIR reviewer
2007 –present	Radiology reviewer
2008 –present	CVIR reviewer
2010 –present	Journal of Urology reviewer
2016	ABR Academic Volunteer Service Award
2019	ABR Academic Volunteer Service Award
2020 - present	Annals of Vascular Surgery reviewer
2020 - present	PLOS One Reviewer
2021 - present	Liver Transplantation Reviewer
2022 – present	Corporate Compliance and Integrity Committee Northwestern Memorial HealthCare
2021 – present	Feinberg School of Medicine Committee on Admissions

Licensure and Certification

Illinois State Medical License	#036091423
Controlled Substance Certification	#336058487

DEA Registration	#BR5941554
Certificate of Insurance	NM Insured
ABR Certified	6/1997
CAQ in Interventional Radiology	11/09/04
Recertification in Interventional Radiology	2015

Honors

Highest Honors	University of Michigan BS, 1988
Alpha Omega Alpha	Northwestern University Medical School MD, 1992
Chief Resident	Northwestern University Diagnostic Radiology Residency 1996–1997
Fellow (FSIR)	Society of Interventional Radiology

Society Memberships

Society of Interventional Radiology	2002 – present
Association of Program Directors in Interventional Radiology	2005 - 2016
Society of Vascular Surgery	1998 - 2006
American Medical Association	1999 - 2012
American Heart Association	1998 - 2006
American Heart Association Cardiovascular Council	1998 - 2006
Radiology Society of North America	2007 – 2016
Irish Society of Interventional Radiology	2016 - present

Society Officerships

APDIR Vice President and President-elect

2011 – 2013

APDIR President

2013 - 2015

PUBLICATIONS (Original peer reviewed articles)

- 1 - **Resnick SA**, Russell EJ, Hanson D, Picaro B. Embolization of Mandibular Malformations via Direct Percutaneous Transmandibular Puncture. *Head and Neck* 1992; 14 (5): 372-9.
- 2 - Omary RA, Henseler KP, Unal O, Chrisman HB, **Resnick SA**, Ryu RK, Saker MB, Maciolek LJ, Strother CM, Finn JP, Debio LI, Grist TM. Comparison of Intraarterial and Intravenous Gadolinium-Enhanced MR Angiography for the detection of Renal Artery Stenosis. *Proc. Intl. Soc. Mag. Reson. Med.* 9 (2001).
- 3 - Omary RA, Henseler KP, Unal O, Chrisman HB, **Resnick SA**, Ryu RK, Saker MB, Nemcek AA, Vogelzang RL, Frayne R, Strother CM, Grist TM. In Vivo Validation of Injection Parameters for Intraarterial Gadolinium-Enhanced MR Angiography. *Proc. Intl. Soc. Mag. Reson. Med.* 9 (2001).
- 4 - Ryu RK, Chrisman HB, Omary RA, Miljkovic S, Nemcek AA Jr, Saker MB, **Resnick SA**, Carr J, Vogelzang RL. The vascular impact of uterine artery embolization: prospective sonographic assessment of ovarian arterial circulation. *J Vasc Interv Radiol.* 2001 Sep;12(9):1071-4.
- 5 - Ken-Pin Hwang, Green JD, Li D, Simonetti OP, **Resnick SA**, Finn JP, Duerk JL, Omary RA. Minimizing Contrast Agent Dose During Intraarterial Gadolinium Contrast-Enhanced MR Angiography: In Vitro Assessment. *J. Mag. Reson. Imaging* 2002; 15: 55-61.
- 6 - Omary RA, Henseler KP, Unal O, Smith RJ, Ryu RK, **Resnick SA**, Saker MB, Chrisman HB, Frayne R, Finn JP, Li D, Grist TM. Validation of Injection parameters for catheter-Directed Intraarterial Gadolinium-Enhanced MR Angiography. *Acad Radiol* 2002; 9: 172-185.
- 7 - Omary RA, Vasireddy S, Chrisman HB, Ryu RK, Pereles FS, Carr JC, **Resnick SA**, Nemcek, Jr. AA, Vogelzang RL. The Effect of Pelvic MRI on the Diagnoses and Treatment of Women with Presumed Symptomatic Uterine Fibroids. *J Vasc Interv Radiol* 2002; 13:1149-1153.
- 8 - Omary RA, Henseler KP, Unal O, Smith RJ, Ryu RK, **Resnick SA**, Saker MB, Chrisman HB, Frayne R, Finn JP, Li D, Grist TM. Validation of Injection Parameters for Catheter-directed Intraarterial Gadolinium-enhanced Angiography. *Acad Radiol* 2002; 9:172-185.
- 9 - Joshi J, **Resnick SA**, Nemcek Jr AA, Vogelzang RL, Omary RA, Carr JC. Filter Induced Thrombotic Occlusion of Inferior Vena Cava Treated with Gianturco Expandable Metallic Stent. *J Vasc Interv Radiol.* *J Vasc Interv Radiol* 2003; 14: 381-385
- 10 - Peterson BG, **Resnick SA**, Eskandari MK. Coil Embolization of an Inferior Pancreaticoduodenal Arcade Aneurysm Associated with Celiac Artery Occlusion. *Cardiovascular Surgery*, 2003;11:515-519.

- 11 - Curtin KR, Shaibani A, **Resnick SA**, Russell EJ, Simuni T. Rheolytic catheter thrombectomy, balloon angioplasty, and direct recombinant tissue plasminogen activator thrombolysis of dural sinus thrombosis with preexisting hemorrhagic infarctions. *AJNR Am J Neuroradiol*. 2004 Nov-Dec;25(10):1807-11
- 12 - Eskandari MK, **Resnick SA**. Salvage of endoluminal exclusion of an Anastomotic Aortic Arch Aneurysm Using a Kissing Carotid Stent Technique. *J Vasc Interv Radiol*. 2004 Nov;15(11):1317-21
- 13 - Chrisman HB, Liu DM, Bui JT, **Resnick SA**, Sato K, Chen R, Vogelzang RL, Omary RA. The safety and efficacy of a percutaneous closure device in patients undergoing uterine artery embolization. *J Vasc Interv Radiol*. 2005 Mar;16(3):347-50
- 14 - Sato K, Lewandowski RJ, Bui JT, Omary RA, Hunter RD, Kulik L, Mulcahy M, Liu D, Chrisman HB, **Resnick SA**, Nemcek Jr. AA, Vogelzang RL, Salem R. Treatment of Unresectable Primary and Metastatic Liver Cancer with Yttrium-90 Microspheres (TheraSphere®): Assessment of Hepatic Arterial Embolization. *Cardiovasc Intervent Radiol*. 2006 Jul-Aug;29(4):522-9.
- 15 - Bui JT, Salem R, Liu D, Kulik L, Mulcahy M, Omary RA, Chrisman HB, **Resnick SA**, Nemcek Jr. AA, Vogelzang RL. Angiographic Appearance of Hepatic Arteries Following Treatment of Unresectable Hepatocellular Carcinoma using Yttrium-90 Microspheres (TheraSphere®). *Cardiovasc Intervent Radiol*. 2006 Jul-Aug;29(4):522-9
- 16 - Eskandari MK, **Resnick SA**, Peterson BG. Aortic Arch Vessel Stenting: A Single Center Experience Utilizing Cerebral Protection. *Arch Surg*. 2006 Jun;141(6):560-3
- 17 - Peterson BG, Pearce WH, **Resnick SA**, Eskandari MK. Stent-graft treatment of thoracoabdominal aortic aneurysms after complete visceral debranching. *J Vasc Interv Radiol*. 2006 Sep;17(9):1519-25
- 18 - Peterson BG, **Resnick SA**, Morasch MD, Eskandari MK. Aortic Arch Vessel Stenting: A single-center experience using cerebral protection. *Arch Surg*. 2006 Jun;141(6):560-3.
- 19 - **Resnick SA**, Romo V. Use of a Partially Deployed Large Wallstent to Act as a Filtration Device During Coil Embolization of a High Flow Renal Arteriovenous Fistula. *J Vasc Interv Radiol*. 2006 Feb;17(2 Pt 1):369-72.
- 20 - **Resnick SA**, Romo V. Translumbar Repair of a Type 2 Aortic Endoleak Associated With an Aortic to Left Renal Vein Arteriovenous Fistula Following Aortic Stent Graft Placement. *J Vasc Interv Radiol*. 2006 Mar;17(3):557-61.
- 21 - **Resnick SA**, Chiang A. Transcatheter embolization of a high-flow renal arteriovenous fistula with use of a constrained wallstent to prevent coil migration. *J Vasc Interv Radiol*. 2006 Feb;17(2 Pt 1):363-7.
- 22 - Heyer KS, **Resnick SA**, Matsumura JS, Amaranto D, and Eskandari MK. Percutaneous Zenith Endografting for Abdominal Aortic Aneurysms. *Ann Vasc Surg*. 2009;23:167-71.
- 23 - Eskandari M, **Resnick SA**. Outcomes Of Amplatzer Vascular Plugs For Occlusion Of Internal Iliacs During Aorto-Iliac Aneurysm Stent Grafting. *Annals of Vascular Surgery*. 2008 Jul 9
- 24 - Park JK, Rhee TK, Cashen TA, Shin W, **Resnick SA**, Gehl JA, Schirf BE, Wang D, Larson AC, Carroll TJ, Omary RA. MR Imaging Assessment of Changes in Renal

- Function with Renal Artery Stent Placement in Swine. *J Vasc Interv Radiol* 2007 18: 1409-1416.
- 25 - Heyer K, Modi P, Morasch M, Matsumura J, Kibbe M, Pearce W, **Resnick SA**, Eskandari M. Secondary Infections of Thoracic and Abdominal Aortic Endografts. *J Vasc Interv Radiol*. 2009 Feb;20(2):173-9.
 - 26 - Anchala P, Wickman C, Chen RI, Faundeen T, Pearce W, Narducy L, **Resnick SA**. Endovenous Laser Ablation as a Treatment of Post-Surgical Recurrent Saphenous Insufficiency. *Cardiovasc Intervent Radiol*. 2009 Dec 25.
 - 27 - Anchala, P, **Resnick SA**. Nonocclusive “island” of stenosis following suture mediated arteriotomy closure. *J Vasc Interv Radiol*. 2009 Dec;20(12):1642-4.
 - 28 - Anchala PR, **Resnick SA**. The treatment of post-operative hemorrhage with venous embolization. *J Vasc Interv Radiol*. 2010 Dec; 21(12):1915-7.
 - 29 - Lewandowski RL, Mulcahy MF, Kulik L, Riaz A, Ryu RK, Baker T, Ibrahim S, Abecassis M, Miller FH, Sato KT, Senthilnathan S, **Resnick SA**, Wang E, Gupta R, Chen RI, Newman SB, Chrisman HB, Nemcek AA, Vogelzang RL, Omary RA, Benson III AB and Salem R. Chemoembolization for Hepatocellular Carcinoma: Comprehensive Imaging and Survival Analysis in a 172 Patient Cohort. *Radiology*. 2010 Jun;255(3):955-65.
 - 30 - Usman AA; **Resnick SA**; Benzuly KH; Beohar N; Eskandari MK. Late stent fractures after endoluminal treatment of ostial supraaortic trunk arterial occlusive lesions. *JVIR* 2010 Sep;21(9):1364-9. Epub 2010 Aug 5.
 - 31 - Heyer K, Tang GL, **Resnick SA**, Eskandari ME. Hybrid thoracoabdominal aortic aneurysm repair: visceral revascularization combined with endovascular abdominal and thoracic aneurysm repair. *JVIR* 2010 May;21(5):735-7.
 - 32 - **Resnick, SA**, Bashi A, Rodriguez, H. Endovascular Repair of Complex Aneurysm Following Whipple Procedure Utilizing Selective Balloon Occlusion and Arteriography. *J Vasc Surg, In Press*.
 - 33 - Naughton PA, Garcia-Toca M, Rodriguez HE, Keeling AN, **Resnick SA**, Morasch MD, Eskandari MK. Endovascular Treatment of Delayed Type 1 and 3 Endoleaks. *CVIR, Cardiovasc Intervent Radiol*. 2010 Nov 25.
 - 34 - Salem R, Lewandowski RJ, Kulik L, Wang E, Riaz A, Ryu RK, Sato KT, Gupta R, Nikolaidis P, Miller FH, Yaghmai V, Ibrahim SM, Senthilnathan S, Baker T, Gates VL, Atassi B, Newman S, Memon K, Chen R, Vogelzang RL, Nemcek AA, **Resnick SA**, Chrisman HB, Carr JC, Omary RA, Abecassis M, Benson AI 3rd, Mulcahy MF. Chemoembolization for hepatocellular carcinoma: comprehensive imaging and survival analysis in a 172-patient cohort. *Gastroenterology*. 2011 Feb;140(2): 497-507.
 - 35 - Salem R, Lewandowski RJ, Kulik L, Wang E, Riaz A, Ryu RK, Sato KT, Gupta R, Nikolaidis P, Miller FH, Yaghmai V, Ibrahim SM, Senthilnathan S, Baker T, Gates VL, Atassi B, Newman S, Memon K, Chen R, Vogelzang RL, Nemcek AA, **Resnick SA**, Chrisman HB, Carr J, Omary RA, Abecassis M, Benson AB 3rd, Mulcahy MF. Radioembolization Results in Longer Time to Progression and

- Reduced Toxicity Compared With Chemoembolization in Patients With Hepatocellular Carcinoma. *Radiology*. 2010 Jun;255(3): 955-965.
- 36 - Naughton PA, Garcia-Toca M, Matsumura JS, Rodriguez HE, Morasch MD, **Resnick SA**, Eskandari MK. Complicated Acute Type B Thoracic Aortic Dissections: Endovascular Treatment For Visceral Malperfusion And Pseudoaneurysms. *Vasc Endovasc Surg* 2011;45(3):219-226.
 - 37 - Esparaz AM, Ryu RK, Gupta R, **Resnick SA**, Salem R, Lewandowski RJ. *JVIR* 2012 Sep;23(9):1233-5
 - 38 - Hickey R, Vouche,M, Sze DY, Hohlastos E, Collins J, Schirmang T, Memon K, Ryu,RK, Sato K, Chen R, Gupta R, **Resnick SA**, Carr JC, Chrisman HB, Nemcek AA, Vogelzang RL, Lewandowski R, Salem R, Cancer Concepts and Principles:Primer for the Interventional Oncologist—Part I. *JVIR* 2013 Aug;24(8):1157-64..
 - 39 - Hickey R, Vouche,M, Sze DY, Hohlastos E, Collins J, Schirmang T, Memon K, Ryu,RK, Sato K, Chen R, Gupta R, **Resnick SA**, Carr JC, Chrisman HB, Nemcek AA, Vogelzang RL, Lewandowski R, Salem R, Cancer Concepts and Principles:Primer for the Interventional Oncologist—Part 2. *JVIR* 2013 Aug;24(8):1167-88.
 - 40 - Vogelzang RL, Atassi R, Vouche M, **Resnick SA**, Salem R. Ethanol Embolotherapy of Vascular Malformations: Clinical Outcomes at a Single Center. *JVIR*. 2014 Feb;25(2):206-13
 - 41 - Siragusa DA, Cardella JF, Hieb RA, Kaufman JA, Kim HS, Nikolic B, **Resnick SA**, Saad WE, Vatakencherry G, Wallace MJ Requirements for training in interventional radiology. *JVIR* 2013 Nov;24(11):1609-12.
 - 42 - Merchant M, Pallan P, Prabhakar N, Saker M, **Resnick SA**. Treatment of traumatic thoracic and iliac venous injury with endovascular stent-grafts. *JVIR* 2013 Dec;24(12):1920-3.
 - 43 - Merchant M, Shah R, **Resnick SA**. Direct aneurysm sac catheterization and embolization of an enlarging internal iliac aneurysm using cone beam computed tomography. *Diagnostic and Interventional Radiology, Diagn Interv Radiol*. 2015 May-Jun;21(3):252-5.
 - 44 - Merchant, M, Mahendra D, Martin, J, Chen, RI, **Resnick, SA**. PortoGastric Fistula complicating remote gastric variceal coil embolization. *Clin J Gastroenterol*. 2013 Oct;6(5):395-7
 - 45 - Smith SJ, Merchant M, Sewall L, **Resnick SA**. *J Vasc Interv Radiol*. 2015 Jan;26(1):139-42.
 - 46 - Desai S, Foltz G, Malaisrie SC, **Resnick SA**. An Endovascular Approach to the Entrapped Central Venous Catheter after Cardiac Surgery. *Cardiovasc Intervent Radiol*. 2016 Mar;39(3):453-7
 - 47 - Said MA, McGuire BB, Liu JS, **Resnick SA**, Nadler RB. Novel use of carbon dioxide arteriography in renal artery pseudoaneurysm in patients with poor renal function. *BMJ Case Rep*. 2014 Dec 9;2014.

- 48 - Annambhotla S, Eskandari M, **Resnick SA**, Rodriguez H. Inadvertent Arterial Placement of Central Venous Catheters: Diagnostic and Therapeutic Strategies. *Ann Vasc Surg*. 2015 Nov;29(8):1567-74.
- 49 - Abboud S, **Resnick SA**. AngioVac extraction of intra-atrial hepatoma masquerading as PICC associated thrombus. *Diag Interv Rad Diagn Interv Radiol*. 2016 Jan-Feb;22(1):72-4
- 50 - Salem R, Vouche M, Baker T, Herrero I, Caicedo J, Fryer J, Hickey R, Habib A, Abecassis M, Koller F, Vogelzang R, Desai K, Thornburg B, Hohlastos E, **Resnick SA**, Lewandowski R, Sato KT, Ryu R, Ganger D, Kulik L. Pre-Transplant Portal Vein Recanalization-Transjugular Intrahepatic Portosystemic Shunt in Patients with Complete Obliterative Portal Vein Thrombosis. *Transplantation*. 2015 Nov;99(11):2347-55.
- 51 - **Resnick SA**, O'Brien D, Strain D, Malaisrie SC, Schimmel D, Salem R, Vogelzang RL. Single center experience using AngioVac with extracorporeal bypass for mechanical thrombectomy of atrial and central vein thrombi. *J Vasc Interv Radiol*. 2016 May;27(5):723-729.
- 52 - Yoon DY, **Resnick SA**, Eskandari MK, Rodriguez HE Endograft Component Separation in Giant Hepatic Artery Aneurysm *J Vasc Surg*. 2016 Oct;64(4):1140
- 53 - Yoon DY, Annambhotla S, **Resnick SA**, Eskandari MK, Rodriguez HE. Inadvertent Arterial Placement of Central Venous Catheters: Diagnostic and Therapeutic Strategies. *Ann Vasc Surg*. 2015 Nov;29(8):1567-74
- 54 - Keller EJ, McGee KA, **Resnick SA**, Treretola SO, Valji K, Johnson MS, Collins JD, and Vogelzang RL. Who We Are and What We Can Become: An Analysis of Professional Identity Formation in IR. *J Vasc Interv Radiol*. 2017 Jun;28(6):850-856
- 55 - Keller EJ, Seeman E, Lee J, Aragona E, Molina H, Salem R, **Resnick SA**, Chrisman HC, Collins JC. The Direct and Indirect Costs of Ultrasound-Guided Peripherally Inserted Central Catheter Repositioning at a Large Academic Medical Center. *JAVA* 2018.
- 56 - Keller EJ, Gupta SA, Desai SS, Sato KT, Vogelzang RL, **Resnick SA** Radiofrequency Wire Recanalization of Refractory Central Venous Occlusions. *J Vasc Interv Radiol*. 2018 Nov;29(11):1571-1577
- 57 - Bondarev S, Gupta SA, **Resnick SA**. A Case of Reverse Pelvic Congestion Syndrome? *JVIR* 2018 Nov;29(11):1584
- 58 - Bondarev S, Gupta SA, **Resnick SA**. Unique Forceps Delivery in IR. *Diagn Interv Radiol*. 2019 May;25(3):242-244
- 59 - Han TM, Bondarev S, Keller EJ, Vogelzang RL, **Resnick SA**. Efficacy of endovascular Z-configuration stenting for malignant versus nonmalignant caval obstruction. *J Vasc Surg Venous Lymphat Disord*. 2020 Nov;8(6):939-944
- 60 - Jain AK, Soult MC, **Resnick SA**, Desai K, Astleford P, Eskandari MK, Rodriguez HE. Detecting iliac vein thrombosis with current protocols of lower extremity venous duplex ultrasound. *J Vasc Surg Venous Lymphat Disord*. 2018 Nov;6(6):724-729.
- 61 - Cost-Effectiveness of a Guided Peripherally Inserted Central Catheter Placement System: A Single-Center Cohort Study. Keller EJ, Aragona E, Molina H, Lee J, Salem R, **Resnick SA**, Chrisman HB, Collins JD. *J Vasc Interv Radiol*. 2019 May;30(5):709-714.

- 62 - Genet M, Hohlastos ES, **Resnick SA**. Orbital Atherectomy in Severely Calcified Visceral Artery Lesions. J Vasc Interv Radiol. 2019 Apr 17.
- 63 - Xiao N, Mansukhani NA, **Resnick SA**, Eskandari MK Giant Celiac Artery Aneurysm J Vasc Surg Cases Innov Tech. 2019 Oct 5;5(4):447-451
- 64 - Keller EJ, Aragona E, Molina H, Lee J, Salem R, **Resnick SA**, Chrisman H, Collins JD. Cost-Effectiveness of a Guided Peripherally Inserted Central Catheter Placement System: A Single-Center Cohort Study. J Vasc Interv Radiol. 2019 Feb 14
- 65 - Riaz A, Vogelzang RL, Young V, Gabr A, Ganger D, Abecassis M, Lewandowski RJ, Thornburg B, Salem R, Ivancev K, **Resnick SA**. Endovascular Management of Acquired Hepatic Arterial-Portal Venous Malformations. Cardiovasc Intervent Radiol. 2020 Mar;43(3):466-477.
- 66 - RiChard J, Thornburg B, Desai S, Patel R, **Resnick SA**. Intracardiac echocardiography (ICE)-guided external iliac transvenous needle biopsy of an extravascular retroperitoneal mass. International Journal of Clinical Skills (2019)13(2),259-263
- 67 - Ahuja A, Lemanski J, Grant T, Dumanian G, Yeldandi A, **Resnick SA**. Development of Traumatic Neuromas in a Patient Following Endovenous Laser Ablation and Microphlebectomy Procedures: A Rare Complication From the Removal of Varicose Veins. Cureus 13(6): e15830.
- 68 - Bondarev S, Keller EJ, Han T, Young VA, Gupta S, Vogelzang RL, Eskandari M, **Resnick SA**. Predictors of Disease Recurrence after Venoplasty and Stent Placement for May-Thurner Syndrome. J Vasc Interv Radiol. 2019 Oct;30(10):1549-1554.
- 69 - Rilling WS, **Resnick SA**, Hohenwarter EJ, Schramm K. Challenging Endovascular Cases Panel – Central Line Misplacement Leading to Stroke. Endovascular Today August 2019
- 70 - Talwar A, Knight G, Al Assadi A, Entezari P, Chen RI; **Resnick SA**, Komanduri S, Gabr A, Thornburg B, Salem R, Riaz A. Post-embolization Outcomes of Splenic Artery Pseudoaneurysms: A Single-Center Experience. Clinical Imaging Vol 80, December 2021, pages 160-166
- 71 - Thirkateh P, Riaz A, Tate MC, Stein S, **Resnick SA**. Combined cut down and endovascular retrieval of orphaned ventriculoatrial shunt with stenting of chronic superior vena cava occlusion. Pediatr Radiol. 2021 Jul;51(8):1531-1534
- 72 - Guitart JR, Ho, KJ, **Resnick SA**, Helenowski I, Pamulapati V. A comparative analysis of computed tomographic and digital subtraction angiography for validation of duplex velocities for superior mesenteric artery in-stent restenosis. Vascular Medicine 2021, Vol. 26(5) 566-568
- 73 - Xiao N, Riopelle D, Agrawal A, Friedewald J, **Resnick SA**. Transplant Renal Vein Stenosis: Diagnosis and Intervention. J Vasc Interv Radiol.. 2023 Apr;34(4):723-726.
- 74 - Keller EJ, Mlambo VC, **Resnick SA**, Vogelzang RL. #PauseBeforeYouPost: Ethical and Legal Issues Involving Medical Social Media. Semin Intervent Radiol. 2022 Jun 30;39(2):203-20
- 75 - Xiao N, Ahuja A, Patel R, Desai S, Nemcek Jr AA, **Resnick SA** Median Arcuate Ligament Compression Associated with Flow-related Visceral Aneurysms – A Single Center 22-year Retrospective Analysis. J Vasc Interv Radiol, 2023 Jul; 34(7) 1176-1182.

- 76 - Zhao, A, **Resnick SA**, Fadhel, M, Burton, C. Deciphering the Radiation Dose Summary Page in Interventional Fluoroscopy. Radiographics. *Accepted*
- 77 - Girardo, J, Molina H, Xiao, N, **Resnick SA**. Extracellular Matrix Enterocutaneous Fistula Plug Placement: An IR Guided Procedure for Fistulae Refractory to Care. AJIR. *Accepted*

PUBLICATIONS (CHAPTERS)

- 1- Eskandari MK, **Resnick SA**. Endovascular therapy for Aneurysms of the Renal Artery. Seminars in Vascular Surgery, Book Chapter. *Elsevier Semin Vasc Surg*. 2005 Dec;18(4):202-8. 2005.
- 2- **Resnick SA**. Endovascular Treatment of Caval Occlusions. Trends in Vascular Surgery. Greenwood Academic Press, Book Chapter, 2006 pp 443-454.
- 3- Eskandari MK, **Resnick SA**. Aneurysms of the Renal Artery. Seminars in Vascular Surgery. WB Saunders Press. Book Chapter, 2005 Dec;18(4):202-8.
- 4- Anchala P, **Resnick SA**. The Current State of Endovascular Therapy in the Evaluation and Management of Renovascular Disease. Seminars of Interventional Radiology. Book Chapter, *Elsevier* 2009.
- 5- Anchala P, **Resnick SA**. Endovenous Laser Vein Ablation. Atlas of Vascular Surgery. Book Chapter, 2010.
- 6- Anchala P, **Resnick SA**. Endovascular Treatment of Inferior Vena Cava Obstructive Disease. Book Chapter. *Elsevier Semin Vasc Surg*. 2011.
- 7 - Merchant, M, **Resnick, SA**. Endovascular Treatment of Gastroduodenal Aneurysms. Book Chapter. *Elsevier Semin Vasc Surg* 2013
- 8 - Habib A, **Resnick SA**, Salem R. Portal Vein Reconstruction with Transjugular Intrahepatic Portosystemic Shunt: A Minimally Invasive Approach for Portal Vein Thrombosis. Current vascular Surgery, 2014
- 9 - O'Brien DC, Huang J, **Resnick SA**. Imaging Techniques. Interventional Radiology: Fundamentals of Clinical Practice. Oxford University Press, 2015.
- 10 - **Resnick SA**. Endovascular Solutions to Central Vein Occlusions. Current Vascular Surgery: PMPH 2016
- 11 - **Resnick SA**, Garcia M, Sista A, Saad N, Sterling K. Treating Chronic Venous Occlusive Disease. FAQ's in Interventional Radiology, Volume VI. 2017
- 11 - Bondarev S, Han T, **Resnick SA**. Inferior Vena Cava and Right Atrial Thromboembolism Diagnosis and Management. Elsevier 2018.
- 12 - Bondarev S, Han T, Young V, **Resnick SA**. Recurrent May-Thurner Syndrome Etiologies and Treatment. PMPH 2017.
- 13 - **Resnick SA**. Advanced Endovascular Solutions to Central Vein Occlusions. Complex Arterial and Venous Problems. PMPH 2018.

- 14 - Bondarev S, Han T, Young V, **Resnick SA**. Recurrent May-Thurner Syndrome Etiologies and Treatment. Complex Arterial and Venous Problems PMPH 2018.
- 15 - **Resnick SA**. Inferior Vena Canal and Right Atrial Thrombus. Thieme 2023.
- 15 - Weber J, Peta A, **Resnick SA**. Catheter Directed Therapies for Pulmonary Embolism: Review of Current Treatment Paradigms. PMPH USA, Ltd. 2018.
- 16 - Xiao, N and **Resnick SA**. Renal Artery Fibromuscular Dysplasia: When and How to Intervene. Current Vascular Surgery: Amika Press 2019.
- 17 - Greene JR, **Resnick SA**, Restrepo R, Lee EY. Spectrum of Imaging Manifestations of Vascular Malformations and Tumors Beyond Childhood: What General Radiologists Need to Know. Radiology Clinics of North America. Radiol Clin N Am 58 (2020) 583-60.
- 18 - **Resnick, SA** Venous Thromboembolism: Practical Guides in Interventional Radiology - Inferior Vena Canal and Right Atrial Thrombus. Book Chapter. Thieme Medical Publishing 2023 *In Press*

PRESENTATIONS

- 1- **Resnick SA**, Bui JT, Sato K, Omary RA, Liu D, Vogelzang RL. "SMART-Lined" TIPS Using the Wallstent/SMART stent Combination: Effect on Portosystemic Gradient Reduction. Society of Interventional Radiology, Annual Meeting, Phoenix Arizona, 2003.
- 2- Sato K, **Resnick SA**, Omary RA. Central Venous Reconstruction Using SMART Stents. Society of Interventional Radiology Annual Meeting, Phoenix Arizona, 2003.
- 3- Chen RI, Shah S, Sato K, Nemcek AA, Vogelzang RL, **Resnick SA**. The Impact of a Computerized Patient Scheduling and Tracking System on a Large Interventional Radiology Practice. Society of Interventional Radiology, Annual Meeting, Phoenix Arizona, 2003.
- 4- Liu D, Chrisman HB, **Resnick SA**, Sato K, Vogelzang RL, Omary RA. The Safety and Efficacy of a Percutaneous Closure Device in Patients Undergoing Uterine Artery Embolization. Society of Interventional Radiology Annual Meeting, Phoenix Arizona, 2003.
- 5- **Resnick SA**. Minimally Invasive Liver-Directed Therapies. Northwestern University Continuing Medical Education Series 2003
- 6- Alam M, **Resnick SA**, Chrisman HB, Pearce WH, Wrone DA. An Interdisciplinary Light and Laser-Based Clinic for the Treatment of Telangiectatic, Reticular, and Varicose Veins: The Northwestern University Vein Clinic. Society of Dermatologic Laser Therapies, Annual Meeting, 2004.
- 7- **Resnick SA**, Koffran, A, Humes, S, Pooler, GM, Demayo, E. Endovascular Management of Vascular Complications in Liver Transplant Patients. International Symposium on Endovascular Therapy, Miami, FL 2004. *First place award for best poster received.*

- 8- **Resnick SA.** Modern Therapy of Venous Disease. PRIMed Symposium, Chicago, IL. 2004.
- 9- **Resnick SA.** Chronic Venous Insufficiency: Imaging Evaluation. SIR Vein Symposium, San Diego, CA. May 13-14, 2005.
- 10- **Resnick SA.** Chronic Venous Insufficiency: Patient Workup. Angiodynamics Vein Symposium, Chicago, IL. 2005.
- 11- Peterson B, Morasch M, Hassoun H, **Resnick SA.** Aortic Arch Vessel Stenting: Is It Making bypass Obsolete?. Western Surgical Association Meeting, Rancho Mirage, CA. 2005.
- 12- **Resnick SA.** Peripheral Arterial Disease: When to Treat? Vascular Medicine for the Practicing Physician Symposium- Bluhm Cardiovascular Institute. Chicago, IL, Oct 22, 2005.
- 13- **Resnick SA.** Endovascular Treatment of Caval Occlusions. Trends in Vascular Surgery Symposium. Chicago, IL, Dec 16, 2006.
- 14- **Resnick SA.** SFA Interventions: Techniques, Tips, and Tricks. 2nd Annual SIR Fellows' Spring Practicum. Chicago, IL, April 26, 2007.
- 15- **Resnick SA.** Renal Interventions: Techniques, Tips, and Tricks. 2nd Annual SIR Fellows' Spring Practicum. Chicago, IL, April 26, 2007.
- 16- **Resnick SA,** Holcomb JM, Faundeen TJ, Wickman C. Endovenous Laser Treatment of Symptomatic Lower Extremity Venous Insufficiency after Saphenous Ligation and Stripping. Society of Interventional Radiology, Seattle, WA 2007.
- 17- JK Park, TK Rhee, TA Cashen, **Resnick SA,** TJ Carroll, RA Omary, et al. Feasibility of MR Imaging Assessment of Renal Function During Endovascular Stent Therapy for Renal Artery Stenosis in Swine. Society of Interventional Radiology, Seattle, WA 2007.
- 18- **Resnick SA.** SIR Morbidity and Mortality Symposium, Learning From Our Mistakes- Renaovascular Complications. Society of Interventional Radiology, Washington DC 2008.
- 19- **Resnick SA.** SFA Interventions: Techniques, Tips, and Tricks. 2nd Annual SIR Fellows' Spring Practicum. Chicago, IL, April, 2008.
- 20- **Resnick SA.** Renal Interventions: Techniques, Tips, and Tricks. 2nd Annual SIR Fellows' Spring Practicum. Chicago, IL, April, 2008.
- 21- Heyer K, Modi P, Morasch M, Matsumura J, Kibbe M, Pearce W, **Resnick SA,** Eskandari MK. Secondary Infection of Thoracic and Abdominal Aortic Endografts. Society of Interventional Radiology, Washington DC 2008.
- 22- **Resnick SA.** Amplatzer Vascular Plug Device for the Treatment of Large Pulmonary AVMs. Society of Interventional Radiology, Washington DC 2008.
- 23- **Resnick SA,** Chen RC, Faundeen TJ. Endovenous Laser Vein Ablation Effectiveness without the Use of Epinephrine in the Tumescence Anesthetic Mixture. Society of Interventional Radiology, Washington DC 2008.

- 24- **Resnick SA**, Chen RC, Faundeen TJ. Microphlebectomy Safety without the Use of Epinephrine in the Tumescant Anesthetic Mixture. Society of Interventional Radiology, Washington DC 2008.
- 25- Usman AA, **Resnick SA**, Benzuly KH, Beohar N, Eskandari MK. Stent Fractures after endoluminal therapy of ostial supraaortic trunk arterial lesions. Society of Interventional Radiology, San Diego, CA. 2009.
- 26- Karkala RK, **Resnick SA**, Gueyinkian S, Stanton P, Bhatia S. Therapeutic embolization of aberrant systemic arterial supply to lungs: Review of the spectrum and approach to therapy. Society of Interventional Radiology, San Diego, CA. 2009.
- 27- Eskandari ME, **Resnick SA**. Complicated Acute Aortic Dissections: Endovascular Treatment Of Visceral Malperfusion And Pseudoaneurysms Midwestern Vascular Society Annual Meeting, 2009 Chicago.
- 28- Nemcek AA, **Resnick SA**. The Swollen leg. In: Brown DB, ed. 2008 Case-Based Review Monograph. Fairfax: Society of Interventional Radiology, 2008; 7-12.
- 29- **Resnick SA**. SFA Interventions: Techniques, Tips, and Tricks. 3rd Annual SIR Fellows' Spring Practicum. Chicago, IL, April, 2009.
- 30- **Resnick SA**. Renal Interventions: Techniques, Tips, and Tricks. 3rd Annual SIR Fellows' Spring Practicum. Chicago, IL, April, 2009.
- 31- **Resnick SA**. SFA Interventions: Techniques, Tips, and Tricks. 4th Annual SIR Fellows' Spring Practicum. Chicago, IL, April, 2009.
- 32- **Resnick SA**. Renal Interventions: Techniques, Tips, and Tricks. 4th Annual SIR Fellows' Spring Practicum. Chicago, IL, April, 2009.
- 33- **Resnick SA**. Renal Artery Stenosis: When to Treat? 4th Annual SIR Fellow's Spring Practicum. Chicago, IL April, 2010
- 34- **Resnick, SA**. Mesenteric Intervention: Occlusive and Aneurysmal Disease. 24th Annual Conference on Vascular Disease. Chicago, IL Oct 2010
- 35- Rapoport MJ, Sato KT, **Resnick SA**. Stent-grafting of symptomatic dialysis access fistula pseudoaneurysms: initial experience and outcomes. Society of Interventional Radiology, 2011.
- 36- Anchala P, Faundeen T, Chen R, **Resnick SA**. Menstrual-Related Saphenous Venous Insufficiency Changes. Society of Interventional Radiology, 2011.
- 37- **Resnick, SA**. Modern Treatment of Lower Extremity Venous Insufficiency. Northwestern Lake Forest Educational Symposium. Nov, 2011.
- 38 - **Resnick, SA**. Interventional Treatment of Inferior Vena Cava. 36th annual Northwestern Vascular Symposium. Dec 8-10, 2011.
- 39 - **Resnick, SA**. Mesenteric Intervention: Atherosclerotic and Aneurysmal Disease. University of Illinois. Dec, 2011.

- 40 - **Resnick, SA.** Modern Interventional Treatment of Deep Vein Thrombosis. Saint Mary's and Saint Elizabeth's Medical Center. Chicago, IL April 2012.
- 41 - **Resnick, SA.** Modern Interventional Treatment of PAD. Saint Mary's and Saint Elizabeth's Medical Center. Chicago, IL Sept 2012.
- 42 - **Resnick, SA.** Current Controversies and Recent Advances in the Endovascular Management of Varicose Veins, VIVA, Las Vegas, NV Oct 2012
- 43 - **Resnick SA.** Peripheral Arterial Disease: Frontline Strategies. VIVA, Las Vegas, NV Oct 2012
- 44 - **Resnick SA.** Critical Limb Ischemia: Tibial and Pedal Intervention: Frontline Strategies. VIVA, Las Vegas, NV Oct 2012
- 45 - **Resnick SA.** Renal Intervention: Blitz. VIVA, Las Vegas, NV Oct 2012
- 46 - Semaan E, Lee J, Rose E, Molina H, Salem R, **Resnick SA**, Chrisman HB, Collins J. Ultrasound guided PICC placement without fluoroscopy: Assessment of economic and non-economic repositioning costs. CIRSE Meeting, Portugal, 2012
- 47 - **Resnick SA.** Advances in Lower Extremity Venous Insufficiency Treatment. OB-Gyne Grand Rounds, Northwestern University, Chicago, IL. Oct 2013.
- 48 - **Resnick SA.** Advances in Lower Extremity Venous Insufficiency Treatment. Medicine Grand Rounds, Northwestern University, Chicago, IL. Oct 2013.
- 49 - **Resnick, SA.** Endovascular Treatment of Gastroduodenal Aneurysms. 38th Annual Northwestern Vascular Symposium. Dec 2013.
- 50 - **Resnick SA.** Interventional Radiology Fellow Subspecialty Training - PAD education. Association of Program Directors in Interventional Radiology annual meeting. Chicago, Illinois. September 24-25, 2013.
- 51 - **Resnick SA.** Medical Student Awareness of Interventional Radiology. Association of Program Directors in Interventional Radiology annual meeting. Chicago, Illinois. September 24-25, 2013.
- 52 - **Resnick SA.** Good Intentions Gone bad: Complications in Endovascular Procedures. International Society of Interventional Radiology annual meeting, Dublin, Ireland. Mar 2014.
- 53 - **Resnick SA.** Industry Training Impact on the Interventional Radiology Fellow Education. Association of Program Directors in Interventional Radiology annual meeting. Scottsdale, Arizona. October 8 – 9, 2014
- 54 – **Resnick SA.** Transition to IR Residency: Implementation. Association of Program Directors in Interventional Radiology annual meeting. Scottsdale, Arizona. October 8 – 9, 2014

- 55 - **Resnick SA.** Interventional Radiology Residency Training Workforce Impact Analysis. Association of Program Directors in Interventional Radiology annual meeting. Scottsdale, Arizona. October 8 – 9, 2014
- 56 - Tumer Y, **Resnick SA**, Sato KT. CO2 vs. Conventional Venography for AVF Planning and AVF Success. Atlanta, Georgia. SIR Annual meeting Nov 2014.
- 57 - **Resnick SA.** Regrets, I've had a few: Complications in Endovascular Procedures. International Society of Interventional Radiology annual meeting, Kildare, Ireland. Mar 2015
- 58 - Keller EJ, **Resnick SA**, Trerotola SO, Valji K, Johnson MS, Vogelzang RL. The Radiological Surgeon: A Study of IR Fellows' Professional Values. SIR Annual meeting Apr 2016
- 59 - **Resnick SA.** Treating Chronic Venous Occlusive Disease – Complications. SIR Annual meeting Apr 2016
- 60 - **Resnick SA.** No Good Deed Goes Unpunished: Complications in Endovascular Procedures. International Society of Interventional Radiology annual meeting, Leinster, Ireland. Mar 2016
- 61 – **Resnick SA.** Chronic Venous Occlusive Disease Intervention – SVC. SIR Annual meeting Apr 2017.
- 62 - Gupta SA, Desai SS, Sato KT, Vogelzang RL, **Resnick SA.** Radiofrequency Wire Recanalization of Upper vs Lower central venous Occlusions: Technical Success and Strategies. SIR Annual meeting Apr 2017.
- 63 - **Resnick SA.** Complications is endovascular management. IR Meltdown meeting. Los Angeles, CA Nov 2018.
- 64 - **Resnick SA.** May-Thurner Syndrome Recurrence. 42nd Annual Vascular Symposium. Chicago, IL Dec 2017.
- 65 - Han TM, Bondarev S, Keller EJ, Vogelzang RL, **Resnick SA.** Efficacy of Endovascular Stenting for Malignant Versus Nonmalignant Caval Obstruction. SIR Annual meeting Apr 2018.
- 66 - Seyal A, Young V, Nemcek AA Jr, Riaz A, **Resnick SA.** Scrutinizing Venous Thrombus Cases for Malignancy: Biopsy Techniques. SIR Annual meeting Apr 2018.
- 67 - **Resnick SA,** Young V, Seyal A, Vogelzang RL, Riaz A. Acquired Arteriovenous Malformations: Identification and Management. CIRSE Annual meeting 2018.
- 68 - Keller EJ, Aragona E, Molina H, Lee J, Salem R, **Resnick SA**, Chrisman HB, Collins JD. Ultrasound and Electrocardiogram-Guided PICCs: When Are They Worth the Extra Cost? SIR Annual meeting Apr 2018.

- 69 - **Resnick SA.** Complications is endovascular management. IR Meltdown meeting. Baltimore, MD Nov 2017.
- 70 - **Resnick SA.** MR Imaging of Vascular Malformations. 45th Annual Veith Symposium. New York, NY Nov 2018.
- 71 - **Resnick SA.** Avoiding Disaster: Identification and Management of Connections to Deep Veins in Superficial Venous Malformations. 45th Annual Veith Symposium. New York, NY Nov2018.
- 72 - **Resnick SA.** Catheter Directed Therapies for Pulmonary Embolism: Review of Current Treatment Paradigms. 43rd Annual Vascular Symposium. Chicago, IL Dec 2018.
- 73 - **Resnick SA.** Magnetic Resonance Angiography in Procedure Planning. 31st Annual Society of Magnetic Resonance Angiography meeting. Nantes, France August 2019.
- 74 - **Resnick SA.** Renal Artery Fibromuscular Dysplasia: When and How to Treat. 44rd Annual Vascular Symposium. Chicago, IL Dec 2019.
- 75 - Xiao N and **Resnick SA.** Percutaneous transluminal angioplasty for treatment of transplant renal artery stenosis. CIRSE Sept 2020.
- 76 - **Resnick SA** and Vogelzang RL. Medical Device Design and Patent. Northwestern University Law School, Patent Law class 2020.
- 77 - **Resnick SA.** Use of IVUS in the treatment of Deep Vein Disease. WIN Venous Conference. July 2020.
- 78 - **Resnick SA.** Medicolegal issues in IR. Society of Interventional Radiology Annual Meeting, Boston, MA March, 2022.
- 79 - Xiao N, Riopelle D, Agrawal A, Friedewald J, **Resnick SA.** Transplant Renal Vein Stenosis: Diagnosis and Intervention. Cardiovascular and Interventional Radiological Society of Europe, Barcelona, Spain, September 2021
- 80 - Xiao N, Ahuja A, Nemcek AA, **Resnick SA.** Median Arcuate Ligament Compression Related Pancreaticoduodenal Arcade Aneurysms - A 22-year Single Center Experience. Society of Interventional Radiology Annual Meeting, Boston, MA March, 2022.
- 81 - **Resnick SA.** Medicolegal issues in IR. IR Meltdown meeting. Austin, TX, Nov 2022.
- 82 - **Resnick SA.** Complications is endovascular management. IR Meltdown meeting. Austin, TX, Nov 2022.
- 83 - Girardo, J, Molina H, Xiao, N, **Resnick SA.** Extracellular Matrix Enterocutaneous Fistula Plug Placement: An IR Guided Procedure for Fistulae Refractory to Care. AIR, Alexandria, VA Sept 2023.

- 84 - Girardo, J, Molina H, Xiao, N, **Resnick SA**. Extracellular Matrix Enterocutaneous Fistula Plug Placemen for Fistulae Refractory to Care. SIR Salt Lake City UT, Mar 2024.

MEETING/COURSE DIRECTORSHIPS

- 1 - APDIR Annual Meeting. San Francisco, CA Mar 2014
- 2 - APDIR Annual Meeting. Atlanta, GA Feb-Mar 2015
- 3 - IR Meltdown meeting. Santa Monica, CA, Nov 2016.
- 4 - IR Meltdown meeting. Baltimore, MD Nov 2017.
- 5 - IR Meltdown meeting. Los Angeles, CA Nov 2018.
- 6 - IR Meltdown meeting. Austin, TX, Nov 2022.

GRANTS/TRIALS

- 1- **Resnick SA**. 2002. Primary Investigator. A Pilot Study of Hepatic Artery Floxuridine (FUDR), Leucovorin (LV), and Dexamethasone (Dex) via Intraarterial Hepatic Catheter by Transcutaneous Subclavian Access as Treatment for Metastatic Colorectal Cancer or Primary Liver Cancer. Industry sponsored clinical trial-\$40,000.
- 2- **Resnick SA**. 2003. Primary Investigator. A Pilot Study of Hepatic Artery Floxuridine (FUDR), Leucovorin (LV), and Dexamethasone (Dex) via Intraarterial Hepatic Catheter by Transcutaneous Subclavian Access as Treatment for Metastatic Colorectal Cancer or Primary Liver Cancer—PHASE 2. Industry sponsored clinical trial-\$100,000.
- 3- **Resnick SA**. 2004. Primary Investigator. Vascular and Interventional Radiology research fellow-industry support-\$50,000.
- 4- **Resnick SA**. 2005. Primary Investigator. Vascular and Interventional Radiology research fellow-industry support-\$15,000.
- 5- **Resnick SA**. Co-Investigator. Alfimeprase for acute peripheral arterial occlusion. Nuvelo Inc. Principle Investigator: Mark Morasch. September 2006
- 5- **Resnick SA**. 2007-2008. Primary Investigator. Interventional Radiology Fellowship-industry support-\$71,000.
- 6- **Resnick SA**. 2008-2009. Primary Investigator. Interventional Radiology Fellowship-industry support-\$50,000.
- 7- The VALOR Thoracic Aortic Aneurysm Stent-Graft trial. Principal Investigator: Eskandari, M, Chrisman, HB. Co-Investigators: **Resnick SA**, Vogelzang RL., Pearce WH. Sponsor:

- W.L. Gore & Associates, Inc. Northwestern Memorial Hospital, Chicago, Illinois, 2004-present
- 8- The HERCULES Trial Herculink Elite Cobalt Chromium Renal Stent Trial to Demonstrate Efficacy and Safety. Principal Investigator: Eskandari M. Co-Investigator: **Resnick SA**. Sponsor: Abbott Vascular. Northwestern Memorial Hospital, Chicago, Illinois, 2007-present.
 - 9- A Fluoroscopic Imaging Study to Assess Peripherally Inserted Central Catheter Placement via ECG in Relation to Radiological Landmarks. Principle Investigator: Chrisman HC. Co-Investigator: **Resnick SA**. Sponsor: Bard Access Systems. Northwestern Memorial Hospital, Chicago, Illinois, 2009-present.
 - 10- VenaTech™ Convertible Vena Cava Filter U.S. Multi-Center Clinical Trial. Sponsor: B. Braun Interventional Systems, Inc. Site Principle Investigator: Lewandowski R, Co-Investigator: **Resnick SA** Northwestern Memorial Hospital, Chicago, Illinois, 2009-present.
 - 11- **Resnick SA**. 2009-2010. Primary Investigator. Interventional Radiology Fellowship-industry support-\$25,000.
 - 12- A Prospective, Multi-Center Study of the Bard Denali Retrievable Inferior Vena Cava Filter System – BPV-09-007. Sponsor: Bard Peripheral Vascular, Inc. Site Principle Investigator: **Resnick SA**. Northwestern Memorial Hospital, Chicago, IL. 2010-present.
 - 13- DURABILITY Iliac study- prospective, multi-center, non-randomized study confirming the safety and effectiveness of stenting using the Protégé® EverFlex™ and Protégé® GPS™ Self-Expanding Stent Systems for the treatment of atherosclerotic lesions in the common and/or external iliac arteries. Sponsor EV3/Covidien. Site investigator: **Resnick SA**. Northwestern Memorial Hospital, Chicago, IL. 2010-present.
 - 14 - Lutonix DEB SFA ISR – prospective, multi-center, randomized study evaluating efficacy of drug coated balloon treatment for SFA in-stent restenosis using Bard Lutonix drug-eluting balloon versus other existing treatment options. Sponsor CR Bard/Lutonix. Site Co-Investigator: **Resnick SA**. Northwestern Memorial Hospital, Chicago, IL. 2014 – present.
 - 15 - PRESERVE Trial – Predicting Safety and Effectiveness of Inferior Vena Cava Filters. Sponsor SIR. Site Co-Investigator: **Resnick SA**. Northwestern Memorial Hospital, Chicago, IL.
 - 16 - ACCESS Trial – Paclitaxel Coated PTA Balloons for Treatment of Dysfunctional AV Fistulae and grafts. Sponsor CR Bard. Site Primary Investigator: **Resnick SA**. Northwestern Memorial Hospital, Chicago, IL.
 - 17 - Prostatic Artery Embolization (PAE) for Treatment of Signs and Symptoms of Benign Prostatic Hyperplasia (BPH). Sponsor Northwestern Medicine. Site Co-Investigator: **Resnick SA**. Northwestern Memorial Hospital, Chicago, IL.
 - 18 - Wrapsody Wave Trial – Prospective, multi-center, randomized study evaluating efficacy of investigational stent graft for dialysis access circuit outflow stenosis. Sponsor Merit

VASCULAR AND INTERVENTIONAL RADIOLOGY FELLOWS TRAINED

2000-2001

Anant Bhawe, MD
James Carr, MD
Alpa Chandarana, MD
Norman Levine, MD
Michael Ludkowski, MD
Sandra Roland, MD

2001-2002

Marc Alonzo, MD
Brian Anderson, MD
Paul Brady, MD
Richard Chen, DO
Francis Facchini, MD
David Hahn, MD
Kent Sato, MD

2002-2003

Adam Finkelstein, MD
David Leggett, MD
Stephen McRae, MD
Uday Mehta, MD
Andrew Park, MD
LeAnn Stokes, MD
Terence Wilkins, MD

2003-2004

James Bui, MD
Karin Dill, MD
Steven Humes, MD
David Liu, MD
Samir Shah, MD
Derek West, MD

2004-2005

Thomas Aquisto, MD
Matthew Fitzpatrick, MD
Michael Hamblin, MD
Kevin Keele, MD
Stanley Kim, MD
Imran Qureshi, MD
James Walker, MD

2005-2006

Alexander Trebelev, MD
Brian Fagan, MD
Jefferey Himmelberg, MD
Mark Clift, MD
Robert Lewandoski, MD
Sudhen Desai, MD
Suveer Tatineni, MD

2006-2007

Jeffery Critchfield, MD
Joseph Gerding, MD
Joseph Holcomb, MD
Carl Kim, MD
Brian Schirf, MD
Steven Sula, MD

2007-2008

Brian Dunfee, MD
Ron Gaba, MD
Sandra Mun, MD
Greg Neri, MD
Paul Speece, MD
David Tuite, MD
Ernest Wiggins, MD
Ronald Workman, MD

2008-2009

Brian Bianco, DO
Richard Bonsall, MD
Marouanne Bouchareb, MD
Ramona Gupta, MD
Ajay Joshi, MD
Siddharth Padia, MD
Parthiban Ramachandran, MD
Timothy Scanlon, MD

2009-2010

Andrew Lipnik, MD
Joshua Tepper, MD
Miguel Fernandez, MD
Christopher Molvar, MD
Jay Mitchell, MD
Eugene Huo, MD
Aoife Keeling, MD
Sireen Reddy, MD

2010-2011

Michael Naumann, MD
Ryan Hickey, MD
Elias Hohlastos, MD
Matthew Howenstein, MD
Jeremy Collins, MD
Benjamin Moreno, MD
Mark Rapoport, MD
Sumanth Atluri, MD

2011-2012

Josh Dowell, MD
Siobahn Flanagan, MD
Neil Mascarenhas, MD
Maurice Yu, MD
Rick Yeh, MD
Mike Stone, MD
Jeff Weinstein, MD
Jeet Minocha, MD

2012 – 2013
Gretchen Foltz, MD
Susan Shamimi-Noori, MD
Nabeel Hamoui, MD
Jim Gehl, MD
Rami Sartawi, MD
Kush Desai, MD
Justin Calvert, MD
Jeremy Hogg, MD

2013 – 2014
Anthony Herrera, MD
Levi Dansby, MD
Anisha Martin, MD
Zachary Love, MD
Bartley Thornburg, MD
William O'Connell, MD
Farhan Mir, MD
Steven Huffman, MD

2014 - 2015
Julia Seol, MD
Brian Imbrogno, MD
David Strain, MD
Zeyad Metwalli, MD
Matt Niemeyer, MD
Shankar Rajeswaran, MD
Noah Schwind, MD
Sabeen Dhand, MD

2015 – 2016
Samdeep Mouli, MD
Ahsun Riaz, MD
Laurence Donohue, MD
Pankit Parikh, MD
Adnan Moin, MD
Bippan Singh, MD
Aron Chary, MD
Marshall Dines, MD

2016 – 2017
Jebb Baker, MD
Aaron Bos, MD
Eric Ericson, MD
Raj Vasnani, MD
Jacob White, MD
George Mikhail, MD
Adeel Shahid, MD
Jon Lindquist, MD

2017 - 2018
Jessica Andreoli, MD
Ketan Shah, MD
Sameer Ahmed, MD
Mark Mangano, MD
Mikin Patel, MD
Aaron Eifler, MD
Suraj Gupta, MD
Alex Keiger, MD

2018 – 2019
Orrie Close, MD
Shamit Desai, MD
Preston Eisworth, MD
Michael Heller, MD
Jamie Richard, MD
Stephen Seedial, MD
Jon Weinstein, MD
Victoria Young, MD

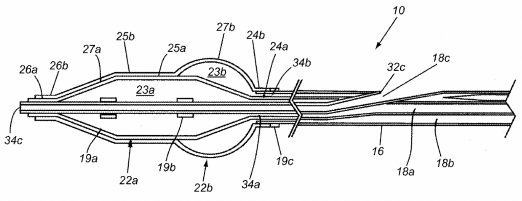
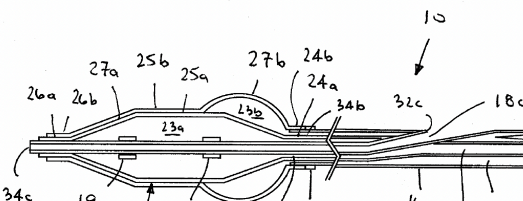
2019 – 2020
Joseph Peter Massa, MD
Adam Beardsly, MD
David Guez, MD
Karan Gulaya, MD
Kathleen Hamrick, MD
Danial Jilani, MD
Seth Stein, MD

2020 - 2021
Peyton Pinkard, MD
Raymond Melikian, MD
Ali Habib, MD
Erica Alexander, MD

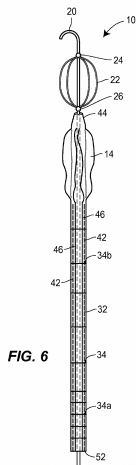
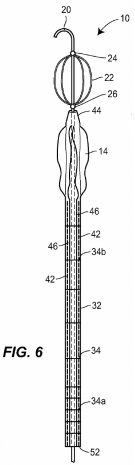
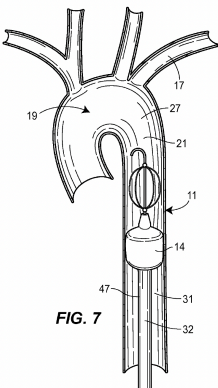
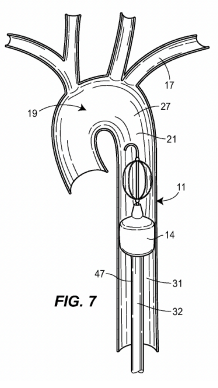
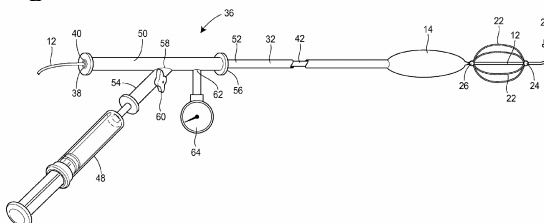
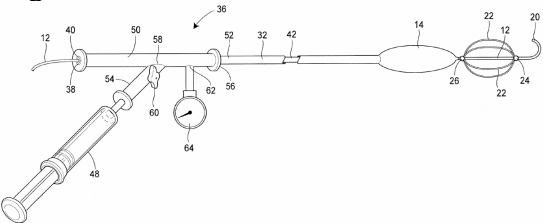
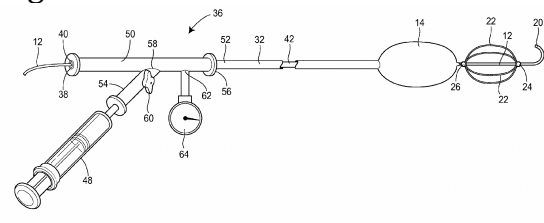
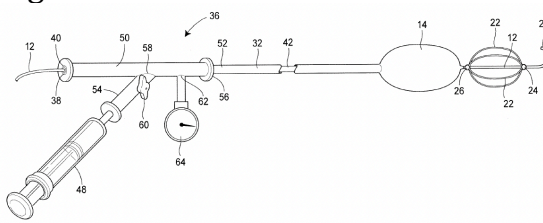
2021 – 2022
Ryan Dolan, MD
Christopher Hesh, MD
Jordan Kapke, MD
Mike Huang, MD
Connor Morton, MD

2022 - 2023
Martin Errea, MD
Corey Area, MD
Simer Grewal, MD
Anish Ganchigar, MD
Julian Hazelton, MD
Ted Rothenberg, MD

APPENDIX B

Sanati Ex-1007	Sanati Publication Ex-1013
<p>Fig 1B:</p>  <p style="text-align: center;">FIG. 1B</p>	<p>Fig 1B:</p>  <p style="text-align: center;">FIG. 1B</p>
<p>7:25-29</p> <p>25a of the inner balloon 22a rather than proximally. In a further alternative, a substantially spherical or bulbous section may be provided on the outer balloon 22b both proximally and distally to the main section 25a of the inner balloon 22a (not shown). In this alternative, the proximal</p>	<p>¶[0039]</p> <p>tion 25a of the inner balloon 22a rather than proximally. In a further alternative, a substantially spherical or bulbous section may be provided on the outer balloon 22b both proximally and distally to the main section 25a of the inner balloon 22a (not shown). In this alternative, the proximal and distal</p>
<p>7:35-47</p> <p>(shown in FIGS. 1A and 1B). Similarly, the outer balloon 22b may also be expandable from a contracted condition (not shown) to an enlarged condition (shown in FIGS. 1A and 1B). One or both balloons 22, e.g., inner balloon 22a, may be formed from substantially inelastic material, e.g., PET, nylon, or PEBAX, such that the balloon 22 expands to a predetermined size in its enlarged condition once sufficient fluid is introduced into the interior of the balloon 22. In addition or alternatively, one or both balloons 22, e.g., outer balloon 22b, may be formed from substantially elastic material, e.g., silicone, polyurethane, or polyethylene, such that the balloon 22 may be expanded to a variety of sizes depending upon the volume and/or pressure of fluid within the interior. In an exemplary embodiment, the inner balloon</p>	<p>¶[0040]</p> <p>(shown in FIGS. 1A and 1B). Similarly, the outer balloon 22b may also be expandable from a contracted condition (not shown) to an enlarged condition (shown in FIGS. 1A and 1B). One or both balloons 22, e.g., inner balloon 22a, may be formed from substantially inelastic material, e.g., PET, nylon, or PEBAX, such that the balloon 22 expands to a predetermined size in its enlarged condition once sufficient fluid is introduced into the interior of the balloon 22. In addition or alternatively, one or both balloons 22, e.g., outer balloon 22b, may be formed from substantially elastic material, e.g., silicone, polyurethane, or polyethylene, such that the balloon 22 may be expanded to a variety of sizes depending upon the volume and/or pressure of fluid within the interior. In an</p>
<p>8:44-49</p> <p>atmospheres (2 ATM). In contrast, the inner balloon 122b may be shaped to expand to a substantially cylindrical shape in the enlarged condition, e.g., having a diameter between about two and eight millimeters (2-8 mm) when expanded using an inflation pressure between about eight and twenty atmospheres (8-20 ATM).</p>	<p>¶[0045]</p> <p>spheres (2 ATM). In contrast, the inner balloon 122b may be shaped to expand to a substantially cylindrical shape in the enlarged condition, e.g., having a diameter between about two and eight millimeters (2-8 mm) when expanded using an inflation pressure between about eight and twenty atmospheres (8-20 ATM).</p>
<p>8:50-53</p> <p>In addition, a main section 25a of the inner balloon 22a may have a substantially uniform diameter, e.g., having a length between about eight and thirty millimeters (8-30 mm). Beyond the uniform diameter portion, the inner bal-</p>	<p>¶[0046]</p> <p>[0046] In addition, a main section 25a of the inner balloon 22a may have a substantially uniform diameter, e.g., having a length between about eight and thirty millimeters (8-30 mm).</p>
<p>8:55-57</p> <p>distal tip 17. The transition portion 27a may be tapered, as shown, or may be substantially blunt, i.e., extending inwardly to the distal tip 17 (not shown). As shown, the main</p>	<p>¶[0046]</p> <p>The transition portion 27a may be tapered, as shown, or may be substantially blunt, i.e., extending inwardly to the distal tip 17 (not shown). As shown, the main portion 25a of the inner</p>
<p>13:6-11</p> <p>lesion 96 within a body lumen 94 without a stent. For example, as shown in FIGS. 3A-3C, during an angioplasty procedure, after positioning the main section 25a of the inner balloon 22a across a stenosis 96, the proximal section 27b of the outer balloon 22b may be inflated to substantially anchor the distal end 16 relative to the body lumen 94.</p>	<p>¶[0069]</p> <p>lesion 96 within a body lumen 94 without a stent. For example, as shown in FIGS. 3A-3C, during an angioplasty procedure, after positioning the main section 25a of the inner balloon 22a across a stenosis 96, the proximal section 27b of the outer balloon 22b may be inflated to substantially anchor the distal end 16 relative to the body lumen 94. Alternatively,</p>

APPENDIX C

Eliason Ex-1009	Eliason PCT Application Ex-1012
<p>Fig. 6</p>  <p>FIG. 6</p>	<p>Fig. 6</p>  <p>FIG. 6</p>
<p>Fig. 7</p>  <p>FIG. 7</p>	<p>Fig. 7</p>  <p>FIG. 7</p>
<p>Fig. 10</p>  <p>FIG. 10</p>	<p>Fig. 10</p>  <p>FIG. 10</p>
<p>Fig. 11</p>  <p>FIG. 11</p>	<p>Fig. 11</p>  <p>FIG. 11</p>

<p>Fig. 12</p> <pre> graph TD A[ENDO VASCULAR PROCEDURE CATEGORY] --> B[NARROW MARGIN PROCEDURE 110] A --> C[WIDE MARGIN PROCEDURE 112] B --> D[FLUOROSCOPY REQUIRED] C --> E[FLUOROSCOPY NOT REQUIRED] </pre> <p>FIG. 12</p>	<p>Fig. 12</p> <pre> graph TD A[ENDO VASCULAR PROCEDURE CATEGORY] --> B[NARROW MARGIN PROCEDURE 110] A --> C[WIDE MARGIN PROCEDURE 112] B --> D[FLUOROSCOPY REQUIRED] C --> E[FLUOROSCOPY NOT REQUIRED] </pre> <p>FIG. 12</p>
<p>4:54-61</p> <p>accomplished. The system of the present disclosure employs 55 such data and provides a self-centering endovascular wire having a J tip sheath, introduced through a transdermal or percutaneous sheath (bridging the skin and subcutaneous tissue) to the torso arterial tree at the femoral artery, to deliver a sufficiently compliant aortic occlusion balloon to a location 60 within the thoracic aorta below the left subclavian artery at the aortic arch. This technology enables aortic occlusion to aug-</p>	<p>¶[0015]</p> <p>The system of the present disclosure employs such data and provides a self-centering endovascular wire having a J tip sheath, introduced through a transdermal or percutaneous sheath (bridging the skin and subcutaneous tissue) to the torso arterial tree at the femoral artery, to deliver a sufficiently compliant aortic occlusion balloon to a location within the thoracic aorta below the left subclavian artery at the aortic arch.</p>
<p>5:64-6:1</p> <p>length markers. The other lumen communicates with the balloon and is used to expand and deflate the balloon. A terminating port with a one-way valve may be provided to be engaged by a fluid source, such as a syringe, for selective inflation and deflation of the arterial occlusion balloon. A</p>	<p>¶[0020]</p> <p>The other lumen communicates with the balloon and is used to expand and deflate the balloon. A terminating port with a one-way valve may be provided to be engaged by a fluid source, such as a syringe, for selective inflation and deflation of the arterial occlusion balloon.</p>
<p>6:5-7</p> <p>adequately inflate the aortic occlusion balloon. The self-centering wire and occlusion balloon may be inserted as a single unit or device.</p>	<p>¶[0020]</p> <p>The self-centering wire and occlusion balloon may be inserted as a single unit or device.</p>
<p>8:47-49</p> <p>The J tip 20 is used to minimize trauma to or perforation of the arterial vessels as the endovascular wire 12 is advanced along the torso arterial tree 11. The J tip 20 is also sufficiently</p>	<p>¶[0046]</p> <p>The J tip 20 is used to minimize trauma to or perforation of the arterial</p>

	vessels as the endovascular wire 12 is advanced along the torso arterial tree 11.
<p>9:12-27</p> <p>Referring now to FIG. 4, a transdermal or percutaneous sheath 28, preferably 6 French, and by way of example having a length of approximately 10 cm with an inner diameter of approximately 0.087 inches is illustrated. The sheath 28 is inserted into the femoral artery 13 through a puncture in the skin 41 (FIG. 2) with a hollow tip needle to provide an access port by way of first a wire and then the sheath 28. The distal end 30 of the sheath 28 is positioned within the external iliac artery 45 (FIG. 1).</p> <p>The endovascular wire 12, the J tip 20, the leading securement bead 24, the trailing securement bead 26, and the unexpanded occlusion balloon 14 (which is disposed proximate to the trailing securement bead 26 and illustrated in FIG. 6) are all of sufficiently small cross-sectional dimensions to pass through the sheath 28. The leading securement bead 24 and</p>	<p>¶[0048] Referring now to Fig. 4, a transdermal or percutaneous sheath 28, preferably 6 French, and by way of example having a length of approximately 10 cm with an inner diameter of approximately 0.087 inches is illustrated. The sheath 28 is inserted into the femoral artery 13 through a puncture in the skin 41 (Fig. 2) with a hollow tip needle to provide an access port by way of first a wire and then the sheath 28. The distal end 30 of the sheath 28 is positioned within the external iliac artery 45 (Fig. 1).</p> <p>¶[0049] The endovascular wire 12, the J tip 20, the leading securement bead 24, the trailing securement bead 26, and the unexpanded occlusion balloon 14 (which is disposed proximate to the trailing securement bead 26 and illustrated in Fig. 6) are all of sufficiently small cross-sectional dimensions to pass through the sheath 28.</p>
<p>9:31-49</p>	<p>¶[0050] Referring now to Fig. 6, the aortic occlusion balloon 14 is carried on a balloon shaft 32 having pre-calibrated length indicia 34 thereon. The pre-calibrated length indicia 34 may include minor length markers 34a in 1cm increments, and major length markers 34b in 5cm increments. The balloon shaft 32 preferably has a length of approximately 90cm (35.43</p>

<p>Referring now to FIG. 6, the aortic occlusion balloon 14 is carried on a balloon shaft 32 having pre-calibrated length indicia 34 thereon. The pre-calibrated length indicia 34 may include minor length markers 34a in 1 cm increments, and major length markers 34b in 5 cm increments. The balloon shaft 32 preferably has a length of approximately 90 cm (35.43 inches) and an outer diameter less than approximately 1.98 mm (0.087 inches), so as to fit through the sheath 28. The balloon shaft 32 includes a lumen 42 (see also FIGS. 10 and 11), permitting the balloon shaft 32 to pass over the endovascular wire 12. A tapered distal end portion 44 of the balloon shaft 32 prevents the balloon shaft 32 from being inserted past the trailing securement bead 26. The balloon shaft 32 will remain over the self-centering endovascular wire 12 during occlusion balloon inflation to provide a rigidity that is sufficient to permit the balloon to be manually maintained at a desired location within the thoracic aorta 47 (FIG. 1), resisting distal or caudal migration, such as might otherwise result from aortic pulsation.</p>	<p>inches) and an outer diameter less than approximately 1.98 mm (0.087 inches), so as to fit through the sheath 28. The balloon shaft 32 includes a lumen 42 (see also Figs. 10 and 11), permitting the balloon shaft 32 to pass over the endovascular wire 12. A tapered distal end portion 44 of the balloon shaft 32 prevents the balloon shaft 32 from being inserted past the trailing securement bead 26. The balloon shaft 32 will remain over the self-centering endovascular wire 12 during occlusion balloon inflation to provide a rigidity that is sufficient to permit the balloon to be manually maintained at a desired location within the thoracic aorta 47 (Fig. 1), resisting distal or caudal migration, such as might otherwise result from aortic pulsation.</p>
<p>9:67-10:3 augmenting heart and brain perfusion. The inflation fluid is a sterile biocompatible fluid introduced to the multi-port and valve assembly 36 (FIGS. 10 and 11) using a fluid source, such as a syringe 48. Upon removal of the sterile inflation</p>	<p>¶[0052] The inflation fluid is a sterile biocompatible fluid introduced to the multi-port and valve assembly 36 (Figs. 10 and 11) using a fluid source, such as a syringe 48.</p>
<p>10:7-32</p>	<p>¶[0053] As illustrated in Figs. 10 and 11, the aortic occlusion balloon 14 is inflated and deflated via a multi-port and valve assembly 36. The multi-port and valve assembly 36 includes a one-way valve, which is preferably pressure gauge calibrated so as to alert a physician when the aortic occlusion balloon 14 has reached its desired inflation pressure. The multi-port and valve assembly 36 further includes a terminating port 38, with a diaphragm 40. The endovascular wire 12 can extend through the diaphragm 40,</p>

<p>As illustrated in FIGS. 10 and 11, the aortic occlusion balloon 14 is inflated and deflated via a multi-port and valve assembly 36. The multi-port and valve assembly 36 includes a one-way valve, which is preferably pressure gauge calibrated so as to alert a physician when the aortic occlusion balloon 14 has reached its desired inflation pressure. The multi-port and valve assembly 36 further includes a terminating port 38, with a diaphragm 40. The endovascular wire 12 can extend through the diaphragm 40, while maintaining fluid-tight communication between the multi-port and valve assembly 36 and the aortic occlusion balloon 14. The multi-way port and valve assembly 36 further includes an elongate tubular barrel section 50 affixed to a proximal end 52 of the balloon shaft 32. The elongate tubular barrel section 50 may have a length of approximately 10 to 15 cm. The elongate tubular barrel section 50 does not pass through the transdermal sheath 28 or enter the body of the patient. In addition to the terminating port 38, which may be considered a first port, the multi-way port and valve assembly 36 includes a second port 56 at a distal end. As discussed above, the multi-way port and valve assembly 36 further includes a diaphragm 40, which is disposed at a proximal end of the elongate tubular barrel section 50. The diaphragm 40 permits the endovascular wire 12 to pass through and extend externally of the first port 38, while maintaining a fluid-tight connection, thereby avoiding leakage of bodily fluid through the first port 38.</p>	<p>while maintaining fluid-tight communication between the multi-port and valve assembly 36 and the aortic occlusion balloon 14. The multi-way port and valve assembly 36 further includes an elongate tubular barrel section 50 affixed to a proximal end 52 of the balloon shaft 32. The elongate tubular barrel section 50 may have a length of approximately 10 to 15 cm. The elongate tubular barrel section 50 does not pass through the transdermal sheath 28 or enter the body of the patient. In addition to the terminating port 38, which may be considered a first port, the multi-way port and valve assembly 36 includes a second port 56 at a distal end. As discussed above, the multi-way port and valve assembly 36 further includes a diaphragm 40, which is disposed at a proximal end of the elongate tubular barrel section 50. The diaphragm 40 permits the endovascular wire 12 to pass through and extend externally of the first port 38, while maintaining a fluid-tight connection, thereby avoiding leakage of bodily fluid through the first port 38.</p>
<p>10:33-40</p> <p>A side port 58 and a branch 54 off the elongate tubular barrel section 50, intermediate the first port 38 and second port 56, enables attachment of the syringe 48 to the multi-way port and valve assembly 36. A one-way valve 60 is actuatable between an open condition (permitting passage of inflation fluid therethrough), as illustrated in FIG. 11, and a closed condition (preventing passage of inflation fluid), as illustrated in FIG. 10. Preferably, the one-way valve 60 is in an open</p>	<p>¶[0054]</p> <p>A side port 58 and a branch 54 off the elongate tubular barrel section 50, intermediate the first port 38 and second port 56, enables attachment of the syringe 48 to the multi-way port and valve assembly 36. A one-way valve 60 is actuatable between an open condition (permitting passage of inflation fluid therethrough), as illustrated in Fig. 11, and a closed</p>

	condition (preventing passage of inflation fluid), as illustrated in Fig. 10.
<p>10:53-64</p> <p>Using a correlation chart or nomogram derived from the statistical data regarding the measurements between the consistently identifiable external measures or landmarks of torso extent (e.g. the symphysis pubis 23 and the sternal notch 25), the physician calculates the proper distance to which the endovascular wire 12 and balloon shaft 32 are to be inserted into the transdermal sheath 28 through a puncture in the skin 41 and into the femoral artery 13 at the location of the femoral head 15, thereby positioning the aortic occlusion balloon 14 at the desired location 21 within the thoracic aorta 47, inferiorly of the left subclavian artery 17 without the aid of fluoroscopy (i.e. fluoroscopy-independent). The major length</p>	<p>¶[0055]</p> <p>Using a correlation chart or nomogram derived from the statistical data regarding the measurements between the consistently identifiable external measures or landmarks of torso extent (e.g. the symphysis pubis 23 and the sternal notch 25), the physician calculates the proper distance to which the endovascular wire 12 and balloon shaft 32 are to be inserted into the transdermal sheath 28 through a puncture in the skin 41 and into the femoral artery 13 at the location of the femoral head 15, thereby positioning the aortic occlusion balloon 14 at the desired location 21 within the thoracic aorta 47, inferiorly of the left subclavian artery 17 without the aid of fluoroscopy (i.e. fluoroscopy-independent).</p>
<p>11:8-14</p> <p>The endovascular, fluoroscopy-independent resuscitative thoracic aortic occlusion system 10 of the present disclosure may be provided to users in the form of a kit, enabling assembly of the same at, by way of example only, a forward surgical hospital close to a battlefield in a civilian trauma setting either outside of a hospital or in a resuscitation room of an emergency department. The system 10 may be applied in clinical</p>	<p>¶[0056]</p> <p>The endovascular, fluoroscopy-independent resuscitative thoracic aortic occlusion system 10 of the present disclosure may be provided to users in the form of a kit, enabling assembly of the same at, by way of example only, a forward surgical hospital close to a battlefield in a civilian trauma setting either outside of a hospital or in a resuscitation room of an emergency department.</p>
<p>11:20-23</p> <p>to the J tip 20. The kit may further include the occlusion balloon 14 that may be disposed proximally on the balloon shaft 32, and advanced over the endovascular wire 12 until it reaches the trailing securement bead 26. The transdermal</p>	<p>¶[0056]</p> <p>The kit may further include the occlusion balloon 14 that may be disposed proximally on the balloon shaft 32, and advanced over the endo</p>

	vascular wire 12 until it reaches the trailing securement bead 26.
11:33-36 The kit may further include the multi-port and valve assembly 36 in fluid communication with both the proximal end of the balloon shaft 32 and a fluid source, such as the syringe 48, as also described above. One of a table, a nomogram, a chart	¶[0057] The kit may further include the multi-port and valve assembly 36 in fluid communication with both the proximal end of the balloon shaft 32 and a fluid source, such as the syringe 48, as also described above.
11:43-61 Referring now to FIGS. 12-18, additional embodiments of the present disclosure are illustrated. Referring to FIG. 12, endovascular procedures in large axial vessels of the human torso may be considered as narrow margin procedures 110 or wide margin procedures 112. In other words, many catheter-based procedures in the aorta and vena cava require exact positioning of devices to be safe and effective, and, therefore, have a narrow margin of error during procedures. The narrow margin procedures 110 require standard fluoroscopy to effectively and accurately direct the procedure. Examples of narrow margin procedures 110 include: (1) placement of stent grafts to treat age-related aneurysms near major branch vessels of the thoracic or abdominal aorta; or (2) treatment of local or localized disease processes such as arterial stenoses caused by atherosclerosis with balloon angioplasty and bare metal stents. Because these procedures entail placing devices at the exact location, i.e., within millimeters, of vital branch or vein locations, they require real time visualization using contrast agents and fluoroscopy.	¶[0058] Referring now to Figs. 12-18, additional embodiments of the present disclosure are illustrated. Referring to Fig. 12, endovascular procedures in large axial vessels of the human torso may be considered as narrow margin procedures 110 or wide margin procedures 112. In other words, many catheter-based procedures in the aorta and vena cava require exact positioning of devices to be safe and effective, and, therefore, have a narrow margin of error during procedures. The narrow margin procedures 110 require standard fluoroscopy to effectively and accurately direct the procedure. Examples of narrow margin procedures 110 include: (1) placement of stent grafts to treat age-related aneurysms near major branch vessels of the thoracic or abdominal aorta; or (2) treatment of local or localized disease processes such as arterial stenoses caused by atherosclerosis with balloon angioplasty and bare metal stents. Because these procedures entail placing devices at the exact location, i.e., within millimeters, of vital branch or vein locations, they require real

	time visualization using contrast agents and fluoroscopy.
<p>12:29-32</p> <p>measurements are taken (in cm), for example, from the femoral artery 13 at the level of the femoral head 15 to the left subclavian artery 17, as the left femoral artery 13 is a common vascular entry point. As also illustrated in FIG. 1, other major</p>	<p>¶[0061]</p> <p>measurements are taken (in cm), for example, from the femoral artery 13 at the level of the femoral head 15 to the left subclavian artery 17, as the left femoral artery 13 is a common vascular entry point.</p>
<p>16:18-38 (claim 4)</p> <p>16:41-45 (claim 6)</p> <p>4. A method for deploying and selectively inflating a thoracic aortic balloon at a desired location within a thoracic aorta of a patient, comprising:</p> <ul style="list-style-type: none"> measuring a distance between at least two readily externally identifiable anatomical landmarks of the patient, said anatomical landmarks including at least a symphysis pubis of the patient and a sternal notch of the patient; comparing the distance between the at least two external anatomical landmarks of the patient to a prediction model and calculating a length to which a calibrated endovascular wire and a balloon shaft of the thoracic occlusion system are to be inserted in the patient, the prediction model having correlation data for distances between the at least two external anatomical landmarks of torso extent of a pool of humans to centerline distances from a femoral artery at a femoral head to a location within the thoracic aorta of humans, the data measured using CT imaging; and inserting the calibrated endovascular wire and the balloon shaft to the length calculated for the patient independent of fluoroscopy. <p>6. The method of claim 4, wherein the method further includes pre-securing the balloon shaft to the endovascular wire proximate a trailing securement bead, allowing the balloon shaft and the endovascular wire to be inserted in the patient and delivered as a single unit.</p>	<p>claims 8, 56, and 57</p> <p>8. The thoracic aortic occlusion system of claim 2, wherein the balloon shaft may be pre-secured to the endovascular wire proximate to the trailing securement bead, such that the balloon shaft and endovascular wire are inserted in the patient and delivered as a single unit.</p> <p>56. A system for determining a length to which an endovascular device of a thoracic occlusion system is to be inserted in a patient without fluoroscopy, the system comprising:</p> <ul style="list-style-type: none"> measuring a distance between at least two anatomical landmarks of the patient, said anatomical landmarks including at least a symphysis pubis of the patient and a sternal notch of the patient; and comparing the distance between the at least two external anatomical landmarks of the patient to one of a table, chart or graph correlating distances between the at least two external anatomical landmarks of a pool of humans to centerline distances from the femoral artery at the femoral head to a location within the thoracic aorta of the humans, to calculate the length to

	<p>which the endovascular device is to be inserted in the patient.</p> <p>57. The system of claim 56, further including inserting the endovascular device to the length calculated for the patient independent of fluoroscopy.</p>
--	--

APPENDIX D – LIST OF MATERIALS CONSIDERED

Ex-1001	U.S. Patent No. 11,857,737 (“the ’737 Patent”)
Ex-1002	Prosecution history of U.S. Patent No. 11,857,737
Ex-1004	U.S. Patent Number 3,467,101 (“Fogarty”)
Ex-1005	S. Chengod, MD. et al., <i>Selective Left Bronchial Intubation and Left-Lung Isolation in Infants and Toddlers: Analysis of a New Technique</i> , Department of Anesthesiology and Intensive Care, Division of Cardiothoracic and Vascular Anesthesiology and Intensive Care, Amrita Institute of Medical Sciences and Research Center, Kerala, India. (2005) (“Chengod”)
Ex-1006	Mark A. Saab, <i>Applications of High-Pressure Balloons in the Medical Device Industry</i> , Medical Device & Diagnostic Industry Magazine (September 2000) (“Saab”)
Ex-1007	U.S. Patent No. 10,004,622 (“Sanati”)
Ex-1008	Dr. David H. Deaton, <i>Image-Guided Thrombectomy in Vascular Surgery</i> , Endovascular Today (July 2005) (“Deaton”)
Ex-1009	U.S. Patent Number 9,131,874 (“Eliason”)
Ex-1010	Daniel J. Scott, et al., <i>A novel fluoroscopy-free, resuscitative endovascular aortic balloon occlusion system in a model of hemorrhagic shock</i> , The Journal of Trauma and Acute Care Surgery, Vol. 75, Issue 1 (July 2013) (“Scott”)
Ex-1011	U.S. Publication Number 2015/0133892 (“Joe”)
Ex-1012	International Application Number PCT/US2011/033368 (“Eliason PCT Application”)
Ex-1013	U.S. Patent Pub. No. 2013/0060316 (“Sanati Publication”)
Ex-1014	X. Gu et al., <i>A New Technique for Sizing of Atrial Septal Defects</i> , Catheterization and Cardiovascular Interventions (1999) (“Gu”)
Ex-1015	Handbook of Endovascular Peripheral Interventions (C.D. Owens & Y. Yeghiazarians eds., Springer 2012)

Ex-1016	PCT publication number WO 2014/036530 to Bagaoisan ("Bagaoisan")
Ex-1017	U.S. Patent No. 8,088,121 to Nishide ("Nishide")
Ex-1018	U.S. Patent No. 5,607,394 to Anderson ("Anderson")
Ex-1019	U.S. Patent No. 5,779,731 to Leavitt ("Leavitt")
Ex-1020	U.S. Patent Publication No. 2008/0188803 by Jang ("Jang")
Ex-1021	John M. Mathis, et. al, <i>Physical Characteristics of Balloon Catheter Systems Used in Temporary Cerebral Artery Occlusion</i> , American Society of Neuroradiology (November 1994) ("Mathis")
Ex-1022	U.S. Patent No. 4,846,174 to Willard et al. ("Willard")
Ex-1023	Patent Owner's Infringement Claim Charts filed in <i>Prytime Medical Devs., Inc. v. Front Line Med. Techs., Inc.</i> , Case No. 6:24-cv-00001, Dkt. No. 1-3 (W.D. Tex. Jan. 2, 2004)
Ex-1024	E.P. Gerstenfeld & J. Michele, <i>Pulmonary vein isolation using a compliant endoscopic laser balloon ablation system in a swine model</i> , Springer Science+Business Media, LLC (2010) ("Gerstenfeld")
Ex-1025	U.S. Patent No. 5,087,246 to Smith ("Smith")
	J. Michael Jaeger, et al., <i>Special Purpose Endotracheal Tubes</i> , Respiratory Care in June 1999 (Vol. 44, No. 6)
	https://www.microvention.com/products/scepter
	A. Metzner et al., <i>One-year clinical outcome after pulmonary vein isolation using the novel endoscopic ablation system in patients with paroxysmal atrial fibrillation</i> , Heart Rythm Society (2011)
	P. Neuzil & L. Sediva, <i>Balloon technology for catheter ablation of atrial fibrillation</i> , Cardioloy Dept., Na Homolce Hospital, Prague, Czech Republic, Cor Et Vasa 54 (2012) (available online at www.sciencedirect.com)