UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

QXMÉDICAL, LLC,

Plaintiff,

v.

VASCULAR SOLUTIONS, LLC; TELEFLEX INNOVATIONS S.À.R.L.; and ARROW INTERNATIONAL, INC.,

Defendants.

Case No. 17-CV-1969 (PJS/TNL)

ORDER

Courtland C. Merrill, Philip J. Kaplan, and Ariel O. Howe, ANTHONY OSTLUND BAER & LOUWAGIE P.A., for plaintiff.

Luke L. Dauchot and Alyse Wu, KIRKLAND & ELLIS LLP; and Tom Vitt and Patrick J. O'Rear, JONES DAY, for defendants.

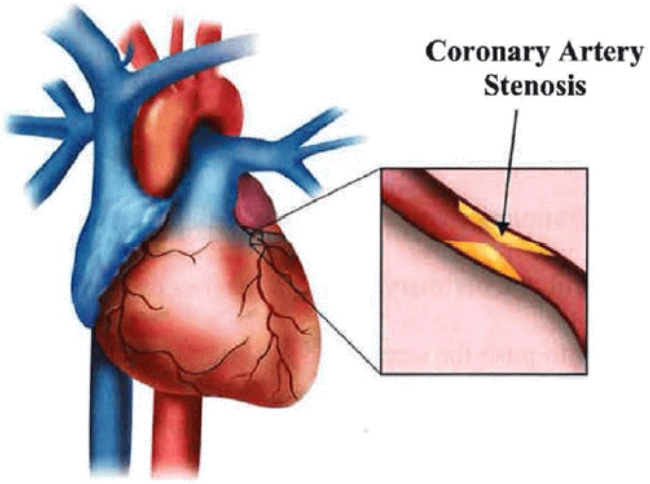
This lawsuit involves six patents—U.S. Patent Nos. 8,048,032 (the "'032 patent"), 8,142,413 (the "'413 patent"), RE45,380 (the "'380 patent"), RE45,760 (the "'760 patent"), RE45,776 (the "'776 patent"), and RE46,116 (the "'116 patent"). All six patents descend from a common patent application and share a common specification and common drawings. The patents are owned by defendant Teleflex Innovations S.à.r.l., whose parent corporation acquired defendant Vascular Solutions, LLC, in February 2017. A third defendant, Arrow International, Inc., has the right to sell products practicing the patents. For convenience, the Court will refer to the defendants collectively as "Vascular Solutions."

In April 2017, Vascular Solutions accused plaintiff QXMédical, LLC ("QXMédical") of patent infringement. In response, QXMédical brought this action, seeking a declaration that its "Boosting Catheter" does not infringe any of Vascular Solutions's patents. This matter is before the Court for construction of certain terms of the patents-in-suit in accordance with *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390-91 (1996).

I. BACKGROUND

Vascular Solutions's patents relate to a medical device known as a "guide extension catheter." A guide extension catheter is used by a heart surgeon to deliver an interventional cardiology device (such as a balloon or stent) into a coronary artery.

Coronary arteries are the arteries that supply oxygenated blood from the aorta to the heart muscle. The buildup of plaque inside a coronary artery can create a "stenosis"—that is, a narrowing of the coronary artery—that decreases blood flow to the heart and increases the risk of heart attack. A coronary artery stenosis looks something like this:

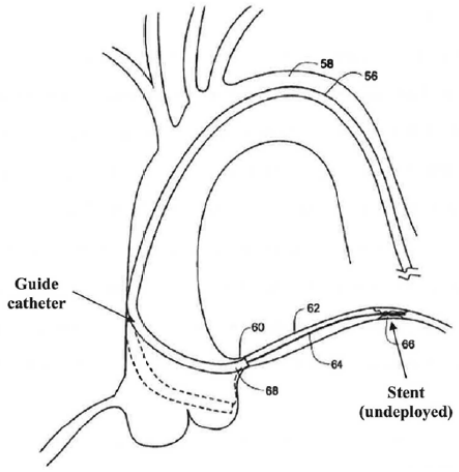


Root Decl. ¶ 8 (ECF No. 59).

One way to treat a stenosis is to use a balloon or stent to reopen the coronary artery. *Id.* ¶ 10. To do so, of course, the surgeon must deliver the balloon or stent to the site of the stenosis. Typically, the surgeon will first insert a long, thin tube called a "guide catheter" into the patient's femoral artery (near the patient's groin) or the patient's radial artery (near the patient's wrist). Then the surgeon will push the guide catheter through the patient's body until the tip of the guide catheter reaches the opening (or "ostium") of the coronary artery. Next, the surgeon will push a long, thin wire—known as a "guidewire"—through the guide catheter, into the coronary artery, and through the site of the stenosis. Finally, the surgeon will slide a balloon or stent

along the guidewire to the site of the stenosis, where the balloon or stent will be expanded. *Id.* ¶¶ 11-13.

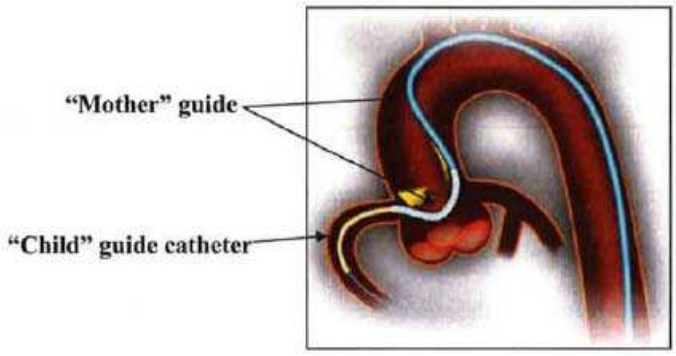
The guide catheter is relatively rigid and often has a curved tip. *Id.* ¶ 15. The combination of these two characteristics means that it is generally unsafe for a surgeon to extend the guide catheter past the ostium and into the coronary artery. *Id.* ¶¶ 15-16. That is why a surgeon uses a guidewire to deliver the balloon or stent to the site of the stenosis. Sometimes, though, a surgeon has to push a balloon or stent through a particularly difficult stenosis. In this situation, the resulting backwards force can cause the guide catheter to dislodge, preventing the surgeon from successfully deploying the balloon or stent. The dotted lines in the diagram below illustrate this problem:



Id. ¶¶ 12, 15-17.

To solve this problem, inventors came up with the idea of using a second catheter within the guide catheter. In this "coaxial" arrangement, the inner catheter (the

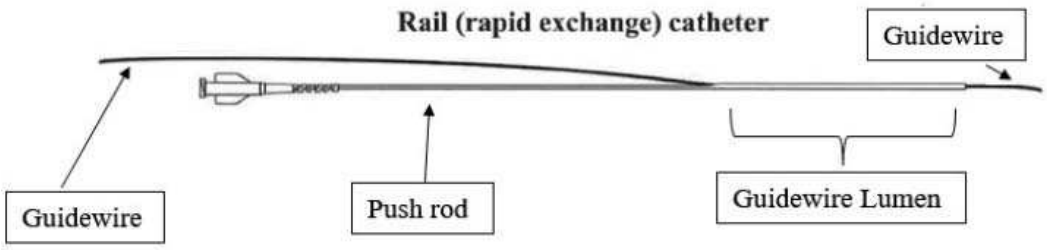
"child catheter") is straighter and more flexible than the outer catheter (the "mother catheter"). This allows the child catheter to be pushed past the end of the mother catheter and into the coronary artery, thereby anchoring the mother catheter and reducing the likelihood of the mother catheter dislodging. The picture below illustrates the use of a child catheter:



Id. ¶ 18.

Vascular Solutions did not invent the mother-and-child catheter system. But Vascular Solutions combined the mother-and-child catheter system with another concept known as a "monorail," "rapid exchange," or "sliding rail" system. *Id.* ¶ 22. A typical child catheter is a long tube that runs along a guidewire from the beginning of the mother catheter (that is, from the opening in the patient's femoral artery or radial artery) past the end of the mother catheter (that is, into the coronary artery). By contrast, a monorail catheter is not tubular along its entire length. Instead, a monorail catheter combines a short tube at the "distal" end (that is, the end closest to the heart)

with a long non-tubular push rod at the "proximal" end (that is, the end closest to the surgeon). The push rod "is used to push and retract the catheter but runs independent of and next to the guidewire." *Id.* ¶ 21. The drawing below depicts a monorail catheter:



Id. This drawing refers to the child catheter as "Guidewire Lumen." All of the items depicted in this drawing would be situated within the mother catheter.

The tip of Vascular Solutions's child catheter is a flexible straight tube that is small enough to fit inside a standard guide catheter but large enough to accommodate the delivery of balloons and stents. *Id.* ¶ 23. Near or at the junction of the flexible tube and the push rod is a side opening that serves as an entry port—first for the guidewire, and then for the balloon or stent that is pushed along the guidewire, through the flexible tube, and into the coronary artery. Root Decl. ¶¶ 23-24.[1]

[1]It should be noted that the commercial embodiment described in the Root declaration—as well as some of the devices claimed in the patents-in-suit—do not look much like the embodiments described and illustrated in the specification.

In 2006, Vascular Solutions[2] filed a patent application for a monorail-type child catheter. This application was ultimately issued as the '032 patent. Claim 1 of the '032 patent contains most of the terms whose meaning is contested in this *Markman* proceeding, and the parties agree that each of the contested terms has the same meaning across all of the patents-in-suit. Claim 1 of the '032 patent claims the following:

> 1. A device for use with a standard guide catheter, . . . the device comprising:
>
> > a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and
> >
> > a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter,

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[2]Technically, Howard Root and his co-inventors applied for the patent, but after the patent was issued, they assigned it to Vascular Solutions.

> such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

'032 patent at 10:21-54.

II. GENERAL PRINCIPLES

Courts, not juries, construe patent claims. *Markman*, 517 U.S. at 391. Disputed terms in a claim must be construed in the context of both that individual claim and "the entire patent, including the specification." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). Indeed, the specification, read in light of the prosecution history, is the primary basis for construing patent claims. *Id.* at 1315. Courts may also rely on "extrinsic evidence"—anything other than the patent and its prosecution history—but that evidence is less important than the intrinsic record. *Id.* at 1317.

In general, claim language means whatever it would have meant, ordinarily and customarily, to a person of ordinary skill in the relevant art at the time the patent application was filed. *Id.* at 1312-13. In some cases, the ordinary and customary meaning of claim language to a person of ordinary skill in the art may be identical to the meaning of that language to a lay person who is not skilled in the art. *See id.* at 1314 (acknowledging that claim construction sometimes "involves little more than the application of the widely accepted meaning of commonly understood words").

Neither of the parties has devoted much attention to defining a person of ordinary skill in the art for purposes of this *Markman* proceeding. QXMédical's expert identifies a person of ordinary skill in the art as "a person having a bachelor's, or higher level, degree in either biomedical or mechanical engineering, or a medical degree, combined with extensive experience working for at least three years as an interventional cardiologist, interventional radiologist, cardiothoracic surgeon, interventionalist, or biomedical engineer, biomedical device designer and/or manufacturer." ECF No. 36-3 ¶ 15. Vascular Solutions's expert identifies a person of ordinary skill in the art as a person having "(1) a minimum of five years of experience performing or observing interventional cardiology procedures and (2) a minimum of five years of experience designing or manufacturing catheters or other devices used in such procedures . . . ." ECF No. 36-2 ¶ 34. Neither party has argued that anything turns on the differences between these definitions. Indeed, neither party has argued (or at least clearly argued) that someone of ordinary skill in the art would interpret any of the disputed language differently than would an educated lay person.

III. CLAIM CONSTRUCTION

A. "substantially rigid"

Claim 1 of the '032 patent describes the proximal portion of the claimed device as being "substantially rigid." '032 patent at 10:38. Both parties ask the Court to construe this term.

QXMédical argues that "substantially rigid" means "largely, but not wholly unable to bend or be forced out of shape; not flexible." ECF No. 36-1 at 2. It is not apparent what would be gained by this construction. "Largely unable to bend" is no clearer or more specific than "substantially rigid." And "not flexible"—which connotes *no* flexibility—would result in a device that does not work, as the substantially rigid portion must be able to navigate the tortuous vascular system of a human being.

Vascular Solutions argues for a functional definition of "substantially rigid": "rigid enough to allow the device . . . to be advanced within the guide catheter." ECF No. 36-1 at 2. It is not surprising that Vascular Solutions proposes a functional definition. Unlike patents that provide specific guidance regarding the meaning of terms of degree such as "substantially,"[3] the only real evidence that the patents-in-suit

[3] *See, e.g.*, *BreathableBaby, LLC v. Crown Crafts, Inc.*, No. 12-CV-0094 (PJS/TNL), 2013 WL 5230724, at *5 (D. Minn. Sept. 17, 2013) (specification defined "a substantial portion of a side rail" as "at least two-thirds of the side rail").

provide regarding the meaning of the term "substantially rigid" is their description of the function of the substantially rigid portion.

Nonetheless, Vascular Solutions's argument—that a structural limitation should be defined in functional terms—initially gave this Court pause. After all, the Federal Circuit has held that "[a]n invention claimed in purely structural terms generally resists functional limitation." *Toro Co. v. White Consol. Indus., Inc.*, 266 F.3d 1367, 1371 (Fed. Cir. 2001). That is particularly true with respect to functions that are not recited in the patent itself.

For example, in *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358 (Fed. Cir. 2001), one of the claims described a solid detergent cast as "substantially uniform." *Id.* at 1361. The patentee persuaded the district court to construe "substantially uniform" to mean "a level of continuity of the elements from top-to-bottom throughout the cast such that a homogeneous cleaning solution is formed over the life of the cast." *Id.* at 1363. On appeal, however, the Federal Circuit noted that nothing in the intrinsic record provided a basis for "adding a functional limitation" to the term "substantially uniform." *Id.* at 1366. Therefore, the Federal Circuit construed "substantially uniform" to mean "largely, but not wholly the same in form," and declined to add a "functional limitation to this phrase." *Id.* at 1369.

At the same time, the Federal Circuit has shown no reluctance to construe claim limitations functionally when such a construction *is* supported by the intrinsic record. For example, in *Cordis Corp. v. Medtronic Ave, Inc.*, 511 F.3d 1157 (Fed. Cir. 2008), the patent claimed a stent with a "smooth surface." *Id.* at 1163. The district court defined the term "smooth" structurally to mean "continuously even . . . , without roughness, points, bumps or ridges . . . ." *Id.* at 1178. On appeal, however, the Federal Circuit relied on the prosecution history to conclude that "the patentee intended for the term 'smooth' to be defined functionally, so that a stent would be considered 'smooth' if it was smooth enough to be capable of intraluminal delivery." *Id.* at 1180. Using that functional definition, the Federal Circuit concluded that the defendant's competing product "infringed the 'smooth surface' limitation" because there was no dispute that it was "capable of intraluminal delivery." *Id.*

Similarly, in *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313 (Fed. Cir. 2005), the Federal Circuit adopted a functional definition of "substantially uniform." In *Medrad*, the patent related to radio frequency coils that were used to create magnetic resonance imaging ("MRI") images. *Id.* at 1315. Citing *Ecolab*, the patentee argued that "it is never proper for a court, when construing claim terms, to consider how a claimed device functions." *Id.* at 1319. The Federal Circuit rejected this argument, calling the patentee's reading of *Ecolab* "unsound" and holding that it is "entirely proper to

consider the functions of an invention in seeking to determine the meaning of particular claim language." *Id.* In *Medrad*, "the claim itself provide[d] little guidance" for how to construe the term "substantially uniform." *Id.* But the preamble of the patent claimed "an imaging system for forming images of a region of interest." *Id.* at 1320. The specification stated that one object of the invention was "to provide greater image uniformity than provided in the prior art." *Id.* And an expert testified that "a substantially uniform magnetic field 'means a sufficient uniformity to give a good image.'" *Id.* Therefore, the Federal Circuit defined a "substantially uniform magnetic field" functionally to mean "a field that is sufficiently uniform to obtain useful MRI images." *Id.*

As in *Cordis* and *Medrad*, Vascular Solutions's proposed functional definition is amply supported by the record. That record makes at least two things clear about the substantially rigid portion of the claimed device:

On the one hand, the substantially rigid portion must have a considerable degree of flexibility. Otherwise, it would not be able to navigate past sharp bends in the vascular system of a human being. This is clear from both the intrinsic and extrinsic evidence. *See, e.g.*, ECF No. 36-2 ¶ 38 (stating that "the substantially rigid portion of the device must be flexible enough to navigate the curve in the aorta and femoral and iliac arteries and other angles in the arterial path"); *see also* Root Decl. ¶ 24 (describing the

substantially rigid portion of the embodiment as flexible enough "to bend to navigate the arch in the aorta").

On the other hand, the substantially rigid portion must be rigid enough to push the tubular structure through the guide catheter and into the coronary artery. Neither party contests this fact, which is supported not only by the specification's description of the functioning of the device, but by claim 1's focus on the degree of rigidity along the *longitudinal* axis: "a substantially rigid portion . . . more rigid along a longitudinal axis than[] the flexible tip portion . . . ." '032 patent at 10:39-40. It is difficult to imagine why the claim would focus on the *longitudinal* rigidity of the substantially rigid portion unless the purpose of the "substantially rigid" limitation is to ensure that the substantially rigid portion will not buckle when it is used as a push rod.

The prosecution history also reflects the examiner's understanding that the purpose of the "substantially rigid" limitation is to ensure that the substantially rigid portion can function as a push rod. Specifically, the examiner expressed his understanding that "substantially rigid" was "only rigid enough to allow the device to be advanced within the guide catheter." ECF No. 60-2 at 12. The examiner's use of the word "only" is puzzling, as it suggests that a push rod that is any more rigid than necessary would not be "substantially rigid." That would be a counterintuitive construction that neither party advocates. But at a minimum, the examiner's comments

provide further evidence that the function of the substantially rigid portion is to push the tubular structure through the guide catheter and into the coronary artery.

In sum, given that Federal Circuit case law supports giving a functional definition to a structural term when such a construction is supported by the intrinsic record—and given that the intrinsic record in this case leaves little doubt that the main function of the substantially rigid portion is to act as a push rod—the Court accepts Vascular Solutions's argument that "substantially rigid" should be defined in the patents-in-suit as "rigid enough to allow the device to be advanced within the guide catheter."

The Court notes that Vascular Solutions' victory may be short-lived—or even pyrrhic. QXMédical argues that Vascular Solutions's construction cannot possibly be correct. First, QXMédical argues that the material that comprises the flexible tip portion is "rigid enough to allow the device to be advanced within the guide catheter." In other words, according to QXMédical, if the flexible tubular structure were to be extended to run throughout the entire guide catheter (similar to a conventional child catheter), the flexible tubular structure could essentially act as its own push rod. Likewise, QXMédical argues that a guidewire is "rigid enough to allow the device to be advanced within the guide catheter." In other words, QXMédical argues that if the flexible

tubular structure was attached to the end of a guidewire, the guidewire could push the structure through the guide catheter and into the coronary artery.

Second, claim 1 of the '032 patent is crystal clear that the substantially rigid portion must be "more rigid . . . than[] the flexible tip portion." '032 patent at 10:39-40. Moreover, according to QXMédical, the specification indicates that the guidewire is flexible. *Cf.* '032 patent at 1:16-29, 2:56-62. Thus, concludes QXMédical, "substantially rigid" cannot mean "rigid enough to allow the device to be advanced within the guide catheter" because both the flexible tip portion and the guidewire are "rigid enough to allow the device to be advanced within the guide catheter" and the patents make clear that both the flexible tip portion and the guidewire are *not* "substantially rigid," but instead "flexible."

QXMédical would have a compelling argument, but for one problem: The evidence in the record simply does not allow the Court to determine whether the factual premises of the argument are true. At the *Markman* hearing, QXMédical could not point to any record evidence proving that the flexible tip portion or the guidewire was rigid enough to act as a push rod. In its brief, QXMédical emphasized that the specification "states that the flexible tip portion, although flexible, can be advanced within the guide catheter." ECF No. 63 at 12. But that's a different point. It is one thing for the flexible tip portion to be rigid enough to *be pushed*, and another thing for the flexible tip portion

to be rigid enough to *do the pushing*. QXMédical also cited several paragraphs from the specification and claimed in a footnote that "the proximal portion of the child catheter is 'rigid enough to advance' the distal portion of the catheter within the mother guide catheter . . . ." *Id.* at 12 n.3 (citing Root Decl. ¶ 17 and '032 patent at 2:17-44). But the cited portions of the '032 patent describe the use of a *conventional* child catheter—that is, the long tubal child catheter of the prior art. *See* '032 patent at 2:17-44. The record does not indicate whether the material that comprises a prior-art child catheter is more or less rigid than the material that comprises the flexible tip portion of the patented inventions. At this point, then, the Court cannot conclude that Vascular Solutions's proposed construction of "substantially rigid" would capture anything that the patents describe as "flexible."

B. "flexible"

Claim 1 of the '032 patent describes the tip portion of the claimed device as being "flexible." '032 patent at 10:29. QXMédical argues that "flexible" should be construed to mean "capable of bending; not rigid." ECF No. 36-1 at 5. Vascular Solutions argues that no construction of "flexible" is necessary and that "flexible" should instead be given its plain and ordinary meaning. *Id.* The Court agrees with Vascular Solutions.

QXMédical's proposed construction of "flexible" as "not rigid" would imply a complete absence of rigidity. Such a construction would not be consistent with the

claims and specification. In addition, construing "flexible" to mean "capable of bending" would not add anything to the plain and ordinary meaning.

C. "rail structure"

Claim 1 of the '032 patent provides that the "substantially rigid portion" must "defin[e] a rail structure without a lumen." '032 patent at 10:40-41. The parties dispute the meaning of "rail structure."

Every monorail system consists of at least three elements: (1) a rail, (2) a car that rides on the rail, and (3) a source of locomotion. It is clear that, in the patented devices, the "rail" is the guidewire. The flexible tubular portion of the device rides along the guidewire, as does the balloon or stent that follows. Nothing rides along the push rod. And thus, the "rail structure" that is defined by the substantially rigid portion cannot be the rail. That leaves the car and the source of locomotion as possibilities.

QXMédical argues that "rail structure" refers to the car that rides along the guidewire. *See* ECF No. 56 at 29 ("[I]n order for the substantially rigid portion claimed in VSI's patents to 'defin[e] a rail structure[,]' the substantially rigid portion must either surround or at least create a partial circumference portion to hold or 'ride' on the guidewire."). Consistent with that argument, QXMédical proposes that "rail structure" be defined to mean a "full-circumferential, greater than 180 degrees, hemicylindrical or arcuate-shaped distal end [that is] able to 'ride' on a guidewire." ECF No. 56 at 27.

One problem for QXMédical is that nothing in the patents-in-suit explicitly requires the "rail structure" that is defined by the substantially rigid portion to ride on the guidewire. And that is unsurprising. As the Court has already discussed, the main function of the substantially rigid portion is to push the flexible tip portion along the guidewire and into the coronary artery. It is the flexible tip portion—which, again, is the tube through which the guidewire is threaded—that rides along the guidewire. Not only is there no reason for the push rod to *also* ride along the guidewire, but, if it did so, it might interfere with the ability of a balloon or stent to later be moved along the same guidewire.

QXMédical's proposed construction runs into another problem. In order for the "rail structure" to function as a car, it would need a lumen—or something close to a lumen. QXMédical recognizes this fact in proposing to define the rail structure as being "full circumferential, greater than 180 degrees, hemicylindrical or arcuate-shaped." But the patents specifically *forbid* the rail structure from having a lumen. *See* '032 patent at 10:40-41 (stating that the rail structure must be "without a lumen"). This means that the rail structure *cannot* be "full circumferential." This also raises the question of why, if the rail structure is meant to be the car, the patents would provide that the car cannot have a lumen—the structure that would best allow it to ride along the guidewire without impeding the passage of balloons or stents.

Of course, a car does not have to be fully circumferential to ride on the guidewire. A less-than-fully-circumferential car can still ride on the guidewire by gripping the guidewire rather tightly. But the problem with this approach has already been noted: Any car that gripped the guidewire tightly would impede the passage of a balloon or stent along the same guidewire. The specification specifically mentions that the rail segment must not "block[] use of the guide catheter" to deliver balloons and stents. '032 patent at 2:55-56. QXMédical's attempt to define "rail structure" to mean, in essence, the car that rides along the guidewire cannot be reconciled with the claims or specification.

Given that the "rail structure" is neither the rail nor the car, the only major component left is the source of locomotion—i.e., the push rod. Reflecting that fact, Vascular Solutions asks that "rail structure" be defined as a "structure . . . that facilitates monorail or sliding rail delivery," ECF No. 36-1 at 6—a definition that is sufficiently broad to capture the push rod. The Court adopts Vascular Solutions's proposed definition.

D. "lumen"

As the Court has already mentioned, claim 1 of the '032 patent specifies that the rail structure cannot have a "lumen." '032 patent at 10:40-41. The parties disagree on the meaning of "lumen." In other words, the parties disagree about what *cannot* be included in the rail structure.

QXMédical asks the Court to construe "lumen" to mean a "passageway or opening." ECF No. 36-1 at 6. Vascular Solutions asks the Court to construe "lumen" more narrowly to mean a "passageway through which interventional cardiology devices are insertable." *Id.* The Court declines to adopt either construction.

As a threshold matter, the Court rejects Vascular Solutions's suggestion that "lumen" refers to only *some* lumens—specifically, lumens that are large enough to accommodate the passage of balloons and stents. The Court does so for two reasons:

First, claim 1 clearly specifies that the substantially rigid portion must define "a rail structure *without* a lumen." '032 patent at 10:40-41 (emphasis added). Claim 1 does not say that the rail structure *can* have a lumen, as long as the lumen is small. And this makes sense: As the specification makes clear—and as Vascular Systems itself has emphasized—it is important that the push rod take up as little space within the guide catheter as possible, so as to leave space for the passage of balloons and stents along the

guidewire. Requiring that the push rod have no lumen helps to accomplish that objective.

Second, if the Court were to read a size limitation into the term "lumen," the Court would render superfluous other language in the patents-in-suit. The claims and specification of the patents often mention a lumen, and almost every time that a lumen is mentioned, its size is specified. For example, claim 1 of the '032 patent describes "the continuous lumen of the guide catheter" as "having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen." '032 patent at 10:25-28. Similarly, claim 1 describes the tip of the child catheter as "defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable." *Id.* at 10:35-38. If "lumen" meant what Vascular Solutions wants it to mean—a "passageway through which interventional cardiology devices are insertable"—then there would be no reason for the patents to provide (as they do repeatedly) that the lumens of both the guide catheter and flexible tip portion must be large enough to allow the passage of interventional cardiology devices. That size limitation would already be baked into the word "lumen."

Vascular Solutions points out that every mention of "lumen" in the patents "is in connection with it serving as a passageway for interventional cardiology devices." ECF

No. 58 at 28. What Vascular Solutions overlooks, however, is that it is referring to occasions on which the patents describe a lumen that is *present*. The purpose of such a lumen is to act as a conduit for balloons and stents. Here, by contrast, claim 1 is referring to a lumen that is *prohibited*. As noted, the purpose of that prohibition is to ensure that the push rod takes up as little room as possible within the guide catheter. It makes perfect sense, then, to require lumens that are *present* to be large enough to accommodate the passage of medical devices (because that is what those lumens do), but to require that the rail structure not have a lumen of any size. Therefore, the Court rejects Vascular Solutions's proposal that "lumen" be defined to mean a lumen of a particular size.[4]

So how should "lumen" be defined? Vascular Solutions and QXMédical both urge the Court to construe "lumen" as a "passageway" or "opening." But "lumen" is commonly understood as simply being the cavity of a tube. For example, the American Heritage Dictionary defines "lumen" as "[t]he inner open space or cavity of a tubular organ . . . ." *Lumen*, The American Heritage Dictionary of the English Language (5th ed. 2018), https://ahdictionary.com/word/search.html?q=lumen (last visited October 29,

[4]To the extent that *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 13-CV-1172 (JRT/SER) (D. Minn. Dec. 9, 2013), held otherwise, the Court respectfully disagrees with that order, which does not address these problems with Vascular Solutions's proposed construction. *See* ECF No. 60-5. Moreover, the Federal Circuit later vacated the order in *Vascular Solutions*, finding, among other things, that "the record is too incomplete on issues of claim construction." *See* ECF No. 64-2.

2018). Merriam-Webster defines "lumen" as "the bore of a tube (as of a hollow needle or catheter)." *Lumen,* Webster's Third New International Dictionary (1993). And Random House defines "lumen" as "the canal, duct, or cavity of a tubular organ." *Lumen*, The Random House Unabridged Dictionary (2018) https://www.dictionary.com/browse/lumen (last visited October 29, 2018).

By contrast, "opening" can refer to many things that are not lumens. A gap between two mountains or two teeth or two offensive linemen can be described as an "opening." A fence can have an "opening" where a gate is (or is not) installed. A cave has an "opening" at its entry point. But none of these openings is a lumen.

Defining "lumen" as "passageway" is also problematic. For one thing, not all passageways are lumens. The Donner Pass is a passageway, but it's not a lumen. The same is true about the aisle up the middle of a church or a secret passageway in an old castle or a path through a forest. On the flip side, not all lumens are passageways. Take, for example, a hollow tube that is filled with air and then sealed so that it can be used as a floatation device. (Think of a pontoon on a boat.) The inside of such a tube would not be a conduit or passageway for anything, but it would surely be a lumen. Finally, construing "lumen" to mean a "passageway" would create a new set of ambiguities: Is a "passageway" any space that is *intended* to be passed through? Or *capable* of being passed through? Or *actually* passed through?

The Court construes "lumen" to have its plain and ordinary meaning: "the cavity of a tube." Nothing in the intrinsic evidence requires "lumen" to be construed differently. To the contrary, every time "lumen" is used in the claims or specification, the word is used to refer to the cavity of a tube.

E. "side opening"/"partially cylindrical opening"

Many of the claims in the patents-in-suit require the device to have a side opening—variously referred to as a "proximal side opening" ('032 patent at 10:65; '413 patent at 12:9; '380 patent at 11:35); "a segment defining a side opening" ('760 patent at 13:54-55, 15:32-33; '116 patent at 14:3-4; *see also* '760 patent at 14:21-22, 14:25-26, 14:27-28; '116 patent at 18:12-13); and "a segment defining a partially cylindrical opening" ('776 patent at 13:41, 15:20).

None of the parties seriously argues that any of these terms is vague or needs construing. Rather, the terms are in dispute because QXMédical insists that the side opening must be located in the substantially rigid portion, and not in the flexible tubular portion. QXMédical thus proposes that "side opening" be defined to require placement in a "section of the substantially rigid portion or segment." ECF No. 36-1 at 13.

QXMédical's argument is a non-starter. Some claims include language that explicitly places the side opening in the substantially rigid portion, *see, e.g.*, '032 patent

at 12:12-20, and that language would be superfluous if "side opening" was *defined* to require that the side opening be placed in the substantially rigid portion. Other claims explicitly place the side opening in the flexible tip portion. *See* '032 patent at 10:63-65; '413 patent at 12:7-13. QXMédical has no coherent explanation for why "side opening" should be defined to require placement in the substantially rigid portion when there are claims that explicitly locate it in the flexible tip portion. Still other claims place the side opening in its own segment, sandwiched between the substantially rigid portion and the flexible tip portion. *See* '380 patent at 13:52-14:5; '776 patent at 13:41-43. Because different claims place the side opening in different portions of the device, the Court will not construe "side opening" (and the related terms) to require the side opening to be placed in the substantially rigid portion.

In sum, the Court finds that all of these phrases—"side opening," "proximal side opening," "a segment defining a side opening," and "a segment defining a partially cylindrical opening"—need no construction and will be given their plain and ordinary meaning.

F. "a material"

Sometimes it is quite clear what a claim limitation intends to say, and it is equally clear that the literal terms of the claim limitation fail to convey that point—or convey that point clearly—because of poor drafting. This is one of those times.

Multiple claims in the patents-in-suit say, in essence, that the portion of the device that defines the side opening must be more rigid than the tubular structure. *See, e.g.*, '760 patent at 14:6-7 ("wherein a material forming the segment defining the side opening is more rigid than the tubular structure"). The purpose of this limitation is clear. Recall that, after the flexible tubular structure is inserted into the coronary artery, a balloon or stent is pushed along the guidewire, into the side opening, through the tubular structure, and into the coronary artery. Having the side opening be surrounded by material that is more rigid than the tubular structure helps to facilitate the passage of the balloon or stent through the side opening in the same way that having an eyelet in a tennis shoe surrounded by a metal or plastic grommet helps to facilitate the passage of a shoelace through an eyelet.

With one exception, the relevant language in the relevant claims clearly expresses this concept. For example, claim 25 of the '760 patent requires "a material forming the segment defining the side opening [that] is more rigid than the tubular structure." '760 patent at 14:6-7. Similarly, claim 52 of the '776 patent requires that "the segment defining the partially cylindrical opening" must be "formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure." '776 patent at 15:22-26.

So far so good. A person of ordinary skill in the art reading these limitations would understand that the material that forms the side opening has to be more rigid (that is, less flexible) than the tubular structure. That person would likely not give a second thought to the claim's use of the word "material"—which, in common parlance, can refer to material that is made up of a single substance (e.g., wood) or material that is a composite of several substances (e.g., concrete).

The problem arises because a single claim—claim 25 of the '776 patent—requires that "the segment defining the partially cylindrical opening [i.e., side opening]" must be "formed from *a material* more rigid than *a material or material combination* forming the tubular structure." '776 patent at 13:43-47 (emphasis added). Read literally, this limitation implies that there is a difference between "material" and "material combination," because if "material" is broad enough to include a combination of several materials, then the phrase "material combination" is superfluous.

Accordingly, QXMédical asks the Court to hold that "'[a] material,' when used in reference to the side opening, means the side opening is made from only one material." ECF No. 36-1 at 26. QXMédical does not explain how "one material" should be defined, which is a problem given that many things that are commonly identified as a single "material" are actually composed of different materials (and given that, at the molecular level, just about everything is composed of multiple materials). But

QXMédical's construction is certainly supported by the literal language of claim 25 of the '776 patent. QXMédical argues that its construction is also supported by the fact that the specification describes an embodiment in which the side opening is cut out of a section of stainless steel or Nitinol. *See* '032 patent at 6:34-51, 7:19-25. In QXMédical's opinion, steel is a single "material" (even though it is an alloy of iron and carbon), and Nitinol is a single "material" (even though it is an alloy of nickel and titanium). Nowhere does the specification discuss a side opening being fashioned out of multiple materials, at least in QXMédical's view.

While QXMédical's construction certainly finds support in the literal language of a single claim, it also makes no sense. As the patents make clear, what matters from a functional standpoint is that the substance out of which the side opening is formed be more rigid that the tubular structure. It does not matter whether that substance is comprised of one material or two materials or ten materials (even if it was clear what "material" means), as long as the area surrounding the side opening is more rigid than the tubular structure. Nothing in the claims, specification, or prosecution history suggests—and QXMédical is unable to identify—any reason why the side opening would have to be made out of only one "material" (however "material" is defined). QXMédical is simply trying to take advantage of sloppy drafting.

For its part, Vascular Solutions has tied itself in knots trying to come up with a construction of claim 25 of the '776 patent that would save it from its bad drafting. Vascular Solutions argues that the contested limitation should be construed to mean that the segment defining the side opening must be "formed from at least one material that is more rigid than a material or material combination forming the tubular structure." ECF No. 36-1 at 26. Vascular Solutions explains:

> [I]magine a device with a side opening formed of materials A, B, and C, and a tubular tip portion being formed of D, E, and F (which can also be conceived of as including a physical combination of materials—or material combination—such as a number of the materials braided together). . . . The claim requires that at least one of materials A, B, or C be more rigid than either (1) one of materials D, E, or F, or (2) a material combination of D/E/F. Thus, the term "material combination" is a separate concept that is entirely consistent with "a material" meaning "one or more materials."

ECF No. 65 at 17.

Putting aside the fact that this tortured explanation almost surely never entered the mind of the patent's drafter or anyone else until it was invented by Vascular Solutions's attorneys, Vascular Solutions's construction makes no more sense than QXMédical's. Suppose, for example, that A is a very rigid material, B and C are very flexible materials, and D, E, and F are moderately flexible materials. Suppose further that the side opening is formed almost entirely of B and C, with only a minuscule

amount of A. In this hypothetical, the area surrounding the side opening would be *less* rigid than the tubular tip portion. In other words, the "more rigid" limitation—which clearly is intended to facilitate the passage of medical devices through the side opening by providing a "grommet" that is more rigid than the flexible tubular structure—would fail of its purpose, even though the terms of that limitation (as construed by Vascular Solutions) would be met.

Again, from a functional standpoint, what matters is that the substance out of which the side opening is formed be more rigid than the tubular structure. And again, it makes absolutely no difference as a functional matter whether that substance is comprised of one material or many—or if, say, one of the five materials that make up the side opening happens to be more rigid than one of the eight materials that make up the tubular structure. Nothing in the claims, specification, or prosecution history even hints that any of this matters.

The Court will therefore construe claim 25 of the '776 patent to mean what a person of ordinary skill in the art would almost surely have understood it to mean, notwithstanding the clumsy drafting. Specifically, the Court adopts the following constructions of the disputed terms:

(1) "wherein a material forming the segment defining the side opening is more rigid than the tubular structure" means "wherein the matter forming the segment defining the side opening is more rigid than the tubular structure";

(2) "formed from a material more rigid than a material or material combination forming the tubular structure" means "formed from matter that is more rigid than the matter forming the tubular structure"; and

(3) "formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure" means "formed from matter having a greater flexural modulus than a flexural modulus of the tubular structure."

ORDER

Based on the foregoing, and on all of the files, records, and proceedings herein, the Court construes the disputed claim language as stated above.

Dated: October 30, 2018

s/Patrick J. Schiltz
Patrick J. Schiltz
United States District Judge