

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

VASCULAR SOLUTIONS LLC;
TELEFLEX INNOVATIONS S.á R.L.,
ARROW INTERNATIONAL, INC.,
AND TELEFLEX LLC,

Court File No. 0:19-cv-01760 (PJS/TNL)

REDACTED

Plaintiffs/
Counterclaim Defendants,

v.

MEDTRONIC, INC. AND
MEDTRONIC VASCULAR, INC.,

**DECLARATION OF JAMES PHELAN IN
OPPOSITION TO MOTION FOR
PRELIMINARY INJUNCTION**

Defendants/
Counterclaim Plaintiffs.

I, James Phelan, declare as follows:

1. I am Senior Program Manager, R&D for Medtronic, Inc. I make this declaration in opposition to Plaintiffs' motion for a preliminary injunction.
2. I have worked at Medtronic for ten years. In my role as Senior Program Manager, R&D, my responsibilities include leading product development programs. I was part of the team that developed the Telescope™ extension guide catheter (GEC) and make this declaration based on personal knowledge.
3. Defendant Medtronic, Inc. is a pioneer in interventional cardiology, and offers hundreds of products used in interventional cardiology procedures. The use of catheter-based technologies to treat coronary artery disease has been around for decades, and is not new by any means.

4. Guide catheters are a critical component of interventional cardiology. They are used by surgeons to deliver a balloon or stent into a coronary artery that has been narrowed by a buildup of plaque. The surgeon first pushes a guide catheter to the ostium of the heart. In difficult cases, the surgeon may also use a guide extension catheter, which is inserted into the guide catheter. The stent or balloon travels through the guide catheter and, if one is being used, the guide extension catheter, to the area of the artery that needs treatment. Medtronic is among the market leaders for devices used in interventional cardiology procedures, including guide catheters, stents and balloons.

5. [REDACTED]

[REDACTED]

6. Starting in 2015, we sought input from over 250 interventional cardiologists concerning their experiences with two of the existing GECs on the market – the GuideLiner sold by Teleflex, and the Guidezilla sold by Boston Scientific. We also analyzed 580 reports of adverse events involving interventional cardiology procedures from the FDA MAUDE database. These efforts identified a need for a better device.

7. After identifying opportunity for improvement, our product development team began working to design a device that would perform better. Rather than a “copy” as Teleflex argues, Medtronic invested several years and [REDACTED] to develop the GEC that was later named Telescope™. I was the team lead and oversaw the development process.

8. We spent more than two years performing extensive preclinical studies. Preclinical studies take place before any testing in humans is done. [REDACTED]

9. Telescope™ is different from the GuideLiner and Guidezilla guide extension catheters in three primary ways, discussed below.

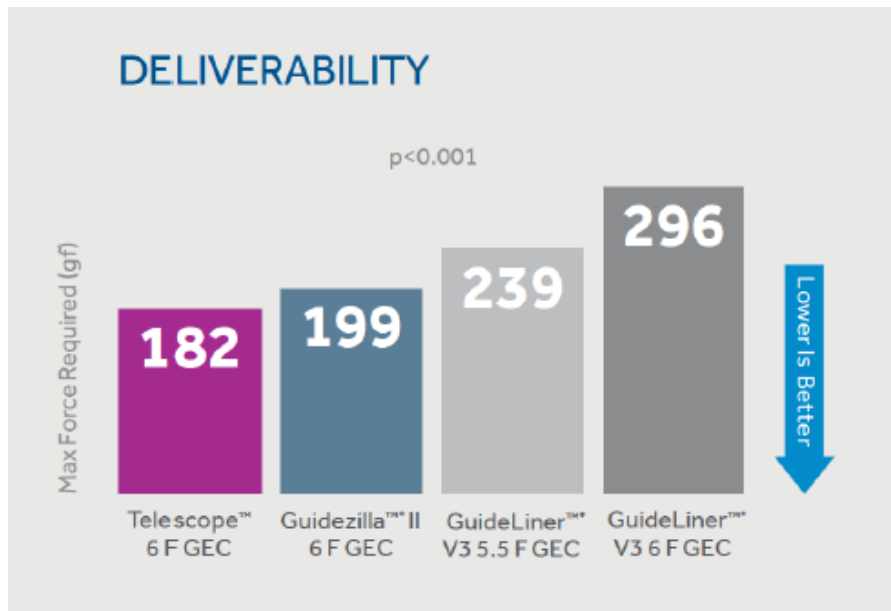
Superior Deliverability

10. First, Telescope™ has superior deliverability. Deliverability refers to the physician's ability to reach the lesion where care is needed. The goal is to allow the physician to advance the GEC in the blood vessel using less force. The need for improved deliverability was identified in our conversations with interventional cardiologists and was a focus of our development efforts.

11. We performed bench testing to determine what force is required to advance the GuideLiner and Guidezilla GECs. We then experimented with different materials and configurations and tested their deliverability.

12. We elected to make the pushrod in the Telescope™ stiffer. The pushrod is a different design than the GuideLiner and Guidezilla GECs.

13. The stiffer push rod in Telescope™ transfers the force that is applied to it by the physician better than less stiff push rods. As is shown in the diagram below, the force required to advance Telescope™ is less than for GuideLiner and Guidezilla:



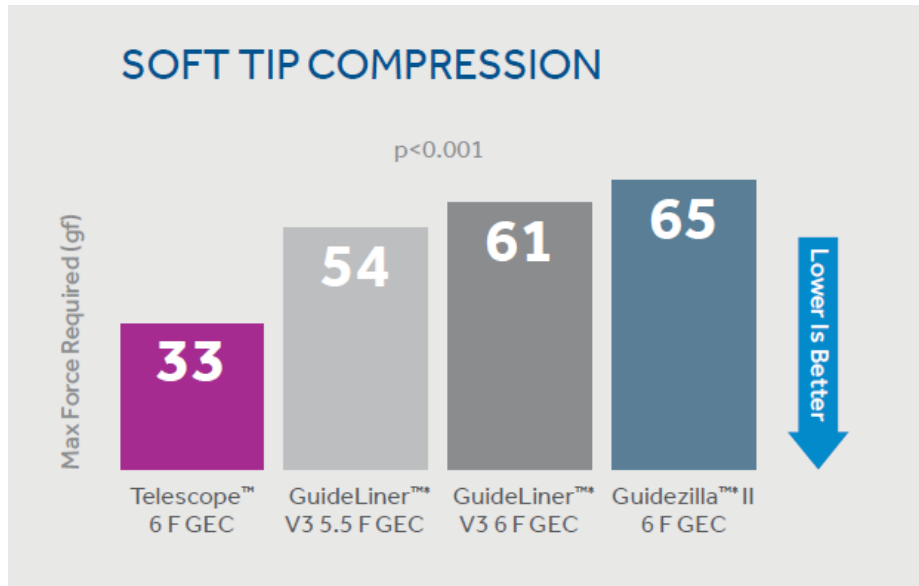
Soft Polymer Tip

14. Second, Telescope™ has a unique soft distal tip that reduces the risk of damage to the blood vessel. As with the push rod, our team analyzed several materials and configurations.

15. [REDACTED]

[REDACTED] We ultimately selected a tip that is softer than in GuideLiner and Guidezilla to reduce the risk of damage to the blood vessel as the GEC is advanced to the lesion. The distal tip in Telescope™ is made from a different material than the main jacket.

16. Our bench testing demonstrates that the Telescope™ requires less force to deflect from the wall of the blood vessel than GuideLiner and Guidezilla, as shown below:



SmoothPass Technology

17. Third, we improved the onramp and entry port. One of the problems that can arise with GECs is that the stent or balloon catches or gets stuck when traveling from the pushrod to the entry port. We designed the onramp and entry port in Telescope™ so that interventional devices like stents and balloons pass through safely. We refer to the design features that allow interventional devices to travel safely through the catheter as our “SmoothPass Technology.”

18. When setting out to improve the channeling of interventional devices in the GEC we again experimented with different materials, shapes and configurations. We

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