UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC Petitioners,

v.

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

DECLARATION OF HOWARD ROOT SUBMITTED IN CONNECTION WITH PATENT OWNER'S RESPONSES



- I, Howard Root, hereby declare and state as follows:
- 1. I make this Declaration in connection with Patent Owner's Responses to Petitions filed in response to the following IPR Petitions:

IPR No.	Patent No.
IPR2020-00126	8,048,032
IPR2020-00128	RE45,380
IPR2020-00129	RE45,380
IPR2020-00132	RE 45,760E
IPR2020-00134	RE 45,760E
IPR2020-00135	RE45,776
IPR2020-00137	RE47,379

I refer to the patents in this table collectively as "the GuideLiner patents," as they are the patents that were obtained for and protect the GuideLiner® guide extension catheter, which was the most successful product introduced by Vascular Solutions, Inc. ("VSI"), a company that I founded and was the Chief Executive Officer of for 20 years. I am also a named inventor on the GuideLiner patents.

2. I was originally trained as a lawyer and worked in private practice from 1985-1990. In 1990, I left private practice to serve as General Counsel at ATS Medical, Inc., a medical device company, which has since been acquired by Medtronic, Inc. I left ATS Medical in 1996 and founded VSI in 1997. I acted as the CEO of VSI from 1997 until 2017. In 2017, VSI was acquired by Teleflex



Incorporated, the current owner of the GuideLiner patents (through a subsidiary entity).

- 3. I am aware that Teleflex has filed suit against Medtronic, Inc. and Medtronic Vascular, Inc. ("Medtronic") for infringement of the GuideLiner patents. I have been retained as a consultant on behalf of Teleflex in connection with that lawsuit and the present IPR Petitions. However, I have no ongoing involvement in the Teleflex business and I have no financial interest in the outcome of the litigation.
- 4. VSI was a relatively small medical company that developed, among other things, specialty catheters for interventional cardiology procedures.

 Throughout my time at VSI, I was personally active in, among other things, product conception and development, legal and marketing efforts, and sales. I was involved with the GuideLiner project and product embodiments at the time the inventions of the GuideLiner patents were conceived and reduced to practice, and at the time the applications that ultimately resulted in the patents-in-suit were filed.

Conception of GuideLiner

5. I attended the annual Transcatheter Cardiovascular Therapeutics ("TCT") conference in 2004, which took place in Washington, D.C. from September 27 to October 1. By that time I had recognized issues physicians were experiencing with guide catheter backout in complex interventional coronary



procedures. I realized that there was a need for a solution in complex interventional coronary procedures that provided better guide positioning, device delivery, and procedural conveniences than what then existed.

- 6. Around the time of the 2004 TCT conference, I conceived of the idea for a guide extension catheter that would provide improved back-up support with rapid exchange delivery, which would offer far more convenience than other options available at the time. Sometime after the TCT conference, but before 2005, my co-inventors and I met to discuss particular ideas for how to make such a device.
- 7. At a high level, the device we developed was a guide extension catheter to be used within a one French size larger guide catheter. The guide extension catheter included a substantially rigid proximal portion comprising a "rail" structure and a tubular portion with a lumen distal of the proximal portion, which together were longer than the overall length of a standard guide catheter. The distal tube portion was reinforced with a braid or coil, and it could have a highly flexible atraumatic "bumper tip." In use, a standard guide catheter would be inserted first into the vasculature until the distal end of the guide catheter was located in the ostium of a cardiac artery within the heart. Our guide extension catheter would then be inserted through the guide catheter until the tubular portion's distal end extended past the distal end of the guide catheter and into the



cardiac artery. An interventional cardiology device, such as a balloon catheter or a stent, would then be inserted through the guide catheter (running alongside the rail of our guide extension catheter), into the proximal end of the tubular portion of our guide extension catheter, and ultimately out of the distal end of the tubular portion and into the cardiac artery.

- 8. We also contemplated that the guide extension catheter would optionally be used together with a dilator. The dilator would be inserted into the tubular portion outside the body and would further assist with guiding the extension catheter past the end of the guide catheter and into the cardiac artery. The dilator would then be removed from the body prior to insertion of an interventional cardiology device such as a stent or balloon catheter.
- 9. **Exhibit 2002** is a true and correct copy of pages from co-inventor Gregg Sutton's laboratory notebook. Conception of the inventions claimed in the GuideLiner patents by the beginning of 2005 is reflected by an entry in Mr. Sutton's lab notebook signed and dated January 4, 2005. This lab notebook entry is called "Guide-Liner Device" (the hyphen was later dropped). The recorded device was described as providing additional back-up support for the delivery of interventional cardiology devices. It was further described as allowing for rapid exchange convenience and fitting in a standard 6 French guide catheter and being one French size smaller than the standard guide catheter. The notebook entry also



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