Claim Element	U.S. Patent No. RE46,116	Medtronic's Telescope Guide Extension Catheter
		Medtronic's Telescope product is available in two sizes: 6F and 7F. When both products are discussed collectively they will be referred to as "Telescope." If referred to separately, they will be referred to as "Telescope 6F" and "Telescope 7F," respectively. Exhibit A – Telescope PowerPoint Presentation Exhibit B – Telescope Instructions for Use Exhibit C – Website for Telescope[1] Exhibit D – Telescope Press Release Exhibit E – FDA letter re: Medtronic's 510k for Telescope
25(p)	(Unasserted) Claim 25: A method, comprising:	Telescope is used to perform a method, and Medtronic instructs doctors regarding that method. Exhibit B.
25(a)	advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	Telescope is configured to be used with a guide catheter having a lumen, a distal end of which is advanced through a main blood vessel to an ostium of a coronary artery. Telescope is specified for use with a guide catheter having a lumen. Telescope is specified to be used with a "required" guide catheter having a certain inner diameter:

French Size (F)	GEC Name	I.D. (in)	O.D. (in)	Required GC I.D. (in)	Extension Length (cm)	Polymer Channel (cm)	Full Length (cm)
5.5	GuideLiner™* V3 GEC[1]	0.051	0.063	6 F ≥ 0.066	25	17	150
6	Telescope™ GEC	0.056	0.067	6 F ≥ 0.070	25	4	150
6	GuideLiner™* V3 GEC[1]	0.056	0.067	6 F ≥ 0.070	25	17	150
6	Guidezilla™* II GEC[2]	0.057	0.067	6 F ≥ 0.070	25	N/A, metal collar	150
7	Telescope™ GEC	0.062	0.075	7 F ≥ 0.078	25	4	150
7	GuideLiner™* V3 GEC[1]	0.062	0.075	7 F ≥ 0.078	25	17	150
7	Guidezilla™* II GEC[2]	0.063	0.073	7 F ≥ 0.078	25	N/A, metal collar	150

[1] https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/coronary-catheters/telescope.html

Exhibit A at 39 (red box added).

The Telescope instructions for use provide:

The guide extension catheter is offered in sizes compatible with 6 Fr and 7 Fr guide catheters and is placed over a guidewire.

Table 1. Product information

Telescope model numbers	Telescope sizes	Telescope distal guide segment length	Compatible guide catheter
TELE6F	6 Fr	25 cm	6 Fr
TELE7F	7 Fr	25 cm	7 Fr

3 Indications for use

Telescope guide extension catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.

8 Clinical procedure

8.1 Packaging contents

The package contains 1 guide extension catheter.

Other items that are required but not provided in the package:

- Guide catheter with an inner diameter large enough to accommodate the specific model of guide extension catheter in use (refer to the label)
- Y-adaptor with hemostasis valve
- 0.36 mm (0.014 in) maximum outer diameter guidewire

8.3 Delivery procedure

Deliver the guide extension catheter according to the following steps:

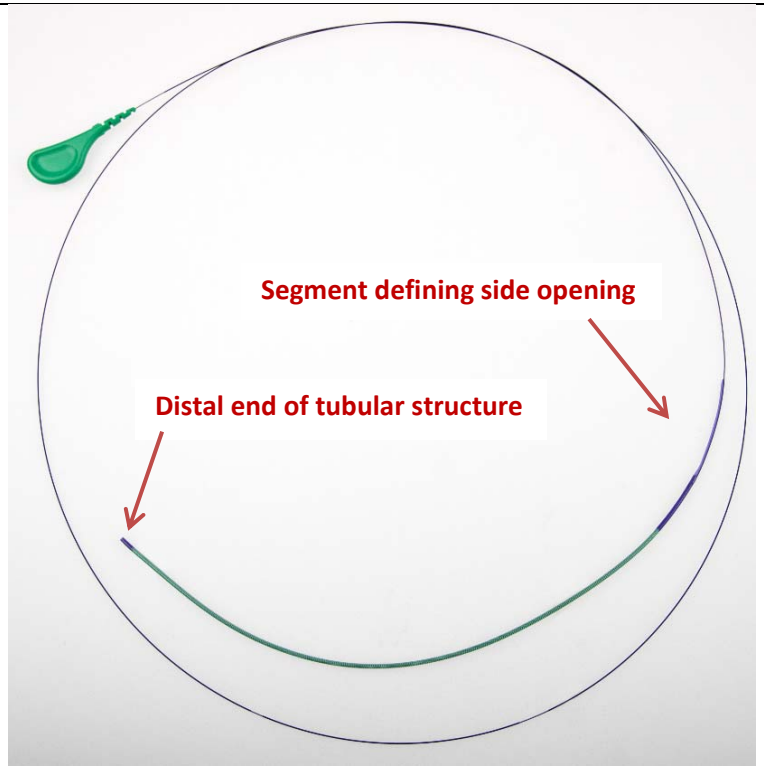
1. Secure the previously inserted guidewire and backload the distal tip of the guide extension catheter onto the guidewire. Advance the guide extension catheter until the catheter is proximal to the hemostasis valve.
2. Open the hemostasis valve and advance the guide extension catheter through the hemostasis valve and into the guide catheter. Ensure that the device distal segment fills with blood, to ensure that no air enters the bloodstream.
3. Under fluoroscopy, advance the guide extension catheter beyond the distal tip of the guide catheter and into the desired location within the vessel.

***

Warning: Do not advance the guide extension catheter more than 15 cm beyond the tip of the guide catheter as the guide extension catheter can become lodged in the guide catheter making it difficult to remove.

EXHIBIT 7

		*** 4. Use fluoroscopy to confirm the desired position of the guide extension catheter in the vessel. 5. If performing an interventional procedure, backload the interventional device over the existing guidewire. Advance the device through the guide catheter and guide extension catheter into the desired vascular space. **Note:** If a second wire is used during the intervention and encounters resistance within the guide catheter, pull the wire back several centimeters and slowly re-advance. 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the guide extension catheter to prevent back-bleeding. 7. Perform the catheterization procedure according to the instructions provided by the manufacturer of the interventional device. After completing the procedure, remove the guide extension catheter before removing the guide catheter from the vessel. Exhibit B (red boxes added).
25(b)	advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, the side opening extending for a distance along a longitudinal axis of the guide extension catheter and accessible from a longitudinal side defined transverse to the longitudinal axis, the tubular structure having a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter;	In use, a distal end of a tubular structure of Telescope, identified below, is advanced through, and beyond the distal end of, the guide catheter, while a segment defining a side opening, identified below, remains within the lumen of the guide catheter.

		The Telescope instructions for use provide: **8.3 Delivery procedure** Deliver the guide extension catheter according to the following steps: 1. Secure the previously inserted guidewire and backload the distal tip of the guide extension catheter onto the guidewire. Advance the guide extension catheter until the catheter is proximal to the hemostasis valve. 2. Open the hemostasis valve and advance the guide extension catheter through the hemostasis valve and into the guide catheter. Ensure that the device distal segment fills with blood, to ensure that no air enters the bloodstream. 3. Under fluoroscopy, advance the guide extension catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. *** **Warning:** Do not advance the guide extension catheter more than 15 cm beyond the tip of the guide catheter as the guide extension catheter can become lodged in the guide catheter making it difficult to remove. *** 4. Use fluoroscopy to confirm the desired position of the guide extension catheter in the vessel. 5. If performing an interventional procedure, backload the interventional device over the existing guidewire. Advance the device through the guide catheter and guide extension catheter into the desired vascular space. **Note:** If a second wire is used during the intervention and encounters resistance within the guide catheter, pull the wire back several centimeters and slowly re-advance. 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the guide extension catheter to prevent back-bleeding. 7. Perform the catheterization procedure according to the instructions provided by the manufacturer of the interventional device. After completing the procedure, remove the guide extension catheter before removing the guide catheter from the vessel. Exhibit B. The side opening of Telescope extends for a distance along a longitudinal axis and is accessible from a longitudinal side defined transverse to the longitudinal axis to receive interventional cardiology devices when positioned within the lumen of the guide catheter.

EXHIBIT 7

DOCKET ALARM

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