

Claim Element	U.S. Patent No. 8,142,413	<p>Medtronic’s Telescope Guide Extension Catheter</p> <p>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.</p> <p>Exhibit A – Telescope PowerPoint Presentation Exhibit B – Telescope Instructions for Use Exhibit C – Website for Telescope¹ Exhibit D – Telescope Press Release Exhibit E – FDA letter re: Medtronic’s 510k for Telescope</p>
1(p)	<p>(Unasserted) Claim 1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:</p>	<p>Telescope is used as a device to perform a method of providing backup support for an interventional cardiology device in the coronary vasculature, and Medtronic instructs doctors regarding that method. Exhibit B.</p> <p>“In difficult cases, GECs provide additional backup support and improve access to distal lesions.” Exhibit A at 2.</p> <p>The Telescope instructions for use state: “The Telescope guide extension catheter is a single-lumen rapid exchange catheter. The guide extension catheter is designed to act as an extension to a traditional guide catheter and to facilitate the delivery of interventional devices into the vasculature. The guide extension catheter is intended to be used within the coronary and/or peripheral vasculature to provide support.” Exhibit B.</p> <p>“In difficult cases, guide extension catheters provide extra backup support and improve access to distal lesions.” Exhibit C.</p> <p>“Telescope(TM) Guide Extension Catheter, a newly designed catheter used to provide additional backup support and access to distal lesions.” Exhibit D.</p> <p>Telescope is specified for use with a standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery.</p>

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

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

Exhibit A at 39 (red box added).

The Telescope instructions for use provide:

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.

		<p>8 Clinical procedure</p> <p>8.1 Packaging contents</p> <p>The package contains 1 guide extension catheter.</p> <p>Other items that are required but not provided in the package:</p> <ul style="list-style-type: none"> • 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 <p>Exhibit B (red boxes added).</p> <p>The continuous lumen of the guide catheter used with Telescope has a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen.</p> <p>See Exhibit A chart above identifying the inner diameters for the required guide catheters.</p> <p>The Telescope instructions for use state: “The Telescope guide extension catheter is a single-lumen rapid exchange catheter. The guide extension catheter is designed to act as an extension to a traditional guide catheter and to facilitate the delivery of interventional devices into the vasculature. The guide extension catheter is intended to be used within the coronary and/or peripheral vasculature to provide support.” Exhibit B.</p> <p>“After positioning a GEC, the ability to deliver stents, balloons, and other interventional devices through the catheter is critical.” Exhibit C.</p> <p>“Telescope(TM) Guide Extension Catheter, a newly designed catheter used to provide additional backup support and access to distal lesions. Guide extension catheters help deliver coronary stents, balloons and other interventional devices during angioplasty procedures that help to restore blood flow through the coronary and peripheral arteries.” Exhibit D.</p> <p>“The guide extension catheter is designed to act as an extension to a traditional guide catheter and to facilitate the delivery of interventional devices into the vasculature. . . . Telescope™ Guide Extension Catheter is intended to be used in conjunction with guide catheters” Exhibit E at 5.</p>
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1(a) inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;

Telescope is configured to be used with a standard guide catheter having a lumen and a distal end. The guide catheter is advanced over a guidewire and into a first artery.

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
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7	Telescope™ GEC	0.062	0.075	7 F ≥ 0.078	25	4	150
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7	Guidezilla™ II GEC ²	0.063	0.073	7 F ≥ 0.078	25	N/A, metal collar	150

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
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3 Indications for use

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		<p>8 Clinical procedure</p> <p>8.1 Packaging contents</p> <p>The package contains 1 guide extension catheter.</p> <p>Other items that are required but not provided in the package:</p> <ul style="list-style-type: none"> • 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 <p>Exhibit B (red box added).</p>												
<p>1(b)</p>	<p>positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;</p>	<p>The distal end of the standard guide catheter is positioned in a branch artery that branches off from a first artery.</p> <p>The Telescope instructions for use state: “The Telescope guide extension catheter is a single-lumen rapid exchange catheter. The guide extension catheter is designed to act as an extension to a traditional guide catheter and to facilitate the delivery of interventional devices into the vasculature. The guide extension catheter is intended to be used within the coronary and/or peripheral vasculature to provide support.” Exhibit B.</p> <p>“The guide extension catheter is designed to act as an extension to a traditional guide catheter and to facilitate the delivery of interventional devices into the vasculature. . . . Telescope™ Guide Extension Catheter is intended to be used in conjunction with guide catheters” Exhibit E at 5.</p> <p>The Telescope instructions for use provide:</p> <p>The guide extension catheter is offered in sizes compatible with 6 Fr and 7 Fr guide catheters and is placed over a guidewire.</p> <p>Table 1. Product information</p> <table border="1" data-bbox="844 1224 1871 1354"> <thead> <tr> <th>Telescope model numbers</th> <th>Telescope sizes</th> <th>Telescope distal guide segment length</th> <th>Compatible guide catheter</th> </tr> </thead> <tbody> <tr> <td>TELE6F</td> <td>6 Fr</td> <td>25 cm</td> <td>6 Fr</td> </tr> <tr> <td>TELE7F</td> <td>7 Fr</td> <td>25 cm</td> <td>7 Fr</td> </tr> </tbody> </table>	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
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