Medtronic

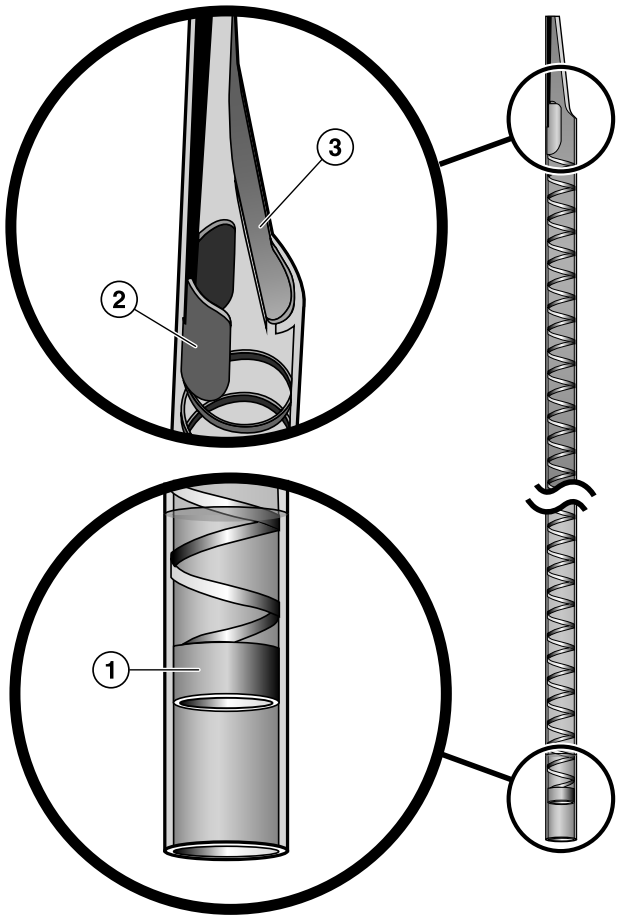
Telescope™

Guide Extension Catheter

Instructions for Use

! USA **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

Figure 1. Distal guide segment



EN 1 Distal marker band
2 Proximal marker band
3 Entry port

1 Explanation of symbols on product or package

Refer to the package labels to see which symbols apply to this product.

Applicable symbol standards

- BS EN ISO 15223-1:2016: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied
- IEC 60417: International Electrotechnical Commission, Graphical symbols for use on equipment
- ISO 7000: Graphical symbols for use on equipment

Symbol	Reference	Symbol title	Explanatory text
	ISO 15223-1 Clause 5.1.1	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 Clause 5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1 Clause 5.4.2	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
GC/MID	N/A	Guide catheter/minimum inner diamter	Indicates the minimum inner diameter of the guide catheter.
	N/A	Quantity	Indicates the quantity of devices present in the package.
LOT	ISO 15223-1 Clause 5.1.5	Lot Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Clause 5.1.4	Use by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1 Clause 5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.
STERILE EO	ISO 15223-1 Clause 5.2.3	Sterlized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
REF	ISO 15223-1 Clause 5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	IEC 60417 Clause 5845	Inner diameter	To indicate a reference to the inner diameter
	ISO 7000 Clause 3079	Open here	To identify the location where the package can be opened and to indicate the method of opening it.
	N/A	Manufactured in	Indicates the manufacturing site of the device. A manufacturing site is the facillity where the product is produced, transformed, or assembled into a medical device.
! USA	N/A	For US audiences only	Indicates the adjacent text/symbology is intended for US audiences only.
	ISO 15223-1 Clause 5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
www.medtronic.com/manuals	ISO 15223-1 Clause 5.4.3	Consult instructions for use at this website	Indicates the need for the user to consult the instructions for use.

2 Description

devices into the vasculature. The guide extension catheter is intended to be used within the coronary and/or peripheral vasculature to provide support.

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

The 150 cm guide extension catheter consists of a hydrophilic-coated, 25 cm single-lumen distal guide segment connected to a stainless-steel polytetrafluoroethylene (PTFE) coated proximal pushwire. The 25 cm distal guide segment contains 2 platinum-iridium radiopaque markers (Figure 1): 1 marker band located 2 mm from the distal end, and another marker band located at the entry port opening. The proximal pushwire contains 2 positioning marks, located at 90 cm (0.5 cm long) and 100 cm (1 cm long) from the distal tip. The guide extension catheter has a tab at the proximal end of the pushwire that is used for device identification. The tab indicates guide catheter compatibility and the resulting guide extension catheter inner diameter.

The hydrophilic coating is positioned on the distal section of the device for a length of approximately 21 cm from the distal tip. Please refer to Chapter 8 for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the preparation for use instructions in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

The guide extension catheter is delivered through a guide catheter resulting in an overall inner diameter that is approximately 1 Fr smaller than the guide catheter.

The guide extension catheter was sterilized with ethylene oxide.

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.

4 Contraindications

The guide extension catheter is contraindicated in the following situations:

- In vessels less than 2.5 mm in diameter
- In vessels in the neurovasculature or the venous system

5 Warnings

- For single-patient and single-procedure use only. **Do not resterilize or reuse the device.** Resterilization or reuse can compromise device performance and increase the risk of inadequate resterilization and cross contamination.
- Do not advance the guide extension catheter into a vessel without a leading guidewire because vessel damage can occur.
- Do not advance the guide extension catheter into a vessel with an effective diameter less than 2.5 mm. Vessel injury, ischemia, and occlusion can occur. If pressure in a vessel dampens after inserting the guide extension catheter, withdraw the guide extension catheter until the pressure returns to normal.
- Use the guide extension catheter before the Use-by date specified on the package.
- Perform PTCA only at hospitals where emergency coronary artery bypass graft surgery can be performed in the event of a potentially injurious or life-threatening complication.
- Do not apply torque to the guide extension catheter during delivery because catheter damage can occur. Torquing the device can result in wire wrap or damage to the device or vessel.
- Due to the size and the nontapered tip of the guide extension catheter, use extreme care to avoid vessel occlusion and damage to the wall of the vessels.
- If strong resistance is encountered during manipulation of the devices, do not force passage. Determine the cause of the resistance before proceeding. If the cause cannot be removed, withdraw all the devices simultaneously.
- Do not use the guide extension catheter if the packaging has been damaged. A damaged package could result in a breach of sterility or device damage.

6 Precautions

- Inspect the guide extension catheter before use for any bends or kinks. Do not use a damaged catheter. Vessel damage and inability to advance or withdraw the catheter can occur.
- Flush the guide extension catheter lumen with sterile, heparinized saline before use.
- Use caution when handling the guide extension catheter during a procedure to reduce the possibility of accidental breakage, bending, or kinking.
- When the guide extension catheter is in the body, manipulate the catheter only under fluoroscopy. Do not attempt to move the catheter without observing the resultant tip response, because catheter damage or vessel injury can occur.
- Do not advance the guide extension catheter more than 15 cm beyond the tip of the guide catheter because

- Do not withdraw an undeployed stent back into the guide extension catheter when the catheter is in the body, because it can dislodge the stent. Instead, simultaneously pull both the guide extension catheter and undeployed stent back into the guide catheter and remove them together.
- Do not inject contrast media solution at high pressure during the procedure.
- This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
- Administer appropriate anticoagulation, antiplatelet, and vasodilator therapy to the patient.

7 Adverse effects

Potential issues that can be associated with the guide extension catheter include, but are not limited to, the following adverse effects:

- Death
- Embolism
- Slow-flow
- Foreign body in patient
- Stent dislodgement
- Thrombus
- Vessel dissection
- Vessel perforation
- Occlusion (CVA/MI/spasm)
- Aneurysm
- Avulsion
- Reaction
- Infection
- Blood loss/hemorrhage/hematoma (vascular access complication)
- Renal failure (contrast induced nephropathy)
- Pulmonary infarct
- Tissue necrosis

The occurrence of the above listed complications may lead to the need for a surgical intervention.

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
- Sterile syringe (for flushing)
- Sterile heparinized saline (for flushing)

8.2 Preparation for use

1. Before use, carefully inspect the guide extension catheter packaging and components for damage.
2. Using sterile technique, transfer the dispenser coil with the guide extension catheter into the sterile field.
3. Remove the guide extension catheter from the dispenser coil. Thoroughly flush the guide extension catheter lumen from the distal tip with sterile, heparinized saline solution.
   Note: Flushing the device prior to use can help to reduce the risk of air embolism during insertion.
4. Immerse the 25 cm distal guide segment of the guide extension catheter in heparinized saline solution to activate the hydrophilic coating.

Caution: Failure to activate the coating might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

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 into a vessel with an effective diameter less than 2.5 mm. Vessel injury, ischemia, and occlusion can occur. If pressure in a vessel dampens after inserting the guide extension catheter, withdraw the catheter until the pressure returns to normal.
   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.
   Warning: Due to the size and non-tapered tip of the guide extension catheter, use extreme care to avoid vessel occlusion and damage to the wall of the vessels.
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.
8. Dispose of the guide extension catheter following standard hospital procedures.

9 Storage and handling

Store in a cool, dry, and dark place.

10 Disclaimer of warranty

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