Medtronic

Micra™ Introducer

Introducer Sheath with Hydrophilic Coating

Instructions for Use

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

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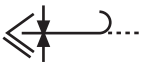
Medtronic, Micra

Explanation of symbols on product labeling
Refer to the device labeling to see which symbols apply to this product.

	Lot number
	Catalogue number
	Use by
	Manufacturer
	Do not use if package is damaged
	Do not reuse
	Sterilized using irradiation
	Nonpyrogenic
	Contents: one device
	Manufactured in
	Inner diameter
	Length
	Maximum guidewire diameter
	Open here
	Consult instructions for use at:
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Micra Introducer

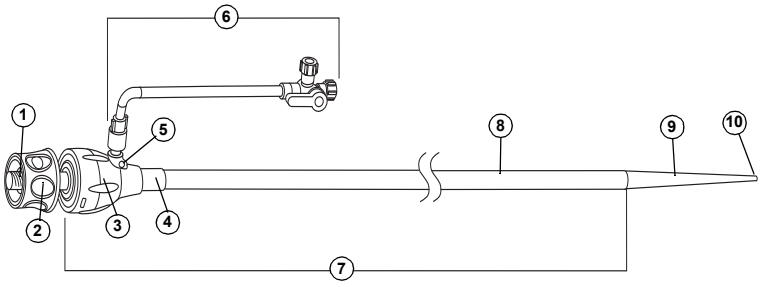
Introducer Sheath with Hydrophilic Coating

1 Device Description

The Micra introducer (Figure 1) is a single-use, disposable, hydrophilically coated sheath that provides a flexible and hemostatic conduit for the insertion of intravascular devices into the venous system to minimize blood loss. The system is comprised of 2 components: a dilator that accommodates a 0.035 in (0.89 mm) guidewire and an introducer.

The dilator is radiopaque and has a tapered, flexible tip that facilitates atraumatic tracking through the vasculature. A female luer taper fitting is located on the proximal end of the dilator grip. The distal end of the dilator grip is threaded to allow the dilator to be secured to the sheath seal housing.

The introducer is comprised of a hydrophilically coated, coil-reinforced sheath that is attached to a rigid seal housing containing the hemostatic valve assembly. A sideport extension with a 3-way valve is permanently attached to the seal housing. A radiopaque markerband is located at the distal tip of the sheath. The introducer also has a suture loop for attaching it to the patient and a strain relief to prevent kinking of the sheath where it joins to the seal housing.



1 Dilator grip female luer taper thread
2 Dilator grip
3 Seal housing with hemostatic valve assembly (sheath hub)
4 Strain relief
5 Suture loop
6 Sideport extension with 3-way valve
7 Introducer
8 Introducer sheath
9 Dilator
10 Dilator tapered tip

Figure 1. Micra introducer sheath

Note: Graphical representation not drawn to scale.

This device does not contain natural rubber latex; however, during the manufacturing process, it may have incidental contact with latex.

2 Indications for Use

The Micra introducer is intended to provide a conduit for the insertion of devices into the venous system and to minimize blood loss associated with such insertions.

3 Contraindications

There are no known contraindications with this device. It is not intended for use except as indicated.

4 Warnings and Precautions

Caution: Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.

- Do not alter this device. Alterations may impair device function.
- Do not cut or puncture the sheath. This could result in major blood loss and vessel trauma.
- Do not use after the Use By date printed on the label.
- This device was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- After use, dispose of the device in accordance with hospital, administrative, or government policies.
- The dilator is only compatible with a 0.035 in (0.89 mm) guidewire.
- Verify sheath, device, catheter, and accessory components size compatibility prior to use. The maximum diameter and length of the instrument or catheter to be introduced should be determined to ensure its passage through the sheath. Introduction of a smaller intravascular device may result in increased blood loss. **Note:** The length of the sheath does not include the strain relief.
- If scar tissue is present, predilatation may be required.
- Adequate vessel access is required to introduce the sheath into the vasculature. Careful evaluation of vessel size, anatomy, tortuosity, and disease state (including calcification, plaque, and thrombus) is required to ensure successful sheath introduction and subsequent withdrawal. If vessel is not adequate for access, major bleeding, vessel damage, or serious injury to the patient, including death, may result. If vessel size is smaller than the introducer sheath's outer diameter, major bleeding, vessel damage, or serious injury to the patient, including death, may result.
- When inserting, manipulating, or withdrawing a device through the sheath, always maintain sheath position.
- When puncturing, suturing, or incising the tissue near the sheath, use caution to avoid damaging the sheath.
- Do not attempt to insert or withdraw the introducer sheath if resistance is felt. The cause of the resistance must be determined before proceeding.
- Do not attempt to simultaneously insert multiple catheters or interventional devices into the sheath.
- Advance and withdraw the sheath (with the dilator fully inserted and locked in) only under fluoroscopic guidance.
- Ensure that the dilator is fully inserted into the introducer to minimize the risk of vascular injury.

5 Adverse Events

5.1 Potential Adverse Events

Adverse events or complications associated with use of the Micra introducer include, but are not limited to:

- allergic response to materials
- blood loss, bleeding, or hematoma
- embolization (micro or macro) with transient or permanent ischemia
- infection
- vascular trauma (eg, dissection, rupture, perforation, or tear)
- death

6 How Supplied

6.1 Sterility

The Micra introducer is individually packaged. It is supplied sterile (electron beam) for single use only.

- Do not reuse or attempt to resterilize.
- If the device is damaged or the integrity of the sterilization barrier has been compromised, do not use and contact a Medtronic representative for return information.

6.2 Contents

- 1 Micra introducer with dilator

6.3 Storage

Store the Micra introducer at room temperature in a dark, dry place to avoid extended exposure to light and moisture.

7 Clinical Use Information

7.1 Physician Training Requirements

Caution: The Micra introducer should only be used by physicians and teams trained in vascular interventional techniques and in the use of similar devices.

7.2 Device Inspection

Carefully inspect the device and packaging for damage or defects prior to use. If the Use By date has elapsed, the device is damaged, or the sterilization barrier has been compromised, do not use the device. Contact a Medtronic representative for return or replacement.

7.3 Additional Equipment Recommended

- 0.035 in (0.89 mm) guidewire
- heparinized saline solution
- 35 cc or larger syringe

8 Instructions for Use

1. Remove device from package and ensure that the inner diameter (ID) of the sheath is appropriate for the maximum diameter of the intravascular device to be introduced.
2. Verify the vessel is of adequate diameter and tortuosity to accommodate the introducer sheath.
3. Open the 3-way valve on the sideport extension.
4. Connect a syringe of heparinized saline solution to the luer fitting on the sideport extension and flush the sheath, tapping the introducer sheath to aid in releasing air bubbles.
5. Close the 3-way valve on the sideport extension.
6. Connect a syringe of heparinized saline solution to the luer fitting on the dilator and flush the dilator.
7. Insert the dilator completely into the introducer sheath and secure by rotating the dilator grip clockwise, approximately one-quarter turn.
8. Follow accepted clinical practice for vessel access and guidewire insertion.
9. Activate the hydrophilic coating by wetting the outer surface of the sheath with heparinized saline. **Note:** For best results, ensure the device remains wet during placement.
10. Advance the sheath with dilator as a unit over the guidewire under fluoroscopic guidance to the desired location. Stop advancement if there is resistance and investigate the cause of the resistance before proceeding.
11. Hold the sheath steady while unlocking and withdrawing the dilator and the guidewire from the sheath until the dilator and guidewire are completely removed from the sheath.
12. Before removing or inserting devices through the introducer, aspirate at least 30 cc through the side arm of the valve to clear the introducer of air. Then flush with heparinized saline.
13. Attach a continuous heparinized saline drip to the sideport extension on the introducer to reduce the risk of thromboembolism.
14. Interventional devices can be interchanged as necessary.
15. Upon removal of the sheath, take precautions to prevent bleeding, vessel damage, or other serious injury. Advancing the guidewire supported by the dilator into the sheath prior to withdrawing the sheath may aid in withdrawal from the vasculature.

9 Disclaimer of Warranty

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