

Instructions for Use: Introducer

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Introducers are not compatible with magnetic resonance imaging

Device description

The needle guide, named Introducer consists of two main parts made of stainless steel:

- a. Mandrel – a needle attached to a standard female Luer
- b. Cannula – a fitting trocar attached to a standard lock hub
- c. The notch on the mandrel is visible under imaging systems and facilitates positioning of the introducer inside the target tissue.

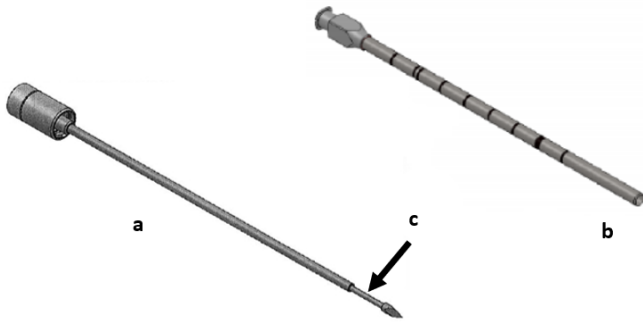


Figure 1: Illustration of the Mandrel (a) and the Cannula (b)

Intended use/ Indications for Use

The introducer is a manual surgical instrument for general use. The Introducer needle is intended to be used by medical professionals as introducers/cannula for percutaneous introduction of surgical devices.

The introducer needle is for use as an accessory in percutaneous procedure.

Clinical decisions



The practitioner is solely responsible for all clinical use of the introducer and is responsible for any results obtained with the device.

The Introducer can be damaged if mishandled. Do not use an introducer that has been bent, dropped, hit against a hard surface or compromised in any manner.

The introducer should be inserted in the target tissue under guidance of a relevant imaging device.

The Introducer is a single-use device supplied in single use sterile packaging.

















Reprocessing single-use devices affects their performance and can cause cross-contamination.

Figure 2: Single use introducer label (Illustration Sample)



Harmonized symbols relating to safety requirements and standards that appear on the introducer label are listed in the table below.

Symbol	Meaning
	Caution-Warning
	Manufacturer
	Date of manufacture
	Do not reuse
	Use by Date
	Catalogue number
	Do not resterilize
	Sterilized using ethylene oxide
	Batch code
	Do not use if package is damaged
	Authorized representative in the European community
	Caution: US federal law restricts this device to sale by or on the order of a physician
	CE mark – mandatory conformity mark for products placed on the market in the European Economic Area
	MR safety warning: the product materials are not compatible with magnetic resonance imaging

Locate the **Peel Here** label to open the pouch.

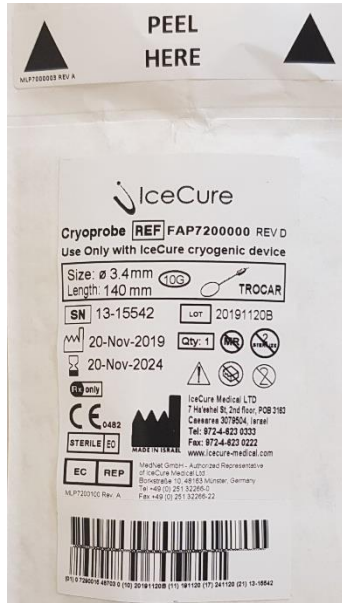


Figure 3: “Peel Here” label



Figure 4: For illustration only Color Tag labels for cryoprobe and the matching introducer

Use of Introducer

The order in which you follow these steps is essential for maintaining sterility and patient safety.



Ensure that the introducer dimensions (diameter and length) are compatible with the surgical tool/needle you intend to guide (see **Technical specifications below**).



Maintain sterility

- Plan the insertion trajectory of the introducer prior to placement.
- Gently remove the introducer tip protector.
- You may need to perform a 3 mm skin incision (for example using #11 blade) before the inserting the introducer.
- Verify that the introducer is located correctly using an imaging system. Make sure that the mandrel notch is located at the center of the target tissue.
- Gently disengage the Luer (or mandrel) from the Hub (or cannula).
- Gently remove the mandrel from the cannula, while maintaining the position of cannula in the target tissue. Mind the angle of removal.
- Insert the surgical tool/needle you intend to guide into the cannula.
- At the end of your procedure, upon clinician decision, gently remove the surgical tool/needle you introduced and the cannula.

When inserting the introducer tip into the target tissue, use the centimeter marks that indicate depth of introducer insertion for reference. There are distinctive markings at 5 (1 black thick line) and 10 cm (2 black thick lines).

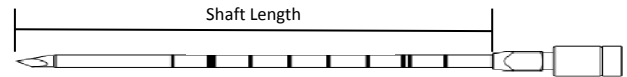


Figure 5: Illustration of introducer marking

Predictable adverse events when using the introducer

Trauma to tissue, incomplete treatment, infection, user accidental injury, needle seeding.

Technical specifications

The packed introducers must be stored in a dry, cool, well-ventilated and clean environment without corrosive gas.

The Introducer Needle is individually packaged and sterilized. Introducer’s characteristics are as follow in the table below:

Introducer reference number	Shaft Length	Compatible cryoprobe reference number	Cryoprobe diameter
FAC9000000	115 mm	FAP7800000	2.4mm/13G
FAC9100000	122 mm	FAP7200000	3.4mm/10G
FAC9200000	167 mm	FAP7400000 (Pencil Tip) FAP7410000 (Trocar Tip)	3.4mm/10G

Diameter: 2.5 mm/13G

FAC9000000

Cannula shaft length: 108 mm, blunt tip
Mandrel shaft length: 128.3 mm, sharp tip

Diameter: 3.5 mm/10G

FAC9100000

Cannula shaft length: 112.5 mm blunt tip
Mandrel shaft length: 135.3 mm, sharp tip

Diameter: 3.5 mm/10G

FAC9200000

Cannula shaft length: 157.5 mm blunt tip
Mandrel shaft length: 180.3 mm, sharp tip (Trocar / Pencil)

Note: Certain configurations are not available in some regions.

Introducer Disposal

Following each cryosurgical procedure, discard the single use Introducer.



For each new procedure, ensure that the previously used single-use introducers have been removed and discarded. Any used cryoprobe, introducer, and temperature sensor must be disposed of as sharp biohazard waste.



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