en Instructions for Use

Peel away Introducer with Dilator

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Device description
The Peel Away Introducers with Dilators are tube like device made of medical grade plastic material, with a long slender hollow body and a tapered tip at the distal end. They are designed for stretching or enlarging the fascial tissue covering a cavity, tract or opening during a procedure and to place a peel Away Sheath. The Dilators are radiopaque for fluoroscopic guidance.

Size (Fr)
10, 12, 14, 16 & 18

Intended Purpose & Duration
Used for dilation & introduction of sheath for creating access for any transluminal access for single time use up to a period of 60 minutes.

Contraindications
Contraindicated in the presence of conditions that create unacceptable risks during dilation/Catheterization.

Potential Complications
Potential complications include but not limited to infection, leakage & Haemorrhage.

Warnings And Precautions
- Use with caution when advancing the dilators to avoid tissues and orifice damages. Use only compatible wire guide. As advancing dilator beyond its length might cause damage to the tissue or orifice.
- Do not use if product is damaged or expired, reuse and resterlization of this device leads to loss in structural integrity and performance. Device is not intended for permanent use.
- This device is intended for use by trained physicians and this device should not be used without comprehensive knowledge of the indications, techniques and risks of the procedure.
- Do not use force to advance any component. If resistance is encountered during placement or removal. Standard techniques shall be applied.
- On completion of the procedure, dispose off the device as per local regulatory guidelines for bio-hazardous medical waste disposal.

Instructions For Use
1. Perform initial access with puncture needle for the purpose of dilation using standard procedure.
2. Introduce the flexible tip of the guidewire into needle which has previously been positioned into the renal collecting system under fluoroscopic control.
3. Advance the guidewire to the desired location. Once the guidewire is in position, remove the puncture needle from the wire guide prior to introduction of the dilators over the guidewire.
4. Using aseptic technique, progressing from the tip, pass the dilator over the guidewire while maintaining the guidewire's position.
5. After dilation, remove the dilator leaving the peel away sheath in the place.
6. Use the sheath as working channel for further interventions and for placing of devices.
7. After placing the device, peel away the sheath by slitting the hub and remove.

Intended population group
Adult male and female individuals who requires interventional access for placement of devices or diagnosis.

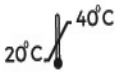
Supply and Storage
The device is packed in primary pack made of polyethylene and the secondary package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from 20^0C to 40^0C and away from direct sunlight.

Report Any Serious Incident
If problems occur using this device or any serious incidents or adverse events, please contact our customer relations department or call to the contact provided in our manufacturing address and competent authority of the Member State in which the user and/or patient is established.

Symbol Glossory And Definations

Standard Reference:

ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer

Symbol	Symbol Title
	Do not re sterilize
	Do not use if package is damaged and consult instructions for use
	Consult instructions for use
	Temperature limit
	Keep away from sunlight
	Do not re-use
	Not made with natural rubber latex
	Sterilized using ethylene oxide
	Non-pyrogenic
	Keep dry
	Medical device
	Single sterile barrier system with protective packaging inside
	Does not contain DEHP
	Unique device identifier
	Date of Manufacture
	Use-by date
	Batch code

	Catalogue number
	Authorized Representative in the European Community/ European Union
	Manufacturer
	Caution
	Prescription

- This device is to be sold by/on the directions of a physician. Sterile (ETO) if package is unopened or undamaged.
- Read all the instructions before use.
- On completion of the procedure, dispose off device and its components if any as per institutional and local regulatory guidelines for bio-hazardous medical waste dispose.

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