en

Instructions for Use

Single Step® Fascial Dilator

BLUENEEM®
Clinicians Trust. Patients Wellbeing

Device description

Fascial Dilator is a tube-like device made of medical grade plastic material, with a long slender hollow body and a long-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 in single step. The Dilators are radiopaque under fluoroscopic guidance.

The Single step® Fascial Dilators are available in following sizes.

Size (Fr)	Length (cm)	Single Step® Fascial Dilator Set
6, 8, 10, 12, 14 & 16	20 & 22	6 – 16 Fr (6, 8, 10, 12, 14 & 16)

Intended Purpose & Duration

Used for single step fascial dilation, intended for stretching or enlarging the fascial tissue covering a cavity, tract or opening prior to a diagnostic or interventional procedure for single time use up to a period of 60 minutes

Indications For Use & Contraindications

Indicated to be used to dilation of fascial tissue during diagnostic or interventional procedure. 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.
- On completion of the procedure, dispose off the device as per local regulatory guidelines for bio-hazardous medical waste disposal.
- Imaging guidance is required for use of this device.
- On completion of the procedure, dispose off the device and its components, if any, as per institutional and local regulatory guidelines for bio-hazardous medical waste disposal.

Instructions For Use

1. Perform initial access with puncture needle which enables the purpose of sequential dilation using standard procedures. Introduce the flexible tip of the guidewire into needle which has previously been positioned into the collecting system under fluoroscopic control.
2. 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.
3. Progressing from the tip, pass the dilator over the guidewire while maintaining the guidewire's position.
4. For sets: Progressing from the smallest to the largest appropriate size, pass the radiopaque dilators over the guidewire while maintaining the Guidewire's position.

Intended population group

Adult male and female individuals undergoing diagnostic or interventional procedures where fascial tissue needs to be stretched or enlarged to perform percutaneous catheter placement procedures. Specifically, they are used to facilitate access and passage of catheters or instruments into a targeted area.

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.

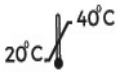
Report Any Serious Incident

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.

Authorized Representative in the European Community
Arazy Group (Ireland) Ltd
19 Baggot Street Lower,
Dublin 2, D02 X658, Ireland
E-mail: Ireland@arazygroup.com

Manufacturer
Blue Neem Medical Devices Pvt Ltd
Plot Nos 270 & 271, Road No 5, Harohalli Industrial Area
II Phase, Kanakapura Taluk, Ramanagara
Karnataka - 562112, India.
Phone: +91 80 29761336
E-Mail: contact@blueneem.com
Website: www.blueneem.com