PRODUCT NAME: PerforX™ Large Bore Catheter Set

This document, supplied separately from the package, is an essential component for using the product manufactured by Blueneem Medical Devices Pvt. Ltd., Bangalore, India. It should be referenced before using the product, as it contains crucial information regarding its safe use .

DEVICE DESCRIPTION:
The large bore catheter is a flexible tube made of Polyvinylchloride. It has a soft tapered, open distal end. Its extraordinary agility makes it easy to penetrate. It is equipped with a hydrophilic coating to minimize trauma. Additionally, multiple large, spirally positioned, oval holes enhance the drainage of thick viscous fluid. This device is available in various types, sizes, and lengths.

Set includes:

- Large bore catheter
- Straightener
- Initial puncture needle
- Guidewire
- 3 Sequential dilators
- Occlusion Dressing
- #11 Scalpel blade

Perforx™ Large bore Catheter is available in the following types, sizes, and lengths

Types	Size (Fr)	Length (cm)
Straight & J Tip	20, 22, 24, 26, 28 & 30	30

INTENDED USE: PerforX facilitate drainage of thick fluids using imaging-guided Seldinger access technique in a variety of drainage applications (abscesses, biliary and thoracic drainage, etc.).

DURATION OF INTENDED USE: up to 30 Days.

CONTRAINDICATIONS (To be mindful of)
Bleeding disorder
Infection at the insertion site
Vasospasm or Vessel Tortuosity
Hematoma Formation
Lack of adequate imaging guidance

INDICATIONS FOR USE: Pleural effusion, ascites, empyema, hematoma, Abscess, Paracentesis, Thoracentesis in complicated cases, etc.

POTENTIAL COMPLICATIONS:
Bleeding and hematoma formation, vessel perforation, infection, Thrombosis or Blood clot formation, Air embolism, Delayed healing and scar tissue formation

WARNINGS:

1. Do not reuse the device.
2. Do not use if package is opened or damaged. Do not use the product of there is doubt that the product is sterile.
3. Do not use if product is damaged or expired
4. Not intended for permanent use. If appropriate for the patient, the catheter may be replaced with a new catheter.
5. Avoid contact with sharp and abrasive objects.
6. Manipulation of the product necessitates the use of ultrasound, fluoroscopy, or alternative imaging guidance.
7. Do not use the dilators in non-sequential manner. Use 3 sequestional dilators in sequentially, Starting from the smallest size and progressing to the largest size.
8. Ensure compatibility of the guidewire before use. The compatible guidewire information is mentioned in the below table

Catheter Size (Fr)	Compatible Guidewire (Inch)
20,22	0.035”
24, 26, 28 & 30	0.038"

9. Use only accessories supplied with package.

PRECAUTIONS:

1. This Product is designed for utilization by proficient physicians with expertise in diagnostic and interventional procedures. Standard protocols for inserting percutaneous drainage catheters should be followed.
2. Not intended for permanent use.
3. Do not force components during removal or replacements. Carefully remove the components if resistance is encountered.
4. Care should be taken in selecting a catheter of the right length depending on the patient anatomy.
5. Periodic evaluation is recommendedoptimal functionality.
6. On completion of the procedure, dispose of the device and its components, if any, as per institutional and local regulatory guidelines for bio-hazardous medical waste disposal.

CONTINUOS DURATION OF INTENDED USE: up to 30 days

INSTRUCTION FOR USE:

1. Begin by applying an appropriate antiseptic solution to prepare the access site, followed by draping in a standard manner.
2. Administer local anaesthesia generously to the surrounding soft tissue of the access site.
3. Create a small incision in the skin, slightly larger than the diameter of the drainage catheter.
4. Utilizing fluoroscopic, CT scan, or ultrasound guidance, proceed to advance the -gauge introducer needle into the defined abscess cavity.
5. Withdraw the stylet, and, using a syringe attached, perform an aspiration to confirm the positioning of the tip within the cavity.
6. Guide the 'J' portion of the guidewire through the needle and into the abscess cavity.
7. Withdraw the needle, ensuring that the guidewire remains in place.
8. While maintaining the position of the wire, progress in dilating the tract and opening into the abscess

cavity. Achieve this by sequentially advancing the dilators (from small to large) over the guidewire. To aid in insertion, remember to rotate the dilators. NOTE: It is of great significance to advance each dilator into the abscess cavity while keeping the position of the guidewire intact.

9. Insert the drainage catheter until its hub is securely locked into place.
10. Progress the drainage catheter/inserter assembly over the wire guide and into the abscess cavity. NOTE: For smoother advancement over the guidewire, rotate the drainage catheter/inserter assembly. Remember to maintain the position of the guidewire while advancing the assembly into the abscess cavity.
11. Remove the catheter inserter and guidewire.
12. Aspirate the contents of the abscess cavity through the drainage catheter.
13. Optionally, under fluoroscopic visualization, inject contrast to confirm proper positioning within the abscess cavity.
    NOTE: Ensure that all side ports of the drainage catheter are positioned within the abscess; the most proximal side port should create a break in the solid radiopaque stripe. In cases of particularly large abscess cavities, it may be beneficial to insert both a small and a large catheter. This allows for irrigation with saline through the small catheter and drainage collection through the large one.
14. Suture the catheter to the skin in a standard manner, and dress it appropriately. Resume drainage as needed.

REFERENCES:

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Blueneem sales representative for information on available literature.

PROCEDURE: CATHETER REMOVAL

- In a sanitized workspace, don a sterile glove after thoroughly scrubbing. Inspect for indications of infection, swelling, or discharge. If there are no abnormalities, ensure sterile gloves are worn, if they haven't been already.
- If the catheter has a clamp, ensure it's closed.
- Hold the catheter hub securely near the insertion site with one hand.
- With the other hand, gently and steadily withdraw the catheter in one smooth motion.
- If resistance is encountered, do not force the catheter. Consult with the healthcare team for guidance
- Dispose of used materials in accordance with medical waste disposal protocols.
- Provide the patient with instructions for post-removal care, such as keeping the site clean and dry
- Record the details of the catheter removal, including date, time, condition of the site, and any specific instructions given to the patient

Always follow institutional policies and procedures for catheter removal, and consult with the healthcare team if there are any concerns or specific protocols to be followed. This procedure is a general guideline and may need to be adapted based on individual patient circumstances.

SUPPLY:

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Store in dark, dry, cool place. Avoid extended exposure to light.

STORAGE:

The device has to be stored in Temperatures from 20^0 to 40^0C.

SYMBOLS USED IN LABELING:

Symbols used on the label are as per EN ISO 15223-1-2021.

BLUE NEEM MEDICAL DEVICES PVT LTD
Plot Nos 270 & 271, Road No 5, Harohalli Industrial Area, II Phase, Kanakapura Taluk, Ramanagara - 562112, India.
Phone: +91 80 29761336
E-Mail: contact@blueneem.com
Website: www.blueneem.com