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Instructions for Use

PerforX® Large Bore Catheter Set

BLUENEEM®
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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 enhance easy insertion. Additionally, multiple large, spirally positioned, oval holes enhance the drainage of thick viscous fluid. The device is available in different sizes and variants.

Size (G)	Length (cm)	Variant
20, 22, 24, 26, 28 & 30	25, 30 & 35	Straight & J-tip configurations

Package / Kit contents

- Radiopaque catheter (Straight or J)
- Catheter straightener/stiffener
- Sequential dilators
- Amplatz Ultra Stiff Guidewire
- Puncture needle
- Occlusion dressing
- Scalpel blade
- Adaptor

Intended Purpose

PerforX® large bore catheter facilitate drainage of thick fluids using imaging-guided Seldinger access technique in a variety of drainage applications (abscesses, biliary and thoracic drainage, and other drainage applications.) for a period of up to 30 days.

Indications For Use & Contraindications

When diagnosed to place drainage catheter percutaneously for Pleural effusion, ascites, empyema, hematoma, Abscess, Paracentesis, Thoracentesis in complicated cases, other percutaneous drainage applications. Contraindications include but not limited to Bleeding disorder, Infection at the insertion site, Vasospasm or Vessel Tortuosity, Hematoma Formation, Lack of adequate imaging guidance.

Potential Complications

Bleeding (including chronic haematuria, post-procedural, intraprocedural, puncture site), Catheter dislocation/dislodgement, Catheter malposition/transcolonic catheter placement, Catheter occlusion/obstruction, Damage to adjacent organs, Mechanical catheter damage and pain, Bile leak, hematoma formation, vessel perforation, infection, Thrombosis or Blood clot formation, Air embolism, Delayed healing and scar tissue formation.

Warnings And Precautions

- Periodic evaluation of catheter us recommended for optimal functionality of the catheter. If a catheter has become malpositioned or if drainage ceases, the catheter should be promptly exchanged or removed.
- Do not use if product is damaged or expired and do not reuse the device.
- Use only accessories supplied along with package.
- Dilation should be in sequential manner starting from smallest to largest. Ensure compatibility of the guidewire before use. Manipulation of the product needs ultrasound or fluoroscopy or other imaging guidance.
- Dispose off the device and its components, if any, as per institutional and local regulatory guidelines for bio-hazardous medical waste disposal.
- This device is intended for use by physicians trained and experienced in diagnostic and interventional techniques, standard techniques for placement of percutaneous drainage catheters should be employed.
- Do not force components during placement or removal. Carefully deploy or remove the components if resistance is encountered.
- Right choice of catheter shall be made based on patient/Surgical requirements; catheter should not remain indwelled for more than 30 days after deployment.

Instructions For Use

Note: Activate the hydrophilic coating, by wetting the catheter with sterile water or saline. For best results, keep catheter surface wet during placement.

Seldinger Access Technique

Catheter

- Under Ultrasound or CT scan, localize the collection system to be drained. Under fluoroscopic guidance, perform procedure using standard procedures of puncture, compatible guidewire placement and dilatation.
- Identify and mark the skin site overlaying the collection system. Anesthetize and mark on skin site. Make a small incision, by using scalpel.
- Under fluoroscopic guidance, introduce the puncture needle provided in the kit at right angles to the skin at the marked site exactly into the collection system. After achieving placement, remove the inner trocar of the needle. Confirm placement via aspiration.
- Then introduce guidewire through needle cannula. On reaching the desired location, remove the outer cannula of the needle while maintaining guidewire position.
- To facilitate passage of the catheter, dilate the musculofascial track using dilators in sequence from smallest to the largest.
- Assemble the catheter and inserter by means of hub locking. Then Load the catheter over the guidewire and progress the catheter inserter assembly into the collecting system. Then remove the guidewire followed by catheter inserter.
- Aspirate the fluid through the drainage catheter. Optionally, if required, under imaging guidance, inject contrast to confirm proper positioning within the collecting system.
- 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.
- Suture the catheter to the skin in a standard practice and dress it appropriately by using occlusion dressing. Resume drainage as needed.

Catheter Removal Procedure

- 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
- Provide the patient with instructions for post-removal care, such as keeping the site clean and dry

Reference & Literature

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.

Supply and Storage

The device is packed in such a way that, all the contents are assembled in tray 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^{o}C to 40^{o}C and away from direct sunlight.

Target Population Group

In patients who have, or might have fluid obstruction due to various reasons, an external drainage tube called a ‘catheter’ is commonly placed percutaneously in order to prevent or to temporarily relieve the obstruction.

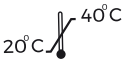
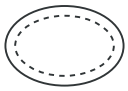
Report Any Serious Incident

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 resterilize
	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 barriersystem 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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