10. Instructions for Use

PERCUTANEOUS SHEATH INTRODUCER

Device Description:

AMECATH Percutaneous Sheath Introducer is a tapered and nailed tube-like sheath ends proximally with haemostatic valves.

Attached to the tube is a side arm end with stopcock. Dilator (obturator) is supplied to facilitate placing the sheath in the vessel.

In some types of the sheath is coated with hydrophilic material.

Range of sizes between 04 to 8 FR and lengths between 4 to 11 Cm

Target patient populations: Adults and children
Intended user: Health Care Professionals

AMECATH Percutaneous Sheath Introducer is available in different designs and Kit configurations to cover all customer needs

Device Construction

Catheter Types

- Micro puncture hydrophilic sheath introducers
- Micro puncture percutaneous sheath introducers with side arm and integrated valve
- Percutaneous sheath introducers with side arm and integrated valve

List of Accessories:

- Introducer Needle - Echogenic
- Straight End Stainless Steel Guide Wire
- Straight End Nitinol Guide Wire
- Introducer Needle
- J End Stainless Steel Guide Wire 0.035 x 50 Cm
- J End Nitinol Guide Wire 0.035 x 50 Cm (for hydrophilic sheath)

Intended Use:

AMECATH Percutaneous Sheath Introducer is a sterile single use device indicated for facilitating the insertion of catheters into patient's vessels (introduce up to a size 0.038" guidewire or a catheter through the skin into a vein or an artery)

Contraindications:

- The sheath should not be placed in patient with bleeding disorders
- In the presence of another device related infection, bacteremia or septicemia is known or suspected.
- If sever chronic obstructive lung disease exists
- Post irradiation of prospective insertion site.
- Previous episodes of venous thrombosis or vascular surgical procedure at the prospective placement site have occurred.
- Local tissue factors will prevent proper devices stabilization and/or access

Warnings and Precautions

General

- For single use only. Do not re-use, reprocess or re-sterilize. Do not use catheter or accessories if any sign of product damage is visible.
- Reprocessing or re-sterilization may damage the device and affect its integrity which may, when re-used, lead to severe deterioration in health and safety of patients.
- The sheaths do not have any magnetic metallic components and can be exposed to various environmental conditions including thermal ignition source (during MRI) as long as no metal component is attached to it.
- Do not attempt to use a guidewire with a maximum diameter greater than specified on package label.
- This device should only be used by physicians thoroughly trained in the technique of catheter delivery systems.
- Device should only be advanced or retracted under fluoroscopic guidance and should only be advanced with the dilator fully inserted.
- Do not attempt to advance or withdraw guidewire, catheter, or other interventional medical device through introducer sheath and/or dilator if resistance is felt. Use fluoroscopy to determine cause. Continued advancement or retraction against resistance may result in damage to the vessel, or breakage of the guidewire, catheter or interventional medical device. Continued advancement or retraction against resistance may result in serious injury.
- Advance dilator/sheath assembly with a twisting motion to avoid damage to the sheath or vessel.

- Do not attempt to insert a catheter or other interventional medical device having a diameter larger than the introducer sheath size indicated. Device damage or breakage may occur.
- It is not recommended to use antimicrobial ointments on catheters as it may cause its degradation.
- Do not use absolute alcohol or acetone-based product on the catheter. 2% chlorhexidine or Iodine based solution is recommended as antiseptic solution

Specific

- Advance and remove sheath only under fluoroscopic guidance.
- Do not attempt sheath advancement without guidewire and dilator secured in place. Severe vascular damage and/or injury may occur.
- Insertion into and removal from artery may cause excessive bleeding and/or other complications.
- Do not continue advancement or retraction of the catheter or other interventional medical device into and out of the introducer if there is resistance. Determine the cause of resistance before proceeding.
- Amecath sheath is not designed for pressure injection. Trying the same injections could result in sheath failure and serious patient injury
- If the catheter through the valve is withdrawn and the sheath introducer is left indwelling, an obturator must be used to guard against any potential bleeding or air embolism.
- Sheath Introducers must be occluded at all times to minimize the risk of patient air embolism or haemorrhage. If catheter introduction is delayed, or the catheter is removed, temporarily cover valve opening with sterile-gloved finger until a catheter or obturator is inserted.
- Remove a PSI as soon as central venous access is no longer indicated.
- Apply petroleum gel gauze and a pressure dressing immediately after PSI removal.
- Do not withdraw the guidewire through a needle after it has been inserted as it may damage the guidewire.
- Insert the dilator into the center of the hemostatic valve, incorrect alignment may cause damage to the valve resulting in blood leakage.
- Lock the dilator into the sheath hub. Failure to lock the dilator to the sheath hub may cause sheath advancement and possible damage to the vessel.
- Rapid withdrawal of the dilator may cause incomplete closing of the valve resulting in blood leakage. If this occurs, reinsert the dilator into the sheath and slowly remove again.
- Do not power inject through the side-port and three-way stopcock.
- Sheath Introducers must be occluded at all times to minimize the risk of patient air embolism or hemorrhage. If catheter introduction is delayed, or the catheter is removed, temporarily cover valve opening with sterile-gloved finger until a catheter or obturator is inserted

Complications

- Hemorrhage
- Air embolism
- Rupture of a major blood vessel led to rapid blood loss
- infection
- perforation of the vessel wall
- emboli
- intimal tear
- thrombus formation
- vessel occlusion
- pseudoaneurysm

How Supplied:

- **AMECATH Percutaneous Sheath Introducer** is a sterile, single use medical device
- Each **AMECATH Percutaneous Sheath Introducer** Kit is packed in a PETG hard blister covered with Tyvek
- Each carton box includes 10 **AMECATH Percutaneous Sheath Introducer** Kits

AMECATH Percutaneous Sheath Introducer method of application

A. General Steps:

1. Catheterize the patient in the usual manner.
2. The Percutaneous Sheath Introducer to be connected via it's end to the extension line or the stopcock.
3. Extension line or stopcock to be connected to guidewire or a catheter.

B. Preparation of Percutaneous Sheath Introducer

4. Verify proper size (diameter and length) is selected.

5. Remove the Introducer Sheath from its packaging and examine for possible damage or defects. Do not use any damaged or defective devices.
6. Flush the dilator, introducer sheath, and sideport with heparinized intravenous fluid.
7. When the sheath will remain in a vessel for an extended period, consider using a continuous drip of heparinized intravenous fluid under pressure administered through the sideport connection.

***Warnings:**

- The implantation technique has a significant influence on the complications and outcome of the sheath introducer. Implantation must be performed by a competent and experienced catheter insertion team. Unexperienced personnel should not be permitted to perform the implantation except under the direct supervision of an experienced physician or surgeon
- Be sure that you are familiar with the possible complications and emergency measures are known and available if any occur.

C. Sheath Placement:

Micro introducers:

1. Follow normal accepted practice for vessel micro puncture using the 21G needle and the 0.018" guidewire supplied.

CAUTIONS*

2. The guidewire should not be withdrawn through the 21-gauge needle. Damage or shearing of the guidewire may occur. If the guidewire tip must be withdrawn while the needle is inserted, remove both the needle and the wire as a unit.
3. Using fluoroscopic guidance, advance the dilator/sheath over the guidewire as a unit; do not allow dilator to back out of the (separate) shea th while advancing. Stop advancement of the assembly if there is resistance. Investigate the cause of resistance before proceeding. Carefully advance the assembly until it is at the desired location. Advance dilator/sheath assembly with a twisting motion to avoid damage to the sheath or vessel.
4. Hold the sheath steady while withdrawing the dilator with its inside guidewire from the sheath until it is completely removed with the guidewire.
5. Advance the selected larger guidewire or a catheter into the sheath
6. Remove the sheath and leave the guidewire or the catheter for further procedure

Sheath introducers with integrated valve and side arm

1. Insert the dilator tip through the valve and completely into the sheath until the dilator hub comes in contact with the hemostasis valve. This ensures that the tapered portion of the dilator is beyond the end of the sheath. Push to click the dilator hub into the valve head.
2. Follow normal accepted practice for vessel puncture or incision and guidewire insertion.
3. Using fluoroscopic guidance, advance the dilator/sheath over the guidewire as a unit; do not allow dilator to back out of the (separate) sheath while advancing. Stop advancement of the assembly if there is resistance. Investigate the cause of resistance before proceeding. Carefully advance the assembly until it is at the desired location. Advance dilator/sheath assembly with a twisting motion to avoid damage to the sheath or vessel.
4. Hold the sheath steady and maintain the guidewire position while withdrawing the dilator from the sheath, over the guidewire until it is completely removed with the guidewire.
5. Advance the selected catheter or other interventional medical device into the sheath, taking care to keep the sheath assembly as straight as possible outside the body and avoid kinking.
6. When exchanging different catheters and devices through the introducer sheath care should be taken to maintain proper guidewire and sheath positions within the vascular system.
7. Carefully support all wires, catheters and devices while pushing across the hemostasis valve.
8. Upon removal of the sheath, precautions should be taken to prevent bleeding, vessel damage, or other serious injury.

N.B for further information on luer connections, please refer to latest version of BS EN ISO 80369-7

SAFETY MEASURES

Air embolism and hemorrhage

Any situation in which there is an open communication (however small) between the central veins and the atmosphere has the potential for 2 major complications: (1) backflow bleeding, which will be more risk if central venous pressures are elevated, and (2) air entrainment into the central veins and the right side of the heart during inspiration in spontaneously breathing patients. Many possible clinical scenarios can initiate these potentially lethal complications.

Warnings:

- Disconnection of the introducer hub from the hemostasis valve/side-port assembly, is the first clinical scenario that presents the potential for lethal complications. The introducer hub is secured to the insertion site using the suture tab, which is located on the hub.

- Tension on the side port IV tubing due to the patient's movement could accidently untwist the Luer-lock adapter and disconnect the hemostasis valve. Accidental disconnection could result in exsanguination within minutes. Similarly, an unobserved, confused patient may unscrew the hub and suffer life-threatening complications.
- Fracture of the sheath-hub connection can likewise allow entrainment of air into the circulation as well as backflow bleeding. To reduce the risk for air embolism and/or bleeding, securely fix and tape the IV tubing of the side port to the patient's skin and avoid traction on the IV tubing.
- An uncapped stopcock attached to the introducer assembly may also be accidentally opened to air. An unobserved patient in a cardiovascular intensive care unit exsanguinated through an uncapped stopcock that was accidentally opened by the patient's movement

Precautions:

- Patients should be visible to hospital personnel at all times, preferably with the caregiver at or near the bedside. Introducers should not be left in patients who are transferred out of the critical care environment to areas where they may not be closely monitored. Ideally, the introducer sheath should be removed upon removal of the cardiac catheter and should not be maintained for IV access.
- Avoid use of stopcocks in the monitoring catheters whenever possible.
- Inspect the site frequently to ensure that the dressings are intact and that stopcocks are in the proper position.
- Air can also enter the central venous system during catheter insertion and removal. Several techniques may be used to reduce the risk of air embolism, including the following:
  - Cover the valve opening with a sterile gloved thumb until the catheter or obturator is inserted.
  - Ask a spontaneously breathing patient to perform a Valsalva maneuver during catheter insertion or removal.
  - If the patient is receiving controlled mechanical ventilator support or cannot cooperate, apply gentle abdominal compression to increase intrathoracic pressure during catheter insertion or removal.
  - Place the patient in the Trendelenburg position, if tolerated.
- The introducer is a large-bore catheter and that following removal, a skin-to-vessel tunnel may allow entry of air into the central venous circulation during spontaneous inhalation. To avoid air entrainment through a skin-to-vessel tunnel immediately after removal of the introducer, cover the site with a gauze dressing to which abundant antiseptic ointment is applied. Rub the ointment- covered dressing over the area of the subcutaneous tract to ensure an airtight seal and use sufficient tape to produce an occlusive dressing.

Vascular Trauma or Perforation by the Introducer Sheath

Another concern surrounding long-term use of the introducer is that the introducer tip is typically rigid and inflexible. Movement of the catheter within the vessel or malposition of the introducer tip against the vessel wall may result in vascular trauma, erosion, or perforation. Elderly or debilitated patients with fragile vascular walls are especially vulnerable to vessel perforation.

Precautions

- Check chest radiographs for correct introducer position after the catheter is inserted, and on subsequent films, and notify the physician if malposition is noted, so that the sheath can quickly be realigned parallel to the vessel wall; and
- Once proper catheter position is noted, secure the introducer assembly in position with tape to prevent displacement.

Introducer Kinking or Collapse

Inaccurate monitoring data damped or flat waveforms, as well as reduced flow or no flow of IV fluids being administered may be the result of kinking or collapse of the introducer.

Precautions

- Frequently inspect the catheter insertion site to ensure integrity of dressings and the proper external positioning of the sheath introducer.

Product Variants:
For variants of **AMECATH Percutaneous Sheath Introducer,** Kindly refer to the catalogue, visit our website on:

"www.amecathgroup.com" , or contact your nearest **AMECATH** representative."

1. Micro Sheath Introducer Kit:
Code Structure: MSI-XXLL-K:

MSI: Micro sheath introducer.

XX: for Sheath size in Fr.

LL: for Sheath Length in cm.

K: Kit Configuration with Contents as per below table.

Reference	Contents
MSI-XXLL-K	• **Micro sheath introducer** • **G21 x 7 cm introducer needle** • **straight end 0.018 x 50 cm Nitinol guide wire**
Hydrophilic coated Micro sheath introducers are available. Please add H at end of the code (MSI-XXLL-HK)	

2. Micro Percutaneous Sheath Introducer Kit:
Code Structure: MPSI-XXLL-K:

MPSI: Micro Percutaneous sheath introducer.

XX: for Sheath size in Fr.

LL: for Sheath Length in cm.

K: Kit Configuration with Contents as per below table.

Reference	Contents
MPSI-XXLL-K	• **Micro Percutaneous sheath introducer with integrated valve and side arm.** • **G21 x 7 cm introducer needle** • **J end 0.018 x 50 cm Nitinol guide wire** • **Guide Wire Nozzle**
Hydrophilic coated Micro Percutaneous sheath introducers are available. Please add H at end of the code (MPSI-XXLL-HK)	

3. Percutaneous sheath introducers Kit:
Code Structure: PSI-XXLL-K:

PSI: Percutaneous sheath introducer.

XX: for Sheath size in Fr.

LL: for Sheath Length in cm.

K: Kit Configuration with Contents as per below table.

Reference	Contents
PSI-XXLL-K	• **Percutaneous Sheath introducer with integrated valve and side arm.** • **G18 x 7 cm introducer needle.** • **J end 0.035 x 50 cm Nitinol guide wire** • **Guide Wire Nozzle**
Hydrophilic coated Percutaneous sheath introducers are available. Please add H at end of the code (PSI-XXLL-HK)	

Storage and Product Safe Disposal

- Store between 5°C to 30°C.
- Do not expose to organic solvents, ionizing radiation or ultraviolet light.
- Rotate inventory so that catheters are used prior to expiration date on the package label.
- Used Product should be disposed as hospital protocol or in sanitary container to prevent possible contamination and cross infection.

❖ *In case of any questions or quiries, Kindly contact the local Authorised Representative or visit* **AMECATH** *website on :*
" www.amecathgroup.com ".

❖ *In case of any Adverse event, Contact your local Health Authority immediately.*

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