Instructions for Use
Reprocessed Swartz Braided Transseptal Guiding Introducer

Reprocessed Device for Single Use

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The Reprocessed Transseptal Catheter Introducer Set consists of a radiopaque sheath and dilator, each with a specially curved distal portion to accommodate positioning against the atrial septum and to accommodate an 0.032" guidewire and a BRK type curved puncture needle. The introducer sheath is fitted with a valve to provide hemostasis during catheter introduction and/or exchange. Located on the valve housing, a sideport with three-way stopcock is provided for aspiration, fluid infusion, blood sampling and pressure monitoring. The dilator is tapered at the distal tip with an internal lumen designed to accept ancillary devices (e.g. needles or guidewires) that have a maximum diameter of 0.032". The dilator inner lumen is also designed with a special geometry at its distal end to limit the exposure of the BRK needle.

INDICATIONS FOR USE

The Reprocessed Transseptal Catheter Introducer Set is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

CONTRAINDICATIONS

- Previous interatrial septal patch or prosthetic ASD closure device.
- Any previous thromboembolic event.
- Known or suspected left atrial myxoma.
- Known or suspected myocardial infraction within the last two weeks.
- Unstable angina.
- Recent Cerebral Vascular Accident (CVA).
- Patients who do not tolerate anticoagulation therapy.
- Patients with an active infection.

WARNINGS

- Do Not alter this device in any way.
- Store in a cool, dark, dry place.

PRECAUTIONS

Special Patient Populations

Prior to the procedure, the patient must be hemodynamically stable. Certain conditions may require special consideration when using this product. These may include, but are not limited to:

- Rotated Heart
- Enlarged aortic root
- Marked right atrial enlargement
- Scoliosis/kyphosis
- Abnormal Left atrial geometry
- Congenital malformations
- Vascular malformations
- Inability to access the right atrium through the IVC

DIRECTIONS

- The package label is detachable and may be affixed to the medical record of the patient.
- Inspect the device and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the device is damaged or if the package is compromised, do not use the device. Return the device and packaging to Innovative Health. Do not attempt to resterilize.
- Remove the device from the package and place it in a sterile work area using aseptic technique

Procedural Considerations

Carefully reading the Instructions before use of this device will help to reduce the potential dangers associated with the transseptal technique such as air emboli or perforation of the aorta or left atrium. Only those physicians who are specially trained in transseptal procedures should use this device. Fluoroscopy should be used to confirm positioning throughout the procedure. Transseptal procedures should be performed only in facilities appropriately equipped and staffed to perform such procedures. Lab capabilities should include, but are not limited to:

  - Intracardiac pressure monitoring capabilities;
  - Systemic pressure monitoring;
  - Contrast media injection, and management of untoward reactions to contrast media;
  - Pericardiocentesis;
  - Surgical backup;
  - Anticoagulation therapy and monitoring

- Maintain monitoring of vital signs throughout the procedure.
- Inspect all components before use.
- Use only a BRK type curved needle with stylet (**not supplied by Innovative Health**).
- Prior to inserting the device into the patient, pre-assemble sheath and dilator, advance the needle through the dilator and check for excessive resistance as the tip of the needle advances through the curvature of the sheath/dilator assembly.
- During insertion, use caution not to create excessive bends in this device. This may inhibit advancement of the needle and may result in inadvertent needle puncture of the dilator/sheath assembly.
- During insertion, always use the stylet to facilitate needle passage through the dilator/sheath assembly. Failure to use the stylet may inhibit advancement of the needle and may result in inadvertent needle puncture of the dilator/sheath assembly or skiving of material from the inner surface of the dilator.
- To minimize the potential for creating a vacuum in the sheath, remove components and make catheter exchanges slowly.

- Once the sheath is inserted into the vasculature and the dilator is removed, aspirate until steady blood return is achieved prior to flushing or infusion.
- All fluid infusion should be through the sideport.
- Thrombus may accumulate in or on the sheath tip during the procedure. Aspirate when removing dilator or catheter.
- In order to minimize embolic risk, either provide a continuous infusion of heparinized solution or periodically aspirate and flush through the sideport while the sheath is positioned in the vasculature.
- Do not remove dilator or catheter rapidly. Damage to the valve may occur, potentially compromising hemostasis.
- If resistance is met when advancing or withdrawing guidewire or introducer, determine the cause and correct before continuing with this procedure.
- Indwelling intracardiac introducer sheaths should always be supported with a catheter or an obturator.
- Do not manipulate the sheath in the heart without a device extending from its distal tip.

Suggested Transseptal Procedure

There are eight (8) major steps in the transseptal technique:

1. Prepare and assemble equipment.
2. Advance sheath/dilator assembly into superior vena cava.
3. Position BRK needle inside assembly.
4. Drag assembly and engage fossa ovalis.
5. Puncture the fossa ovalis with the BRK needle.
6. Advance sheath/dilator assembly over fixed needle.
7. Advance the sheath over fixed dilator and needle into left atrium.
8. Remove the dilator and needle from the sheath.

Note: TRANSSEPTAL NEEDLE IS NOT SUPPLIED BY INNOVATIVE HEALTH.

Note: Typical variations may occur within these steps, depending on available capabilities and operator preference. Please refer to the Original Manufacturer's Instructions for Use for additional information regarding transseptal procedures.

EXPLANATION OF SYMBOLS

Rx only	Federal Law in the USA restricts this device to sale by or on the order of a physician
STERILE EO	Sterilized by Ethylene Oxide Gas
REF	Catalog Number
SN	Serial Number
LOT	Lot Number
	Use by Date
	Do Not Reuse
	Do Not Resterilize
	Consult Instructions for Use
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight and Radioactive Sources
	Non-pyrogenic

As the reprocessor, Innovative Health is solely responsible for this device. All Original Manufacturer (OM) information is provided for device identification and may contain trademarks from third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with Ethylene Oxide (EO) gas. Even though the product is processed in compliance with all applicable laws and regulations relating to EO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with EO. The packaging may expose you to EO, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

Please refer to www.innovative-health.com for product warranty.