

## **Transseptal Needle**

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## Transseptal Needle

**Federal law restricts this device to sale or on the order of a physician.**

**Read instructions for Use prior to use of this device.**

**See individual sterile package label for contents.**

**Single-use disposable medical device.**

**Contents are sterile if package is unopened and undamaged.**

**Do not re-sterilize.**

### 1 PACKAGE CONTENTS

The transseptal needles are supplied sterile. The needle and stylet are placed in thermoformed plastic tray. The tray is placed inside a pouch, which is heat-sealed. The pouch is placed in a paper box.

### 2 DESCRIPTION

The Transseptal Needle consists of a luminal stainless steel needle and solid stainless steel stylet. The distal section of the needle is curved to facilitate positioning within the heart when used with a SNP introducer kit. Within this curved section, there is an abrupt step down in the outer diameter of the needle to mate with the internal diameter of the dilator of a SNP Introducer Kit. The distal tip of the needle is beveled to facilitate the puncture process. The proximal end of the needle is configured with a pointer arrow (indicating distal curve orientation) and is fitted with a shutoff valve to provide needle lumen access for aspiration, fluid injection / infusion, blood sampling, pressure monitoring, and stylet and / or guide wire insertion. The stylet is straight and isodiametric throughout its length. The proximal end of the stylet is fitted with a curved clip to lock onto the proximal needle hub when inserted into the needle lumen. The stylet is designed to facilitate needle advancement within the dilator. The needle is available in various useable lengths and distal curve configurations.

### 3 INDICATIONS FOR USE

Intracardiac Catheter Introducer Kit is intended for introducing various cardiovascular catheters into heart. Transseptal Needle is intended for puncture the interatrial septum during a transseptal catheterization procedure.

### 4 CONTRAINDICATIONS

- Previous interatrial septal patch or prosthetic atrial septal defect closure device
- Any previous thromboembolic event
- Known or suspected myocardial infarction within the last two weeks
- Unstable angina
- Recent pulmonary emboli
- Recent Cerebral Vascular Accident (CVA)
- Patient who do not tolerate anticoagulation therapy
- Patient with an active infection

### 5 WARNINGS

- 5.1 Do not alter this device in any way.
- 5.2 Do not reuse this device. After use, thorough cleaning of biological and foreign material is not possible. Adverse patient reactions may result from reuse of this device.
- 5.3 The devices must be appropriately disposed according to local regulations.
- 5.4 Minimize X-ray exposure during the procedure. And the device should only be used in radiation shielded operation rooms.

### 6 PRECAUTIONS

- 6.1 The devices are used by professional physicians only.
- 6.2 Store in a cool, dark, dry place.
- 6.3 Inspect all components prior to use.
- 6.4 Open or damaged packages could not be used in operation.
- 6.5 During transseptal procedures, the Intracardiac Catheter Introducer Kit manufactured by Synaptic Medical Limited must only be used assembly with the Transseptal Needle manufactured by us. If the Intracardiac Catheter Introducer Kit or Transseptal Needle manufactured by other manufacturers is used, there may be risks.
- 6.6 Do not reshape the Transseptal Needle.

For Single Use Only! Single-use devices are designed and tested for only one patient application. These are disposable devices and are not designed for reprocessing and reuse. Reuse of designated "single-use" devices creates a risk of patient or user infections (Viral, Bacterial, Prion and Endotoxin exposure, e.g.) due to protein retention in plastic materials (from prior use) and the difficulty in cleaning the narrow structures at material interfaces and introducer lumen diameter following direct blood contact. Aqueous based cleaning process may introduce pyrogens. There is no validated method to remove prions from these devices. Contamination or reprocessing cleaning agent residues may lead to adverse patient reactions. Furthermore, cleaning, disinfection and sterilization methods not tested or approved by SNP used on the introducer may compromise the structural integrity of the introducer plastic materials (PE, Polycarbonate, ABS, PVC, and Silicone Rubber) and compromise design characteristics leading to devices malfunction or failure resulting in patient injury, permanent impairment or death. Use of non-SNP packaging may compromise device functional and sterility due to compromise protection from shipping and handling damages. And the absence of labeling after reprocessing, may lead to misuse of the introducer and impaired traceability. Reprocessing and reuse may result in patient or user injury, permanent impairment or death.

### 7 "USE-BY"DATE

Use the product prior to the "Use By" data on the package label.

### 8 ENVIRONMENT CONDITIONS

The following environment conditions should be met for storage, transport and use:

Temperature : -20 and 55°C

Humidity: 10% and 90%.

### 9 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 interior vena cava

## 10 PROCEDURAL CONSIDERATIONS

- Carefully reading the instructions before use of this device will help to reduce the potential risks associated with the use of this device, such as air embolism or perforation of the aorta or left atrium.
- Only those physicians who are specially trained should use this device.
- Fluoroscopy should be used to confirm positioning throughout the procedure.
- Do not create a vacuum in the introducer. Remove components and make catheter exchanges slowly.
- Aspirate blood from the sidearm prior to infusion.
- Provide a continuous fluid infusion when the introducer remains in the vessel.
- Prior to inserting the transeptal needle into the patient, pre-assemble the sheath introducer and dilator. This may inhibit advance the needle/stylet assembly through the dilator and check for excessive resistance as the tip of the needle advances through the curvature of the sheath introducer/dilator assembly.
- During insertion of the transeptal needle, 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 introducer assembly.
- During insertion of the transeptal needle, always use the stylet to facilitate needle passage through the dilator / sheath introducer assembly. (Failure to use the stylet may inhibit advancement of the needle and may result in advertent needle puncture of the dilator / sheath introducer assembly or skiving of material from the inner surface of the dilator.)
- Intracardiac 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.

## 11 POTENTIAL COMPLICATIONS

Complications that may occur during use of this device include, but are not limited to:

- Air embolism
- Cardiac perforation
- Cardiac tamponade
- Conduction system disturbances such as SA node, AV node or His-Purkinje system block
- Hematoma or excessive bleeding at the vascular access site
- Stroke
- Thromboembolism
- Valvular damage
- Cardiac arrhythmias
- Intimal tear

## 12 DIRECTIONS FOR USE

### Left Heart Access with the Assistance of Accessory (Transeptal Needle)

**NOTE:** Typical variations may occur within these steps, depending on available capabilities and operator preference. These optional steps will be listed as "OPT", and details discussed.

#### 1) Prepare and assemble equipment

- Prepare the Transeptal Guiding Introducer Kit
  - Preparing the transeptal catheter introducer kit requires the following items:
    - One transeptal sheath introducer, dilator and guide wire
    - One length-matching Transeptal needle, with a stainless steel stylet
    - Syringes for aspiration and flushing
    - Sterile heparinized saline
  - Flush the dilator and the sheath introducer with sterile heparinized saline.
  - After flushing, position the stopcock on the sidearm of the sheath introducer so that it is in the closed to the sheath introducer position.
  - Insert the dilator fully into the transeptal sheath.
- Prepare the Transeptal Needle
  - Remove the stylet from the transeptal needle and flush the needle with sterile heparinized saline.
  - Re-insert the stylet into the transeptal needle and lock it onto the shutoff valve.
  - Insert the transeptal needle and stylet into the sheath/dilator.

**Note:** due to the stop feature of the dilator, when fully engaged, there will be a gap between the dilator hub and needle pointer flange. (See Fig.1)

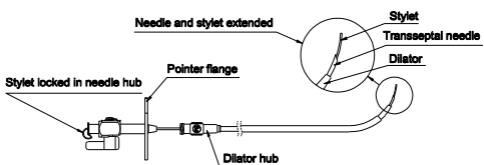


Fig.1

- Two measurements should be made:
  - Measurement 1. Withdraw the needle assembly until the tip of the stylet is just within the tip of the dilator. Measure the distance from the pointer flange and the dilator hub, Record this measurement for use during the procedure. (See Fig. 2)

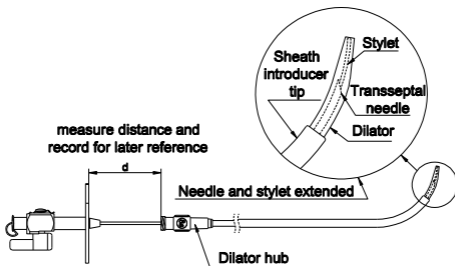


Fig.2

- Measurement 2. Measure the distance between the pointer flange and the dilator hub with only the needle tip (without the stylet inserted) just inside the tip of the dilator. (See Fig.3.)

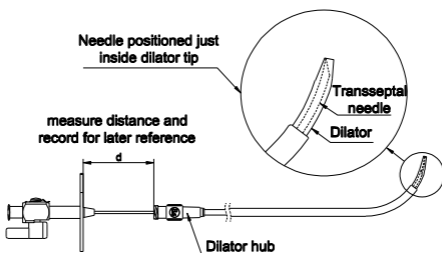


Fig.3

**CAUTION:** It is critical to maintain the distance between the pointer flange and the dilator hub during initial insertion into the sheath introducer / dilator assembly. This ensures that the stylet does not extend beyond the dilator tip which could result in patient injury. Once the stylet is removed, it is critical to maintain the distance of the 2nd measurement to prevent patient injury with the needle tip until septal puncture is desired.

- Remove the transseptal needle from the dilator.
  - Flush the needle again.
  - Reinsert and lock the stylet.
  - Flush the dilator again.
  - This completes the preparation.
- 2) ADVANCE SHEATH INTRODUCER / DILATOR ASSEMBLY INTO SUPERIOR VENA CAVA**
- Obtain femoral venous access (right femoral preferred). OPT: a larger ( $\geq 2.5$  French sizes greater than the transseptal introducer) standard length sheath may be used to obtain and maintain venous access for device exchange and haemostasis.
  - Introduce the guide wire into the superior vena cava (SVC).  
Note: 0.032" is the maximum guide wire diameter that can be used with the dilator.
  - Insert the transseptal sheath and dilator assembly into the vein over the guide wire and advance the assembly until the sheath tip is in the SVC. Orient the dilator tip medially.
- 3) POSITION THE TRANSEPTAL NEEDLE AND STYLET ASSEMBLY INSIDE THE SHEATH INTRODUCER / DILATOR ASSEMBLY**
- Remove the guide wire from the dilator.
  - Fully aspirate and then flush the dilator with clean heparinized saline, ensuring that no air enters the bloodstream.
  - Separate the sheath introducer and dilator by withdrawing the dilator a distance sufficient to accommodate the needle curve. (See Fig.4.). This will facilitate passage of the transseptal needle curve through the rigid hubs of the dilator and sheath introducer.

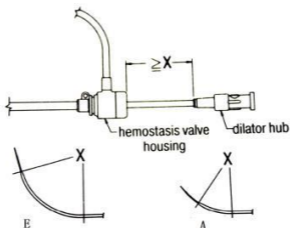


Fig.4

- Confirm that the stylet is locked onto the haemostasis valve of the transseptal needle.
- Insert the transseptal needle/stylet into the dilator, letting the needle rotate freely as it advances.
- After the needle curve is advanced beyond the hemostasis valve hub of the sheath, reconnect the sheath introducer and dilator by sliding the sheath introducer back over the dilator while maintaining the sheath introducer tip position in the SVC (Do not advance the dilator).
- Advance the needle and stylet until the pointer flange is the predetermined distance from the dilator hub (Measurement 1).
- Remove the stylet and set aside. (Do not discard.)
- Turn the stopcock to the off position.
- With the stylet removed, advance the transseptal needle near the dilator tip (Measurement 2).
- Attach a syringe to the dilator hub and aspirate until blood return is observed,

then discard the syringe.

**NOTE: the use of a slip-tip (non-Luer-Lock) syringe may prevent aspirating air.**

- Flush the needle with clean heparinized saline, ensuring that no air enters the bloodstream. Close the stopcock.
- OPT: Attach a 3-way rotating stopcock to the hemostasis valve hub of the transeptal needle.
- OPT: Attach a syringe with radiopaque contrast media to the stopcock. Aspirate the transeptal needle until blood is observed. Then load the needle with the contrast media under fluoroscopic guidance.
- OPT: Connect a pressure monitoring line to the stopcock.
- OPT: Use a standard 3-port manifold setup to connect contrast, pressure and flush lines.

#### 4) ENGAGE THE FOSSA OVALIS

- Visualize and identify anatomic landmarks.
- Set the fluoroscopy unit to an appropriate angle parallel to the plane of the mitral valve and orthogonal to the plane of the septum, This will typically be approximately 30 to 40 degrees left anterior oblique (LAO).
- OPT: During electrophysiology procedures, the coronary sinus and His bundle catheter positions can serve as useful anatomic landmarks. In the appropriate LAO view, the coronary sinus catheter will be seen in profile. The fossa ovalis is located at or slightly below the level of His bundle catheter and superior and posterior to the coronary sinus ostium.
- OPT: Placing a pigtail angiographic / hemodynamic monitoring catheter in the non-coronary cusp of the aortic valve can serve as a useful anatomic landmark.
- OPT: Observe the pressure waveform being recorded through the transeptal needle.
- Adjust the pointer flange so that the needle is perpendicular to the fossa ovalis (typically between 3:00~5:00 o'clock, as viewed from the foot end of the patient). (See Fig 5.)

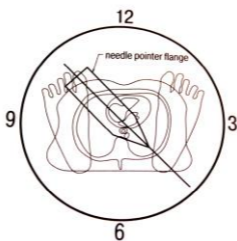


Fig. 5

- Also, confirm that the needle tip is inside the dilator by fluoroscopy and by your previous measurements.
- After confirming that the tip of the needle is within the dilator, drag the entire sheath/dilator/needle assembly slowly. Prevent any movement of the assembly parts relative to each other. It is critical to maintain the previous orientation of the pointer flange while dragging assembly.
- In the LAO view (orthogonal to the interatrial septum) observe the tip of the dilator during the drag for abrupt medial (or rightward) movement, indicating the tip has engaged the fossa ovalis. (See Figs. 6a., 6b & 6c.)

**Note: If the fossa ovalis is probe patent, the dilator tip will now move into the left atrium with ease.**



a) Starting position in SVC



b) Initial medial movement in RA



c) Abrupt medial movement onto fossa ovalis

Fig 6

- OPT: If pressure is being monitored through the needle, note that the pressure through the needle will not be accurate at this point, since the tip is against the fossa ovalis.

#### 5) PUNCTURE THE FOSSA OVALIS WITH THE TRANSEPTAL NEEDLE

- Confirm the correct location of the sheath introducer/dilator/needle assembly on the fossa ovalis before advancing the transeptal needle.
- Once the correct location is confirmed, extend the transeptal needle to full engagement within the sheath introducer/dilator assembly and advance across the interatrial septum.
- OPT: Under pressure monitoring, entry into the left atrium is confirmed when the pressure tracing shows a left atrial pressure waveform.
- OPT: Left atrial access can be confirmed via fluoroscopy with contrast injections.
- If there is any resistance to needle advancement, retract the needle, re-evaluate the anatomic landmarks.

**CAUTION: If pericardial or aortic entry occurs, do not advance the dilator over the needle, if the needle has penetrated the pericardium or aorta, it must be withdrawn. Monitor vital signs closely.**

**6) ADVANCE THE SHEATH INTRODUCER/DILATOR ASSEMBLY INTO THE LEFT ATRIUM**

- While maintaining a fixed needle position within the left atrium, advance the sheath introducer/dilator assembly fully over the needle into the left atrial cavity.

**7) ADVANCE THE SHEATH INTRODUCER OVER THE FIXED DILATOR AND NEEDLE INTO THE LEFT ATRIAL**

- Maintain the position of the dilator and needle across the septum.
- While maintaining the dilator a fixed location, advance the sheath introducer fully over the dilator into the left atrial cavity.

**8) WITHDRAW THE TRANSEPTAL NEEDLE AND THE DILATOR**

**CAUTION: There is a risk of air infiltration when withdrawing objects from the hemostasis valve of the sheath introducer. Take precautions to prevent air infiltration by withdrawing objects slowly to prevent vacuum buildup in the sheath and fluoroscopically monitor the sheath during ensuring device insertion for the presence of air.**

- Turn the needle stopcock to the off position and disconnect any attachments to the hemostasis valve of the transeptal needle.
- Remove the needle from the dilator, The needle may be cleaned and set aside for repeat use in this procedure. Otherwise, discard by appropriate means for contaminated sharp objects.
- Immediately attach a syringe to the dilator and aspirate. Continue aspirating blood while holding the sheath introducer and withdraw the dilator. The blood should be arterial blood.
- Once the dilator is removed, aspirate blood through the sidearm of the sheath introducer, and then flush it with heparinized saline, taking care to avoid air bubbles.
- The sheath introducer is now in place in the left atrium.

**13 SYMBOL DEFINITION**



DO NOT RE-USE



USE-BY DATE



BATCH CODE



STERILIZED USING  
ETHYLENE OXIDE



DATE OF MANUFACTURE



CATALOGUE NUMBER



MANUFACTURER



CONSULT INSTRUCTIONS FOR  
USE



KEEP AWAY FROM SUNLIGHT



KEEP DRY



DO NOT RESTERILIZE



TEMPERATURE LIMITATION



DO NOT USE IF PACKAGE IS  
DAMAGED



HUMIDITY LIMITATION

**Note: The symbols section contains all the symbols that may be used on product labels. Product is labeled as required.**

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