# NaviEase®Intracardiac Catheter Introducer Kit

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**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 Intracardiac Catheter Introducer consists of a sheath introducer, a dilator and a guide wire. The introducer kit is supplied sterile in a single sterile barrier. The device is packaged in a tray which is placed inside a pouch. The pouch is heat-sealed to create a sterile barrier. And the pouch is placed inside a paper box.

## 2 DESCRIPTION

The Intracardiac Catheter Introducer Kits consist of a sheath introducer, a dilator and a guide wire. Each introducer has a specially curved distal portion to accommodate positioning catheters in the cardiac anatomy. Introducers are available in a variety of French sizes and usable lengths. Each introducer is fitted with a haemostasis valve to minimize blood loss during blood aspiration, fluid infusion, blood sampling, pressure monitoring, and catheter introduction. Each introducer features vent holes to reduce cavitation during aspiration and device withdrawal. A radiopaque tip marker enables visualization under fluoroscopy.

The Introducer Kit produced by Synaptic Medical could be divided into two groups. One refers to those used in right heart access while the other refers to those used in left heart access. For left heart access, transseptal needle is needed for puncturing at the interatrial septum and then the sheath introducer is delivered through the interatrial septum to reach the left side of the heart.

## 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 The French size specified represents the inner diameter of the introducer.

6.6 Do not attempt to insert a catheter having an outer diameter larger than the indicated introducer size.

6.7 The SNP sheath introducer is designed to interlock only with SNP dilators. Use of a non-SNP component may result in serious complications.

6.8 Do not attempt to use a guide wire larger than the maximum diameter specified on package label.

6.9 Do not push the guide wire or the dilator / sheath introducer too hard during introduction.

6.10 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.

6.11 When the Intracardiac Catheter Introducer Kit is used together with the PENTARAY catheter manufactured by Biosense Webster, Inc., the insertion depth the guide sheath of PENTARAY catheter inserted into the hemostasis valve of the device shall not exceed 5mm. Excessive insertion may cause failure or even damage to the PENTARAY catheter and introducer kit.

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℃
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**

10.1 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.

10.2 Only those physicians who are specially trained should use this device.

10.3 Fluoroscopy should be used to confirm positioning throughout the procedure.

10.4 Prior to inserting the device into the patient, flush sheath introducer and dilator with heparinized saline and pre-assemble sheath introducer and dilator.

10.5 Do not create a vacuum in the introducer. Remove components and make catheter exchanges slowly.

10.6 Aspirate blood from the sidearm prior to infusion.

10.7 Provide a continuous fluid infusion when the introducer remains in the vessel.

10.8 Fibrin may accumulate in or on the sheath introducer tip during the procedure. Aspirate blood through the stopcock when removing dilator or catheter.

10.9 To remove the sheath introducer, reinsert the dilator over a guide wire into the sheath introducer. Then remove the dilator and sheath introducer as a unit.

10.10 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

10.11 Maintain monitoring of vital signs throughout the procedure.

10.12 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**

**12.1 Right Atrium Access**

**NOTE: Typical variations may occur within these steps, depending on available capabilities and operator preference.**

- Thoroughly flush the sheath introducer through the sidearm, filling sheath tube with heparinized saline.
- Thoroughly flush dilator, filling dilator tube with heparinized saline.
- Assemble the dilator and sheath introducer and lock the dilator into the Haemostasis Valve of sheath introducer.
- Once dilator is fully positioned in sheath introducer, inject additional saline through the sidearm to ensure all air is removed from the area between dilator and sheath introducer.
- Position the guide wire into the targeted cardiac location.
- Introduce the dilator / sheath introducer assembly over the guide wire into the vascular site. For introducers with shaped distal tips, always advance the sheath introducer/dilator assembly over appropriate sized guide wire for advancement to the desired anatomical site. Verify with fluoroscopy.

**CAUTIONS: Do not advancement without guide wire. Vascular damages and/or injury may occur.**

**CAUTIONS: Do not allow guide wire to inadvertently advance completely into the patient.**

- Separate the snap-lock hubs of the dilator and sheath introducer and slowly retract the dilator.
- Remove the guide wire.
- Aspirate and flush.
- Remove the dilator slowly from the sheath introducer.

**CAUTION: Never advance the sheath introducer without the dilator or catheter extended beyond the tip.**

**CAUTIONS: Always withdraw components slowly to minimize the vacuum created during withdrawal.**

- When a sheath introducer with sidearm is used, follow normal practice of using a continuous drip of anticoagulant fluid through the sidearm when the guiding introducer is in the vessel.
- Follow manufacture's recommendations for the catheter or device being introduced via the guiding introducer.

**TO REMOVE THE DEVICE**

- Reinsert the guide wire into the introducer.
- Over the guide wire, reinsert the dilator fully into the sheath introducer to aid in

straightening the tip portion. Then remove the dilator and introducer as a unit.

**12.2 Left Heart Access with the Assistance of Accessory (Transseptal 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 Transseptal Guiding Introducer Kit
  - Preparing the transseptal catheter introducer kit requires the following items:
    - One transseptal sheath introducer, dilator and guide wire
    - One length-matching Transseptal 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 transseptal sheath.
- Prepare the Transseptal Needle
  - Remove the stylet from the transseptal needle and flush the needle with sterile heparinized saline.
  - Re-insert the stylet into the transseptal needle and lock it onto the shutoff valve.
  - Insert the transseptal 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)**

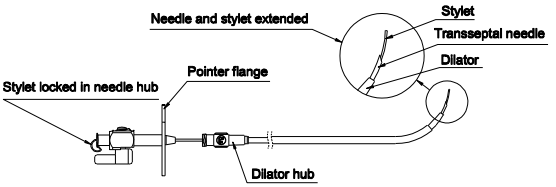



Fig.1

- 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)

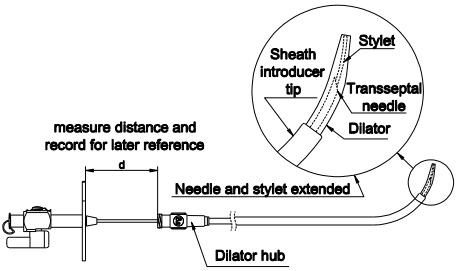



Fig.2

  - 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.)

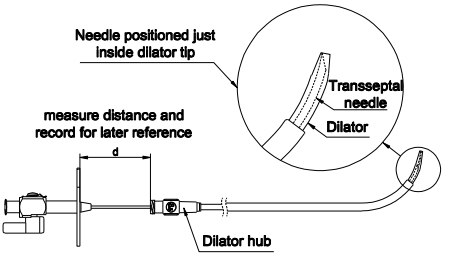



Fig.3

**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(≥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 TRANSSEPTAL 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.

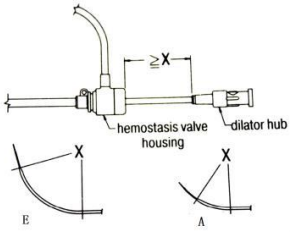



Fig.4

- Conform 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 than no air enters the bloodstream. Close the stopcock.
- OPT: Attach a 3-way rotating stopcock to the hemostasis valve hub of the transseptal needle.
- OPT: Attach a syringe with radiopaque contrast media to the stopcock. Aspirate the transseptal 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 pigtal 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 transseptal 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.)

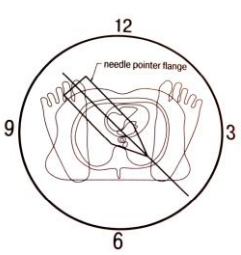



Fig. 5

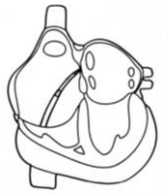
- Also, conform that the needle tip is inside the dilator by fluoroscopy and by your previous measurements.
- After confirming that the tip of the needle is within the dilator, drag the entire sheath/dilator/needle assembly slowly. Prevent any movement of the assembly parts relative to each other. It 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 TRANSSEPTAL NEEDLE**

- Confirm the correct location of the sheath introducer/dilator/needle assembly on the fossa ovalis before advancing the transseptal needle.
- Once the correct location is confirmed, extend the transseptal 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 TRANSSEPTAL 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 transseptal 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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