



Instruction for Use

Steerable Intracardiac Catheter Introducer Kit & Accessory (Transseptal Needle)

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Steerable Intracardiac Catheter Introducer Kit & Accessory (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

Steerable Intracardiac Catheter Introducer Kit

The steerable introducer set consists of steerable sheath, a dilator and guidewire. The introducer sheath consists of handle, side arm and sheath with two side ports of symmetrical distribution on the top. Dilator consists of expansion tube and connecting base. Guidewire is made up of cored wire and bonding wire with coating on the outer surface

Accessory (Transseptal Needle)

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. The intracardiac catheter introducer and the transseptal needle are further packaged into a bigger box.

2 DESCRIPTION

The Steerable Intracardiac Catheter Introducer Kit is used in intracardiac electrophysiological techniques. It includes a collection of sterile devices designed to provide a pathway for the introduction of various cardiovascular catheters (or biopsy devices) into heart chambers, including both the right side and the left side of the heart. The most common percutaneous access sites are the femoral veins. Along the femoral vein, the catheter goes all the way up to inferior vena cava, further into the right atrium. Access to the left atrium is established through transseptal approach which requires a transseptal needle puncturing at the interatrial septum and accessing the left atrium. Various studies have demonstrated that the use of Introducer kit to perform endomyocardial biopsy and cardiac catheterization may reduce the complications associated with this procedure.

The Introducer Kit typically includes items of a steerable sheath introducer, a dilator and a guidewire. During operation, the groin vein is punctured with a sharp hollow needle called a trocar. The dilator is introduced into vessel through trocar, and then the trocar is withdrawn. The guidewire is then advanced through the lumen of the trocar and positioned into the targeted cardiac location. The steerable sheath introducer/dilator assembly is passed over the guidewire into the vascular site. Finally remove the guidewire and dilator and the access is established. Various catheters (or biopsy devices) could be inserted into heart chambers through the sheath introducer. A trocar is not included in this kit.

The Steerable Intracardiac catheter introducer kit and transseptal needle are applicable for following surgical procedures:

Atrial septum puncture, establish the access to left atrium, diagnose and treat Atrial Fibrillation.

The diagnosis and treatment of atrioventricular nodal reentrant tachycardia (AVNRT), atrioventricular reentrant tachycardia (AVNRT), atrial flutter, as an assist to fix the position of duct.

3 INDICATIONS FOR USE

The Steerable Intracardiac Catheter Introducer Kit is intended to introduce various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

4 CONTRAINDICATIONS

- Previous intra-atrial septal patch
- known or suspected atrial myxoma
- Myocardial infarctions within the last two weeks
- Unstable angina
- Recent cerebral vascular accident (CVA)
- Patients who do not tolerate anticoagulation therapy
- Patients with active infection
- Presence of atrial thrombus

5 WARNINGS

- 5.1 Store in a cool, dark, dry place
- 5.2 Inspect all components before use.
- 5.3 The French size specialized represents the inner diameter of the introducer sheath.
- 5.4 Do not attempt to insert a catheter having a distal tip or body size larger than the introducer size indicated.
- 5.5 Do not attempt to use a guidewire larger than the maximum diameter specified on the package label
- 5.6 Do not use if the package or items in the kit appear to be damaged or defective.
- 5.7 Only those physicians who are trained in transseptal procedures and catheter delivery systems should use the device and they should read the instructions carefully
- 5.8 Do not put the sterilized package in a place that is damageable, wet, otherwise infection or inflammation may be caused
- 5.9 Dispose the device properly after use, otherwise infection may be caused
- 5.10 For Single Use Only! Do not reuse or re-sterilize it. reusing may cause infection, inflammation, device damaging.

6 PRECAUTIONS

- 6.1 Carefully reading the instructions before use of this device will help to reduce the potential risks and complications
- 6.2 Use X-ray exposure during the procedure to confirm the location
- 6.3 Continuously monitoring the patient's vital signs during the procedure
- 6.4 The device is applicable to venous only.
- 6.5 Inspect all components before use to make sure they could be used

- effectively
- 6.6 Prior to inserting the device into patient, flush the introducer with heparinized saline and re-sample the introducer and dilator
 - 6.7 During insertion, keep the device straight in case the components damaged by resistance
 - 6.8 Do not create a vacuum in the introducer. Remove components and make catheter exchanges slowly.
 - 6.9 Aspirate blood prior to fluid infusion from the sideport
 - 6.10 Provide continuous liquid infusion, i.e. heparinized saline, while the introducer remains in the vessel
 - 6.11 Fibrin may accumulate in the tip or on the surface of steerable introducer during procedure. aspirate blood with three-way valve after withdrawing dilator or guidewire
 - 6.12 Prior to withdrawing steerable introducer, reinsert aspirate into introducer through guidewire, then withdraw them as a unit.

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

- 10.1 Conduct pulmonary arteriography in transseptal procedures to determine the size and position of the left atrium and interatrial septum
- 10.2 Prior to inserting the device, rotate collar to deflect the tip clockwise 180 and counterclockwise 90
- 10.3 Inject heparinized saline from the sideport of introducer to clean it thoroughly
- 10.4 Inject heparinized saline in the dilator to clean it thoroughly
- 10.5 Assemble dilator and sheath and insert the dilator into the handle of sheath
- 10.6 Re-inject heparinized saline through the sideport after dilator fully insert into the sheath to aspirate all air between the dilator and sheath.
- 10.7 Introduce a 0.032 guidewire into the superior vena cava and confirm location through fluoroscopy
- 10.8 Introduce the unit into the superior vena cava and confirm location through fluoroscopy
- 10.9 Separate dilator and sheath and introduce the sheath for 1cm slowly
- 10.10 Withdraw the guidewire
- 10.11 Permit aspirating blood to clear all the air in dilator. Clean if necessary.
- 10.12 Follow the manufacturer's instructions when introduce guidewire or device through sheath
- 10.13 Prior to removing the steerable introducer, reinsert the guidewire through the introducer
- 10.14 Reintroduce the dilator over the guidewire, straighten the steerable introducer, then remove the dilator, guidewire, and introducer as a unit

11 POTENTIAL COMPLICATIONS

Lots of serious side effects may be caused during cardiac catheter operation including pulmonary embolism, myocardial infarction, stroke, cardiac tamponade and death.

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 Deflection and Radiopaque

The handle of Steerable Intracardiac Catheter Introducer is equipped with the rotation collar, turn the collar in clockwise, the tip can be steered from 0 to 180 degree(s), while turn the collar in counterclockwise, the tip can be steered from 0 to 90 degree(s). The steerable introducer features distal vent holes to facilitate aspiration and minimize cavitation and radiopaque to improve fluoroscopic visualization.

12.2 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.

12.3 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 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)

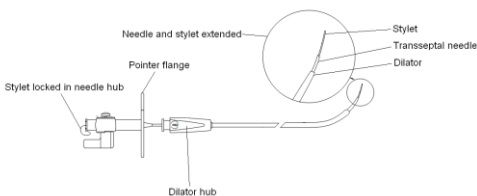


Fig.1

- 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.)

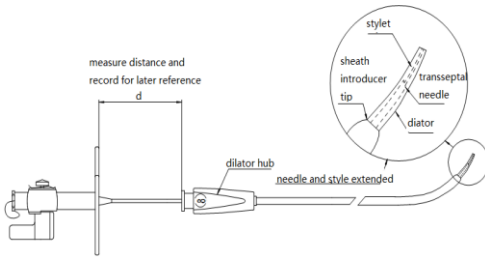


Fig.2

- 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.)

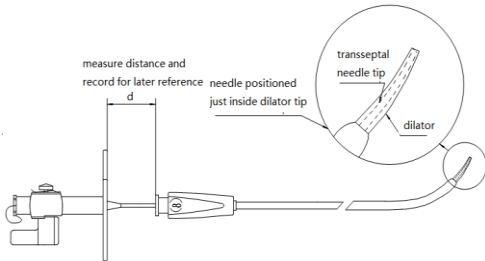


Fig.3

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 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. This will facilitate passage of the transseptal needle curve through the rigid hubs of the dilator and sheath introducer.
- 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 that 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 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 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.)

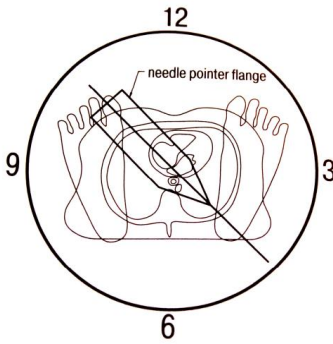


Fig. 5

- Also, 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.)

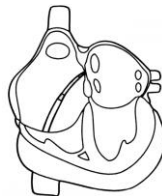
Note: If the fossa ovalis is probe patent, the dilator tip will now move into the left atrium with ease.



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.

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

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13 SYMBOL DEFINITION



DO NOT RE-USE



BATCH CODE



DATE OF

MANUFACTURE



USE-BY DATE



STERILIZED USING
ETHYLENE OXIDE



CATALOGUE NUMBER



MANUFACTURER



KEEP AWAY
FROM SUNLIGHT



DO NOT
RESTERILIZE



DO NOT USE IF PACKAGE IS DAMAGED



AUTHORISED REPRESENTATIVE
IN THE EUROPEAN COMMUNITY



CONSULT INSTRUCTIONS
FOR USE



KEEP DRY



TEMPERATURE LIMIT

SYNAPTIC MEDICAL LIMITED

100, 6th Kechuang Street,
Economic and Technological Development Area,
Beijing, P.R.China 100176
www.synapticmed.com

EUROPEAN AUTHORIZED REPRESENTATIVE

Wellkang Ltd t/a Wellkang Tech Consulting
Suite B, 29 Harley Street, London W1G 9QR England, United Kingdom