MicroPort™
Electrophysiology

PathBuilder™

Transseptal Needle

Instructions for Use

(Prior to use, read the instructions carefully, particularly with attention to various warnings and precautions.)

Shanghai MicroPort EP MedTech Co., Ltd.

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CE 0123

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【WARNING】

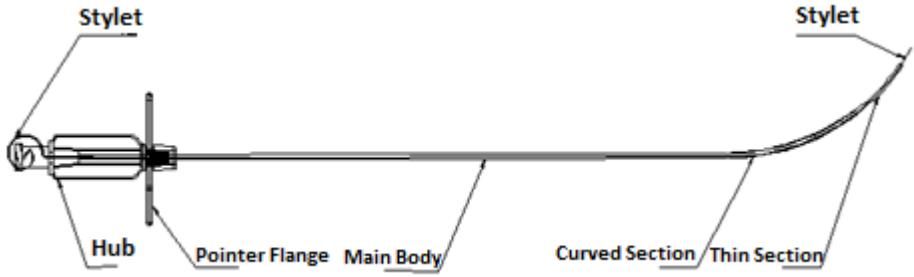
- Do not reuse this device. The biological materials and foreign bodies attached cannot be removed thoroughly after use, so any reuse of this product may lead to adverse effect of patients.
- The "Use By" date on the device package and the sterile packaging should be inspected prior to use. Do not use the device if past the "Use By" date or the packaging appears damaged.
- Do not alter this device in any way.
- Do not use excessive force to advance or withdraw the device when resistance is encountered.
- Procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and physician due to the x-ray beam intensity and duration of the fluoroscopic imaging. Procedures should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps taken to minimize this exposure.
- When used, device shall be disposed of as medical waste according local laws and regulations.
- Only those physicians who are trained in transseptal procedures and catheter delivery systems should use this device.
- If the patient with a history of heparin induced thrombocytopenia (HIT), bivalirudin is a preferred alternative to heparin for anticoagulation during procedures.

【PACKING LIST】

- A transseptal needle
- An instructions for use

【OVERVIEW】

Pathbuilder™ Transseptal Needle manufactured by Shanghai MicroPort EP MedTech Co., Ltd. is indicated for atrial septal puncture when accessing from femoral vein and to build a pathway from the right atrium to the left atrium together with the transseptal guiding introducer. The product structure diagram is as shown below:



Pathbuilder™ Transseptal Needle is consisted of thin section, curved section, main body, pointer flange, hub and stylet. The pointer flange indicates the curve orientation of the Pathbuilder™ Transseptal Needle. The thin section of the Pathbuilder™ Transseptal Needle fits well with that of the dilator which fixes the maximum length of the needle into the dilator.

【PRODUCT SPECIFICATION】

Pathbuilder™ Transseptal Needle can be classified into different specifications based on curve shape, diameter as well as length.

Pathbuilder™ Transseptal Needle has two specifications of 18Ga(1.21mm) and 19Ga(1.10mm) according to its diameter. The Pathbuilder™ Transseptal Needle of 18Ga(1.21mm) has two curve shapes of M and L, the effective length of the M curved type includes three specifications: 710mm, 890mm and 980mm, the effective length of the L curved type includes three specifications: 710mm, 890mm and 980mm; the Pathbuilder™ Transseptal Needle of 19Ga(1.10mm) has two curved types of S and M, the effective length of both is 560mm. Physicians can make choices based on actual needs.

Table 1: Specification of Pathbuilder™ Transseptal Needle

Model	Curve	Length (mm)	Diameter (Ga/mm)
TN S 56 19	S	560	19/1.10
TN M 56 19	M	560	19/1.10
TN M 71 18	M	710	18/1.21
TN M 89 18	M	890	18/1.21
TN M 98 18	M	980	18/1.21
TN L 71 18	L	710	18/1.21
TN L 98 18	L	980	18/1.21
TN L 89 18	L	890	18/1.21

【INDICATIONS FOR USE】

PathBuilder™ Transseptal Needle is indicated for building a pathway from femoral vein into left atrium through atrial septum puncture.

【INDICATIONS】

Atrial fibrillation

【CONTRAINDICATIONS】

1) Intra-atrial septal patch;
2) Atrial myxoma;
3) Myocardial infarction within the last two weeks;
4) Unstable angina;
5) Cerebral vascular accident (CVA) within the last two weeks;
6) Patients who do not tolerate anticoagulation therapy;
7) Patients with an active infection;
8) Left atrial thrombus which is presence after more than three weeks of anticoagulation

【TARGET GROUP】

18-75 years old adults, men or non-pregnant women

【ACCESSORIES REQUIRED FOR USING PRODUCT】

- Steerable introducer

PathBuilder™ Steerable Introducer	PathBuilder™ Transseptal Needle		
	Model	Diameter	Length
SIS7185	TNM9818 TNL9818	18Ga(1.21mm)	980mm
SIM7185			
SIL7185			
SIXL7185			
SIS6185	TNM8918 TNL8918	18Ga(1.10mm)	890mm
SIM6185			

- Transseptal guiding introducer

PathBuilder™ Transseptal Guiding Introducer	PathBuilder™ Transseptal Needle		
	Model	Diameter	Length
TS L0 63 8	TNM7118 TNL7118	18Ga (1.21mm)	710mm
TS L1 63 8		18Ga (1.21mm)	710mm
TS L2 63 8		18Ga (1.21mm)	710mm
TS L3 63 8		18Ga (1.21mm)	710mm
TS L4 63 8		18Ga (1.21mm)	710mm
TS L0 63 85		18Ga (1.21mm)	710mm
TS L1 63 85		18Ga (1.21mm)	710mm
TS L2 63 85		18Ga (1.21mm)	710mm
TS L3 63 85		18Ga (1.21mm)	710mm
TS L4 63 85		18Ga (1.21mm)	710mm
TS L0 81 8	TNM8918	18Ga (1.21mm)	890mm

TS L1 81 8	TNL8918	18Ga (1.21mm)	890mm
TS L2 81 8		18Ga (1.21mm)	890mm
TS L3 81 8		18Ga (1.21mm)	890mm
TS L4 81 8		18Ga (1.21mm)	890mm
TS L0 81 85		18Ga (1.21mm)	890mm
TS L1 81 85		18Ga (1.21mm)	890mm
TS L2 81 85		18Ga (1.21mm)	890mm
TS L3 81 85		18Ga (1.21mm)	890mm
TS L4 81 85		18Ga (1.21mm)	890mm
TS R0 63 8	TNM7118 TNL7118	18Ga (1.21mm)	710mm
TS R1 63 8		18Ga (1.21mm)	710mm
TS R2 63 8		18Ga (1.21mm)	710mm
TS R3 63 8		18Ga (1.21mm)	710mm
TS R4 63 8		18Ga (1.21mm)	710mm
TS R0 63 85		18Ga (1.21mm)	710mm
TS R1 63 85		18Ga (1.21mm)	710mm
TS R2 63 85		18Ga (1.21mm)	710mm
TS R3 63 85		18Ga (1.21mm)	710mm
TS R4 63 85		18Ga (1.21mm)	710mm
TS R0 81 8	TNM8918 TNL8918	18Ga (1.21mm)	890mm
TS R1 81 8		18Ga (1.21mm)	890mm
TS R2 81 8		18Ga (1.21mm)	890mm
TS R3 81 8		18Ga (1.21mm)	890mm
TS R4 81 8		18Ga (1.21mm)	890mm
TS R0 81 85		18Ga (1.21mm)	890mm
TS R1 81 85		18Ga (1.21mm)	890mm
TS R2 81 85		18Ga (1.21mm)	890mm
TS R3 81 85		18Ga (1.21mm)	890mm

TS R4 81 85		18Ga (1.21mm)	890mm

【RISKS AND SIDE EFFECTS】

Complications that may occur during use of this device include scratches of endocardium and vessel wall cause reactions like inflammation or abscess; toxic reaction; complications caused by vascular puncture (such as pseudoaneurysm, arteriovenous fistula, local hematoma, or ecchymosis and infection); radiation injury; thrombosis / air embolism; injury to coronary artery; serious coagulation reactions; pericardial tamponade; cardiac / artery perforation; pericardial effusion; cerebral embolism / cerebral apoplexy / stroke; thoracotomy to remove foreign body.

【DIRECTIONS FOR USE】

1. Prepare and assemble equipment

Preparing the equipment requires the following items:

- One transseptal sheath and dilator,
- One matching transseptal needle and a stainless steel stylet,
- One 0.032”(0.81mm), 180cm guidewire with a 3mm”J”tip,
- Syringes for aspiration and flushing,
- Sterile heparinized saline

- Flush the transseptal sheath and dilator with sterile heparinized saline and insert the dilator fully into the sheath.
- Remove the stylet from the needle and flush the needle with sterile heparinized saline. Re-insert the stylet into the needle and lock it onto the hub.
- Insert the needle assembly into the sheath/dilator. Due to the stop feature of the dilator, there will be a gap between the dilator hub and the needle pointer flange. (See Fig.1. Magnification is 2.9).

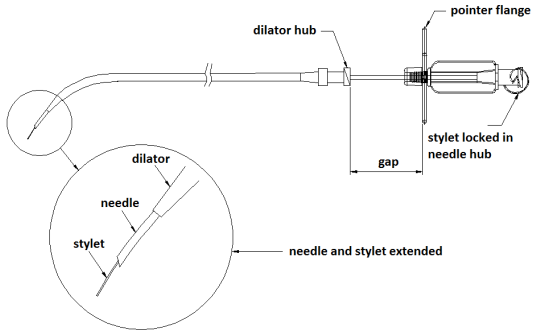


Fig. 1

- Withdraw the needle assembly until the tip of the stylet is just within the tip of the dilator.

2. Advance sheath/dilator assembly into superior vena cava.

- Introduce the prepared guidewire from femoral vein (right femoral preferred) to superior vena cava. Note: 0.032 inch(0.81mm) is the maximum guidewire diameter that can be used with the transseptal dilator.
- Insert the transseptal sheath/dilator assembly over the guidewire and advance the assembly into the superior vena cava.

3. Position the needle/stylet assembly inside the sheath/dilator assembly.

- Remove the guidewire from the dilator
- Aspirate and then flush the dilator with clean heparinized saline, ensuring that no air enters the bloodstream.
- Separate the sheath and dilator by withdrawing the dilator by a distance sufficient to accommodate the needle curve. This will facilitate passage of the needle curve through the dilator and sheath hubs.
- Insert the needle/stylet assembly into the dilator, letting it rotate freely as it advances.

- After the needle curve is advanced beyond the hemostasis valve hub of the sheath, reconnect the sheath and dilator by sliding the sheath back over the dilator slowly.(do not advance the dilator)
- Advance the needle/stylet assembly and confirm that the needle tip is inside the dilator by fluoroscopy.
- After removing the stylet, attach a syringe to the needle hub and aspirate until blood return is observed. Then discard the syringe.
- Fill the syringe and flush the needle with clean heparinized saline, ensuring that the syringe is attached to the needle hub and no air enters the bloodstream.

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 LAO.
- Adjust the needle pointer so that the needle is perpendicular to the fossa ovalis (typically between 3:00 and 5:00 o'clock, as viewed from the foot end of the patient). (See Fig.2. Magnification is 2.9).

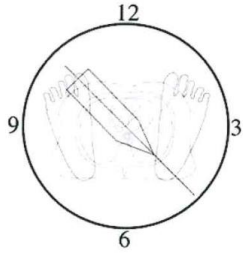


Fig. 2

- Confirm that the needle tip is inside the dilator by fluoroscopy. Then drag the entire assembly slowly. Prevent any movement of the assembly parts relative to each other. Maintain the previous orientation of the needle pointer.
- Observe the tip of the dilator during the drag for medial (or rightward) movement, indicating the tip has engaged the fossa ovalis.

5. Puncture the fossa ovalis

- Once the correct location is confirmed, advance the needle across the interatrial septum.
- Under pressure monitoring, entry into the left atrium is confirmed when the pressure tracing shows a left atrial pressure waveform.

If there is any resistance to needle advancement, 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/dilator assembly

- While maintaining a fixed needle position, advance the sheath/dilator assembly over the needle.

7. Advance the sheath over the fixed dilator and needle into the left atrium.

- Withdraw the needle into the dilator until it is just inside the tip. Maintain the position of the dilator across the septum.
- With the dilator in a fixed location, advance the sheath over the dilator.

8. Withdraw the needle and the dilator

- Disconnect any attachments to the needle hub
- Immediately aspirate blood through the side arm of the sheath after withdrawing the needle and dilator slowly at the same time. The blood should be arterial blood.
- Under pressure monitoring, the pressure tracing still shows a left atrial pressure waveform. The sheath is now in place in the left atrium.

9. Advance the catheter

- Insert electrode catheter into the sheath slowly and observe extension length of catheter by fluoroscopy.

10. Remove the sheath

- After removing the catheter, re-insert the guidewire over the sheath. Then re-insert the dilator over the guidewire and keep the sheath straight. At last remove the sheath, the dilator and the guidewire as a whole.

【STERILIZATION】

PathBuilder™ Transseptal Needle has been sterilized by epoxy ethane before delivery.

【STORAGE & TRANSPORTATION REQUIREMENTS】

The product shall be stored in a shady and cool, dry, clean, and well-ventilated warehouse which is in natural air circulation environment. The temperature during storage shall be kept between 18℃ and 28℃.
In transit, the product shall be protected from heavy load, direct sunlight and rain or as specified in the ordering contract.

【MANUFACTURING DATA】

See label statement for service life.

【PERIOD OF VALIDITY】

The sterilization period of validity is three years under specified storage conditions.

【SYMBOLS DESCRIPTION】

1.		DO NOT REUSE
2.		CONSULT INSTRUCTIONS FOR USE
3.		PROTECT FROM HEAT SOURCE AND RADIATION SOURCE
4.		KEEP DRY
5.		USE BY
6.		BATCH CODE
7.		CATALOGUE NUMBER
8.		STERILIZED USING ETHYLENE OXIDE
9.		NO NOT USE IF PACKAGE IS DAMAGED
10.		QUANTITY OF PRODUCT CONTAINED 1
11.		DATE OF MANUFACTURE
12.		MANUFACTURER
13.		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
14.		TEMPERATURE LIMITATION

【AFTER-SALES SERVICE】

With “providing the medical sector with high quality and efficacy medical products” as its top operational objective, Shanghai MicroPort EP MedTech Co., Ltd. (hereinafter referred to as MicroPort EP) guarantees that its products are free of defects in materials or manufacturing when the clients receive them. For other questions relating to the products, please directly consult the company.

【SOLEMN STATEMENT】

The potential adverse event listed in the user manual, collected by Shanghai MicroPort EP MedTech Co., Ltd. (MicroPort EP), is based on the information, data from clinical trials and markets of China and other countries or regions instead of real condition occurred. The potential adverse event is taken as the product features sufficiently warned and explained instead of the defects or potential risks. Subject to the current scientific level and knowledge of MicroPort EP, the product may have some undetected or unknown potential risks and that cannot be considered defects or faults of the product.

MicroPort EP will not responsible for any medical cost or direct and indirect loss caused by the improper usage (including reuse), improper model choice, maloperation or other accident caused by human, illegal purchase, risks cannot be detected by current technology or potential adverse event or risks listed in this user manual, regardless of any guarantee, contract, tort or other regulations the claim is based on.

【MANUFACTURER】

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