Cathlink™ Electrode Lead Introducer Sheath Set
Instruction for Use

Kossel Medtech (Suzhou) Co., Ltd.

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Caution: Please read all instructions carefully before use. Failure to follow the warnings and precautions may result in complications.

Product Name

Cathlink^{TM} Electrode Lead Introducer Sheath Set

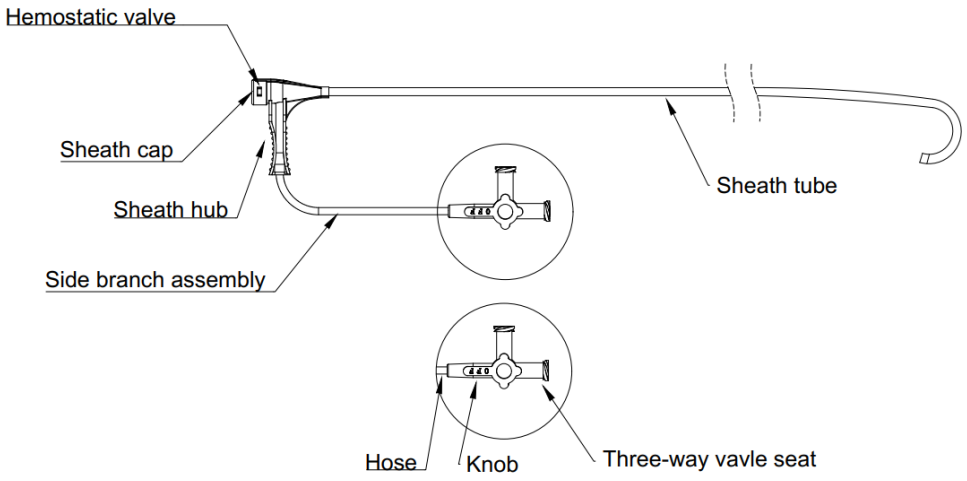
Product Structure and Model Specifications

Product Structure

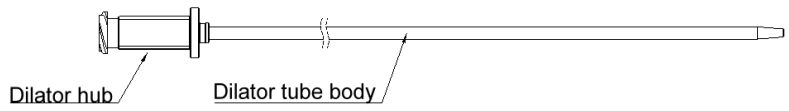
The electrode lead introducer sheath set consists of an introducer sheath, a dilator, and a fixing tool. The introducer sheath is composed of a sheath tube, a sheath cap, a sheath hub, a hemostatic valve, and a side branch assembly. The sheath tube is made up of inner layer, outer layer, and metallic intermediate layer. The dilator consists of a dilator tube body and a dilator hub. The side branch assembly comprises a three-way valve seat, a knob, and a hose. The introducer sheath and dilator in this product are non-hydrophilic. The specific structural diagram is shown in Fig. 1.

The specification of the introducer sheath is 2.4mm (7.2F), the inner diameter is 2.4 mm, and the outer diameter is 2.9 mm. It includes four nominal lengths, 32cm, 34cm, 39cm, 43cm, and seven curved shapes marked as S, M, L, B, C, D, and E. The diagram of the curved shapes is shown in Fig. 2.

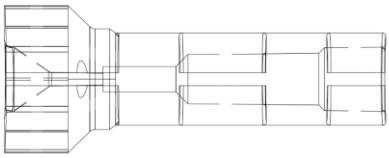
The dilator has a specification of 2.3mm (6.9F), with an outer diameter of 2.3 mm and an inner diameter of 1.3 mm. The effective lengths available are: 39.5cm, 41.5cm, 46.5cm, and 52.5cm. All dilators of the above specifications are straight type.



Introducer Sheath



Dilator



Fixing tool

Fig. 1 Electrode Lead Introducer Sheath Set Structure Diagram

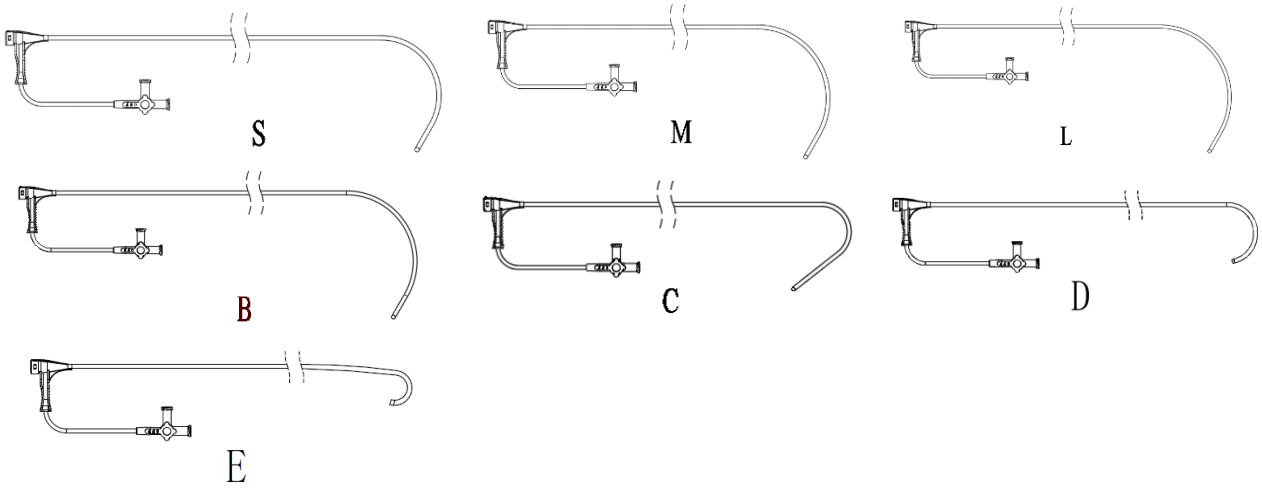


Fig. 2 Introducer Sheath Curved Shapes Diagram

Product Model Specification

The electrode lead introducer sheath set is available in 17 specifications as shown in the Table 1.

Intended Purpose

The Cathlink™ Electrode Lead Introducer Sheath Set consists of an introducer sheath, a dilator, and a fixing tool, which is used to facilitate the delivery of transvenous leads to their cardiac target sites.

Indications for Use

The Cathlink™ Electrode Lead Introducer Sheath Set is indicated for use in the right atrium and right ventricle. Introducer sheaths are also designed to facilitate the implantation of leads in or near the conduction system (e.g., His bundle or left bundle branch area).

Intended Patient Population

Patients with bradyarrhythmia who have indications for cardiac pacemaker implantation and require ventricular lead placement.

Contraindications

- The patient's ventricular anatomical structure is not suitable.
- The patient has an active systemic infection.
- Patients with mechanical tricuspid valve or severe tricuspid valve disease (ventricular implantation of electrode leads).

Precautions

- The product is sterilized by ethylene oxide, and is sterile and non-pyrogenic for single use only.
- Do not allow the product to come into contact with any liquids other than blood, saline, or control solutions.
- During the surgical procedure, care should be taken to ensure that the hemostatic valve is not damaged and the side branch assembly remains closed, so as to reduce the possibility of air entry or bleeding.
- When removing the introducer sheath, it is recommended to use a special cutting knife designed for introducer sheath removal.

Warning

- The product must be used only by physicians with experience in cardiovascular surgery.
- Do not use if the sterile barrier package is damaged.
- Do not use the product if it has expired.
- Do not push, pull, or rotate the introducer sheath with excessive force. If there is resistance or intermittent advancement, the cause of the resistance should be immediately identified, and appropriate measures should be taken before proceeding further.
- The product is for single use only. After use, it must be disposed of as medical waste and must not be reused, reprocessed, or resterilized.

Potential Complications

- Air embolism
- Allergic reaction to contrast medium
- Arteriovenous fistula formation
- Bleeding at the insertion site
- Brachial plexus injury
- Cardiac tamponade
- Hemothorax
- Infection
- Cardiac arrhythmia
- Mediastinal widening
- Perforation
- Pneumothorax

- Displacement
- Incision
- Endocarditis
- Conduction block
- Hematoma formation
- Subclavian artery puncture
- Thrombophlebitis
- Valve damage
- Vascular occlusion
- Vascular injury

Procedure Steps for Electrode Lead Introducer Sheath Set

Device Preparation

1. Open the sterile barrier package in the sterile field and remove the product from the package.

2. Flush the introducer sheath with sterile normal saline through the side branch port on the sheath hub.

3. Insert the dilator into the introducer sheath.

4. Flush the dilator with sterile normal saline through the dilator hub.

Recommended Procedure Steps

1. Obtain and confirm venous access.

2. Under X-ray guidance, advance the introducer sheath and dilator to the desired position in the cardiac chamber under the guidance of a guidewire (≤0.035 inch).

3. Remove the dilator and guidewire.

4. Under X-ray guidance, advance the electrode lead through the introducer sheath to the desired position. Before inserting the electrode lead, ensure that the outer diameter of the electrode lead is smaller than the inner diameter of the introducer sheath.

5. Secure the fixing tool to the tail of the electrode lead, and rotate the electrode lead to fix the tip of the electrode lead at the desired position on the myocardial wall.

6. Once the electrode lead is positioned at the desired location, the introducer sheath can be cut using a special cutting knife to complete sheath withdrawal. During cutting, hold the electrode lead and the cutting knife together with one hand, and retract the introducer sheath toward the cutting knife to cut the sheath hub with the other hand. Continue to slowly withdraw the introducer sheath from the blood vessel, aligning it with the cutting knife until the entire introducer sheath is cut and removed.

Shelf Life

The shelf life of the electrode lead introducer sheath set is three years. The expiration date is indicated on the label of the electrode lead introducer sheath set; expired products must not be used.

Storage Conditions

1. Store in a room temperature, dry, and well-ventilated environment.
2. Do not sterilize by other high-temperature and high-pressure methods or re-sterilize.
3. Do not contact organic solvents.
4. If there is any question about the product before use, contact the agent or manufacturer directly.
5. To avoid environmental contamination, dispose of it properly.

Transportation Conditions

1. The product shall be transported at room temperature and protected from light.
2. During transportation, the product must not be squeezed, wetted, or exposed to direct sunlight. Handle with care during loading.

Clinical Benefits

The Cathlink™ Electrode Lead Introducer Sheath Set is indicated for use in cardiac electrode lead placement procedures to establish a stable delivery pathway for devices. The Kossel claims that the Cathlink™ Electrode Lead Introducer Sheath Set has direct clinical benefits:

1. Effectively reducing the risk of intraoperative vascular injury and improving procedural convenience.
2. Ensuring accurate electrode lead placement and reducing the risk of postoperative adverse complications.

Graphical Symbols for Medical Device Labeling

 Manufacturer

 Batch code

 Catalogue number

 Consult instructions for use or consult electronic instructions for use

 Keep away from sunlight

 Keep dry

 Date of manufacture



Sterilized using ethylene oxide


Do not re-use


Do not use if package is damaged and consult instructions for use


Do not resterilize


Use-by date


Single sterile barrier system with protective packaging inside


Single sterile barrier system with protective packaging outside

Production Date: See Labels

Valid period: See Labels


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Table 1. Basic Dimension Parameter Table of Electrode Lead Introducer Sheath Set

Serial No.	Specification	Introducer Sheath				Dilator			Fixing Tool		
		Inner Diameter /mm	Outer Diameter /mm	Length /cm	Curved Shape	Inner Diameter /mm	Outer Diameter /mm	Length /cm	Inner Diameter /mm	Outer Diameter /mm	Length /mm
1	KVH32S	2.4	2.9	32	S	1.0	2.3	39.5	3.1	5.8	24
2	KVH39S	2.4	2.9	39	S	1.0	2.3	46.5	3.1	5.8	24
3	KVH43S	2.4	2.9	43	S	1.0	2.3	52.5	3.1	5.8	24
4	KVH32M	2.4	2.9	32	M	1.0	2.3	39.5	3.1	5.8	24
5	KVH39M	2.4	2.9	39	M	1.0	2.3	46.5	3.1	5.8	24
6	KVH43M	2.4	2.9	43	M	1.0	2.3	52.5	3.1	5.8	24
7	KVH32L	2.4	2.9	32	L	1.0	2.3	39.5	3.1	5.8	24
8	KVH39L	2.4	2.9	39	L	1.0	2.3	46.5	3.1	5.8	24
9	KVH43L	2.4	2.9	43	L	1.0	2.3	52.5	3.1	5.8	24
10	KH39B	2.4	2.9	39	B	1.0	2.3	46.5	3.1	5.8	24
11	KH43B	2.4	2.9	43	B	1.0	2.3	52.5	3.1	5.8	24
12	KH39C	2.4	2.9	39	C	1.0	2.3	46.5	3.1	5.8	24
13	KH43C	2.4	2.9	43	C	1.0	2.3	52.5	3.1	5.8	24
14	KA34D	2.4	2.9	34	D	1.0	2.3	41.5	3.1	5.8	24
15	KA39D	2.4	2.9	39	D	1.0	2.3	46.5	3.1	5.8	24
16	KA34E	2.4	2.9	34	E	1.0	2.3	41.5	3.1	5.8	24
17	KA39E	2.4	2.9	39	E	1.0	2.3	46.5	3.1	5.8	24