EverPace™

EasyLoop™

Circular Mapping Catheter

Instructions for Use

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

Shanghai MicroPort EP MedTech Co., Ltd.

CE 0123

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【CATHETER DESCRIPTION】

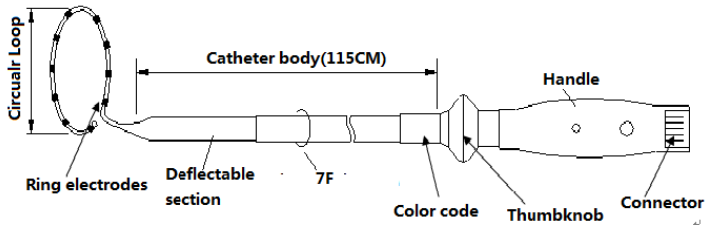


Fig. 1: The appearance of EasyLoop™ Circular Mapping Catheter

The EasyLoop™ circular mapping catheter (EasyLoop for short) is a diagnostic catheter which is designed for cardiac electrophysiological mapping.

It is mainly composed of a circular loop, a deflectable section, the main body and control handle.

Ten electrodes equally spaced on the distal tip of circular loop are used to obtain the intracadiac electrograms. All electrodes can be used for the purposes of cardiac electrophysiological mapping and stimulation. There are 4 specifications with different loop diameters of 12mm, 15mm, 20mm, and 25mm.

The deflectable section is controlled by the thumbknob on the handle. By pushing forward on the catheter thumbknob, the tip is deflected; when the thumbknob is pulled back, the catheter tip straightens. The EasyLoop has only one shape of curve, a “P” shape, which is represented by the color code at the end of the catheter body.

At the end of the handle, a connector for a connecting cable is provided. Through this cable, the EasyLoop can interface with external equipment.

During the procedure, the EasyLoop is deployed in the right or left atrium through an 8F guiding sheath then the curve is adjusted by manipulating on of the thumbknob, and the circular loop is delivered to the peristome of the pulmonary vein. Rotate the catheter clockwise

and place the circular into the pulmonary vein peristome. The catheter and the recording equipment are connected by a connecting cable. The electrodes on the loop can collect voltage signals and also display them on multi-channel recording equipment, and by the means the mapping function is achieved.

【PRODUCT SPECIFICATION】

There is a fixed diameter loop at the end of the deflectable part of EasyLoop. Curve type is labeled with code and color band. There is only P curve type for EasyLoop, and it is labeled with black band near the handle. The EasyLoop has 4 specifications in accordance with its different loop diameters. Doctors can choose suitable one according to patients' data.

Table 1: Specification for EasyLoop™ Circular Mapping Catheter

Order Code	Curve/Color	Length	French	Loop Diameter	Ref. Pulmonary Vein Size
EPQ7P012	P/Black	115 cm	7F≈2.33mm	12 mm	8~12mm
EPQ7P015				15 mm	10~15mm
EPQ7P020				20 mm	12~20mm
EPQ7P025				25 mm	16~25mm

【INTENDED USE】

The EasyLoop catheter is indicated for electrophysiological mapping the cardiac structures of the heart, for recording or stimulation. The catheter is designed to obtain electrograms in the atrial region of the heart.

【INDICATIONS】

"Paroxysmal Atrial fibrillation" and "Persistent Atrial fibrillation"

【CONTRAINDICATIONS】

- Structural heart diseases(including congenital heart disease, rheumatic heart disease, hypertensive heart disease and pulmonary heart disease);
- Patients with advanced heart failure (NYHA Functional Class III–IV);
- Acute heart failure;

- Patients with obvious bleeding liability and hematologic disorder;
- Active system infection;
- Pregnant or lactating;
- For patients with left atrium thrombus (LATH), mucous tumor or interatrial septum or patch, septum perforation is not advised;
- Use in child;
- Unstable angina and acute myocardial infarction within three months;
- Stroke and transient ischemic attack within the last two weeks;
- Patients with intracardiac mural thrombus or subjected to ventriculotomy or atriotomy in the past 4 weeks.

【TARGET GROUP】

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

【WARNINGS】

- The procedure for the cardiac catheterization produces the potential for significant X-ray exposure, which can result in acute radiation injury as well as increase the risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging;
- Cardiac catheterization should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure and steps are taken to minimize this exposure;
- Do not expose the catheter to organic solvents such as alcohol;
- Do not autoclave the catheter;
- Do not immerse the proximal handle or cable connector in fluids, electrical performance

could be affected;

- Do not introduce EasyLoop tip folded into the transseptal sheath;
- Do not use the EasyLoop in conjunction with transseptal sheaths featuring side holes larger than 1.25mm in diameter;
- When the catheter is connected to the supply mains-operated stimulator, inadvertently introducing leakage current may enter into the heart. Please use the internal power -operated simulator;
- Before handling the external pulse generator, the patient cable or indwelling leads, steps shall be taken to equalize the electrostatic potential between the user and the patient, for example by touching the patient at a site remote from the pacing lead.
- The catheter shall be connected to the non-implantable pulse generator before the pacing leads are connected to the catheter.
- When handling indwelling leads, the terminal pins or exposed metal are not to be touched nor be allowed to contact electrically conductive or wet surfaces.
- This device is packaged for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness or death. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

【PRECAUTIONS】

- Do not attempt to operate the EasyLoop prior to completely reading and understanding the Instructions for Use;

- Cardiac catheterization procedures should be performed by appropriately trained personnel in a fully equipped electrophysiology laboratory;
- Careful manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement and placement should be done under fluoroscopic guidance through a guiding sheath. Do not use excessive force to advance or withdraw the catheter through the guiding sheath when resistance is encountered. In addition, extra care should be taken while inserting, aspirating and manipulating the guiding sheath;
- The sterile packaging of the catheter should be inspected prior to use;
- The EasyLoop Circular Mapping Catheter is intended for single use only;
- Do not resterilize and reuses;
- Always pull the thumbknob of the catheter back before insertion or withdrawal to assure that the catheter tip assumes its original shape;
- To place EasyLoop, torque (or rotate) shaft clockwise only;
- The Microport EP EasyLoop Circular Mapping Catheter has not been shown to be safe and effective for radio frequency (RF) ablation;
- The catheter may not be appropriate for patients with artificial valve, whereas it can be used for patients with aortic heart valve if no retrograde approach through aortic heart valve is performed. A relative contraindication for cardiac catheter procedures is active systemic infection;
- The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle or patch;
- The retrograde approach is contraindicated because of risk of entrapping the EasyLoop™ in the left ventricle or valvular apparatus. The EasyLoop™ is not recommended for use in the ventricles;

- When used, catheter shall be disposed of as medical waste according local laws and regulations.
- Do not use near MRI equipment since movement or heating of the catheter may occur and the image on the display may become distorted.

【ADVERSE REACTIONS】

Pulmonary embolism, myocardial infarction, stroke, cardiac tamponade, death, vascular bleeding, local hematomas, thrombosis, AV fistula, pseudoaneurysm, thromboembolism, vasovagal reactions, cardiac perforation, air embolism, arrhythmias, valvular damage, pneumothorax and hemothorax, pulmonary edema, hypoxia, pleural effusion, ARDS, pacemaker/ICD malfunction, pulmonary vein stenosis, electrical shock, open-heart surgery, infection, bacterial myoendocarditis

【DEVICES USED IN COMBINATION】

- Transseptal sheath matching the catheter, 8F or above;
- Cable for mapping catheter;
- Electrophysiological (EP) recording equipment, such as Columbus™ 3D EP Navigation System.

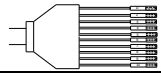
【CABLE SELECTION】

Cable is used for connecting the EasyLoop to external recording or stimulating device. The connector on one end of the cable is suitable for the EasyLoop and the pins on the other end of the cable are suitable for recording device. Cable C0G 010 is designed and manufactured by MicroPort EP for connecting EasyLoop.

There are numbers, such as D、2、3, on the connector pin. The number is corresponding to the electrode, and the electrode serial number begins from the distal end.

Table 2: Specification of connection cable

Order Code	Parameters	
	Pin number	Connector

		(for recording equipment)
C0G 010	10	

【SUGGESTED INSTRUCTIONS FOR USE】

1) Estimate the size at peristome of pulmonary vein, choose suitable circular diameter type according to the introduce range;
2) Follow standard practice for vessel punctureand built an access from thigh vena to left atria;
3) Remove the catheter from its package carefully and place it in a sterile work area;
4) Confirm that the thumbknob is pulled back completely, that is to say the deflectable part is straight. Then from the circular tip end, insert the catheter into the guiding sheath;
5) Advance the catheter through guiding sheath under the fluoroscopy guidance slowly, until the circular comes out;
6) Adjust the radius of curvature by manipulating the thumbknob, and delivered the circular near to the peristome of pulmonary vein. Rotate the cathete clockwise and place the circular into the pulmonary vein peristome;
7) Connect the catheter and the recording equipment together by an introducing cable;
8) If the IECG signals are not clear, adjust the circular's position slightly;
9) When the operation is finished, confirm that the thumbknob has been pulled back completely, and then remove the catheter through the guiding sheath. Dispose of the catheter according to the local law or regulations;
10) Don't rotate the catheter counter-clockwise when the circular is near or at the pulmonary vein opening;
11) If there are any questions regarding the use or performance of this product, please consult with the local distributor or the manufacturer.

【TRANSPORTATION REQUIREMENTS】

In transit, the product shall be protected from heavy load, direct sunlight and rain or as specified in the ordering contract. The temperature during transportation shall be kept between 0℃ and 45℃.

【STORAGE 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 0℃ and 45℃.

【SHELF LIFE】

The shelf life of product is three years while it meets the conditions for storage.

【STERILIZATION】

This product has been sterilized with ethylene oxide gas. Never re-sterilize and reuse it. Do not use the catheter if the package is open or damaged. Use the catheter prior to the expiration date shown on the package label.

【SYMBOLS EXPLANATION】

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.		**DO NOT USE IF PACKAGE IS DAMAGED**
10.		**QUANTITY OF PRODUCT CONTAINED 1**

11.		**TEMPERATURE LIMITATION**
12.		**TYPE CF APPLIED PART**
13		**DATE OF MANUFACTURE**
14		**MANUFACTURER**
15		**AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY**

【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 Co.) 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】

Shanghai MicroPort EP MedTech Co., Ltd. expressly states herein that its **EasyLoop™ Circular Mapping Catheter** is disposable and cannot be reused. MicroPort EP Co. will not recommend, indicate and imply in any manner the reusability of the system, and will not assume the responsibility for any accident or product damage resulting from reuse.

EasyLoop™ Circular Mapping Catheter can be connected and used only with the compatible devices specified herein, and MicroPort EP Co. will not assume the responsibility for damage to product device, procedure failure and the like resulting from operating mistakes or any other human factors.

【MANUFACTURER】

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