EverPace™

EasyLoop™

3D Circular Mapping Catheter

Instructions for Use

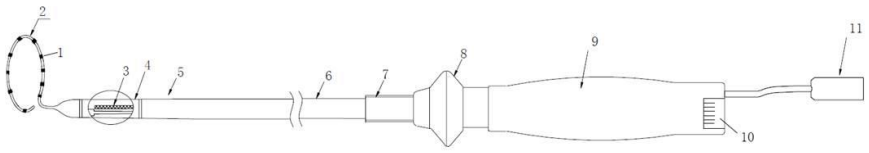
(Prior to use, read the instructions carefully, particularly with attention to various warnings and precautions.)

Shanghai MicroPort EP MedTech Co., Ltd.

EasyLoop™ 3D Circular Mapping Catheter

Shanghai MicroPort EP MedTech Co., Ltd.

【CATHETER DESCRIPTION】



1-Ring electrodes; 2-Circular loop section; 3-Sensor; 4-Sensor section; 5-Deflectbale section; 6-Main body section; 7-Color code; 8-Thumbknob; 9-Handle; 10-Connector for 3D catheter cable; 11-Connector for mapping catheter cable

Fig. 1: The appearance of EasyLoop™ 3D Circular Mapping Catheter

The EasyLoop™ 3D circular mapping catheter 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. 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 3D has only one shape of curve, a "P" shape, which is represented by the color code at the end of the catheter body.
When used with a 3D cardiac electrophysiological mapping system, EasyLoop™ 3D circular mapping catheter can detect the location of the circular loop and the distal end of the deflectable section via a magnetic location sensor embedded in the catheter.
At the end of the handle, a connector for a connecting cable is provided. Through this cable, the EasyLoop 3D can interface with external equipment.
During the procedure, the EasyLoop 3D 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 3D. Curve type is labeled with code and color band. There is only P curve type for EasyLoop 3D, and it is labeled with black band near the handle. The EasyLoop 3D has 4 specifications in accordance with its different loop diameters. Doctors can choose suitable one according to patients' data.

Table 1: Specification for EasyLoop™ 3D Circular Mapping Catheter

Model	Curve/Color	Length	French	Loop Diameter	Ref. Pulmonary Vein Size
EPQN7P012	P/Black	115 cm	7F	12 mm	8~12mm
EPQN7P015				15 mm	10~15mm
EPQN7P020				20 mm	12~20mm
EPQN7P025				25 mm	16~25mm

【INTENDED USE】

EasyLoop™ 3D Circular Mapping Catheter is indicated for electrophysiological mapping of the cardiac structures of the heart. This catheter is designed to obtain electrograms in the atrial region of the heart. EasyLoopTM 3D Circular Mapping Catheter provides location information when used with a compatible 3D EP navigation system.

【INDICATIONS】

Atrial fibrillation

【CONTRAINDICATIONS】

- Structural heart disease (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;
- For patients with left atrium thrombus (LATH), mucous tumor or interatrial septum or patch, septum perforation is not advised;
- Unstable angina and acute myocardial infarction within three months;
- 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 3D tip folded into the transseptal sheath;
- Do not use the EasyLoop 3D in conjunction with transseptal sheaths featuring side holes larger than 1.25mm in diameter;
- 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.
- The catheter only can be used by physician in the catheter lab of the hospital.

【EMC Information & Technical Description】

EasyLoop™ 3D Circular Mapping Catheter requires special precautions in electromagnetic compatibility (EMC), and must be installed and used in accordance with the EMC information provided in this Description. Portable and mobile RF communication devices will affect the operations of EasyLoop™ 3D Circular Mapping Catheter.

Warning: Using unprescribed accessories, converters or cables other than the converters and cables which are approved as internal replacement parts by EasyLoop™ 3D Circular Mapping Catheter's manufacturer, may lead to increased radiation or decreased anti-interference ability of the diagnostic catheter.

Warning: EasyLoop™ 3D Circular Mapping Catheter should not be placed close to other equipment or be stacked. If the conditions above are not satisfied, you should observe and verify that it works normally with its working configuration.

Electromagnetic radiation

EasyLoop™ 3D Circular Mapping Catheter is intended for use in the following specified electromagnetic environment. The customer or user should ensure that it works in such an environment.

Radiation test	Compliance	Electromagnetic environment guidance
Radiated emission CISPR 11: 2016	Group 1 Class A	EasyLoop™ 3D Circular Mapping Catheter its RF energy only for the internal functions in standby tests. Therefore, its RF emission is very low with a very small chance of interference from the nearby electronic equipment.
Conducted emission CISPR 11: 2016	Not applicable	
Radiated emission CISPR 11: 2016	Group 1 Class A	EasyLoop™ 3D Circular Mapping Catheter is used in non-domestic equipment and facilities that are not directly connected to low-voltage public power grid in home dwellings.
Voltage fluctuation / Scintillation emission IEC 61000-3-3:2017	Not applicable	
Harmonic radiation IEC 61000-3-2:2018	Not applicable	

Electromagnetic anti-interference

EasyLoop™ 3D Circular Mapping Catheter is intended for use in the following specified electromagnetic environment. The customer or user should ensure that it works in such an environment.

Anti-interference test	Test level	Working level
Electrostatic discharge (ESD) IEC 60601-1-2:2014	±8kV contact discharge ± 15 kV air discharge	±8kV contact discharge ± 15 kV air discharge
EFT IEC 60601-1-2:2014	±1kv 100kHz repetition frequency	±1kv 100kHz repetition frequency
Surge IEC 60601-1-2:2014	Line-to-ground：±2kv	Line-to-ground：±2kv
Voltage drop IEC 60601-1-2:2014	0% U_T; 0.5 cycle： At 0°，45°，90°，135°，180°，225°，270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycle： Single phase： at 0°	0% U_T; 0.5 cycle： At 0°，45°，90°，135°，180°，225°，270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycle： Single phase： at 0°
Voltage Interruptions	0% U_T; 250/300 cycle	0% U_T; 250/300 cycle
Power frequency(50 Hz) Magnetic field IEC 60601-1-2:2014	30A/m	30A/m

Note: UT is the AC power supply voltage before applying the corresponding test level. Test EasyLoop™ 3D Circular Mapping Catheter in 100 and 230 VAC.

Electromagnetic anti-interference

EasyLoop™ 3D Circular Mapping Catheter is intended for use in the following specified electromagnetic environment. The customer or user of the deflectable curve mapping catheter should ensure that it works in such an environment.

Anti-interference Test	Test Level	Compliance Level	Electromagnetic environment Guidance
Conductive RF IEC 60601-1-2:2014	0.15MHz-80MHz	3 V	The portable and mobile RF communication devices shall not be used within a certain distance to any part of EasyLoop™ 3D Circular Mapping Catheter, including the cable and the recommended distance may be calculated by the equation applicable to the transmitter frequency.
	In ISM bands between 0.15MHz and 80MHz 80% AM at 1kHz	6V	
Radiation RF IEC 60601-1-2:2014	80-2.7GHz	3 V/m	

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL
385	280-390	TETRA 400	Pulse modulation [b] 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c] ± kHz deviation 1kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse Modulation [b] 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation [b] 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation [b] 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802, 11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation [b] 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802, 11 a/n	Pulse Modulation [b] 217 Hz	0.2	0.3	9

【PRECAUTIONS】

- Do not attempt to operate the EasyLoop 3D 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 3D 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 3D, torque (or rotate) shaft clockwise only;
- The Microport EP EasyLoop 3D 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 3D in the left ventricle or valvular apparatus. The EasyLoop™ 3D 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.

【DEVICES USED IN COMBINATION】

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

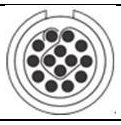
【CABLE SELECTION】

Cable is used for connecting the EasyLoop 3D to external recording device. The connector on one end of the cable is suitable for the EasyLoop 3D and the pins on the other end of the cable are suitable for recording device. Cable C0G 014 and EPS150C are designed and manufactured by MicroPort EP for connecting with catheter. The C0G 014 cable is the mapping catheter cable, and EPS 150C cable is the 3D catheter cable.

The C0G 014 cable should be connected with the connector for mapping catheter cable in the fig. 1, the EPS150C should be connected with the connector for 3D catheter cable in the fig. 1. The other end of these two cables should be connected with Columbus™ 3D EP Navigation System.

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

Type of cable	Model	Parameters	
		Pin number	Connector (for recording equipment)
Mapping catheter cable	C0G 014	14	
3D catheter cable	EPS150 C	14	

【SUGGESTED INSTRUCTIONS FOR USE】

1) Estimate the size at peristome of pulmonary vein, choose suitable circular diameter type according to the introduce range;
2) Remove the catheter from its package carefully and place it in a sterile work area;
3) Follow standard practice for vessel punctureand built an access from thigh vena to left atria;
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;
   Note: Don't rotate the catheter counter-clockwise when the circular is near or at the pulmonary vein opening;
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) The location information of the catheter will be displayed through the connected 3D EP Navigation System;
10) 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;
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.

【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 two 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™ 3D 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™ 3D 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】

Shanghai MicroPort EP MedTech Co., Ltd.
Address: Building 23&28, Lane 588, Tianxiong Rd., 201318 Shanghai, PEOPLE'S REPUBLIC OF CHINA
Postcode: 201318
Tel: +86 (21) 60969600
Fax: +86 (21) 20903925
E-mail: customerservice@ everpace.com
Website: www. everpace.com

【AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY】

MicroPort Medical B.V.
Address: Paasheuvelweg 25, 1105BP Amsterdam, The Netherlands

Contact person: HH Chang
E-mail: cs@microport-int.com
Tel: +31(0)205450100-8
Fax: +31(0)205450109

Manufacturer:

Shanghai MicroPort EP MedTech Co., Ltd.

Address: Building 23&28, Lane 588, Tianxiong Rd., 201318 Shanghai, PEOPLE'S REPUBLIC OF CHINA

Tel: +86 (21) 60969600 | Fax: +86 (21) 20903925

E-mail: customerservice@everpace.com

Website: www.everpace.com

A-C6C14-007, Rev.:A, Revision date : 2021-09