RithmID-SD

Steerable Diagnostic

Electrophysiology Catheter

Instructions for Use

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Caution: Federal law restricts this device to sale by or on the order of a physician.
STERILE: Sterilized with ethylene oxide gas. For single use only.
Do not use if the package is open or damaged.

1 DESCRIPTION

The RithmID-SD Steerable Diagnostic Electrophysiology Catheter is designed to facilitate electrophysiological mapping of the heart.

This catheter is available in a variety of curve shapes and electrode numbers. It contains an array of platinum electrodes at the distal tip that can be used for recording electrical signals.
The RithmID-SD Steerable Diagnostic Electrophysiology Catheter has several tip configurations. A piston in the handle is attached to an internal pull wire, which changes the radius of curvature. When the piston is pushed forward with the thumb knob, the radius of the curvature is reduced. When the thumb knob is pulled back, the radius of the curvature is increased until the tip section returns to its natural state. The high torque shaft allows the curve to be maneuvered so that the distal tip can be facilitated at the desired site accurately.

The catheter is intended to be used in combination with electrophysiology (EP) recording equipment. The catheter's proximal end is connected to the Redel 10 pin connector of the interface cable with the other end of the connector providing the corresponding 10 Shielded Tip Pins, which is compatible with most standard recording equipment. The catheter may be connected to a commercially available EP recording system using a connection cable with Redel connector in the pin configuration corresponding to this catheter. Such equipment systems must be "patient isolated," or have an isolated patient cable.

For the use of the recording equipment and interface cables, please refer to their Instructions for Use.

The catheter shaft and electrode tip are patient

applied parts. The applied parts are TYPE CF with respect to protection against electric shock. In order to maintain the electrical safety afforded by the catheter, it should only be connected to medical electrical equipment which complies with IEC60601-1 and/or ANSI/AAMI ES 60601-1.

2 INDICATIONS FOR USE

The RithmID-SD Steerable Diagnostic Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

3 CONTRAINDICATIONS

- Do not use the device in patients with prosthetic valves.
- Do not use the device in patients with active system infection.
- The device is contraindicated for via the transseptal approach in patients with left atrial thrombus or myxoma, or interatrial baffle or patch.
- The device is contraindicated for via the retrograde transaortic approach in patients with aortic valve replacement.
- The device is contraindicated for transcatheter ablation.
- Do not use the device in patients with a totally obstructed Coronary Sinus.
- This device is indicated only for adults.
- The catheter should not be used in patients unable to receive heparin or an acceptable alternative to achieve the adequate anticoagulation.

4 WARNINGS

- This device should be used by or under the supervision of physicians thoroughly trained in the techniques of transvenous electrophysiology studies.
- Cardiac catheterization 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 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 potential radiation exposure associated with the procedure, and steps taken to minimize this exposure. Careful consideration must therefore be given for the use of this catheter in pregnant women and children.

- Vascular perforation is an inherent risk of any electrode placement. Do not force the catheter through the vessel.
- Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures.
- Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
- Do not autoclave the catheter.
- Do not use if the package is opened or damaged.
- Pacemaker patients must be under close surveillance when used with this catheter.
- Connection of a PATIENT to H.F. surgical equipment and an ELECTROMYOGRAPH or EVOKED RESPONSE EQUIPMENT may result in burns at the site of the catheter electrodes and possible damage to the recording equipment or biological amplifiers.
- Avoid accidental contact between connected but unused catheters and other conductive parts, including those connected to ground.
- The doctor must consider the mapping inaccuracy or potential harm to the patient caused by the leakage of current when multiple EP recording equipment are used in one procedure.
- The catheter is for single use only. Do not re-sterilize and reuse. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.
- No modification of this equipment is allowed.
- Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this

equipment and result in improper operation.

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the RithmID-SD including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

5 PRECAUTIONS

- The RithmID-SD Steerable Diagnostic Electrophysiology and systems are intended for use only in X-ray shielded rooms due to electromagnetic compatibility requirements and other hospital safety guidelines.
- Do not expose the catheter to organic solvents such as alcohol.
- Personnel handling the catheter should wear gloves.
- Do not attempt to operate the catheter prior to completely reading and understanding the instructions for use.
- Excessive bending or kinking of the catheter may cause damage to the catheter. Manual pre-bending of the distal curve can damage the steering mechanism and may cause patient injury.
- Store in a cool, dry, and dark place.
- The sterile packaging and catheter should be inspected prior to use.
- The long-term risk of protracted fluoroscopy has not been established. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement and placement should be done under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- Catheters must be removed from patient before any defibrillation/HF-surgical procedure.
- The patient should not come into contact with grounded metal parts or parts with appreciable capacitance to ground. Skin-to-skin contact should be avoided by insertion of dry gauze if necessary. Electrodes and connector pins

must not contact other conductive parts and ground.

- Do not use catheters in patients with sensitization problems or allergies to materials contained in the catheter.
- The risk of igniting flammable gases or other materials is inherent in electrosurgery. Precautions must be taken to restrict flammable materials from the electrosurgical suite.
- Catheters must be removed from the patient before MRI.
- Disregarding the information on safety is considered ABNORMAL USE.
- Regularly inspect and test re-usable cables and accessories.
- After use, the catheters should be appropriately disposed in accordance with local regulations.
- Use both fluoroscopy and electrogram data to monitor catheter advancement and reduce risk of tissue injury.
- The catheter produced by Synaptic Medical has not been shown to be safe and effective for electrical ablation or for use in the coronary vasculature other than the coronary sinus.
- Use only with interface cables manufactured by Synaptic Medical since patient or operator injury may occur if incompatible cables are used.
- Do not use with electrosurgical or high frequency surgical instruments.

6 STERILIZATION AND SHELF LIFE

Sterilization

- The catheter is provided sterile. Do not re-sterilize or re-use.

Shelf Life

- All catheters are labeled with an expiration date. Use the catheter prior to the “Use By” date on the package label.

7 ENVIRONMENTAL CONDIDITIONS FOR USE, STORAGE, AND TRANSPORTATION

The catheter must be stored in a cool, dry, and dark place.

Environmental conditions for transport, storage, and use:

- Temperature: 10˚C to 40 ˚C

8 DIRECTIONS FOR USE

a) Remove the catheter from the package. Inspect the overall condition of the catheter carefully.

b) Choose a proper blood vessel for catheter insertion.

c) Apply local anesthesia before creating vascular access.

d) Create access into the vessel by an insertion needle first.

e) Insert an introducer sheath into the chosen blood vessel by the guidance of the insertion needle.

f) Insert the catheter into the introducer sheath and blood vessel.
   - Confirm the thumb knob is pulled back completely prior to inserting the catheter into the introducer sheath.

g) Connect the lead pins and connectors to the appropriate recording equipment and connect the cable connector of the catheter to the connector of the interface cable.

h) Advance the catheter to the area of endocardium under investigation. Use both fluoroscopy and electrograms to aid in proper positioning.
   - Adjust the radius of curvature as necessary by manipulating the thumb knob. Pushing the thumb knob forward causes the catheter tip to bend (curve); when the thumb knob is pulled back, the tip straightens.

i) Prior to removal of the catheter, confirm that the thumb knob has been pulled back completely. Remove the catheter and dispose it in an appropriate manner.

j) Always use fluoroscopy when inserting, removing, and positioning the catheter.

k) Do not re-sterilize and/or reuse the catheter. After use, dispose of product and packaging per hospital and/or

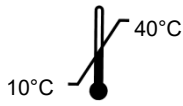
government policy.

l) If there are any questions regarding the use or performance of this product, please consult with the local distributor or the manufacturer.

9 ADVERSE REACTIONS

A number of serious adverse reactions have been documented for cardiac catheterization procedures including pulmonary embolism, myocardial infarction, stroke, cardiac tamponade, and death. The following complications associated with cardiac catheterization have also been reported in the literature: vascular bleeding, local hematomas, thrombosis, AV fistula, pseudoaneurysm, thromboembolism, vasovagal reactions, cardiac perforation, air embolism, arrhythmias, valvular damage, pneumothorax, and hemothorax.

10 SYMBOL DEFINITION

 DO NOT REUSE	 USE BY
 BATCH CODE	 STERILIZED USING ETHYLENE OXIDE
 DATE OF MANUFACTURE	 CATALOGUE NUMBER
 MANUFACTURER	 ATTENTION
 KEEP AWAY FROM SUNLIGHT	 CONSULT INSTRUCTIONS FOR USE
 DO NOT RESTERILIZE	 KEEP DRY
 DO NOT USE IF PACKAGE IS DAMAGED	 TYPE CF APPLIED PART
 TEMPERATURE LIMITATION	 PRESCRIPTION ONLY DEVICE

11 TECHNICAL INFORMATION

Applied Parts	Catheter Shaft and Tip
Degree of Protection against electric shock	Type CF
Degree of Protection against Ingress of Liquids	IPX0
Mode of Operation	Continuous
Oxygen Rich Environments	Not suitable for use in an oxygen rich environment
Environmental Conditions for Transport, Storage, and Use	Temp: 10˚C to 40 ˚C
Accessories	Interface Cable C2500-10
Conditions of Use	In order to maintain the electrical safety afforded by the catheter, it should only be connected to medical electrical equipment which complies with IEC60601-1 and/or ANSI/AAMI ES 60601-1.
Essential Performance	The essential performance of the device consists of acquiring electrical signals, arriving at the target anatomical location, and performing without the need of replacing the device.
Cables	The catheter has an effective length of 1050mm and is connected to a connection cable (part number C2500-10) with a length of 2.5m.

12 ELECTROMAGNETIC INTERFERNECE

Potential Electromagnetic or Other Interference Between the Catheter and Other Devices

The Catheter has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class A and EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical

medical installation. The equipment can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between the equipment
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected
- Consult Synaptic Medical for help

ELECTROMAGNETIC COMPATIBILITY (EMC)

TABLES for RF emissions class A

Manufacturer's Declaration of Electromagnetic Emissions

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The Catheter is intended for use in the electromagnetic environment specified below. The customer or the user of the Catheter should assure that it is used in such an environment		
Emissions Tests	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Catheter system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Catheter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. The EMISSIONS
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations IEC 61000-3-3	Complies	

		characteristics of this equipment make it suitable for use in industrial areas and hospitals. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Manufacturer's Declaration of Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Catheter is intended for use in the electromagnetic environment specified below. The customer or the user of the Catheter should assure that it is used in such an environment			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±15kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines N/A	Mains power quality should be that of a typical commercial or hospital environment. There is no signal line in External Controller.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode N/A	Mains power quality should be that of a typical commercial or hospital environment. There is no Earth connection to the Catheter.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle <5% UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 30 cycles <5% UT (>95% dip in UT) for 300 cycles	5% UT (>95% dip in UT) for 0,5 cycle <5% UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 30 cycles <5% UT (>95% dip in UT) for 300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Catheter requires continued operation during power mains interruptions, it is recommended that the Catheter system be powered from an uninterrupted power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	34 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Conducted RF immunity is tested at Mains with 3 seconds Dwell Time and 1% Step Size with 80% AM at 1 kHz.
Radiated RF IEC 61000-4-3 Radio Frequency Electromagnetic Field Amplitude Modulated	3 V/m 80 MHz to 2,7 GHz	15 V/m 80 MHz to 2,7 GHz	Radiated RF immunity is tested at 80% AM at 1 kHz with 3 seconds Dwell Time.
NOTE: UT is the a.c mains voltage prior to application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and the Catheter

The Catheter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Catheter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Catheter as recommended below, according to the maximum output power of the communications equipment.

Portable and mobile RF communications equipment should be used no closer to any part of the External Controller, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

Rated maximum output power of transmitter (W)	Frequency Band (MHz)	Immunity Test Level (V/m)	Separation Distance (m)
1.8	380-390	27	0.3
2	430-470	28	0.3
0.2	704-787	9	0.3
2	800-960	28	0.3
2	1700-1990	28	0.3
2	2400-2570	28	0.3
0.2	5100-5800	9	0.3

DISCLAIMER OF WARRANTY AND LIMITATION OF LIABILITY

IF THERE ARE ANY QUESTIONS REGARDING THE USE OR PERFORMANCE OF THIS PRODUCT, PLEASE CONSULT WITH THE LOCAL DISTRIBUTOR OR THE MANUFACTURER.

THERE IS NO EXPRESS OR IMPLIED WARRANTY, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ON THE PRODUCE(S) DESCRIBED HEREIN. UNDER NO CIRCUMSTANCES SHALL SYNAPTIC MEDICAL CORPORATION BE LIABLE FOR ANY SPECIAL, DIRECT, INCIDENTAL, CONSEQUENTIAL, OR OTHER DAMAGES OTHER THAN AS EXPRESSLY PROVIDED BY SPECIFIC LAW.

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