Khelix

CE 2797

Loop Electrophysiology Catheter

Schleifen-Elektrophysiologie-Katheter | Cathéter Électrophysiologique En Boucle | Catetere Ad Anello Per Elettrofisiologia | Elektrofysiologiekatheter Met Lus | Catéter de Electrofisiología En Bucle | Cateter de Eletrofisiologia Em Alça | Elektrofysiologikateter Med Slinga | Elektrofyziologický Katetr Se Smyčkou | Elektrofysiologisk Kateter Med Løkke | Elektrofysiologikateter Med Sløyfe | Hurkos Elektrofiziológiai Katéter | Примков електрофизиологичен катетър | Καθετήρας ηλεκτροφυσιολογίας με βρόχο |Elektrofüsioloogilisel uuringul kasutatav silmuskateeter | Spiralni elektrofiziološki kateter | Cilpveida elektrofizioloģijas katetrs | Elektrofizjologiczny cewnik pętlowy | Cateter electrofiziologic cu buclă | Elektrofiziološki kateter z zanko | 環圈電生理導管 |

Instructions for use

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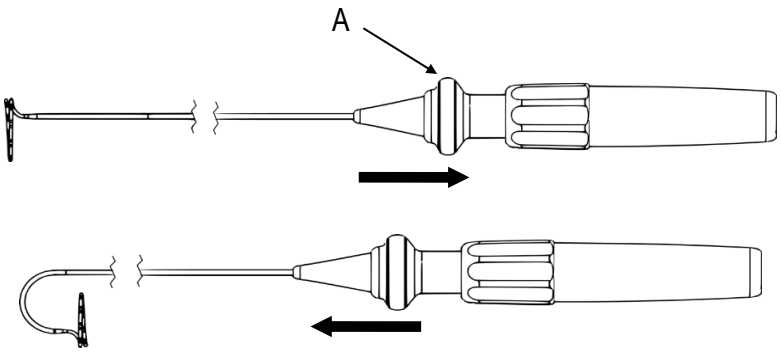

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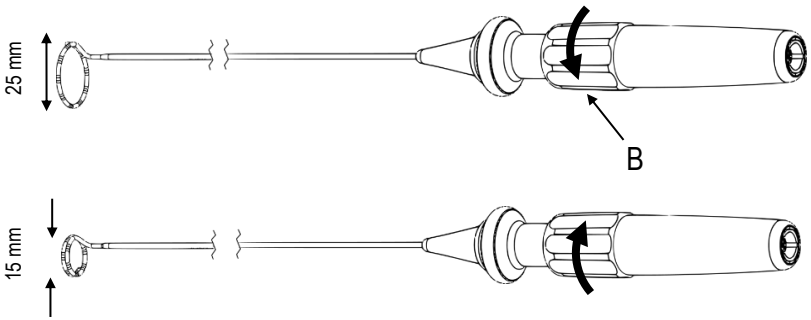

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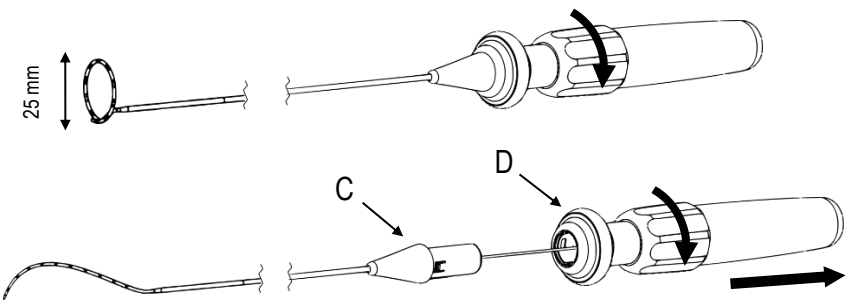

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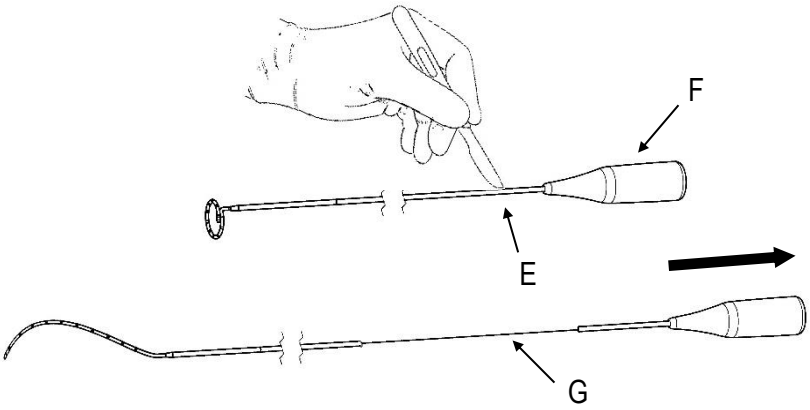

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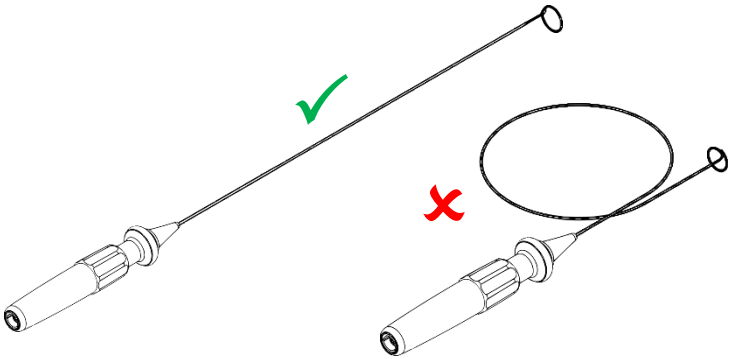

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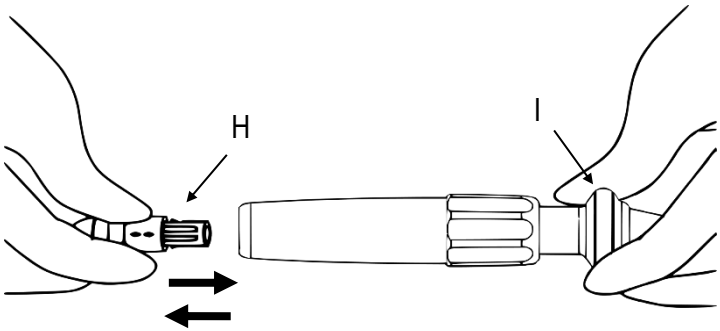

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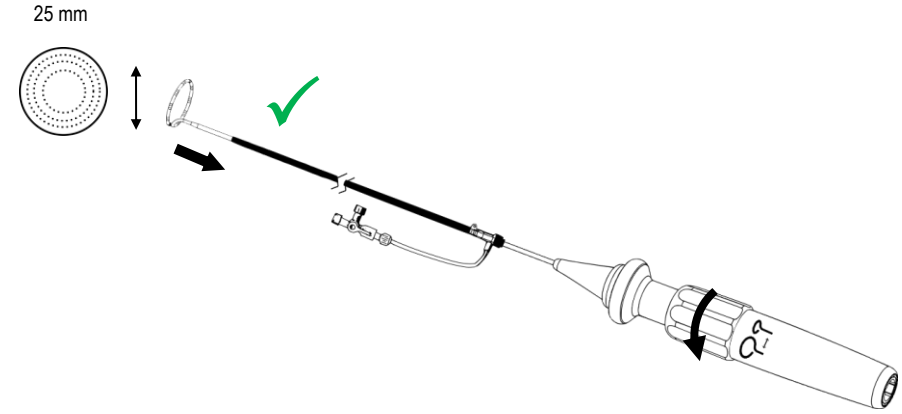

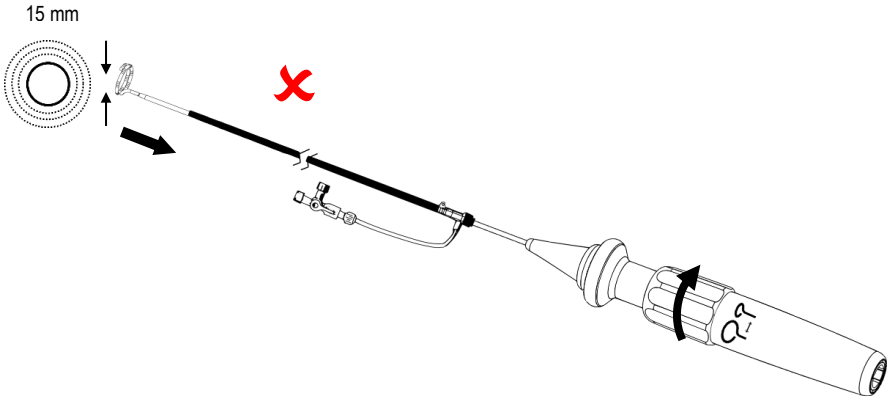

KHELIX LOOP ELECTROPHYSIOLOGY CATHETER

- Caution: Federal law restricts this device to sale by or on the order of a physician.
- STERILE. Sterilized with Ethylene Oxide.
- Do not use if the package is open or damaged.
- The catheter is for single use only. Do not reuse, reprocess or re-sterilise the device.
- Use the device prior to the "Use By" date on the package label.

These instructions apply to the following products:

Table 1: Product Names

Product Name	Product Reference Number (REF)
Fixed Loop Steerable Electrophysiology Catheter	Ref: [SC1-*-*], [SC2-*-*]
Variable Loop Steerable Electrophysiology Catheter	Ref: [SC1-*-*], [SC2-*-*]
Loop Fixed Electrophysiology Catheter	Ref: [SCF-*-*]

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EO). Even though the product is processed in compliance with all applicable laws and regulations relating to EO exposure, Proposition 65, a State of California voter initiative, requires the following notice:
Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

DEVICE DESCRIPTION

The Khelix Loop Electrophysiology Catheter is designed to facilitate electrophysiological mapping of the heart. It consists of a handle and a shaft with a distal loop containing an array of platinum-iridium electrodes for stimulation and recording. The device is available in a number of different electrode configurations, curve types and loop diameters, and the following model types:

Loop Fixed:	The curve shape of the catheter tip on these devices is fixed and cannot be deflected. The loop diameter is fixed and cannot be adjusted.
Fixed Loop Steerable:	The catheter tip on these devices can be deflected in one direction. The loop diameter is fixed and cannot be adjusted.
Variable Loop Steerable:	The catheter tip on these devices can be deflected in one direction. The loop diameter can be adjusted.

Tip Deflection
On the deflectable and variable loop models the distal tip can be deflected in one direction by pushing the deflection knob **(A)**. The tip is straightened by pulling the knob to the original position **[Image 1]**.

Loop Diameter Adjustment
On the variable loop models the diameter of the loop can be adjusted by rotating the loop adjustment rotator sleeve **(B)** located on the handle as shown in **[Image 2]**. Rotating the sleeve anti-clockwise (with distal tip facing away) increases the diameter of the loop. Rotating the sleeve clockwise reduces the diameter of the loop.

⚠ The loop diameter should only be increased when the loop is fully within the heart chamber.

Khelix Loop Electrophysiology Catheter interfaces with standard electrophysiological recording equipment, such as ECG monitoring equipment, impedance based navigational equipment and cardiac stimulation equipment, via the Khelix Diagnostic Extension Cable (supplied separately).

Khelix Loop Electrophysiology Catheter is intended to be used with the following accessory:

Table 2: Accessory for Khelix Loop Electrophysiology Catheter

Khelix Diagnostic Extension Cable

This accessory is available and sold separately by CathRx Ltd.

Loop Release Methods
In all model types the catheter sheath is constructed of a stylet within a catheter sheath. In the event the distal loop is entangled within the cardiac structures, the inner stylet can be withdrawn from the outer catheter sheath, reducing the stiffness in the distal loop and the force required to free the loop.

⚠ The loop release methods provided below are intended for single deployment only. After disentanglement from the heart structure, the catheter must be removed from the patient and discarded.

Fixed and Variable Loop Steerable Electrophysiology Catheter

To reduce the stiffness in the distal loop:
1. Straighten the catheter by pulling the deflection knob back to its most proximal position.
2. On the variable loop catheter only, select the largest loop size by fully rotating the variable loop rotator anti-clockwise.
3. Firmly grasp the blue collar **(C)** with one hand while holding the catheter handle deflection knob **(D)** with the other. Slowly pull back the handle until it detaches from the blue collar **[Image 3]**. This action withdraws the inner stylet from the outer catheter sheath, reducing the stiffness in the distal loop and minimising its ability to maintain its circular shape.

⚠ Only deploy the loop release mechanism when the catheter is in the neutral position, i.e. un-deflected. If used otherwise, damage to the mechanism will result in the catheter failing to deflect or to change loop size.

Loop Fixed Electrophysiology Catheter

To reduce the stiffness in the distal loop, use a scalpel to cut through the outer blue catheter sheath **(E)** proximal to the blue collar **(F)**. The sheath must be cut around its entire circumference, exposing the inner metal stylet **(G)**. Refer to **[Image 4]**. There is no need to cut through the stylet, which is very hard and will not be damaged by a scalpel. Once the entire circumference of the sheath is cut, the inner stylet can be withdrawn from the outer catheter sheath by gripping the sheath in one hand and pulling back the blue collar with the other.

INDICATIONS

The Khelix Loop Electrophysiology Catheter is indicated for the electrical recording or stimulation of endocardial structures. In particular, the catheter is used for obtaining and recording electrograms from the atrial region of the heart.

INTENDED USER

Khelix Loop Electrophysiology Catheter is used by interventional cardiologists in electrophysiology (EP) studies to determine the cause of an abnormal heart rhythm, to locate the site of origin of an abnormal heart rhythm, to decide the best treatment for an abnormal heart rhythm, and/or to check the effectiveness of ablation therapy.

CONTRAINDICATIONS

- The catheter has not been shown to be safe and effective for radio frequency (RF) ablation.
- The transeptal approach is contraindicated in patients with left atrial thrombus, myxoma, or an inter-atrial patch or baffle.
- The use of this catheter may not be appropriate for use in patients with prosthetic valves.
- Electrophysiology procedures are contraindicated for patients with unstable cardiac conditions, e.g. acute myocardial infarction, unstable angina, hemodynamic instability.
- There is a relative contraindication for cardiac catheterisation procedures in patients with active systemic infection.

ADVERSE REACTIONS

A number of serious adverse reactions have been documented for cardiac catheterisation procedures, including cardiac tamponade, pulmonary embolism, myocardial infarction, stroke and death.

The following additional complications associated with cardiac catheterisation have also been reported in the literature: vascular bleeding, local haematoma, thrombosis, AV fistula, pseudoaneurysm, thromboembolism, vasovagal reaction, cardiac perforation, air embolism, arrhythmia, valvular damage, pneumothorax and haemothorax.

DIRECTIONS FOR USE

At point of use
1. Inspect the catheter and packaging before opening. The contents of the package are sterile unless the package is opened or damaged.
2. If the package is opened or damaged, or if the package was opened and the catheter unused, do not use the catheter. Do not attempt to resterilise.
3. A detachable package label has been provided and may be affixed to the medical record of the patient.

Start of Procedure
1. Remove new catheter from its sterile packaging using aseptic technique. Place device on a sterile working area.
2. Inspect the catheter for any damages. Do not use the catheter if kinked.
3. Inspect the catheter for damage to the insulation or connectors. The connector contacts must be dry.
4. Test all functions of the catheter. When testing the deflection and loop diameter adjustment mechanisms, ensure the catheter is held straight rather than coiled as shown in **[Image 5]**.

5. Connect the extension cable by inserting the distal end of the cable into the socket located at the proximal end of the catheter handle. Prior to connection, ensure the key (raised ridges) on the cable connector are aligned with the key slots inside the connector socket of the catheter handle **(H)**. To prevent catheter shaft deflection during connection, grip the catheter deflection knob **(I)** during cable insertion **[Image 6]**.

The catheter must only be used with Khelix Diagnostic Extension Cable.

6. Ensure the catheter is un-deflected and the loop is fully open (maximum diameter) prior to insertion into the vasculature or into an introducer.

During Procedure

To reduce the risk of entrapping cardiac structures, position the catheter by torqueing (or rotating) the shaft in a clockwise direction only.

1. Vascular access is created with a minimum 8 French haemostasis introducer sheath to accommodate the catheter.
2. Advance the catheter through the vascular access site into the desired intracardiac position using fluoroscopic and ECG guidance.

For Variable Loop Steerable Electrophysiology Catheter, when not in regions intended for mapping, manipulate the catheter with the loop in the fully expanded position to further reduce the risk of entrapping cardiac structures.

For Variable Loop Steerable Electrophysiology Catheter, the loop must be in the fully expanded position unless fully within the heart chamber or damage to the catheter may occur.

End of Procedure

1. Prior to removing the loop catheters, straighten the catheter by pulling the deflection knob to the neutral position. On the variable loop catheter, select the largest loop size by fully rotating the loop adjustment rotator anti-clockwise.

For Variable Loop Steerable Electrophysiology Catheter, to avoid entrapment of the loop on cardiac structures or the distal end of the introducer and consequential potential damage to anatomical structures, do not attempt to pull the catheter, or withdraw it into the introducer sheath, with the loop in a contracted position. The loop should be in the fully expanded position (loop adjustment rotator turned fully anti clockwise) to minimise tension on the loop structure. Refer to **[Image 7]**.

2. Remove the catheter from patient.
3. Disconnect extension cable from catheter by gripping the extension cable pin head where the arrows are printed on the pin head and pull outwards. To prevent catheter shaft deflection during disconnection, grip the catheter deflection knob during disconnection.
4. Dispose the catheter according to standard hospital procedure for biologically contaminated material.

STORAGE

Keep dry.
Keep away from sunlight.

DISPOSAL

Dispose device according to standard hospital procedure for biologically contaminated material.

WARNINGS AND PRECAUTIONS

- Do not attempt to operate the catheter prior to completely reading and understanding these Instructions for Use.
- 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.
- The catheter should only be used by clinicians trained in cardiac electrophysiology procedures, in a fully equipped electrophysiology laboratory.
- The catheter is for single use only. Do not reuse, reprocess or resterilise the devices. Reuse, reprocessing or resterilisation may compromise the structural integrity of the device and/or lead to device failure. For example, detachment of small components like tip, ring electrode dislocates, unable to sense signals in heart. Risk of cross contamination and poor catheter handling.
- Use of anti-coagulants should be considered for left-side procedures to reduce risk of thrombi formation and stroke.
- Cardiac catheterisation procedures present the potential for significant X-ray exposure. Exposure to X-rays can result in acute radiation injury as well as increased risk for somatic and genetic effects in both patients and electrophysiology laboratory staff, due to the X-ray beam intensity and duration of the fluoroscopic imaging. Steps should be taken to minimise X-ray exposure.
- In view of the potential for X-ray exposure and the associated risks, careful consideration must be given for the use of the device in pregnant women.
- The retrograde approach is contraindicated because of risk of entrapping the catheter in the left ventricle or valvular apparatus. The catheter is not recommended for use in the ventricles. To reduce the risk of entrapping cardiac structures in the mapping-electrode portion of the catheter, torque (or rotate) the catheter shaft in a clockwise motion only.
- The catheter should not be used in the ventricles because of the potential risk of entrapment in ventricular anatomic structures or in the valvular apparatus.
- Care should be taken when introducing, manipulating and withdrawing the catheter to avoid cardiac trauma and possible damage to the catheter which may result in detachment of catheter components.
- The catheter electrodes, the catheter and extension cable connectors, and the dispersive electrode, should not contact other conductive parts and earth.
- To avoid char formation on the catheter electrodes, do not apply RF energy when an ablation catheter is in contact with one or more of catheter electrodes.
- Do not expose the catheter to organic solvents such as alcohol.
- Do not immerse the catheter handle or any cable connector in fluid as electrical performance could be affected.
- The catheter is MR unsafe. Do not use the catheter system near MRI equipment, as movement or heating of the catheter may occur, and the image or display may become distorted.
- The catheter is a type CF applied part. Any equipment used in connection with this device and its accessories must be defibrillation-proof type CF and meet IEC 60601-1 and IEC 60601-1-2.
- The catheter, together with its accessories, has been tested to allow connection with stimulation equipment with a rated current of 25mA, and a rated voltage of 27V.
- If the catheter becomes kinked, dispose of it. Replace with an undamaged device.
- Serious incidents related to the device should be reported to the manufacturer and the competent authority of your country.

WARRANTY AND DISCLAIMER

CathRx warrants that if it determines that a product was defective or faulty in materials and/or workmanship at the time of purchase, CathRx will, at its option, provide a replacement CathRx product or refund the purchase price of the defective or faulty product.

This limited warranty only applies if the following conditions are met:

- The product was packaged and labelled by CathRx;
- The product is returned to CathRx for evaluation within 30 days of identification of the defect or fault by the original purchaser;
- The product has not been repaired, altered, modified, mishandled or reprocessed inappropriately;
- The product has been used, stored, cleaned, sterilised and reprocessed in accordance with the product labelling and these Instructions for Use; and
- The product is not used after the 'Use By' date marked on the packaging.

OTHER THAN AS EXPRESSLY SET OUT IN THIS LIMITED WARRANTY, TO THE MAXIMUM EXTENT PERMITTED BY LAW, CATHRX MAKES NO WARRANTY IN RELATION TO THE PRODUCT, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF SAFETY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR THAT THE PRODUCT WILL BE DEFECT OR FAULT FREE. TO THE MAXIMUM EXTENT PREMITTED BY LAW, CATHRX EXCLUDES ALL SUCH WARRANTIES.

CathRx accepts no liability and the purchaser of the product assumes all liability, whether based on warranty, tort, contract, negligence, under statute or otherwise, for any kind of loss or damage (including special, incidental or consequential) or injury (including death) arising directly or indirectly as a result of or in connection with the products, including arising as a result of the handling, possession, use or misuse of the product. CathRx's entire liability, including for a breach of warranty or condition which cannot lawfully be modified or excluded, is limited, at the option of CathRx, to either the replacement of the CathRx product or the refund of the purchase price of the product. The remedies set forth in this limited warranty are the exclusive remedy available to any person. The use of the product is deemed to be acceptance of the terms and conditions of this limited warranty.