

Instruction for Use

Cold Knife

Device Description

The Cold Knives are provided for use in Urology procedures. The configurations available include:

Family	Channels	Single/Double Stem	Length(CM)	Straight /Half Moon	For Manuf.
Cold Knife (COK)	24 27	Single Stem-(SS) Double Stem-(DS)	30	Straight-(S) Half moon-(H)	Storz (S) Wolf (W) Olympus (O)

Intended Purpose

The Cold Knife are indicated for the ablation/coagulation of soft tissue and is intended for use with compatible resectoscope. This device is a monopolar electrode designed to deliver radio frequency energy that is supplied by an electrosurgical generator cleared for medical use.

Intended User

This device is intended for the coagulation of soft tissue during surgical procedures. It must be used only by qualified urologists trained in surgical techniques and authorized by the Competent Authority in the country where they practice. The device is for professional use only in controlled clinical or surgical environments.

Medical Conditions to be Treated

- Superficial tumors or lesions in the bladder or urethra
- Urethral strictures causing urinary obstruction
- Anatomical abnormalities leading to urinary flow obstruction
- Complications related to restricted urine flow, including risk of recurrent urinary tract infections or retention

Performance Characteristics of the Device

The Cold Knife is a monopolar electrode intended for use with a compatible resectoscope, and an electrosurgical generator cleared for medical use. It delivers controlled radiofrequency energy for precise cutting, excision, and coagulation of soft tissue within the urinary tract. The device is specifically designed to excise urethral strictures and superficial bladder or urethral lesions with high accuracy, ensuring effective restoration of urine flow while minimizing collateral tissue damage. Its construction supports stable energy delivery, reliable surgical performance, and enhanced precision in delicate urological procedures.

Indications

For removing superficial tumors or lesions in the bladder or urethra, particularly when precision is required. To directly excise strictures in the urethra, allowing for better urine flow and preventing complications. In some cases, cold knife procedures can help alleviate obstructions caused by anatomical abnormalities.

Contraindications

Local and/or systemic infection, thermal damage to surrounding structures, local hematoma, dissection and perforation, and patient discomfort during and/or after energy application.

Precautions, Warnings& Complications

- Carefully read all instructions for use and product labeling. The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.
- Caution: All medical staff is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment. The doctor must be trained in the proper use of the device.
- Warning: All components of the Cold Knives are for single use only.
- Caution: Do not use the device if there is any indication that the sterility of the device has been compromised.
- Warning: All medical staff should carefully review product labeling and instruction sheets before using this device. Inappropriate use of the instrument could adversely affect the procedure or cause injury to the patient and/or surgeon.
 - Refer to the applicable operating and maintenance manual for the resectoscope.
 - This device should only be used by a physician who is familiar with the use of electrosurgical instruments, devices and power generators. Consult the medical literature regarding techniques, complications and hazards prior to any endoscopic procedure.
 - Do not bend or change the angle or shape of the distal end. Doing so may cause poor function, damage to the resectoscope and injury to the physician and/or the patient.
 - Constant irrigation is required throughout the procedure. The distal tip of the device should be kept in view and submerged in the irrigant at all times.
 - CAUTION: Only non-conductive irrigants should be used.
 - Care should be taken to avoid severe impacts, side stresses or bends at sharp angles.
 - When endoscopic device are used together, ensure that any isolation or ground is not violated.

Intended Patient Population

The Cold Knife can be used in patients of all age groups based on doctors' decision.

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Shelf-life of the Product

The shelf life of the Cold Knives is 3 years (Indicated on product label with the use-by symbol and date). Store the Cold Knives at a dry, cool place at 12-35°C. Avoid extended exposure to light.

Sterility – This product is Sterile unless the package has been opened or damaged

- The Cold Knives have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change colour from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct colour.
- If the sterile package is damaged or possibly opened, do not use. Contact “Distributor” and replace the product.
- The Cold Knives are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

- Suggested instructions for using Cold Knives:
- Remove the device from the package and examine it for damage. Do not use if there are visible signs of damage.
- Assemble the working element and resectoscope according to the instructions provided by the resectoscope manufacturer.
- Insert the device into the working channel of the resectoscope in a manner consistent with the instructions of the resectoscope.
- Ensure that the device is securely locked in to position by pulling carefully on the device stabilizer sleeve (if applicable). Do not squeeze the stabilizer sleeve.
- Attach resectoscope to the electrosurgical generator.
- Insert combined assembly into the resectoscope sheath and position at the point where initial application of electrical energy will be delivered.
- Maintain constant irrigation through the resectoscope using sterile irrigant. Keep the distal tip of the device in view and submerged in the irrigant at all times.
- Duration of contact with the body is 1 day.















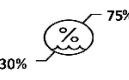




Removal Instructions

Retrieve cystoscopically by gently pulling on electrodes or retrieval line with grasping forceps or equivalent. If resistance is encountered during removal of the electrodes, stop and determine cause of resistance before proceeding.

Disposal Instructions

Dispose of all equipment, in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
	Catalogue Number		Unique Device Identifier		Do not re-sterilize		Country of Manufacture		Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Humidity Limit
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		



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Bibliography

- Indications: <https://www.sciencedirect.com/topics/nursing-and-health-professions/resectoscope>
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
- EN ISO 20417:2020 – Medical Devices – Information to be supplied by the manufacturer.