Instruction for Use
Flexible Catheter

Device Description
A Flexible catheter is a flexible tube that is passed through the trachea and into the body. Intended for single use. Duration of Contact with the body is 1 day.
The configurations available include:

Family	Size (Fr.)	Length (cm)		Type	Accessories
		Proximal Length	Distal Length		
Flexible Catheter	5 6	40	30	Single Leader Blind End, Single Leader Button FS, Single Leader Button RS, Double Leader, Universal Catheter	Soft Button Hard Button

Intended Purpose
The Flexible catheter is intended for use in brachytherapy procedures to ease the insertion of isotopes.

Intended User

This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Medical Conditions to be Treated
Flexible Catheter

- Temporary or intermittent urinary drainage in patients with urinary retention
- Management of post-operative urinary retention
- Bladder drainage during diagnostic or therapeutic urological procedures
- Relief of urinary obstruction due to urethral stricture or prostatic enlargement

Soft & Hard Button

- Continuous bladder irrigation to prevent clot retention following urological surgeries
- Maintenance of catheter patency in patients with hematuria or clot formation
- Management of post-operative bladder irrigation after transurethral or open urological procedures
- Prevention of catheter blockage in patients with high-risk of encrustation or debris accumulation

Performance Characteristics of the Device
Flexible Catheter is a thin flexible tube with closed tip. The device is supplied along with Hard Button and Soft Button for the fixture of the catheter or to avoid the movement of flexible catheter after placing in the body.

Indications
- Brachytherapy
- Laryngeal and Hypopharyngeal Cancer

Contraindications
- Severe un-correctable coagulopathy
- Hemodynamic Instability

Precautions & Warnings
Carefully read all instructions for use and product labelling. Do not use this product without reading and understanding the complete instructions enclosed herein. 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.

Precautions:

- The intended user of the device must be an otolaryngologist or oncologist specializing in the treatment of ENT disorders or cancer and related procedures authorized by the Competent Authority of the country in which the physician is practicing.
- Each physician is responsible for using the appropriate technique and deciding on the indication for use of this device.
- Confirm the information on the label and that the product has not reached its expiration date and there is no damage to the packaging or device.
- Device is not recommended for use in patients with the above-mentioned contraindicated conditions.
- Store the Flexible Catheter at a temperature between 12-35^{0}C and a Humidity range of 30-70%.
- Store in a dry, cool place. Avoid extended exposure to sun light.

Warnings:

- Flexible Catheters are for single use only.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient such as bio-contamination due to release of infectious agents from device into the body which further may result in Infection.
- Do not use the device if there is any indication that the sterility of the device has been compromised. If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.
- Do not reprocess or re-sterilize, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to failure which, in turn, may result in patient injury.

Intended Patient Population
- The Flexible Catheters can be used in patients of all age groups based on doctors’ decision.
- The device can be used in both male and female patients.

Shelf-life
The shelf life of the Flexible Catheters is 3 years (Indicated on product label with the following use-by symbol).

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

- The Flexible Catheters 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.
- Exposure to high levels of Ethylene Oxide may result in presence of residual ETO which leads to Toxic Reaction in the body resulting in tissue damage.
- The Flexible Catheters is packed single. Product in each pack must be utilized immediately when opened.

Directions for Use

Open the package from the Chevron side ('V' Notch) of the pouch. Suggested instructions for using Flexible Catheters:

- Insert the single leader (thin end of the flexible catheter) portion of the flexible catheter into the hollow space of the Peek Needle.
- Make a puncture at the desirable position using a peek needle.
- Pull the peek needle along with flexible catheter through the puncture, once the peek needle has come out fully, remove the peek needle and leave the
- Once the catheter is inserted and is in place remove the peek needle.
- A hard button is connected at the distal end of the catheter to hold the catheter in place from within the body, pull the catheter slowly until the surface of the hard button touches the inner surface of the throat.
- Once the distal end of the flexible catheter connected with hard button touches the inner surface of the throat, insert a soft button from outside to hold the catheter in place and use as intended.

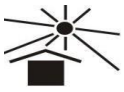
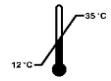
Removal Instructions

- Remove the catheter by gently pulling on the end.
- If resistance is encountered during the removal of the catheter, stop and determine the 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
REF	Catalogue Number	UDI	Unique Device Identifier		Do not re sterilize		Country of Manufacture	MD	Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
LOT	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Humidity Limit
STERILE EO	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		

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Bibliography

- Single Use medical device: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf
- 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.