MEDORAH MEDITEK

MEDORAH®

BOUGIE DILATOR

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

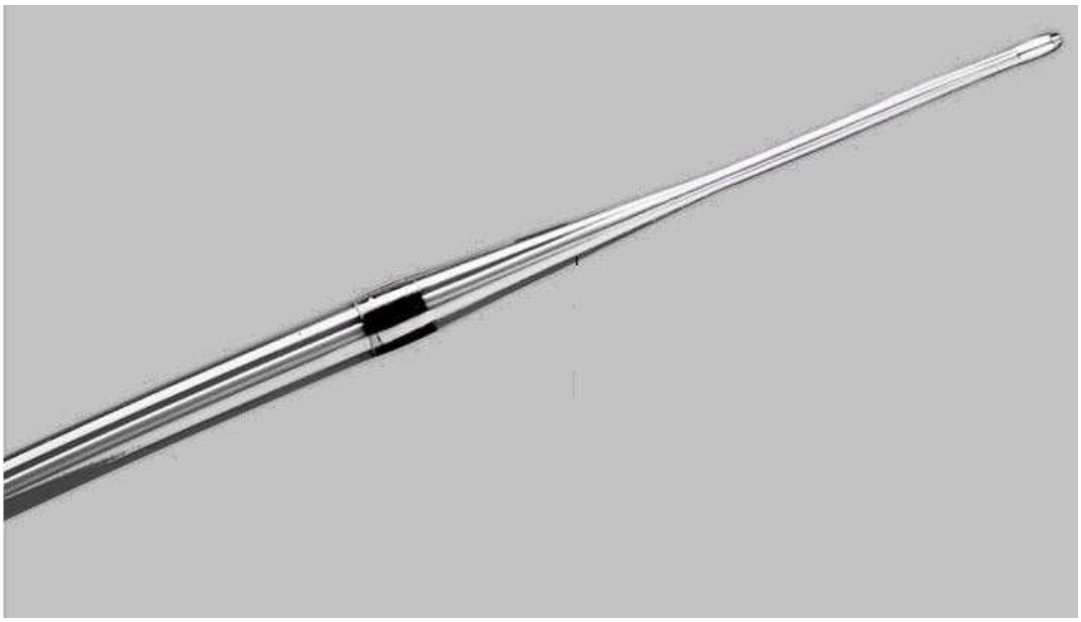
MEDORAH® Bougie Dilator

Intended Use / Indications for use

Intended use- Bougie dilator is intended to be used to dilate or expand the narrowing lesion of esophageal strictures, stenosis, and to temporary ease the esophageal carcinoma, under endoscopic visualization.

Device Description

MEDORAH® Bougie Dilator is made of flexible yet strong material in order to dilate the benign and malignant strictures of the esophagus. It has a channel for the guidewire to pass through it. The guide wire is first introduced and further a dilator is advanced over it. Tube diameter increases from the distal (Tapered end) to the proximal end. Tip is marked which is used for fluoroscopic guidance.



Contraindications

The MEDORAH® Bougie Dilator is contraindicated for, but not limited to:

- Uncooperative patient
- Asymptomatic strictures
- Inability to advance the dilator through the strictured area
- Coagulopathy
- Active ulcer and severe cervical arthritis.
- Known or suspected perforation
- Severe inflammation or scarring near the dilation site.
- Recent myocardial infarction

Potential Complications

- Hypotension
- Fever
- Respiratory depression or arrest
- Perforation
- Cardiac arrhythmia or arrest
- Hemorrhage
- Infection/sepsis
- Aspiration
- Allergic reaction to medications

Warnings

The entire User's Manual must be read thoroughly before using the device. It must be used by or under the supervision of a physician/s trained in the placement of device. A detailed knowledge of the techniques, procedures, clinical applications and risks associated with the procedure is necessary before using the device.

- Do not use if the packaging is opened or damaged when it is received.
- If the device is contaminated, it may lead to injury, illness or death of the patient.
- If an abnormality is detected that would prohibit proper working condition, do not use.

Procedure

- Examine the device visibly before use with particular attention to any bends and breaks. Do not use if any abnormality is detected. If no abnormality is detected, move on to the next step.
- Inspect the strictured area by endoscopy.
- Advance the guidewire into the accessory channel of the endoscope until it reaches beyond the tip of scope.
- As Guidewire reaches to the target site, slowly withdraw endoscope in 5-10cm increments while simultaneously advancing the guidewire in 5-10cm increments to ensure that the guidewire remains in position.
- Once the endoscope is removed completely, inspect the position of the guidewire fluoroscopically.
- Lubricate the dilator and carefully advance it over the pre-positioned guidewire to the strictured area.
- Proceed with esophageal dilation. Select a bougie based on the size of the strictures, beginning with a smaller French-sized bougie and gradually increasing the size. Hold the bougie at the blunt, proximal end.
- Remove the dilator and guidewire from the patient once the procedure is done.

Storage

Store the device under defined temperature limit and avoid direct sunlight Follow the First-in, First-out rules and do not use the device beyond its expiry date.

Change of performance

If the device's performance is changed or the intended purpose is lost, further actions shall be taken according to the medical specialist's decision considering the clinical condition of patients.

Disposal of a used device

The device used must be disposed off according to the hospital, local and country regulations. Disposal is the responsibility of the user.

Explanation of symbols

	Date of Manufacture		Use-By Date
	Catalogue Number		Do Not Reuse
	Consult Instructions for use		Caution
	Keep away from direct sunlight		Batch Code
	Do not use if package is damaged		Manufacturer
	Sterilized using Ethylene Oxide		Keep dry
	Do Not Resterilize		

Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by following appropriate procedures and reasonable care has been applied in designing and manufacturing of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this device as well as other factors relating to patient, diagnosis, treatment, surgical procedures, and other matters beyond Medorah Meditek Pvt. Ltd.'s control directly affect the device and the results obtained from its use. Medorah Meditek Pvt. Ltd.'s obligation under this warranty is limited to the repair or replacement of this device and Medorah Meditek Pvt. Ltd. shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Medorah Meditek Pvt. Ltd. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Medorah Meditek Pvt. Ltd. assumes no liability with respect to devices reused, reprocessed or re-sterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.

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