MEDORAH MEDITEK

MEDORAH®

OTW Biliary Balloon Dilator

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

MEDORAH® OTW Biliary Balloon Dilator

Intended Use / Indications for use

Intended use- MEDORAH® OTW Biliary Balloon Dilator is intended to use for endoscopic dilation of strictures in the biliary tree.

MEDORAH® OTW Biliary Balloon Dilator is supplied sterile and is intended for single use only.

Device Description

MEDORAH® OTW Biliary Balloon Dilator is a catheter shaped tube used for the dilation of the and strictures in the biliary tree. It consists of a balloon attached at the distal end of the device. It also consists of two ports one for guide wire and another for inflation device.

MEDORAH® OTW Biliary Balloon Dilator consists of double lumen tube; first lumen is connected with the balloon at the distal end and inflation port at the proximal end; the second lumen is for guide wire insertion. The balloon lumen is designed in such a way that it can easily enable passage of the guidewire without compromising the effectiveness of the balloon. Guidewire guides the balloon and when it reaches the desired location, an inflation device is used to inflate the balloon.

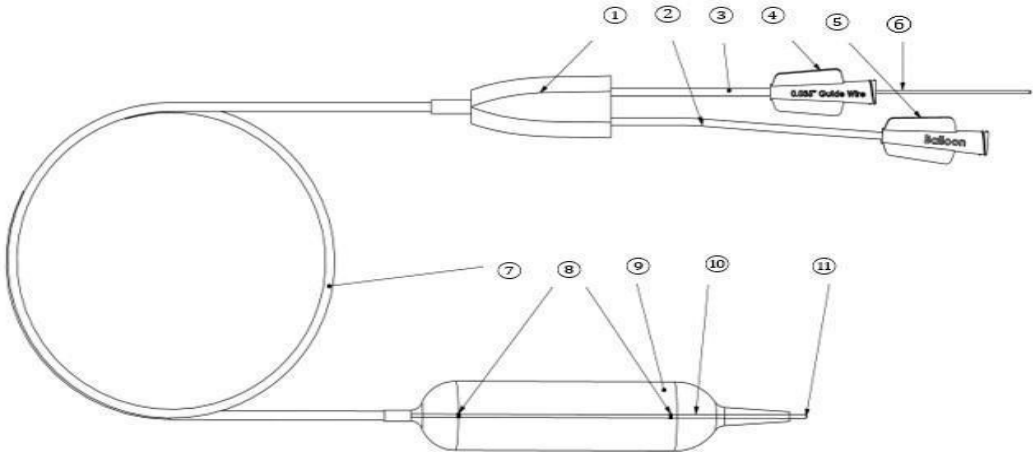
The MEDORAH® OTW Biliary Balloon Dilator is capable of inflating to single size diameter. MEDORAH® OTW Biliary Balloon Dilator is composed of dual ports at the proximal end of the device, one for entry of guidewire and the other port for inflation of balloon, known as balloon port, pipes connecting each port to the hub, Luer-lock Y-connector (hub) which consists of a guide wire lumen and a balloon inflation lumen, Catheter and a balloon at the distal end and a distal soft tip. Catheter is available in different lengths as per the intended use. Maximum guide wire diameter is 0.035". The balloon is designed to reach specific diameters at specific pressures (see compliance table on the labels). Two radiopaque markers are placed under the balloon segment of the catheter to provide visual reference points fluoroscopically for balloon positioning within the stricture. The catheter includes a smooth, soft and tapered atraumatic tip to facilitate advancement of the catheter through the stricture.

MEDORAH® OTW Biliary Balloon Dilator Specifications

Balloon Length: 30mm and 40mm

Balloon Diameter: 6mm, 8mm,

10mm Catheter Length: 190cm



①	Hub
②	Tube Connecting Balloon Port
③	Tube Connecting Guidewire Port
④	Balloon Port
⑤	Guidewire Port
⑥	Guidewire 0.035 inch
⑦	Catheter
Ⓑ	Radiopaque Marker
⑨	Balloon
⑩	Inner tube
⑪	Guidewire 0.035 inch

Contraindications

Those specific to ERCP and any procedures to be performed in conjunction with balloon dilation including, but not limited to:

- Asymptomatic strictures
- Inability to advance the balloon dilator through the strictured area,
- Known or suspected perforations
- Severe inflammation or scarring near the dilation site

Potential Complications

The following complications may occur when using the MEDORAH® OTW Biliary Balloon Dilator:

- Perforation
- Haemorrhage
- Aspiration
- Fever
- Sepsis/Infection
- Hematoma
- Allergic reaction to contrast agent
- Pancreatitis
- Cholangitis

Warnings

These instructions must be followed, as well as instructions from compatible components and hospital regulations for infection prevention, safe use, cleaning and sterilization. Failure to do so may result in serious injury to the patient and/or the user.
The following applies to the product:

- The device is designed and intended for single use only. DO NOT RESTERILIZE AND/OR REUSE.
- Reuse or resterilisation may create a risk of contamination as well as compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, transmission of infectious diseases and death. The manufacturer will not be responsible for any direct, incidental or consequential damages resulting from resterilisation or reuse.
- Inspect the device, prior to procedure, to verify functionality and lack of damaged parts. Do not use the device if the outer or the inner package is damaged or opened.
- When the catheter is in the body, it should be manipulated while under sufficient and/or high quality fluoroscopy. Prior to withdrawing the catheter from the lesion, the balloon must be completely deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Do not use any other medium to inflate the balloon. Use only the recommended inflation medium.
- Do not expose the device to organic solvents, e.g. alcohol.
- To prevent balloon burst, do not exceed the inflation pressure given for the largest diameter on the catheter's hub and package label.
- If the balloon does rupture or a significant loss of pressure within the balloon occurs, deflate the balloon completely and carefully remove the balloon and endoscope together

as a unit. Do not attempt to withdraw a ruptured balloon through the endoscope. Continue procedure with a new catheter.
- Only physicians thoroughly trained and educated in the performance of balloon dilatation should use this device.
- Use prior to "Use Before" date.

Precautions

- Do not pre-inflate balloon.
- Prior to insertion of balloon dilator, negative pressure is mandatory to maintain balloon profile.
- Endoscope should remain as straight as possible when advancing or withdrawing balloon dilator.
- Entire balloon should be extended beyond tip of endoscope, and be completely visualized and positioned before inflation.
- During withdrawal of balloon dilator from endoscope, negative pressure is mandatory to maintain balloon deflation.
- Apply a water-soluble lubricant to balloon to allow easier passage through accessory channel.
- Endoscopy should be used to confirm proper placement of the catheter.
- Verify that the shaft segment of the catheter is within endoscopic view.
- This ensures that the balloon has exited the endoscope completely. Fluoroscopy may be used to confirm balloon placement.

Procedure

Product Preparation:

1. Consult the product label to determine whether device is suitable.
   Consult the appropriate operational channel.
2. Before using, check the package for any damage. If the package is damaged, do not use it. Once the expiration date has been confirmed, carefully open the package.
3. Gently take the device out of its package and unwrap it. Avoid using too much force as this could harm the device and impair its functionality.
4. Do not use this device if there are any visible symptoms of damage.
5. Avoid testing or pre-inflating the balloon before insertion. Do not pre-inflate or test the balloon before insertion.

Instructions for use

- To keep track of the balloon's pressure, attach the balloon to an inflating tool with a gauge.

- Before removing the protective sleeve, provide negative pressure on the catheter to enable passage through the endoscope.
- Take off the balloon's protective covering.
- To make the balloon easier to pass through the endoscope accessory channel, lubricate it.
- When inserting the catheter through the scope, keep the vacuum applied to it.
- Move the catheter into the endoscope in short, deliberate steps of two or three centimetres.
- The guidewire can be advanced past the catheter's distal end once the balloon has left the distal end of endoscope and entered the endoscopic view. To guide the catheter using the guidewire:

(i) Move the guidewire past the catheter tip to the appropriate location (fluoroscopy is suggested).

(ii) Once the balloon part is in the desired place, advance the catheter across the extended section of the guidewire.

- The MEDORAH® Balloon Dilator has 2 radiopaque markers and are positioned beneath the balloon to aid in correct placement over the stricture.
- Compare the balloon's proximal and distal radiopaque markers with the stricture's position.
- Inflate the balloon in accordance with the balloon inflation instructions once it is positioned across the stricture.

Caution: Never inflate a balloon with fluids.

- The Medorah® OTW Biliary Balloon Dilator can be expanded to a single diameter specified on the package and hub labels. Inflate the balloon to the pressure corresponding to the smallest diameter listed and maintain it until the desired dilation is attained. For larger balloon diameters, increase pressure incrementally, adhering to the maximum inflation pressure stated on the catheter hub and package labels.

Caution: In the event of balloon rupture during the procedure, halt the process promptly and initiate necessary remedial measures.

- Carefully monitor the balloon pressure throughout the dilation process. Minor adjustments may be necessary to sustain the correct pressure, which is a normal occurrence.
- To remove the balloon, utilize the inflation device to create negative pressure. While under direct endoscopic observation, ensure complete withdrawal of any liquid from the balloon before gradually removing the catheter from the endoscope.

Note: Ensure all fluid is removed before attempting to remove the balloon. Depending upon the inflation balloon size and chosen medium, this may take between 10-30 seconds.

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.

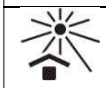
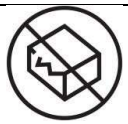
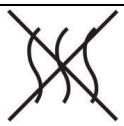
Disposal of a used device

After use, this product may be a potential biohazard. It must be disposed of according to hospital, local and country regulations. Disposal is the responsibility of user.

Storage

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment. Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.

Explanation of Symbols

	Date of Manufacture		Use-By Date
	Catalogue Number		Do not re-use
	Consult instructions for use		Caution
	Keep away from sunlight		Batch Code
	Do not use if package is damaged		Manufacturer
	Non-Pyrogenic		Keep dry
	Do Not resterilize		Sterilized using Ethylene Oxide
	Temperature Limitation		

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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