



# **CAPTOR® TRIPLE LUMEN STONE EXTRACTION BALLOON**

## **Instructions for Use**

**Medorah Meditek Pvt. Ltd.**

**[www.medorah.com](http://www.medorah.com)**

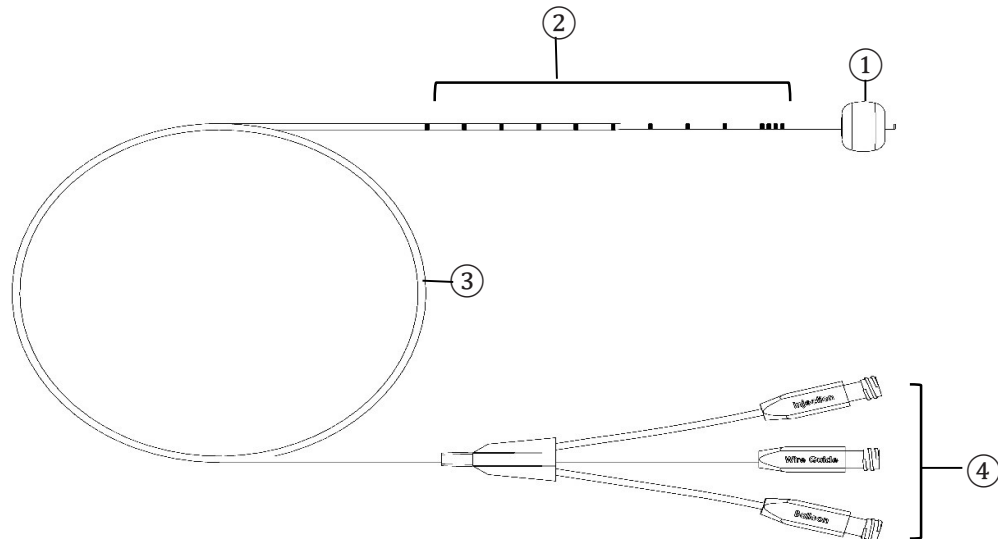
# CAPTOR® Triple Lumen Stone Extraction Balloon

## Product Description

CAPTOR® Triple Lumen Stone Extraction Balloon is designed in triple lumen configuration with three proximal ports for contrast access, guidewire and balloon inflation. The balloon is located distally on the catheter with two radiopaque markers on either side of the balloon.

## Intended Use

CAPTOR® Triple Lumen Stone Extraction Balloon is intended to use for dilating the sphincter muscles and removing the stones from the common bile duct.



|   |                       |
|---|-----------------------|
| ① | Balloon               |
| ② | 13-Endoscopic markers |
| ③ | Catheter              |
| ④ | 3-Ports               |

## **Contraindications**

- Application in the central cardiovascular system is contraindicated.
- Specific contraindications for primary endoscopic procedures to access the desired injection site
- Severe coagulopathy
- Not fasting patients
- Fragility of the intestinal wall: e.g., highly florid inflammation of the colon (e.g., ulcerative colitis, diverticulitis, ulcerative colitis, toxic megacolon)
- Peritonitis, acute abdomen, e.g., intestinal perforation, ileus
- Sepsis
- Co-morbidity, e.g., severe cardiopulmonary diseases and decompensation
- Uncontrollable hemorrhagic diatheses
- Pregnancy
- Recently created gastrointestinal anastomosis
- Use of natural latex rubber balloon is contraindicated in patients with a known hypersensitivity to latex

## **Complications**

- The following complications may occur when using the Stone Extraction Balloons:
- Injury to the mucous membrane or tissue, particularly in the case of mutated tissue
- Bleeding due to injuries
- Perforation of blood vessels, stomach or intestinal wall or other organs
- Ulcers in or necrosis of injected tissue
- Stricture formation
- Allergic reaction
- Pancreatitis
- Cholangitis
- Aspiration,
- Hemorrhage,
- Infection,
- Allergic reaction to contrast or medication hypertension, respiratory depression or arrest, cardiac arrhythmia or arrest.
- Additional complications that can occur during endoscopic balloon extraction include: stone impaction, localized inflammation, and pressure necrosis.
- Those specific to endoscopic procedures

## **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:

- Sterile only, if packaging is undamaged or unopened.

- For single use only. Do not reuse, reprocess or resterilize several times. Reuse, reprocessing or repeated sterilization of the instrument may affect its structural integrity and may cause malfunction, resulting in contamination, infection and serious injury.
- If the instrument accidentally becomes dirty before treatment, it must be disposed off immediately.
- No cleaning agents shall be applied.
- Do not use the device after the date of expiry.
- All components should be carefully checked for compatibility and integrity before use.
- Do not use defective instruments. If defects occur, dispose off the instrument and replace it with a new one.
- Never use the product outside the recommended technical specifications (intended use).
- Never tamper with the structural conditions of the instrument, avoid kinks and other damage, and immediately discontinue use in the event of a malfunction.
- Never force instruments into the working channel.
- This product contains natural rubber latex which may cause allergic reactions.

### **Precautions**

- Do not insert the instrument into the endoscope's working channel while the device is open. This may lead to patient injury, such as perforation, bleeding, or mucous membrane damage. It can also damage the endoscope and/or instrument.
- The compatibility of the diameter of the device and the diameter of the endoscope working channel is essential for obtaining optimal results during the procedure.
- These devices are compatible with an endoscope accessory channel of 2.8 mm or larger. Always refer to the package label for the minimum channel size required for this device.
- Wearing of protective clothing (gloves, goggles, gown, etc.) is absolutely necessary.
- This device should be used by a trained physician.
- Remove the protective cap prior to use.
- Read the IFU carefully prior to use.
- A function test and/or visual inspection should be carried out prior to any use. As a result, we therefore refer to the corresponding sections in this user manual.
- The guide wire diameter and the inner lumen of the wire-guided device must be compatible.
- Assessment of the size of the stone and the ampullary orifice must be made to determine the necessity of sphincterotomy. In the event a sphincterotomy is required, all necessary precautions must be followed.
- Injection of contrast during ERCP must be monitored fluoroscopically. Overfilling of the pancreatic duct may cause pancreatitis.

### **Procedure**

- The Balloon Catheter must be inserted deflated over the guidewire into the endoscope's working channel.

- Insert the deflated balloon into the biliary duct until the distal tip is located above the stone to be removed.
- Pull the plunger of the syringe and connect it to the transparent stopcock at the proximal end of the catheter.
- Open the stopcock.
- Push the plunger of the syringe carefully to inflate the balloon. Air capacity specified for each balloon must be respected to avoid its destruction.
- Close the stopcock to prevent the air from leaking out of the balloon.
- Gently withdraw the inflated balloon catheter to pull the stones out of the biliary duct and drop them into the duodenum. They can be expelled naturally out of the body through the intestines.

*Note: If more than one stone is to be removed, extract one stone at time.*

- Open the stopcock and deflate the balloon.
- Remove the entire instrument out of the endoscope carefully.

*Note: Sharp stones can destroy the balloon and should be removed with an extractor basket or a lithotripsy basket.*

**For Multiple sizing balloons:** *Inflate the balloon using fluoroscopic monitoring until the balloon is visualized occluding the duct. If desired, adjust the size of the balloon by using the reference marks on the syringe. To achieve the smallest balloon size, inflate the balloon to the next largest size and gently pull back the syringe to the initial size. Lock the stopcock.*

### Storage Conditions

Store the device under normal temperature and avoid direct sunlight. Follow the First In, First Out rules and do not use the device beyond its date of expiry.









### Disposal of a used device








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

### Goods Return Policy

Refer to the company's return goods policy. Please contact the branch office or customer service at [info@medorah.com](mailto:info@medorah.com) or call +91 124-4712471.

### Symbols used on product label

|   |                              |   |               |
|---|------------------------------|---|---------------|
|  | Date of Manufacture          |  | Use-By Date   |
|  | Catalog 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                        |
|  | Contains or presence of natural rubber latex |  | Sterilized using Ethylene Oxide |
|  | Do not resterilize                           |   |                                 |

### Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by the appropriate procedures. This warranty is in lieu of and excludes all other warranties not expressly set forth herein which are beyond Medorah Meditek Pvt. Ltd. control such as warranties implied to the application of law, sales or specially purpose suitability after handling over, storage, cleaning and sterilization of this product as well as matters related to the patient, diagnosis, treatment, surgical procedures, and any other details. 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 product other than the replacement of it. Medorah Meditek Pvt. Ltd. shall neither take any additional responsibility nor authorize such responsibility or duty to other person related to this product.



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