PACKAGING

Medical device delivered in a peel-off pouch as inner packaging and a cardboard packaging box.
One (1) unit per box (one (1) catheter with a protection tubing in a hoop).
Do not use if the package is opened or damaged.
Use before the expiry date clearly indicated on the label.

Store in a dry place below 40° C. Keep away from light.

Labeling symbols definition

- Manufactured by
- REF — Device reference
- LOT — Device Lot number/Serial Number
- Expiry date, Use before date, Use by
- STERILE EO — Sterilized by Ethylene Oxide
- Device Intended for Single Use only. Do Not reuse
- Caution, consult accompanying documents
- Do not use if package has been opened or damaged
- Keep dry
- Keep away from sunlight
- 15°C 40°C — Temperature limitation
- Non pyrogenic
- Production date

Manufactured by:

NATEC Medical Ltd.
Maeva Centre Building
Ebene Business Park
Réduit, Mauritius

Distributed by:

ENVASTE Ltd.
Maeva Centre Building
Ebene Business Park
Réduit, Mauritius
www.envaste.com

EC REP

Emergo Europe
Molenstraat 15
2513 BH
The Hague, Netherlands

CE 0459

Instructions for use ref. CO000854 – Rev 11/2013

Maohe

STONE EXTRACTION BALLOON CATHETER

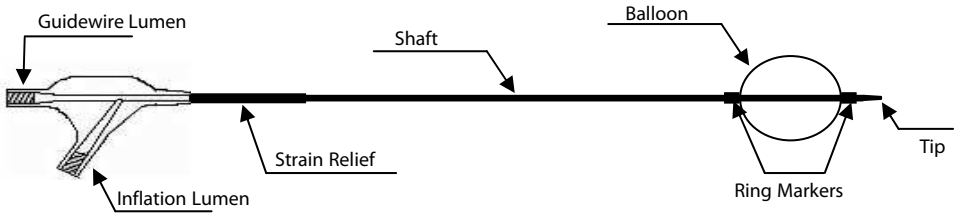
INSTRUCTIONS FOR USE

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. FAILURE TO OBSERVE ALL WARNINGS AND PRECAUTIONS MAY RESULT IN COMPLICATIONS

Caution: Federal law restricts this device to sale by or on order of a physician.

CONTENTS: One (1) MAOHE Extraction Balloon Catheter sterilized with ethylene oxide gas. Non-pyrogenic.

These instructions apply to all balloon diameters and lengths.



PRODUCT INFORMATION

Balloon compliance is measured at 37.5° C (In vitro Compliance).

The balloon compliance table is available on the product label.

The balloon diameter variation with respect to inflation volume are indicated on the label affixed on both the inner package and the packaging box.

Do not exceed the maximum inflation volume recommendation.

Max Guide Wire Diameter: 0.025" (0.64 mm) or 0.035" (0.96mm)

Destroy product after use. After use, eliminate the product according to safety requirements related to product contaminated by blood.

I. DEVICE DESCRIPTION

The Mahoe stone extraction balloon catheter is composed of a proximal dual-lumen tubing, and a balloon at the distal tip. The proximal shaft has a Luer-lock Y-connector (hub) for balloon inflation at its proximal end. The hub consists of a guide wire lumen and an inflation lumen.
Catheter length is 200 cm.
The Maohe stone extraction balloon catheter is compatible with guide wire diameter size of 0.025" (0.64 mm) or 0.035" (0.96mm). Please refer to information printed on the label

The balloon is designed to reach specific diameters at specific inflation volume (see compliance table on the label). The balloon has two radiopaque markers to aid in positioning the balloon relative to the biliary stone or sludge from the bile or pancreatic duct. The radiopaque marker bands indicate the occlusion section of the balloon.
The catheter includes a smooth, soft and tapered atraumatic tip to facilitate advancement of the catheter through the stricture.
The Mahoe stone extraction balloon catheter is available in balloon a size: 8.5, 12 & 15mm and 9 & 16mm. Balloon diameters are printed on the "inflation leg" of the hub, and the lot number is printed on the middle flat section of the hub. These details are also printed on the labels.

II. INDICATIONS

The Mahoe stone extraction balloon catheter is intended to be used for endoscopic extraction of stones and sludge from the bile or pancreatic duct and the occlusion of the bile duct after the application of contrast medium.

III. CONTRADICATIONS

Those specific to ERCP and any procedures to be performed in conjunction with balloon stone extraction. Use of this natural latex rubber balloon is contraindicated in patients with a known hypersensitivity to latex.

IV. WARNINGS

This device should be used only by physicians who are experienced and have a thorough understanding of the clinical and technical aspects of gastroscopy.

- During inflation do not inflate balloon beyond the maximum indicated inflation volume.
- Always inflate the balloon with air. Never inflate with liquid, contrast medium, carbon dioxide or any other gas.
- Do not advance balloon if resistance is encountered. Assess the cause of resistance before proceeding.

V. PRECAUTIONS FOR USE

- Refer to package label for minimum channel size required for this device.
- Observe the guidewire diameter recommended on the product label.
- When extracting stones from the bile system, it may be necessary to perform papillotomy if the stone does not pass the papilla. Observe safety measures, warning notices and contraindications.
- Check the instrument after removing it from the packaging for kinks and breaks. In addition, we recommend you perform a functional check of the balloon. Should you determine that the instrument has been damaged, do not use it and please notify or branch office.

VI. POTENTIAL COMPLICATIONS

Complications that may result from this procedure include:

- Acute pancreatitis
- Cholangitis,
- Aspiration,
- Perforation,
- Hemorrhage,
- Infection,
- Sepsis,
- Allergic to contrast or medication,
- Hypotension,
- Respiratory depression or arrest,
- Cardiac arrhythmia

VII. SELECTION, PREPARATION OF DEVICE COMPATIBILITY WITH ACCESORIES

1. Verify the balloon integrity prior to use by attaching enclosed pre-measured syringe to stopcock and inflating balloon with **air only**. If any leakage is detected, do not use. Notify Envaste for return authorization.

Note: Stopcok is in open position, allowing access to balloon, when two arms are aligned with catheter and syringe. To maintain balloon inflation, turn stockcock arm to 90°.

2. With duodenoscope elevator open, advance deflated balloon in short increments through accessory channel until it is visualized exiting scope.

Note: Prior to advancing device over a pre-positioned wire-guide, close Tuohy-Borst adapter, if applicable, flush wire guide lumen with sterile water or saline to facilitate advancement. If applicable, re-open Tuohy-Borst adapter to allow advancement of device over wire guide.

3. Prior to advancing device into duct, flush sideport of injectable stylet or injection port, as applicable, with contrast to expel all air.

Note for double lumen devices: To inject over a pre-positioned wire guide, a side arm adapter must be attached to color-coded wire guide hub.

4. Position deflated balloon above stone to be removed.

Note: If more than one stone is to be removed, extract one stone at a time. **Note for triple lumen devices:** Contrast may be injected through injection port with wire guide in place.

5. After verifying desired position of balloon, open stopcock by lining it up with lumen. Attach pre-measured syringe to inflation port, then inflate balloon with **air only**. Inflation may be maintained by turning the stopcock arm 90° to close position.

Note for multiple sizing balloons: Inflate as indicated on syringe. For 8.5mm, inject to 12mm mark then pull back gently to 8.5 mm mark and lock stopcock.

6. Using fluoroscopic visualization and keeping endoscopes elevator open, gently withdraw inflated balloon toward papilla.

Warning: Do not exert excessive pressure on ampulla while extracting stones. If stone does not pass easily, reassess need for sphincterotomy.

7. Repeat extraction process, one stone at a time, until duct is clear.
8. Once balloon is visualized in duodenum, turn stopcock to open position and deflate balloon.
9. Loosen Tuohy-Borst adapter (if applicable) and withdraw deflated balloon from accessory Channel.

Note: When removing balloon from endoscope, wire guide may be left in place to facilitate introduction of compatible wire-guided devices.

VIII. DISCLAMER OF WARRANTY AND LIMITATION OF REMEDY

We declare under our sole responsibility that the product listed above conforms to the requirements of EC Directive 93/42/EEC. Due to the biological differences of each patient, the effectiveness cannot be guaranteed unconditionally. The terms of use such as diagnosis and indication, handling, storage, cleaning, sterilization of the product, patient-related factors, treatments, surgical procedures and other circumstances have a direct effect on the instrument and the results of its use. They are not subject to our control. Success cannot be guaranteed, side effects cannot be excluded. Envaste is not liable for any resulting losses, damages or costs, which may result directly or indirectly from the use of this instrument. No liability or warranty for reprocessed or resterilized instruments is assumed.
This warranty is exclusive and to the exclusion of all other written, spoken or legal warranties. No representative of the company may change these warranty terms and conditions. The customer is therefore in agreement that the products are subject to these terms & conditions.