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.

2. Monitor the pressure using an inflation device and pressure gauge system. As dilatation takes place, the pressure reading may fluctuate. Adjust the balloon pressure as necessary to meet the pressure given for the desired diameter (a slight drop in pressure is normal).

Catheter Withdrawal

1. The Amara Wireguided Balloon Dilator is designed for rapid deflation. To deflate completely, maintain endoscopic view of the proximal end of the balloon as a vacuum is applied using the inflation device.

Precaution: Do not pull back on the catheter until the balloon is deflated completely.

Warning: THE BALLOON MUST BE THOROUGHLY DEFLATED AND ALL FLUID REMOVED PRIOR TO WITHDRAWAL (approximately 10-30 seconds depending on the balloon size and inflation medium).

Precaution: For improved withdrawal, straighten the distal **end of the endoscope as much as possible. Any excess** bend in the working Channel will increase the force needed to withdraw the catheter through the endoscope.

2. Slowly remove the catheter from the endoscope.

Precaution: If excessive resistance is felt, remove the endoscope and balloon catheter together as a complete unit to prevent damage to body tissue, the catheter or endoscope.

3. After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, administrative and/or local government policy related to product contamination by blood. For one time use only. Do not reuse. Do not re-sterilize. Read instructions prior to use.

XII. DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

The manufacturer has exercised reasonable care in the manufacture of this device. Both manufacturer and distributor excludes all warranties, whether express or implied by operation of law or otherwise, including but not limited to, any implied warranties of merchantability or fitness, since handling and storage of this device as well as factors relating to the patient, the diagnosis, treatment, surgical procedures, and other matters beyond our control directly affecting this device and the results obtained from its use. Both manufacturer and distributor shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this device. The manufacturer neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

XIII. NOTICE TO USER AND/OR PATIENT

Any serious adverse event occuring in connection with the device, should be reported to Envaste Ltd. and the competent authority of the member state in which the user and/or the patient is established.

LABELING SYMBOLS DEFINITION

- Manufactured by
- REF — Device reference
- LOT — Device Lot number
- Expiry date, Use before date, Use by
- STERILE EO — Single Sterile barrier system with protective packaging outside. Sterilized by Ethylene Oxide
- Device Intended for Single Use only. Do Not reuse
- Caution, consult instructions for use
- Do not resterilize
- Balloon diameter
- NP — Nominal pressure
- RBP — Rated burst pressure
- MD — Medical device
- UDI — Unique Device Identifier
- Do not use if package has been opened or damaged
- Keep dry
- Keep away from sunlight
- Non pyrogenic
- MU — Country of manufacture Date of manufacture
- Usable catheter length
- BALLOON — Balloon length
- EC REP — European Representative

Manufactured by:

Envaste Ltd.
4th Floor, Maeva Tower Building,
Ebene Business Park,
Reduit 72201, Mauritius
www.envaste.com

Distributed by:

Envaste Ltd.
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Ebene Business Park,
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EC REP

Envaste Ltd.
Innovation In Business Centre,
Unit 9, GMIT
Dublin Road, Galway
Ireland

CE 1984

Instructions for use ref: 0910013 – Rev 05 , 21 Jan 2025 CE marking date: 18 May 2021

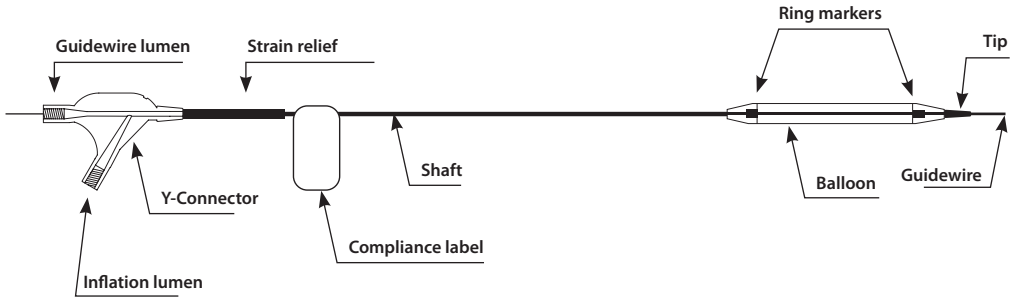
Wireguided

Amara

BALLOON DILATOR

INSTRUCTIONS FOR USE

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



CONTENTS: One (1) AMARA Wireguided Balloon Dilator 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 package as well as on the product label.
The balloon diameter variation with respect to pressure and Rated Burst Pressure (RBP) are indicated on the label affixed on both inner packages, packaging box as well as on the product label.
Do not exceed the RBP recommendation.

Maximum Guide Wire Diameter: 0.035" (0.89mm).

Minimum Working Channel Alimentary Tract:	**Minimum Working Channel Biliary Tract:**
≥ Ø2.8 mm	≥ Ø3.7 mm

DISPOSAL

After use, dispose product and packaging in accordance with hospital, administrative and/or local government policy. For one time use only. Do not reuse. Do not re-sterilize. Read instructions prior to use.

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 coiled in an insert card).
Do not use if the package is opened or damaged.
Use before the expiry date clearly indicated on the label.

STORAGE AND HANDLING

Store in a dry place at room temperature. Keep away from light.

PERFORMANCE FEATURES

Three stage balloon catheter allows controlled and gradual dilation.

CLINICAL BENEFITS

Relieves obstruction caused by strictures in alimentary tract and facilitation of biliary stone extraction.

I. DEVICE DESCRIPTION

The AMARA Wireguided Balloon Dilator is capable of 3 distinct and progressively larger diameters sizes via controlled radial expansion. The Amara Wireguided is composed of a proximal dual-lumen shaft, a single lumen distal tubing, a balloon at the distal end and a distal soft tip. The proximal shaft has a Luer-lock Y-connector (hub) for balloon inflation at its proximal end. The hub consists of a guidewire lumen and an inflation lumen. Catheter is available in 180 or 240 cm lengths.
Maximum guidewire diameter is 0.035" (0.89 mm).

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.
The AMARA Wireguided Balloon Dilator is available in balloon size 6/7/8mm, 8/9/10mm, 10/11/12mm, 12/13.5/15mm, 15/16.5/18mm and 18/19/20mm with a length of 55mm. Balloon diameter and length are printed on the "inflation leg" of the hub, and the lot number is printed on the flap between inflation and guidewire leg of hub. These details are also printed on the labels.

	Balloon Size	Catheter length	Inflation Pressure
Ref #	mm	cm	Atm
GDB-0210655S	6-7-8x55	180	3-6-10
GDB-0210855S	8-9-10x55	180	3-5.5-9
GDB-0211055S	10-11-12x55	180	3-5-8
GDB-0211255S	12-13.5-15x55	180	3-4.5-8
GDB-0211555S	15-16.5-18x55	180	3-4.5-7
GDB-0211855S	18-19-20x55	180	3-4.5-6
GDB-0220655S	6-7-8x55	240	3-6-10
GDB-0220855S	8-9-10x55	240	3-5.5-9
GDB-0221055S	10-11-12x55	240	3-5-8
GDB-0221255S	12-13.5-15x55	240	3-4.5-8
GDB-0221555S	15-16.5-18x55	240	3-4.5-7
GDB-0221855S	18-19-20x55	240	3-4.5-6

Basic UDI-DI 60913190GDBTG

II. INDICATIONS

The AMARA Wireguided Balloon Dilator is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. Also indicated in adults for endoscopic dilatation of the Sphincter of Oddi following sphincterotomy. (Dilatation Assisted Stone Extraction DASE).

III. INTENDED PURPOSE

To dilate strictures of the alimentary tract and the Sphincter of Oddi during endoscopic procedures.

IV. INTENDED USER

This device should only be used in healthcare setting by physicians who are professionally experienced in the clinical and technical aspects of endoscopic balloon dilation.

V. PATIENT GROUP

Adults and adolescents who do not meet contraindications and regardless of gender.

VI. CONTRAINDICATIONS

Those specific to the primary endoscopic procedure to be performed in gaining access to the dilation site.

Those specific to dilation include, but are not limited to:

- Uncooperative patient
- Asymptomatic rings, webs or strictures
- Inability to advance balloon dilator through strictured area
- Coagulopathy
- Known or suspected perforation
- Severe inflammation
- Scarring near dilation site

PHYSICIAN SHOULD BRIEF THE PATIENT ON CONTRAINDICATIONS AND UNDESIRABLE SIDE-EFFECTS.

VII. WARNINGS

- 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 of the device and/or cause patient infection or cross-infection, including, but not limited to the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Reuse or resterilisation may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness 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, verify functionality and damages. 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 air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium.
- Do not expose the device to organic solvents, e.g. alcohol.
- Do not exceed the Rated Burst Pressure (RBP). The RBP is based on the results of the in vitro testing. At least 99.9% of the balloon (with 95% confidence) will not burst at or below their RBP. Use of a pressure monitoring device is recommended to prevent over pressurization. Inflation in excess of the rated burst pressure may cause the balloon to rupture.
- To reduce the risk of digestive or GI tract damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- Use prior to "use before" date.

VIII. PRECAUTIONS FOR USE

- 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.

IX. UNDESIRABLE SIDE EFFECTS/RESIDUAL RISKS

Complications that may result from this procedure include:

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

X. SELECTION, PREPARATION OF DEVICE COMPATIBILITY WITH ACCESSORIES

1. Open the package and remove Amara Wireguided Balloon Dilator from the pouch.
2. Carefully extend the catheter from the coiled configuration.
3. Insert carefully the guidewire size specified on the packaging label through the guidewire lumen.

Note: Do not pre-inflate, pretest balloon or attempt to refold balloon into protective sleeve.

XI. INTRODUCTION AND DILATATION

Catheter insertion for Dilatation of the Alimentary Tract

The Amara Wireguided Balloon Dilator is designated to pass through the endoscope channel size specified on the package label. Removal of the rubber valve covering the working Channel may facilitate the insertion of larger balloon sizes (ie., 15mm or larger).
1. Attach the balloon to a 60 ml (cc) inflation device with gauge to monitor balloon pressure.
2. To facilitate passage through the endoscope, apply negative pressure to the catheter before removing protective sleeve.
3. Remove the protective sleeve from the balloon.
4. Apply a lubricating agent to the balloon to facilitate passage through the endoscope accessory channel.
5. Maintain vacuum in the catheter during insertion through the scope.
6. Advance the catheter into the endoscope using short deliberate, 2-3cm movements. Due to variations in endoscope construction, some resistance may be experienced immediately upon entering the endoscope and again 2-3cm before exiting the distal end of the working channel.
7. Once the balloon has exited the distal end of the endoscope and is within the endoscopic view, the guidewire may be advanced beyond the distal end of the catheter. To use the guidewire as a catheter guide:
   • Advance guidewire into desired position beyond catheter tip (fluoroscopy is recommended).
   • Advance catheter over extended portion of the guidewire until balloon segment is in desired position.

The Amara Wireguided Balloon Dilator includes 2 radiopaque markers, located under the balloon to help proper placement across the stricture. Match the distal and proximal radiopaque markers of the balloon with the location of the stricture.
8. If desired, a standard 0.035" (0.89mm) guidewire may be placed through the endoscope across the stricture area, and the catheter back loaded over the guidewire.
   Precaution: 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.
9. Once the balloon is in position across the stricture, inflate the balloon per the Balloon Inflation instructions.

Catheter insertion for Dilatation of the Sphincter of Oddi Following Sphincterotomy

The balloon size should be selected based on the size of the stone and must not exceed the diameter of the distal bile duct. Inflate the balloon to the desired diameter by utilizing the balloon OD/Inflation pressure chart. Watch the waist of the balloon to determine complete balloon expansion. Once inflated, maintain position for 10 to 60 seconds until desired effect is reached.

If upon completion of the initial procedure an additional procedure is desired, it may be performed as long as the balloon diameter does not exceed the diameter of the distal bile duct.
1. With the standard 0.035" (0.89mm) guidewire already positioned in the common bile duct, backload the Amara Wireguided Balloon Dilator over the guidewire.
2. Advance the catheter through the scope until it exits the distal end of the scope.
3. Once the balloon has exited the distal end of the duodenoscope and within endoscopic view, advance the balloon catheter over the guidewire.
4. Under fluoroscopic visualization, position the balloon across the Sphincter of Oddi. The Amara Wreguided Balloon Dilator includes 2 radiopaque markers, located under the balloon to help proper placement across the stricture. Match the distal and proximal radiopaque markers of the balloon with the location of the stricture.
5. Once the balloon is in the proper position, inflate the balloon as per the Balloon Inflation instructions.

Balloon Inflation

Balloon must be filled with fluid. Depending on the technique, the balloon can be filled with either sterile water, sterile saline, or a contrast mixture (e.g. 70/30 saline and contrast medium).

Warning: NEVER USE AIR OR A GAS MEDIUM TO INFLATE THE BALLOON.

1. Each Amara Wireguided Balloon Dilator is capable of reaching the 3 distinct diameters listed on the package and hub labels. Inflate the balloon to the pressure corresponding to the smallest balloon diameter and maintain until desired dilatation is achieved. To achieve larger balloon diameters, increase pressure as indicated up to the maximum inflation pressure listed on the catheter hub and package labels.

Warning: 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