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 relation to 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.

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.

STORAGE AND HANDLING

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

PERFORMANCE FEATURES

The balloon is designed to reach specific diameters at specific pressures (see compliance table on the label).

CLINICAL BENEFITS

Facilitation of stone removal, acute dilation of intramural ureter, and restoration of urinary flow.

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
- EC REP — European Representative
- Usable catheter length
- BALLOON — Balloon length

Manufactured by:

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

Distributed by:

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

EC REP

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

CE 1984

Instructions for use ref. 0910001 – Rev 07, 30 Jan 2025 ; CE marking date: 18 May 2021

Tahina

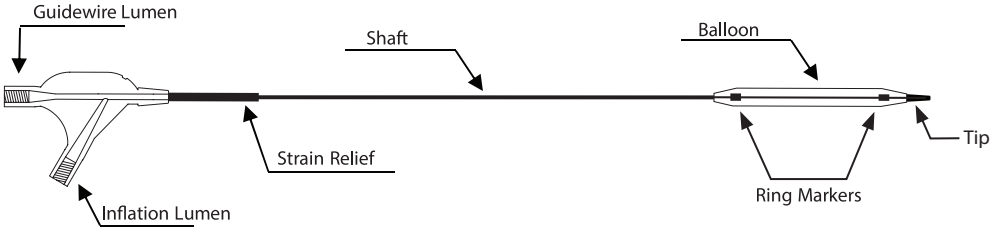
Ureteroscopy

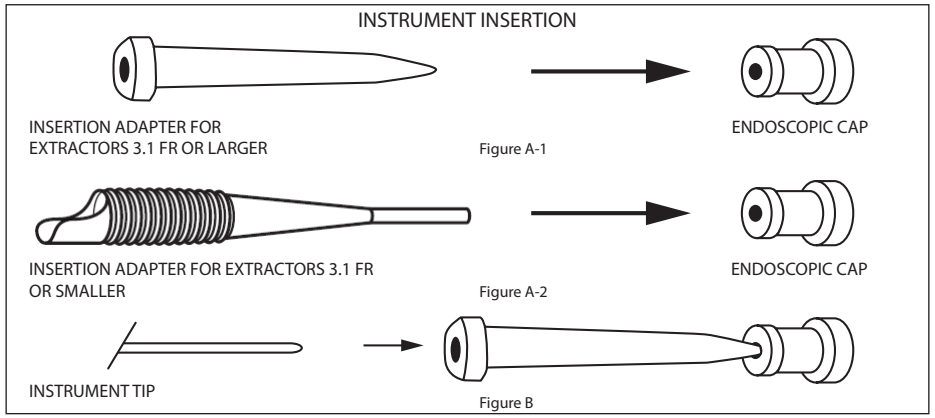
.018"URETEROSCOPY BALLOON DILATOR

INSTRUCTIONS FOR USE

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

CONTENTS: One (1) TAHINA 0.018" Ureteroscopy 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 product label.
The Balloon Nominal Pressure (NP) and Rated Burst Pressure (RBP) are indicated on the label affixed on both the inner package and the packaging box.

Do not exceed the RBP recommendation.

Max Guide Wire Diameter: 0.018" (0.46 mm).
Minimum ureteroscope channel of 5F (1.67 mm / 0.0657").

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.

I. DEVICE DESCRIPTION

The TAHINA 0.018" ureteroscopy balloon dilator is composed of a proximal single-lumen tubing, a single lumen distal shaft 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 guidewire lumen and an inflation lumen.

Catheter length is 75 cm.

Maximum guidewire diameter is 0.018" (0.46 mm).

The balloon is designed to reach specific diameters at specific pressures (see compliance table on the label). The balloon has two radiopaque markers to aid in positioning the balloon relative to the surrounding tissue. The radiopaque marker bands indicate the dilating section of the balloon.

The catheter includes a smooth, soft and tapered atraumatic tip to facilitate advancement of the catheter through the stricture. Hydrophilic coating is present on part of the proximal shaft and balloon in order to facilitate catheter advancing through the target dilatation site.

The TAHINA 0.018" ureteroscopy balloon dilator is available in balloon diameters of 4 and 5 mm and length of 40mm. Nominal balloon diameter and lengths are printed on the inflation leg of the hub and the lot number is printed on the flap between the inflation and guidewire leg of the hub. These details are also printed on the labels.

	Balloon Size	Catheter length	Nominal Pressure	Rated Burst Pressure
Ref #	mm	cm	Atm	Atm
UDB-0204040S	4.0x40	75	8	20
UDB-0205040S	5.0x40	75	8	20

Basic UDI-DI 60913190UDB-029E

II. INDICATIONS

The TAHINA 0.018" ureteroscopy balloon dilator is intended to be used through a ureteroscope for ureteral dilatation prior to stone manipulation or ureteroscopy, and dilatation of the intramural ureter.

III. INTENDED PURPOSE

Ureteral dilation, including the intramural ureter, through a ureteroscope before stone manipulation or ureteroscopy.

IV. INTENDED USER

This device should only be used in healthcare setting by physicians who are professionally trained and experienced in the clinical and technical aspect of ureteroscopy balloon dilation techniques.

V. PATIENT GROUP

Tahina 0.018" Ureteroscopy Balloon Dilator is intended to be used in adults who do not meet contraindications and regardless of gender.

VI. CONTRAINDICATIONS

None known.

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 intramural ureter damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stricture.

• Use prior to "use before" date.

VIII. PRECAUTIONS FOR USE

• Do not pre-inflate the 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.

• Lubrication of the balloon is optional. Use of lubricant may ease placement. Use of a water soluble lubricant is recommended.

• Do not exceed the maximum rated burst pressure (listed on label) for this balloon device.

• A minimum scope channel of 5.0 Fr is required for use of this device.

• To prevent damage to balloon catheter, fully deflate balloon and remove telescope from ureteroscope before withdrawing the balloon.

• To ensure proper regulation of balloon pressure, use of a balloon inflation device and pressure gauge is recommended.

IX. UNDESIRABLE SIDE-EFFECTS/RESIDUAL RISKS

Complications that may result from this procedure include:

• Over inflation of the balloon, this could result in trauma to the surrounding tissues.

• Failure to break and retrieve the stone: an alternative procedure may be necessary.

• Perforation of the ureter: usually a JJ stent is required for a few weeks after such an injury.

• Detachment of the ureter from kidney: this is very rare and is sometimes unavoidable, but may require open surgery to repair.

• Abdominal or back discomfort.

• Bleeding: this usually settles quickly.

• Urine infection: this usually requires antibiotics only.

PHYSICIAN SHOULD BRIEF THE PATIENT ON UNDESIRABLE SIDE -EFFECTS.

X. SELECTION, PREPARATION OF DEVICE COMPATIBILITY WITH ACCESSORIES

Prior to ureteroscopy dilatation, carefully examine all equipment to be used during the procedure, including the dilatation catheter, to verify proper function.

Verify that the catheter and the sterile inner packaging have not been damaged in shipment and that the catheter size is suitable for the specific procedure for which it is intended.

Selection of balloon size and compatibility with accessories:

The expanded diameter of the balloon should not exceed the inner diameter of the stricture area. Verify that the selected accessories accommodate the balloon catheter as labeled.Prepare the inflation device according to the manufacturer's instructions.

Balloon Catheter Preparation:

1. Remove the catheter from its packaging and place in the sterile field.
2. Inspect the balloon catheter to ensure no damage has occurred during shipment.
3. Connect a stopcock to the connector of the balloon lumen and flush thoroughly. Connect a 10ml syringe partially filled with contrast medium and saline solution to the stopcock. Never use air or any gaseous medium to inflate the balloon.
4. Hold the catheter with the distal tip pointing down and apply negative pressure with the syringe to evacuate all air from the balloon. Maintain the suction for 20 to 30 seconds and make sure that no bubbles are seen passing through the diluted contrast medium. Close the stopcock, release the plunger carefully and disconnect the syringe.
5. Carefully remove the protection tubing from the balloon and discard.
6. Flush the guidewire lumen by connecting a syringe prefilled with saline solution onto the "guidewire leg" of the hub. **Note:** all air should be expelled from the balloon lumen prior to inserting the dilatation catheter. Do not attempt pre-inflation technique to purge the balloon lumen.

XI. INTRODUCTION AND DILATATION

1. Attach the endoscopic cap to the accessory channel of the ureteroscope.
2. If the set contains an instrument insertion adapter, place the adapter securely into the endoscopic cap on the scope (Figure A-1 and Figure A-2), then carefully insert the instrument into the scope (Figure B).
3. Advance the catheter through the accessory channel down the length of the scope.
4. When the ureteroscope is positioned as desired, advance the catheter until the entire balloon extends beyond the end of the scope.
5. Fill the syringe with dilute (30 percent solution) contrast medium. Eliminate air from the syringe.

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

6. Lock the syringe onto the stopcock. Open the stopcock and inflate the balloon to recommended pressure.

Warning: To prevent balloon burst, do not exceed the RBP recommendation written on the labels. If the balloon does rupture or a significant loss of pressure within the balloon occurs, deflate the balloon completely and carefully remove from the ureteroscope together as a unit. Do not attempt to withdraw a ruptured balloon through the ureteroscope. Continue procedure with a new catheter.

7. Close the stopcock for at least 30 seconds to maintain pressure and allow adequate dilatation.
8. Time, rather than excessive pressure, is the key factor in ureteral dilatation.
9. Deflate the balloon via syringe aspiration.

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

Warning: THE BALLOON MUST BE THROUGHLY DEFLATED AND ALL FLUID REMOVED PRIOR TO WITHDRAWAL.

10. Slowly remove the catheter from the ureteroscope.

Precaution: if excessive resistance is felt, remove the ureteroscope together as a complete unit to prevent damage to body tissue, the catheter or ureteroscope.

11. 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