-toscope together as a complete unit to prevent damage to body tissue, the catheter or cystoscope.
8. 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
- EC REP — European Representative
- Usable catheter length
- BALLOON — Balloon length
- 15°C 40°C — Temperature limitation

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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EC REP

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

CE 1984

Instructions for use ref. 0910003 – Rev 08, 18 Sept 2025 ; CE marking date: 18 May 2021

Tahina

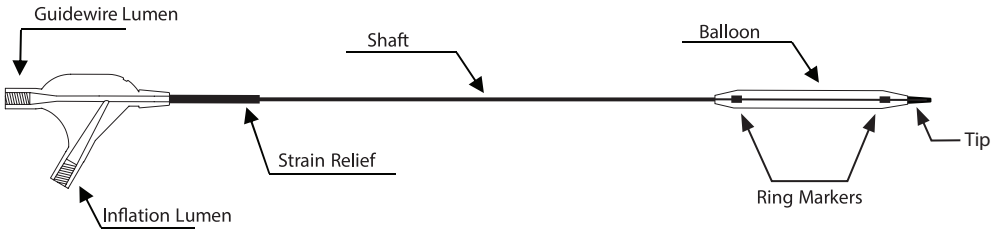
Ureteral

.038" URETERAL 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 .038" Ureteral 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: 0.038" (0.97 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 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

Management of ureteral strictures, facilitation of stone removal and restoration of urinary flow.

I. DEVICE DESCRIPTION

The TAHINA 0.038" Ureteral 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 guide wire lumen and an inflation lumen. Catheter length is 75 cm.

Maximum guidewire diameter is 0.038" (0.97 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 stenosis. 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 stenosis. Hydrophilic coating is present on part of the proximal shaft and balloon in order to facilitate catheter advancing through the vascular district and the vessels stenosis.

The TAHINA .038" Ureteral Balloon Dilator is available with balloon diameters of 4.00, 5.00 and 6.00 mm with lengths of 40, 60, 100 mm. Nominal balloon diameter and lengths are printed on the inflation leg of the hub and lot number is printed on the flap between the inflation and the guidewire leg of the hub. These details are also printed on the label.

	Balloon Size	Catheter length	Nominal Pressure	Rated Burst Pressure
Ref #	mm	cm	Atm	Atm
UDB-0104040S	4.0x40	75	8	20
UDB-0104060S	4.0x60	75	8	20
UDB-0104100S	4.0x100	75	8	18
UDB-0105040S	5.0x40	75	8	20
UDB-0105060S	5.0x60	75	8	20
UDB-0105100S	5.0x100	75	8	18
UDB-0106040S	6.0x40	75	8	20
UDB-0106060S	6.0x60	75	8	20
UDB-0106100S	6.0x100	75	8	18

Basic UDI-DI 60913190UDB-019C

II. INDICATIONS

The TAHINA .038" Ureteral Balloon Dilator is indicated for ureteral dilation prior to stone manipulation or ureteroscopy, and dilation of the intramural ureter.

III. INTENDED PURPOSE

Ureteral dilation, including the intramural ureter, 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 ureteral balloon dilatation.

V. PATIENT GROUP

Tahina 0.038" Ureteral 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

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

• Do not pre-inflate balloon.

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

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

• This device is intended for single (one) use – only do not re-sterilize and/or reuse, as this can potentially result in compromised device performance and increase risk of complications (patient infection, transmission of infectious disease, etc…).

IX. UNDESIRABLE SIDE EFFECTS/RESIDUAL RISKS

Complications that may result from this procedure include:

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

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

• Abdominal or back discomfort.

• Delayed bleeding or hemorrhage

• Infection leading to septicemia.

PHYSICIAN SHOULD BRIEF THE PATIENT ON UNDESIRABLE SIDE -EFFECTS.

X. SELECTION, PREPARATION OF DEVICE COMPATIBILITY WITH ACCESSORIES

Prior to dilation, 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. Connect the prepared prefilled inflation device to the stopcock and hand-tight the hubs securely.
7. Open the stopcock and ensure that a meniscus of contrast medium is seen in balloon port.
8. 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. Under fluoroscopic control, cystoscopically pass a guidewire (up to 0.038" in diameter) the desired distance into the ureter beyond the area of planned dilatation.
2. Activate the catheter hydrophilic coating by immersing the balloon and catheter in a sterile physiological solution for approximately 30 seconds.
3. Carefully advance the balloon catheter over the previously placed guidewire under fluoroscopic guidance utilizing the radiopaque markers to ensure proper positioning. Advance the catheter so that the entire balloon exceeds beyond the end of the cystoscope before inflating the balloon.
4. Inflate the balloon until the desired inflation pressure is reached and maintain pressure.

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

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 cystoscope together as a unit. Do not attempt to withdraw a ruptured balloon through the cystoscope.

Continue procedure with a new catheter.

5. Close the stopcock on the inflation device for at least 30 seconds to maintain pressure and allow adequate dilatation. Time, rather than excessive pressure, is the key factor in Transluminal dilatation.
6. 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 THOROUGHLY DEFLATED AND ALL FLUID REMOVED PRIOR TO WITHDRAWAL.

7. Slowly remove the catheter from the cystoscope.

Precaution: if excessive resistance is felt, remove the cys-