IX. 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 affect 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..

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 protection tubing in a hoop, one (1) Amplatz sheath).
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 40º C. Keep away from light.

LABELING SYMBOLS DEFINITION

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

Manufactured by:

NATEC Medical Ltd.
Maeva Centre Building,
Silicon Avenue,
Ebene Business Park,
Reduit 72201, Mauritius
www.natec-medical.com

Distributed by:

Envaste Ltd.
Maeva Centre Building,
Silicon Avenue,
Ebene Business Park,
Reduit 72201, Mauritius
www.envaste.com

EC REP
EMERGO EUROPE
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

CE 0459

Instructions for use ref. CO000799 – Rev 04/2017 , CE marking date: May 2013

Nephrostomy

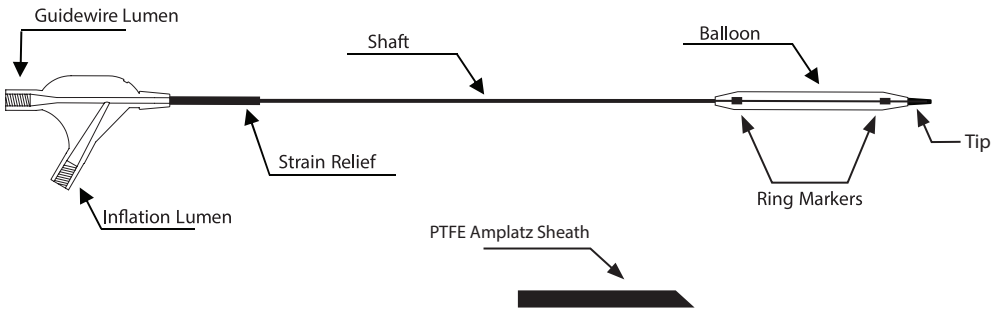
Tahina

NEPHROSTOMY BALLOON CATHETER

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 Nephrostomy Balloon Catheter and One (1) Amplatz sheath, both sterilized with ethylene oxide gas. Non-pyrogenic.



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)
A PTFE radiopaque Amplatz Sheath matching the balloon size is supplied.
After use, dispose product and packaging in accordance with hospital, administrative and/or local government policy related to product contaminated by blood. For one time use only. Do not reuse. Do not re-sterilize. Read instructions prior to use.

I. DEVICE DESCRIPTION

The TAHINA Nephrostomy dilatation balloon catheter 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. A PTFE radiopaque Amplatz sheath matching the balloon size is supplied.

Catheter length is 55 cm.

PTFE radiopaque Amplatz sheath length is 17 cm.

Maximum guide wire 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 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 surrounding tissue. Hydrophilic coating is present on the balloon in order to facilitate catheter advancing through the target dilatation site and ease placement of the Amplatz sheath.

The TAHINA Nephrostomy Balloon Catheter is available in balloon sizes of 8 and 10 mm. Nominal balloon diameter and lengths are printed on the inflation leg of the hub and lot number is printed on the flap between inflation and guide wire leg of hub. These details are also printed on the label.

II. INDICATIONS

The TAHINA Nephrostomy Balloon Catheter is indicated to dilate the musculofascia, renal capsule and parenchyma to establish and maintain a percutaneous tract.

III. CONTRAINDICATIONS

None known.

IV. 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, to verify functionality and lack of damaged parts. 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 nephrostomy tract, 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.
- Only physicians thoroughly trained and educated in the performance of PCNL and nephrostomy balloon dilatation should use this device. Physicians should keep themselves informed and updated on recent publications about PCNL and nephrostomy balloon dilatation techniques.
- Use prior to "use before" date.

V. PRECAUTIONS FOR USE

- This device is intended for use by physicians trained and experienced in techniques for balloon catheter dilation.
- Lubrication of the balloon is optional. Use of lubricant may ease placement. Use of water soluble lubricant is recommended.
- Do not pre-inflate the balloon.
- Do not exceed the maximum rated burst pressure (listed on label) for this balloon 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…).

VI. POTENTIAL COMPLICATIONS

Complications that may result from this procedure include

- Over inflation of the balloon, this could result in trauma to the surrounding tissues.
- Significant loss of functioning kidney tissue.
- Blocking of a kidney artery.
- 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.

VII. SELECTION, PREPARATION OF DEVICE COMPATIBILITY WITH ACCESSORIES

Prior to nephrostomy 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 Amplatz sheath. 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 and Amplatz sheath from its packaging and place in the sterile field.
2. Inspect the balloon catheter and Amplatz sheath 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 though 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 guide wire lumen by connecting a syringe pre-filled with saline solution onto the "guidewire leg" of the hub.
9. Backload the Amplatz sheath over the balloon and secure it at the proximal end of the catheter.
10. Verify that the sheath is properly oriented with the beveled tip distal on the balloon catheter.

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.

VIII. INTRODUCTION AND DILATATION

1. Under fluoroscopic control, pass a guide wire (up to 0.038" in diameter) at the desired distance through the renal capsule and beyond the area of planned dilatation.
2. Carefully advance the balloon catheter over the previously placed guide wire under fluoroscopic guidance utilizing the radiopaque markers and into final position in the kidney.
3. 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 dilation site. Continue procedure with a new catheter.

4. Advance the Amplatz sheath over the inflated balloon and into the proper position.

Note: The tolerances of the sheath and the inflated balloon are very close. If resistance is encountered when advancing the sheath, it may be necessary to decrease balloon inflation to facilitate sheath passage.

5. 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.

6. Gently remove the device. Removal of the catheter is facilitated by rotating the shaft counterclockwise during withdrawal. Using excessive force to withdraw the balloon can inflict trauma to tissue.
7. While removing the balloon catheter, carefully hold the sheath in place, ensuring its position has not changed.
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.