Allium Ureteral Stent (URS)

Instructions For Use

Manufactured by

Allium Ltd.
**DEVICE NAME:**

**ALLIUM Ureteral Stent (URS)** is intended to be inserted into the lower ureter to allow free flow of urine from the kidney to the bladder by supporting the obstructed area of the ureteral lumen, keep it open and prevent its re-obstruction.

The **ALLIUM Ureteral Stent** is intended for endoscopic (retrograde), percutaneous (antegrade) insertion or combined antegrade/retrograde insertion (under cystoscopic and fluoroscopic guidance) into the ureter of patients diagnosed with chronic ureteral obstruction caused by benign or malignant causes. It is intended to remain in the ureter up to 1 year.

**DEVICE DESCRIPTION:**

The **ALLIUM Ureteral Stent** are offered in 2 configurations:

- The URS stent equipped with an anchor
- The URS-O-R stent without an anchor.

Both stents have a tubular shape body with a high radial force segment to keep open the stenosed part after its dilation, and low radial force upstream end for reducing friction between the upper end of the stent and the ureter. The aim of the low radial force downstream end is to adapt to the shape and function of the intramural ureteral segment and prevent or reduce vesicoureteral reflux. The URS anchoring intravesical segment is for preventing upward migration.

The URS has 3 radiopaque markers at each end and 1 at the anchor.

The URS-O-R has 3 radiopaque markers at each end.

The **ALLIUM Ureteral Stent** system is composed of 2 main elements:

1. The stent
2. Deployment device

The stent has a metal structure with self-radial-expanding design (24 or 30 Fr in expanded diameter), completely covered with a thin layer of polymeric material and is easy to remove. The Ureteral stents have radiopaque markers to enhance their fluoroscopic visibility: The URS-O-R stent has 3 radiopaque markers at both ends and the URS stent have another single radiopaque marker on the anchor. Once inserted into the occluded ureter using the specially designed 10 Fr deployment device the stent is released for self-expansion in the occluded part of the ureter. The stent does not change its length during deployment. Following deployment the deployment device is then carefully removed from the body.

**URS Insertion system**

The deployment device for retrograde insertion has a black outer visual marker (OVM) on the overtube and beneath it 4 yellow inner visual markers (IVM) on the inner tube, both indicating the place of the wire connecting the anchor to the body of the stent.
The deployment device for **antegrade insertion** has a **black outer visual marker (OVM)** on the overtube and beneath it a **yellow inner visual marker (IVM)** on the inner tube, both indicating the place of the wire connecting the anchor to the body of the stent.

**Allium Ureteral Stent (URS) Ordering Information**

**Retrograde Delivery System with anchor -80 cm**

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<thead>
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**Antegraded Delivery System with anchor -80 cm**

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<td>URS-A-10-120</td>
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**URS-O-R Insertion system**

**R-** A radiopaque marker on the overtube that mark the beginning of the high radial force segment of the stent.

**OVM-** A **black outer visual marker** on the overtube mark the distal end of the high radial force segment.

**IVM - 4 yellow inner visual markers** on the inner tube, indicating the distal end of the stent.

**URS-O-R-Retrograde System**

**Allium Ureteral Stent (URS-O-R) Ordering Information**

**Retrograde Delivery System Without Anchor -80 cm**

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INDICATIONS FOR USE:
ALLIUM Ureteral Stents are indicated for use in malignant or benign ureteral occlusions necessitating long-term or chronic ureteral stenting (i.e. patients indicated for inserting double-J stents for 6 months or longer):
- Pelvic malignancies compressing the ureter
- Non-operative, occluding, primary or infiltrative ureteral malignancies
- Uretero-intestinal anastomotic strictures
- Latrogenic benign strictures of the ureter

CONTRAINDICATIONS
The insertion of ALLIUM Ureteral Stent is contraindicated in patients who
- Have an active urinary tract infection (increased WBC count, fever, chills etc) or has had two diagnosed acute urinary tract infections in the past year accompanied with increased WBC count, fever, chills.
- Have a hematuria that has not been previously evaluated and treated.
- Cannot tolerate any form of antibiotic treatment.
- Have a post-surgical anatomy that precludes cystoscopic or percutaneous approach.
- Currently are receiving any anticoagulation therapy (patients should stop it at least a week before stent insertion).
- Have a history of allergy to iodine preparations.
- Have a history of illness, medication or surgery that may affect the efficacy of the stent.

POTENTIAL COMPLICATIONS
Potential complications associated with insertion of the Allium Ureteral Stents (URS) are similar to all other ureteral stents. They may include, but are not limited to the following:
Failure to access the obstructed site, pain/discomfort, perforation of the ureter, bleeding, urinary frequency or urgency, stent misplacement or migration, stent obstruction by tissue or stone, infection, sepsis, allergic reaction to the nickel-titanium alloy irritation. Mild hematuria is possibly to occur and related to device insertion, particularly during the first few days after insertion. If the symptoms persist patients should be instructed to contact their physician.

PRECAUTIONS
Checking the device: The device should be visually inspected for any damage prior to use. If any damage to the product or to its sterile packaging is observed THE DEVICE SHOULD NOT BE USED.
Training: Proper training is required to position and deploy the Allium Ureteral Stents. Prior to its use; the technical information supplied with this device should be carefully reviewed.
Stent positioning: Manipulation of the deployment device and stent positioning should be done using high-quality endoscopic and fluoroscopic equipment.

WARNINGS
General:
- The Allium Ureteral Stents (URS) are indicated to be used in the ureter when the occlusion is not involving the intramural ureter or the ureteral orifice. Its design allows inserting the main body into the occluded ureter with its lower soft segment at the intramural part. At the end of the delivery, the anchoring segment should be situated in the bladder.
- If the intramural part or the ureteral orifice is involved in the occlusion it is recommended to use the URS-O-R and leave 1 cm of the main body (the high radial force segment) protruding through the orifice into the bladder. Stents used in this localization have a higher tendency for migration toward the bladder.
- The Allium Ureteral Stents are not intended for definitive treatment of ureteral diseases or of the complications of ureteral diseases.
- The Allium Ureteral Stents and their delivery mechanism should not come in contact with organic solvents at any time before their use.
- Allium Ureteral Stents should not be used in blood vessels.

Device Related:
Note that the mounting of the Allium Ureteral Stent (URS) to the deployment systems for retrograde and antegrade insertion are different. The "Retrograde System" cannot be
used for antegrade insertion and the "Antegrade System" cannot be used for retrograde insertion.

- **Single use device:** The Allium Ureteral Stent (URS) is intended for Single Use Only-DO NOT RESTERILIZE.
- Reuse, reprocessing, resterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient.
- Reuse, reprocessing, resterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user.
- The device should not be used if the package is open or damaged or if the device has been contaminated prior to insertion.
- The constricted stent and delivery system should be visually inspected for damage prior to use.
- Re-mounting an expanded stent into the delivery system should not be attempted.
- Re-use of the stent should not be attempted. This can seriously damage the patient’s health.
- The stent should only be placed under cystoscopic visualization (retrograde insertion) or under direct fluoroscopic visualization combined with cystoscopic guidance (antegrade insertion).
- Catheterization through an implanted stent is not recommended. Introduction and passage of a catheter through the stented ureter into the kidney may dislodge the stent and/or damage the cover.
- Transureteral instrumentation while the stent is in place is not recommended. Longitudinal compression of the stent by instrumentation could dislodge the stent.
- The stent may migrate during and after placement: If this occurs, the stent should be removed and a new one may be considered for insertion instead.

**DIRECTIONS FOR USE**

**Pre-procedural preparation**

The antibiotic prophylaxis for each patient is a broad spectrum oral or intravenous antibiotic to be started at least 3 hours before the procedure and continued according to protocols used by the hospital for percutaneous or endoscopic transurethral double-J stent insertion procedures.

**Choosing the appropriate URS**

**Components of the Deployment Device**

A - Inner tube with a channel for passing the guide-wire, ending with a Luer connector covered with a vented cap

B - Locking knob of the Y-connector

C - Irrigation port of the Y-connector

D - Over-tube covering the stent

OVM - Black visual marker on the over-tube

IVM - 4 Yellow visual markers on the inner tube
The Biliary Stent was determined to be MR-conditional. Non-clinical testing demonstrated that the Biliary Stent is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

**Static Magnetic Field**
- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

**MRI-Related Heating**
In non-clinical testing, the Biliary Stent produced the following temperature rises during MRI performed for 15-min of scanning (i.e., per pulse sequence) in 1.5-Tesla/64-MHz (Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner) and 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR systems:

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<tbody>
<tr>
<td>MR system reported, whole body averaged SAR</td>
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<td>2.9-W/kg</td>
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<tr>
<td>Calorimetry measured values, whole body averaged SAR</td>
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<td>2.7-W/kg</td>
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<tr>
<td>Highest temperature change</td>
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<td>+3.5°C</td>
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</table>

These temperature changes will not pose a hazard to a human subject under the conditions indicated above.

**Artifact Information**
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Biliary Stent. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 5-mm relative to the size and shape of this implant.
System Preparation:
Prior to insertion of the stent and as part of its preparation the deployment device should be flushed as following:
1. Ensure that the Y-connector knob (B) is closed tightly.
2. Fill a syringe with 5-10 ml irrigation water/saline solution.
3. Connect the syringe to the irrigation port (C) of the Y connector.
4. Slowly flush the system while making sure that the water is coming out between the over-tube tip and the conical tip (D). Flushing the system is a must for easy and smooth deployment of the stent.
5. After irrigation, open the Y-connector knob (B) and ensure that it remains open completely during deployment of the stent.

Identifying, Measuring and Dilation of the Ureteral obstruction and Stent Insertion:

Instructions for URS Retrograde Insertion:

- Perform a retrograde ureterography to identify, mark and measure the site and length of the occlusion and its distance from the ureteral orifice. This is done by marking the landmarks using external radiopaque markers applied to the skin. If the patient has a nephrostomy catheter the ureterography can be performed antegrade. Measuring is done under a combination of endoscopy and fluoroscopy using a ureteral catheter.
- Use a cystoscope (21 Fr or larger) with a single working channel allowing passage to 10-12 Fr instruments.
- Choose the "Retrograde System" with the appropriate stent length (the upstream end of the stent should be at least 10 mm above the upper end of the occlusion).
- Pass a 0.035" guide-wire through the occlusion.
- Under fluoroscopy perform dilatation of the stenosis to at least 14 Fr.

Leaving the guide wire in place insert the stent mounted on its 10 Fr deployment device through the working channel of the cystoscope into the ureter and advance it until the black outer visual marker (OVM) is at the ureteral orifice.

- Holding the stent in position, verify that the knob (B) of the Y-connector is open.
- Pull the Y-connector towards the rear Luer (A) carefully, using a constant force while holding the rear Luer (A) firmly fixed. This pulling will move backward the black outer visual marker (OVM).
- Ensure the correct positioning of the stent by identifying the yellow inner visual markers (IVM) at the ureteral orifice. At least 3 of the 4 markers should remain below the orifice during the entire deployment procedure.
- Under fluoroscopy, follow the expansion of the stent (expansion of the 3 radiopaque markers at the upstream end).
- Continue pulling the over-tube until the anchoring segment is released completely and is seen in the bladder.
- After complete expansion of the stent, verify that the stent has been completely released from the deployment system by gently pushing it in and out.
- Under fluoroscopic and/or endoscopic control carefully remove the deployment device, taking care not to dislodge the stent.
- After removing the entire deployment device remove the guide wire.

Instructions for URS-O-R Retrograde Insertion:

- If the intramural part or the ureteral orifice is involved in the occlusion, perform a retrograde ureterography to identify, mark and measure the site and length of the occlusion and especially the existence of additional proximal strictures. This is done by marking the landmarks using external radiopaque markers applied to the skin. If the patient has a nephrostomy catheter, the ureterography can be performed antegrade. Measuring is done under a combination of endoscopy and fluoroscopy using a ureteral catheter.
- Use a cystoscope (21 Fr. or larger) with a single working channel allowing passage of 10-12 Fr instruments.
• Choose the “URS-O-R Retrograde System” with the appropriate stent length (the upstream end of the stent should be at least 1 cm above the upper end of the occlusion and at least 1.5 cm of stent body protruding into the bladder).
• Pass a 0.035” guide-wire through the occlusion.
• Under fluoroscopy perform dilatation of the stenosis to at least 14 Fr.

Leaving the guide wire in place, insert the guide wire into the tip of the 10 Fr deployment device.

Carefully advance deployment device over the guide wire through the working channel of the cystoscope.

Using fluoroscopy guidance, advance the deployment device over the guide wire into the ureter until the black outer visual marker (OVM) is at the ureteral orifice.

• Holding the stent in position, verify that the knob (B) of the Y-connector is open.
• Pull the Y-connector towards the rear Luer (A) carefully, using a constant force while holding the rear Luer (A) firmly fixed. This pulling will move backward the black outer visual marker (OVM).
• Ensure the correct positioning of the stent by identifying that all the yellow inner visual markers (IVM) are 1 cm from the ureteral orifice during the entire deployment procedure.
• Under fluoroscopy, follow the expansion of the stent (expansion of the 3 radiopaque markers at the upstream end).
• Continue pulling the over-tube until the distal segment is released completely and is seen in the bladder by the cystoscope.
• After complete expansion of the stent, verify that the stent has been completely released from the deployment system by gently pushing it in and out.
• Under fluoroscopic and/or endoscopic control, carefully remove the deployment device, taking care not to dislodge the stent.
• After removing the entire deployment device remove the guide wire.

Instructions for Antegrade Insertion under Endoscopic and Fluoroscopic Guidance:
• Insert a nephrostomy catheter to the kidney.
• Under fluoroscopy perform an antegrade ureterography through the nephrostomy catheter.
• Identify the obstructed area and mark the target area for the stent using external radiopaque markers applied to the beginning and the end of the obstruction.
• Measure the distance between the upstream end of the obstruction and the ureteral orifice by retrogradely inserting a ureteral catheter.
• Insert antegradely a 0.035” guide-wire toward the bladder passing the occlusion. Verify that the distal end of the guide-wire starts to loop in the bladder.
• Pull the bladder end of the guide wire until it comes out from the urethral meatus.
• If a standard length guide wire is used hold firmly its proximal and distal ends with a strong forceps to prevent its accidental entering into the nephrostomy tract or the urethra.
• Dilate the obstructed area using a dilatation balloon inserted either antegradely or retrogradely to at least 14 Fr.
• Choose the “Antegrade System” with the appropriate stent length (the upstream end of the stent should be at least 10 mm above the upper end of the occlusion)
• Make sure that 100 cm of the guide-wire is out of the nephrostome.
• Over the guide-wire insert antegradely the stent mounted on its deployment device into the ureter and advance it to pass the occlusion area. Follow passage of the stent through the occlusion by fluoroscopy and entering of the tip of the deployment system into the bladder using a flexible cystoscope.
• Verify that the black outer visual marker (OVM) enters the bladder.
• Holding the stent in position, verify that the knob (B) of the Y-connector is open.
• Pull the Y-connector towards the rear Luer (A) carefully, using a constant force while holding the rear Luer (A) firmly fixed. This pulling will move backward the black outer visual marker (OVM) which will enter into the orifice.
• Ensure the correct positioning of the stent by identifying at least 3 of the yellow inner visual markers (IVM) are at the ureteral orifice. This marker should remain below the orifice during the entire deployment procedure.
• Under fluoroscopy, follow the expansion of the stent.
• After complete release of the stent pull backward the deployment device until it reaches the upper ureter and perform an antegrade ureterography by injecting contrast through the irrigation port (C) to verify accurate stent placement.
• Carefully remove the entire deployment device through the nephrostomy tract
• Remove the guide wire.
• Leaving a nephrostomy catheter after stent insertion for a few days is optional.

Instructions for Combined Antegrade-Retrograde insertion:
An alternative technique for inserting the Allium Ureteral Stent (URS) is the combined antegrade-retrograde insertion. In such a combined approach dilation of the occlusion can be done either retrogradely or antegradely.
• Pass antegradely a double-length guide-wire into the bladder through the nephrostomy tube.
• Turn the patient to a lithotomy position.
• Pull the bladder end of the guide wire at least 100 cm out of the urethral meatus.
• Insert the stent mounted on a “Retrograde System” following the Instructions for Retrograde Insertion described above.

Suggested Patient Follow Up:
Patients implanted with Allium Ureteral Stent (URS) should be followed like the patients inserted a double-J ureteral stent.

Stent Removal Steps
The Allium Ureteral Stent (URS) is a temporary device and is designed to be easily removed from the ureter.
• The Allium Ureteral Stent (URS) can be removed under vision (endoscopically).
• Removal of stent should be done under sedation, general or regional anesthesia.
• Under cystoscopic vision the anchoring segment is identified and engaged with a foreign body forceps.
• Pulling the engaged stent outward together with the working element may initiate unraveling of the stent.
• All the elements together with the cystoscope are pulled outward.
  For verifying that the entire stent came out the second small wire loop at the up-stream end of the stent should be seen on the removed stent.

DISCLAIMER OF WARRANTIES
Allium, Ltd. warrants that reasonable care has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties whether expressed, implied, written or oral, including but not limited to any warranties of merchantability of fitness for a particular purpose. As a result of biological differences in individuals, no product is 100% effective under all circumstances. Because of this fact, and since Allium, Ltd. has no control over the conditions under which the device is used, diagnosis of the patient, methods of administration or its handling after the device leaves our possession, Allium, Ltd. does not warrant either a good effect or against any ill effect following its use. Allium, Ltd. shall not be liable for any incidental or consequential loss, damage, or expense arising directly or indirectly from the use of this device. Allium, Ltd. will replace any device that we feel was defective at the time of shipment. No representative of Allium, Ltd. may change any of the foregoing or assume any additional liability or responsibility with this device.
## Labeling Information

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For further questions or information, please contact the manufacturer:

**Allium, Ltd.**  
Ha-Eshel 2  
P.O.BOX 3081  
Caesarea Industrial Park 38900 Israel  
**Phone:** +972 – 4 - 6277 166  
**Fax:** +972 – 4 - 6277 266  
E-mail: info@allium-medical.com  
**REF:** 243-0127  

**Authorized Representative in the European Committee**  
**MEDNET GmbH**  
Borkstrasse 10  
D-48163 Munster  
Germany