Allium
Bulbar Urethral Stent System (BUS)

Instructions For Use

Manufactured by
Allium Ltd.
Device Name: *Allium Bulbar Urethral Stent (BUS)*

**Device Description:**
The **BUS** is a temporary device intended for transurethral insertion into the male urethra diagnosed with a stricture of the bulbar urethra. It is a single use device intended to remain in the urethra up to 1 year, to open the occluded urethral passage and allow spontaneous urination. The stent is comprised of a coiled super-elastic structure covered with a copolymer. Once inserted into the urethra with the aid of its special inserter, the stent is released to allow its self-expansion.

The **BUS** has a round body to tutor the bulbar urethra after being dilated. Since the caliber of the stent is larger than the penile urethra, this stent do not need to have an anchor.

The **BUS** System includes:
1. A **Meatal Shield** (for optional use in narrow urethral meatus) (Figure 1)
2. A delivery tool containing the **BUS** crimped into a 24 Fr tube mounted on a deployment handle (Figure 2)

The **BUS** set contains an optional “**Meatal Shield**” to prevent trauma to the meatus and distal urethra during insertion of the delivery device. It is recommended to be used when the urethral meatus is smaller than 24 Fr. The device is composed of a sheath (b) and a mandrel (c). The mandrel of this shield also acts as a progressive dilator to the meatus and the distal urethra, allowing secure insertion of the 24 Fr delivery tool.

**Figure 1- Components of the Meatal shield:**
a - Assembled Meatal Shield
b - Urethral Tube
c - The dilating conical tip mandrel with a central channel to allow passage to a guide wire

**Figure 2 - The Endoscopic Delivery Tool for Deploying the BUS**
(Note that the optical element is mounted and locked in place)

**Pre Treatment Evaluation of BOO:**
It is recommended to perform the following basic evaluation prior to initiation of treatment for Bladder Outlet Obstruction (BOO) with a stent: history, physical examination, PVR (post-void residual urine), DRE (digital rectal examination), prostate sonography (abdominal and/or trans-rectal), uroflowmetry, PSA (prostate specific antigen), urethrography and urinalysis.
If indicated by the results of the basic evaluation, a more extensive workup may be required.

**Indications for Use:**
The use of the **BUS** System is indicated for the management of BOO caused by bulbar urethral strictures. The **BUS** is not intended for definitive treatment of urethral strictures.

**Contraindications:**
The insertion of a **BUS** is contraindicated in men who:
1. Are younger than 18.
2. Have an acute infection of the prostate or urethra.
3. Have an acute upper urinary tract infection.
4. Are immuno-compromised, have a prosthetic heart valve or other implanted device, or have any other conditions in which the patient is at significant risk from urinary tract infection.
6. Are currently receiving anticoagulation therapy.
7. Have irreversible atonic/acontractile bladder.
8. Have a urethro-cutaneous or urethra rectal fistule.
10. A history of any illness, medications or surgery that may affect the efficacy of the stent.
11. Patients who use “constriction rings” and/or vacuum erection devices.
12. Patients who use injectable medications to obtain erection.
13. Patients with penile implants and/or implanted artificial urinary sphincters.

**Informing Patients, Potential Adverse Events and Complications:**
- It should be explained to patients that the stent is used instead of repeated urethral dilations or endoscopic manipulations of their recurring stricture.
- Patients should be informed about post-voiding urinary dribbling and post-ejaculatory seminal dribbling.
- Some patients can develop reactive tissue proliferation at one or both ends of the stent. This tissue can cause a secondary obstruction. The possibility of such an occurrence has to be explained to the patients. In most cases this tissue disappears spontaneously after stent removal.

**Precautions:**
- **Checking the device:** The constricted stent and delivery system should be inspected for damage prior to use. Prior to delivery, the physician should ensure that the stent is covered by the over-tube.
- **Training:** Proper training is required to position and deploy the **BUS**. Prior to its use, the technical information supplied with the device should be carefully reviewed.

**Device Related Warnings:**
- Single use device: The **BUS** 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 stent and delivery system should be inspected for damage prior its use.
- Remounting of a stent into the delivery system should not be attempted, since this will damage the cover of the stent.
- Positioning of the main body of the stent across the external sphincter may render the patient incontinent.
- The stent is intended to be used for a period of up to 1 year and is not intended as a permanent option to treat urethral obstructions.
- Bladder catheterization with an implanted stent is not recommended. Introduction and passage of a catheter through the stented urethra into the bladder may dislodge the stent and/or damage the polymeric cover.
- The use of transurethral instrumentation while the stent is in place is not recommended because longitudinal compression of the stent by instrumentation could dislodge the stent.
- The stent should be inserted and positioned only according to the Instructions for Use (IFU) accompanying the device.
- Under-vision insertion should not be attempted in patients in whom bleeding may impede the visualization process.
- The stent should not be used in patients with bladder stones.
- The stent may migrate during and after placement. If this occurs, the stent should be removed and a new one inserted.

**INSERTION INSTRUCTIONS FOR THE BUS**

The BUS is a temporary device intended for transurethral insertion into the Proximal Anterior Urethra. The BUS once inserted into the bulbar urethra with the aid of its endoscopic delivery tool, is released to allow its self-expansion.

The BUS is available in 3 lengths:

<table>
<thead>
<tr>
<th>Catalogue No.</th>
<th>Body Length [mm]</th>
<th>Main Body Caliber</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUS-50</td>
<td>50</td>
<td>45 Fr</td>
</tr>
<tr>
<td>BUS-55</td>
<td>55</td>
<td>45 Fr</td>
</tr>
<tr>
<td>BUS-60</td>
<td>60</td>
<td>45 Fr</td>
</tr>
</tbody>
</table>

**Figure 4 - BUS segments and their correlation with the proximal anterior urethral anatomy**

*Note:* The "body" of the stent is composed of the high radial force "Main Body" and the "Sphincteric Segment" having a gradually decreasing radial force. The overall length of the stent is identical in both the crimped and expanded state.
Pre-procedural preparation
- Prescribe a broad spectrum oral antibiotic for prophylaxis to be started at least 3 hours before the procedure and continue according to your hospital's endoscopic transurethral procedures protocol.

The following equipment should be prepared for endoscopic use of the BUS:
4 mm (12 Fr) Optic Element (0°, 5° or 30°) compatible with the BUS

Note: The BUS is not compatible with Olympus Cystoscope system
- BUS System (It is recommended to have all the sizes available in the OR)

MRI INFO-BUS

MRI Information

MR Conditional

The Bulbar Urethral Stent was determined to be MR-conditional. Non-clinical testing demonstrated that the Bulbar Urethral 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 Bulbar Urethral 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:

<table>
<thead>
<tr>
<th></th>
<th>1.5-Tesla</th>
<th>3-Tesla</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR system reported, whole body averaged SAR</td>
<td>2.9-W/kg</td>
<td>2.9-W/kg</td>
</tr>
<tr>
<td>Calorimetry measured values, whole body averaged SAR</td>
<td>2.1-W/kg</td>
<td>2.7-W/kg</td>
</tr>
<tr>
<td>Highest temperature change</td>
<td>+2.0°C</td>
<td>+2.3°C</td>
</tr>
</tbody>
</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 Bulbar Urethral 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.

<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Void Size</td>
<td>1,212-mm2</td>
<td>231-mm2</td>
<td>1442-mm2</td>
<td>317-mm2</td>
</tr>
<tr>
<td>Plane Orientation</td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
<td>Perpendicular</td>
</tr>
</tbody>
</table>

Dilation of the Stenosis

Note: It is recommended to measure the stricture length and the distance to the sphincter prior to dilation.
- Dilate the stenotic area to at least 28 FR
Choosing the Appropriate Stent Length

- Appropriate length of the stent to be chosen is based upon the distance between the downstream end of the external sphincter and the length of the strictured segment with the addition of 1 cm. Since the Sphincteric Segment of the BUS will be situated just below the external sphincter and the “Body” segment of the stent should cross by approximately 10 mm below the end of the stricture into the healthy urethra the stent should be chosen accordingly, i.e. if the measured length is 4 cm a BUS 50 is chosen.

![Bladder, Posterior Urethra, Bulbar Urethra, Sphincter diagram]

Figure 5 - Choosing the correct stent length and its appropriate position in the bulbar urethra

Preparation of the BUS Deployment System

- Remove the deployment system from its tray.
- Insert a 0°, 5° or 30° optic element of a cystoscope until the lens at its tip reaches the tip of the device. Then using the provided locking clips lock the position of the lens to prevent its forward and backward movement.
- Hold the deployment system with its tip upward. Inject 15-20 ml saline through the water inlet port. This will remove the air entrapped between the crimped stent and the inner tube of the delivery mechanism. Check that the irrigation fluid entered between the folds of the crimped stent. Filling of saline eases the endoscopic visualization of the stent and its release.
- Connect the irrigation fluid and the light cable.

Inserting the Meatal Shield

- Check that the mandrel of the Meatal Shield is fully inserted into the shield tube.
- Gently insert the lubricated Meatal Shield into the urethral meatus in a clockwise rotating motion.
- Retrieve the mandrel leaving the Meatal Shield tube in position.

Stent Deployment

<table>
<thead>
<tr>
<th>Note: Do not try to pull back the partially released stent into the delivery tool. This may cause irreparable damage to the stent.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insert the stent deployment system with the optical element mounted through the Meatal Shield tube and advance it under vision until you see the downstream end of the external sphincter. Do not enter the sphincter.</td>
</tr>
<tr>
<td>Unlock the trigger by sliding the lock downward. Always keeping the sphincter in the field of view start pulling the trigger gently for deploying the stent. Pull the trigger all the way until it stops, and then release it. The device has a ratchet mechanism for returning the trigger. (The number of pulls needed for complete stent release depends on the stent length. Each full pull releases about 10-15 mm of the stent.)</td>
</tr>
</tbody>
</table>
| During deployment if you find that the positioning is unsatisfactory (far from the sphincter), stop pulling the trigger and push gently the deployment tool forward to
reposition the partly expanded stent. Then continue the deployment by pulling the trigger until the entire stent is released.

- According the length of the stent, pull the trigger 5-8 times. This will ensure that the entire stent is released.
- Remove the posterior lock of the optical element.
- Verify that the stent is released by pulling outward the optical element and moving the handle in semi-circular movements. When the stent is completely disconnected from the delivery tool you will notice that the small holes of the transparent inner tube will accompany the turns of the handle and that the expanded stent does not move.
- If the stent did not disconnect completely wait a few minutes, then using gentle and semi-circular movements try to disconnect the delivery tool from the stent.
- Then return the optical element to its previous place and lock it.
- Under vision, by slowly pulling the entire deployment tool outward with semi-circular movements observe the expanded stent and its relationship with the sphincter. Confirm that any part of the stent is not in the sphincter.

**Voiding Function Assessment**

- If the patient feels that his bladder is full after removing the delivery tool and the meatal shield, ask him to pass urine and stop the stream voluntarily to re-assure that the sphincteric function is intact. If the patient cannot voluntarily stop the stream, check the position of the stent endoscopically using a small caliber cystoscope (up to 17 Fr). If the stent appears to be compromising the function of the external sphincter a “repositioning maneuver” can be tried. In case this maneuver is not successful, the stent should be removed and another one inserted.

**Repositioning Maneuver**

**Never try to reposition the Allium Temporary Stents with a foreign body forceps. The forceps can damage the polymeric cover.**

If **any part of the stent is seen in the external sphincter** the stent should be pulled outward. For doing this:

- Fill the urethra with 20 ml of lubricating jelly.
- Gently insert a 12 Fr Foley Catheter through the stent.
- Insert a small caliber cystoscope (up to 17 Fr) beside the catheter up to the sphincteric segment of the main body of the stent.
- Slowly pull back the catheter until the lower edge of its empty balloon is seen coming out of the sphincter.
- Fill the balloon with 4-5 ml saline solution.
- Under vision, gently pull the catheter outward. This pulling will move the stent outward. Continue the gentle pull until the sphincteric segment appears just below the sphincter.
- Evacuate the balloon and under vision gently pull out the catheter and then the cystoscope.

**Do not inflate the balloon in the body of the stent and try to pull it. This will cause unraveling of the stent and may not move the stent outward.**

If the stent is seen **far below the external sphincter** the stent should be pushed inward. For doing this:

- Fill the urethra with 20 ml of lubricating jelly.
- Gently insert a 12 Fr Foley Catheter through the stent.
- Insert a small caliber cystoscope (up to 17 Fr) beside the catheter into of the main body of the stent.
- Slowly pull back the catheter until the empty balloon is seen just below the sphincteric segment of the stent.
- Fill the balloon which is in the lumen of the stent with 5-6 ml saline solution.
- Under vision, gently push the balloon of the catheter upward with the tip of the cystoscope. This pushing will move the stent inward. Continue the gentle push until the sphincteric segment touches the downstream end of the external sphincter.
• Evacuate the balloon and under vision gently pull out the catheter and then the cystoscope.

Removing the Stent
• The Stent is a single-use device and is designed to be removed at the end of its intended indwelling time.
• The stent can be removed under vision using a rigid endoscopic or a strong flexible endoscopic foreign body forceps.
• Under vision insert a 19-21 Fr cystoscope until the down-stream end of the stent is seen in the bulbar urethra.
• Insert the foreign body forceps through the cystoscope.
• Catch the distal small retrieval loop with the forceps.
• Disconnect the sheath from the bridge of the cystoscope together with the flexible forceps, and start pulling the loop toward the sheath. This may initiate tearing the polymeric cover. Continue to pull outward the metal wire **together with the endoscope sheath**.
• Verify that the entire stent came out by checking that the second small loop at the up-stream end of the stent came out.

**Note**: Do not try to remove stent by pulling the wire through the sheath, this might cause the stent to tangle and get caught in the sheath.

**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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>This Symbol Means</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Do Not Reuse" /></td>
<td>Do Not Reuse</td>
</tr>
<tr>
<td><img src="image" alt="Use By" /></td>
<td>Use By</td>
</tr>
<tr>
<td><img src="image" alt="Batch Code" /></td>
<td>Batch Code</td>
</tr>
<tr>
<td><img src="image" alt="Sterilization Using Ethylene Oxide" /></td>
<td>Sterilization Using Ethylene Oxide</td>
</tr>
<tr>
<td><img src="image" alt="Catalog Number" /></td>
<td>Catalog Number</td>
</tr>
<tr>
<td><img src="image" alt="Caution, Consult Accompanying Documents" /></td>
<td>Caution, Consult Accompanying Documents</td>
</tr>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="Authorized Representative in the European Committee" /></td>
<td>Authorized Representative in the European Committee</td>
</tr>
<tr>
<td><img src="image" alt="Consult Instructions for Use" /></td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td><img src="image" alt="Store in Dry Place at Room Temperature" /></td>
<td>Store in Dry Place at Room Temperature</td>
</tr>
<tr>
<td><img src="image" alt="Do Not Use if Package is Damaged" /></td>
<td>Do Not Use if Package is Damaged</td>
</tr>
</tbody>
</table>

---

**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:** 243-0124  

---

**Authorized Representative in the European Committee**

**MEDNET GmbH**  
Borkstrasse 10  
D-48163 Munster  
Germany