Allium

Round Posterior Urethral Stent System

(RPS)

Instructions For Use

Manufactured by

***Allium Ltd*.**

Device Name: ***Allium Round Posterior Urethral Stent (RPS)***

Allium Urethral Stents are intended for use temporarily in male Bladder Outlet Obstruction to de-obstruct or tutor the urethral passage open and allow the patient to pass urine spontaneously and on demand.

Device Description:

The **RPS** is a temporary device intended for transurethral insertion into the male posterior urethra diagnosed with Bladder Outlet Obstruction (BOO) caused by stenotic posterior urethra, stenotic bladder-neck caused by urethro-vesical or urethro-neovesical anastomotic stenosis. It is a single use device intended to remain in the urethra up to 1 year, to open the occluded passage and allow spontaneous urination. The stent is comprised of a coiled super-elastic structure covered with a co-polymer. Once inserted into the urethra with the aid of its special deployment tool, the stent is released to allow its self-expansion.

The **RPS** System includes a deployment tool containing the ***RPS*** crimped into a 19 Fr tube mounted on a deployment handle (Figure 1). The **Deployment Tool** is composed of a handle, a trigger and the tube containing the crimped stent.

Figure 1 - The Deployment Tool of the RPS

Pre Treatment Evaluation of BOO:

It is recommended to perform the following basic evaluation prior to initiation of treatment for BOO with a stent: history, physical examination, PVR (post-void residual urine), DRE (digital rectal examination), Transrectal urethro-vesical junction sonography, 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 **RPS** System is indicated for the management of BOO in adult males (18 years or older). They are intended for use to provide temporary relief of the obstructions developing after prostate surgery, anastomotic stenoses developing after radical prostatectomy or cysto-prostatectomy or posterior urethral strictures.

The **RPS** is not intended for definitive treatment of bladder-neck stenoses or posterior urethral strictures.

Contraindications:

The insertion of a RPS is contraindicated in men who:

1. Are younger than 18.
2. Have an acute infection of the 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.
5. Cannot tolerate any form of antibiotic treatment.
6. Are currently receiving anticoagulation therapy.
7. Have irreversible atonic/acontractile bladder.
8. Have a urethro-cutaneous or urethro rectal fistule.
9. Cystolithiasis.
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.

Recommendations to Patients:

- The RPS, when used after radical prostatectomy or radical cysto-prostatectomy may increase the possibility of stress incontinence or incontinence. The reason is the fibrotic changes at the sphincteric level and the lack of a long enough posterior urethra. This possibility should be explained to the patient.
- Patients should be informed that during the indwelling time of the RPS they may have to wear a Cunningham type penile clamp for keeping dry. This clamp should be opened every 2-3 hours for urination. The use of condom-collectors during the day is not recommended.
- Patients should be trained to perform Kegel exercises during the indwelling time of the RPS to reinforce and keep active their voluntary sphincter. It is recommended to perform these exercises for about 30 seconds each time and at least 10 times a day.
- Patients should be recommended to try to stop the stream, during each urination for activating their voluntary sphincter.

Precautions:

Checking the device: The crimped stent and deployment tool 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 **RPS**. Prior to its use, the technical information supplied with the device should be carefully reviewed.

Device Related Warnings:

- **Single use device:** The **RPS** 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 deployment tool should be inspected for damage prior its use.
- Remounting of a stent into the deployment tool should not be attempted, since this will damage the cover of the stent.
- Positioning of the main body or the anchoring segment 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 the reason of the obstruction.
- 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 can dislodge the stent.
- The stent should be inserted and positioned only according the Instructions for Use (IFU) accompanying the device.
- The stent may migrate during and after placement. If this occurs, the stent should be removed and a new one inserted.
- Use of the stent should be discontinued in those patients who develop a urethral abscess.

FLUOROSCOPIC INSERTION INSTRUCTIONS FOR THE Round Posterior Urethral Stent (RPS)

The **RPS** is a temporary device intended for–transurethral insertion into the male urethra diagnosed with Bladder Outlet Obstruction (BOO), caused by stenosis of the posterior urethra and/or stenosis of the bladder-neck developing either after transurethral resection of the prostate or after radical prostatectomy or radical cystoprostatectomy followed by orthotopic bladder reconstruction. It is a single-use device intended to remain in the urethra up to 1 year, to open the occluded bladder neck and posterior urethral passage and allow spontaneous urination. The **RPS** once inserted into the posterior urethra with the aid of its insertion tool, is released to allow its self-expansion.

For deploying the RPS there is a need for a minimum of 15-20 mm, long posterior urethra. Shorter posterior urethral length may cause ineffective tutoring of the bladder neck by the body of the stent.

The **RPS** is available in one length:

Catalogue No.	Body Length	Trans- Sphincteric Segment Length [mm]	Anchoring Segment Length [cm]	Main Body Caliber
RPS-40	40	20	14	45 Fr

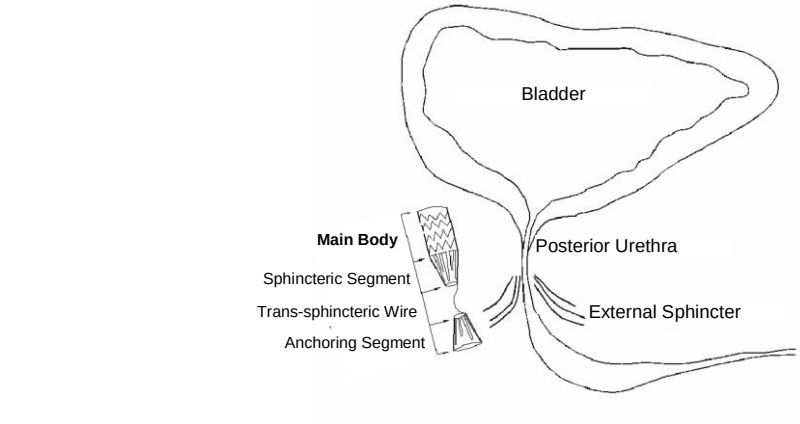

Figure 2 - RPS segments and their correlation with the posterior urethral anatomy

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 and its various segments are 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 hospitals endoscopic transurethral procedures protocol.
- Prescribe an oral or rectal non-steroidal anti-inflammatory drug to be started the evening before the procedure and to be continued for 3-4 days thereafter.
- The **RPS** is inserted under fluoroscopy.
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Fluoroscopic Evaluation of the Posterior Urethra

- Perform an ascending urethrogram under fluoroscopy and ask the patient to contract his anus. The fusiform narrowing is the place of the external sphincter.
- Mark the sphincter with a metal marker applied to the skin.
- Continue to fill the urethra until the contrast material reaches the bladder.
- Evaluate the approximate length of the posterior urethra.

Dilation of the Stenosis

- Under vision or under fluoroscopy pass a 0.035" or a 0.037" guide wire through the stenosis into the bladder.
- Dilate the stenosis with one of the following standard techniques to at least 22 Fr:

1. High-pressure balloon (12 mm caliber)
2. Cold knife urethrotomy
3. Transurethral incision of the stenosis
4. Transurethral resection of the stenotic tissue
5. Laser evaporation of the stenotic tissue
6. Progressive catheter dilation

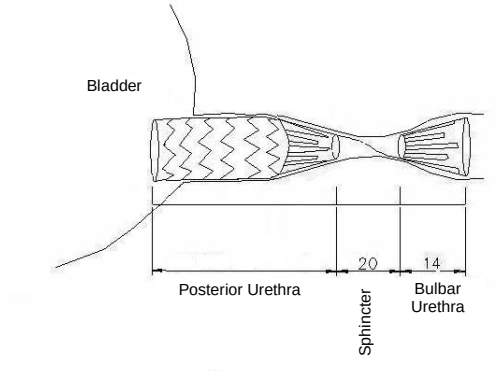

Figure 3 - Appropriate Position of the Stent ***[****All dimensions in millimeters]*

Insertion of the RPS:

The RPS should be inserted only under fluoroscopic guidance.

- After generously lubricating the urethra insert the deployment tool as inserting a Tiemann catheter until its tip reaches the bladder (urine will appear through the end of the deployment device) and insert the device 3-4 cm further. If the bladder is not full inject 100-150 ml saline to fill it.
- Under fluoroscopy position the trans-sphincteric wire segment of the stent to cross the skin marker indicating the place of the external sphincter. This will assure that the external sphincter is not disturbed by the body of the stent, and also that the body of the stent is positioned at the bladder neck.
- Unlock the trigger by sliding the lock downward.
- By slowly pulling the trigger 5-6 times release the stent.
- Each full pull of the trigger releases approximately 10-15 mm of the stent and its anchor.
- During release, fluoroscopically assure that the position of the trans-sphincteric wire remains in the sphincter.
- After complete release of the stent, gently and using semi-circular movements pull the entire deployment tool outward.

Appropriate Position of the Stent

- If the prostate was removed during previous surgery, the length of the remaining posterior urethra is very short (±2 cm). In such cases a part of the "body" of the 3 cm stent will be situated in the posterior urethra with a part of it protruding into the bladder.

Voiding Function Assessment

- If the patient feels that his bladder is full after removing the delivery tool, 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 RPS with a foreign body forceps. The forceps can damage the polymeric cover.**
- **The entire repositioning maneuver should be done under constant endoscopic visualization.**

If the **main body of the stent is** seen **into the external sphincter** the stent should be pushed carefully toward the bladder until the sphincter is crossed only by the trans-sphincteric wire.

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.
- Fill the balloon which is in the lumen of the body of the stent with 5-6 ml saline solution.
- Under vision, with the tip of the cystoscope gently push the balloon of the catheter toward the bladder. This pushing will move the stent inward.
- Pull back the cystoscope about 1-2 cm and check if the sphincteric segment entered the posterior urethra and the trans-sphincteric wire is crossing the sphincter. If not continue to push gently the balloon.
- If the repositioning is satisfactory evacuate the balloon and under vision gently pull out the catheter and then the cystoscope.

If the **anchoring bulbar segment** of the stent is seen **in or above the external sphincter** the stent should be pulled outward.

For doing this:

The same endoscopic maneuvers described above are done, but instead of pushing the main body toward the bladder, the catheter with its inflated balloon in the main body of the stent, is gently **pulled** outward, until the entire bulbar segment enters the bulbar urethra.

Do not inflate the balloon in the anchoring bulbar segment and try to pull it. This will cause unraveling of the bulbar segment and will not move the stent outward.

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 one of the distal loops on the distal end of the stent with the forceps. (Engage the metal wire of the anchor with the forceps or catch one of the distal loops of the stent main body 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.

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