

**Allium
Triangular Prostatic Urethral Stent
System
(TPS)**

Instructions For Use



Manufactured by

Allium Ltd.

Device Name: *Allium Triangular Prostatic Urethral Stent (TPS)*

Allium Triangular Prostatic Urethral Stent (TPS) has a triangular cross section body to fit the prostatic urethral lumen occluded by enlarged prostate lobes. This stent has a bulbous anchoring segment for preventing migration.

Device Description:

The **TPS** is a temporary device intended for–transurethral insertion into the male urethra diagnosed with Bladder Outlet Obstruction (BOO), caused by an enlarged prostate gland (benign or malignant). 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 co-polymer. Once inserted into the urethra with the aid of its special inserter, the stent is released to allow its self-expansion.

The **TPS** System includes:

1. A delivery tool containing the TPS crimped into a 19 Fr tube mounted on a deployment handle (Figures 1a and 1b)
2. A Foley-type catheter with markings (for indicating the landmarks) (Figure 2)



Figure 1 a - The Delivery Tool for Deploying the TPS
(note the Tiemann-type distal end with its non-inflated balloon)



Figure 1 b - The Delivery Tool for Deploying the TPS
(note the Tiemann-type distal end with its inflated balloon)

The **Foley-type Marking Catheter** (accompanying the TPS Kit as an accessory) has markers at 1 cm intervals, starting below the balloon for marking the distance between the bladder-neck and the veru montanum (the length of the prostatic urethra)

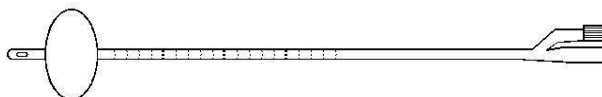


Figure 2 - The Foley-type Marking Catheter

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), 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 **TPS** System is indicated for the management of BOO in adult males (18 years or older). It is intended for use in the following obstructions to provide temporary relief of the obstructions: prostatic enlargement (benign or malignant), or for use after minimally invasive

treatments (MIT) based on thermal tissue damage of the prostate (by heating: microwave, RF thermotherapy, laser coagulation surgery, hot water etc; by freezing: cryotherapy); or interstitial irradiation (brachytherapy) for prostate cancer, which may cause post-procedural temporary edema and severe voiding difficulties or urine retention.

The **TPS** is not intended for definitive treatment of prostatic disease or of the complications of prostatic disease or urethral strictures.

Contraindications:

The insertion of a TPS 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.
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.

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 **TPS**. Prior to its use, the technical information supplied with the device should be carefully reviewed.

Device Related Warnings:



- **Single use device:** The **TPS** 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. Re-use of any of the components of the TPS system or the entire system can seriously damage the health of the patient.
- 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.
- The delivery system of the TPS contains natural latex which may cause allergic reactions.
- 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 urethral obstructions.

- The Foley-type Marking Catheter (supplied as an accessory) should be used to mark the distances between the identified landmarks to determine the appropriate stent length.
- 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 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 Triangular Prostatic urethral Stent (TPS)

The **TPS** is a temporary device intended for-transurethral insertion into the male urethra diagnosed with BOO, caused by an enlarged prostate gland (benign or malignant). The **TPS** once inserted into the prostatic urethra with the aid of its insertion tool, is released to allow its self-expansion.

The **TPS** is available in 5 lengths:

Catalogue No.	Body Length [mm]	Trans-Sphincteric Segment [cm]	Anchoring Segment Length [cm]	Main Body Caliber
TPS-30	30	20	14	Equivalent to 45 Fr
TPS-40	40			
TPS-50	50			
TPS-60	60			
TPS-65	65			

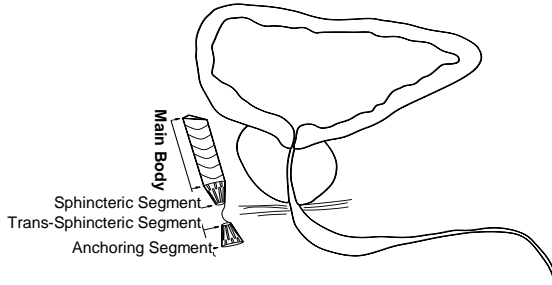


Figure 3 - TPS segments and their correlation with the posterior urethral anatomy

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.

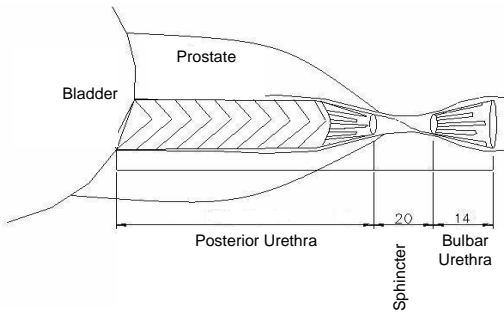


Figure 4 - Choosing the correct stent length and its appropriate position
 [All dimensions in millimeters]

Pre-procedural preparation

- A broad-spectrum antibiotic for prophylaxis should be started at least 3 hours before the procedure and continued according to the endoscopic transurethral procedures protocol used in your institution.
- It is recommended to prescribe an oral or rectal non-steroidal anti-inflammatory drug to be started the evening before the procedure and continued for 3-4 days thereafter.
- The following equipment should be prepared for insertion of the **TPS**:
 - # Cystoscope for measuring the prostatic urethral length
 - # **TPS** kit + accompanying accessory Marking Catheter
 - # Rigid or strong flexible endoscopic foreign body forceps

It is important to have a complete kit with all the lengths of stents in the OR or in the office to choose the accurate stent size after measuring the prostatic urethral length.

Measurement of the Prostatic Urethra

Endoscopic Measurement:

- Insert the Marking Catheter until it reaches the bladder and inflate its balloon with 10ml saline. Pull the balloon until it touches the bladder neck.
- Insert a small caliber cystoscope (up to 17 Fr) with a 0°, 5° or 30° lens beside the catheter enabling vision of the bladder neck.
- Measure the prostatic urethral length by counting the marks on the Marking Catheter from the bladder neck to the down-stream end of the Veru Montanum (prostatic apex). The measured length is the length of the prostatic urethra.

Measurement by Trans-Rectal Ultrasound (TRUS):

- Using TRUS measure the length of the prostatic urethra (on the sagittal axis of the gland - the distance between the bladder-neck and the apex).

Choosing the Appropriate Stent Length

Appropriate length of the stent to be chosen is based upon the length of the measured prostatic urethral length. Since the **Body** of the TPS will be situated in the prostatic urethra above the external sphincter the "**Body**" segment of the stent should fit the measured prostatic urethral length (± 0.5 cm.). If the measured prostatic urethral length is 4 cm a TPS 40 is chosen.

IMPORTANT

Since the apex of the triangular stent should be positioned at 12 o'clock position of the bladder neck it is a must to keep the deployment tool with its handle between the legs of the patient in downward position.

Do not try to pull back the partially released stent into the delivery tool. This may cause irreparable damage to the stent.

MRI INFO– TPS

MRI Information



MR Conditional

The Triangular Prostatic Stent was determined to be MR-conditional.

Non-clinical testing demonstrated that the Triangular Prostatic 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 Triangular Prostatic 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:

	1.5-Tesla	3-Tesla
MR system reported, whole body averaged SAR	2.9-W/kg	2.9-W/kg
Calorimetry measured values, whole body averaged SAR	2.1-W/kg	2.7-W/kg
Highest temperature change	+2.5°C	+3.0°C

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 Triangular Prostatic 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.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	1,770-mm ²	293-mm ²	2,293-mm ²	372-mm ²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

Stent Deployment

The delivery system is intended for inserting the TPS either directly or under fluoroscopic control. It is recommended to insert the stent with at least full bladder. Inform the patient to drink 2-3 glasses of liquid 1-2 hours before the procedure. If the bladder is not full, saline can be filled through the deployment system.

Caution: Remove the protective cover by pulling from its ring!

Direct insertion:

- Take an Endoscopic Measurement of the Prostatic Urethra as described above.
- Choose the appropriate stent length mounted on the delivery system.
- After generously lubricating the urethra insert the delivery system as inserting a Tiemann tip Foley catheter until its tip reaches the bladder (urine will appear through

the end of the device). Then insert the device 3-4 cm further. If the bladder is not full inject 100-150 ml saline to fill it.

- Inflate the balloon of the deployment device with 10 ml saline and gently pull the device outward until the balloon reaches the bladder neck. **For accurate positioning of the stent, keeping the gentle traction during the delivery is important.** This will assure that the bladder end of the stent is at the bladder neck.
- Assure that the handle of the deployment device is at 6 o'clock position between the legs of the patient. This will assure that the apex of the triangular stent is at 12 o'clock position of the prostatic urethra
- Unlock to release the trigger by sliding the lock downward before starting the release.

Release of the stent:

The total length of the stent is composed of Body Length (30 to 65 mm, in 5 mm increments) + Trans-sphincteric wire (20 mm) + Anchoring segment (14 mm).

- Pull the trigger minimum 14 times (depending on the length of the stent) to release the stent. Each full pull of the trigger releases approximately 10-15 mm of the stent and its anchor.
- Deflate the balloon gently and assure that the saline is completely withdrawn from the balloon. In case of difficulty in retrieving all the saline, gently push the insertion device 2-3 cm toward the bladder and continue evacuating the balloon.
- With small rotating maneuvers gently remove the deployment device from the urethra. Incomplete balloon deflation or hasty removal of the delivery tool may pull the stent outward and cause its malpositioning.
- After removing the deployment device, ask the patient to pass urine and stop the stream voluntarily to check the integrity of the sphincter.

Fluoroscopic Insertion:

- After taking an accurate measurement of the prostatic urethral length (as described in Measurement of the Prostatic Urethra) perform a retrograde urethrogram and mark the place of the sphincter using a metallic skin marker.
- Choose the appropriate stent length mounted on the delivery system.
- After generously lubricating the urethra insert the delivery system as inserting a Tiemann tip Foley 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.
- Inflate the balloon of the deployment device with 10 ml saline containing 1-2 cc of contrast and gently pull the device outward until the balloon reaches the bladder neck. Verify fluoroscopically that the balloon is at the bladder neck. This will assure that the bladder end of the stent is positioned at the bladder neck.
- Under fluoroscopy verify that the trans-sphincteric wire is at the level of the skin marker
- Assure that the handle of the deployment device is at 6 o'clock position between the legs of the patient. This will assure that the apex of the triangular stent is at 12 o'clock position of the prostatic urethra.
- Unlock to release the trigger by sliding the lock downward before starting the release.

Insertion and release of the TPS can be followed also by TRUS.

Release of the stent:

The total length of the stent is composed of Body Length (30 to 65 mm, in 5 mm increments) + Trans-sphincteric wire (20 mm) + Anchoring segment (14 mm).

- Pull the trigger minimum 14 times (depending on the length of the stent) to release the stent. Each full pull of the trigger releases approximately 10-15 mm of the stent and its anchor.
- The TPS has 2 radiopaque markers at its bladder end: one at the apex of the last loop at the bladder end and the second at the middle of its base loop. Verify fluoroscopically that the 2 markers are one over the other or very near to each other. This will verify that the apex of the triangular stent is at 12 o'clock position of the prostatic urethra
- Deflate the balloon (assure that the saline is completely withdrawn from the balloon by fluoroscopy) and with small rotating maneuvers gently remove the deployment device from the urethra. Removal of the deployment device can be followed fluoroscopically. Incomplete balloon deflation or hasty removal of the delivery tool may pull the stent outward and cause its malpositioning.

- After removing the deployment device, ask the patient to pass urine and stop the stream voluntarily to check the integrity of the sphincter.

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. 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 Urethral Stents with a foreign body forceps. The forceps can damage the polymeric cover.

If the **main body of the stent is seen in the external sphincter** the stent should be pushed forward, toward the bladder.

For doing this :

- Fill the urethra with 20 ml of lubricating jelly.
- Gently insert a 12 Fr Foley Catheter through the stent until it reaches the bladder (urine will appear from its port). **Do not inflate the balloon.**
- 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 prostatic urethra. 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 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 or use a forceps for pulling this segment. This will cause unraveling of the main body and 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 anchoring end of the stent is seen in the bulbar urethra.
 - Insert the foreign body forceps through the cystoscope.
 - 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.**
- Do not try to remove the stent by pulling the wire through the sheath, this might cause the stent to tangle and get caught in the sheath or breakage of the stent wire.**
- Verify that the entire stent came out by checking that the second small loop at the up-stream end of the stent came out.

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

Symbol	This Symbol Means
	Do Not Reuse
	Use By
	Batch Code
	Sterilization Using Ethylene Oxide
	Catalog Number
	Caution, Consult Accompanying Documents
	Manufacturer
	Authorized Representative in the European Committee
	Consult Instructions for Use
	Store in Dry Place at Room Temperature
	Do Not Use if Package is Damaged

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