Allium’s One Platform Delivery System (OPS) for Urethral Stents

Allium Medical’s One Platform Delivery System is a unique gun-like system, specially designed to allow easy insertion and deployment of Allium’s three urethral stents: Triangular Prostatic Stent (TPS), Round Posterior Urethral Stent (RPS) and the Bulbar Urethra Stent (BUS).

The system introduces new capabilities that elevate the stenting procedure to the next level: accurate positioning under direct scope visualization and overall streamlined workflow.

The OPS platform allows stenting procedures to be performed both in hospitals, as well as in a clinic based environment.
**Key Benefits:**

1. Site specific design provides larger lumen patency and reduces tissue irritability.
2. Long Term Indwelling eliminates the need for recurrent procedures, significantly reduces costs and promotes patients longer relief.
3. Unique Polymeric Coating prevents tissue in-growth as well as reduces encrustation, stone formation and calcification.
4. Stent’s High Flexibility ensures minimal irritation and maximal patient comfort.
5. Varying radial forces along the stent’s body provide excellent stent fixation and adaptability to the patient’s anatomy.
6. Easy Placement and accurate positioning enabled by direct visualization, as well as radiopaque markers on the distal and proximal ends of the stent.
7. A special anchor attached to the Stent’s body by a trans-sphincteric wire reduces Stent migration, while protecting the sphincter functionality.

A-traumatic and easy removal of the Stent by unraveling it into a thread-like strip

**Accurate Deployment:**

TPS - Triangular Prostatic Urethral stent  
RPS - Round Posterior Urethral Stent  
BUS - Bulbar Urethral Stent
The OPS Platform:

Allium’s One Platform Delivery System is a sterile, single use Endoscopic system used for trans-urethral insertion of Prostate, Bladder Neck and Bulbar Urethral Stents into the male urethra, diagnosed with a stricture, in order to open the occluded passage and allow spontaneous urination.

The OPS system is preloaded with stents in various lengths and shapes, inserted into the urethra and then released to facilitate the Stent self-expansion in the desired anatomical site.

The Urethral Stent System consists of:

1. An endoscopic delivery tool preloaded with a Urethral Stent compatible with any 4mm optical element
2. Meatal Shield for easy and safe insertion

Delivery System Benefits:

1. Same insertion and deployment technique for all three urethral stents
2. Direct scope vision
3. Accurate anatomical positioning
4. Compatible with any 4mm optical component
5. Quick, safe and simple procedure
6. Enhanced workflow efficiency

<table>
<thead>
<tr>
<th>Urethral Stent Type</th>
<th>BUS</th>
<th>TPS RANGE</th>
<th>RPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulbar Urethral Stent</td>
<td>Round, without anchor</td>
<td>Triangular Prostatic Urethral Stent</td>
<td>Round Posterior Urethral Stent</td>
</tr>
<tr>
<td>Diameter: 15mm</td>
<td>Triangular, with anchor</td>
<td>Triangular height: 15mm</td>
<td>Diameter: 15mm</td>
</tr>
<tr>
<td>Lengths: 50, 60 or 80mm</td>
<td>Lengths: 30, 40, 50, 60mm</td>
<td>Length: 30, 40mm</td>
<td></td>
</tr>
<tr>
<td>R80mm</td>
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</tr>
</tbody>
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Using the One Platform Delivery System:

Step 1 - Optical Element Fixation into the Delivery System

Optical element is inserted into the delivery system until its lens reaches the edge of the delivery system.

Step 2 - Delivery System preparations

Irrigation fluid is connected to the water inlet port and the light cable is connected to the light cable port of the optical element.

Step 3 - Meatal Shield Insertion

The meatal shield is lubricated and gently inserted into the patient’s urethral meatus in a rotational motion. The mandrel is then retrieved leaving the dilator sheath in position.

Step 4 - Stent Insertion

The delivery system with the optical element is inserted through the meatal shield dilator sheath, and is advanced under vision until reaching the desired deployment location of the stent in the Urethra.

Step 5 - Stent Deployment

The delivery system trigger is unlocked by pressing the green safety lock button. While securing the delivery system in the desired location, the trigger is squeezed for stent deployment. The trigger should be squeezed several times until the stent is fully released from the delivery system and deployed.

Step 6 - Delivery System removal

The delivery system is gently pulled back using semicircular movements while affirming under vision that the stent is deployed. Finally, the meatal shield dilator sheath is slowly pulled outward with semi-circular movements.