BULKAMID®

Urethral Bulking System

Standard Operating Procedure

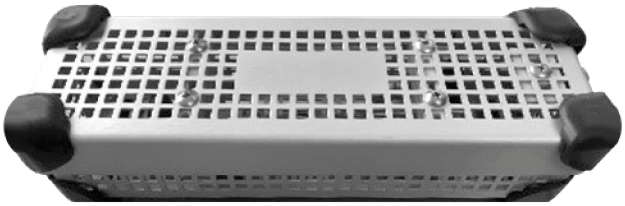
Axonics

BULKAMID®

Contents

Products

Bulkamid Reusable Devices

Product Description and Code	Contents	
Bulkamid sterilization container Code: OM-1000-CI		
Bulkamid cystoscope with accessories Code: 41-0152A	Zero-degree Bulkamid cystoscope with universal connections (length – 11.3cm)	
	Universal adapters to fit all light cables	
	Protection sheath for transportation	

Cystoscope Sterilization Instructions

The Bulkamid sterilization container, scope, universal adaptors and protection sheath should be washed at ≤ 95°C prior to being sterilized in an autoclave at either:

134°C for 5 to 20 minutes, or

137°C for 3 to 18 minutes.

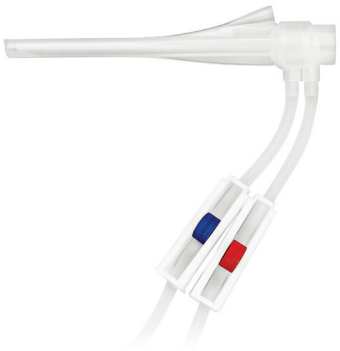
Sterilization may also be performed using the STERRAD® System (gas plasma technology).

The disinfection methods in our labeling have been validated with specific products:

- For manual cleaning, Cidezyme/Enzol (Johnson and Johnson) can be used.
- For automated cleaning, neodisher MediClean forte 0.5% can be used
- For high-level disinfection, Cidex OPA can be used

Please refer to the Bulkamid Scope Information for Use Leaflet for further information, available at www.bulkamid.com.

Bulkamid Single Use Devices

Product Description and Code	Contents	
Bulkamid Urethral Bulking System (Bulkamid kit) Code: 50050	2x 1ml Bulkamid syringes	
	2 x 23G, 12cm needles	
	1 x Bulkamid rotatable sheath	

Standard Equipment Required for the Bulkamid Procedure

Operating Room equipment

Light cable (standard grey cable).

Drip stand with 0.5L -1L sterile water.

Standard infusion set without internal valve or filter.

Equipment for disinfection of the vulva.

Disposable 10-12 Fr catheter (in/out catheter).

Hegar dilators, size 5 – 8, (available in the operating room, if required).

Anesthesia options

Anesthetic gel (for application inside the urethra and as lubricant on the rotatable sheath).

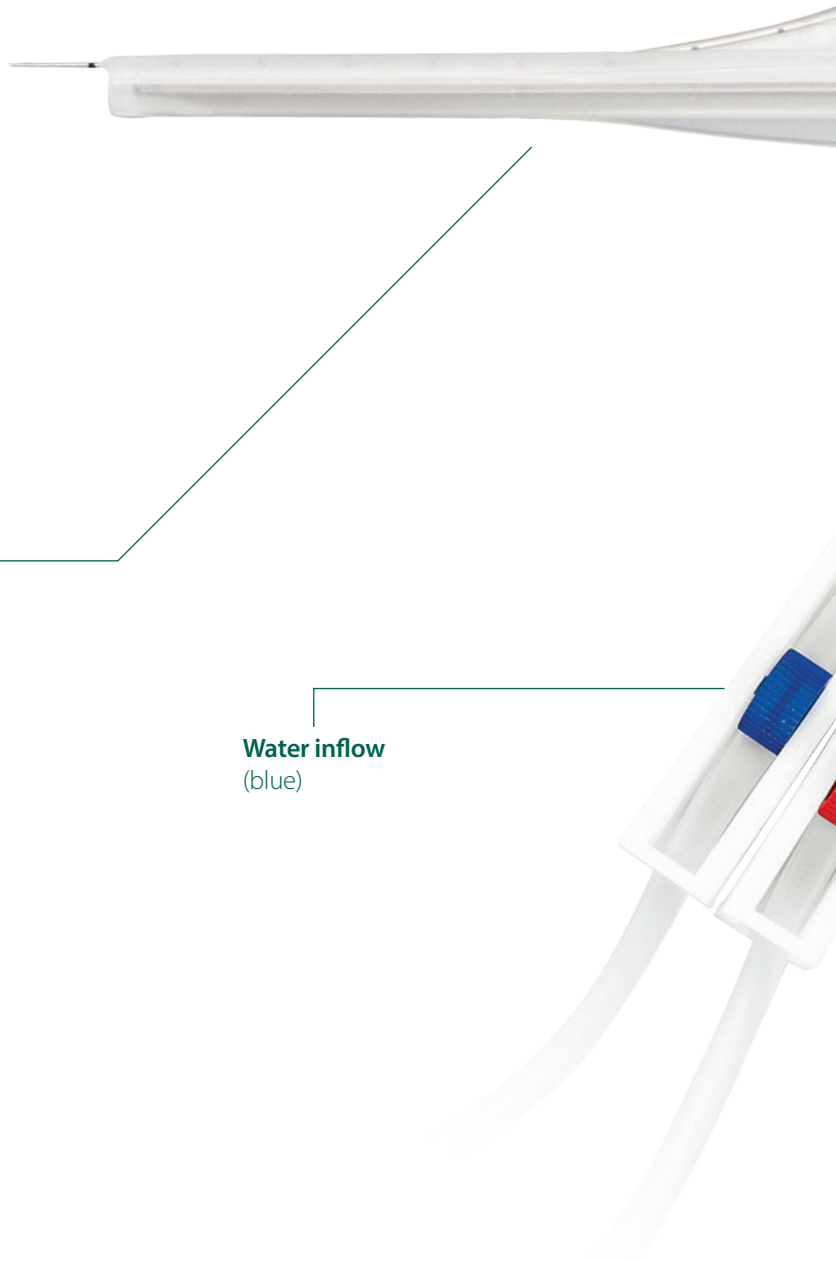
Anesthetic injection: e.g. 10ml of lidocaine 0.5 – 1% with or without epinephrine, 1 x 10ml syringe and a 25G x 1.5in needle.

The Bulkamid System

23G 12cm long needle

Rotatable sheath (360-degree rotation)
diameter 22 Fr

Water inflow
(blue)



1ml hydrogel syringe
with luer lock

Needle channel

Bulkamid scope
(camera connection fits all standard cameras)

Light cable connection
(fits all standard systems with the use of different adaptors)

Water outflow
(red)

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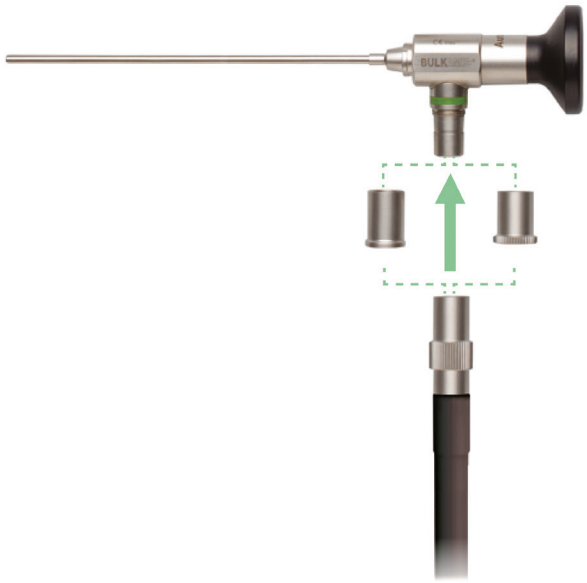
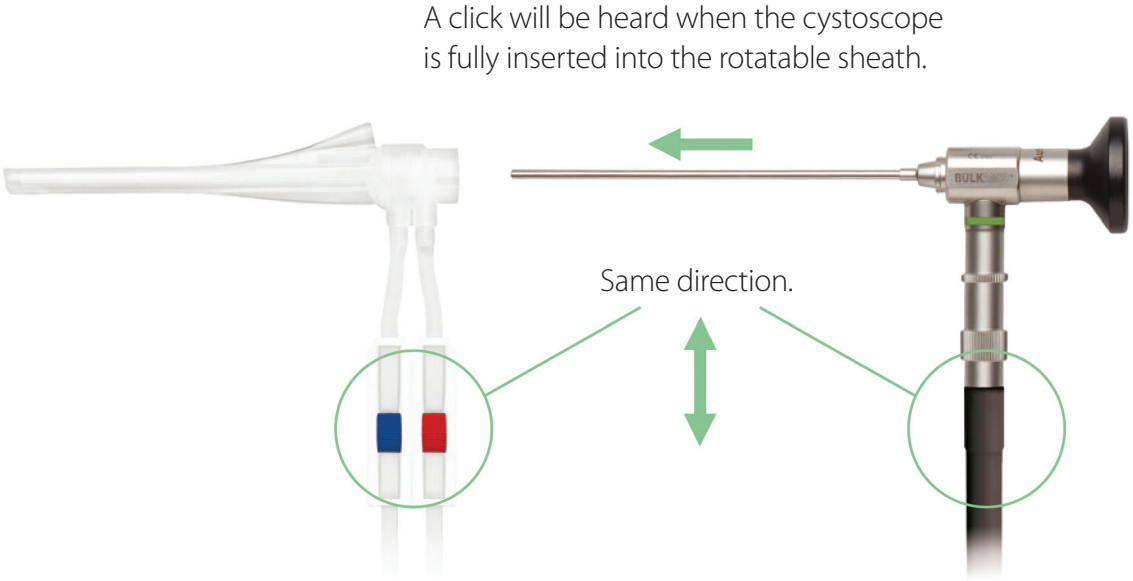
Pre-Procedure Preparation

Assembly of the Bulkamid System

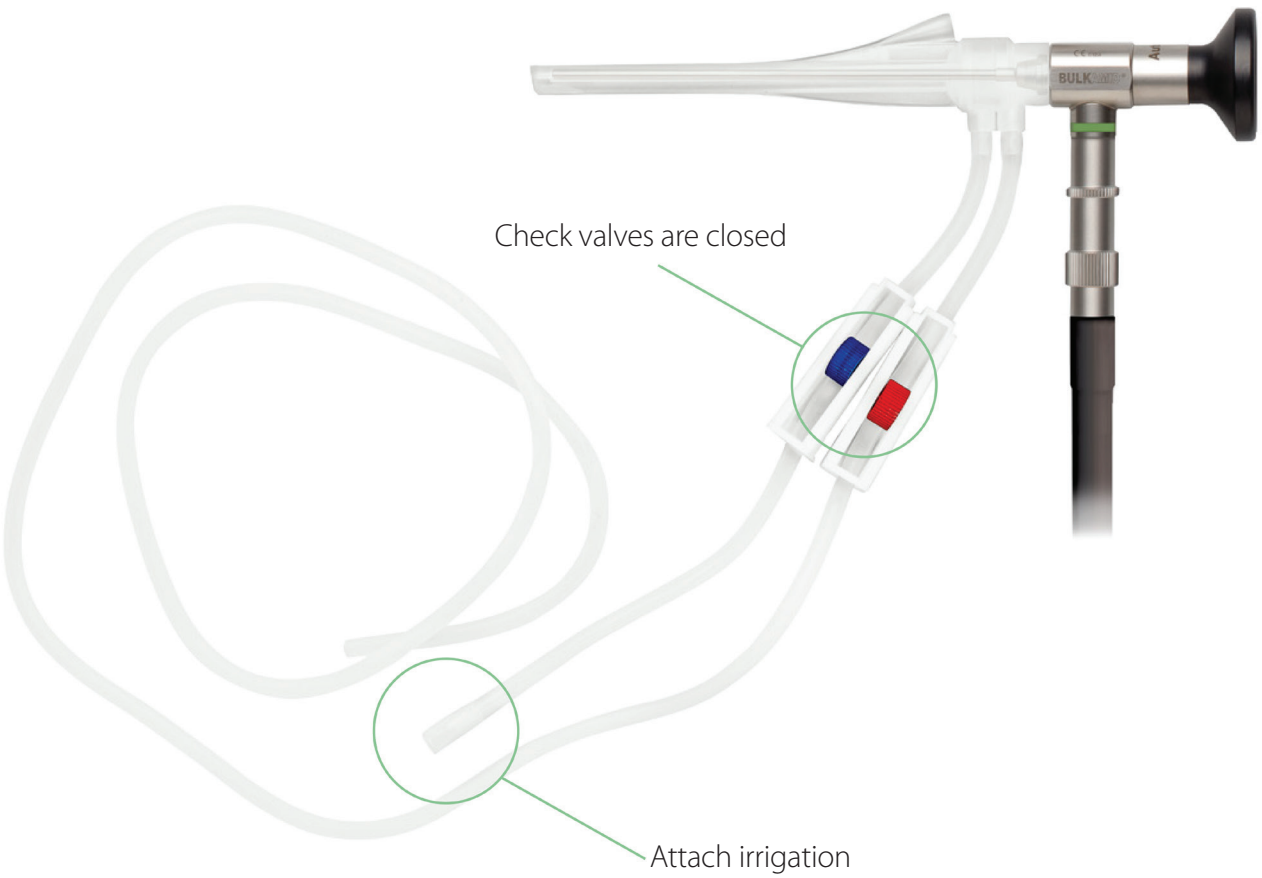
1. Attach the light cable to the Bulkamid cystoscope (ensure correct adaptor).



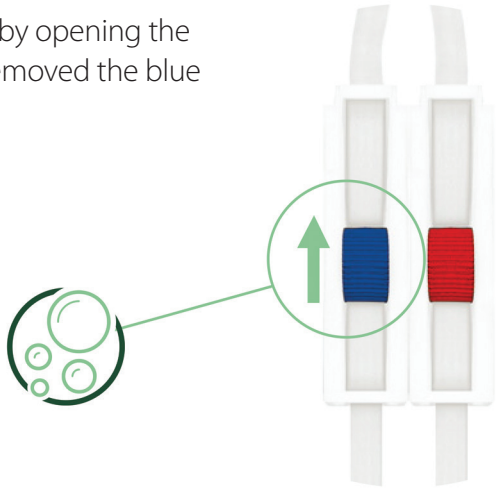
2. Place the cystoscope into the Bulkamid rotatable sheath (ensure the light cable and irrigation tubes are pointing in the same direction).



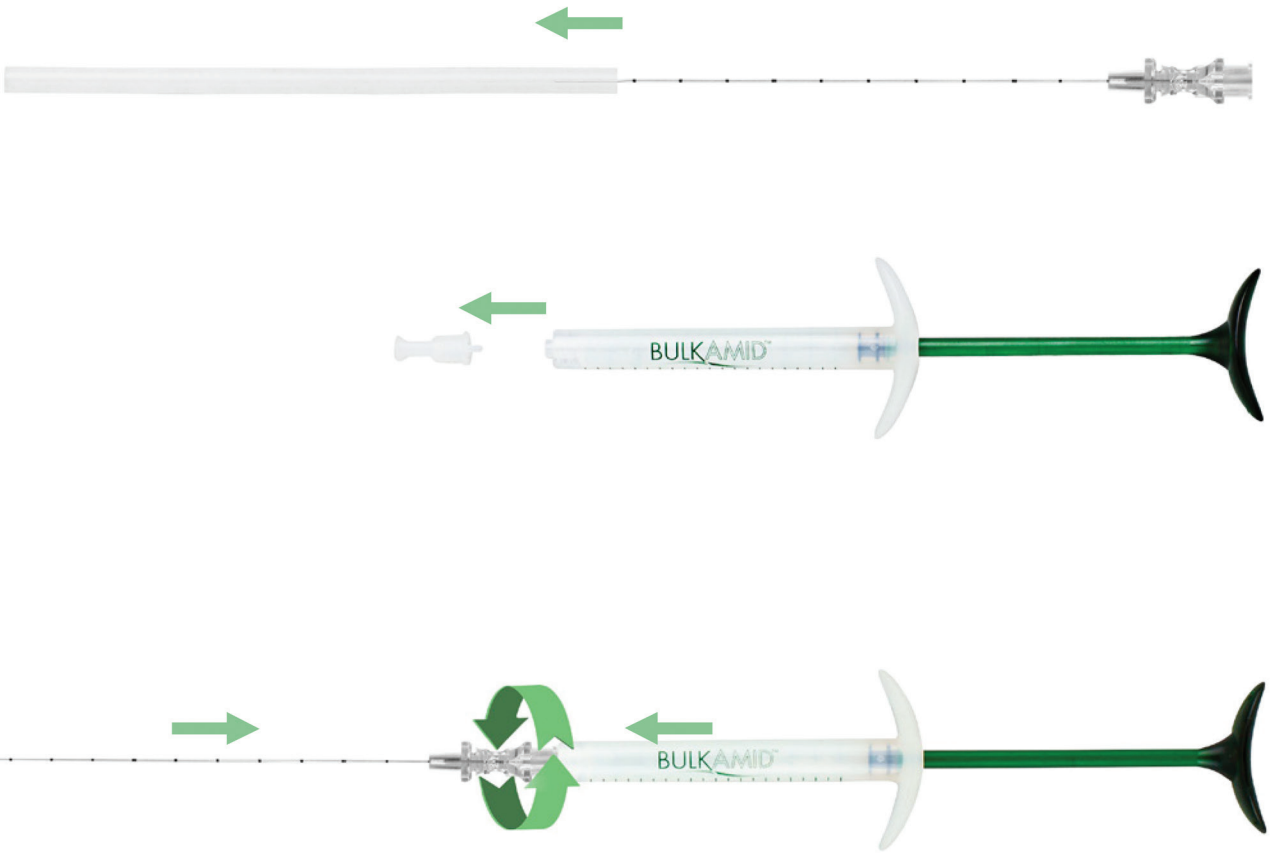
3. Attach the irrigation system to the short tube with the blue inflow valve on the rotatable sheath. Make sure the red and blue valves are closed before opening the water valve on the irrigation system.



4. Remove any air bubbles from the irrigation system by opening the blue inflow valve. Once all air bubbles have been removed the blue inflow valve is closed.



5. Remove the protection sheath from the needle. Remove the cap from the Bulkamid syringe and attach the 23G needle (turn counter-clockwise until tight).



Make sure that the needle is correctly mounted onto the syringe to prevent leakage of hydrogel during the procedure or the needle being pushed off the syringe tip.

6. Prime the needle by advancing the syringe plunger until hydrogel appears at the tip of the needle. This will remove any air from the Bulkamid needle.

This completes the assembly of the Bulkamid system.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Patient Positioning & Preparation

1. Place the patient in the lithotomy position.
2. Drape the patient and disinfect the vulva in accordance with local protocol.
3. Place the anaesthetic gel inside the urethra, and inject 5-10 ml lidocaine 0.5-1% with or without epinephrine or similar bilaterally to the urethra (3 and 9 o'clock) 5-10 minutes prior to the procedure.

Anesthetic gel
If an anesthetic gel is used, keep the remaining gel to one side for use on the tip of the rotatable sheath as a lubricant, prior to the sheath being inserted into the urethra.

Anesthetic injection
Surgeons may choose a 1.5in/25G needle to inject anesthetic into the submucosa tissue, 5-10 minutes prior to procedure. This needle allows the anesthetic to be positioned at the level where the Bulkamid hydrogel will be injected, while causing minimal trauma to the surrounding tissue. Inject 3 ml at the 1.5in depth (needle fully inserted) and 2 ml when retracting the needle from the injection site.

Screening and Prevention of Urinary Tract Infection
Prior to the procedure test the patient's urine in order to exclude Urinary Tract Infection (UTI). Do not proceed if infection is present. To minimize the possibility of urinary tract infection, it is advised to administer prophylactic antibiotics in accordance with the local anti-microbial protocol prior to surgery.

Alignment of monitor and needle position
Before identifying the first needle entry point make sure the 12 o'clock position on the monitor corresponds to the 12 o'clock position of the needle on the rotatable sheath. This will allow accurate placement of the Bulkamid injections.

Orientation of light cable and irrigation system
To allow free movement of the rotatable sheath throughout the procedure it is recommended to align the light cables and irrigation tubes at 6 o'clock (facing downwards), underneath the Bulkamid scope and rotatable sheath. This will provide a better grip and balance.

Set up of correct irrigation flow. Ensure half full drip chamber and flush for bubbles
Irrigation should be set with the inflow (blue valve) full and with the outflow (red valve) closed throughout the procedure. This will help to visualize the bladder neck to ensure precise positioning of Bulkamid hydrogel in the proximal half of the urethra and for the cushion to reach the midline of the urethral lumen. Elevation of the water bag is used to improve the water pressure.

Patient comfort
If the patient experiences the need to void during the procedure the bladder can be emptied by using the disposable 10-12 Fr catheter, or by opening the red outflow valve.


BULKAID

Bulkamid Procedure

1. Place anesthetic gel onto the rotatable sheath ensuring that gel does not enter the tip of the sheath as this may affect visibility. Carefully advance the Bulkamid system into the urethra until the bladder is visualized and inspected (ensure the blue inflow valve is open and the red outflow valve is closed).

2. Insert the Bulkamid needle into the needle channel on the rotatable sheath and advance the sheath and needle towards the bladder until the tip of the sheath is adjacent to the bladder neck. Rotate the sheath (rotatable part only) so that the needle channel is in line with the first injection site at 7 to 8 o'clock. (Fig. 1)

Dilation of the urethra

The Bulkamid rotatable sheath is 22 Fr (7-8 Hegar dilator). If the urethral meatus is too narrow, dilation with Hegar dilators may be required prior to insertion of the rotatable sheath.

3. Extend the needle into the bladder until the 2cm mark on the needle is visible. (Fig. 2)

4. Retract the entire Bulkamid system backwards with the needle remaining extended, until the tip of the needle is level with the bladder neck. (Fig. 3)

5. Fully retract the needle into the rotatable sheath, taking care to maintain the position of the rotatable sheath in the urethra. The tip of the rotatable sheath now marks the first injection site (approximately 1.5 - 2cm distal to the bladder neck (Fig. 4).

Identification of Injection Sites

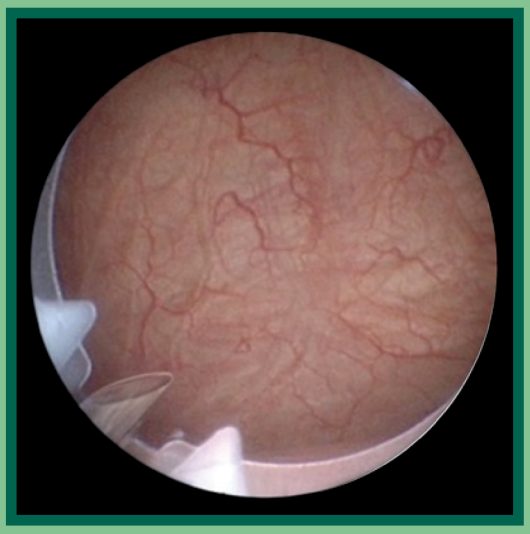

Fig. 1

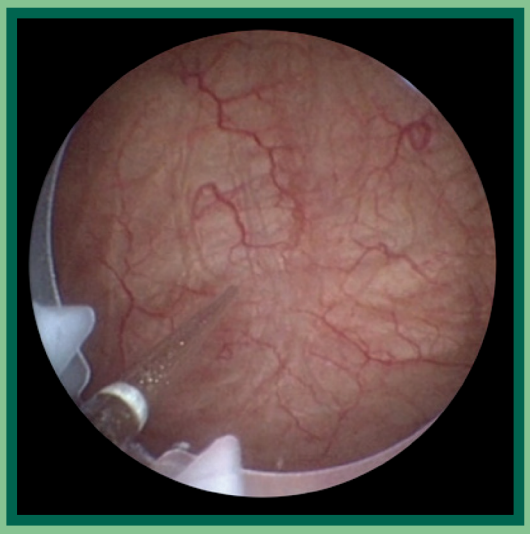

Fig. 2

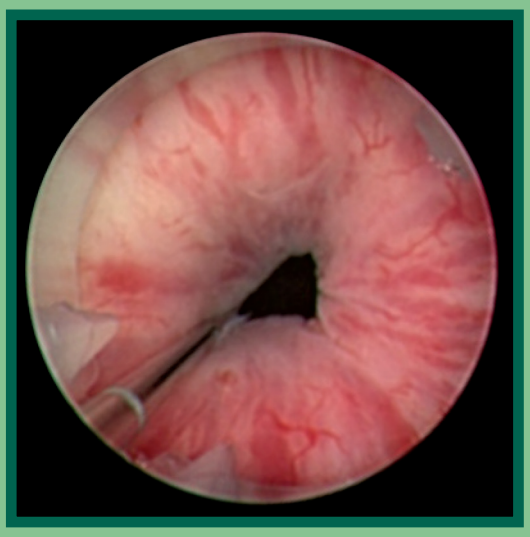

Fig. 3

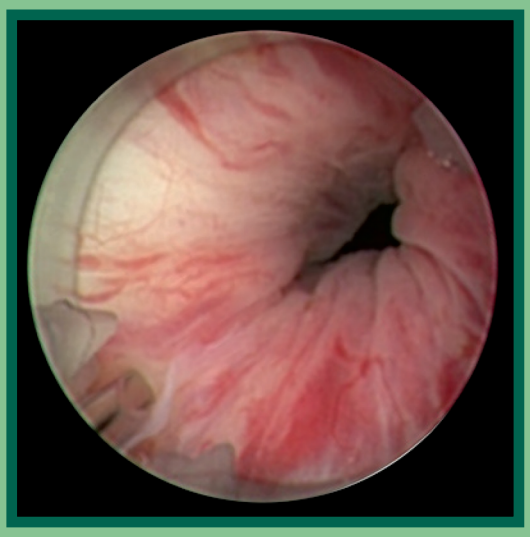

Fig. 4

Initial Injection Site
(e.g. 7 to 8 o'clock)

6. Advance the needle into the submucosal tissue ensuring that the needle pathway is parallel to the urethral wall and the bevel of the needle is facing towards the lumen.

   Continue to advance the needle until the 1cm mark on the needle is aligned with the tissue surface. (Fig.5)

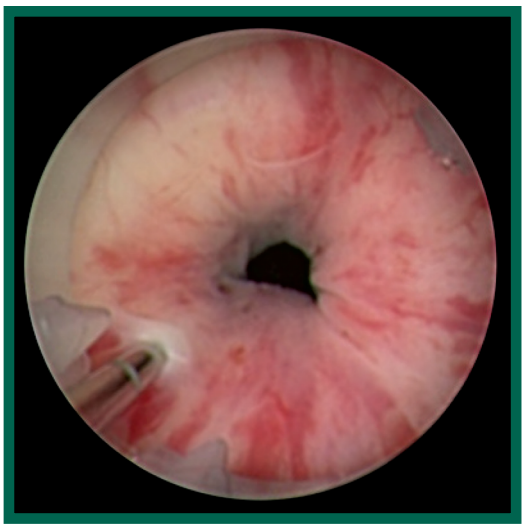

Fig. 5

7. Inject the Bulkamid hydrogel until the urethral tissue (cushion) reaches the midline of the urethral lumen. (Fig. 6)

   Note: If a cushion does not begin to form, slowly retract the Bulkamid needle in the tissue while injecting the hydrogel until the tissue allows the cushion to form. Alternatively, fully retract the needle from the tissue and reinsert the needle at a shallower angle but using the same injection hole prior to injecting Bulkamid.

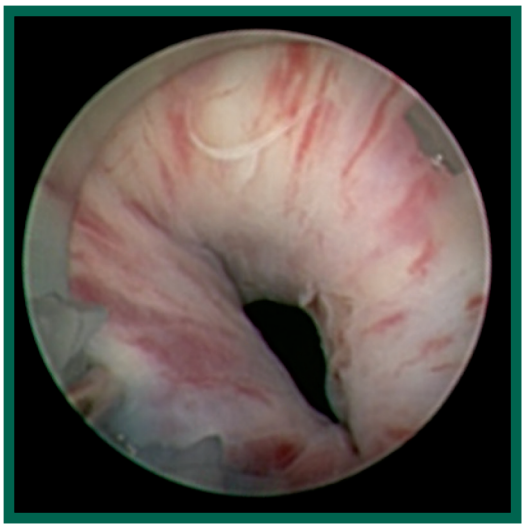

Fig. 6

Rotation of sheath
When rotating the sheath to the next injection site, ensure that the position of the Bulkamid system is maintained within the urethra and only the rotatable portion of the sheath is moved. This will ensure that all injection sites are at the same level/plane and coaptation of the urethra is effectively achieved. Previous injection sites should be used as an indicator for the needle entry point of future injections.

Ensure the sheath is not advanced past the bladder neck
Take care not to introduce the Bulkamid system past the bladder neck once the first cushion has been injected as this may cause extravasation of the Bulkamid hydrogel.

Subsequent Injection Sites
(e.g. 4-5, 1-2 and 10-11 o'clock)

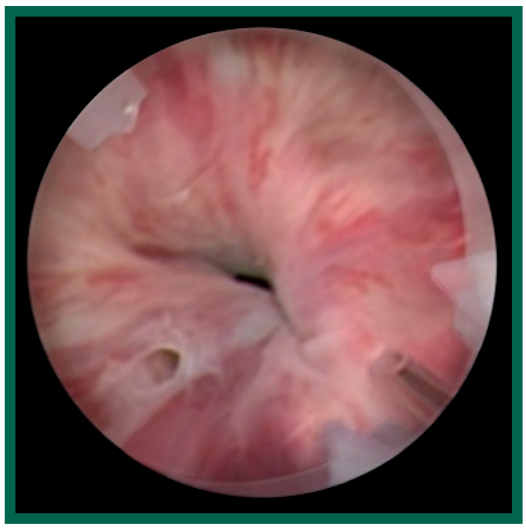

Fig. 7

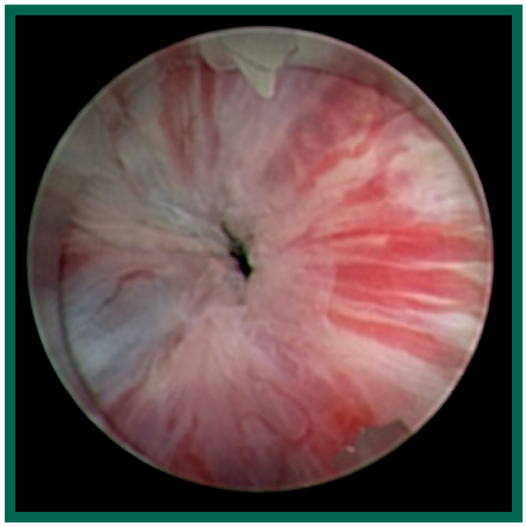

Fig. 8

8. Retract the needle into the rotatable sheath. Turn the rotatable sheath to the next injection site at e.g. 4 to 5 o'clock. The first injection site should be used as a guide to ensure the same plane for the injection.

9. Advance the needle into the urethral tissue until the 1cm mark on the needle is in line with the tissue surface. Inject the Bulkamid hydrogel until the urethral wall (cushion) reaches the midline of the urethra, and meets the first cushion. (Fig. 7) Retract the needle into the rotatable sheath.

10. Repeat steps 8 –11 at the remaining injection location(s) to achieve complete coaptation of the urethra. (Fig. 8)

    Once the final cushion has been injected, monitor the patient until the first normal voiding.

    Take care not to use any hard tube to empty the bladder as this may cause extravasation of the hydrogel. Use a soft disposable catheter 10 -12 Fr. With the awake patient, the fluid can be left in the bladder in order to test the voiding ability immediately after the treatment.

Post-Operative Care

Patients may resume normal work and daily activities within 24 hours of the procedure.

Possible Transient Events

Difficulty in voiding postoperatively. If this occurs the patient may be instructed to perform intermittent catheterization with a disposable 10 -12 Fr. catheter.

Pain and light bleeding during the first voiding episodes.

Urinary tract infection.

Top Up Injection of Bulkamid

If a top up injection is required to improve treatment efficacy this can be carried out 4-6 weeks after the initial injection. Injections can be done at same injection sites or where cushion(s) are missing to reach coaptation.

Troubleshooting

Situation	Cause	Possible Actions
I have injected the Bulkamid hydrogel, but no cushion is forming.	This can occur if the needle is angulated too deep in the tissue, causing the Bulkamid hydrogel to be placed deep in the tissues.	Slowly retracting the Bulkamid needle while continuing to inject the hydrogel until the correct plane is reached and the cushion begins to form.
		Adjust the angulation of the Bulkamid system by retracting the needle from the tissues and reinserting it at a shallower angle prior to injecting Bulkamid.
The cushion is forming but it has not reached the midline of the urethra.	If the Bulkamid hydrogel has been injected into the correct plane (submucosal tissue) but the cushion has not reached the midline it may be due to an insufficient volume of the hydrogel being injected.	Injecting additional hydrogel into the existing cushion through the same needle pathway used in the initial injection.
The patient's bladder keeps filling up during the procedure.	If the bladder keeps filling up during the procedure it can be emptied between injections.	Closing the blue inflow valve and opening the red outflow valve between injections.
		Using a disposable catheter Fr 10-12.
It is difficult to maintain visualization of the internal meatus.	This is often caused by an inconsistent irrigation flow.	Elevating the water bag.
		Putting pressure on the water bag.
		Ensuring that the red outflow valve is closed through the procedure.
		Ensuring the connection between scope and rotatable sheath is tight.

Ordering Information

Item Number	Description
50050	Bulkamid Urethral Bulking System
41-0152A	Bulkamid cystoscope
OM-1000-CI	Bulkamid sterilization container

IMPORTANT SAFETY INFORMATION:

Indications: The Bulkamid Urethral Bulking System is indicated for urethral injection for the treatment of stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD) in adult women who have SUI or stress predominant mixed incontinence.

Contraindications: Bulkamid Urethral Bulking System must not be used in patients suffering from acute urinary tract infection.

Warnings: Implantation and use of the Bulkamid Urethral Bulking System incurs risks beyond those normally associated with surgery. These risks include, but are not limited to urethral bleeding, tissue ischemia, urethral injury or obstruction. The Bulkamid Urethral Bulking System should not be used in patients with urethral or bladder neck strictures until the strictures have been corrected. Use of the Bulkamid Urethral Bulking System in patients with strictures may cause injury and/or urethral obstruction. Over-correction using Bulkamid Hydrogel may lead to obstruction. Do not use Bulkamid Hydrogel in male patients.

Precautions: The Bulkamid Urethral Bulking System is only to be administered by a qualified physician, e.g. gynecologist, urologist, or urogynecologist. Safety and effectiveness of Bulkamid have not been established in patients with a fragile urethral mucosal lining, with urethral hypermobility with a straining angle >30º from horizontal bladder neck, predominant urge incontinence, detrusor overactivity, known polyuria (≥ 3L/24h), unevaluated hematuria, prolapse stage greater than Stage II using the ICS Pelvic Organ Prolapse Quantification (POPQ) exam, BMI >35 kg/m2, neurogenic bladder, less than 18 years of age, have active Herpes Genitalis, or for re-injection of Bulkamid Hydrogel less than 4 weeks after initial injection. The effect of Bulkamid has not been evaluated in women during pregnancy, delivery or lactation. The effect of Bulkamid on subsequent pregnancy and delivery, and the impact of subsequent pregnancy on the effect of Bulkamid, is unknown. Therefore, the risks and benefits of the device in women of childbearing potential should be carefully assessed.

Caution: U.S. Federal law restricts this device to sale and use by, or on the order of, a physician.

For a complete listing of indications, contraindications, warnings and precautions, go to **www.bulkamid.com/isi.**

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