Summary of Safety and Clinical Performance (SSCP)

Allium Ureteral Stent – URS

This document includes: SSCP intended for patients

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The summary of safety and clinical performance was written according to the Medical Device Regulation (EU) 2017/745 and the MDCG 2019-9 Rev. 1 Summary of safety and clinical performance A guide for manufacturers and notified bodies (March 2022)

Contents

The information presented below is intended for patients or lay persons. The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions for Use to provide information on the safe use of the device.

1 Device identification and general information

1.1 Device trade name(s)

Allium Ureter Stent (URS)

1.2 Manufacturer's name and address

Allium Ltd.

2nd Ha-Eshel St.

P.O.BOX 3081

Caesarea Industrial Park 3079501 Israel

1.3 Basic UDI-DI

7290013096

1.4 Year when the first certificate (CE) was issued covering the device

The Allium Ureteral Stent URS received CE mark on 2008.

2 Intended Use of the Device

2.1 Intended Purpose

The Allium Ureteral Stent (URS) is a temporary implant. URS is intended to treat adults over the age of 18 years old with blocked upper urinary tract, and which have difficulty with normal urination (ureteral obstructions) or tears leading to urine leaks (fistulae).

The URS opens the narrowed part of the ureter and allows to pass urine more easily from the kidney to the bladder (ureteral patency). The URS stent can be left inside the ureter for up to 3 years (indwelling time).

2.2 Indication(s) and Target Population(s)

URS is indicated for male and female patients over the age of 18 years, diagnosed with narrowing of the upper urinary tract (ureteral obstruction) or tears leading to urine leaks

(fistulae). This narrowing may result from previous surgeries (surgical interventions), cancer tumors (malignant or benign etiologies) or cancer treatments.

2.3 Contraindications and/or limitations

- Male or female under 18 years old
- Active urinary tract infection
- Fever
- Unusual tendency to bleed (Coagulation diathesis).

3 Device Description

3.1 Description of the Device

The URS device is composed of 2 main elements:

- The URS - ureteral stent
- Delivery device (used for insertion and deployment of the URS in the obstructed ureter).

The Allium Ureteral Stent (URS) is a temporary implant (not permanent) capable of expanding to fit the size of the urinary tube (self expandible). It is made from special flexible metal (a nitinol wire skeleton), covered by a special plastic layer (proprietary polymeric coating). The URS stent is inserted into the body either through the penis (retrograde insertion) or through a small incision in the hip through the kidney and down the urinary tract (antegrade insertion) until reaching the narrowed section. URS stents are shaped like a tube to better fit the urinary tract without moving and once in place and help to freely pass urine (relieve ureteral obstruction and sustain ureteral patency). The URS stents can include an anchor to help keep stent from moving up into the kidney (reduces risk of migration).

URS can remain inside the body for up to 3 years before it needs to be replaced (lifetime of up to 3 years indwelling time). URS stent is designed to come apart if stent removal is done becomes difficult (facilitated retrieval under difficult conditions by unravelling).

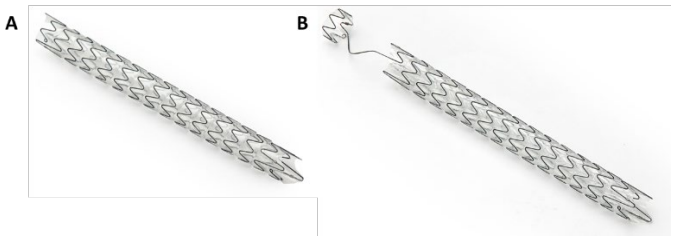

Figure 1 - A: URS Ureteral Stent - B: URS with Anchor Segment

Endoscopic Delivery System –The URS delivery system is a single use, ready to use, stent mounted, X10Fr insertion tube with a working length of 80cm. The URS delivery system (Figure 2) is composed of the following components:

1. Tip with radiopaque marker
2. Outer tube
3. OVM - Outer Visual Marker (black line on the outer tube)
4. Luer lock irrigation port
5. Homeostasis knob
6. Green cap

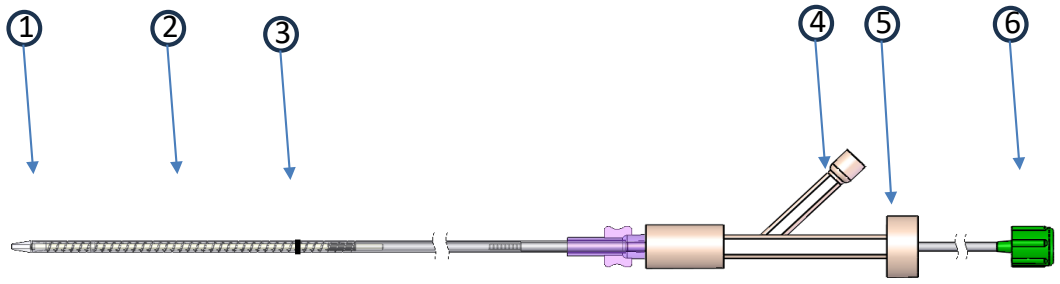

Figure 2 - URS Delivery System

3.2 Mode of action (how the URS device is achieving its intended purpose)

URS flexible metal body is designed to expand (self expandible) to open the narrowing in the upper urinary tract (ureteral obstruction). This force (high radial force mid-segment) keeps the stent in its place and not to move (reduce risk of migration) to allow to pass urine freely.

URS stent is fully covered by a plastic layer (proprietary polymer) designed to support its shape and prevent stent block from tissue growth (ingrowth) and particles setting on the inside (reduce the risk of stent encrustation). The URS stent with anchor is designed to reduce the risk of stent moving out of place (migration) into the kidney.

3.3 Usage

The Ureteral Stent (URS) and Delivery system are for **SINGLE USE** only.

3.4 Description of any Accessories which are Intended to be Used in Combination with the Device

URS device does not include any accessories.

3.5 Description of any Other Devices and Products which are Intended to be Used in Combination with the Device

URS device is not intended to be used in combination with other products.

4 Information on any residual risks and any undesirable effects, warnings and precautions

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.1 Potential Risks and Control Measures

Evaluation of potential risks was carried out by the manufacturer. All identified risks were controlled and found to be within acceptable limits of probability.

Table 1 – Potential Risk Summary

Potential Risk	Description of Risk	Control Measure	Probability of occurrence of harm.
Biological Contamination	The risk of a non-sterile product leading to infection or other complications	The device is sterile device in a sterile package	Remote risk probability
Biocompatibility	The potential use of materials leading to inflammation (non bio-compatible)	Only acceptable materials used	Improbable risk probability
Foreign body reaction	Breakage of a small part of the stent system which can move out of place (part migration) in urinary system	Device is designed to resist breaking	Improbable risk probability
Allergic Reactions	The possibility of allergic reactions to any of the materials	Non allergic materials used	Improbable risk probability

Stent Migration	The risk of stent moving out of place (migration) to the kidney	The design of the stent keeps it in place	Remote risk probability
Stent Removal Difficulties	The inability to remove the stent	The plastic coating and design are intended for easy removal	Remote risk probability
Severe Bleeding	Severe bleeding during stent removal	The design of the stent and materials used reduce injury risk	Remote risk probability

4.2 Undesirable Effects

The following are well known risks in the medical field of indwelling ureteral stents:

Allergic to the metal, Failure of the bladder to empty properly leading to repeated infections (e.g. ureteral reflux ,Reflux-VU), Stent blockage, Stent moved out of place, Bleeding, Infection, injury to urinary tract (e.g. bladder, ureter, kidney, renal pelvis), Leaking of blood or fluid into the tissue around it (Extravasation), Loss of kidney function; Swelling; Trouble to pass urine, Urgency to urinate, Burning sensation while urinating, Night urination, Blood in urine, Inability to hold-in urine, Pain or discomfort; Stent break (fragmentation), urine leak in the body from tear (Fistula); Kidney Swelling (Hydronephrosis); Stone formation ; Tissue damage; Stent damage from wearing out (Erosion), Death.

4.3 Warnings and precautions

A list of warnings and precautions, as mentioned in the IFU, pertaining to the device are presented in Table 2.

Table 2 - Warnings and Precautions Summary

Warning / Precaution	Potential (negative) Effect	Explanation / Details
The **Allium Ureteral Stents** and their delivery system should not come in contact with organic solvents at any time before their use	Impairment of URS structure and function	Potential chemical damage to stent and or delivery system.

Warning / Precaution	Potential (negative) Effect	Explanation / Details
Patients should stop anticoagulation therapy prior to the stent implantation at physician's discretion	Excessive bleeding during implantation a procedure	Anticoagulant therapy is not recommended when patients are scheduled for any type of surgical intervention.
Positioning of the stent may require the use of iodine. The device should not be used in patients who are allergic to iodine	Patient Anaphylactic shock	Stent delivery can include use of iodine; patients allergic to iodine can go into shock if exposed.
Implantation of Allium URS stents in unconventional anatomical circumstances (including during surgical procedures) other than mentioned in this IFU should be consulted with Allium Ltd. prior to use	Patient injury	URS stents may be implanted in patients with difficult anatomy or following a complication during surgery. To avoid patient injury, contact Allium Ltd for advice.
The stent and delivery system should be visually inspected for damage prior to use.	Patient Infection	Sterile package might be damaged. A specific instruction in the IFU directs Doctors to check all parts of the device before using.
The Allium URS is a single use device**- DO NOT REUSE**, reprocess, re-sterilize, or repackage.	Patient Infection	The device is for one use only! Doctors should not re-use device or re-sterilize or repack.
Trans ureteral instrumentation/manipulation in a separate procedure while the stent is in place is not recommended. Longitudinal compression on the stent by instrumentation could dislodge the stent.	Patient injury	If another device is passed through the stent, it may move it out of place or break it which may lead to injury to ureter.
Do not use high energy sources such as laser or electrosurgical equipment on or near the stent, this may cause damage to the surface of the stent and stent	Patient injury	High energy devices such as electrical surgical knife and laser may cause damage to the stent by heating which may lead to injury to the ureter.

Warning / Precaution	Potential (negative) Effect	Explanation / Details
fragmentation.		
Removal of stent in patients after radiation therapy should be performed with caution due to possible underlying ureteral irradiation damage.	Patient injury	Patients undergoing radiation therapy should be examined for tissue damage (known complications of radiotherapy) before trying to remove URS.
The safety and effectiveness of the combined use of the device with other biocompatible materials has not been evaluated.	Potential patient harm	Interactions with unknown substances may cause chemical damage to stent or delivery system.

4.4 Other relevant aspects of safety, including a summary of any Field Safety Corrective Action (FSCA), and Field Safety Notice (FSN) if applicable.

No corrective actions (FSCA) or reports (FSNs) were issued for OPS stents since they were first sold in 2008 up to now.

5 Summary of Clinical Evaluation and Post-Market Clinical Follow-Up (PMCF)

5.1 Clinical background of the device.

The URS stent has been sold and used in hospitals for over 15 years. Several professional clinical publications have been published on the use of ureteral stents.

5.2 The Clinical Evidence for the URS Device

5.2.1 Performance

The clinical parameters for the URS device are summarized in Table 3. Clinical evidence has been reported in 9 clinical articles.

Table 3 - URS Clinical Performance Summary

Kidney Function – parameter	URS – Clinical performance
Kidney swelling (Hydronephrosis volume) (high grades represent worsened kidney function)	URS use was shown to decrease kidney swelling (Hydronephrosis) from grade **2 to grade 1** which is the normal range of kidney volume.

Blood creatinine levels (above normal creatinine levels are indicative of impaired kidney function)	After stent placement (implantation), creatinine levels were shown to be in the normal (sub pathological) levels, indicating that the kidney is functioning normally. • **84.3-89.08µmol/L (range min-max) after 1-year** • **and 90.1 µmol/L after 2 years**
Stent Function	
Open Ureter rates(patency) (measured by stent function over time indicating an open ureter)	Reported as - % of URS stents that were functional when tested: • **84% after 1-year** • **and 57.1% after 2 years**. This is data collected from only 2 studies with a limited number of patients.
Stent Survival (Indwelling time) (measured as time of implanted URS until stent removal by the doctor)	Allium URS stent survival was demonstrated in patients from **2.6 - 31.6 months** (range) supporting the design and function of the stent.

Patients show improvement in kidney function parameters after URS implantation. In addition, URS was shown to have a long-term positive effect, improving the Quality of life of patients (reducing the need for frequent stent replacement). The URS is intended for long indwelling time of up to 3 years.

5.2.2 Safety Data

Safety parameters presented in Table 4 clearly show that Allium stents are safe for patients. This is understood from the low rates of adverse events shown in the clinical studies.

Table 4 - Safety Parameters of Adverse Events Reported on URS

Safety Parameter (Adverse reaction following use of ureteral stents)	**Allium URS** (Range min-max)
Overall Complication Rate of Stent implantation Procedure (Perioperative)	0%
Overall pain- Incidence during indwelling time (postoperative, persistent, intermittent pain)	4-16%
Bloody Urine (Hematuria) and Bleeding	12.5%
Urinary Urgency, Incompetence (Lower Urinary Tract Symptoms)	0-8.3%

Infection (Urinary Tract Infections)	0-6.7%
Stent Blockage by Sediment (Encrustation)	0-6.7%
Stent Obstruction	1-33.3%
Stent Dislodgement from intended position (Migration)	0-26%
Complications related to Stent Removal Procedures (measured at 12-14 months after implantation)	11.7% (one study 17 patients)
Infection rate of Ureter fistulas	0%

6 Suggested Training for Users

6.1 User Profile

Only special doctors trained in stenting and surgeries and other procedures of the urinary system (interventional urology) are allowed to use the URS stent.

6.2 Training for Users

Since the doctors are specifically trained for such procedures, they do not need specific training.

Summary of Safety and Clinical Performance (SSCP)

One Platform System (OPS) Urethral Stents Family of Devices–
Bulbar Urethral Stent (BUS), Round Posterior Stent (RPS) and Triangular Prostatic Stent (TPS Plus)

This document includes: SSCP intended for patients

Manufacturer's reference number for the SSCP:	GEN-QA-MDE-008
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The summary of safety and clinical performance was written according to the Medical Device Regulation (EU) 2017/745 and the MDCG 2019-9 Rev. 1 Summary of safety and clinical performance A guide for manufacturers and notified bodies (March 2022)

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1 Device identification and general information

1.1 Device trade name(s)

One Platform System (OPS) Urethral Stents Family of Devices

- Bulbar Urethral Stent (BUS)
- Round Posterior Stent (RPS)
- Triangular Prostatic Stent (TPS Plus)

1.2 Manufacturer's name and address

Allium Ltd.

2nd Ha-Eshel St.

P.O.BOX 3081

Caesarea Industrial Park 3079501 Israel

1.3 Manufacturer's single registration number (SRN)

IL-MF-000009302

1.4 Basic UDI-DI

7290013096

1.5 Year when the first certificate (CE) was issued covering the device

CE MARK was received on 2008.

2 Intended Use of the Device (BUS, RPS, TPS Plus)

2.1 Intended Purpose

OPS Urethral Stent	***Intended Purpose***
BUS	The Bulbar Urethral Stent is a temporary implant. BUS is intended for males over the age of 18 years with blocked lower urinary tract (bulbar urethra), and which have difficulty with normal urination. The BUS opens the narrow part of the urinary duct (bulbar obstruction) and allows to pass urine more easily (maintain bulbar urethral patency). The BUS can be left inside the urethra for up to 3 years (indwelling time).
RPS	The Round Posterior Stent is a temporary implant. RPS is intended for males over the age of 18 years with blocked urinary tract close to the bladder (posterior urethra), and which have difficulty with normal urination. The RPS opens the narrow part of the urinary duct (bladder neck obstruction) and allows to pass urine more easily (maintaining urethral patency). The RPS can be left inside the urethra for up to 3 years (indwelling time).
TPS Plus	The Triangular Prostatic Stent Plus is a temporary implant. TPS Plus is intended for males over the age of 18 years with blocked prostate urinary tract (prostatic urethra), and which have difficulty with normal urination. The TPS Plus opens the narrow part of the urinary duct and allows to pass urine more easily (maintaining urethral patency). The TPS Plus can be left inside the urethra for up to 3 years (indwelling time).

2.2 Indication(s) and Target Population(s)

OPS Urethral Stent	***Indication for Use***
BUS	The BUS is indicated for male patients over 18 years old, diagnosed with narrowing of the lower urinary duct (bulbar urethral obstruction).
RPS	The RPS is indicated for male patients over 18 years old, diagnosed with narrowing of the urinary duct just under the bladder (Bladder Neck Obstruction).

TPS Plus	The TPS Plus is indicated for male patients over 18 years old, with narrowing of the urinary duct in the prostate (prostatic urethral obstruction).

2.3 Contraindications and/or limitations

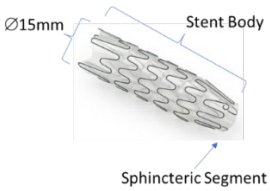
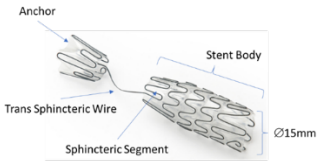
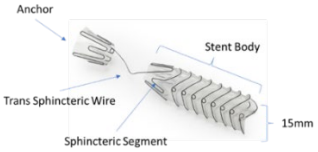
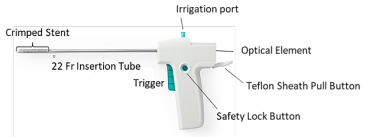
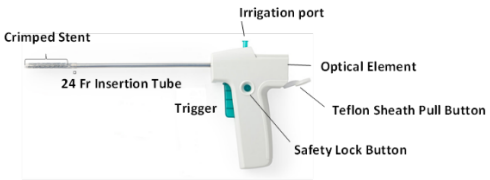
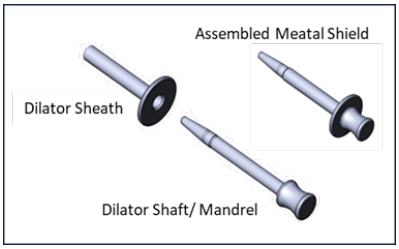
- Male under 18 years old
- Active urinary tract infection
- Fever
- Unusual tendency to bleed (Coagulation diathesis) -
- Weakness of bladder muscle causing difficulty to pass urine (Irreversible atonic/a contractile bladder)
- Patient currently with device to help with erection ("Constriction rings" and/or vacuum erection devices)
- Patients with penile implants and/or artificial urinary valve (sphincters)

3 Device Description

3.1 Description of the Device

One Platform System (OPS) Urethral Stent Family of Devices			
	BUS	**RPS**	**TPS PLUS**
Product Trade Name	**Bulbar Urethral Stent (BUS)**	**Round Posterior Stent (RPS)**	**Triangular Prostatic Stent (TPS Plus)**
General Device Description	The Allium Bulbar Urethral Stent (BUS) is a temporary (not permanent) implant capable of expanding to fit the size of the urinary duct (self expandible). It is made from a flexible metal (a nitinol wire skeleton), covered by a special plastic layer (proprietary polymeric	The Allium Round Posterior Stent (RPS) is a temporary (not permanent) implant capable of expanding to fit the size of the urinary duct (self expandible). It is made from a flexible metal (a nitinol wire	The Allium Triangular prostate stent (TPS Plus) is a temporary (not permanent) implant capable of expanding to fit the size of the urinary duct (self expandible). It is made from a flexible metal (a nitinol wire

One Platform System (OPS) Urethral Stent Family of Devices			
	BUS	**RPS**	**TPS PLUS**
	coating). The BUS is inserted into the body through the penis until reaching the narrowed area of the urinary duct (trans-urethral delivery into the male bulbar urethra). BUS is a tubular shaped body to better fit the urinary tube without moving once in place (high radial force mid-segment). The BUS is intended to allow urine flow (relieve urethral obstruction) throughout its lifetime of up to 3 years before it needs to be replaced (indwelling time). BUS stent is designed to come undone if stent removal becomes difficult (facilitated retrieval under difficult conditions by unravelling). The BUS consists of: • Bulbar Urethra Stent) • Endoscopic Delivery Tool • Metal Shield	skeleton), covered by a special plastic layer (proprietary polymeric coating). The RPS is inserted into the body through the penis until reaching the narrowed area of the urinary duct (transurethral insertion into the male posterior urethra). RPS is a tubular shaped body to better fit the urinary tube without moving once in place (high radial force mid-segment). In addition, RPS includes an anchor which ensures the stent remains in its intended place (reduce risk of migration). The RPS is intended to allow urine flow (relieve posterior urethral obstruction) throughout its lifetime of up to 3 years before it needs to be replaced. RPS stent is designed to come undone if stent removal becomes difficult (facilitated retrieval under difficult conditions by unravelling).	skeleton), covered by special plastic layer (a proprietary polymeric coating). The TPS Plus is inserted into the body through the penis until reaching the narrowed area of the urinary duct (transurethral insertion into the male posterior urethra). TPS Plus is a triangular shaped body to better fit the urinary tube without moving once in place and freely pass urine (high radial force mid-segment). In addition, TPS Plus includes an anchor which ensures the stent remains in its intended place (reduce risk of migration). The TPS Plus is intended to allow urine flow (relieve prostatic urethral obstruction)throughout its lifetime of up to 3 years before it needs to be replaced. The TPS PLUS consists of: • Triangular Prostatic Stent • Endoscopic Delivery Tool

One Platform System (OPS) Urethral Stent Family of Devices			
	BUS	**RPS**	**TPS PLUS**
		The RPS consists of • Bulbar Urethra Stent) • Endoscopic Delivery Tool • Metal Shield	• Metal Shield
Urethral Stent			
Endoscopic Delivery System			
Meatal shield Figure		The Meatal shield is placed in the male penis opening and is intended to reduce pain from stent insertion (atraumatic transurethral insertion). Once in place, the inner part of the shield is removed and the stent can pass through. The meatal shield is removed only after the delivery system has been removed.	

3.2 Design characteristics- material/substances in contact with patient tissues

One Platform System (OPS) Urethral Stent Family of Devices			
	BUS	**RPS**	**TPS PLUS**
Stent Material Composition	BUS stent is comprised of a flexible metal called "nitinol" and is fully covered by a special plastic layer (proprietary polymer coating).	RPS Stent is comprised of a flexible metal called "nitinol" and is fully covered by a special plastic layer (proprietary polymer coating).	TPS Plus Stent is comprised of a flexible metal called "nitinol" and is fully covered by a special plastic layer (proprietary polymer coating).
Size	Diameter: 15mm Length: 50,60 and 80 millimeters	Diameter: 15mm Length:30 and 40 millimeters	Diameter: 15mm Length:30, 40 and 50 millimeters
Contact with patient/ Duration	**YES** / up to 3 years	**YES** / up to 3 years	**YES** / up to 3 years
Endoscopic Delivery System	The BUS, RPS and TPS Plus delivery system 's outer tube is made of Teflon.		
Contact with patient/ Duration	**YES** / under 30 minutes (time of procedure).		

3.3 How the device is achieving its intended mode of action

Table 1 – OPS Urethral Stent Family of Devices Mode of Action

One Platform System (OPS) Urethral Stent Family of Devices		
BUS	**RPS**	**TPS PLUS**
Mode of Action		
The Allium Bulbar Stent (BUS) expands to open the narrowing in the lower urinary duct (high radial force mid-segment designed to relieve urethral obstruction). The front end of the BUS is more cone shaped designed not to disrupt bladder function (ensure a flexible fit and preserve sphincter function). The BUS stent is fully covered by a special plastic layer (proprietary polymer) designed to support its shape and prevents stent block from particles setting on the inside (reduce risk of stent encrustation).	The Allium Round Posterior Urethral Stent (RPS) expands to open the narrowing in the lower urinary duct (high radial force mid-segment, designed to relieve bladder neck obstruction). The anchor is connected by a flexible wire which passes through the bladder opening. Both the anchor and connecting wire are designed to safeguard bladder function (adaptable anatomical fit and preserving sphincter function). The RPS stent is fully covered by a special plastic layer (proprietary polymer) designed to support its shape and prevents stent block from particles setting on the inside (reduce risk of stent encrustation).	The Allium Triangular Prostatic Stent (TPS Plus) expands to open the narrowing in the lower urinary duct (high radial force mid-segment, designed to relieve prostatic urethral obstruction). The anchor is connected by a flexible wire which passes through the bladder opening. Both the anchor and connecting wire are designed to safeguard bladder function (adaptable anatomical fit and preserving sphincter function). The TPS Plus stent is fully covered by special plastic layer (proprietary polymer) designed to support its shape and prevents stent block from particles setting on the inside (reduce risk of stent encrustation).

3.4 Information about medicinal substances in the device

OPS Urethral Stents Family of devices do not have any medicinal substances in the device.

3.5 Description of any accessories which are intended to be used in combination with the device

OPS Urethral Stents Family of devices do not include any accessories.

4 Risks and Warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.1 How potential risks have been controlled or managed

Evaluation of potential risks was carried out by the manufacturer. All identified risks were controlled and found to be within acceptable limits of probability.

Table 2 - Potential Risk Summary

Potential Risk	Description of Risk	Control Measure	Probability of occurrence of harm.
Biological Contamination	The risk of a non-sterile product leading to infection or other complications	The device is a sterile device in a sterile package	Remote risk probability
Biocompatibility	The potential use of materials leading to inflammation (non-bio-compatible)	Only acceptable materials used	Improbable risk probability
Allergic Reactions	The possibility of allergic reactions to any of the materials	Non allergic materials used	Improbable risk probability
Stent Migration	The risk of stent moving out of place (migration) to the kidney	The design of the stent keeps it in place	Occasional probability
Compromised sphincter function	The risk of bladder outlet malfunction because the stent was not placed correctly or moved out of place (migration)	The stent design is meant to keep bladder function	Occasional probability

Severe Bleeding	Severe bleeding during stent removal	Stent will come apart to single strip for easy removal	Remote risk probability

4.1.1 Undesirable Effects

The list of the following undesirable effects, are known for patients who have implanted stents inside their body:

Allergic reaction to the metal (titanium alloy), Sperm leakage (post ejaculatory seminal dribbling), Urinating many times a day or urgency to urinate (reactive urinary frequency or urgency). Tissue growth near the stent end or into the stent (reactive tissue proliferation at one or both ends of the stent). Stent blockage (Occlusion/ Obstruction), Stent moved out of place (migration – e.g. dislodgement), Bleeding (Hemorrhage), Infection (e.g. sepsis, peritonitis, urinary tract infection), Injury to urinary tract (Perforation, Extravasation), Stent block from particles setting on the inside (Encrustation), Swelling (Edema). Symptoms relating to passing urine: inability to hold-in urine (Incontinence), Burning sensation while urinating (Dysuria), Night urination (Nocturia) and Blood in urine (Hematuria). Pain or discomfort, Stent break (Stent fragmentation), Urine leak in the body from tear (Fistula), Urinary tract stones (Stone formation), Tissue damage, Stent damage from wearing out (Erosion).

4.2 Warnings and precautions

A list of warnings and precautions, as mentioned in the Instruction for Use (IFU), are presented in Table 3.

Table 3 - Warnings and Precautions for OPS Family of Devices

Warning / Precaution	Potential (negative) effect	Explanation / Details
The **Allium OPS Urethral stent Family of Devices** and their delivery system should not come in contact with organic solvents at any time before their use	Impairment of stent positioning / stent integrity	Potential chemical damage to stent and/ or delivery system.
Patients should stop anticoagulation therapy prior to the stent implantation at physician's discretion	Excessive bleeding during implantation a procedure	Anticoagulant therapy is not recommended when patients are scheduled for any type of surgical intervention.

Warning / Precaution	Potential (negative) effect	Explanation / Details
The stent and delivery system should be visually inspected for damage prior to use.	Patient Infection	Sterile package might be damaged. A specific instruction in the IFU directs Doctors to check all parts of the device before using.
The device should not be used if the package is open or damaged or if the device has been contaminated prior to insertion.	Patient Infection	Sterile package might be damaged. A specific instruction in the IFU directs Doctors to check seal of sterile package before using.
The Allium URS is a single use device**- DO NOT REUSE**, reprocess, re-sterilize, or repackage.	Patient Infection	The device is for one use only! Doctors should not re-use device or re-sterilize or repack.
Re-mounting an expanded stent into the delivery system should not be attempted.	Patient Injury	Once the stent has expanded, trying to pull back on the delivery system may injure the stent and urethra.
Trans urethral instrumentation/manipulation in a separate procedure while the stent is in place is not recommended. Longitudinal compression on the stent by instrumentation could dislodge the stent.	Patient injury	If another device is passed through the stent, it may move it out of place or break it which may lead to injury to urethra.
Do not use high energy sources such as laser or electrosurgical equipment on or near the stent, this may cause damage to the surface of the stent and stent fragmentation.	Patient injury	High energy devices such as electrical surgical knife and laser may cause damage to the stent by heating which may lead to injury to the urethra.
The safety and effectiveness of the combined use of the device with other biocompatible materials has not been evaluated.	Potential patient harm	Interactions with unknown substances may cause chemical damage to stent or delivery system.

4.3 Summary of any Field Safety Corrective Action (FSCA), and Field Safety Notice (FSN) if applicable.

No corrective actions (FSCA) or reports (FSNs) were issued for OPS stents since they were first sold in 2008 up to now.

5 Summary of Clinical Evaluation and Post-Market Clinical Follow-Up (PMCF)

5.1 Clinical Background of the Device.

The OPS Urethral Stents Family of Devices have been sold and used in hospitals for over 15 years. Several professional clinical publications have been published on the use of urethral stents.

5.2 Clinical Evidence on OPS Family of Devices

5.2.1 Performance

Allium OPS Urethral Stent Family of Devices clinical evidence has been reported in 9 professional clinical articles.

- Bulbar Urethral Stent (BUS)- reported in 6 clinical articles.
- Round Posterior Stent (RPS) - reported in 1 clinical article.
- Triangular Prostatic Stent (TPS) – reported in 2 clinical articles.

Table 4 - Summary of Clinical Data - Performance and Safety

OPS Family Member	Stent function success (% of patients)	Side effects (Adverse Events)	(% of patients)
BUS	81.4%	• Implantation procedure complications	0%
		• Sudden inability to urinate	0%
		• Pain	6.7%
		• Discomfort	1.8%
		• Infection	6.3%

RPS	100%	• Implantation procedure complications • Sudden inability to urinate • Pain • Discomfort • Infection	0% 2.4% 9.5% 4.8% 4.
TPS	96.1%	• Implantation procedure complications • Sudden inability to urinate • Pain • Discomfort • Infection	0% 7.1% 18% 0% 5%

5.2.2 Safety

Clinical studies clearly show that Allium stents are safe for patients. This is understood from the low rates of side effects (adverse events) reported shown in Table 4 above.

6 Suggested Profile and Training for Users

6.1 User Profile

Only special doctors trained in stenting and surgeries and other procedures of the urinary system are allowed to use the OPS stents.

6.2 Training for Users

Since the doctors are specifically trained for such procedures, they do not need specific training.