



Allium Stents

Clinical Brochure



Allium
Urological Solutions



Safety

Prevent ingrowth & reduce encrustation and hyperplasia

- » Fully covered embedded nitinol in proprietary polymeric coating
- » Designed to prevent tissue in-growth
- » Reduced encrustation, stone formation and calcification

Easy & safe placement & removal

- » Simple placement, self-expandable
- » Easy insertion under vision and/or fluoroscopy for accurate positioning
- » Easy removal - stent slides out or unravels
- » Always retrievable



Clinical Superiority

3 years indwelling time

- » Improved quality of life, designed for a long indwelling period
- » Cost effective, eliminates the need for recurrent procedures

Patient comfort

- » Extremely flexible to ensure minimal irritation
- » Maximum patient comfort
- » Full patency

The Only Stent On The Market With:

- » CE approval for 3 years indwelling time
- » Nitinol skeleton fully embedded in a patent polymer
- » Unique back up unraveling mechanism
- » Anchor fixation mechanism



Ureteric Stent Clinical Studies

URS Study 1

A New Self-Expanding, Large-Caliber Ureteral Stent: Results of a Multicenter Experience

- » 40 patients (49 Ureters)
- » Up to 63 months indwelling time
- » Low migration rate
- » Only one stent occluded
- » Stent can be easily removed
- » All stents were successfully implanted with low rate of migration and with high long-term efficiency

URS Study 2

Multicenter Experience with Allium Ureteral Stent for the Treatment of Ureteral Stricture and Fistula

- » 92 patients (107 Ureters)
- » Mean follow up - 27 months
- » Low migration rate
- » Less than 1% stent obstruction
- » Stent can be easily removed
- » The use of Allium ureter stents is feasible, safe and effective

URS Study 3

Allium Stent for Treatment of Ureteral Stenosis

- » 12 patients
- » No migration, encrustation, infection, hematuria or voiding symptoms, caused by bladder irritation
- » No reoccurrence of stenosis

URS Study 4

The First 100 Cases With Allium Ureteral Stent In The Management Of Ureteral Disorders

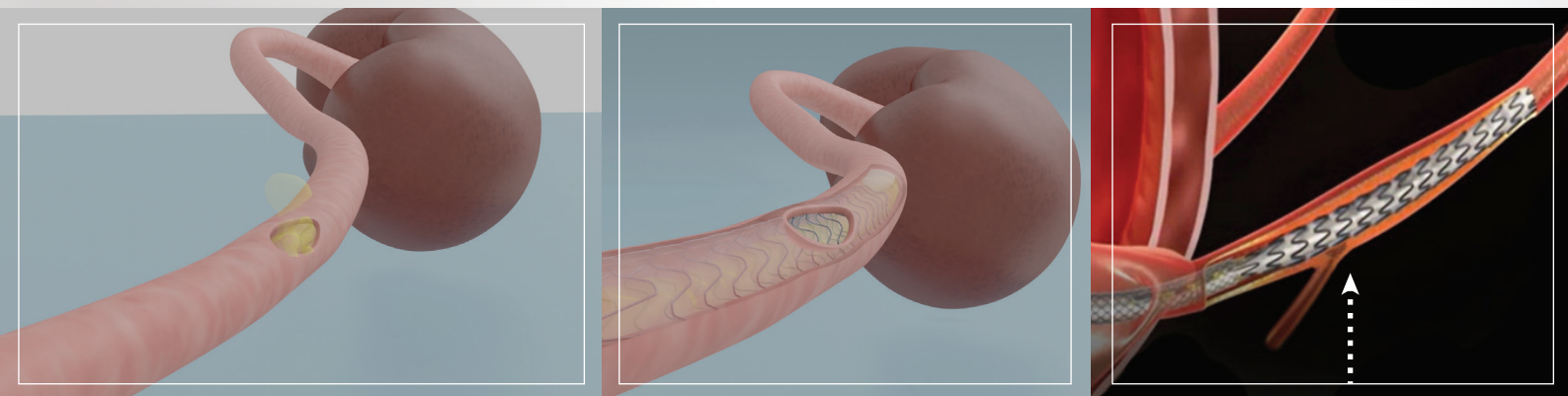
- » 100 patients
- » Low migration rate
- » Allium ureteral stent can be considered a device that require a short learning curve, minimal post operative complications, lower negative impact on the quality of life of patients

- Joerg Neymeyer, Retrospective study on Safety and Performance of Allium URS-Study project (fistula) -in process.
- F. De Marco, "Allium Ureteral Stent in the management of ureteral disorders",INI Grottaferrata and University La Sapienza Rome-in process.

1. B. Moskovitz, S. Halachmi and O. Nativ, "A New Self-Expanding, Large-Caliber Ureteral Stent: Results of a Multicenter Experience", JOURNAL OF ENDOUROLOGY, vol. 26, no. 11, pp. 1523-1527, November 2012. 2. B. Z, M. G, H. S, N. O and M. B, "Multicenter experience with allium ureteral stent for the treatment of ureteral stricture and fistula," Harefuah, vol. 154, no. 12, pp. 753-756, December 2015. 3. L. C., S. M., F. G., D. N. C., T. G., M. L., S. I. and D. D. C, "Allium stent for treatment of ureteral stenosis", MINERVA UROLOGICA E NEFROLOGICA, vol. 65, no. 4, pp. 277-283, December 2013. 4. F. De Marco, "The first 100 cases with Allium Ureteral Stent in the management of ureteral disorders", INI Grottaferrata and University La Sapienza Rome. 5. Xiaoshuai Gao, Turun Song, Liao Peng, Chi Yuan, Wei Wang, Jixiang Chen, Kaiwen Xiao, Xin Wei, "Self-expanding metal ureteral stent for ureteral stricture: Experience of a large-scale prospective study from a high-volume center - Cross-sectional study", International Journal of Surgery 95 (2021) 106161. 6. WANG Qi, LIU Miao-yu, DONG Wen-min, ZHANG Wei-yu, WANG Huan-ru, XU Ke-xin, XU Tao, HU Hao, "Allium ureteral stent for ureteral stenosis: outcomes and initial experiences", J Mod Urol, Vol. 25 No. 7 Jul. 2020. 7. DONG Wen-min, WANG Ming-ru, HU Hao, WANG Qi, XU Ke-xin, XU Tao, "Initial clinical experience and follow-up outcomes of treatment for ureteroileal anastomotic stricture with Allium coated metal ureteral stent", J Mod Urol, Vol. 25 No. 7 Jul. 2020. 8. DONG Wen-min, WANG Ming-ru, HU Hao, WANG Qi, XU Ke-xin, XU Tao, "Initial clinical experience and follow-up outcomes of treatment for ureteroileal anastomotic stricture with Allium coated metal ureteral stent", JOURNAL OF PEKING UNIVERSITY(HEALTH SCIENCES) Vol. 52 No. 4 Aug. 2020.

New CE Clinical Indication

Ureteric Fistula Treatment



Placement of a fully polymeric covered Nitinol stent to minimize and close the leakage of a ureteric fistula

Recently published

Complication Management Cases



1. Malposition of Metallic silicon covered stent. Intraoperative resolution
Horacio Sanguinetti*, Lucas Yirula, Agustin Gonzalez Cazon, Norberto Bernardo, CABA, Argentina
Vol. 203, No. 4S, Supplement, Friday, May 15, 2020, THE JOURNAL OF UROLOGY.
2. Novel Treatment Strategy for Management of Traumatic Bulbar Urethral Rupture Using Temporary Urethral Stent after Primary Realignment; Retrospective Comparison between Thermo-Expandable Urethral Stent and Self-Expandable Polymer-Coated Urethral Stent Sun
Sun Tae Ahn, Dong Hyun Lee, Jong Wook Kim and Du Geon Moon *
J. Clin. Med. 2020, 9, 1274.
3. A Rare Case Report of the Use of Allium Stent in Management of a Gunshot Injury with Incomplete Tear of the Proximal Part of the Right Ureter
Iztok Ditz, MD and Jure Bizjak, MD
JOURNAL OF ENDOUROLOGY CASE REPORTS Volume 5, Number 4, December 2019.

Triangle Prostatic Stent Clinical Studies

TPS Study 1

Allium™ TPS - A New Prostatic Stent for the Treatment of Patients with Benign Prostatic Obstruction

- » 51 patients
- » No stent migrations
- » No stent occlusion
- » Symptoms improvement measured by IPSS (7.7 vs. 26.4)
- » All stents were successfully implanted in all patients

TPS Study 2

A Two-Stage Treatment Procedure for the Difficult to Treat Bladder Neck Contractures with Concomitant Incontinence

- » 14 patients were treated with TPS prior placement of artificial sphincter, in order to control fibrotic scar tissue growth
- » Only 1 stent was migrated
- » The efficacy of the bladder neck stenosis treatment was 93%
- » The results are very promising both on stabilization of the vesicourethral stenosis, as well as patients' safety and tolerability

Round Posterior Stent Clinical Studies

RPS Study 3

A New Self-expanding, Large Caliber Allium Bladder-neck Stent (RPS) in Posterior Urethral or Urethro-vesical Anastomotic Stenosis

- » 10 patients
- » "The Allium RPS is the first "covered stent" specially designed for use in the bladder-neck. Preliminary results indicate that they are safe and effective to maintain bladder-neck patency"

RPS Study 4

Minimal invasive management of bladder neck contracture using Allium round posterior stent: the long-term results

- » 42 patients with recurrent BNC (post-TURP, Monopolar, Bipolar & Radical prostatectomy)
- » Median range follow up - 59 months
- » No adverse events related to RPS placement or the procedure recorded
- » 14% stent migration

Important! Clinical success is defined as a stricture resolution for the long term follow up after stent removal.

1. G. Yildiz, Z. Bahouth, S. Halachmi, G. Meyer, O. Nativ and B. Moskovitz, "Allium™ TPS-A New Prostatic Stent for the Treatment of Patients with Benign Prostatic Obstruction: The First Report", JOURNAL OF ENDOUROLOGY, vol. 30, no. 3, pp. 319-322, 2016.
2. I. Adamakis, E. Fragkiadis, I. Katafigiotis, G. Kousournas, K. Stravodimos and C. A. Constantinides, "A two staged treatment procedure for the difficult to treat bladder neck contractures with concomitant incontinence. In the search of a solution to a complex problem," Archivio Italiano di Urologia e Andrologia, vol. 87, no. 3 pp. 233-237, 2015.
3. C. F. M. B, N. O, R. P, H. C, O. I and J. J.P.S, "A New Self-expanding, Large Caliber Allium Bladder-neck Stent (RPS) in Posterior Urethral or Urethro-vesical Anastomotic Stenoses: Preliminary Results," in 28th World Congress of Endourology, Chicago, 010.
4. Kerem Teke, Efe Bosnali, Onder Kara, Murat Ustuner, Ibrahim E. Avci, Mustafa M. Culha, "Minimal invasive management of bladder neck contracture using Allium round posterior stent: the long-term results", Prostate International, in press.

Bulbar Urethral Stent - BUS

BUS Study 1

Recanalization of Urethral Stricture New-Generation Temporary Covered Biocompatible Metal Endoprostheses

- » 40 patients
- » Only 5% migration rate
- » The stent clinical use represents a therapeutic advance in the management of strictures of the male urethra

BUS Study 2

Bulbar Urethral Stents for Bulbar Urethral Strictures: Long-Term Follow-Up after Stent Removal

- » 168 patients with recurrent bulbar stricture after internal urethrotomy
- » Median range follow up - 71 months
- » No adverse events related to the stent or the procedure recorded
- » No post-procedure complication observed
- » Migration - 16 cases - 9.5%

Clinical success strongly depends on the indwelling time and the number of DVIU (direct visual internal urethrotomy) previously provided (clinical success is based on the stricture resolution).

Important! Clinical success is defined as a stricture resolution for the long term follow up after stent removal.

BUS Study 3

Management of Recurrent Bulbar Urethral Stricture a 54 Patients Study with Allium Bulbar Urethral Stent

- » 54 patients
- » Only 4% migration rate
- » All patients reported good urinary flow after stent placement
- » The unique characteristics of the stent make it an excellent solution for the treatment of bulbar strictures

BUS Study 4

Allium™ Bulbar Urethral Stent: An Updated Long-Term Multi-Center Study with A New Treatment Modality for Bulbar Urethral Stricture

- » 64 patients
- » Up to 18 month indwelling time
- » Only 9% migration rate
- » The overall success rate was achieved in 48 of 64 patients (75%)

1. M. Z, M. B, T. C, H.-D. J, S. V, S. Di, M. D and M. S, "Recanalisation of urethral strictures with new-generation temporary covered biocompatible metal endoprostheses," Acta Chirurgica Iugoslavica, vol. 3, pp. 123-127, 2007.
2. Murat Üstünera, Kerem Tekeb, Efe Bosnalib, Önder Karab, Seyfettin Çiftçib, Mustafa Melih Çulhab, "Bulbar Urethral Stents for Bulbar Urethral Strictures: Long-Term Follow-Up after Stent Removal", Urologia Internationalis DOI: 10.1159/000514417.
3. Melih Culha1*, Unsal Ozkuvanci2*, Seyfettin Ciftci1*, Ali Saribacak3*, Murat Ustuner1*, Ufuk Yavuz1*, Hasan Yilmaz1*, Levend Ozkan1* Management of recurrent bulbar urethral stricture-a 54 patients study with Allium bulbar urethral stent (BUS) Int J Clin Exp Med 2014;7(10):3415-3419 www.ijcem.com /ISSN:1940-5901/IJCEM0001834.
4. M. Culha1, Z. Bahouth, U. Ozkuvanci, S. Halachmi, L. Ozkan, O. Nativ, A. Saribacak, M. Ustuner, U. Yavuz, S. Ciftci, H. Yilmaz and B. Moskovitz, "Allium™ Bulbar Urethral Stent: An Updated Long-Term Multi-Center Study with New Treatment Modality for Bulbar Urethral Stricture," Open Journal of Urology, vol. 6, pp. 43-48, 2016.

“I have placed hundreds of Allium stents and found them to be the best stents in the market. Allium stents are easy to insert and remove, function effectively even after 3 years.”

*Dr. Joerg Neymeyer, Chair, Section of Urogynecology,
Charite Hospital, Medical University of Berlin*



“Allium Medical has introduced an improvement of a well-known and widely used product in endourological practice - stents. Designed uniquely for each type of stricture, made of nitinol, and coated with a specially designed co-polymer, these stents have advantages over other known stents”.

*Prof. Boaz Moskovitz, Head Department of Urology,
Bnei-Zion Medical Center, Haifa, Israel*

Contact us

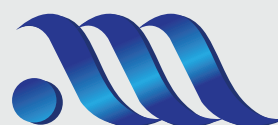
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