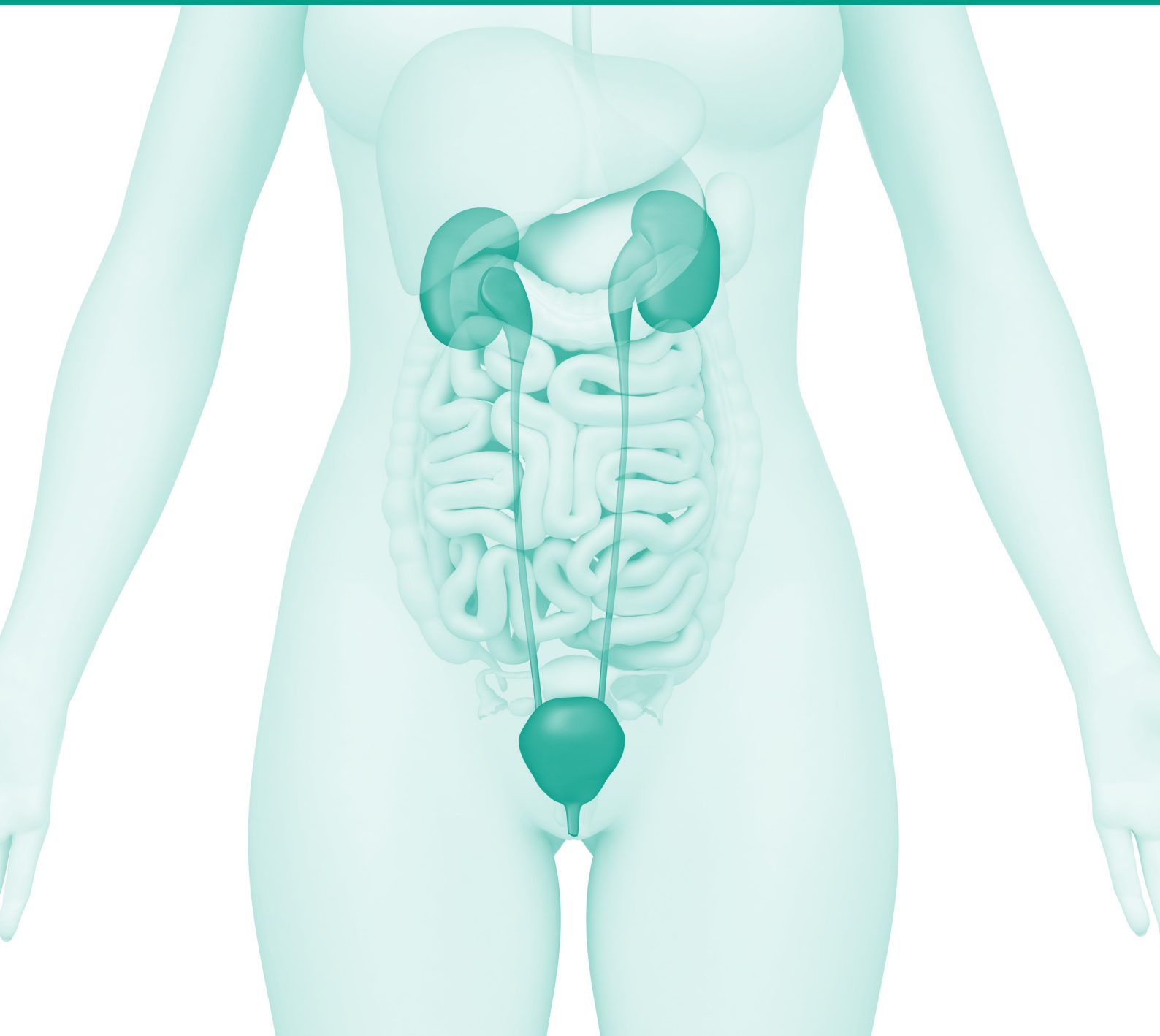


URIGLOW[®]
Transilluminating Ureteric Stents



Our company

APR Medtech is a specialist independent medical technology company providing high quality medical devices and support services to the NHS and private healthcare sector.

Our products offer intelligent clinical solutions designed to help advance healthcare and improve patient outcomes. Our extensive experience within the healthcare industry, deep knowledge of the clinical areas in which we work and a genuine passion for what we do, ensures the delivery of real value to our customers.

Service and support

One of the key elements of our customer support service is product training. We want to be sure that our products are always used in the optimal way to the benefit of both our customers and their patients.

If you would like one of our team to visit, either to attend a procedure or run a training session on one of our products, then please get in touch. We will be more than happy to oblige.

Get in touch

Please contact us on [01844 340 620](tel:01844340620) or email info@aprmedtech.com

Additional information is also available on our website www.aprmedtech.com

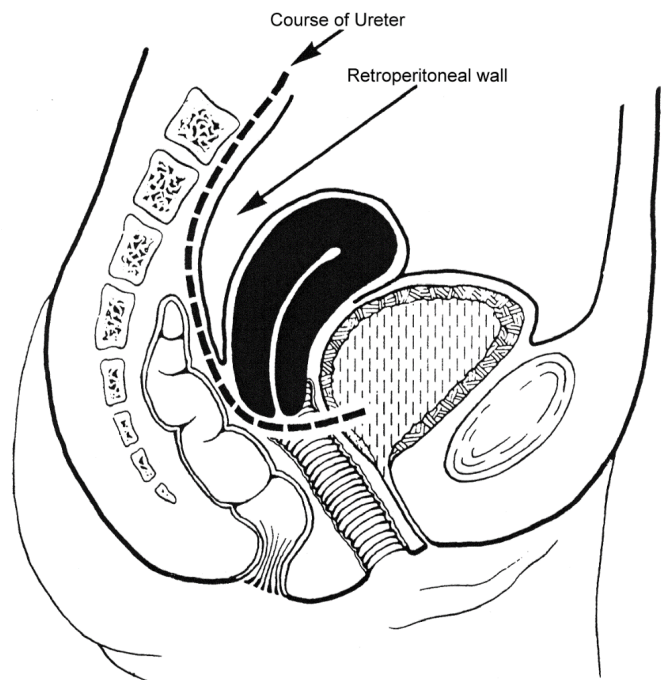
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INTRODUCTION

The problem

- The ureter is not a free structure within the pelvis as it runs behind and is adherent to the retroperitoneal wall where it cannot not be seen directly. In open surgery it can be palpated, but in laparoscopic surgery the ureter cannot be easily detected in its normal state.
- The close proximity of the ureters to the uterus, cervix and uterine ligaments can make open gynaecological and colorectal surgery hazardous, particularly in hysterectomy when the ovary is adherent to the posterior pelvic wall due to endometriotic deposits or tumour.
- There is an established complication rate of between 1-1.5% in abdominal hysterectomy which involves damage to ureters either by accidental division or by ligation. In almost every case of accidental ureteric damage, poor vision and distorted anatomy has been a significant contributor.
- Laparoscopic Assisted Vaginal Hysterectomy (LAVH) has been adopted as an alternative to conventional abdominal hysterectomy, the advantages being considerably shorter recovery times, shorter hospital stay and a superior cosmetic result.
- However, this procedure may be deemed hazardous as there is a chance of including the ureters in the division of the uterosacral ligaments.
- Laparoscopic ablation of endometriosis with laser or diathermy also present complications when deposits are found in the lower pelvis.
- There is a significant risk that the ureter could be damaged by the laser or diathermy as thermal penetration often extends several millimetres from the point of contact.
- Surgeons may leave some deposits untreated rather than risk damaging the ureters. This may reduce the efficacy of the procedure.



URIGLOW® Transilluminating Ureteric Stents

This product illuminates the ureter from the inside. Light shines through the thin peritoneum and identifies the position and track of the ureter. In practice the URIGLOW® appears as a line of 6 glowing dots which can be seen in the lower pelvis. As the stent is inserted or withdrawn, the track of the ureter is demonstrated. The device has particular use in those procedures which put the ureter at risk:

- Laparoscopic Assisted Vaginal Hysterectomy (LAVH)
- Laser/diathermy ablation of endometriosis
- Complicated pelvic dissection – open or laparoscopic
- Uterosacral nerve plexus ablation
- High and low anterior resection



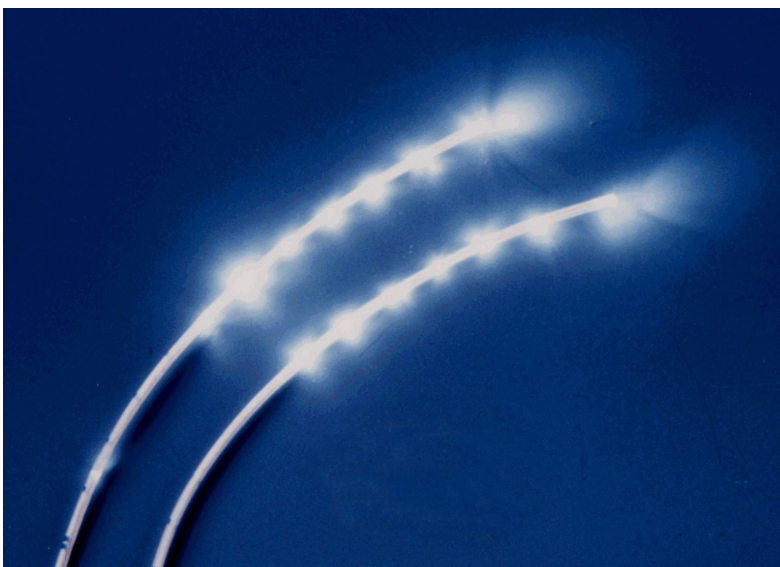
PRODUCT DESCRIPTION

URIGLOW® Transilluminating Ureteric Stents

- The URIGLOW® is a fibre optic ureteric stent designed to connect to a high intensity laparoscopic light source. See page 8 for guidance on light sources.
- It is inserted into the ureter through a standard operating cystoscope as for any conventional ureteric catheter. The stent has universal markings to assist in correct placement.
- The distal tip is specially prepared to emit light from 6 points 1cm apart which allows easy identification of the position and track of the ureter. The catheter can be inserted and withdrawn during the operative procedure to demonstrate different portions of the ureteric tract.

Construction

- The URIGLOW® is an acrylic single fibre bundle 1m long covered in a medical grade PVC coating.
- The ends of the stent are sealed with medical grade epoxy resin, the distal end is then domed whilst the proximal end is cut and polished.
- Markings are conventional 1cm graduations commencing 75mm from the tip.
- The 6 glow points are produced by etching the refractive coating to release light from the fibre.



PRODUCT DESCRIPTION

Specifications

Optical fibre: 1.9mm (6Fr) OD x 100cm radiopaque marker line.

Active tip: 6 x 1cm high intensity emission points. 1st point 15mm from distal domed tip.

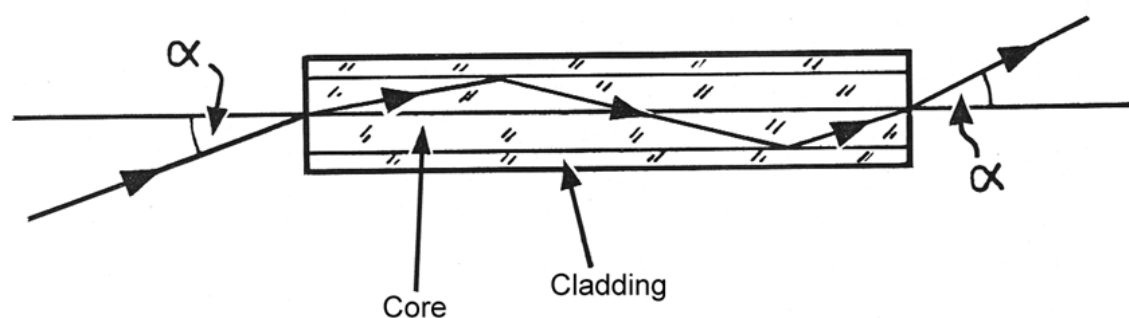
Marker positions from the distal tip:

- 1st single blue marker: 75mm
- 2nd single blue marker: 85mm
- 3rd single blue marker: 95mm
- 4th single blue marker: 105mm
- 5th double blue marker: 120mm
- Mid-point of RED marker: 175mm
- Mid-point of wide BLUE marker: 285mm

Fibre optic transmission

All fibre optic cable systems rely on a property of light known as total internal reflection. When light passes from one medium to another which is optically less dense e.g. from glass to air, the ray is bent away from the normal.

If the incident ray meets the surface at such an angle that the refracted ray is bent away at an angle of more than 90° , then the light cannot emerge at all and is totally internally reflected. In practice this is commonly achieved by applying a vacuum coating to an acrylic fibre.



PRODUCT DESCRIPTION

URIGLOW® Light Guide Coupler (LGC)

- Light guide connection: Experience has shown that some high intensity light sources can produce significant levels of infrared radiation. Modern light sources may have infrared filters but can still produce high infrared outputs.
- Infrared radiation can cause heating when in close proximity to tissue and could damage the ureter if allowed to reach the URIGLOW® stent.
- The URIGLOW® LGC is specifically designed to minimise this potentially harmful infrared radiation.
- The URIGLOW® LGC is a precision optical device designed to absorb up to 90% of infrared radiation present in the output of medical light sources.
- It safely and securely links URIGLOW® Transilluminating Ureteric Stents to fibre optic cables.

Reference: Phipps J.H. & Tyrrell. N.J. 'Transilluminating ureteric stents for preventing operative ureteric damage' Br. J. Obstet. Gynaecol. 1992. 99. pp81-84.



PRODUCT DESCRIPTION

Light sources

- Laparoscopic light sources have become highly complex devices during recent years. This is principally due to the introduction of HD video camera systems.
- There are various types of light source, the differentiation is based upon the type of bulb system that they use.

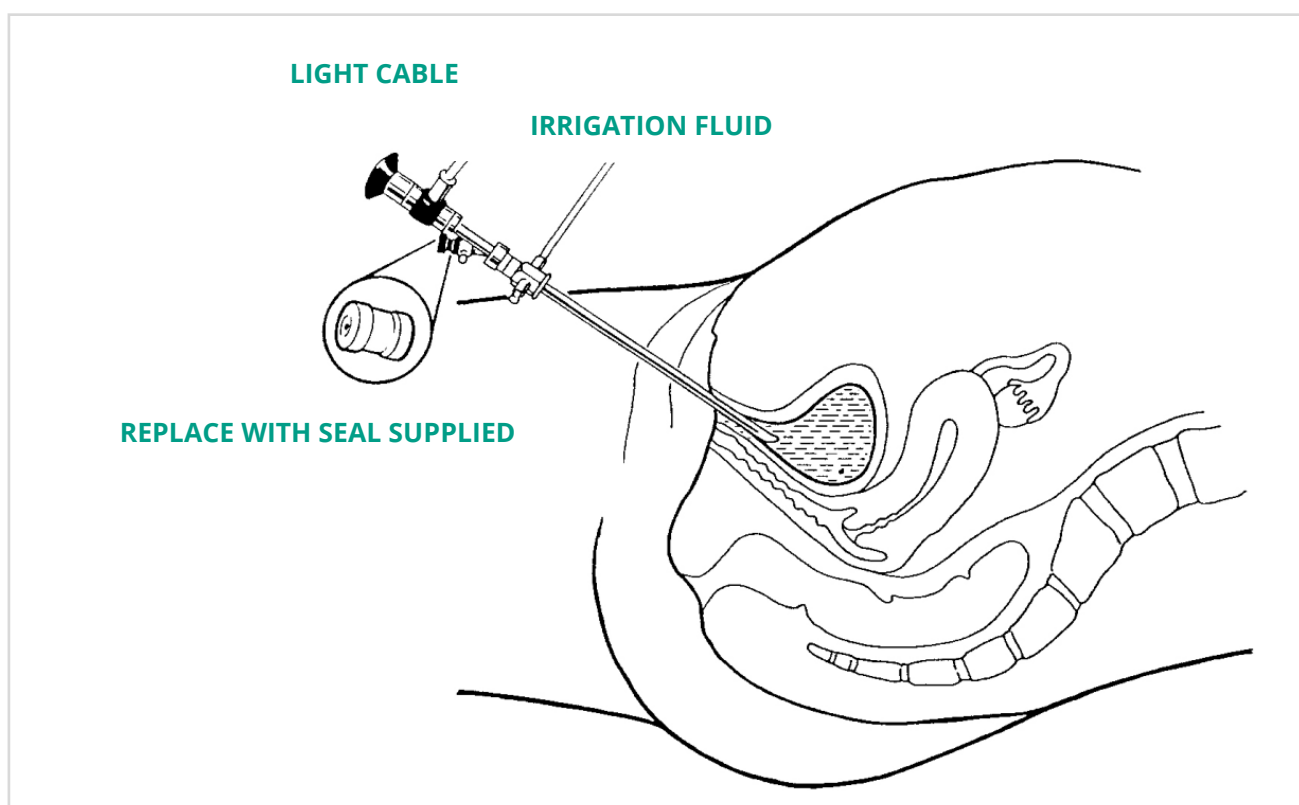
Type	Output colour	Min. output required
Quartz halogen	3500°K	250W
Metal halide	4500°K	250W
Xenon	6000°K	250W
Mercury arc	6000°K	250W
LED	6000°K	50W (where stated)

- Quartz halogen and metal halide light sources rely on a filament, usually of a tungsten alloy inside a sealed envelope containing a combination of halogens (iodine, fluorine, chlorine and bromine) or rare gases such as xenon. The 'brilliance' of the light is determined by the operating temperature of the filament. In principle, the hotter the filament, the brighter the light source.
- The halogen and halide sources produce light from lower in the electromagnetic scale and have high yellow and red spectrums. These are acceptable for direct illumination (laparoscopy) but when passed through tissue as in the URIGLOW[®] application, there is significant absorption of light.
- Xenon and mercury arc sources produce a brilliant 'white' light using a significantly hotter output. However, these sources produce a wide infrared spectrum which means that the light, although bright, is intensely hot and can cause burning of tissue if placed in close proximity.
- LED light sources are a recent addition and use clusters of light emitting diodes producing light typically comprised of 3 different frequencies. Light outputs of LED light are not usually quoted in watts and therefore comparison with filament and arc systems is more difficult. LED light sources also have the advantage of producing less output in the IR spectrum, especially compared to xenon and mercury arc systems. As a good guideline, if your LED light source is suitable for laparoscopy, it will have sufficient output to illuminate the URIGLOW[®].
- In ALL cases the URIGLOW[®] **MUST** be used with the URIGLOW[®] Light Guide Coupler.

PROCEDURAL INFORMATION

Unpacking stents and loading the cystoscope

- The URIGLOW[®] set contains two stents in a protective tray complete with a specific URIGLOW[®] seal for the cystoscope and two spare white nylon screws for the coupler, in case these have been lost or removed prior to sterilisation.
- The stent should be carefully removed from the tray and the active end (with markings) identified.
- Placement of the URIGLOW[®] requires a 0° or 30° operating cystoscope with a >2.0mm channel for ureteric catheter placement.
- Remove the existing seal from the channel port and replace with the seal supplied in the tray. The special URIGLOW[®] seal has a larger diameter hole than normal to permit easier passage of the stent.



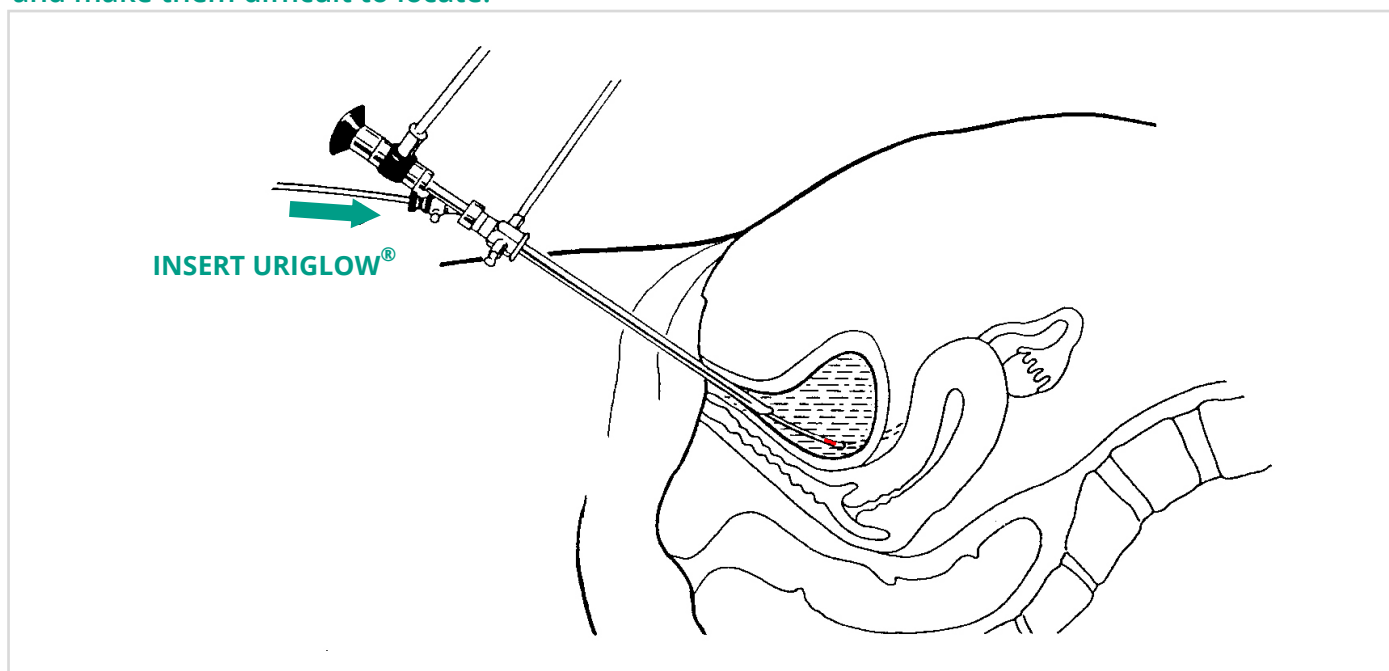
- USE THE SEAL PROVIDED IN THE TRAY FOR THE OPERATING CHANNEL OF THE CYSTOSCOPE. USE OF ANY OTHER SEAL MAY CAUSE DAMAGE TO THE URIGLOW[®].
- Carefully insert the URIGLOW[®] into the operating channel of the cystoscope until the stent is just protruding from the distal end of the scope.

PROCEDURAL INFORMATION

Cystoscopy and ureteric cannulation

- It is strongly recommended that the cystoscopy and stent insertion are completed as a separate procedure prior to the draping and preparation for the primary surgery. This makes attachment of the stents and positioning of the Light Guide Coupler easier and safer.
- A clinician may prefer to ask a urological trained colleague to place the URIGLOW[®] although the technique is not difficult to learn and most are quite capable of performing cystoscopy and placing ureteric stents safely after appropriate guidance and mentoring.
- The cystoscope is inserted into the urethra and the bladder filled with water. The surgeon will then examine the internal surface of the bladder and identify the position of the ureteric orifices. These normally appear as two small impressions five centimetres apart at the base of the bladder.

IMPORTANT: Over-distension of the bladder with the irrigating fluid can often close the ureters and make them difficult to locate.

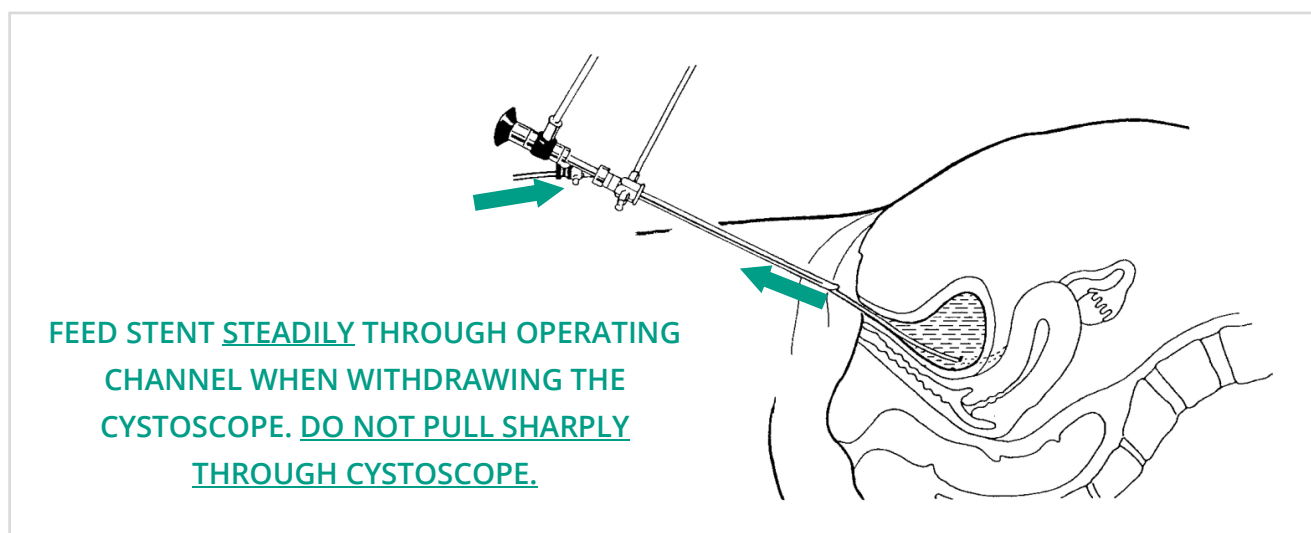


- Once identified, the URIGLOW[®] can be carefully threaded through the cystoscope channel into the ureteric orifice.
- The URIGLOW[®] should be inserted up to the last RED marking at the ureteric orifice.
- Both stents should be withdrawn following insertion of the second stent so the RED marker is at the external urethral meatus. This typically positions the illuminated portion of the stent in the lower pelvic ureter.

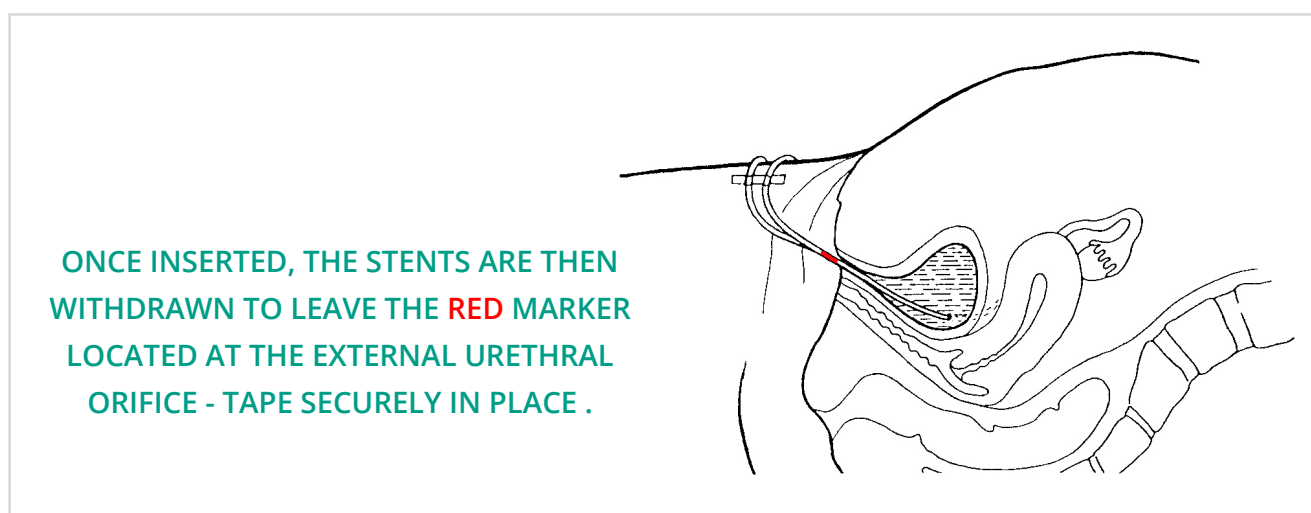
PROCEDURAL INFORMATION

Removal of the cystoscope and securing the URIGLOW®

- After insertion of the first stent, the URIGLOW® is gently threaded through the scope to allow withdrawal.
- Avoid 'stripping' the cystoscope along the stent during withdrawal - it may damage the fibre bundle and will reduce light emission.



- The URIGLOW® can be secured to the upper leg with tape by placing one x 10cm piece along the length of the fibre and two x 5cm pieces across the line of the stent.
- Take care to see that if the legs are to be lowered for open surgery, that the URIGLOW® stents are not accidentally pulled out.
- The process can then be repeated for the second stent.



MOUNTING THE URIGLOW[®] LGC

Using the URIGLOW[®] Light Guide Coupler (LGC)

CAUTION: TO ENSURE PATIENT PROTECTION URIGLOW[®] TRANSILLUMINATING URETERIC STENTS MUST ONLY BE USED IN CONJUNCTION WITH THE URIGLOW[®] LGC.

- For the connection of URIGLOW[®] Transilluminating Ureteric Stents to Storz-type fibre light guides.
- The LGC is designed to protect the URIGLOW[®] Transilluminating Ureteric Stents and ureters by reflecting and absorbing the infrared radiation present in the output of medical light sources.
- Mounting the LGC requires use of the URIGLOW[®] LGC Bracket (see pages 13-14).



WARNING: THE URIGLOW[®] LGC IS DESIGNED TO ABSORB IR RADIATION AND WILL HEAT UP.

DO NOT ALLOW IT TO COME INTO CONTACT WITH THE PATIENT.

ENSURE THAT AIR CAN CIRCULATE FREELY AROUND THE COUPLER WHEN IN USE. DO NOT WRAP.

Recommended position
for the Light Guide
Coupler

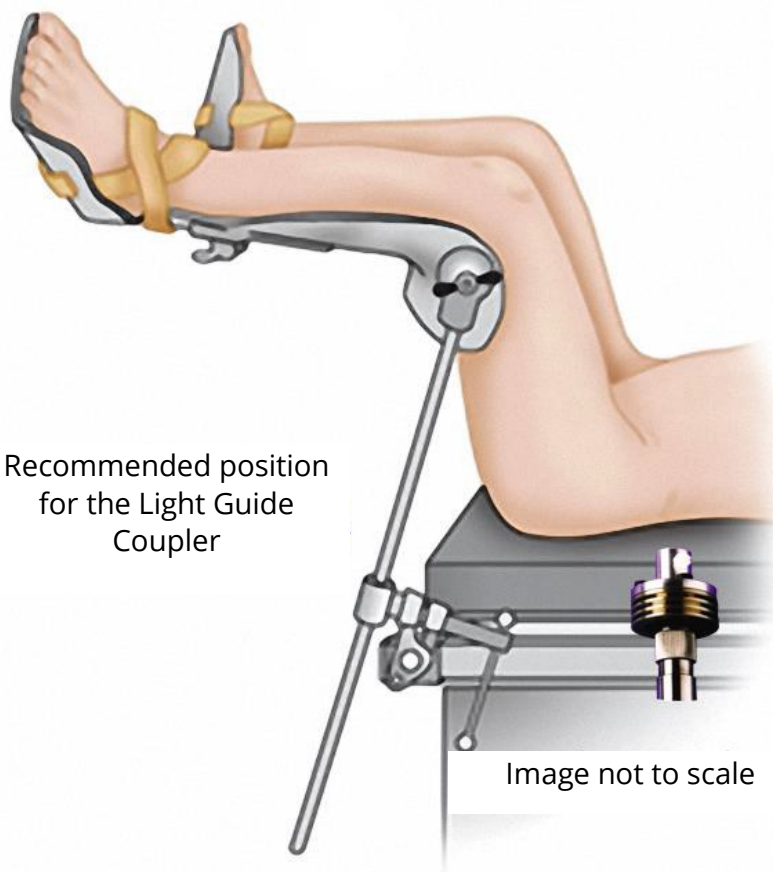


Image not to scale

MOUNTING THE URIGLOW® LGC

Mounting the URIGLOW® Light Guide Coupler (LGC) using the URIGLOW® LGC Bracket

- The URIGLOW® LGC Bracket may be used to support the LGC on operating tables with and without rails.



- Slide the LGC into the opening on the LGC Bracket until it locks fully into the slot (lower image).



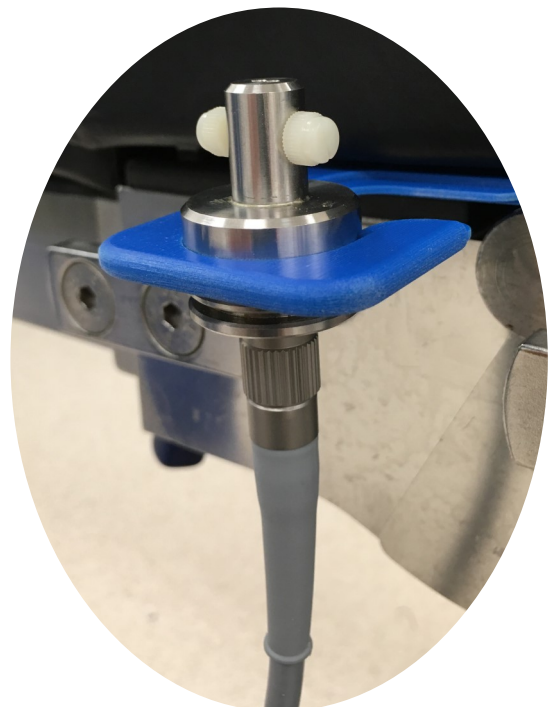
MOUNTING THE URIGLOW® LGC

Mounting the URIGLOW® Light Guide Coupler (LGC) using the URIGLOW® LGC Bracket

- The LGC should be supported on the uppermost groove – see image right.
- Selecting an appropriate side of the operating table, the bracket complete with LGC can be inserted under the table mattress with the wide section innermost.



- It is recommended that the LGC and bracket are positioned prior to the placing of the patient onto the operating table, however the final position of equipment may not always permit this.



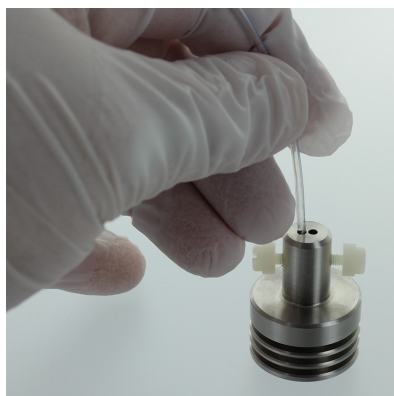
The URIGLOW® LGC Bracket may be surface decontaminated only. It may not be autoclaved.

ALWAYS EXERCISE CAUTION DURING ANY MOVEMENT OR REPOSITIONING OF THE PATIENT.

ATTACHING THE STENTS

Attaching the stents to the URIGLOW[®] Light Guide Coupler (LGC)

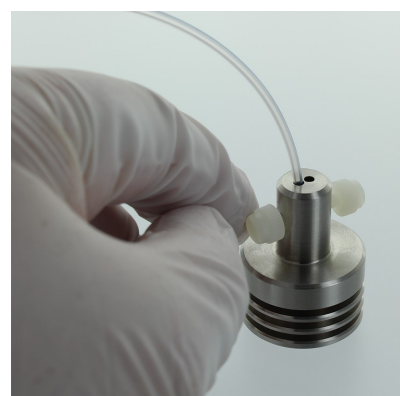
- Undo the nylon screws in the LGC – they do not need to be fully removed, simply loosened to allow the stent to be fully inserted into the LGC.
- Every URIGLOW[®] stent pack contains two spare white nylon screws should they be required.



Locate the tip of the stent into the LGC



Gently insert the stent 12-15mm until it reaches the bottom of the LGC barrel



Lightly tighten the nylon screws to secure the stent
DO NOT OVERTIGHTEN

- The LGC may be used with one or two stents.

USING THE URIGLOW[®]

Ureteric identification - in laparoscopy and open surgery

- Once initial laparoscopy or laparotomy has been performed, it is important to establish the correct position and function of the URIGLOW[®] stents.
- With the light source activated, the surgeon should examine the lower pelvis for the presence of glowing lines - indicating the track of the ureter.
- If the URIGLOW[®] is not immediately obvious, the surgical assistant should gently withdraw or insert the stent by no more than 20mm - the red marker should normally be at the external urethral orifice to demonstrate the lower pelvic ureter.
- The URIGLOW[®] can be inserted further to demonstrate the mid and upper portions of the ureteric tract.

Laparoscopic technique – use of shade

- Identification of the URIGLOW[®] relies on differential illumination. The light emitted by the URIGLOW[®] stent must, by definition pass through the ureter and the surrounding tissue.
- During the identification process, there is a temptation to approach the surgical area where they are expected to appear too closely, thus swamping the light output from the URIGLOW[®] stents with the light from the laparoscope.
- There is also a temptation to turn down the laparoscope light source – in modern systems where camera and light source are electronically linked, this may reduce the resolution of the camera and actually reduce visibility.
- In both cases the best technique is to withdraw the laparoscope from the field placing the lower or mid pelvis in partial shade. The light from the URIGLOW[®] then becomes visible, provided the tissue surrounding it is sufficiently thin to permit transmission.

URIGLOW[®] removal

- The URIGLOW[®] stents are easily removed at the end of the procedure, by gently withdrawing the stent through the urethra. There is not normally any reason to re-cystoscope the patient to remove the stents unless there is evidence of active bleeding.
- It is quite normal for the patient to experience light haematuria for 6-8 hours post insertion.
- The device is strictly for single use and no attempt should be made to re-sterilise the stent.

LIGHT GUIDE COUPLER

Light Guide Coupler—Cleaning and Sterilisation

The URIGLOW® Light Guide coupler is not sterile in use and in normal usage should only require surface decontamination with 70% Isopropyl Alcohol (IPA) wipes.

If more significant contamination has occurred:

- Initial Cleaning: Remove White Securing Screws and discard. Each URIGLOW® Stent set contains replacement securing screws.
- Rinse blood and saline solutions from the coupler as soon as possible following use. When cleaning by hand, the coupler should be cleaned with a soft nylon brush under cool or warm running water. Very hot water will cause coagulation of proteinous substances and should not be used.
- Mechanical washing machines and ultrasonic cleaners, using instrument detergents of strength recommended by the manufacturer may be used followed by a clean rinse. Neutral (Ph7) detergents should be used during manual, mechanical or ultrasonic cleaning. The use of high pH alkaline detergents may be used but can result in the formation of brown or orange staining on the instrument.
- The concentration and volume of detergents used should be in line with the detergent manufacturer's instructions, taking into account regional water quality variations

Sterilisation: The recommended method for sterilisation is steam sterilisation @ 134°C (+3°C – 0°C) for minimum of 3 minutes.

This recommendation should be used in conjunction with the standards and guidelines laid down in ISO 17665-1:2009 (as amended): Sterilization of Health Care Products - Moist heat. Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices and ISO/TS 17665-2:2009 Sterilization of health care products: Moist heat - Part 2: Guidance on the application of ISO 17665-1

The URIGLOW® LGC is a precision optical instrument, repeated autoclaving will reduce the overall life of the device

DO NOT IMMERSE IN GLUTERALDEHYDE OR SIMILAR DISINFECTANT SOLUTIONS.

THIS WILL RESULT IN IRREPARABLE DAMAGE TO THE COUPLER

URIGLOW® ORDERING INFORMATION

Transilluminating Ureteric Stents & Light Guide Coupler

URIGLOW® Transilluminating Ureteric Stents provide rapid identification of the lower pelvic ureters during open and laparoscopic surgery.

HIGH VISIBILITY in a wide range of operative conditions has been achieved by using a new type of optical fibre, ensuring better intra-operative performance and easier detection.

THE URIGLOW® LIGHT GUIDE COUPLER (LGC) is a reusable precision optical device designed to absorb up to 90% of infrared radiation present in the output of medical light sources. The URIGLOW® LGC safely and securely links fibre optic cables to the URIGLOW® Transilluminating Ureteric Stents.

HIGH LEVEL IR ABSORPTION The URIGLOW® LGC is designed to absorb up to 90% of light source IR output which means there is no detrimental heating effect in the ureters from high intensity light sources.

ROBUST DESIGN Solid stainless steel construction securely protects the delicate IR mirror and lens assembly.

SECURE ATTACHMENT The URIGLOW® LGC will securely attach the URIGLOW® Transilluminating Ureteric Stents to any standard Storz/ACMI screw type light cable fitting.

ROBUST DESIGN The URIGLOW® LGC is designed for steam sterilisation. Autoclave: 134°C (+3°C – 0°C) for a minimum of three minutes. Carefully follow instructions provided with the unit.



SPECIFICATIONS

Optical fibre:

1.9mm (6Fr) OD x 100cm radiopaque marker line.

Active tip:

6 x 1cm high intensity emission points.

1st point 15mm from distal domed tip.

Marker positions from the distal tip:

1st single blue marker: 75mm

2nd single blue marker: 85mm

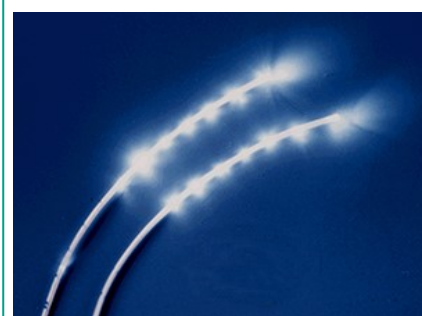
3rd single blue marker: 95mm

4th single blue marker: 105mm

5th double blue marker: 120mm

Mid-point of RED marker: 175mm

Mid-point of wide BLUE marker: 285mm



Description	Product code
URIGLOW® Transilluminating Ureteric Stents Packed: Two stents in protective tray, complete with cystoscope bung and instruction sheet. For single use.	R57412
URIGLOW® Light Guide Coupler For attachment of URIGLOW® stents to fibre light sources with outputs >250W. Storz fitting fibre cable. Reusable.	R57411

CLINICAL ARTICLES

Below are a selection of clinical articles related to the use of lighted ureteral stents, iatrogenic ureteral injury during colorectal and gynaecological surgery and its management

- Boyan WP Jr, Lavy D, Dinallo A, Otero J, Roding A, Hanos D, Dressner R, Arvanitis M. Lighted ureteral stents in laparoscopic colorectal surgery; a five-year experience. *Ann Transl Med* 2017;5(3):44. doi: 10.21037/atm.2017.02.01.
- Burks FN, Santucci RA. Management of iatrogenic ureteral injury. *Ther Adv Urol*. 2014;6:115–124. doi: 10.1177/1756287214526767.
- Park JH, Park JW, Song K, Jo MK. Ureteral injury in gynecologic surgery: a 5-year review in a community hospital. *Korean journal of urology*. 2012;53(2):120–125.
- Manoucheri E, Cohen SL, Sandberg EM, Kibel AS, Einarsson J. Ureteral injury in laparoscopic gynecologic surgery. *Rev Obstet Gynecol*. 2012;5:106–11.
- Redan JA, McCarus SD. Protect the ureters. *JSLs*. 2009;13:139–41.
- Vakili B, Chesson RR, Kyle BL, et al. The incidence of urinary tract injury during hysterectomy: a prospective analysis based on universal cystoscopy. *Am J Obstet Gynecol*. 2005;192(5):1599–1604.
- Chahin F et al. The Implications of Lighted Ureteral Stenting in Laparoscopic Colectomy. *JSLs*(2002)6:49-52.
- Senagore AJ, Luchtefeld M. An initial experience with lighted ureteral catheters during laparoscopic colectomy. *J Laparoendosc Surg*. 1994;4(6):399–403.
- Phipps J.H. & Tyrrell. N.J. Transilluminating ureteric stents for preventing operative ureteric damage. *Br. J. Obstet. Gynaecol*. 1992. 99. pp81-84.

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