

INVITATION TO TENDER
FOR ENDOSCOPY, ENDOUROLOGY & ONCOLOGY ABLATION CONSUMABLES &
ASSOCIATED PRODUCTS
ITT REFERENCE PROJECT_1333
ATTACHMENT 4b LOT 2 SPECIFICATION

LOT 2: ENDOUROLOGY CONSUMABLES & ASSOCIATED PRODUCTS

Introduction:

Endourology is also known as minimally invasive urologic surgery. The procedure does not require extensive incisions, as small cameras known as endoscopes can be inserted through small incisions in the urethra, bladder or ureter, before being used to locate problems and perform operations. Endourology use minimally invasive techniques to treat tumours of the lining of the kidney and ureter as well as correct problems in the kidneys and ureters present since birth or acquired later in life, such as obstruction of the junction between the kidney and ureter.

Types of Endourology Procedures:

Percutaneous Nephrolithotomy (PCNL) This operation is carried out under general anaesthetic, then begins by inserting a telescope-like instrument known as a cystoscope into the bladder, a tube is then passed up the ureter into the kidney, this tube allows the kidney to be filled with dye (contrast medium) which helps the surgeon to localise the kidney with x-rays.

The patient is then moved into a prone (lying face down) or supine position (lying horizontally with the face and torso facing up), under an x-ray machine, the kidney is punctured with a fine needle, the needle position is confirmed by either outflow of urine or dye from the needle.

Once the needle is positioned in the kidney, an incision is made in the back and the needle tract into the kidney is stretched to allow a telescope to be passed into the kidney.

Other stone fragmentation tools such as a laser or an ultrasonic probe will also be inserted through this tract for stone fragmentation and removal.

Ureteroscopy (URS)

A **ureteroscopy** is a procedure that looks into the ureter and kidney. It involves inserting a special telescope, called a **ureteroscope**, into the urethra, then passing it through to the bladder and then on into the ureter and kidney. The operation is usually performed under general anaesthetic.

Stone Laser Lithotripsy Kidney, Ureter or Bladder (LASER)

The procedure uses shock waves to break kidney stones into small, sand-like particles that can then pass out of the body through urination.

Extracorporeal Shock Wave Lithotripsy (ESWL)

Extracorporeal shock wave lithotripsy (ESWL) is a non-surgical procedure for treatment of kidney stones. It uses high-energy shock waves from outside of the body to break down the kidney stones into small crystals. After the procedure, the kidney stones should be small enough to pass out of your body in your urine.

Cystoscopy (CYSTO)

The examination will use a cystoscope, which is a fibre-optic tube that can move around bends in the urinary system. It is about the thickness of a pencil and has a tiny video camera on one end, so the clinician can view an image of your urinary system on a screen, can be used to remove stones or tumours.

Nephroscopy

Treats tumours within the lining of the kidney or stones within the kidney.

Percutaneous nephrolithotomy

This treatment is a bit more invasive than those using an endoscope. The surgeon makes a small cut in the back to insert a sheath — or tube — into the kidney to create a path. The surgeon then inserts tools to break down large kidney stones and removes them through the tube.

Bladder Stone Removal / Cystolitholapaxy (BLADDER)

The most common procedure is a cystolitholapaxy, where a thin tube (cystoscope) with a camera at the end is used to find the bladder stones. The cystoscope will then use stone-crushing devices, lasers or ultrasound to break up the stones, the stone fragments are then removed by a retrieval or suction device and a catheter is inserted.

Holmium laser enucleation of the prostate (HOLEP)

A thin telescope-like instrument is inserted into the urethra, the high-powered laser is then inserted through this instrument and used to carefully remove the excess prostate tissue that is causing obstruction of the urethra. The residual pieces (or lobes) of the prostate are removed by the clinician. When the clinician has finished lasering excess prostate tissue, a catheter will be inserted, depending on the time of your surgery, the catheter will be removed on the evening of surgery.

Transurethral resection of the prostate (TURP)

TURP is a surgical procedure that involves cutting away a section of the prostate. The prostate is a small gland in the pelvis only found in men, it is located between the penis and bladder and surrounds the urethra. If the prostate becomes enlarged, it can place pressure on the bladder and urethra. This can cause symptoms that affect urination.

Prostatic Urethral Lift (PUL)

The Prostatic Urethral Lift procedure is a tissue sparing procedure. Surgeons may want to use this technique as an alternative to tissue-removing procedures.

Prostatic Urethral Temporary Implant (PUTI)

The Prostatic Urethral Temporary Implant procedure is a tissue sparing procedure that requires no long-term implant.

Lot 2 Structure:

Sub Lot	Title
2.1	Single use ridged scopes (ridged & flexible)
2.2	Accessories for scopes
2.3	Ureteral Catheters
2.4	Lithotripter
2.5	Accessories and consumables for lithotripter
2.6	Urethral dilators
2.7	Guidewires
2.8	Urethral Access products
2.9	Prostate Biopsy Needles, forceps and accessories
2.10	Stones retrieval Products
2.11	Ureteral Stents, Urethral and nephrostomy Guidewires
2.12	Prostatic Ablation Devices
2.13	Laser fibres
2.14	Supplementary instruments set
2.15	Bladder Evacuator and syringe
2.16	Irrigation Fluid Managements Systems Continues Pressure Pump-Mono Chamber and dual chamber
2.17	Electrodes, curette, probe and blades
2.18	Cleaning accessories
2.19	Prostatic urethral lift
2.20	Prostatic Urethral Temporary Implant
2.21	Percutaneous nephrostomy kit
2.22	Transport and storage

Standards and Legislation

STANDARDS AND LEGISLATION

Where products are classed as Medical Devices as per the definition under Medical Devices Regulation 2017/745 the following will apply:

**[Medical Devices Regulations 2002](#) (SI 2002 No 618, as amended)
(UK MDR 2002)**

All products must have their CE or UKCA marking evident on the product and/or packaging.

Or

Medical Devices Regulation 2017/745

All products must have their CE marking evident on the product and/or packaging.

Active Implantable Medical Device Directive (AIMDD) 90/385/EEC (as amended) or Medical Devices Regulation 2017/745 All products must have their CE marking clearly evident on the product and/or packaging.

BS EN 45502-1:2015 or equivalent Active implantable medical devices. General requirements for safety, marking and information to be provided by the manufacturer

ISO9001

Sub Lot 2.1 single use Urology Scopes include, but shall not be limited to;

- Rigid cystoscope
- Rigid ureteroscope
- Rigid resectoscope
- Rigid nephroscope
- Flexible cystoscope
- Flexible ureteroscope
- Flexible resectoscope
- Flexible nephroscope

Sub Lot 2.2 Accessories for Scopes include, but shall not be limited to;

- Cystoscope sheath
- Ureteroscope sheath
- PCNL operating sheath
- Resectoscope Sheath
- Urethrotome sheath
- Introducer sheath
- PCNL sheath adaptor
- Fiber fixation
- Cystoscope adaptor
- Resectoscope adaptor
- URS adaptor
- Handpiece
- Monitors
- Working insert
- Telescope bridge

Sub Lot 2.3 Ureteral Catheters include, but shall not be limited to;

- Ureteral Catheters (single and dual lumen) +/- guidewires
- Ureteral balloon dilation catheter
- Low pressure urethral balloon dilation catheter
- High pressure urethral balloon dilation catheter
- Drug-Coated urethral balloon dilation catheter

Sub Lot 2.4 Lithotripter include, but shall not be limited to;

- Generator
- Connection cables
- Extracorporeal shockwave
- Laser
- Electrohydraulic
- electromechanical
- Ultrasonic
- Ballistic
- Dual action

Sub Lot 2.5 Accessories for Lithotripter include, but shall not be limited to;

- Probe with oscillating tip
- Probe without oscillating tip
- Shock pulse nose cone
- Stone crushing devise
- Shock pulse probes
- Suction valve
- Sterile sleeves
- Seal
- Suction control
- Measuring equipment
- Telescope stopper
- Foot switch
- Probe kit
- Handpiece

Sub Lot 2.6, and 2.7 Urethral Dilator sets, guidewires include, but shall not be limited to;

- Flexible guidewire
- Ridged guidewire
- Straight tip
- Angled tip
- Hydrophilic
- PTFE
- Renal dilators
- Ureteral dilators
- Renal dilator

Sub Lot 2.8 Urethral Access Products, but shall not be limited to;

- Renal sheath,
- Clear sheath
- Ureteral access sheath
- Navigator sheath
- Meatus clamp
- Urethrotome
- Puncture cannula
- Insertion aid
- guides
- Applicator
- Attachment for bladder catheter
- Bougie
- Telescope bougie set
- Orifice stretcher and ruler
- Fiber optic ureter probe

Sub Lot 2.9 Prostate Biopsy Needles, and forceps and accessories include, but shall not be limited to;

- Urethral biopsy forceps
- Cup biopsy forceps
- Prostate biopsy needle
- Handpiece
- Injector needle

Sub Lot 2.10 Stones retrieval Products include, but shall not be limited to;

- Stone retrieval Baskets
- Stone catches
- Stone retrieval forceps
- Articulating Stone retrieval basket

Sub Lot 2.11 Ureteral Stents, Urethral, nephrostomy and trans perineal Guidewires include, but shall not be limited to;

- specialised stents,
- stenosis stent
- tumour stent
- extra anatomical stents,
- diversion stents,
- endopyelotomy stents
- anti reflux valve
- double pig tail,
- dual durometer
- silicone
- single j loop +/- tether
- steerable
- ureteral stent with guidewire
- ureteral stent without guidewire
- urethral diversion sent +/- guidewire
- ureteral stent +/- tether
- ureteral stent with positioner
- ureteral stent with magnetic retrieval
- ureteral stent with lockable pusher
- ureteral stent – multilength
- extra anatomical stent

Sub Lot 2.12 Prostatic Urethral or Transperineally, Ablation Devices include, but shall not be limited to;

- Aqua
- Laser
- Bipolar Radiofrequency

Sub Lot 2.13 Laser fibres include, but shall not be limited to;

- Single use holmium fibres
- Single use lithotripsy fibres
- Reusable holmium fibres

- Reusable lithotripsy fibres

Sub Lot 2.14 Supplementary instruments set include, but shall not be limited to;

- Cytology brush
- Scissors
- Forceps
- Knife
- Injection needle
- Three-ring handle
- Meatotome
- Optical scissors
- Optical forceps
- Rectal Spacer

Sub Lot 2.15 Bladder Evacuator and syringe include, but shall not be limited to;

- Bladder syringe
- Bladder evacuator

Sub Lot 2.16 Irrigation Fluid Managements Systems Continues Pressure Pump-Mono Chamber and dual chamber and accessories include, but shall not be limited to;

- Adaptors
- Pumping systems
- Inflation devices
- Irrigation lines
- Irrigation and aspiration line

Sub Lot 2.17 Electrodes, curette, probe and blades include, but shall not be limited to;

- Unipolar electrode
- Bipolar electrode
- Flexible unipolar electrode
- Curette
- Morcellator blade
- Laser hand instrument

Sub Lot 2.18 Cleaning accessories include, but shall not be limited to;

- Filling rod
- Cleaning adaptor
- Cleaning brush
- Cleaning rods for handpiece

Sub Lot 2.19 and Sublot 2.20

Prostatic Urethral Lifts and Prostatic Urethral Temporary Implants

Sub Lot 2.21 Percutaneous nephrostomy equipment include, but shall not be limited to;

- Percutaneous nephrostomy drainage kit malecot
- Percutaneous nephrostomy drainage kit pigtail
- Nephrostomy puncture cannula
- Nephrostomy catheters
- Nephrostomy balloon dilation catheter

Sub Lot 2.22 Transport and storage include, but shall not be limited to

- Container
- Leakage tester
- Pressure compensation cap
- Protective cover
- Wire tray
- Multiport bridge