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GREENLIGHT XPS™ LASER THERAPY SYSTEM

Versatility

Spotlight on GreenLight XPS™

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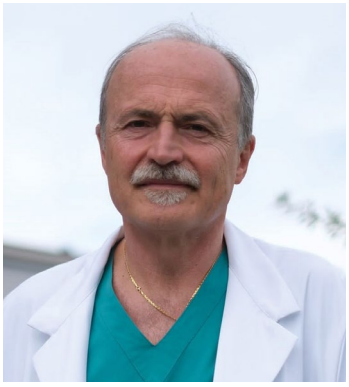
Dr Cindolo acts as a surgical tutor and researcher for GreenLight procedures



Giovanni Ferrari, Prof.

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Prof. Ferrari introduced GreenLight Laser Technology in Italy for the minimally invasive treatment of BPH and is a tutor and opinion leader for the technology

The following summary was developed based on the available clinical evidence and experience of Dr Cindolo and Prof. Ferrari with the Greenlight XPS™ Laser Therapy System and their patients' outcomes.

The GreenLight XPS Laser Therapy System offers a versatile solution for a broad range of patients with benign prostatic hyperplasia (BPH), from classic vaporisation to enucleation.

It is a safe and effective alternative to standard surgical procedures that can be tailored to patient needs.[1-4]

What is GreenLight™ Laser Therapy?

GreenLight Laser Therapy combines a 532 nm wavelength with advanced laser technology to remove the excess of prostate tissue. The system is designed to vaporise and coagulate soft tissue using light (Box 1).[5]

The 532 nm green laser light emitted is strongly absorbed by oxyhaemoglobin in red blood cells. Absorption of the laser light energy results in the generation of heat, which bursts cells and effectively vaporises the targeted tissue (Figure 1). Additionally, the heat can coagulate blood vessels near the resected tissue, allowing for a clear surgical field. If bleeding occurs, the console also has a pulsed coagulation feature.[5] Importantly, GreenLight Laser is not impeded by the irrigating agent during the procedure and can efficiently and rapidly vaporise prostatic tissue (Figures 2 and 3).[6]

GreenLight Laser Therapy allows the surgeon to approach the tissue from various angles and distances (up to 3mm away from tissue) without needing direct contact with the tissue.[7]

In addition, by modifying the power of the laser, the surgeon can easily switch from coagulation settings for haemostatic control (30 W) to vaporisation settings (80–180 W).[7]

Box 1. The GreenLight XPS Laser Therapy System

The GreenLight XPS Laser Therapy uses the 180W XPS system that offers 50% more power compared to the previous 120W system while offering a wider area of effect. The depth of optical penetration is less than 2 mm, allowing for precise vaporisation/coagulation.[7]

The system also incorporates:

- Moxy laser fiber, which makes removal of the prostate tissue more efficient[8]
- FiberLife feature, designed to help detect conditions such as excessive heat before they cause fibre damage[5]
- TruCoag Hemostatic Control feature uses pulsating light to cauterise ruptured vessels, reducing bleeding fast and in multiple situations.[9]

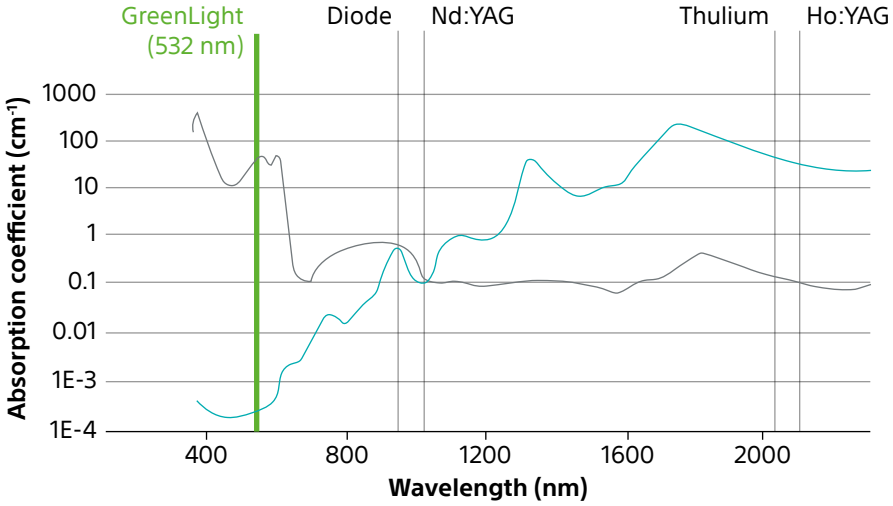
Tips and Tricks

'In addition to the GreenLight XPS Laser Generator, Moxy Fiber is used for PVP (set: 180 W for vaporisation and 40 W for coagulation) and Laser Fiber 2090 for enucleation (set: 120 W for vaporisation and 20 W for coagulation). For enucleation, the surgeon needs a dedicated 30° Wolf 24.5 Ch double-flow steel tip endoscope and a Piranha morcellator.'

Dr Cindolo and Prof. Ferrari.

Laser physics

Figure 1. Absorption coefficient spectra of endogenous tissue chromophores[6,9-11]



Greenlight (532 nm) interacts preferentially with the vascularised prostatic adenoma tissue, but not with the non-vascular surrounding surgical capsule.[7]

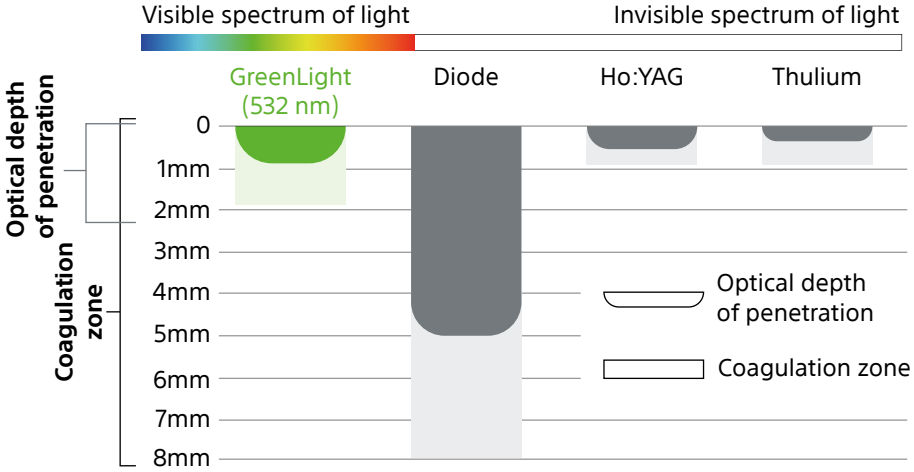
Oxyhaemoglobin
Water

Nd:YAG, neodymium yttrium aluminium garnet; Ho:YAG, holmium yttrium aluminium garnet.

Figure 2. Laser optical depth of penetration and coagulation zone[6,9,12]

Depth of penetration is dependent on laser physics. Too deep could lead to unwanted post-operative symptoms and too shallow could lead to slower, less efficient tissue vaporisation.

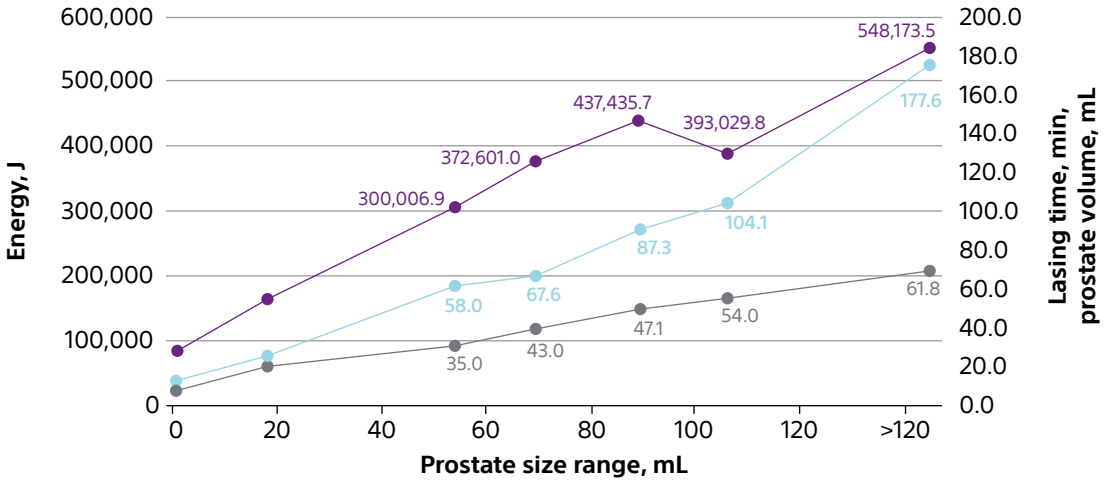
Deep coagulation may lead to increased dysuria and irritative symptoms.



Ho:YAG, holmium yttrium aluminium garnet.

Procedural efficiency

Figure 3. Lasing time[13]



58 gram prostate
35 min
300,007 J

87 gram prostate
47 min
437,436 J

178 gram prostate
62 min
548,174 J

- Average energy, J*
- Average prostate volume according range, mL*
- Average lasing time (min)*

*per range prostate volume

The GreenLight XPS Laser Therapy System and MoXy Liquid Cooled Fiber provide efficient tissue vaporisation.

Ho:YAG, holmium yttrium aluminium garnet; J, joule.

Versatility of GreenLight Laser Therapy

The treatment approach for patients with lower urinary tract symptoms (LUTS) related to BPH (LUTS/BPH) should consider several factors including the patient's gland size, clinical signs, and goals for durability and quality of life.[14] Transurethral Resection of the Prostate (TURP) has long been considered the reference technique for treating LUTS/BPO in patients with a 30–80 ml prostate size. However, alternative surgical procedures have been developed in recent years.[14]

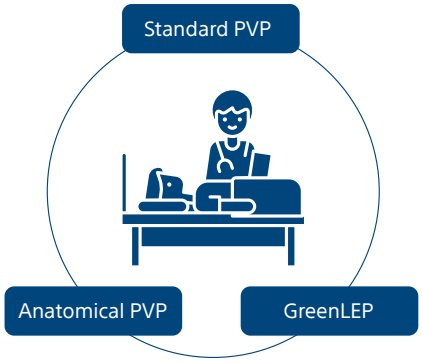
GreenLight Laser Therapy is a **safe, effective and reliable** procedure for the treatment of a wide range of patients with BPH, including those who are on anticoagulants.[1-4, 15]

It **offers a versatile approach** as it can be used to address a wide range of prostate sizes and patient types through a single platform.[3, 15-17]

The surgeon can perform three surgical approaches (Box 2):[1]

- standard photovaporisation (PVP);
- anatomical PVP; and
- GreenLight enucleation of the prostate (GreenLEP).

With GreenLight Laser Therapy, both vaporisation and enucleation techniques can be utilised in the same prostate. The surgeon can convert from one approach to another to complete the procedure without changing the equipment.[18]



Box 2: The three surgical approaches used by the GreenLight Laser Therapy

Standard PVP

- In standard PVP, the surgeon ablates the adenomatous tissue by vaporisation from the prostatic urethra towards the prostatic capsule (inside out in a centrifuge way)[1,18]

Anatomical PVP

- Anatomical PVP involves the surgeon localising the capsule at the apex of the adenoma, following back to the bladder neck, and finally vaporising laterally in both sides and anteriorly with exact knowledge of the depth of the capsule[1]

GreenLEP

- During GreenLEP, the Greenlight laser is used to find the anatomical plane between the prostatic capsule and the adenoma, dissecting and detaching the prostatic lobes (outside in) in a circular way, and the entire adenoma is finally morcellated.[1,18] In this technique, the transitional zone is excised in a single piece 'en bloc' using a Greenlight laser with a 180-W side-firing fibre[18]

  GreenLEP requires minor lasing time and little energy compared with standard and anatomical PVP techniques[1]

Tips and Tricks

'GreenLEP is most suitable for patients with larger prostates (>80 ml) and highly experienced surgeons.'

Dr Cindolo and Prof. Ferrari.

Advantages of GreenLight Laser Therapy

GreenLight Laser Therapy helps provide BPH patients with clinical outcomes at 12 months similar to monopolar TURP, with shorter hospital stays and fewer complications.[19,20] It has been proven safe and effective for patients with urinary retention and those on anticoagulation therapy, irrespective of prostate size.[3] Patient satisfaction levels post-GreenLight are high.[1,16]

Tips and Tricks

'The eligibility of a patient for GreenLight Laser Therapy mirrors the eligibility criteria of standard TURP. The majority of men with LUTS related to BPH are good candidates.'

Dr Cindolo and Prof. Ferrari.

The proportion of patients free from complications with GreenLight Laser Therapy is similar to other traditional prostate surgical treatments.[21] In many cases, an ambulatory procedure is possible.[1,22] The duration of hospitalisation and catheterisation are significantly shorter for PVP, and savings can be expected when more than 32% of patients are treated as day cases. (Box 3).[21,23-25]

GreenLight Laser Therapy is appropriate for the majority of patients with BPH, including those with comorbidities:

- Patients who are medically complicated or high-risk[2,3]
- Patients with anticoagulation therapy[3]
- Patients with urinary retention[3]
- Patients with small-medium (<80 ml) or large (≥80 ml) prostates[3]

Box 3: Key advantages of GreenLight Laser Therapy

Surgeon

- All comorbidities, including patients on anticoagulants[2,3,26]
- Therapy tailored to individual patient's needs[27]
- Allows switching between resection and vaporisation during surgery, if needed[18]

Patient

- Possible shorter hospital stays than TURP[28]
- Lower risk of complications/morbidities *versus* TURP (e.g. bleeding, capsule perforation)[23]
- Comparable recovery time to TURP[21]
- Potential shorter period of catheterisation *versus* TURP[21]

Healthcare system

- Possible cost-effective alternative to TURP[25,27]
- Possible reduction in hospital stay *versus* TURP[21]

Different surgical approaches with GreenLight Laser Therapy

The European Association of Urology (EAU) guidelines recommend different treatment approaches for moderate-to-severe LUTS according to the size of the prostate and other factors such as cardiovascular risk.[14]

TURP has remained the reference standard for men with prostate volumes of 30–80 mL, while open prostatectomy is universally recommended for patients with prostates larger than 80 mL when no other enucleation techniques are available.[7,14] Laser vaporisation and enucleation are recommended by the EAU guidelines for patients at high risk of bleeding.[14] Although TURP and open prostatectomy could be effective, patients are at risk of bleeding complications that may require transfusions as well as electrolyte abnormalities such as transurethral resection syndrome (Table 1).[29,30]

Table 1. Benefits and disadvantages of surgical options for the treatment of LUTS associated with BPH.*

	Open prostatectomy	TURP	PVP	EEP	Robotic/ laparoscopic prostatectomy
Prostate volume >80 mL					
Efficacy					
Durability					
Length of hospital stay/ complications					
Safety in patients with comorbidities and/ or anticoagulants					
Cost savings					
Availability					

= very beneficial
= beneficial
= not beneficial

Note: Based on the perspective and experience of Dr Cindolo and Prof. Ferrari
EEP, endoscopic enucleation of the prostate; TURP, transurethral resection of the prostate; PVP, photovaporisation of the prostate

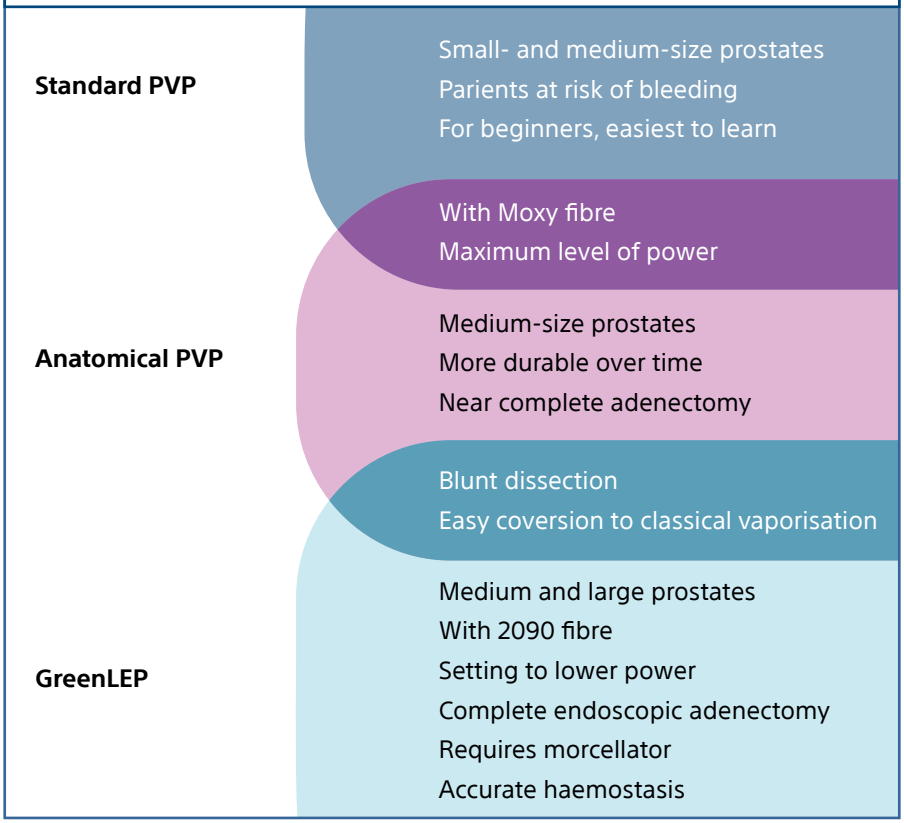
The selection of the surgical approach of GreenLight Laser Therapy will depend on multiple factors (Box 4).

Tips and Tricks

'An open and frank discussion about therapeutical possibilities, safety of GreenLight Laser Therapy and patient expectations are fundamental elements that play an important role when offering PVP or GreenLEP to a patient.'

Dr Cindolo and Prof. Ferrari.

Box 4. Selection of the surgical approach



Note: Based on the perspective and experience of Dr Cindolo and Prof. Ferrari

Focus on GreenLEP

Since 2016, endoscopic enucleation of the prostate (EEP) has been supported to treat BPO in patients with medium and large prostate glands, safely and efficiently replacing open prostatectomy.[31] EEP can be performed with Greenlight Laser, namely GreenLEP, with durable efficacy outcomes (International Prostate Score System [IPSS] and peak flow [Q_{max}]) and safety profile (transfusion, infection, stricture, etc.).[31]

Benefits of GreenLEP include:[18,32]

- Easier definition of the surgical capsule (lack of disruption with mechanical peeling)
- Minimal transfer of thermal energy to the capsule (decreased postoperative dysuria)
- Easier surgical learning curve (ability to transition to vapoenucleation/vaporisation during surgery)

The surgeon's level of dexterity and experience and good recognition of the anatomical structures are essential factors determining each decision strategy's choice and preference.

Surgeon's learning curve

Surgical experience is likely to impact on the perioperative and functional outcomes after GreenLight Laser Therapy procedures.[4,33]

Compared with other endoscopy enucleation laser techniques, the learning curve for GreenLEP tends to be shorter and more straightforward for novice enucleators who have GreenLight experience, who feel more comfortable due to the simplified technique.[34] In contrast with other laser techniques, GreenLight Laser Therapy allows the option to adapt the surgical strategy during a single procedure without modifying functional outcomes.[15]

Tips and Tricks

'Prostate volume and dexterity of the surgeon are the main factors affecting the duration of surgery.'

Dr Cindolo and Prof. Ferrari.

According to Dr Cindolo and Prof. Ferrari, the learning curve for GreenLight Laser Therapy is 20 patients for standard PVP, 30 patients for anatomical PVP and 22 (best results in time after 200) patients for GreenLEP.

Deep knowledge of the physical principles that are the theoretical basis of this powerful laser generator is considered by Dr Cindolo and Prof. Ferrari to be one of the best ways to be proficient and safe during surgery.

Simulators are an innovative way to learn the basic principles of a good GreenLight Laser treatment (including rotation, swiping and identifying of the target zone following the light beam). Dr Cindolo and Prof. Ferrari report a structured programme involving theory, use of the simulator and tutored live surgery with clinical cases of increasing complexity seems to be the best schema for a good learning pathway.

Tips and Tricks

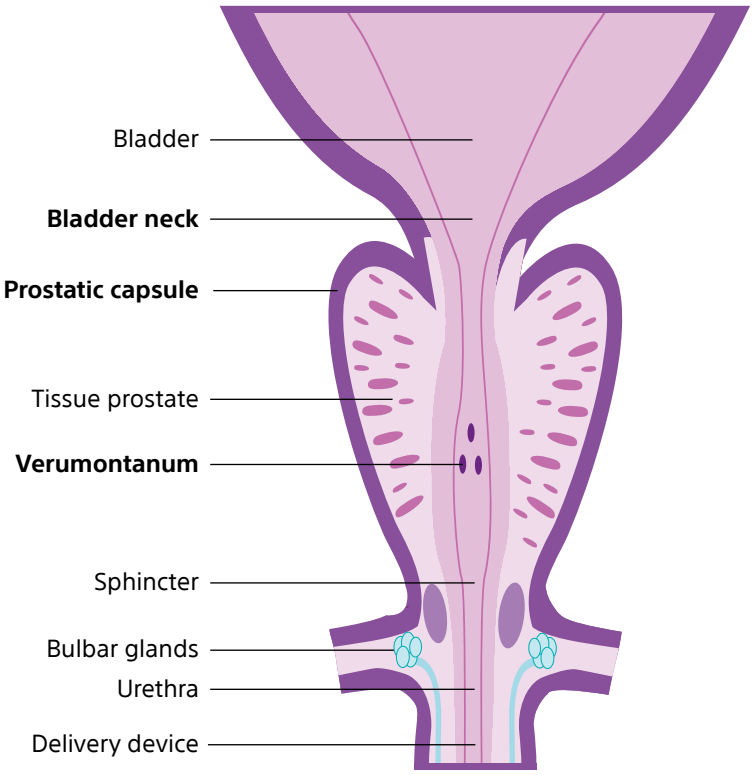
'First cases are best performed on patients with glands approximately 50 mL and with minimal median lobe component.'

Dr Cindolo and Prof. Ferrari.

Recognition of anatomical structures

Recognition and respect of the key anatomic structures of the prostate are essential for the safe use of GreenLight Laser Therapy and optimal outcomes for patients.*

- The **bladder neck** is one of the more relevant landmarks of PVP or enucleation. Respecting of its integrity, using gentle movements without mechanical forces during enucleation and a small amount of energy during PVP, ensures a negligible risk of bleeding, urine leakage, postoperative bladder neck strictures and dysuria
- The prostatic **capsule** is the second most crucial anatomical element that should be recognised and preserved from excessive laser activity. Intense coagulation or vaporisation of the capsule could induce major emptying symptoms and painful and burning urination. This can be overcome by limiting the use of laser coagulation on this tissue
- The **verumontanum** is the third critical element as it helps the surgeon identify the sphincter area. Its presence and preservation of prostatic tissue around are of great importance for ejaculation-sparing techniques



*Based on the perspective of Dr Cindolo and Prof. Ferrari.

Summary

GreenLight Laser Therapy is a safe and effective procedure that offers versatility for the surgeon who can use three different treatment approaches from a single console – standard or anatomical vaporisation versus enucleation. The choice and preference of the strategy are dependent on several factors, including the size and characteristics of the prostate and the surgeon's level of skill and experience. Surgeons can treat small, medium and large prostates using the same technology to address their patients' needs.

GreenLight Laser Therapy allows the treatment of high-risk or medically complicated patients.[2,3,26] It is proven to be safe and effective for patients on anticoagulation therapy and those with large prostates.[3] Other benefits include shorter hospital stays, fewer perioperative complications, plus improved cost-effectiveness compared to traditional prostate surgery.[23-25] GreenLight Laser Therapy is a patient-centred approach that ensures satisfaction for different types of patients.[1,16]

In conclusion, GreenLight Laser Therapy is a versatile, safe and cost-effective alternative for BPH treatment. Together with its simplicity, reliability and haemostatic properties it offers an alternative option for patients with BPH.

Tips and Tricks

'As a new user of GreenLight Laser Therapy, you will be fascinated by the versatility of this energy source. This laser accompanies every surgeon throughout his clinical practice, moving from basic skills for small-/medium-size prostates to larger prostates and more complex cases.'

Dr Cindolo and Prof. Ferrari.

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The GreenLight™ Laser Therapy is intended for incision/excision, vaporization, ablation, haemostasis and coagulation of soft tissue, including photoselective vaporization of the prostate for BPH. The laser system is contraindicated for patients who: are contraindicated for surgery, contraindicated where appropriate anaesthesia is contraindicated by patient history, have calcified tissue, require haemostasis in >2mm vessels, have uncontrolled bleeding disorders, have prostate cancer, have acute urinary tract infection (UTI) or severe urethral stricture. Possible risks and complications include, but are not limited to, irritative symptoms (dysuria, urgency, frequency), retrograde ejaculation, urinary incontinence, erectile dysfunction, haematuria – gross, UTI, bladder neck contracture/outlet obstruct, urinary retention, perforation - prostate, urethral stricture.

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