

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Medical technology guidance scope

### The PLASMA system for transurethral resection of the prostate

#### 1 Technology

##### 1.1 *Description of the technology*

The PLASMA system (formerly called TURis, Olympus Medical) is a bipolar electrosurgery system for use when surgical intervention for lower urinary tract symptoms (LUTS), presumed secondary to benign prostatic hyperplasia, is indicated. The PLASMA system consists of the ESG-400 Olympus generator (including power cable and trolley); the resectoscope which incorporates the active working element, PRO 12° 4 mm telescope, PRO inner sheath, PRO 26FR outer sheath, and electrodes; a light guide cable; and ESG-400 saline cable. Only the loop electrode in the PLASMA system is indicated for resection.

The surgeon uses the active working element to position the loop electrode in order to conduct resection. The electrode is the only single-use element of the system. The electrode carries the current from the resectoscope, delivers it to the tissue and completes the circuit using conductive irrigation fluid (saline). The loop electrode is used to cut tissue. Roller electrodes are used after resection for haemostasis. Loop electrodes are available in different sizes and angles to accommodate different anatomies and morphologies; the choice is made by the surgeon.

##### 1.2 *Relevant diseases and conditions*

The PLASMA system is intended for use in the treatment of benign prostatic hyperplasia.

[The NICE guideline on lower urinary tract symptoms](#) defines benign prostatic hyperplasia as histopathologically confirmed hyperplastic change (i.e. abnormality or changes at the cell level) in the prostate. About half of men with BPH will develop benign prostatic enlargement (BPE), which refers to an increase in size of prostate gland.

The prevalence of BPH increases with age. BPH affects about 1 in 3 men over the age of 50. An analysis of the UK General Practice Research Database found that lower urinary tract symptoms suggestive of BPH are present in 3.5% of men in their 40s and in 35% in their 80s (Logie et al. 2001). LUTS secondary to BPH include poor flow, frequent micturition, urgency, and nocturia. Untreated, BPH can result in urinary tract infection (UTI), acute or chronic urinary retention, and obstructive renal failure. Although LUTS secondary to BPH do not usually cause severe illness, they have a negative impact on quality of life which potentially can include reduced sexual function.

### **1.3 Current management**

Current treatment options for benign prostatic hyperplasia when conservative management options have been unsuccessful or are not appropriate in the [NICE guideline on lower urinary tract symptoms](#) include:

- monopolar or bipolar transurethral resection of the prostate (TURP)
- transurethral vapourisation of the prostate (TUVP)
- holmium laser enucleation of the prostate (HoLEP; at centres specialising in the technique or with mentorship arrangements in place)
- transurethral incision of the prostate (TUIP; only in prostates smaller than 30 g)
- open prostatectomy (only in prostates larger than 80 g).

Minimally invasive treatments such as transurethral needle ablation (TUNA), transurethral microwave thermotherapy (TUMT), high-intensity focused ultrasound (HIFU), transurethral ethanol ablation of the prostate (TEAP) and

laser coagulation are [not recommended by NICE](#) for people with lower urinary tract obstructive symptoms.

NICE medical technologies guidance has been published on the following technologies:

- [The TURis system for transurethral resection of the prostate \(MTG 23\)](#) is being updated with this guidance.
- [The UroLift prostatic urethral lift system \(MTG 26\)](#) which is recommended as an alternative day-case treatment option for LUTS caused by BPH in men aged 50 years and older, who have a prostate of less than 100 ml without an obstructing middle lobe. This can be done in a day-surgery unit.
- [The GreenLight XPS \(MTG 29\)](#) which is recommended for treating benign prostatic hyperplasia in non-high-risk patients, and can also be done as a day-case procedure.

NICE has published interventional procedures guidance on transurethral water vapour ablation ([IPG 625](#)) and water jet ablation ([IPG 629](#)) for lower urinary tract symptoms caused by benign prostatic hyperplasia. The IPG 625 recommends that transurethral water vapour ablation can be used with standard arrangements for clinical governance, consent and audit.

## **1.4 Regulatory status**

The PLASMA system first received a CE mark in April 2012 as a class IIb device for electrosurgery and endoscopic applications.

## **1.5 Claimed benefits**

The benefits to patients claimed by the company compared to monopolar TURP are:

- Reduced risk of transurethral resection (TUR) syndrome through the use of saline irrigation fluid instead of glycine.
- Reduced risk of post-operative blood transfusion due to intraoperative bleeding.

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- A shorter surgical procedure leading to fewer intra and post-operative complications and a lower level of hospitalisation.
- Earlier catheter removal time for improved patient comfort.

The benefits to the healthcare system claimed by the company are:

- A quicker procedure compared to monopolar TURP so more patients can be treated.
- Fewer complications during and after surgery resulting in lower re-admission rates.
- Reduced costs associated with post-operative blood transfusion, healthcare-associated infection, shorter length of stay, reduced post-operative irrigation and no patient return electrode required.
- The use of saline irrigation fluid is cheaper and easier to access than glycine.

## 2 Decision problem

Population	Adults with lower urinary tract symptoms (LUTS) presumed secondary to benign prostatic hyperplasia (BPH), in whom TURP is indicated
Intervention	TURP using the PLASMA system (formerly known as TURis)
Comparator(s)	<ul style="list-style-type: none"> <li>• TURP using a monopolar system</li> <li>• TURP using other bipolar systems</li> </ul>
Outcomes	<p>The outcome measures to consider include:</p> <ul style="list-style-type: none"> <li>• Hospital length of stay</li> <li>• Procedural blood loss and blood transfusion requirement</li> <li>• Time of removal of urinary catheter post-operatively</li> <li>• TUR syndrome</li> <li>• Re-admittance for repeat procedures</li> <li>• Duration of surgical procedure</li> <li>• Healthcare associated infection</li> <li>• Relief of symptoms associated with BPH (IPSS)</li> <li>• Maximum flow rates (Qmax)</li> <li>• Residual urine volumes</li> <li>• Benign prostatic hyperplasia impact index (BPHII)</li> <li>• Reduction in prostate volume</li> </ul>

	<ul style="list-style-type: none"> <li>• Quality of life measures, e.g. International Prostate Symptom Score Quality of Life (IPSS-QOL)</li> <li>• Device-related adverse events</li> <li>• Procedural complication rate during and after surgery</li> </ul>	
Cost analysis	<p>Cost models should consider 2 scenarios for the adoption of the PLASMA system:</p> <ul style="list-style-type: none"> <li>- Hospitals which currently have an Olympus ESG-400 generator</li> <li>- Hospitals which currently do not have an Olympus ESG-400 generator.</li> </ul> <p>Costs will be considered from an NHS and personal social services perspective.</p> <p>The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared.</p> <p>Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include the length of stay, use in a day case scenario, and the incidence of adverse events, such as TUR syndrome and urethral stricture.</p>	
Subgroups to be considered	<ul style="list-style-type: none"> <li>• Individuals with prosthetic lower limbs</li> <li>• Individuals with a cardiac pacemaker</li> </ul>	
Special considerations, including those related to equality	<p>It has been suggested that men aged 80 years and over, especially those with frail health and comorbidity, have been found to have an increased risk of morbidity following TURP, though effectiveness of the intervention is not affected.</p>	
Special considerations, specifically related to equality	<p>Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?</p>	No
	<p>Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?</p>	No
	<p>Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?</p>	No
Any other special considerations	<p>See cost analysis. PLASMA requires the use of an Olympus ESG-400 generator. Some hospitals who currently perform monopolar TURP and use other bipolar TURP systems produced by Olympus may already own an ESG-400 generator and avoid this cost.</p> <p>Resection is performed using loop electrodes. Haemostasis is performed using roller electrodes. Use of a hybrid technique with PLASMA button electrodes for haemostasis has been reported.</p>	

## 3 Related NICE guidance

### Published

- NICE clinical guideline 97 (2010) [Lower urinary tract symptoms in men: management](#)
- NICE interventional procedure guidance 629 (2018) [Transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia](#)
- NICE interventional procedure guidance 625 (2018) [Transurethral water vapour ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia](#)
- NICE medical technology guidance 29 (2016) [GreenLight XPS for treating benign prostatic hyperplasia](#)
- NICE medical technology guidance 26 (2015) [Urolift for treating lower urinary symptoms of benign prostatic hyperplasia](#)
- NICE medical technology guidance 23 (2015) [The TURis system for transurethral resection of the prostate](#)

### In development

NICE is developing the following guidance:

- [Rezum for treating benign prostatic hyperplasia](#). NICE medical technology guidance. Publication expected April 2020.

## 4 External organisations

### 4.1 Professional

The following organisations have been asked to comment on the draft scope:

- Association for Perioperative Practice
- British Association of Day Surgery
- British Association of Urological Surgeons
- British Urological Group (BUG)
- British Uro-oncology Group

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- PSA Prostate Cancer Support Association
- Royal College of Anaesthetists
- Royal College of Surgeons of England
- The Association for Perioperative Practice
- The College of Operating Department Practitioners

## **4.2 Patient**

NICE's [Public Involvement Programme](#) contacted the following organisations for patient commentary and asked them to comment on the draft scope:

- Bladder and Bowel UK
- Bladder Health UK
- Everyman
- Men's Health Forum (MHF)
- Orchid - Fighting Male Cancer
- Prostate Cancer UK
- Prostate Help Association (PHA)
- Tackle Prostate Cancer
- Urology User Group Coalition