NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1542 - Transvaginal laser therapy for stress urinary incontinence and IP1817 Transvaginal laser therapy for urogenital atrophy**

Your information

Name:	Christian Phillips
Job title:	Consultant Gynaecologist & Urogynaecologist. Visiting Professor
Organisation:	Hampshire Hospitals Foundation Trust. University of Winchester
Email address:	[redacted]
Professional organisation or society membership/affiliation:	GMC: 4214386. BSUG (executive committee). IUGA (Scientific committee. Chair of RCOG Pelvic Floor Clinical Studies Group. EUGA (Education committee)
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 4214386. RCOG 120170.

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

x☐ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience

1	Please describe your level of experience with the procedure/technology, for example: – Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for	I have extensive personal experience using the vaginal laser due to my involvement in research using lasers for various gynaecological applications. In my role on BSUG Executive / IUGA / EUGA and RCOG PFCSG, I am aware of trends and controversies / issues regarding the widespread adoption of lasers in our specialist field. **Research:** Chief investigator for 3 clinical studies evaluating the safety and efficacy of the Erbium Yag laser Smooth Mode (Fotona, Slovenia): 2 in SUI and 1 in prolapse. i. Chief Investigator for VESPER: SUI: laser vs sham treatment for stress incontinence. 2019-present. https://clinicaltrials.gov/ct2/show/NCT03996070?term=laser&cond=stress+urinary+incontinence&draw=5&rank=12 ii. Chief Investigator for VESPER: Prolapse: laser vs sham treatment for prolapse. 2019-present https://clinicaltrials.gov/ct2/show/NCT03995797?term=laser&cond=prolapse&draw=2&rank=2 iii. Chief investigator for UK for Fotona Incontilase multicentre RCT: laser vs sham treatment for stress incontinence. 2016 – 2019.. https://clinicaltrials.gov/ct2/show/NCT03098992?term=laser&cond=stress+urinary+incontinence&draw=5&rank=10 (Chief investigatorfor UK) **Publications:** Phillips C, Hillard T, Salvatore S, Toozs-Hobson P, Cardozo L. “Lasers in gynaecology”. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2020 Aug 1;251:146-55. I am the primary author for a RCOG scientific impact paper on the use of vaginal lasers in GSM (currently under review by RCOG)

	this procedure/technology, please indicate your experience with it.	**Presentations:** "Lasers in gynaecology: Workshop, EUGA, Madrid, Oct 2019 "The role of lasers in gynaecology and urogynaecology". RCOG World Congress, London, 2019. Debate: "This house believes that lasers are now the treatment of choice for GSM": IUGA , Vienna, 2018.
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research. KoL and trainer in Fotona laser
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?	Energy based devices (EBD's (which include radiofrequency devices and lasers) have been used in the field of medical aesthetics and dermatology for 20-30 years so are not new per se. In these applications, lasers and EBD's are mainly used for properties promoting tissue and collagen remodelling. The literature suggests lasers can cause shrinkage of collagen with subsequent remodelling of the connective tissue of the dermis, resulting in favourable treatment of wrinkles, fine lines, scars tissue and other applications in the field of aesthetic medicine that require remodelling of the connective tissue of the dermis. As patients have reported favourable outcomes, with minimal "downtime" or morbidity after laser therapy for aesthetic and dermatological conditions, they have increasingly become adopted into general use. As a result, clinicians have started to explore whether the tissue remodelling properties seen with laser therapy to the dermis may also be adopted as a non-surgical treatment to the vaginal epithelium and subepithelial fascia for gynaecological conditions typified by faulty / damaged connective tissues. Lasers have traditionally been used in gynaecology for surgery, excision and ablation of tissues so the application for collagen remodelling is perceived as new and "novel".
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	This procedure appears to be more efficacious in women with mild to moderate SUI and not efficacious in severe SUI. It is unlikely to replace standard conservative care (physiotherapy) but may act as an interim treatment before considering more invasive and permanent surgical options for SUI and replace surgery for women with mild / moderate SUI. It is likely to become part of the hierarchy of treatments from conservative through surgical and provide greater patient choice, provided there is sufficient evidence on medium term (and with time long term) efficacy, safety and need for repeat treatments.

Current management

5	Please describe the current standard of care that is used in the NHS.	Women with SUI are initially referred for physiotherapt and pelvic floor training. If this is insufficient to treat the complaint women are offered the following options: • Do nothing • Urethral Bulking • TVT mid urethral sling (currently paused) • Colposuspension: open or laparoscopic • Autologous fascial sling
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	There are numerous energy based devices (EBD's) on the market, all claiming to promote collagen remodelling and treat SUI. These include radiofrequency EBD's and lasers. The two main categories of laser used for tissue remodelling in gynaecology are categorised dependent on the medium used to generate the laser energy source: CO2 laser and Erbium Yag laser. In addition, there is also a difference in the effects the specific laser may have on tissue. The two main types of effect are "ablative" or "non-ablative" collagen remodelling of the subepithelial connective tissue. The ablative lasers (both CO2 and Erbium Yag) create short pulse, high peak power and rapidly scanned focused micro ablation to the epithelium and subepithelial tissue by creating microscopic columns of thermal injury into the deeper tissues without destruction of superficial tissue. This subsequently stimulates fibroblast activation and collagen production without fibrosis. The Erbium Yag laser SMOOTH, (Fotona, Slovenia) has a patented "smooth mode" which exerts a non-ablative effect on tissues and creates a gradual thermal effect, resulting in a controlled heating of the subepithelial connective tissue which is rich in water and promotes breakage of the collagen cross linkages and shortening of the collagen fibres and then, over a period of time, new collagen fibre formation. Different lasers will have different tissue penetration and can cause different collateral thermal injury and tissue fibrosis in the epithelial layer. Radiofrequency EBD's have a less selective action on tissues compared with either CO2 or Erbium Yag lasers. RF devices emit focused electromagnetic waves which generate heat upon meeting tissue impedance. The amount of heat generated in the tissue is a direct result of the current and contact time between device and tissue. At tissue temperatures between 40 to 45°C, RF can induce fibroblasts to produce collagen through activation of heat shock proteins and initiation of the inflammatory cascade.

		There are only few clinical trials are need to be disease specific. The Fotona (Slovenia) has the most evidence for SUI and Mona Lisa (Italy) the most evidence for GSM.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	This is an outpatient based treatment with no / minimal downtime for the patient. After initial capital costs for purchasing the machine, the treatments are relatively cheap and easy to provide. The procedure takes 30 minutes and is relatively painless, well tolerated and the safety profile for the technology is excellent provided laser users follow correct standards and protocols of care.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Evidence suggests the efficacy for the procedure is more beneficial in women with mild to moderate stress urinary incontinence and those with genitourinary syndrome of the menopause. **Ref: Kuszka A, Gamper M, Walser C, Kociszewski J, Viereck V. Erbium: YAG laser treatment of female stress urinary incontinence: midterm data. International Urogynecology Journal. 2019 Dec 11:1-8.**
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes. This procedure is less invasive, cheaper and had a favourable side effect profile compared with treatments for SUI other than physiotherapy. This has the potential to prevent unnecessary surgery and overtreatment of mild and moderate SUI in women who have failed with pelvic floor education and still have SUI symptoms.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Less. The capital investment for a laser and handpieces would be £60000. However, treatment costs thereafter are significantly cheaper as only need outpatient facilities compared to alternatives below: TVT (Paused): £400-500 per tape plus theatre / hospital costs for inpatient / day case Urethral Bulking: £800 per patient for bulking agent plus theatre / hospital costs for day case procedure

		Colposusupension / Autologous sling: laparoscopic instrument consumables plus significantly larger hospital inpatient costs for 1-2 days hospital stay
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	In long term cost savings to NHS as consumables for laser are cheap and the outpatient setting is significantly cheaper but initial capital investment to purchase laser much higher for trusts. We also do not know what the need / protocol for number of treatments in the initial treatment phase (3/4/5) or the need for repeat "top up" treatments: ? 12 /18 / 24 months.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The outpatient room needs to be laser compliant: Blinds on all windows, lockable door, have laser hazard signs and laser safety officer nominated with usual laser safety audits / restrictions: these are present in most hospital settings.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes. Laser safety course and "core of knowledge" which is updated every 3 years (1/2 day) for every laser user, plus manufacturer training on applications and use of the laser (1 day)

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Poor efficacy if performed in wrong patient population: ie. Mixed urinary incontinence, OAB, severe SUI. Urgency, frequency, tissue oedema and mild discharge occurs in 60-80% lasting 2-5 days and very mild and transient. Pain unlikely during procedure (<1%). Burns very unlikely unless laser is not used correctly and proper safety standards / procedures followed (<1 in 10,000).
15	Please list the key efficacy outcomes for this procedure/technology?	Short to medium term improvement in symptoms of mild to moderate SUI, GSM and mild prolapse.

16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Currently we only have medium term data / follow up (up to 2 years). We do not know what longer term effects may be. Patients are likely to require repeat "top up" treatments but we do not know the treatment interval, number or effect of repeated treatments.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Yes. Following issues surrounding mesh implants for SUI and prolapse, the paucity of well-designed clinical trials and the wide adoption of lasers both by gynaecologists and non gynaecologists, concerns over the safety and efficacy of lasers and long term implications are widely publicised. Current recommendations are for use unless part of well-designed clinical trials or with special arrangements for clinical governance, consent, and audit.

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Kuszka A, Gamper M, Walser C, Kociszewski J, Viereck V. Erbium: YAG laser treatment of female stress urinary incontinence: midterm data. International Urogynecology Journal. 2019 Dec 11:1-8. Phillips C, Hillard T, Salvatore S, Toozs-Hobson P, Cardozo L. Lasers in gynaecology. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2020 Aug 1;251:146-55.

19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	https://clinicaltrials.gov/ct2/show/NCT03996070?term=laser&cond=stress+urinary+incontinence&draw=5&rank=12 **VESPER SUI STUDY: Clinical trials identifier: NCT03996070** **Chief Investigator: Christian Phillips** **RECRUITING** Brief Summary: Patients seen with stress urinary incontinence (SUI) that have failed conservative treatments will be offered to participate in a sham controlled RCT of outpatient therapy with the Fotona Smooth Erbium Yag **laser**. Patients will be randomised to either outpatient **laser** treatments or sham treatments. Patients will be blinded to which arm they have been randomised. Patients will be asked to complete appropriate relevant symptom and quality of life questionnaires prior to treatment and then at 6 and 12 months following the final treatment. At 6 months Sham patients will be un-blinded and offered the **laser** therapy if they wish. https://inglishdesign.co.uk/site/index.php/2019/07/01/kitchen-design-harrogate-2/ **Vaginal CO2 Laser for Stress Incontinence** **RECRUITING** Brief Summary: Our aim with this study is to determine if transvaginal CO2 **laser-** treatment (DEKA SmartXide2 **Laser** System, MonaLisa Touch), renders significant effect in women with SUI. To best test this hypothesis, the study will be performed in a prospective, randomised controlled fashion in our institution. We will measure the effect as patient reported improvement using a validated scale (ICIQ-UI SF) as well as an objective measurement (stress test) https://clinicaltrials.gov/ct2/show/NCT03098992?term=fotona&draw=2&rank=1 **The Efficacy and Safety of Fotona Smooth® Device for the Treatment of Stress Urinary Incontinence** **NCT03098992** **COMPLETED: RESULTS AWAITED** Brief Summary:

		Patients with stress incontinence will be assigned to two groups, an active group, where the **Fotona** Dynamis Er:YAG Laser System will be used, and a sham group where a very low laser setting will be used, and parameter presentations will be masked. Participants will be adult females, 18 years old and older with clinical and urodynamic diagnosis of Stress Urinary Incontinence,who have had no significant improvement in urinary incontinence from at least one previous conservative treatment, such as behavioral measures, pelvic floor muscle training or the use of absorbent pads

Other considerations

20	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	The procedure could be offered to all women with mild to moderate SUI who have not improved after physiotherapy. Historical HES data showed the number women undergoing surgery for SUI from 2007-2018 showed total numbers having surgery increased from 6000- per year to 12000 per year in 2010. If 2/3 had mild to moderate SUI estimates of 4000 to 8000 women may wish / qualify for treatment.
21	Are there any issues with the usability or practical aspects of the procedure/technology?	Not really. Laser safety training and manufacturer training for clinicians skilled in treating women with SUI: ie: gynaecologists / urogynaecologists, female urologists.
22	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	• Initial capital costs for laser. • The wide number companies selling lasers that have little / no evidence for their safety / efficacy and claiming their product is the same as other lasers which do have evidence for their safety / efficacy. • Poor training, poor regulation of laser use, especially outside the hospital setting (ie aestheticians / laser clinics using aesthetic lasers for gynaecological applications by users Not trained in gynaecology / urogynaecology).
23	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Large, Sham controlled RCT's and patient selection (currently underway).

24	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: **Database / audit of treatment parameters for all patients and audit of outcomes:** **PROMS: Baseline, 6,12, 24 and 60 months** • Validated symptom score for urinary incontinence: ICIQ-SF, ICIQ UI, Kings Health questionnaire, • Validated vaginal symptoms score questionnaire: ICIQ VS • Validated sexual function score questionnaire,: PISQ 12, FSFI • Patient Global Impression of Improvement: PGI-I • QoL, Health economic evaluation over time (12 months) **Objective measure of incontinence:** • 1 hour, 4 hour or 24 hour pad weight: 6,12, 24 (and 60 months long term) • ? Ultrasound of bladder neck mobility: baseline, 6 and 12 months. Procedure acceptability score: during treatments Adverse outcome measures (12 months initially but up to 60 months long term): Side effects: urgency / frequency, oedema, discharge, discomfort, visual analogue scale of pain experienced, burns, (immediate / short term 1-2 weeks)

Further comments

25	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	none

NICE National Institute for Health and Care Excellence

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	**FOTONA initiated grant** (£7000) grant towards VESPER Prolapse study grant (grant is for study consumables and research nurse time only: NO Payment to myself whatsoever) **BSUG research grant** (£10000) for VESPER SUI study (grant is for study consumables and research nurse time only: NO Payment to myself whatsoever)	**November 2019** **November 2019**	**Ongoing** **Ongoing**
Non-financial professional	Chair RCOG Pelvic Floor Clinical studies group BSUG executive committee IUGA Scientific Committee EUGA Education Committee	**Nov 2017** **Nov 2016** **July 2017** **July 2018**	**Present** **Present** **Present** **Present**
Indirect	Spouse is director of Castlehouse Medical: UK distributor of Fotona lasers.	**January 2020**	**Ongoing**

x ☐ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Christian Phillips**
Dated:	**01.10.2020**