

National Institute for Health and Care Excellence

IP1569 Transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia

IPAC 12/07/18

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 Company Procept BioRobotics	1.1	<p>Dear National Institute for Health and Care Excellence, I am writing as part of the Public Consultation period for IP1569 – Transurethral water jet ablation for LUTS caused by BPH. Thank you for the opportunity to comment.</p> <p>I see from the project documents the recommendation from the IP Committee is the procedure should only be used with special arrangements for clinical governance, consent, and audit or research. We appreciate the committee’s recommendation and understand the committee felt the limited evidence and longer-term follow up prevented it from being recommended for use with standard arrangement.</p> <p>Subsequent to the committee review on 12 April 2018, there have been 3 additional publications which strengthen Aquablation’s evidence portfolio and also include longer-term follow up. I have attached 3 of the recent publications with a brief description of each publication:</p> <ol style="list-style-type: none"> 1. Aquablation versus transurethral resection of the prostate: 1 year United States – cohort outcomes (Kasivisvanathan, CJU June 2018) - one year follow up on US cohort of 	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The 3 additional cited studies have been added to the evidence in table 2 of the overview.</p> <p>The Committee considered this comment and discussed the additional evidence, but decided not to change the guidance.</p>

		<p>patients from WATER Study where previously only 6 month data was available</p> <ol style="list-style-type: none"> 2. Pooled Aquablation Results for American Men with Lower Urinary Tract Symptoms due to Benign Prostatic Hyperplasia in Large Prostates (60–150 cc) (Chughtai, Advanced Therapies June 2018) – a pooled analysis from 2 FDA IDE studies including WATER II which was a single arm study assessing safety and efficacy of Aquablation in large prostates (80 -150ml). 3. Symptom Relief and Anejaculation after Aquablation or TURP: Subgroup Analysis from a Blinded Randomized Trial (Plante BJU 2018) – subgroup analysis of outcomes in larger prostates from the WATER Study <p>These 3 publications strengthen the clinical evidence position of Aquablation and provide longer-term follow up out to one year. In addition, it provides evidence on the safety and effectiveness of Aquablation in larger prostates where the European Urologic Guidelines suggest open prostatectomy or HoLEP for larger prostates. In addition, we have an active post-market registry, OPEN WATER, using Waterjet Ablation Therapy for Endoscopic Resection of prostate tissue in prostates 30 – 150 mL in size. The</p>	
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			<p>registry has NHS portfolio status and is included in the NIHR CRN portfolio (reference RENA 34207).</p> <p>With this additional evidence we ask the IP committee if they would consider Standard Arrangement as their recommendation.</p> <p>Please let us know if you have any questions or we can provide any additional information. Thank you for your consideration and we will look forward to seeing you in July.</p> <p>Best regards,</p> <p>■</p>	
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