National Institute for Health and Care Excellence

IP1701 Prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia

IPAC 08/11/18

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Company Medi-Tate	**3.5**	Dear Sir or Madam, I am contacting you from Medi-Tate, the manufacturer of iTind, prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia. We have some comments on the consultation document for IP1701. 1. **The document says that the iTind is not suitable for treating small prostates. However, this is incorrect.** In the MT01 study published in the BJUi entitled “Temporary implantable nitinol device (TIND): a novel, minimally invasive treatment for relief of lower urinary tract symptoms (LUTS) related to benign prostatic hyperplasia (BPH): feasibility, safety and functional results at 1 year of follow-up” (attached), you can see that the average prostate volume treated in the study was 29.5ml, which is relatively small. Therefore, one could infer that the majority of the study results reflect the efficacy	Thank you for your comment. The consultee refers to the Porpiglia (2015) study that is included in the overview. The committee decided to remove section 3.5 of the draft guidance.

			of the device in treating small prostates. As this was a first in man study, a conservative approach was taken and it was decided to perform the first cases on patients with small prostates. In saying that, halfway through the study, once positive results had been observed in the first patients, it was decided increase the upper prostate volume to 60ml. Therefore, while the total average prostate volume of the entire study population remained small, the device also demonstrated efficacy in treating larger prostates in several patients. The relatively small average prostate volume was one of the limitations of this first study, and this is why we increased the upper prostate volume to 75ml in subsequent studies, one of which will be published imminently.	
2	Consultee 1 Company Medi-Tate	**3.5**	2. **The document says that iTind does not treat high bladder neck/ the bladder neck. However, this is incorrect.** The mechanism of action of the device is the exertion of radial force of the device struts at the site of the prostatic urethra AND bladder neck, which then leads to tissue ischaemia, necrosis, and three longitudinal “incisions” in the prostatic urethra AND the bladder neck. Therefore, the device is also relieving the obstruction at the site of the bladder neck and not only the prostatic urethra. This mechanism of action is also described in the same study referred to above.	Thank you for your comment. The consultee refers to the Porpiglia (2015) study that is included in the overview. The committee decided to remove section 3.5 of the draft guidance.

not endorsed by NICE, its officers or advisory committees."