

## National Institute for Health and Care Excellence

### IP1840 Tunnelled peritoneal drainage catheter insertion for refractory ascites in cirrhosis

IPAC date: 08-09-2022

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 NHS professional	1	I am in agreement with the draft recommendations that long-term drains use in cirrhosis should be in research settings. Hopefully the national REDUCe 2 trial will provide evidence one way or another.	Thank you for your comments.
2	Consultee 2 Company	1.1	<p>We understand the concerns highlighted by the committee about the limited safety and efficacy evidence on the procedure. BD is committed to delivering quality and safe innovative technologies.</p> <p>Clinician education and training for the PeritX™ system are provided by BD through extensive on-site onboarding training as well as ongoing support through various training programmes as well as electronic applications. BD is committed to providing training support of the drainage technique to primary care teams through direct and digital platforms within 48 hours of patient discharge. These will ensure that any safety risks associated with improper process and/or product use are limited.</p> <p>This is a procedure that would greatly benefit the patient population of interest by providing better symptom control, allowing independence and the flexibility to fit the treatment around their daily lives.</p>	Thank you for your comments.
3	Consultee 2 Company	2.3	The following statement was included in the procedure description: <i>“A fenestrated drainage catheter is tunnelled subcutaneously from a second incision 5 cm away from the guidewire insertion site.”</i> We observed that 5cm is the specified distance between the second incision and the guidewire insertion site. We would like to highlight that the	<p>Thank you for your comments.</p> <p>IPAC considered and amended the wording in section 2,3 (removed reference to 5cm)</p>

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			instructions for use for our technology specifies a range of 5-8 cm.	Please respond to all comments
4	Consultee 2 Company	3.6	It was raised to the committee that the procedure may increase the risk of bacterial peritonitis in people with refractory ascites in cirrhosis, although peritonitis can occur with ascites regardless of insertion of a tunnelled catheter for peritoneal drainage.	Thank you for your comments. IPAC considered your comments and amend the wording in 3.6 slightly (please refer to the guidance)
5	Consultee 2 Company		<a href="#">Consultation comments\Emailed Comments\50-9050A PeritX Mini Kit (361-42401) IFU.pdf</a> Indications for Use The PeritX™ Peritoneal Catheter Mini Kit System is indicated for intermittent, long term drainage of symptomatic, recurrent, malignant and non malignant ascites that does not respond to medical management of the underlying disease and for the palliation of symptoms related to recurrent ascites. The use of the PeritX™ Peritoneal Catheter for non malignant ascites is limited to patients who are intolerant or resistant to maximum medical therapy, refractory to large volume paracentesis (LVP) and are not candidates for a trans-jugular intrahepatic portosystemic shunt or LVP. The PeritX™ Peritoneal Catheter is indicated for adults only.	Thank you for the updated IFU. We expect the user to use the IFU.

*"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."*