

**National Institute for Health and Care Excellence**

**IP727/2 - Sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair**

IPAC date: 12 January 2016

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 Manufacturer (Boston Scientific)	1	We support the draft recommendations proposed by NICE following their review of the available evidence and would like to thank them for the opportunity to comment during this consultation.	Please respond to all comments  Thank you for your comments. Consultee agrees with the draft recommendations in section 1 of the document.
2	Consultee 2 NHS Professional.	1 & General	<p>Sacrocolpopexy surgery has been known for correction of prolapse specially vaginal vault prolapse. Performing sacrocolpopexy during hysterectomy either laparoscopic or robotic or vaginal or abdominal hysterectomy do not reduce the risk of potential major complications in terms of mesh expulsion, erosion, fistula (potential long term morbidity and poor health), failure and recurrence of prolapse.</p> <p>The evidences are mostly case control studies and of very small numbers. There is a lack of any randomised control studies to eliminate selection bias and operator bias. More importantly the follow ups are of very short duration.</p> <p>There must be significant under reporting of the complications as patient populations move and attend different clinicians. Mesh erosions and expulsions are serious complications in terms of significant morbidity and even mortality due to infection and recurrent surgeries. Patient's sexual activity and health could be seriously impaired.</p> <p>Therefore unless we have further evidence and robust data and trials I will be concerned with any recommendation of using mesh to repair uterine prolapse and sacrocolpopexy during hysterectomy.</p>	<p>Thank you for your comments.</p> <p>1.1 in the document clearly states that <i>'current evidence on the safety and efficacy of sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research'</i>.</p> <p><b>IPAC added a statement to section 1 of the guidance that 'NICE may update the guidance on publication of further evidence'.</b></p>

*"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."*