

**National Institute for Health and Care Excellence**  
**IP378/3 Bioprosthetic plug insertion for anal fistula**

IPAC 11/07/19

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 Company Cook Biotech	<b>2.5</b>	To my knowledge, there is only one device (two different designs) commercially available for this procedure in the UK, the Biodesign Anal Fistula Plug.	Thank you for your comment. Section 2.5 has been removed.
2	Consultee 1 Company Cook Biotech	<b>Title</b>	Of the data used to support the findings of the committee, 8 out of 9 sources involved the Biodesign Anal Fistula Plug from Cook Biotech Inc. Although Section 2.4 says the plug is "usually made of porcine intestinal submucosa", the term "bioprosthetic" in the title suggests that plugs from other animal sources could also be used -- in the absence of clinical data. Purified forms of biologic material (i.e., bovine collagen, silk, fish skin) are not the same as the Biodesign fistula plug in their complexity and composition, should be not be expected -- in the absence of clinical evidence -- to perform in the same manner, and should therefore not be lumped into the single category. I propose that the title of the document be updated to reflect this, by naming the procedure "Extracellular Matrix plug insertion for anal fistula" or "Biologic Extracellular Matrix plug insertion for anal fistula".	Thank you for your comment.  The committee considered this comment but decided not to change the guidance.

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