FSN Ref: 2024FA0006 (2024-001)

FSCA Ref: 2024FA0006 (2024-001)

Date: 30 July 2024

Urgent Field Safety Notice
Biodesign® Fistula Plug

For Attention of: Chief Executive / Risk Management / Purchasing

Contact details of local representative (name, e-mail, telephone, address etc.)*
Cook Medical Europe Ltd. O'Halloran Road National Technology Park Limerick, Ireland E-mail: European.FieldAction@CookMedical.com Phone: Please refer to the attached Country Contacts List For any further information or support concerning the information within this FSN, please contact your local Cook Medical Sales Representative or Cook Medical Europe Ltd.

FSN Ref: 2024FA0006 (2024-001) FSCA Ref: 2024FA0006 (2024-001)

Urgent Field Safety Notice (FSN)
Biodesign® Fistula Plug
Labelled Expiration Date Incorrect

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The Biodesign® Fistula Plug consists of a cylinder of SIS with a reinforced button on one end. The devices are packaged in a PETG tray which is inserted into a Tyvek-film inner pouch and an outer foil header pouch. After sterilization, the header portion of the foil-header pouch is removed, and the packaged devices are placed in a box for distribution.
1.	2. Commercial name(s)
	Biodesign® Fistula Plug
1.	3. Primary clinical purpose of device(s)*
	The Biodesign Fistula Plug is for implantation to reinforce soft tissue for repair of anorectal fistulas. The plug is supplied sterile and is intended for one-time use. The FP is comprised of an extracellular matrix (ECM) and is fully remodelled during the healing process.
1.	4. Device Model/Catalogue/part number(s)*
	C-FPS-0.2-2, C-FPS-0.4-2, C-FPS-0.7-2
1.	5. Affected serial or lot number range
	See Attachment 1

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Cook Biotech Inc. discovered a discrepancy between the correct product shelf life versus the shelf life presented on the finished product labelling. The affected products expire prior to the expiration date printed on the product labelling.
2.	2. Hazard giving rise to the FSCA*
	An initial analysis by the manufacturer has determined that the risks to patient safety are different relative whether the affected devices are implanted before or after the true expiration date. For use of a device prior to the true expiration date, there is no additional or different patient risk because the product is identical to that approved by the regulatory authorities. For devices that are implanted after the true expiration date, there are additional health risks presented to the patient from use of a device at, or within several months after the true expiration date. The potential existing patient harm severities remain the same, with a slightly increased likelihood of harms being actualized. None of these harms include serious patient injury or death
2.	3. Probability of problem arising
	There is no probability of increased risk for devices used prior to their actual expiration date. As determined by the Health Risk Assessment performed by Cook Biotech Inc., the potential increase in probability of risk for devices used after their actual expiration date is expected to be minor.

FSN Ref: 2024FA0006 (2024-001) FSCA Ref: 2024FA0006 (2024-001)

2.	4. Predicted risk to patient/users
	There is no increased risk to patients/users for devices used prior to their actual expiration date. There are no new risks identified for devices used after their actual expiration date; however, there is potential for an increase in probability of harm relating to already identified adverse events which include impaired healing, device migration, persistence, pain, discharge, inflammation, abscess, allergic reaction, fever, foreign body reaction, infection, and increased procedural time.
2.	5. Further information to help characterise the problem
	Patient risk will increase if device is used after the true expiration date.
2.	6. Background on Issue
	This discrepancy was due to an error in the automatic updates of Cook Biotech Inc.'s Enterprise Resource Planning (ERP) system. This error has been corrected, and this issue for devices distributed in the EU is limited to the devices listed in Attachment 1.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☒ Quarantine Device ☒ Return Device Please complete the enclosed Customer Reply Form. Where devices are indicated as being returned, our Customer Services department will contact you to organize the return and issue you with the relevant Returns Authorization number. Please include contact details on the Customer Reply form. Returned Device(s) should be addressed to: Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler GERMANY Credit will be provided for the returned affected device(s) where applicable.	
3.	2. By when should the action be completed?	Within 5 business days from receipt of form
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No Historical experience with the SIS device material suggests that patient health risks related to the remodeling characteristics of the device are only very minimally impacted by storage time. As such, the additional patient health risks from delayed or reduced remodeling/incorporation arising from use of the device at or shortly after the true	

FSN Ref: 2024FA0006 (2024-001) FSCA Ref: 2024FA0006 (2024-001)

	expiration date are identical to those of in-date and newly manufactured devices. Therefore, because there are no additional risks from this product attribute, no additional follow-up is necessary.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal Confirm removal of devices that have not been used or destroyed. This issue has been included in the scope of corrective action CAPA 2024-CR-002. All actions from 2024-CR-002 have been implemented aside from removal of devices that have not been used or destroyed.	
3	6. By when should the action be completed?	Within 5 days from receipt of form.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Cook Biotech Inc.**
	b. Address	**1425 Innovation Place West Lafayette, IN 47906 USA**
	c. Website address	**www.cookbiotech.com**
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. List of attachments/appendices:	**Attachment 1 – Affected Product 2024FA0006 (2024-001) Rev 2**

FSN Ref: 2024FA0006 (2024-001) FSCA Ref: 2024FA0006 (2024-001)

		Field Action Customer Reply Form – 2024FA00006 **Field Action Distributor Importer Reply Form – 2024FA00006**
4.	6. Name/Signature	

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*