To the attention of Medical Device Vigilance Manager / Central Pharmacy

Saint Priest, October 8th, 2020

Subject: **URGENT - FIELD SAFETY NOTICE** – CODMAN® BACTISEAL® EVD CATHETER SET–No CE marked Products – Safety information

Legal manufacturer:
Integra LifeSciences, 11 Cabot Boulevard, Mansfield, MA02048, USA
EC Rep :
INTEGRA LIFESCIENCES (France) SAS – Immeuble Séquoïa 2 – 97 Allée Alexandre Borodine – 69800 SAINT PRIEST
Medical devices:
The BACTISEAL EVD Catheters are made of silicone tubing and are supplied sterile. BACTISEAL EVD Catheters are subjected to a treatment process by which the silicone tubing is impregnated with rifampin and clindamycin hydrochloride. The catheter supplied in the BACTISEAL EVD Catheter Set is made of radiopaque (barium sulfate impregnated) silicone. The catheter in the BACTISEAL Clear EVD Catheter Set is made of clear silicone with a barium sulfate impregnated stripe. Laboratory studies show BACTISEAL treated catheters reduce the colonization of gram-positive bacteria on the tubing surface. The quantities of rifampin and clindamycin hydrochloride, used to impregnate the BACTISEAL EVD Catheter, are only a fraction of a therapeutic dose of these two antibiotics and have no potential for any systemic therapeutic effect. Each of the BACTISEAL EVD Catheters is a 35 cm silicone catheter. The catheter is marked with numbers or rings at each centimeter between 3 cm and 15 cm from the proximal tip. These markings serve as a scale to determine depth of insertion. The catheter characteristics vary by catalog number.

Primary clinical purpose of device(s):
The CODMAN BACTISEAL EVD Catheter and CODMAN BACTISEAL Clear EVD Catheter Sets (BACTISEAL EVD Catheters), are indicated for gaining access to the ventricles of the brain and can be used with dimensionally compatible devices for draining cerebrospinal fluid (CSF) and other fluids of similar physical characteristics as a means of reducing intracranial pressure and CSF volume.

Concerned reference(s) and batches:
821749 (lots 4451857; 4451858); 821750 (lots 4451876; 4451880; 4451883; 4561693)

Dear Valued Customer,

The purpose of this letter is to notify you that the legal manufacturer Integra LifeSciences, is voluntarily issuing a Field Safety Notice for:

- Codman EVD Bactiseal 1.9mm I.D.Catheter Set (Part# 821749) this product is made of silicone tubing and is supplied sterile
- Codman Bactiseal Clear EVD catheter 1.9mm I.D. Catheter Set (Part# 821750) This product is subjected to a treatment process by which the silicone tubing is impregnated with rifampin and clindamycin hydrochloride.

As background, Integra acquired the Codman Bactiseal products from Johnson & Johnson in 2017. Following the acquisition, the product codes at issue here continued to be manufactured at two facilities – (1) a facility in Raynham, MA still operated by Codman & Shurtleff, Inc., a Johnson & Johnson subsidiary, and (2) a facility in Le Locle, Switzerland acquired by Integra from Johnson and Johnson. The products (821749 and 821750) manufactured at Raynham are CE marked and intended for European distribution and the products manufactured out of Le Locle are not CE marked and intended for US distribution.

Integra LifeSciences released certain lots of Bactiseal products (Parts# 821749 and 821750) to European Economical Countries where the CE mark is required prior to commercialization. Based on ILS legal manufacturer Health Hazard Evaluation, this occurrence has no impact on product safety,

design, intended use, or performance of the products at issue. In addition, no complaint has been received due to this issue and Integra is waiting for the CE certificate before the end of October.

The assessment completed by the legal manufacturer Integra LifeSciences, concluded that Product safety and patient impact due to product shipped to non-authorized countries is low. However, there is a high regulatory compliance risk since regulatory approval has not been received for the manufacturing transfer and legal manufacturer change prior to distribution.

The risks mentioned above have been assessed based on standard ISO 14971 and other applicable regulations listed in our internal procedures.

However, out of an abundance of caution, **Integra LifeSciences has chosen to ask you to quarantine the lots listed below until Integra provides further guidance.**

Futher advice or information is expected in follow-up FSN related to this issue as soon the CE certificate is granted by our Notified Body.

No other products or lot numbers were impacted and should be used with confidence.

We are notifying you of the Field Safety Corrective Action as our records indicate that you have been supplied with:

Product Code	Lot Number(s)
821750	4451876; 4451880; 4451883; 4561693
821749	4451857 ; 4451858

Table 1: Product and Distribution information Table

To mitigate the risk, we kindly ask you to:

☑ Identify Device ☑ Quarantine Device

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially concerned devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

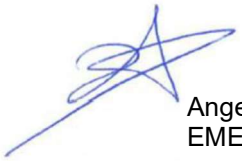
Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Customer reply is required. A form is attached to this Field Safety Notice. The receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information. **We expect a response within 3 weeks.**

The National Competent Authority of your country has been alerted of this Field Safety Corrective Action.

Please feel free to contact me at angelique.aubert@integralife.com for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,



Angelique AUBERT
EMEA Compliance Coordinator

Enclosed: Field Safety Notice Customer Reply Form (2 pages)

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-N-2020-HHE-014-040920
FSN Date*	8th of October 2020
Product/ Device name*	CODMAN® BACTISEAL® EVD CATHETER SET
Product Code(s)	821749 ; 821750 ;
Batch/Serial Number (s)	4451857 ; 4451858 ; 4451876 ; 4451880 ; 4451883; 4561693

2. Customer Details	
Account Number	
Healthcare Organization Name*	
Organization Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organization		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
☐	Other Action (Define):	
☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here

Signature*	Customer sign here
Date*	

4. Return acknowledgement to sender	
Email	emea-fsca-neuro@integralife.com
Customer Helpline	+33 (0) 4 37 47 59 16
Postal Address	Regulatory Affairs Integra Immeuble Séquoia 2, 97 allées Alexandre Borodine Parc technologique de la Porte des Alpes 69800 Saint Priest, France
Web Portal	www.integralife.eu
Fax	+33 (0)4 37 47 59 30
Deadline for returning the customer reply form*	3rd of November 2020

Mandatory fields are marked with *

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.