

Saint Priest, October 8th, 2020

To the attention of Quality Assurance Dpt or
Regulatory Affairs Dpt or Management

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 Distributor Reply Form (2 pages)

Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-N-2020-HHE-014-040920
FSN Date*	8 th 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. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	emea-fsca-neuro@integralife.com
Distributor 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
Deadline for returning the Distributor reply form*	3 rd of November 2020

4. Distributors/Importers (Tick all that apply)		
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
<input type="checkbox"/>	I have identified customers that received or may have received this device	
<input type="checkbox"/>	I have attached customer list	

<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication:
<input type="checkbox"/>	I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor print name here
Signature*		Distributor sign Here
Date *		

Mandatory fields are marked with *

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

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