Date: 09 December 2022

URGENT FIELD SAFETY NOTICE (REMOVAL)
BIOSTOP™ G Bioresorbable Cement Restrictor (all lots)

Subject Product:

Model Number *	Description **
5463-08-000	BIOSTOP G BIORESORBABLE CEMENT RESTRICTOR SIZE 8
5463-10-000	BIOSTOP G BIORESORBABLE CEMENT RESTRICTOR SIZE 10
5463-12-000	BIOSTOP G BIORESORBABLE CEMENT RESTRICTOR SIZE 12
5463-14-000	BIOSTOP G BIORESORBABLE CEMENT RESTRICTOR SIZE 14
5463-16-000	BIOSTOP G BIORESORBABLE CEMENT RESTRICTOR SIZE 16
5463-18-000	BIOSTOP G BIORESORBABLE CEMENT RESTRICTOR SIZE 18
5463-20-000	BIOSTOP G BIORESORBABLE CEMENT RESTRICTOR SIZE 20
* Reference Attachment A Instructions for Identifying Subject Product / ** UDI-DI on GS1 0603295a0035792	

Dear Valued Customer,

Please be advised that DePuy Ireland U.C. initated a field safety notice (removal) of all lots of BIOSTOP™ G Bioresorbable Cement Restrictor listed in the table above. BIOSTOP™ G Bioresorbable Cement Restrictor is a bioresorbable plug for orthopaedic use. It is designed to seal the medullary canal before introducing bone cement, during joint replacement surgery with cemented prostheses. It is used to contain cement penetration within the medullary canal and enables cement pressurisation prior to and during introduction of the implant.

Our records show that you, or your facility, received one or more units of the product listed above. Please carefully review this notice for the steps that you should take to respond to this field safety notice (removal).

Reason for the Field Safety Notice (Removal):
All lots of BIOSTOP G Bioresorbable Cement Restrictor are being removed as a precautionary measure because recent *in vitro* testing of endotoxin levels from a sample restrictor fully dissolved in solution were calculated at >20,000 endotoxin units (EU)/device over 24 hours, based on restrictor size. This exceeds the recommended value of 20 EU/device over 1 hour as referenced in the current FDA regulatory guidance, “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labelled as Sterile Guidance for Industry and Food and Drug Administration Staff” (issued on January 21, 2016).

Potential Patient Impact:
In general, endotoxins have a potential to initiate inflammatory responses, ranging from a mild fever to potentially impact or damage to vital organs. The BIOSTOP G cement restrictor resorbs over a period of several days up to 2 weeks, depending on the size of the restrictor. Due to the resorbable nature of the cement restrictor, any endotoxins present should be released gradually over this time period. As a result it should be unlikely to reach a threshold required to promote a clinical response. The restrictor is located in the intramedullary canal which could also help to reduce a systemic inflammatory response. If an inflammatory response occurred, it would be expected to happen immediately after the surgery in which the product is used. BIOSTOP G should be completely resorbed within two weeks, and any inflammatory response resulting from endotoxins attributed to BIOSTOP G is not expected after this time. Treatment for post-operative injury and inflammation is part of the standard of care for any type of surgery. The inflammatory response can be induced by tissue injury and any foreign material (e.g., cement restrictors) used during the surgery, as well as endotoxins. Healthcare providers

who have used BIOSTOP G on patients should continue to follow those patients pursuant to their standard of care for those procedures.

To date, we have seen no evidence of a signal in any postmarket surveillance data reviews, including complaints related specifically to endotoxins.

Alternative Restrictors

The following DePuy Synthes polyethylene (PE) cement restrictors are recommended alternatives. **NOTE: Please check with your local Sales Manager for alternative product availability in your Market.**

Image of PE Restrictor	PE Restrictor Size	PE Restrictor Product Code
	Size 1 - 8.25mm	546010000
	Size 2 - 10.75mm	546012000
	Size 3 - 13.25mm	546014000
	Size 4 - 15.75mm	546016000
	Size 5 - 18.25mm	546018000
	Size 6 -20.75mm	546020000
	Size 7 - 23.75mm	546022000

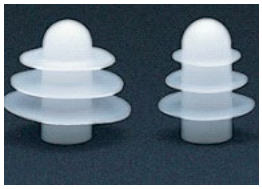
Image of PE Restrictor	PE Restrictor Size	PE Restrictor Product Code
	Small fits canal 10.5mm to 16.0mm	546110000
	Large fits canal 16.5mm to 22.5mm	546112000

Image of Harding PE Restrictor	Hardinge PE Restrictor Size	Hardinge PE Restrictor Product Code
	Universal	963204000

Please Take the Following Steps:

1. Examine your inventory immediately to determine if you have the subject products and quarantine them immediately. DO NOT USE THE SUBJECT PRODUCTS.
2. Contact your DePuy Synthes Sales Consultant or contact the customer support services at (enter country contact) to coordinate the return/credits of the subject products.
3. Review, complete, sign, and return the attached Business Response Form (page 5 of this letter) toat

(enter country contact) within three (3) business days of receipt of this notification. Please include in the email subject: FA 2191283 BIOSTOP

4. Please complete the attached Business Response Form even if you do not have the subject products on hand.
5. Forward this notice to anyone in your facility that needs to be informed (e.g., those who manage, transport, store, stock, or use the subject products).
6. If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice.
7. Post a copy of this notice in a visible area for awareness and keep a copy for your records.

This field safety notice (removal) has been reported to the relevant health authorities. If you have any questions, please contact your local DePuy Synthes Sales Consultant. For Medical Information request, please visit our website: https://www.jnjmedicaldevices.com/mir.

Sincerely,

Kimberly Long
Staff Quality Systems Recall Coordinator
Email: OneMD-Field-Actions@its.jnj.com

Attachment A: Instructions for Identifying Subject Product

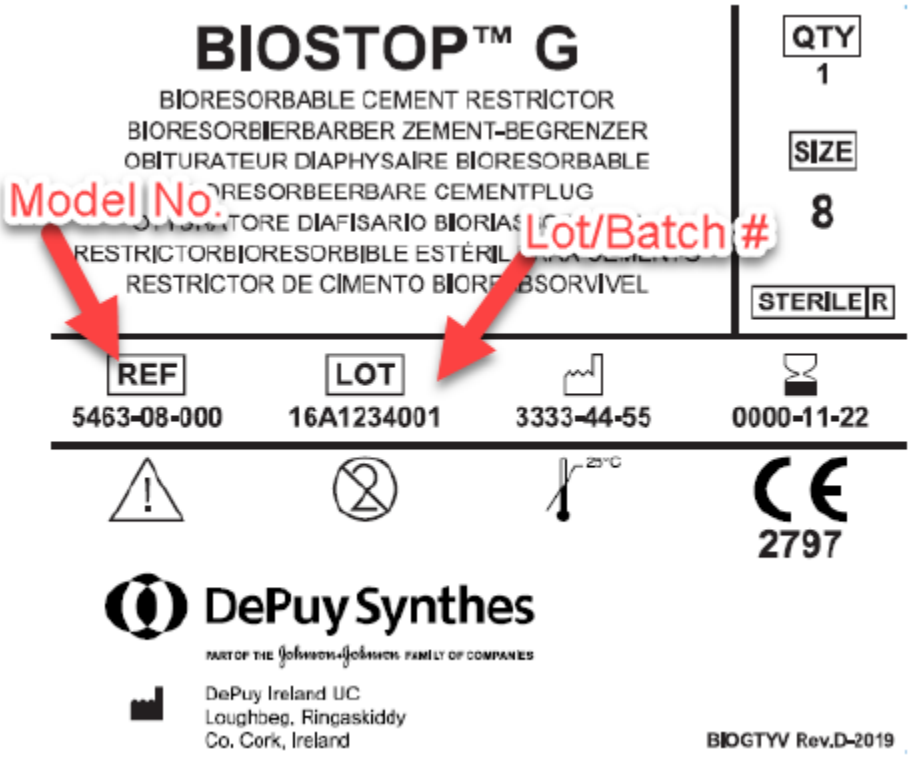


Figure 1: Example Label for Model No. 5463-08-000

URGENT FIELD SAFETY NOTICE (REMOVAL)

BIOSTOP™ G Bioresorbable Cement Restrictor (all lots)

Business Response Form

Subject Product:

Model Number *	Description **	Enter Lots Returned	Quantity Returned
546308000	BIOSTOP G BIORESORBABLE CEMENT RESTRICTOR SIZE 8		
546310000	BIOSTOP G BIORESORBABLE CEMENT RESTRICTOR SIZE 10		
546312000	BIOSTOP G BIORESORBABLE CEMENT RESTRICTOR SIZE 12		
546314000	BIOSTOP G BIORESORBABLE CEMENT RESTRICTOR SIZE 14		
546316000	BIOSTOP G BIORESORBABLE CEMENT RESTRICTOR SIZE 16		
546318000	BIOSTOP G BIORESORBABLE CEMENT RESTRICTOR SIZE 18		
546320000	BIOSTOP G BIORESORBABLE CEMENT RESTRICTOR SIZE 20		
* Reference Attachment A Instructions for Identifying Subject Product / ** UDI-DI on GS1 0603295a0035792			

☐ **The subject product has been located. A copy of this notice is being retained and I have read and understood the notification.**

For product returns: Please call customer service following the typical returns process in order to acquire a return number prior to shipping product. Please enclose a photocopy of the completed Business Response Form as a packing slip in the box containing the product(s) you are returning. Return all identified affected product to: GMED Healthcare | JDE 8.12 Returns Dept. | ATTN: RETURNS FA 2191283 (SS NR-0185196) | Rue de Luxembourg 5 | ZI Trazegnies | BE - 6180 Courcelles | Belgium | TEL: 32-7-146-9404

☐ **None of the subject product is available for return. A copy of this notice is being retained and I have read and understood the notification.**

Please complete this Business Response Form (BRF) Form within 3 days after the receipt of this notification. Please return this form via email to at (enter country contact). Please include in the email subject: FA 2191283 BIOSTOP.

Your Name/Title:	Facility/Business Name:
Signed*:	Date:
Address:	
Account Number:	
RGA Number	
J&J Sales Rep (as applicable):	
Email Address:	Telephone Number:
Comments (if any):	
**Your signature provides confirmation that you have received and understood this notification.*	