

ArcRoyal uc

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06 Oct 2022

## Field Safety Notice

BBraun Gelita-Tampon  
**Type of Action:** Product Recall  
FSN-22-J-001

**Commercial Name:** Custom Procedure Trays containing BBraun Gelita-Tampon 8 x 5 x 1 cm  
ArcRoyal Code 10-007953, Supplier Code 2070600

**ArcRoyal Identifier:** FSN-22-J-001 **BBraun Identifier:** INC QA/114/22

**Type of Action:** Recall of BBraun Gelita-Tampon 8 x 5 x 1 cm ArcRoyal Code 10-007953,  
Supplier Code 2070600 contained within custom procedure tray GEA041

### **Attention: This letter is to inform you of a Field Safety Notice initiated by BBraun**

ArcRoyal received a Field Safety Notification from BBraun (BBraun FSN reference INC QA/114/22) on the 6<sup>th</sup> of Oct 2022. The notification detailed that BBraun is conducting a Field Safety Corrective Action to recall all lots still within shelf life of BBraun Gelita-Tampons.

#### **Details:**

During routine bioburden testing, BBraun was informed that the endotoxin concentration of the product in some samples was measured above the limit. Since these “outliers” in testing cannot be reconciled at this time, it has been decided to take a very conservation approach and recall all product, even that found to be within specification.

#### **Details of affected devices:**

ArcRoyal Code	BBraun Code	Description	Pack Code	Work Order/Lot
10-007953	2070600	Gelita-Tampon 8 x 5 x 1 cm	GEA041	718841, 719508

The affected listed code is contained within ArcRoyal custom procedure tray GEA041.

#### **Clinical risk**

Bacterial endotoxins, found in the outer membrane of gram-negative bacteria are members of a class of phospholipids called lipopolysaccharides (LPS). LPS are not exogenous products of gram negative bacteria. Endotoxin is commonly found everywhere in the environment, and it is the most significant pyrogen in parenteral drugs and medical devices. The release of LPS from bacteria takes place after death and lysis of the cell. Endotoxins can elicit a pyrogenic/inflammatory response from the human body. In rare cases, septic or anaphylactic shock might occur. If the hospital uses a product affected by this issue, an

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acute pyrogenic reaction might be expected within 2-5 days after use. If the patient presents the complication described, the hospital protocol for such situations will be acted upon accordingly. No further follow-up of the patient is required.

#### **Actions for customers to take**

**Based off the instructions received from BBraun, ArcRoyal requires that the following actions are taken:**

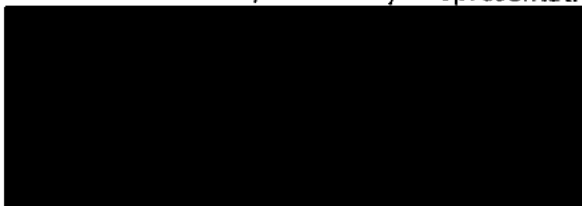
1. Complete and return the completed Field Safety Corrective Action Response Form, Appendix I, to ArcRoyal ([ArcRoyal.QARAQueries@owens-minor.com](mailto:ArcRoyal.QARAQueries@owens-minor.com)) confirming receipt of this notification. **\*This should be done even if you have no affected product\***
2. Please identify and quarantine any of the listed product in your organization. Once units documented and returned in Appendix I, Field Safety Corrective Action Response Form, ArcRoyal will arrange immediate return of affected product.

**NOTE:** If you no longer use the product or it is no longer in your inventory, it is still important that you return the Customer Response Form for our reconciliation purposes.

#### **Transmission of this Advisory**

ArcRoyal are committed to patient safety and would appreciate your immediate attention and cooperation to this matter. Please immediately forward this information to all departments within your organisation. Attached is the Field safety notice issued by BBraun with the instructions to notify all end users affected by this notification.

We sincerely apologize for any inconvenience that this may cause and thank you for your business and continued support. If you have any questions or concerns, please do not hesitate to contact your ArcRoyal representative.



13 Oct 2022

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**Appendix I**  
**FSN-22-J-001**  
**(BBraun reference INC QA/114/22)**  
**Field Safety Notice Corrective Action Response Form**

Please complete this form as acknowledgement that you have received, read and understood the actions to be taken in relation to FSN-22-J-001 (BBraun reference INC QA/114/22) and product below:

ArcRoyal Code	BBraun Code	Description	Pack Code	Work Order/Lot Number
10-007953	2070600	Gelita-Tampon 8 x 5 x 1 cm	GEA041	718841, 719508

The completed response form should be immediately returned via email to:  
**Email:** ArcRoyal.QARAQueries@owens-minor.com

- We have received the notice and have stock to return.

Units to return:

Pack Code	Work Order/Lot Number	Quantity left in stock of affected packs

- We have received the notice and all stock has been used.

Facility Name	
Facility Address	
Printed name and Title	
Signature and Title	
Phone Number/Fax Number	

