



01 May 2018

“Contact Person:”

“Company:”

“Address 1:”

“Address 2:”

## URGENT: FIELD SAFETY NOTICE

Attention: Quality/Regulatory Affairs Department:

GALT MEDICAL CORP. has initiated a Field Safety Corrective Action of the products listed in Appendix A. Please direct this notice to the appropriate personnel in the Quality/Regulatory Affairs, or to those responsible for inventory management of the affected product.

### Scope of Field Safety Notice:

The product being impacted by this FSN is listed below and no other products are affected.

Product	Device Description	Lot
DRC-002-08	5F x 15cm Centeze Centesis Catheter	17321338

### Reason for Field Safety Notice:

The products listed might contain unsafe levels of bacterial endotoxins (Pyrogens) that was introduced during a manufacturing step. Bacterial Endotoxins also called pyrogenic bacteria can activate the inflammatory process and produce fever, chills, and hypotension in a patient.

### Status of Product:

We have identified the lots listed above as the only affected product that was distributed to you. The problem has been investigated, and we will take steps to assure this problem does not recur.



**Action to be Taken:**

GALT MEDICAL CORP is voluntarily initiating this product Field Safety Notice and requesting the return of products in inventory. The following steps should be taken:

1. Identify and segregate the lot (s) that is in your possession.
2. Complete the enclosed Field Safety Notice and email or fax it to the attention of the Field Safety Notice Coordinator at [Quality@Galtneedletech.com](mailto:Quality@Galtneedletech.com) or **214-778-1433**. The form lists the catalog number, lot number and quantity our records indicate your facility has received.

**It is important that even if you do not have any product remaining in your possession that you fill out the attached form noting zero quantity to be returned and fax the form to GALT MEDICAL CORP.**

3. Ship the product to GALT MEDICAL CORP.

**Reference Return Authorization Number RMA# XXX-XXXX on the outside of the shipping box and include a copy of the Field Safety Notice Reply Form with your shipment.**

GALT MEDICAL CORP. appreciates your understanding and cooperation with this matter and regrets any inconvenience this has caused you. If you have any additional questions or concerns or need more detailed instruction on how to comply with this notice, please do not hesitate to contact your local sales representative or Field Safety Notice Coordinator at 214-778-1306. You may also e-mail your questions to [quality@galtneedletech.com](mailto:quality@galtneedletech.com).

Sincerely,

Galt Medical Corp.

David Derrick  
Director Quality and Regulatory Affairs.  
Galt Medical Corp.



# Galt Medical Corp.

## Medical Device Field Safety Notice Reply Form

“Contact Person:”

“Company:”

“Address 1:”

“Address 2:”

1. Our records indicate you have received the following product

Product	Device Description	Lot
DRC-002-08	5F x 15cm Centeze Centesis Catheter	17321338

2. Check your inventory and enter the quantity of the affected products you have in your possession in the “Quantity to be Returned” column. **Enter a “0” in the “Quantity to be Returned” column if you no longer have any of the listed product.** If there is a discrepancy between the product you have and the identity and quantity of product listed above, please explain in the comment area below or on an attached note.

**ALL PRODUCT WITHIN THE SCOPE OF THE FIELD SAFETY NOTICE SHOULD BE RETURNED**

3. **Sign and date this form. Email it back to [Quality@GaltMedical.com](mailto:Quality@GaltMedical.com) or it may be faxed to 214-778-1433.**

4. Return the product to:

Galt Medical Corp.  
2220 Merritt Drive  
Garland, TX 75041  
**ATTN: Field Safety Notice Coordinator**

**Return Authorization Number: RMA# XXX-XXXX**

You may use Galt’s shipping Account Number (Fed Ex: 143996344 / UPS: E79217) to pay for shipping the product to Galt Medical Corp.

**BE SURE TO WRITE THE RETURN AUTHORIZATION NUMBER ON THE OUTSIDE OF THE SHIPPING BOX AND INCLUDE A COPY OF THIS COMPLETED FORM WITH YOUR SHIPMENT**

Form Completed By: \_\_\_\_\_ Phone Number: \_\_\_\_\_  
(Please Print)

Signature: \_\_\_\_\_ Date: \_\_\_\_\_



**Comments:**



01 May 2018

- “Contact Person:”
- “Company:”
- “Address 1:”
- “Address 2:”
- “RMA#:”

## URGENT: MEDICAL DEVICE FIELD SAFETY NOTICE

Attention: Procurement, Interventional Radiology, Surgery, or Electrophysiological departments:

GALT MEDICAL CORP. has initiated a Field Safety Notice of the products listed in Appendix A. Please direct this notice to the appropriate personnel in the Procurement, Interventional Radiology, Surgery, or Electrophysiological department, or to those responsible for inventory management of the affected product.

### Scope of Field Safety Notice:

The product impacted by this FSN is listed below and other products are not affected.

Product	Device Description	Lot
DRC-002-08	5F x 15cm Centeze Centesis Catheter	17321338

### Reason for Field Safety Notice:

The products listed might contain unsafe levels of bacterial endotoxins (Pyrogens) that were introduced during a manufacturing step. Bacterial Endotoxins also called pyrogenic bacteria can activate the inflammatory process and produce fever, chills, and hypotension in a patient.

### Status of Product:

We have identified the lots listed above as the only affected product that was distributed to you. The problem has been investigated, and we have taken steps to assure this problem does not recur.

### Action to be Taken:

GALT MEDICAL CORP is voluntarily initiating this product Field Safety Notice and requesting the return of products in inventory. The following steps should be taken:

3. Identify and segregate the effective lot(s) that are in your possession.



4. Reach out to your customers to whom you have distributed any of this product to determine if they have inventory in stock for return.
5. **Complete the enclosed Field Safety Notice Reply Form and email or fax it to the attention of the Field Safety Notice Coordinator at [quality@galtneedletech.com](mailto:quality@galtneedletech.com) or 214-778-1433.** The form lists the product number, lot number and quantity our records indicate your facility has received.

**It is important that even if you do not have any product remaining in your possession that you fill out the attached form noting zero quantity to be returned and fax the form to GALT MEDICAL CORP.**

4. Ship the product to GALT MEDICAL CORP. using Galt's carrier account information listed on the form.
5. Reference Return Authorization Number RMA# XXX-XXXX on the outside of the shipping box and include a copy of the Field Safety Notice Reply Form with your shipment.
6. Once the completed Field Safety Notice Reply Form has been received and processed, Galt will issue a credit to you for the product returned and enter a new PO for new products, using your original PO number so your new invoice will pair with your credit.
  - a. New inventory for bulk, non-sterile product is estimated to ship in 4-5 weeks, while sterile product is scheduled to ship in 6-7 weeks. Some product will be available to ship sooner, if available upon receipt of the returned product.

GALT MEDICAL CORP. appreciates your understanding and cooperation with this matter and regrets any inconvenience this has caused you. If you have any additional questions or concerns or need more detailed instruction on how to comply with this notice, please do not hesitate to contact your local sales representative or Field Safety Notice Coordinator at 214-778-1306. You may also e-mail your questions to [quality@galtneedletech.com](mailto:quality@galtneedletech.com).

Please ensure you notify your customers within 48 hours of receipt of this notification.

Sincerely,

Galt Medical Corp.

David Derrick  
Director Quality and Regulatory Affairs.  
Galt Medical Corp.



# Galt Medical Corp.

## Medical Device Field Safety Notice Sales Representative Reply Form

I \_\_\_\_\_ have removed the following product from the hospital listed \_\_\_\_\_:  
(Sales Representative Name) (Date)

Product	Device Description	Lot
DRC-002-08	5F x 15cm Centeze Centesis Catheter	17321338

- Return the product to the following location:  
Galt Medical Corp.  
2220 Merritt Drive  
Garland, TX 75041  
**ATTN: Field Safety Notice Coordinator**

**Return Authorization Number RMA# XXX-XXXX**

- You may use FedEx Account Number (Fed Ex: 143996344 / UPS: E79217) to pay for shipping the product to Galt Medical Corp.
- Sign and date this form. Email it back to [quality@galtneedletech.com](mailto:quality@galtneedletech.com) or it may be faxed to 214-778-1433.**
- Write the return authorization number on the outside of the box and include a copy of this completed form with the product.
- For questions, call David Derrick at 1-214-778-1306.
- Leave a copy of this form with the appropriate hospital personnel and record the name, title, and contact number of this person below:

\_\_\_\_\_  
(Name) (Title) (Contact phone number)

\_\_\_\_\_  
Sales Representative Signature Date