GALT MEDICAL CORP. 2220 MERRITT DRIVE / GARLAND, TEXAS 75041-6146 / 972-271-5177/ FAX: 972-271-4706

URGENT: FIELD SAFETY NOTICE

Galt VTI®ValvedTearaway Introducer
FSCA Number:1649395-07-25-2014-001-R
Return of Medical Devices to Galt Medical Corp.

21October 2014

Attention: Interventional Radiology, Surgery, or Electrophysiological departments:

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

Scope of Recall:
The product covered under this Field Safety Corrective Action is Galt's ValvedTearaway product (**VTI®**). Non-tearaway products and other valved products are not affected. Catalog Numbers covered in this Field Safety Corrective Action are:
INT-104-06, INT-104-07, INT-104-08, INT-104-09, INT-104-10, INT-104-11, INT-104-12, INT-104-17, INT-104-18, INT-104-19, INT-104-20, INT-104-21, INT-104-22, INT-104-23, INT-108-06, INT-108-07, INT-108-09, INT-108-10, INT-108-11, INT-108-12, INT-108-17, INT-108-18, INT-108-19, INT-108-20, INT-108-21, INT-108-22, INT-108-22, KIT-043-06, KIT-043-07, KIT-043-08, KIT-043-09, KIT-043-10, KIT-043-11, KIT-053-06, KIT-053-07, KIT-053-08, KIT-053-09, KIT-053-10, KIT-053-11, KIT-053-12, KIT-053-17, KIT-053-18, KIT-053-19, KIT-053-20, KIT-053-21, KIT-053-22, VTI-002-06, VTI-002-07, VTI-002-08, VTI-002-09, VTI-002-09, VTI-002-10, VTI-002-11, VTI-002-12, VTI-002-17, VTI-002-18, VTI-002-19, VTI-002-20, VTI-002-21, VTI-002-22, VTI-002-23, VTI-003-06, VTI-003-07, VTI-003-08, VTI-003-09, VTI-003-10, VTI-003-11, VTI-003-12, VTI-003-17, VTI-003-18, VTI-003-19, VTI-003-20, VTI-003-21, VTI-003-22, VTI-003-23

Reason for Field Safety Corrective Action:
The **VTI®** products contain a valve that is manufactured in two halves that are bonded together. The bonding agent was over applied on some products, and this over application has the potential to dislodge when objects are inserted through the valve.

Status of VTI®Product:
The lots listed in the attachment were shipped to you and are the only product affected by this Field Safety Corrective Action. 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 Corrective Action and requesting the return of products in inventory. The following steps should be taken:

1. Identify and segregate the recalled lot (s) that is in your possession.

2. Complete the enclosed VTI®Field Safety Corrective Action Reply Form and email or fax it to the attention of the VTI®Recall Coordinator at Quality@GaltMedical.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 recalled product to GALT MEDICAL CORP.

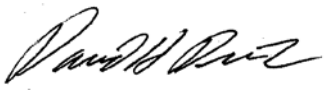
   Reference Return Authorization Number RMA# VTI-1001on the outside of the shipping box and include a copy of the VTI®Field Safety Corrective Action Reply Form with your shipment.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected 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.

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 Corrective Action Coordinator at 214-778-1306. You may also e-mail your questions to quality@galtmedical.com.

Sincerely,

Galt Medical Corp.



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

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VTI®Field Safety Corrective Action Reply Form

1. Our records indicate you have received the product listed on Appendix A.

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 SAFTEY CORRECTIVE ACTION SHOULD BE RETURNED

3. **Sign and date this form. Email it back to 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: VTI®Field Safety Corrective Action Coordinator

   Return Authorization Number:RMA# VTI-1001

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: