



June 12, 2017

URGENT: FIELD SAFETY NOTICE

TISSU-TRANS PRODUCTS

Customer Name
Street Address
City, State, Zip Code

Dear Device Customer/Distributor,

The purpose of this letter is to advise you that Shippert Medical Technologies is doing a field safety notice on Tissu-Trans Filtron 100, Tissu-Trans Filtron 250, Tissu-Trans Filtron 500, Tissu-Trans 1000, Tissu-Trans 2000, Tissu-Trans MEGA 1500 and Tissu-Trans Syringe Fill 360 used for fat transfer and liposuction and to ensure optimal safety of our products the company has made the decision to perform a voluntary recall of the Tissu-Trans product that have not yet exceeded the shelf life of 3 years and use the Tyvek header pouch.

Shippert Medical has not received any customer complaints or reports of serious injuries and/or deaths.

Reason for the Field Safety Corrective Action:

Results from a visual examination performed on the packaging has revealed that the seal integrity of the Tissu-Trans product sterile packages listed above cannot be assured prior to usage without a visual inspection of the seal.

To ensure optimal safety of our products the company has made the decision to perform a voluntary recall of all Tissu-Trans product that have not yet exceeded the shelf life of 3 years and use the Tyvek header pouch.

Shippert has not received any customer complaints or reports of serious injuries and/or deaths due to the lack of sterility.

Risk to Health:

If a pouch that was improperly sealed were to be subjected to potential contamination, there is the possibility that the product might become contaminated. If the product become contaminated and is used on a patient, there is a risk to the patient of infection/inflammation.



How to recognize that the device may fail.

Perform a visual inspection of the pouch seal and if the seal is incomplete, has channels or bubbles that would cause seal failure, there is the potential for possible ingress.

Actions to be taken by the Customer/User:

Please be aware that only the products listed on the FSCA Letter are affected by this voluntary field action. Please read the following instructions and carry out the described actions.

1. Please remove all affected products from your inventory and store them in a separate area. These products must not come into clinical use.
2. Please forward this letter to all staff members in your organization that needs to be aware of this information letter and the initiated field safety notice.
3. Please complete the FSCA Letter indicating the quantity of products that have already been used and the quantity of products that are being returned as well as your contact details.
4. Please return the completed and signed FSCA Letter to Shippert by fax, email or mail within 10 calendar days, even if you are not going to return any product.
5. If you have any additional questions regarding return of the products, replacement or shipping, please contact customer service at (800) 888-8663.
6. Please only return affected products listed in the FSCA Letter to Shippert. Replacement product will be issued and sent for all returned products.
7. In case you, as a distributor, have passed these products to third parties, please forward a copy of this information to each party and ensure that you receive back the information about products already used and products to be returned from your customers (i.e. hospitals).

This information should be completed in the FSCA Letter.

8. Please ensure that your organization and your customers are aware of the content of this field action letter as soon as possible.



Product and Distribution Information:

Product Name	Catalog Number	Lot Number
Tissu-Trans Filtron 100	3-TT-FILTRON 100	12018, 12045, 12076, 12109
Tissu-Trans Filtron 250	3-TT-FILTRON 250	12005, 12019, 12044, 61286, 61421
Tissu-Trans Filtron 500	3-TT-FILTRON 500	11934, 11948, 11984, 12002, 12020, 12046, 61118, 61287, 61363, 61446
Tissu-Trans Filtron 1000	3-TT-FILTRON 1000	12004, 12047, 12077, 61235
Tissu-Trans Filtron 2000	3-TT-FILTRON 2000	11947, 12003, 12078, 12110
Tissu-Trans MEGA 1500	3-TT-MEGA 1500	12082, 12111, 61116, 61236, 61288, 61364, 61464
Tissu-Trans Syringe Fill 360	3-TT-SFILL 360	12079, 61117, 61143, 61405

Type of Action by the Company:

Shippert Medical will replace returned product affected by the recall and not used by the customer with new product.

The return of this FSCA Letter is requested for Shippert to complete this voluntary field action. Therefore, your cooperation in this matter is greatly appreciated.

Your cooperation in this matter is greatly appreciated.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

We thank you and apologize for this inconvenience.

Sincerely,

Nicole Dove
Quality Assurance/Regulatory Affairs Director

Contact Information:
Monday – Friday, 8:00AM to 4:00PM, Central Standard Time
(800) 888-8663 or (651) 789-3921



URGENT FIELD SAFETY NOTICE RESPONSE
Acknowledgement and Receipt Form
Response is Required

Customer Information:

TISSU-TRANS PRODUCTS

I have read and understand the field action instructions provided in the attached letter.

Yes___ No___

Any adverse events associated with this product?

Yes___ No___

If yes, please explain:

Affected Product Information:

Please fill out legibly the last two columns and complete your contact data.

Catalog Number	Description	Lot Number	Invoice Number	Delivered Quantity	Used Quantity	Quantity to be Returned*



Return Response Box:

Return product to:
Shippert Medical
Attn: Recall 2017-May
815 Northwest Parkway, Suite 100
St. Paul, MN 55121

Ship Via:

UPS Ground
Account #: 801785

Fax: (651) 789-3921

Email: quality@shippertmedical.com

Distributors:

I have checked my stock and have quarantined inventory consisting of _____ units.

I have identified and notified my customers that were shipped or may have been shipped this product by _____ (specify date and method of notification).

Signature of Receipt: _____

Name / Title:	
Phone number:	
Email address:	
Date:	
Signature	

FAX FORM BACK TO: 888-229-1941
ATTN: NICOLE DOVE

If you have additional questions regarding the return of the products, replacement or transport please contact customer service at (800) 888-8663.