Shippert Medical Technologies

1. Administrative information	
To which NCA(s) is this report being sent? Italy, Austria, Germany, Spain, Switzerland, Denmark, Sweden, United Kingdom, Belgium, Netherlands, Greece	
Type of Report _X_ Initial Report __ Follow up Report __ Final Report	
Date of this report January 10, 2018	
Reference number assigned by the manufacturer Tissu-Trans Recall January 2018	
FSCA reference number assigned by NCA unknown	
Incidence reference number assigned by NCA unknown	
Name of the coordinating national competent authority (if applicable) Dutch Healthcare Inspectorate PO Box 2680 NL – 3500 BS Utrecht	
2. Information on submitter of the report	
Status of submitter __ Manufacturer _x_ Authorized representative within EEA, Switzerland and Turkey __ Others (identify the role):	
3. Manufacturer information	
Name Shippert Medical	
Contact Name Nicole Dove	
Address 6248 S Troy Circle, Unit A	
Postcode 80111	City Centennial

Phone (800) 888-8663	Fax (800) 284-0864
E-mail ndove@summitmedicalusa.com	Country United States
4. Authorized representative information	
Name CEpartner4U	
Contact Name Rogier Nusselder	
Address Esdoornlaan 13	
Postcode 3951 DB	City Maarn
Phone +31343-441156	Fax
E-mail office@cepartner4u.com	Country The Netherlands
5. National contact point information	
National contact point name If available	
Name of the contact person	
Address	
Postcode	City
Phone	Fax
E-mail	Country
6. Medical device information	
Class __ AIMD __ MDD Class III __ MDD Class IIb _x_ MDD Class IIa __ MDD Class I	 __ IVD Annex II List A __ IVD Annex II List B __ IVD Devices for self-testing __ IVD General
Nomenclature system (preferable GMDN)	Nomenclature code

Nomenclature text	
Commercial name/brand name/make Tissu-Trans Products	
Model number Tissu-Trans Filtron 100 Tissu-Trans Filtron 250 Tissu-Trans Filtron 500 Tissu-Trans Filtron 1000 Tissu-Trans Filtron 2000 Tissu-Trans MEGA 1500 Tissu-Trans Syringe Fill 360	Catalogue number 3-TT-FILTRON 100 3-TT-FILTRON 250 3-TT-FILTRON 500 3-TT-FILTRON 1000 3-TT-FILTRON 2000 3-TT-MEGA 1500 3-TT-SFILL 360
Serial number(s) n/a	Lot Numbers: 61472, 61601, 61816, 61817, 61818, 61819, 61878, 61736, 61801, 61948, 62050, 62139 61507, 61578, 61682, 61689, 61849, 61879, 62011, 62088, 62108 61508, 61636, 61683, 61753, 61804, 61812, 61813, 61814, 61815, 61862, 61917, 61949, 61991, 62052, 62089, 62134, 62156 61627, 61687, 61839, 61920, 62051, 62087 61688, 61759, 61846, 61847, 61848 61471, 61625, 61754, 61840, 61945, 61950, 62135, 62137, 62157 61656
Device Manufacturing date various	Expiry date various
Software version number (if applicable) n/a	
Accessories/associated device (if applicable) n/a	
Notified body (NB) ID-number LNE/G-MED, CE0459	

Shippert
Medical Technologies

7. Description of FSCA

Background information and reason for the FSCA

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

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.

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

Description and justification of the action (corrective/preventive)

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 recall.

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.

Shippert
Medical Technologies

Advice on actions to be taken by the distributor and the user See above	
Progress of FSCA, together with reconciliation data (Mandatory for a final FSCA) n/a - initial	
Attached please find _x_ Field Safety Notice (FSN) in English __ FSN in national language __ Others (please specify):	FSN Status _x_ Draft __ Final

These countries within the EEA and Switzerland and Turkey are affected by this FSCA

Within EEA, Switzerland and Turkey:

_x_ AT	_x_ BE	__ BG	_x_ CH	__ CY	__ CZ	_x_ DE	_x_ DK	__ EE	_x_ ES
__ FI	__ FR	_x_ GB	_x_ GR	__ HU	__ IE	__ IS	_x_ IT	__ LI	__ LT
__ LU	__ LV	__ MT	_x_ NL	__ NO	__ PL	__ PT	__ RO	_x_ SE	__ SI
__ SK	__ TR								

Candidate Countries:
__ HR

__ All EEA, Candidate Countries, Switzerland and Turkey

Others:
Japan, Kuwait, Australia, Saudi Arabia, New Zealand, Israel

8. Comments

I affirm that the information given above is correct to the best of my knowledge.

Signature

Nicole Dove
Director Quality Assurance/Regulatory Affairs

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Shippert
Medical Technologies

January 10, 2018

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.

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 pouch integrity of the Tissu-Trans product sterile packages listed above cannot be assured prior to usage without a visual inspection of the pouch.

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.

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 is punctured, it would be subjected to potential contamination, there is the possibility that the product might become contaminated.

How to recognize that the device may fail.

Perform a visual inspection of the pouch if the pouch has a cut or hole, 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	61472, 61601, 61816, 61817, 61818, 61819, 61878, 61736, 61801, 61948, 62050, 62139
Tissu-Trans Filtron 250	3-TT-FILTRON 250	61507, 61578, 61682, 61689, 61849, 61879, 62011, 62088, 62108
Tissu-Trans Filtron 500	3-TT-FILTRON 500	61508, 61636, 61683, 61753, 61804, 61812, 61813, 61814, 61815, 61862, 61917, 61949, 61991, 62052, 62089, 62134, 62156
Tissu-Trans Filtron 1000	3-TT-FILTRON 1000	61627, 61687, 61839, 61920, 62051, 62087
Tissu-Trans Filtron 2000	3-TT-FILTRON 2000	61688, 61759, 61846, 61847, 61848
Tissu-Trans MEGA 1500	3-TT-MEGA 1500	61471, 61625, 61754, 61840, 61945, 61950, 62135, 62137, 62157
Tissu-Trans Syringe Fill 360	3-TT-SFILL 360	61656

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 undersigned confirms that this notice has been sent to 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

Shippert Medical Technologies

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

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.