

Boissy l'Aillerie, the 19th of October 2023

URGENT FIELD SAFETY NOTICE

Fat Washer 800

Lot : N010306


Product Recall : Fat Washer 800, Groupe Sebbin, lot N010306

For the attention of	Quality managers Pharmacist of Health Centre Surgeons using Groupe Sebbin products
Device type	Closed system for the harvesting and rapid treatment of autologous fat tissue for reinjection back into the patient
Commercial name	FatWasher 800
Primary clinical purpose	The Fat Washer 800 is a device allowing to perform a lipofilling operation by transferring adipose tissue from an area rich in adipose tissue to another area of the body of the same subject. Indications: The Fat Washer 800 is intended for subjects who need to receive a lipofilling treatment (liposuction of adipose cells in one site and injection of these treated cells in another site on the same subject). It is used in aesthetic and reconstructive surgery for lipo-modelling and to promote healing processes but also for research laboratories that perform stem cell cultures.
Device model	Reference LS 08 001
Affected batch	N010306
Software / associated devices	NA
Description of the product problem	After receipt of complaints and internal investigation on products on the warehouse, it appears that some devices may present failure and lack of integrity and leak.
Hazard giving rise to the FSCA	The risks identified are <ul style="list-style-type: none"> - To get a defective device and not be able to manage the procedure - To process with a defective device, lose the sterility of closure system and expose the adipose tissue to operation room environment.
Probability of problem arising	On 10 samples of this batch taken from the warehouse, 2 present a leakage.
Predicted risk to patient/users	If the healthcare centre / surgeons do not have any other system, the surgery could be cancelled whereas the patient is already anesthetized. In extremely rare case, the patient may suffer from infection.

<p>Action to be taken by distributors</p>	<p>1-Identify the device and the batch number Stop any delivery of Fat Washer 800 batch N010306 despite order <i>Please send back the Distributor Reply Form</i></p> <p>2-Put in quarantine the devices</p> <p>3-Identify the customers who received this batch devices.</p> <p>4-Inform the customers and send them the FSN as soon as possible and no later than the 27th of October. <i>Please send back the Customer Reply Form</i></p> <p>5-Organize the return of the Fat Washer 800 batch N010306 from the customer pharmacy and deposit. Organize with the manufacturer the return of the devices to Groupe Sebbin warehouse.</p>
<p>Action to be taken by user</p>	<p>Identify the device and the batch number: Fat Washer 800 batch N010306 Put in quarantine the device Organize with the distributors the return of the device <i>Please send back the Customer Reply Form</i></p> <p>Identify the patients for whom the devices Fat Washer 800 batch N010306 were used. Contact the patient if no follow up was done, to ensure the post-operative period runs well</p>
<p>Timeline</p>	<p>The action should be completed as soon as possible. The information to the user should not exceed 27th of October 2023.</p>
<p>Manufacturer information</p>	<p>Groupe Sebbin, 39 Parc d'Activité des Quatre Vents, 95651 Cergy Pontoise, France Tel : +33 1 34 42 13 28, Email : vigilance@sebbin.com</p>
<p>The Competent (Regulatory) Authority of your country has been informed about this communication to customers</p>	<p>First information is transmitted to French National Authority (ANSM) and Notified Body mdc. Once the acknowledgments are received, the FSCA is transmitted to each NCA where the products were sent.</p>

We apologise for any inconvenience and disruption this situation may cause to your organisation and your activities.

We would like to thank you for your involvement and for the work required to manage this recall.


Quality and Regulatory Affairs Director

Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN 2023-10-001
FSN Date*	19 October 2023
Product/ Device name*	Fat Washer 800
Product Code(s)	LS 08 001
Batch/Serial Number (s)	N010306

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	vigilance@sebbin.com
Distributor/Importer Helpline	+33 1 34 42 13 28
Postal Address	17 rue des Oziers 95310 Saint Ouen l'Aumône France
Web Portal	www.sebbin.com
Deadline for returning the Distributor/Importer reply form*	27 October 2023

4. Distributors/Importers (Tick all that apply)		
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
<input type="checkbox"/>	I have identified customers that received or may have received this device	
<input type="checkbox"/>	I have attached customer list	
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication:
<input type="checkbox"/>	I have received confirmation of reply from all identified customers	

FSN Ref: FSN 2023-10-001 EN

FSCA Ref: RA-EX-23-10-001

<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form)
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN 2023-10-001
FSN Date*	19 October 2023
Product/ Device name*	Fat Washer 800
Product Code(s)	LS 08 001
Batch/Serial Number (s)	N010306

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation			
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A	
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A	
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A	
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:
		Date Returned(DD/MM/YY):	
		N/A	Comments:
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
<input type="checkbox"/>	Other Action (Define):		
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A	

FSN Ref: FSN 2023-10-001 EN

FSCA Ref: RA-EX-23-10-001

<input type="checkbox"/>	I have a query please contact me	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	vigilance@sebbin.com
Customer Helpline	+33 1 34 42 13 28
Postal Address	17 rue des Oziers 95310 Saint Ouen l'Aumone France
Web Portal	www.sebbin.com
Deadline for returning the customer reply form*	3 November 2023

*Mandatory fields are marked with **

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.