SEFFILINE Srl
Via delle Lame,98
40122 Bologna (BO)
Italy
Phone: +39 051 6494945
CF e PI: 03743721205

FSN Rif: FSN01-23

FSCA Rif: FSCA01-23

Date: 08.08.2023

Voluntary Urgent Field Safety Notice (UNSF)
Medical device recall

To the attention of owners of medical devices of Seffiline S.r.l. relating to the following products / batch numbers:

	Name	Lots
1.	**SEFFIHAIR 3.1**	**2302L1**
2.	**SEFFICARE 3.1**	**2303L2**
3.	**SEFFIGYN 3.1**	**2303L3**
4.	**SEFFILLER 3.1**	**2303L4**

Dear Customer,

The purpose of this communication is to inform you of an urgent voluntary safety notice regarding Seffiline devices relating to the aforementioned lot numbers, due to the incorrect inclusion in the kits of luer-lock connectors different from the specifications defined in the configuration of the product marked CE 0425, or transfers for luerlock syringes supplied by a supplier other than the one qualified by Seffiline S.r.l..
If you have received this letter, it means that you have purchased a Seffiline S.r.l. device belonging to one of the lots involved and for this reason we ask you to pay attention to this notice and follow the instructions below.

We remain at your disposal for further information.

Seffiline S.r.l.

SEFFILINE Srl
Via delle Lame,98
40122 Bologna (BO)
Italy
Phone: +39 051 6494945
CF e PI: 03743721205

Voluntary Urgent Field Safety Notice (UNSF)
SEFFIHAIR 3.1- SEFFICARE 3.1- SEFFIGYN 3.1- SEFFILLER 3.1
Associated risks

	1. Information about the devices involved*
1.	**1. Device Type***
	The Seffiline Line (SEFFIHAIR 3.1 - SEFFICARE 3.1 - SEFFIGYN 3.1 - SEFFILLER 3.1) is designed for the doctor who wants to perform autologous transplantation of adipose tissue tissue and volume restoration. The devices of the Seffiline line do not require any other device for harvesting, preparation and grafting. Thanks to a guide, they allow in complete safety the guided pick-up, simple and standardized. The tissue obtained from the device does not require manipulation, but is prepared with a closed system that preserves the sterile environment.
1.	**2. Commercial name**
	SEFFIHAIR 3.1 - SEFFICARE 3.1 - SEFFIGYN 3.1 - SEFFILLER 3.1
1.	**3. Unique Device Identifier (UDI-DI)**
	Not applicable because device in class IIa CE marked according to Directive 93/42 and subsequent amendments.
1.	**4. Primary clinical purpose of the device***
	The main clinical applications of the device are: • Volume recovery • Autologous grafting of adipose tissues Numerous studies proved that subcutaneous adipose tissue is composed of fat cells and stromal tissue (SVF) containing mesenchymal cells and, in particular, of adipose derived stem cells (ADSCs). The treatment involves the grafting of the tissue collected and prepared with Seffiline devices in the same patient (autologous graft) in order to obtain a better trophism of the integumentary tissues and the restoration of volumes.
1.	**5. Catalogue Numbers***
	SEFFIHAIR – SEFFICARE – SEFFIGYN – SEFFIGYN.
1.	**6. Software version**
	Not applicable
1.	**7. Serial numbers or Lots involved**
	Lots: SEFFIHAIR 3.1: 2302L1; SEFFICARE 3.1: 2303L2; SEFFIGYN 3.1: 2303L3 – SEFFIGYN 3.1: 2303L4.
1.	**8. Associated devices**
	None

SEFFILINE Srl
Via delle Lame,98
40122 Bologna (BO)
Italy
Phone: +39 051 6494945
CF e PI: 03743721205

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	**1. Description of the product problem***
	During the assembly of the kits, two transfers for luerlock syringes supplied by a supplier other than the one qualified by Seffiline S.r.l. were mistakenly inserted. Seffiline is publishing this Urgent Safety Notice to warn Distributors and Professional Users (Medical) that in the devices:lots involved (SEFFIHAIR 3.1: 2302L1; SEFFICARE 3.1: 2303L2; SEFFIGYN 3.1: 2303L3 – SEFFIGYN 3.1: 2303L4) there are transfers for luerlock syringes similar in form and function to those qualified by the manufacturer, which, however, have not been subject to conformity assessment by the company.
2.	**2. Hazard giving rise to the FSCA***
	Possible breakage/cracking of the luerlock syringe transfers during tissue transfer from the 10ml VacLok® syringe to the 10ml settling syringe by the professional user (Doctor), with possible dispersion of the patient's biological material.
2.	**3. Probability of problem arising**
	Users who use Seffiline products with the lot numbers involved (SEFFIHAIR 3.1: 2302L1; SEFFICARE 3.1: 2303L2; SEFFIGYN 3.1: 2303L3 – SEFFIGYN 3.1: 2303L4) may notice cracking and/or breaking luerlock syringe transfers.
	4. Predicted risk to patient/users
2.	Cracking or breaking luerlock syringe transfers results in biological material leaking. This event does not entail danger either for the user or for the patient because the user during the fluidization operation, must be equipped with sterile gloves and PPE required for the handling of biological material. With regard to the patient, the only drawback is related to the possible impossibility of completing the grafting procedure by the doctor.
2.	**5. Further information to help characterise the problem**
	None
2.	**6. Background on Issue**
	It has been reported to us that a doctor, while using the Seffiller Kit Lot 2303L4, expiring 31/01/26, found the rupture of the luerlock syringe connection during the tissue transfer phase from the 10ml VacLok® syringe to the 10ml settling syringe.
2.	**7. Other information relevant to FSCA**
	Nothing relevant to add

SEFFILINE Srl
Via delle Lame,98
40122 Bologna (BO)
Italy
Phone: +39 051 6494945
CF e PI: 03743721205

3. Type of Action to mitigate the risk*

1. Action to be taken by the User*

☒ Identify Device ☐ Quarantine Device ☐ Return Device ☒ Destroy Device

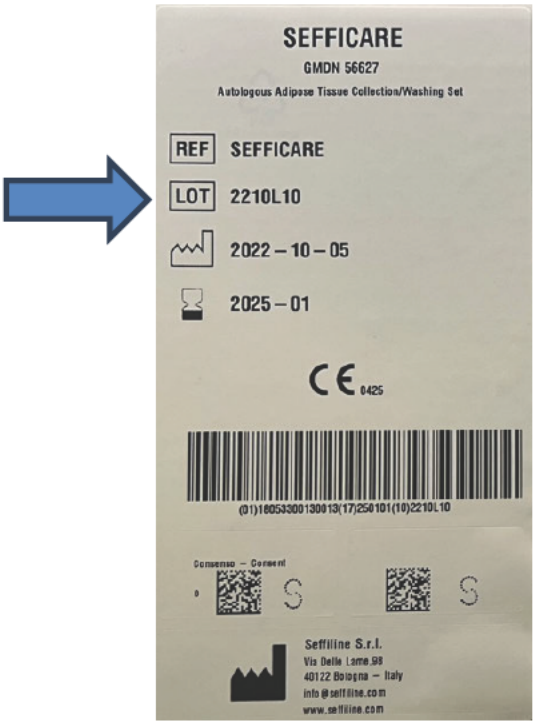
☐ On-site device modification / inspection

☐ Follow patient management recommendations

☐ Take note of amendment / reinforcement of Instructions For Use (IFU)

☐ Other ☐ None

Checking the lot number of the device
You can check the lot number on the device label:



SEFFILINE Srl
Via delle Lame,98
40122 Bologna (BO)
Italy
Phone: +39 051 6494945
CF e PI: 03743721205

3.	**2. Is the customer's response required?*** (If so, please refer to the attachment specifying the deadline to be met for the return)	Yes. The Distributor/Customer must respond by filling out the attached form by 30/09/23
3.	**3. Action being taken by Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3.	**4.** Is the FSN required to be communicated to the patient /lay user?	N/A.

	4. General Information*	
4.	1. FSN Type*	New.
4.	2. Further advice or information already expected in follow-up FSN? *	No.
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Seffiline S.r.l.
	b. Address	Via Delle Lame, 98 – 40122 Bologna (IT)
	c. Website address	www.seffiline.com
4.	4. The competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. Name/Signature	[redacted] [redacted] Sig [redacted]

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback

SEFFILINE Srl
Via delle Lame,98
40122 Bologna (BO)
Italy
Phone: +39 051 6494945
CF e PI: 03743721205

ON-SITE SECURITY NOTICE
DISTRIBUTOR CORRECTIVE ACTION RESPONSE FORM

Please read this form together with the FSN 01-23 and return it, completed in its entirety and signed, as soon as possible and in any case no later than September 30, 2023 to both of the following emails:

Quality Management cbrandoli@seffiline.com
Customer Service info@seffiline.com

Device recipient:

Organization Name	
Recipient's address:	
Contact name	
Phone number	
Email	

The following products have been distributed to our facility:

Invoice no.	Sales order number	Product code/ REF. n.	LOT NUMBER	Quantity delivered	Serial

Distributors (select all relevant answers and detail, where appropriate)

SEFFILINE Srl
Via delle Lame,98
40122 Bologna (BO)
Italy
Phone: +39 051 6494945
CF e PI: 03743721205

☐	I confirm that I have received, read and understood the field safety notice.	
☐	I checked the stock, quarantined and disposed of the affected stocks	Add details to Table 1
☐	I have identified customers who have received, for certain or probably, the product in question.	
☐	I have informed customers of this field safety notice Identified.	Sending date:
☐	I have received a confirmation response from all identified customers.	Attached are the answers.
☐	I attach Declaration of destruction of medical devices	Attached, the documents
☐	Neither I nor my customers have in stock the product covered by this notice as those received have ALL been previously used without any problem	

Table 1. Quarantined stocks: Record the quantity for each LOT disposed of.

LOT NUMBER	Units in stock

FORM completed and returned by:	
Name and surname (IN BLOCK LETTERS):	
Position:	
Signature	
Date (dd/mm/yyyy):	

It is important that your organization takes the actions detailed in the field safety notice and confirms that it has received the field safety alert. It is necessary to provide an answer because this allows us to monitor the progress of corrective actions.

Your organization remains responsible for criminal and civil liability in the event of false statements regarding this Security Notice.

SEFFILINE Srl
Via delle Lame,98
40122 Bologna (BO)
Italy
Phone: +39 051 6494945
CF e PI: 03743721205

ON-SITE SECURITY NOTICE CUSTOMER CORRECTIVE ACTION RESPONSE FORM

Please read this form together with the FSN 01-23 and return it, completed in its entirety and signed, as soon as possible and in any case no later than September 30, 2023 to both of the following emails and to the undersigned distributor.

Quality Management cbrandoli@seffiline.com
Customer Service info@seffiline.com

Device recipient:

Addressee	
Recipient's address:	
Contact name	
Phone number	
Email	

The following products were delivered to you:

Invoice no.	Sales order number	Product code/ REF. n.	LOT NUMBER	Quantity delivered	Serial

SEFFILINE Srl
Via delle Lame,98
40122 Bologna (BO)
Italy
Phone: +39 051 6494945
CF e PI: 03743721205

Customer action taken (Select all relevant responses)		
☐	I confirm that I have received the field safety alert and have read and understood it.	
☐	I have taken all the actions required by the field safety advisory.	
☐	I checked the stock, quarantined and disposed of the affected stocks	Add details to Table 1
☐	I attach Declaration of destruction of medical devices	Attached, the documents
☐	I do not have devices of the affected LOTS to return as those received have ALL been previously used without any problem	

Table 1. Quarantined stocks: Record the quantity for each LOT disposed of.

LOT NUMBER	Units in stock

FORM completed and returned by:	
Name and surname (IN BLOCK LETTERS):	
Position:	
Signature:	
Date (dd/mm/yyyy):	

It is important that your organization takes the actions detailed in the field safety notice and confirms that it has received the field safety alert. It is necessary to provide an answer because this allows us to monitor the progress of corrective actions.

Your organization remains responsible for criminal and civil liability in the event of false statements regarding this Security Notice.

DECLARATION OF DESTRUCTION OF MEDICAL DEVICES

The undersigned _____, born in _____ on _____, as a doctor / owner / legal representative of the company _____, based in _____, street _____,

DECLARE

Following the FSN 01-23 security notice of 8 August 2023 by Seffiline S.r.l. to have proceeded to destroy the following devices by opening them, thus making them non-sterile and no longer usable.

I also provided for their correct disposal according to current regulations.

Device	Lot	Serial numbers

Attach picturesDatw of open devices

Date_____

In faith _____