

27 May 2020

Urgent Field Safety Notice

Groupe Sebbin Silicone implants, Skin Expanders

For attention of : Pharmacist of Health Centre
 Surgeons using Groupe Sebbin products

Urgent Field Safety Notice

Groupe Sebbin Silicone implants, Skin Expanders

Risk addressed by FSN: that the User cannot have access to IFU

1 – Information on Affected Devices

1.1: Device types: Silicone Implants and Tissue Expanders

1.2: Commercial name

The detailed list of reference and commercial name is presented hereafter. All the existing volume models are involved.

Reference	Name of product
LS 01 XX	Testicular implant Smooth, Naturgel™ 1 cohesive
LS 02 XX	Facial implant, Silicon elastomer
LS 03 XX	Calf Implant with insert pocket, Smooth, Naturgel™ 1.5 cohesive
LS 04 XX	Gluteus Implant, Round, Smooth, ExtrafirmGel ultra cohésive
LS 05 XX	Anatomical gluteus Implant, Smooth, ExtrafirmGel ultra cohésive
LS 06 XX	Gluteus Implant, Biconvex, Smooth, ExtrafirmGel ultra cohésive
LS 07 XX	Nasal conformer,
LS 80 XX	Skin Expander, Crescent, Smooth with base
LSRS 80 XX	Skin Expander, Crescent, Smooth without base, valve linked
LS 82 XX	Skin Expander, Rectangular, Smooth with base
LSR 82 XX	Skin Expander, Rectangular, Smooth without base, tube middle
LSR 82C XX	Skin Expander, Rectangular, Smooth without base, tube on the side
LSRS 82 XX	Skin Expander, Rectangular, Smooth without base, valve linked
LS 62 XX	Skin Expander, Rectangular, rounded edges, Smooth with base
LSR 62 XX	Skin Expander, Rectangular, rounded edges, Smooth without base
LSR 62C XX	Skin Expander, Rectangular, rounded edges, Smooth without base, tube side
LSRS 62 XX	Skin Expander, Rectangular, rounded edges, Smooth without base, valve linked
LS 89 SF XX	Skin Expander, Anatomical Short, Smooth with base
LS 89 TF XX	Skin Expander, Anatomical Tall, Smooth with base
LS 83 XX	Skin Expander, Round, Smooth with base
LSR 83 XX	Skin Expander, Round without base
LS 88	Skin Expander, Kidney shape, Smooth with base
LSR 88	Skin Expander, Kidney shape, Smooth without base
LS 81 XX	Skin Expander, Cylindrical, Smooth with base

These products are packaged in the new branded box from Lot 20004.



1. 3: Unique Device Identifier

1. 4: Primary clinical purpose of device

The silicone implants are designed to the plastic, reconstructive and aesthetic surgery. They are designed to the surgeons conducting surgery in operating theatres in compliance with applicable standards.

Skin expander are medical devices intended for increasing tissue surface area to allow a permanent implantation and/or to carry out a particular local plastic procedure.

I. 5: Device model / catalogue /part number

All catalogue number detailed in Appendix 1

1. 6: Software version

N.A.

1.7: Affected serial or lot number range

From lot number 20004.

1.8: Associated devices

N.A.

2 – Reason for Field Safety Corrective Action

2.1: Description of the product problem

From lot 20004, the IFU is proposed according to electronical form with all information on the product box to have access to the website and collect the IFU. Nevertheless, the Notified Body notified that it has not yet made a decision on Groupe Sebbin proposal whereas it must to according to Regulation 207/2012.

There is no problem to the product on its own which is not impacted.

2.2: Hazard giving rise to the FSCA

The hazard is that adequacy to electronic IFU has not been verified by the Notified Body as requested by regulation 207/2012, consequently the surgeon could not have access to the IFU.

There is no risk for the patient.

There is no residual risk if the FSN action is taken: The surgeon will receive IFU with the product box.

If the action is not taken on time: there are all details and information to have an IFU in all box products.

2.3 Probability of problem arising

Probability that the surgeon cannot have access to the IFU is minimal: all the information are given to have IFU from the website or from the company directly.

2.4 Predicted risk to patient/users

The IFU being not used when the product box is opened (because of the surgery), there is no risk for the patient. The surgeon should know the IFU before surgery. The User has all information to have access to the IFU.

2.5 Further information to help characterise the problem

N.A.

2.6 Background on Issue

The request of this FSCA was done by the Notified Body who did not formally answer to the notification of the manufacturer.

No issue was reported by any surgeon on the access to the website to get the eIFU.

2.7 Other information relevant to FSCA

N.A.

3- Type of Action to mitigate the risk

3.1: 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

If the User cannot get the paper IFU, he has to contact his distributor who will send it as soon as possible by any tool.

The distributor will send separately IFU with the eIFU box products. The IFU is not put in the box to not removed the plastic film which protects the product (to be sure that the sterile product is not damaged and the patient card and patient information labels are not lost).

Since the 20th of May, all products leaving Groupe Sebbin facility have a paper IFU included in the box.

3.2: By when should the action be completed

The User having in stock the “eIFU boxes” can request IFU as long as necessary.

The action to give the notice will last until there is a need.

It is not time critical.

3.3: The FSN required to be communicated to the patient?

No need to be communicated to the patient and there is no lay user of these products.

3.4. Is customer Reply required?

No, the risk is not considered as major. A proof of reading of the information will be collected.

3.5. Action being taken by manufacturer

- Product Removal On-site device modification/inspection
- Software upgrade IFU or labelling change
- Other None

The manufacturer has informed each distributor having received the new branded box, from lot 20004.

The manufacturer has requested the distributor to inform his user and provide an IFU each time an eIFU box is sent.

The paper IFU is re-inserted in the blue branded package, with a blue sticker identifying them from the other ones since the 20th of May.

3.6: By when should the action be completed?

The action of sending separate IFU will last until distributor has “eIFU” product boxes.

It is not time critical.

3.7: Is the FSN required to be communicated to the patient/ lay user?

No: The patient does not need to be informed.

Surgeons are the one using the medical device.

3.8: If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?

N.A

4- General Information

4.1: FSN Type

New

4.2 For updated FSN, reference number and date of previous FSN

N.A.

4.3 For Updated FSN, key new information as follows:

N.A.

4.4 Further advice or information already expected in follow-up FSN? *

No

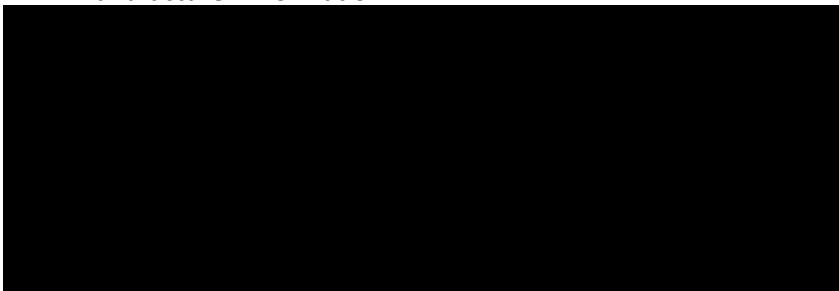
4.5 If follow-up FSN expected, what is the further advice expected to relate to:

N.A.

4.6: Anticipated timescale for follow-up FSN

N.A.

4.7: Manufacturer information



4.8: The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Each National Competent authority where product box with eIFU information were sent has been informed by the same FSCA.

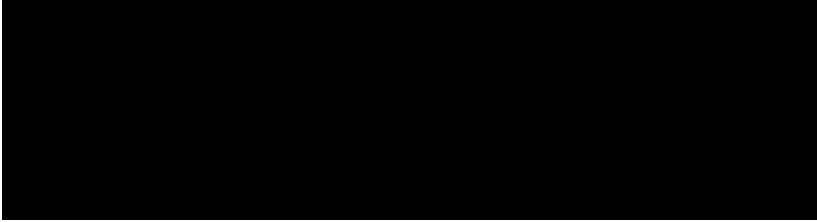
4.9: List of Appendices

[Annex 1 with all models of products](#)

FSN Ref: [FSN 20-05-002](#)

FSN Ref: [FSCA 20-05-002](#)

4.10 Name / Signature



APPENDIX 1: Device models

Silicone implants

Product name	Ref	Ref	Product name	Ref	Ref
Testicular implant Smooth Naturgel™ 1 cohesif	LS 01 025	LS 01 050	Calf Implant with insert pocket, Smooth Naturgel™ 1.5 cohesive	LS 03 120	LS 03 185
	LS 01 034	LS 01 053		LS 03 175	LS 03 190
	LS 01 040			LS 03 180	LS 03 195
Gluteus Implant, Round, Smooth ExtrafirmGel ultra cohésive	LS 04 200	LS 04 330	Anatomical gluteus Implant, , Smooth ExtrafirmGel ultra cohésive	LS 05 185	
	LS 04 235	LS 04 360		LS 05 260	
	LS 04 270	LS 04 400		LS 05 335	
	LS 04 300	LS 04 440		LS 05 400	
Gluteus Implant, Biconvex, Smooth Content: ExtrafirmGel ultra cohésive	LS 06 370				
	LS 06 410				
	LS 06 480				
	LS 06 530				
Chin implant Silicon elastomer	LS 02 101		Extended Chin implant Silicon elastomer	LS 02 111	
	LS 02 102			LS 02 112	
	LS 02 103			LS 02 113	
Round malar implant Silicon elastomer	LS 02 221		Anatomical malar implant right Silicon elastomer	LS 02D 231	LS 02D 234
	LS 02 222			LS 02D 232	LS 02D 235
	LS 02 223			LS 02D 233	LS 02D 236
Anatomical malar implant left Silicon elastomer	LS 02D 231	LS 02D 234			
	LS 02D 232	LS 02D 235			
	LS 02D 233	LS 02D 236			
Nasal conformer baby major axis 5 mm minor axis 4.5 mm	LS 07 0801		Nasal conformer child major axis 8 mm minor axis 6.3 mm	LS 07 0901	
Nasal conformer baby major axis 6 mm minor axis 5 mm	LS 07 0802		Nasal conformer teenager major axis 9 mm minor axis 7 mm	LS 07 1001	
Nasal conformer baby major axis 7 mm minor axis 5.5 mm	LS 07 0803		Nasal conformer adult major axis 10 mm minor axis 7 mm	LS 07 1101	
			Firm Nasal conformer adult major axis 10 mm minor axis 7 mm	LS 07 1102	

Skin Expander

Product name	Ref	Ref	Product name	Ref	Ref
Skin Expander, Crescent Right, Smooth with base	LS 80 D 30	LS 80 D 220	Skin Expander, Crescent Left, Smooth with base	LS 80 G 30	LS 80 G 220
	LS 80 D 60	LS 80 D 400		LS 80 G 60	LS 80 G 400
	LS 80 D 120	LS 80 D 500		LS 80 G 120	LS 80 G 500
	LS 80 D 160			LS 80 G 160	
Skin Expander, Crescent Right, Smooth without base, valve linked	LSRS 80 D 30	LSRS 80 D 220	Skin Expander, Crescent Left, Smooth without base, valve linked	LSRS 80 G 30	LSRS 80 G 220
	LSRS 80 D 60	LSRS 80 D 400		LSRS 80 G 60	LSRS 80 G 400
	LSRS 80 D 120	LSRS 80 D 500		LSRS 80 G 120	LSRS 80 G 500
	LSRS 80 D 160			LSRS 80 G 160	
Skin Expander, Rectangular, rounded edges, Smooth with base	LS 62 090	LS 62 480	Skin Expander, Rectangular, rounded edges, Smooth without base	LSR 62 090	LSR 62 480
	LS 62 145	LS 62 540		LSR 62 145	LSR 62 540
	LS 62 160	LS 62 670		LSR 62 160	LSR 62 670
	LS 62 240	LS 62 1000		LSR 62 240	LSR 62 1000
	LS 62 270	LS 62 1300		LSR 62 270	LSR 62 1300
	LS 62 340	LS 62 2000		LSR 62 340	LSR 62 2000
Skin Expander, Anatomical Short, Smooth with base	LS 89SF 240	LS 89SF 405	Skin Expander, Anatomical Short, Smooth with base	LS 89TF 285	LS 89TF 460
	LS 89SF 275	LS 89SF 450		LS 89TF 330	LS 89TF 520
	LS 89SF 320	LS 89SF 500		LS 89TF 370	LS 89TF 590
	LS 89SF 360			LS 89TF 415	
Skin Expander, Round, Smooth with base	LS 83 030	LS 83 350	Skin Expander, Round without base	LSR 83 030	LSR 83 350
	LS 83 050	LS 83 500		LSR 83 050	LSR 83 500
	LS 83 070	LS 83 700		LSR 83 070	LSR 83 700
	LS 83 125	LS 83 1000		LSR 83 125	LSR 83 1000
	LS 83 200	LS 83 1300		LSR 83 200	LSR 83 1300
Skin Expander, Kidney shape, Smooth with base	LS 88 120		Skin Expander, Kidney shape, Smooth without base	LSR 88 120	
	LS 88 340			LSR 88 340	
	LS 88 730			LSR 88 730	

Product name	Ref	Ref	Ref	Ref	Ref
Skin Expander, Rectangular, Smooth with base	LS 82 016	LS 82 150	LS 82 280	LS 82 620	LS 82 1500
	LS 82 045	LS 82 160	LS 82 304	LS 82 640	LS 82 2000
	LS 82 060	LS 82 180	LS 82 330	LS 82 760	
	LS 82 100	LS 82 192	LS 82 380	LS 82 950	
	LS 82 110	LS 82 240	LS 82 560	LS 82 1100	
Skin Expander, Rectangular, Smooth, without base, tube middle	LSR 82 016	LSR 82 150	LSR 82 280	LSR 82 620	LSR 82 1500
	LSR 82 045	LSR 82 160	LSR 82 304	LSR 82 640	LSR 82 2000
	LSR 82 060	LSR 82 180	LSR 82 330	LSR 82 760	
	LSR 82 100	LSR 82 192	LSR 82 380	LSR 82 950	
	LSR 82 110	LSR 82 240	LSR 82 560	LSR 82 1100	
Skin Expander, Rectangular, Smooth without base, tube on the side	LSR 82C 016	LSR 82C 150	LSR 82C 280	LSR 82C 620	LSR 82C 1500
	LSR 82C 045	LSR 82C 160	LSR 82C 304	LSR 82C 640	LSR 82C 2000
	LSR 82C 060	LSR 82C 180	LSR 82C 330	LSR 82C 760	
	LSR 82C 100	LSR 82C 192	LSR 82C 380	LSR 82C 950	
	LSR 82C 110	LSR 82C 240	LSR 82C 560	LSR 82C 1100	
Skin Expander, Rectangular, Smooth without base, valve linked	LSRS 82C 016	LSRS 82C 150	LSRS 82C 280	LSRS 82C 620	LSRS 82C 1500
	LSRS 82C 045	LSRS 82C 160	LSRS 82C 304	LSRS 82C 640	LSRS 82C 2000
	LSRS 82C 060	LSRS 82C 180	LSRS 82C 330	LSRS 82C 760	
	LSRS 82C 100	LSRS 82C 192	LSRS 82C 380	LSRS 82C 950	
	LSRS 82C 110	LSRS 82C 240	LSRS 82C 560	LSRS 82C 1100	
Skin Expander, Cylindrical, Smooth with base	LS 81 060	LS 81 220	LS 81 400	LS 81 1000	
	LS 81 125	LS 81 250	LS 81 700	LS 81 1100	
	LS 81 150	LS 81 350	LS 81 800	LS 81 1200	