

FSN Ref: [FSN 20-05-001](#)

FSN Ref: [FSCA 20-05-001](#)

27 May 2020

Urgent Field Safety Notice
Groupe Sebbin Mammary Implants

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

Urgent Field Safety Notice**Groupe Sebbin Mammary Implants****Risk addressed by FSN: that the User cannot have access to IFU****1 – Information on Affected Devices****1.1: Device types: Silicone Gel Filled Mammary Implants****1.2: Commercial name**

The detailed list of reference and commercial name is presented in Appendix 1. All the existing volume models are involved.

LS5X, LS7X, LS9X: Round mammary implant

LSMXX: Integrity round mammary implant

LSAXX: Anatomical mammary implant

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



Involved New branded package

1. 3: Unique Device Identifier

GTIN number with device model.

1. 4: Primary clinical purpose of device

The mammary 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.

1. 5: Device model / catalogue /part number

All catalogue number detailed in Appendix 2

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 electronic 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 according to Regulation 207/2012.

There is no problem to the implant 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 information 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

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

[Each National Competent authority where product boxes with eIFU information were sent has been informed by the same FSCA.](#)

4.9: List of Appendices

[Annex 1 with all products denominations](#)

[Annex 2 with all product references](#)

4.10 Name / Signature

[Ketty KICHENIN, PhD](#)

[Groupe Sebbin, Regulatory and Quality Affairs Director](#)

K. Kichenin

APPENDIX 1: List of Commercial Name

Reference (XXX = vol)	Labelling
LS 50 XXX	Round Mammary Implant, Smooth, Moderate Profile, Naturgel™ I cohesive
LS 51 XXX	Round Mammary Implant, Smooth, High Profile, Naturgel™ I cohesive
LSC 54 XXX	Round Mammary Implant, Smooth, Moderate Profile, Naturgel™ 2 high cohesive
LSC 55 XXX	Round Mammary Implant, Smooth, High Profile, Naturgel™ 2 high cohesive
LS 70 XXX	Round Mammary Implant, Semi-smooth, Moderate Profile, Naturgel™ I cohesive
LS 71 XXX	Round Mammary Implant, Semi-smooth, High Profile, Naturgel™ I cohesive
LS 74 XXX	Round Mammary Implant, Semi-smooth, Semi moderate Profile, Naturgel™ I cohesive
LSC 72 XXX	Round Mammary Implant, Semi-smooth, Moderate Profile, Naturgel™ 2 high cohesive
LSC 73 XXX	Round Mammary Implant, Semi-smooth, High Profile, Naturgel™ 2 high cohesive
LSC 76 XXX	Round Mammary Implant, Semi-smooth, Semi-Moderate Profile, Naturgel™ 2 high cohesive
LS 90 XXX	Round Mammary Implant, Micro textured, Moderate Profile, Naturgel™ I cohesive
LS 91 XXX	Round Mammary Implant, Micro textured, High Profile, Naturgel™ I cohesive
LSC 92 XXX	Round Mammary Implant, Micro textured, Moderate Profile, Naturgel™ 2 high cohesive
LSC 93 XXX	Round Mammary Implant, Micro textured, High Profile, Naturgel™ 2 high cohesive
LSMRF XXX	Mammary Implant Round Matrix, Semi smooth, Full Profile, EverlastGel
LSMRL XXX	Mammary Implant Round Matrix, Semi smooth, Low Profile, EverlastGel
LSMRM XXX	Mammary Implant Round Matrix, Semi smooth, Moderate Profile, EverlastGel
LSMRS XXX	Mammary Implant Round Matrix, Semi smooth, Semi-moderate Profile, EverlastGel
LSATF XXX	Anatomical Mammary Implant, Macro-textured, Tall height, Full projection, Naturgel™ 3 high cohesive
LSATM XXX	Anatomical Mammary Implant, Macro-textured, Tall height, Moderate projection, Naturgel™ 3 high cohesive
LSATL XXX	Anatomical Mammary Implant, Macro-textured, Tall height, Low projection, Naturgel™ 3 high cohesive
LSATS XXX	Anatomical Mammary Implant, Macro-textured, Tall height, Slim projection, Naturgel™ 3 high cohesive
LSASF XXX	Anatomical Mammary Implant, Macro-textured, Short height, Full projection, Naturgel™ 3 high cohesive
LSASM XXX	Anatomical Mammary Implant, Macro-textured, Short height, Moderate projection, Naturgel™ 3 high cohesive

LSASL XXX	Anatomical Mammary Implant, Macro-textured, Short height, Low projection, Naturgel™ 3 high cohesive
LSASS XXX	Anatomical Mammary Implant, Macro-textured, Short height, Slim projection, Naturgel™ 3 high cohesive
LSAXSF XXX	Anatomical Mammary Implant, Macro-textured, Extra Short height, Full projection, Naturgel™ 3 high cohesive
LSAXSM XXX	Anatomical Mammary Implant, Macro-textured, Extra Short height, Moderate projection, Naturgel™ 3 high cohesive
LSAXSL XXX	Anatomical Mammary Implant, Macro-textured, Extra Short height, Low projection, Naturgel™ 3 high cohesive
LSAXSS XXX	Anatomical Mammary Implant, Macro-textured, Extra Short height, Slim projection, Naturgel™ 3 high cohesive

APPENDIX 2: Device model

Reference	GTIN14	Reference	GTIN14	Reference	GTIN14
LS 50 080	03661854000232	LS 51 615	03661854000850	LSC 55 495	03661854002830
LS 50 100	03661854000249	LS 51 805	03661854000867	LSC 55 540	03661854002847
LS 50 120	03661854000256			LSC 55 590	03661854002854
LS 50 140	03661854000263	LSC 54 090	03661854002274	LSC 55 645	03661854002861
LS 50 160	03661854000270	LSC 54 110	03661854002281		
LS 50 180	03661854000287	LSC 54 130	03661854002298		
LS 50 200	03661854000294	LSC 54 155	03661854002304		
LS 50 220	03661854000300	LSC 54 175	03661854002311		
LS 50 240	03661854000317	LSC 54 200	03661854002328		
LS 50 260	03661854000324	LSC 54 220	03661854002335		
LS 50 280	03661854000331	LSC 54 240	03661854002342		
LS 50 300	03661854000348	LSC 54 265	03661854002359		
LS 50 330	03661854000355	LSC 54 285	03661854002366		
LS 50 360	03661854000362	LSC 54 310	03661854002373		
LS 50 390	03661854000379	LSC 54 330	03661854002380		
LS 50 430	03661854000386	LSC 54 365	03661854002397		
LS 50 470	03661854000393	LSC 54 395	03661854002403		
LS 50 510	03661854000409	LSC 54 430	03661854002410		
LS 50 560	03661854000416	LSC 54 475	03661854002427		
LS 50 610	03661854000423	LSC 54 520	03661854002434		
		LSC 54 560	03661854002441		
LS 51 085	03661854000669	LSC 54 615	03661854002458		
LS 51 105	03661854000676	LSC 54 670	03661854002465		
LS 51 125	03661854000683				
LS 51 145	03661854000690	LSC 55 090	03661854002670		
LS 51 165	03661854000706	LSC 55 110	03661854002687		
LS 51 185	03661854000713	LSC 55 130	03661854002694		
LS 51 205	03661854000720	LSC 55 150	03661854002700		
LS 51 225	03661854000737	LSC 55 175	03661854002717		
LS 51 245	03661854000744	LSC 55 195	03661854002724		
LS 51 265	03661854000751	LSC 55 215	03661854002731		
LS 51 285	03661854000768	LSC 55 235	03661854002748		
LS 51 305	03661854000775	LSC 55 255	03661854002755		
LS 51 335	03661854000782	LSC 55 280	03661854002762		
LS 51 365	03661854000799	LSC 55 300	03661854002779		
LS 51 395	03661854000805	LSC 55 320	03661854002786		
LS 51 435	03661854000812	LSC 55 350	03661854002793		
LS 51 475	03661854000829	LSC 55 385	03661854002809		
LS 51 515	03661854000836	LSC 55 415	03661854002816		
LS 51 565	03661854000843	LSC 55 455	03661854002823		

Reference	GTIN14	Reference	GTIN14	Reference	GTIN14
LS 70 080	03661854013096	LS 71 615	03661854014727	LSC 73 495	03661854014895
LS 70 100	03661854013102	LS 71 805	03661854016752	LSC 73 540	03661854014901
LS 70 120	03661854013119			LSC 73 590	03661854014918
LS 70 140	03661854013126	LSC 72 090	03661854013317	LSC 73 645	03661854014925
LS 70 160	03661854013133	LSC 72 110	03661854013324		
LS 70 180	03661854013140	LSC 72 130	03661854013331	LS 74 080	03661854013515
LS 70 200	03661854013157	LSC 72 155	03661854013348	LS 74 100	03661854013522
LS 70 220	03661854013164	LSC 72 175	03661854013355	LS 74 120	03661854013539
LS 70 240	03661854013171	LSC 72 200	03661854013362	LS 74 140	03661854013546
LS 70 260	03661854013188	LSC 72 220	03661854013379	LS 74 160	03661854013553
LS 70 280	03661854013195	LSC 72 240	03661854013386	LS 74 180	03661854013560
LS 70 300	03661854013201	LSC 72 265	03661854013393	LS 74 200	03661854013577
LS 70 330	03661854013218	LSC 72 285	03661854013409	LS 74 220	03661854013584
LS 70 360	03661854013225	LSC 72 310	03661854013416	LS 74 245	03661854013591
LS 70 390	03661854013232	LSC 72 330	03661854013423	LS 74 270	03661854013607
LS 70 430	03661854013249	LSC 72 365	03661854013430	LS 74 295	03661854013614
LS 70 470	03661854013256	LSC 72 395	03661854013447	LS 74 325	03661854013621
LS 70 510	03661854013263	LSC 72 430	03661854013454	LS 74 370	03661854013638
LS 70 560	03661854013270	LSC 72 475	03661854013461	LS 74 415	03661854013645
LS 70 610	03661854013287	LSC 72 520	03661854013478	LS 74 470	03661854013652
		LSC 72 560	03661854013485	LS 74 510	03661854013669
LS 71 085	03661854014536	LSC 72 615	03661854013492	LS 74 560	03661854013676
LS 71 105	03661854014543	LSC 72 670	03661854013508		
LS 71 125	03661854014550			LSC 76 080	03661854013683
LS 71 145	03661854014567	LSC 73 090	03661854014734	LSC 76 100	03661854013690
LS 71 165	03661854014574	LSC 73 110	03661854014741	LSC 76 120	03661854013706
LS 71 185	03661854014581	LSC 73 130	03661854014758	LSC 76 140	03661854013713
LS 71 205	03661854014598	LSC 73 150	03661854014765	LSC 76 160	03661854013720
LS 71 225	03661854014604	LSC 73 175	03661854014772	LSC 76 180	03661854013737
LS 71 245	03661854014611	LSC 73 195	03661854014789	LSC 76 200	03661854013744
LS 71 265	03661854014628	LSC 73 215	03661854014796	LSC 76 220	03661854013751
LS 71 285	03661854014635	LSC 73 235	03661854014802	LSC 76 245	03661854013768
LS 71 305	03661854014642	LSC 73 255	03661854014819	LSC 76 270	03661854013775
LS 71 335	03661854014659	LSC 73 280	03661854014826	LSC 76 295	03661854013782
LS 71 365	03661854014666	LSC 73 300	03661854014833	LSC 76 325	03661854013799
LS 71 395	03661854014673	LSC 73 320	03661854014840	LSC 76 370	03661854013805
LS 71 435	03661854014680	LSC 73 350	03661854014857	LSC 76 415	03661854013812
LS 71 475	03661854014697	LSC 73 385	03661854014864	LSC 76 470	03661854013829
LS 71 515	03661854014703	LSC 73 415	03661854014871	LSC 76 510	03661854013836
LS 71 565	03661854014710	LSC 73 455	03661854014888	LSC 76 560	03661854013843

Reference	GTIN14	Reference	GTIN14	Reference	GTIN14
LS 90 080	03661854000010	LS 91 615	03661854000645	LSC 93 540	03661854002649
LS 90 100	03661854000027			LSC 93 590	03661854002656
LS 90 120	03661854000034	LSC 92 090	03661854002076	LSC 93 645	03661854002663
LS 90 140	03661854000041	LSC 92 110	03661854002083		
LS 90 160	03661854000058	LSC 92 130	03661854002090		
LS 90 180	03661854000065	LSC 92 155	03661854002106		
LS 90 200	03661854000072	LSC 92 175	03661854002113		
LS 90 220	03661854000089	LSC 92 200	03661854002120		
LS 90 240	03661854000096	LSC 92 220	03661854002137		
LS 90 260	03661854000102	LSC 92 240	03661854002144		
LS 90 280	03661854000119	LSC 92 265	03661854002151		
LS 90 300	03661854000126	LSC 92 285	03661854002168		
LS 90 330	03661854000133	LSC 92 310	03661854002175		
LS 90 360	03661854000140	LSC 92 330	03661854002182		
LS 90 390	03661854000157	LSC 92 365	03661854002199		
LS 90 430	03661854000164	LSC 92 395	03661854002205		
LS 90 470	03661854000171	LSC 92 430	03661854002212		
LS 90 510	03661854000188	LSC 92 475	03661854002229		
LS 90 560	03661854000195	LSC 92 520	03661854002236		
LS 90 610	03661854000201	LSC 92 560	03661854002243		
		LSC 92 615	03661854002250		
LS 91 085	03661854000454	LSC 92 670	03661854002267		
LS 91 105	03661854000461				
LS 91 125	03661854000478	LSC 93 090	03661854002472		
LS 91 145	03661854000485	LSC 93 110	03661854002489		
LS 91 165	03661854000492	LSC 93 130	03661854002496		
LS 91 185	03661854000508	LSC 93 150	03661854002502		
LS 91 205	03661854000515	LSC 93 175	03661854002519		
LS 91 225	03661854000522	LSC 93 195	03661854002526		
LS 91 245	03661854000539	LSC 93 215	03661854002533		
LS 91 265	03661854000546	LSC 93 235	03661854002540		
LS 91 285	03661854000553	LSC 93 255	03661854002557		
LS 91 305	03661854000560	LSC 93 280	03661854002564		
LS 91 335	03661854000577	LSC 93 300	03661854002571		
LS 91 365	03661854000584	LSC 93 320	03661854002588		
LS 91 395	03661854000591	LSC 93 350	03661854002595		
LS 91 435	03661854000607	LSC 93 385	03661854002601		
LS 91 475	03661854000614	LSC 93 415	03661854002618		
LS 91 515	03661854000621	LSC 93 455	03661854002625		
LS 91 565	03661854000638	LSC 93 495	03661854002632		

Reference	GTIN14	Reference	GTIN14
LSM RL 080	03661854017322	LSM RM 240	03661854017704
LSM RL 100	03661854017339	LSM RM 275	03661854017711
LSM RL 120	03661854017346	LSM RM 310	03661854017728
LSM RL 140	03661854017353	LSM RM 345	03661854017735
LSM RL 160	03661854017360	LSM RM 380	03661854017742
LSM RL 180	03661854017377	LSM RM 415	03661854017759
LSM RL 200	03661854017384	LSM RM 450	03661854017766
LSM RL 220	03661854017391	LSM RM 500	03661854017773
LSM RL 245	03661854017407	LSM RM 550	03661854017780
LSM RL 270	03661854017414	LSM RM 240	03661854017704
LSM RL 300	03661854017421	LSM RM 275	03661854017711
LSM RL 330	03661854017438	LSM RM 310	03661854017728
LSM RL 370	03661854017445	LSM RM 345	03661854017735
LSM RL 410	03661854017452	LSM RM 380	03661854017742
LSM RL 460	03661854017469	LSM RM 415	03661854017759
LSM RL 510	03661854017476	LSM RM 450	03661854017766
LSM RL 560	03661854017483	LSM RM 500	03661854017773
		LSM RM 550	03661854017780
LSM RS 085	03661854017490	LSM RM 610	03661854017797
LSM RS 105	03661854017506	LSM RM 670	03661854017803
LSM RS 130	03661854017513		
LSM RS 170	03661854017520	LSM RF 130	03661854017810
LSM RS 190	03661854017537	LSM RF 150	03661854017827
LSM RS 210	03661854017544	LSM RF 190	03661854017834
LSM RS 235	03661854017551	LSM RF 215	03661854017841
LSM RS 270	03661854017568	LSM RF 240	03661854017858
LSM RS 300	03661854017575	LSM RF 275	03661854017865
LSM RS 330	03661854017582	LSM RF 305	03661854017872
LSM RS 360	03661854017599	LSM RF 330	03661854017889
LSM RS 390	03661854017605	LSM RF 360	03661854017896
LSM RS 450	03661854017612	LSM RF 390	03661854017902
LSM RS 490	03661854017629	LSM RF 420	03661854017919
LSM RS 530	03661854017636	LSM RF 460	03661854017926
LSM RS 600	03661854017643	LSM RF 500	03661854017933
		LSM RF 545	03661854017940
LSM RM 115	03661854017650	LSM RF 595	03661854017957
LSM RM 130	03661854017667	LSM RF 650	03661854017964
LSM RM 155	03661854017674		
LSM RM 190	03661854017681		
LSM RM 220	03661854017698		

Reference	GTIN14	Reference	GTIN14	Reference	GTIN14
LSA TS 175	03661854015663	LSA SS 150	03661854015762	LSA XSS 160	03661854015885
LSA TS 245	03661854015670	LSA SS 210	03661854015779	LSA XSS 185	03661854015892
LSA TS 270	03661854015687	LSA SS 235	03661854015786	LSA XSS 210	03661854015908
LSA TS 360	03661854015694	LSA SS 280	03661854015793	LSA XSS 290	03661854015915
		LSA SS 315	03661854015809		
LSA TL 215	03661854002878	LSA SS 405	03661854015816	LSA XSL 190	03661854015922
LSA TL 250	03661854002885			LSA XSL 215	03661854015939
LSA TL 285	03661854002892	LSA SL 185	03661854003080	LSA XSL 250	03661854015946
LSA TL 330	03661854002908	LSA SL 210	03661854003097	LSA XSL 330	03661854015953
LSA TL 375	03661854002915	LSA SL 245	03661854003103		
LSA TL 420	03661854002922	LSA SL 280	03661854003110	LSA XSM 215	03661854015960
LSA TL 475	03661854002939	LSA SL 325	03661854003127	LSA XSM 250	03661854015977
LSA TL 530	03661854015700	LSA SL 370	03661854003134	LSA XSM 295	03661854015984
LSA TL 595	03661854015717	LSA SL 415	03661854003141	LSA XSM 330	03661854015991
		LSA SL 470	03661854015823	LSA XSM 375	03661854016004
LSA TM 250	03661854002946	LSA SL 525	03661854015830	LSA XSM 430	03661854016011
LSA TM 285	03661854002953			LSA XSM 530	03661854016028
LSA TM 330	03661854002960	LSA SM 210	03661854003158		
LSA TM 375	03661854002977	LSA SM 245	03661854003165	LSA XSF 250	03661854016035
LSA TM 420	03661854002984	LSA SM 280	03661854003172	LSA XSF 285	03661854016042
LSA TM 475	03661854002991	LSA SM 325	03661854003189	LSA XSF 330	03661854016059
LSA TM 530	03661854003004	LSA SM 370	03661854003196	LSA XSF 375	03661854016066
LSA TM 595	03661854015724	LSA SM 415	03661854003202	LSA XSF 420	03661854016073
LSA TM 660	03661854015731	LSA SM 470	03661854003219	LSA XSF 475	03661854016080
		LSA SM 525	03661854015847	LSA XSF 595	03661854016097
LSA TF 290	03661854003011	LSA SM 590	03661854015854		
LSA TF 335	03661854003028				
LSA TF 380	03661854003035	LSA SF 245	03661854003226		
LSA TF 425	03661854003042	LSA SF 280	03661854003233		
LSA TF 480	03661854003059	LSA SF 325	03661854003240		
LSA TF 535	03661854003066	LSA SF 370	03661854003257		
LSA TF 600	03661854003073	LSA SF 415	03661854003264		
LSA TF 665	03661854015748	LSA SF 470	03661854003271		
		LSA SF 525	03661854003288		
		LSA SF 590	03661854015861		
		LSA SF 655	03661854015878		