

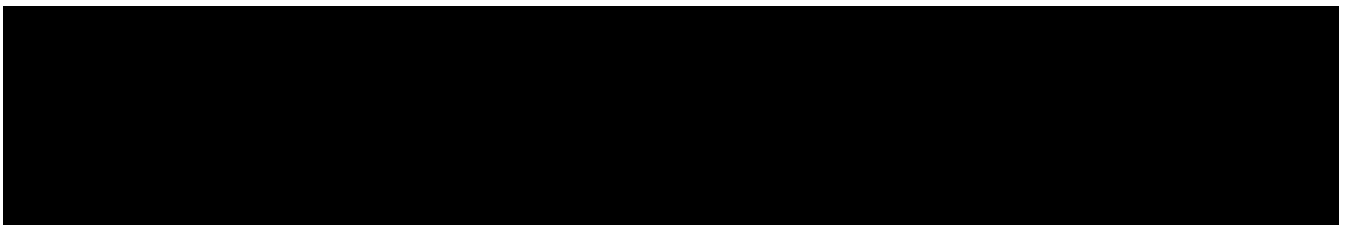
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26 May 2020

Urgent Field Safety Notice
Groupe Sebbin Sizer Implants

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



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

Mammary Sizer , ref GAB XXX

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

**1. 3: Unique Device Identifier**

Not defined.

1. 4: Primary clinical purpose of device

Inflatable as silicone gel prefilled mammary Sizers medical devices are ancillary devices for determining the volume and profile of the final gel prefilled mammary implant.

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 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 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 in his medical office. 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 on the website.

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.

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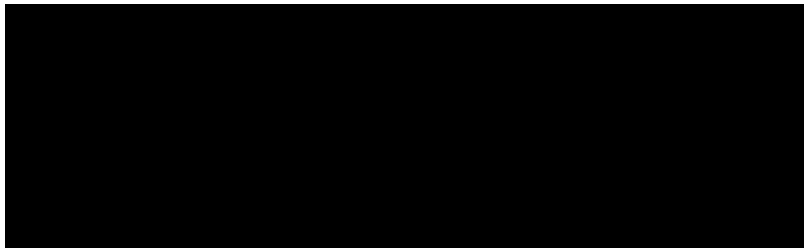
4.8: The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

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

4.9: List of Appendix

[Appendix 1 with all name and products models.](#)

4.10 Name / Signature



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APPENDIX 1: Device models

Product name	Ref	Ref	Ref	Ref
Mammary sizer prefilled, smooth, semi Moderate Profile, cohesive silicone gel	GAB 33 080	GAB 33 180	GAB 33 295	GAB 33 510
	GAB 33 100	GAB 33 200	GAB 33 3 25	GAB 33 560
	GAB 33 120	GAB 33 220	GAB 33 370	
	GAB 33 140	GAB 33 245	GAB 33 415	
	GAB 33 160	GAB 33 270	GAB 33 470	
Mammary sizer prefilled, smooth, Moderate Profile, cohesive silicone gel	GAB 35 080	GAB 35 180	GAB 35 280	GAB 35 430
	GAB 35 100	GAB 35 200	GAB 35 300	GAB 35 470
	GAB 35 120	GAB 35 220	GAB 35 330	GAB 35 510
	GAB 35 140	GAB 35 240	GAB 35 360	GAB 35 560
	GAB 35 160	GAB 35 260	GAB 35 390	GAB 35 610
Mammary sizer prefilled, smooth, High Profile, cohesive silicone gel	GAB 36 085	GAB 36 185	GAB 36 285	GAB 36 435
	GAB 36 105	GAB 36 205	GAB 36 305	GAB 36 475
	GAB 36 125	GAB 36 225	GAB 36 335	GAB 36 515
	GAB 36 145	GAB 36 245	GAB 36 365	GAB 36 565
	GAB 36 165	GAB 36 265	GAB 36 395	GAB 36 615
Mammary sizer prefilled, smooth, semi Moderate Profile, high cohesive silicone gel	GAB 30 080	GAB 30 180	GAB 30 295	GAB 30 510
	GAB 30 100	GAB 30 200	GAB 30 325	GAB 30 560
	GAB 30 120	GAB 30 220	GAB 30 370	
	GAB 30 140	GAB 30 245	GAB 30 415	
	GAB 30 160	GAB 30 270	GAB 30 470	
Mammary sizer prefilled, smooth, Moderate Profile, high cohesive silicone gel	GAB 31 090	GAB 31 200	GAB 31 310	GAB 31 475
	GAB 31 110	GAB 31 220	GAB 31 330	GAB 31 520
	GAB 31 130	GAB 31 240	GAB 31 365	GAB 31 560
	GAB 31 155	GAB 31 265	GAB 31 395	GAB 31 615
	GAB 31 175	GAB 31 285	GAB 31 430	GAB 31 670
Mammary sizer prefilled, smooth, High Profile Content: high cohesive silicone gel	GAB 32 090	GAB 32 195	GAB 32 300	GAB 32 455
	GAB 32 110	GAB 32 215	GAB 32 320	GAB 32 495
	GAB 32 130	GAB 32 235	GAB 32 350	GAB 32 540
	GAB 32 150	GAB 32 255	GAB 32 385	GAB 32 590
	GAB 32 175	GAB 32 280	GAB 32 415	GAB 32 645
Mammary sizer Round, smooth, Low Profile, high cohesive silicone gel	GAB RL 080	GAB RL 180	GAB RL 300	GAB RL 510
	GAB RL 100	GAB RL 200	GAB RL 330	GAB RL 560
	GAB RL 120	GAB RL 220	GAB RL 370	
	GAB RL 140	GAB RL 245	GAB RL 410	
	GAB RL 160	GAB RL 270	GAB RL 460	
Mammary sizer Round, smooth, Semi Moderate Profile, high cohesive silicone gel	GAB RS 085	GAB RS 210	GAB RS 360	GAB RS 600
	GAB RS 105	GAB RS 235	GAB RS 390	
	GAB RS 130	GAB RS 270	GAB RS 450	
	GAB RS 170	GAB RS 300	GAB RS 490	
	GAB RS 190	GAB RS 330	GAB RS 530	
Mammary sizer Round, smooth, Moderate Profile, high cohesive silicone gel	GAB RM 115	GAB RM 240	GAB RM 415	GAB RM 670
	GAB RM 130	GAB RM 275	GAB RM 450	
	GAB RM 155	GAB RM 310	GAB RM 500	
	GAB RM 190	GAB RM 345	GAB RM 550	

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Product name	Ref	Ref	Ref	Ref
	GAB RM 220	GAB RM 380	GAB RM 610	
Mammary sizer Round, smooth, Full Profile, high cohesive silicone gel	GAB RF 130	GAB RF 275	GAB RF 420	GAB RF 650
	GAB RF 150	GAB RF 305	GAB RF 460	
	GAB RF 190	GAB RF 330	GAB RF 500	
	GAB RF 215	GAB RF 360	GAB RF 545	
	GAB RF 240	GAB RF 390	GAB RF 595	
Anatomical Mammary Sizer, Smooth, Tall height, Slim projection High cohesive silicone gel	GAB TS 175			
	GAB TS 245			
	GAB TS 270			
	GAB TS 360			
Anatomical Mammary Sizer, Smooth, Tall height, Low projection High cohesive silicone gel	GAB TL 215	GAB TL 375	GAB TL 595	
	GAB TL 250	GAB TL 420		
	GAB TL 285	GAB TL 475		
	GAB TL 330	GAB TL 530		
Anatomical Mammary Sizer, Smooth, Tall height, Moderate projection High cohesive silicone gel	GAB TM 250	GAB TM 420	GAB TM 660	
	GAB TM 285	GAB TM 475		
	GAB TM 330	GAB TM 530		
	GAB TM 375	GAB TM 595		
Anatomical Mammary Sizer, Smooth, Tall height, Full projection High cohesive silicone gel	GAB TF 425	GAB TF 665		
	GAB TF 480			
	GAB TF 535			
	GAB TF 600			
Anatomical Mammary Sizer, Smooth, Short height, Slim projection High cohesive silicone gel	GAB SS 150	GAB SS 315		
	GAB SS 210	GAB SS 405		
	GAB SS 235			
	GAB SS 280			
Anatomical Mammary Sizer, Smooth, Short height, Low projection High cohesive silicone gel	GAB SL 185	GAB SL 325	GAB SL 525	
	GAB SL 210	GAB SL 370		
	GAB SL 245	GAB SL 415		
	GAB SL 280	GAB SL 470		
Anatomical Mammary Sizer, Smooth, Short height, Moderate projection High cohesive silicone gel	GAB SM 210	GAB SM 370	GAB SM 590	
	GAB SM 245	GAB SM 415		
	GAB SM 280	GAB SM 470		
	GAB SM 325	GAB SM 525		
Anatomical Mammary Sizer, Smooth, Short height, Full projection High cohesive silicone gel	GAB SF 245	GAB SF 415	GAB SF 655	
	GAB SF 280	GAB SF 470		
	GAB SF 325	GAB SF 525		
	GAB SF 370	GAB SF 590		
	GAB XSS 160			
	GAB XSS 185			

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Product name	Ref	Ref	Ref	Ref
Anatomical Mammary Sizer, Smooth, Extra Short height, Slim projection High cohesive silicone gel	GAB XSS 210			
	GAB XSS 290			
Anatomical Mammary Sizer, Smooth, Extra Short height, Low projection Content: High cohesive silicone gel	GAB XSL 190			
	GAB XSL 215			
	GAB XSL 250			
	GAB XSL 330			
Anatomical Mammary Sizer, Smooth, Extra Short height, Moderate projection High cohesive silicone gel	GAB XSM 215	GAB XSM 375		
	GAB XSM 250	GAB XSM 430		
	GAB XSM 295	GAB XSM 530		
	GAB XSM 330			
Anatomical Mammary Sizer, Smooth, Extra Short height, Full projection Content: High cohesive silicone gel	GAB XSF 250	GAB XSF 475		
	GAB XSF 285	GAB XSF 595		
	GAB XSF 330			
	GAB XSF 375			
	GAB XSF 420			
Mammary sizer inflatable, smooth, Moderate Profile	LS 38 080	LS 38 180	LS 38 280	LS 38 430
	LS 38 100	LS 38 200	LS 38 300	LS 38 470
	LS 38 120	LS 38 220	LS 38 330	LS 38 510
	LS 38 140	LS 38 240	LS 38 360	LS 38 560
	LS 38 160	LS 38 260	LS 38 390	LS 38 610
Mammary sizer inflatable, smooth, High Profile	LS 39 085	LS 39 185	LS 39 285	LS 39 435
	LS 39 105	LS 39 205	LS 39 305	LS 39 475
	LS 39 125	LS 39 225	LS 39 335	LS 39 515
	LS 39 145	LS 39 245	LS 39 365	LS 39 565
	LS 39 165	LS 39 265	LS 39 395	LS 39 615