

Customer address

Genay, **date**

URGENT : FIELD SAFET NOTICE

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (if appropriate)

Our Ref.: EN 020/F/ ACAP-20-0035

Dear Customer,

Details on affected devices

Groupe Lépine has decided to voluntarily recall all of the lots listed below from the CSB CAPUCHON product range

The CSB CAPUCHON range is used in combination with orthopaedic pins for osteosynthesis.

- CSB CAPUCHON implants are lockable and have the function of protecting soft tissues in contact with pin cuts (barbs).
- These implants consist of a plug pre-assembled on a breakable screw, which breaks at the end of locking on the pin.

Description of the problem

Groupe Lepine has identified a potential (random) machining defect in certain units which could result in difficulty in locking the cap on the pin. The defect being random, all the units belonging to the incriminated lots do not necessarily have this defect. If a defective cap is used, the patient impact is considered to be limited; indeed, the defect is immediately detected intraoperatively; the surgeon having the possibility of using another cap.

As a precaution and in order to avoid any risk of incident, Groupe Lepine has nevertheless decided to recall the lots listed below.

Concerning the patients having been implanted with a cap belonging to one of the defective references / lots, Groupe lepine does not recommend any particular follow-up of the patients, because if the locking was possible, it is that the implant used was functional.

Pursuant to article L1111-2 of the French public health code, Groupe Lepine invites the healthcare professionals concerned to take this information into account and take the appropriate measures

Advise on action to be taken by the user

- immediately examine your inventory and quarantine product subject to recall,
- complete and return the enclosed response form as soon as possible (by fax or mail),
- contact the export assistant of Groupe lépine to deal with exchange,
- In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall.

Sincerely yours,

Laurence Fiscus
Quality and Regulatory Affairs Director
Vigilance Officer

REFERENCES	LOTS
CS08	269762600
	270397500
	270411600
CS10	268232800
	269090700
	269115800
	269115900
	270297300
	270297400
CS12	268955200
	269132700
	270155700
	270155800
	270184100
	270325500
	270325600
	270397600
	270397700
	270397800

REFERENCES	LOTS
CS18	269178300
	269178400
	269370800
	269370900
	269399200
	269399300
	269587600
	269587700
	269676100
	269734300
	269734400
	269868300
	269868400
	270156000
	270184400
CS40	270210400
	270386100
CSB08F	266517400
	266763200
	269440900
	269600900
	269625000
	269690800

REFERENCES	LOTS
CSB12F	268984700
	268984800
	268984900
	269301400
	269857000
	270028000
	270028100
	270028200
	270132700
	270132800
	270428500
	270428600
	270428700
270428800	
270428900	
270429000	

REFERENCES	LOTS
CSB18F	269115500
	269153400
	269153401
	269177500
	269177501
	269177600
	269177700
	269177701
	269333400
	269369700
	269369800
	269369900
	269370000
	269370100
	269370200
269370300	
269370400	
269370500	
269585800	
269586100	

REFERENCES	LOTS
CSB18F	269586200
	269586300
	269674400
	269762100
	269762200
	269781700
	269781800
	270090800
	270090900
	270091000
	270091100
	270091200
	270132900
	270133000
	270133100
	270133200
	270325100
	270325200

REFERENCES	LOTS
CSB20F	270429800
	270429900
	270430000
CSB25F	269286300
	270325300

RECALL RETURN RESPONSE FORM

CSB CAPUCHON

Please check ALL appropriate boxes.

- I have read and understand the recall instruction provided in the 'reference' letter
- I have checked my stock and have quarantined inventory consisting of:
 - No more stock
 - Quantity left:

Reference	Lot number	Quantity

- Indicate disposition of recalled product:
 - Returned
 - Destroyed
- I have identified and notified my customers that were shipped or may have been shipped this product.

Name: _____

Position: _____

Firm Name: _____

Address: _____

Please fax or mail completed return response form to:
Groupe Lépine
Laurence Fiscus – Vigilance officer
 175 RUE JACQUARD – CS 50307 – 69727 GENAY CEDEX – FRANCE
 Phone: +33 (0)4 72 33 02 95 – Fax: + 33 (0)4 72 35 96 50