
Urgent Field Safety Notice Recall

Commercial name: SQUALE references SQP-CP-1413XXS – Anterior cervical cage

Urgent field safety notice N°: 2018_FA_002

Date: On the 11th of April 2018

To the attention:

- Operating room Supervisors / Medical Devices Supervisors / Pharmacists
- Logistic Supervisors
- Distributors

Device concerned: SQUALE references SQP-CP-1413XXS – Anterior cervical cage

Designation of devices concerned:

<u>Reference(s)</u>	<u>Batch number</u>
SQP-CP-141304S SQP-CP-141305S SQP-CP-141306S SQP-CP-141307S	<u>Cf. Batch list in appendix</u>

Description of the detected incident:

The devices packaging (packaging under double pouches) presents alteration defects due to the presence of radiographic markers, which might affect the integrity of the packaging.

These defects could cause a loss of the medical device sterile state.

Even though no clinical consequence on patients has been reported, OSD proceeds to a voluntary recall of the concerned devices.



Recommended actions for the users

We would ask you to:

- Immediately examine the possible presence of these devices in your inventory and place them absolutely in quarantine
- Diffuse this letter to all the persons concerned within the establishment, your company
- If it is necessary, diffuse this letter to the Competent Authority of your country
- Proceed to the immediate interruption of the device use or its distribution
- Complete and sign the acknowledgement form and send it to OSD within 5 working days by fax +33 (0)4 90 80 02 39 or by email at the following address vigilance@osdevelopment.fr
- We will contact your company in order to organize the concerned devices picking
- Save a copy of this urgent field safety notice

We are aware of the trouble that this situation can cause and in order to help you, we remain at your disposal for any further information:

By phone +33 (0)4 32 74 01 10

By email: vigilance@osdevelopment.fr

The French Competent Authority, ANSM, has been informed of this action. Thank you to inform the person concerned by this recall and the resulting action in order to guarantee its efficiency.

We draw your attention to the necessity to inform all side effects noted concerning these devices to OSD.

On behalf of OSD we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be cause.

Yours Sincerely.

Quality and Regulatory Affairs Department



ACKNOWLEDGMENT FORM

Urgent notification

**Orthopaedic & Spine Development
Recall – Urgent Field Safety Notice 2018_FA_002
April 11th 2018****Attention to:**

- Operating room Supervisors / Medical Devices Supervisors / Pharmacists
- Logistic Supervisors
- Distributors

Contacts: Fax +33 (0)4 90 80 02 39 or email vigilance@osdevelopment.fr**Establishment:****Name:****Function:****We confirm that we have received and understood this urgent notification.**

Our inventory has been checked and the results are the following:

 We have checked all the storage sites and all other places in our establishment and we do not have these products in stock / we no longer have these products in stock. We have some concerned products in stock, listed in the table below.

If the products cannot be returned, thank you to indicate below whether they have been used, lost or destroyed.

Reference	Batch number	Quantity to return	Quantity used, lost or destroyed

Date:**Signature:**Please send this form under 5 working days by fax +33 (0)4 90 80 02 39 or by email vigilance@osdevelopment.fr. We apologize for the inconvenience and we will contact your establishment in order to organize the picking of the identified devices.

APPENDIX

Reference	Batch number
SQP-CP-141304S	GSE-283/B GSE-293/A GSE-293/B GSE-335-1/A GSE-335-1/B GSE-335-1/C GSE-348/A GSE-396/A GSE-396/B GSE-418/A GSE-438/A GSE-418/B GSE-418/C GSE-438/B GSE-418/D GSE-418/E GSE-438/C GSE-418/F GSE-438/D GSE-438/E
SQP-CP-141305S	GSE-294/A GSE-294/B GSE-310/A GSE-344/A GSE-310/B GSE-344/B GSE-349/A GSE-397/A GSE-397/B GSE-419/A GSE-419/B GSE-419/C GSE-419/E GSE-419/F GSE-419/G GSE-439/A GSE-439/B GSE-419/H GSE-439/C GSE-439/D GSE-457/A GSE-457/B
SQP-CP-141306S	GSE-311/A GSE-345/A GSE-345/C GSE-345/D GSE-398/A GSE-398/B GSE-420/A GSE-398/D GSE-420/B GSE-420/C GSE-420/D GSE-420/F GSE-420/G GSE-458/A GSE-458/B GSE-458/C GSE-458/D GSE-458/E GSE-458/F GSE-490/A GSE-490/B

Reference	Batch number
SQP-CP-141307S	GSE-286/C GSE-312/A GSE-312/B GSE-312/C GSE-312/D GSE-338-1/A GSE-338-1/B GSE-338-1/C GSE-351/A GSE-338-1/D GSE-399/A GSE-399/B GSE-421/A GSE-421/B GSE-421/D GSE-421/E GSE-421/F GSE-440/A GSE-440/B GSE-440/C GSE-440/D GSE-459/A GSE-440/E GSE-459/B