July 8th, 2019

To: Hospitals

Urgent FIELD SAFETY NOTICE

Reference: FSN0719

Affected product:

REF-number	LOT-number	Description
SIS-1201	All products	GLACE™ CMF **6 mm screw only**

Skulle Implants Corporation is conducting a medical device Field Safety Corrective Action for the GLACE™ CMF 6 mm screws due to a risk of breakage.

This medical device Field Safety Corrective Action pertains only for the GLACE™ CMF 6 mm screws. Other GLACE™ products (screws, templates, instrument, plates) are not affected.

Our records indicate that you have received the extra instruction on 10th of November 2016 and may have received the affected product. We have decided to make this field safety notice, collect affected products from the market and stop selling the affected product.

Risks

Skulle Implants` risk analysis (SI-12277, rev. 16) of screw function is indicating risk where head of the screw comes off during the tightening of the screw. Immediate health consequences that may result from this is prolonged surgery due to removal of the defective screw and need of placing new screw. No long-range health consequences are anticipated since the risk is associated only with the screw tightening process.

User Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.

2. If you still have affected product at your facility, assist your Skulle Implants sales representative and quarantine all affected product.

3. Take action according to one of the options below:

I. First option: Your Skulle Implants sales representative will remove the affected product from your facility.

II. Second option: You can send the affected unused products back to Skulle Implants` factory. Skulle Implants Corporation, Lemminkäisenkatu 60, 20520 Turku, Finland.
III. Third option: You can discard the affected products and let Skulle Implants` to come aware that you have discarded the affected products.

4. Complete Attachment 1 – Certificate of Acknowledgement and send to hanna.nikkila@skulleimplants.com. **This form must be returned even if you do not have affected products at your facility anymore.**

5. Retain a copy of the acknowledgement form with your records in the event of a compliance audit of your facility's documentation.

6. If you have further questions or concerns after reviewing this notice, please contact your Skulle Implants` sales representative.

Other Information:
This medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

Please keep Skulle Implants` informed of any adverse events associated with this product or any other Skulle Implants` product by emailing hanna.nikkila@skulleimplants.com

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.

We would like to thank you for your co-operation in advance and regret any inconveniences caused by this Field Safety Corrective Action.

Contact reference person:

Hanna Nikkilä, COO
+358 400 27 99 96
hanna.nikkila@skulleimplants.com
Skulle Implants Oy
Lemminkäisenkatu 60
20520 Turku
Finland

Sincerely,

…

ATTACHMENT 1

Certificate of Acknowledgement

Affected Product: GLACE™ CMF 6 mm screws. REF: SIS-1201
Please return the completed form to your Skulle Implants Corporation:
hanna.nikkila@skulleimplants.com

☐ I received and understood the Field Safety Notice.

Regarding the product:

☐ All inventories for the affected products have been checked and following products are to be returned:

SIS-1201,_____pcs.

LOT-numbers: _____

OR

☐ The affected products which are unavailable for return have been: ☐ discarded
SIS-1201,_____pcs.
LOT-numbers: _____

OR

☐ Already collected by Skulle Implants`sales person
SIS-1201,_____pcs.
LOT-numbers: _____

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Safety Notice.

_____ _____
Hospital Department

_____
Signature & printed name
Date:____/_____/2019

NOTE: This form and affected product must be returned to Skulle Implants Corporation before this action is considered closed for your account. It is important that you complete this form and email a copy to hanna.nikkila@skulleimplants.com