

Urgent Field Safety Notice

Commercial name of the affected product:

CERAMENT™ | BONE VOID FILLER, A0210

CERAMENT™ | G, A0450

CERAMENT™ | V, A0451

FSCA-identifier: BS2018-11-15-01

Type of action (e.g. chapter 4 definition of a FSCA): Update of the IFU for all three products with addition of a precaution.

Date: 2018-11-28

Attention: Dear BONESUPPORT customer:

Details on affected devices:

CERAMENT™ | BONE VOID FILLER, A0210

CERAMENT™ | G, A0450

CERAMENT™ | V, A0451

For more information: <https://www.bonesupport.com/en-eu/>

Description of the problem:

An analysis of three product Complaints concerning migration of CERAMENT out of a bone void into the soft tissue led to an investigation that concluded with a recommendation to adapt application of the product in certain limited circumstances. These circumstances are constrained to the use of the product in benign bone tumours in children, and in particular Aneurysmal Bone Cysts (ABC), treated with open surgery.

As a result of the above, it was decided to update the IFUs of BONESUPPORT products with the addition of a Precaution:

In CERAMENT™ | BONE VOID FILLER:

“In Aneurysmal bone cysts (ABCs) and other bone cysts prone to producing large volumes of fluid, there is increased risk of wound drainage, soft-tissue inflammation and wound breakdown if treated by open surgery. Use CERAMENT™ | BONE VOID FILLER in bead form rather than complete void filling for these indications”.

In CERAMENT™ | G:

“In Aneurysmal bone cysts (ABCs) and other bone cysts prone to producing large volumes of fluid, there is increased risk of wound drainage, soft-tissue inflammation and wound breakdown if treated by open surgery. Use CERAMENT™ | G in bead form rather than complete void filling for these indications”.

In CERAMENT™ | V:

“In Aneurysmal bone cysts (ABCs) and other bone cysts prone to producing large volumes of fluid, there is increased risk of wound drainage, soft-tissue inflammation and wound breakdown if treated by open surgery. Use CERAMENT™ | V in bead form rather than complete void filling for these indications”.

This Field Safety Notice (FSN) is hence provided to effectively communicate this safety information.

Background

Clinical experience has shown that, in a minority of cases, when the product is used in treatment of Aneurysmal bone cysts (ABCs) and other bone cysts prone to producing large volumes of fluid, there is increased risk of wound drainage, soft-tissue inflammation and wound breakdown if treated by open surgery. It is likely that continued production of fluid by remaining disease elements leads to a build-up of hydrostatic pressure around the CERAMENT as it degrades, forcing CERAMENT-breakdown fluid and solid remnants out through the wound. To mitigate this risk, it is suggested that CERAMENT be applied in bead form rather than complete void filling for these indications, since this will allow the hydrostatic pressure to dissipate between the beads. Accordingly, changes are being made to the product IFU.

Any possible risk to patients associated with previous use of affected devices.

None – this phenomena is restricted to the first few weeks after surgery, since after this time the product has degraded.

Advise on action to be taken by the user:

Acknowledgement that the information has been received

Follow the IFU and if applicable its amendments.

Inform BONESUPPORT of any observations, either past or present, that mirror those detailed herein.

Transmission of this Field Safety Notice: (if appropriate)

Until notified otherwise, distributors/sales team should provide a copy of this FSN and the updated IFU to all who need to be aware within your organization or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

To confirm receipt of this FSN please complete and return the attached acknowledgement (Appendix A).

Please contact BONESUPPORT's Chief Medical Officer: Michael Diefenbeck, +46 46 286 53 70 or European Medical Adviser: Dr Paul Hercock, +46 46 286 53 70, for questions related to this FSN.

Relevant Competent Authorities have been advised of this FSN.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

Sincerely,



Gabriella Gärd

 BONESUPPORT™
Scheelevägen 19, Ideon
SE-223 70 Lund, Sweden

Regulatory Affairs Specialist & Complaint Manager

BONESUPPORT AB

e-mail: gabriella.gards@bonesupport.com

Tel no. +46 46 286 53 70

The undersign confirms that this notice has been notified the appropriate Regulatory Agency (Closing paragraph)

Signature

 BONESUPPORT™
Scheelevägen 19, Ideon
SE-223 70 Lund, Sweden

APPENDIX A:

This letter acknowledges receipt of the Field Safety Notice (ref BS2018-11-15-01) dated November 2018 issued by BONESUPPORT AB.

I have received the FSN

Please fax or e-mail this completed document to:

+46 46 2865371

or

gabriella.gards@bonesupport.com

Print Name: _____

Signature: _____

Hospital/Distributor: _____

City: _____

Country: _____

Telephone number or
e-mail address: _____