

»Company«
 FAO: »Title« »First name« »Last name«
 »Address«
 »Country code« – »Postcode« »Place«

Your reference/your letter dated Our reference/our letter dated Extension, name Date
 -44, Genrich 22.06.2018

<p><u>Urgent Field Safety Notice</u></p> <p>USER INFORMATION</p> <p>regarding</p> <p>Handling of fractured ceramic inserts and ceramic head fractures</p>

Procedure number	CAPA-2018-03-003
Sender	OHST Medizintechnik AG Grünauer Fenn 3 14712 Rathenow
Addressee	Distribution partners of OHST Medizintechnik AG
Identification of affected medical devices	<ul style="list-style-type: none"> • Ceramic femoral heads • Ceramic cup inserts of OHST Medizintechnik AG See annex for detailed information
Background	<p>This urgent field safety notice is being sent as a result of the publication of the AE recommendation “Recommendation for handling fractured ceramic inserts and ceramic head fractures” (Heller, K.-D., Perka, C.) dated 15 March 2017.</p> <p>The purpose of this notice is to create awareness on how to deal with fractured ceramic inserts and ceramic head fractures and to identify the necessary measures to be taken by the end user. It serves as a supplement to the information provided in the respective instructions for use of the identified medical devices (see annex).</p>

Field safety notice	<p>Please be hereby explicitly advised that, in case of an intraoperative change of the femoral head, only femoral heads without a ceramic cone are to be used. This is valid irrespective of the materials used in the previous cone pairing.</p> <p>If a ceramic component is damaged or fractured, a revision at the earliest possible date is recommended. In this case, the use of metal femoral heads is contraindicated in revision surgery, as this may lead to serious and partly life-threatening complications. In the rare event of a ceramic fracture, thorough debridement with removal of all visible ceramic particles as well as careful wound irrigation is absolutely essential during the surgical procedure. After that, the inner cone of the cup must be assessed. If the inner cone of the titanium cup does not exhibit any major damages, a ceramic inlay should again be implanted. Should it no longer be possible to use a ceramic inlay with the cup owing to damage of the inner cone or lack of availability, a cup inlay of highly cross-linked polyethylene should be implanted instead. Alternatively, replacing the cup and implanting a new ceramic inlay is also possible. In this case, the fractured or damaged head should be replaced by a ceramic head in connection with a revised hip stem.</p>
Cause	<ul style="list-style-type: none"> • Potentially fractured ceramic component
Risk	<ul style="list-style-type: none"> • Residual ceramic particles can lead to massive metal debris in the articulation. This, in turn, can lead to high systemic metal ion concentrations in the blood and local tissue damage with osteolysis and pseudotumours.
What measures must be taken by the addressee?	<ul style="list-style-type: none"> • Information and training of end users
Contact person	<p>Heiner Genrich Safety Officer Phone: +49 (03385) 54 20 44 Fax: +49 (03385) 54 20 99 Email: safety.officer@ohst.de</p>

Disclosure of the information provided in this FSN

Please ensure within your organisation that all users of the devices listed in the annex and other persons to be informed are made aware of this field safety notice. If you have supplied the devices to third parties, please forward a copy of this information to them. Please confirm that you have passed on the information provided in this field safety notice by returning the enclosed acknowledgement of receipt to the above contact person within two weeks of receiving it.

Please keep this information at least until the measure has been concluded.

The Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this “Urgent Field Safety Notice”.

Heiner Genrich
Dipl.-Ing (FH)
Safety Officer



Please return by 17/04/2018 to:

Fax: +49 (03385) 54 20 99

Email: safety.officer@ohst.de

Acknowledgement of receipt of the Urgent Field Safety Notice

regarding

Handling of fractured ceramic inserts and ceramic head fractures

of 05 April 2018

Sender:

»Company«

»Address«

»Country code« – »Postcode« »Place«

Contact person:

Name (in block capitals): _____

Phone or email: _____

We hereby acknowledge that we have received the above Urgent Field Safety Notice and have forwarded it to all users and interested persons for their information.

Date

Signature