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Urgent Safety Notice

Recall

regarding

ELEC®plus Ceramic Femoral Head

and

ELEC®plus Revision Ceramic Femoral Head

Lüdinghausen, 24.04.2026

Sender: ARTIQO GmbH
Mario Frank
Hans-Böckler-Straße 57
59348 Lüdinghausen

Recipient: Users of ELEC®plus and ELEC®plus Revision Ceramic Femoral Heads

Identification of the medical devices concerned:

Name	Article No. / Serial No.
ELEC®plus Ceramic Femoral Head ELEC®plus Revision Ceramic Femoral Head	see Appendix

Respected users of the ELEC®plus and ELEC®plus Revision Ceramic Femoral Heads manufactured by ARTIQO,
Respected customers,

we are writing to inform you that ARTIQO GmbH is initiating a recall of the ELEC®plus and ELEC®plus Ceramic Femoral Heads as legally manufactured by ARTIQO.

Description of the problem, including the identified cause:

During a routine dose verification test as part of the sterilisation validation for the Ceramic Femoral Heads manufactured by ARTIQO, repeated instances of non-sterile test results were identified.
As a result of these failed verification tests, production of the affected products has currently been suspended.
The microorganisms identified are *Deinococcus* spec. and *Roseomonas mucosa*. According to the literature, both microorganisms are inactivated by the effectively applied radiation dose of at least 27.7 kGy.

Laboratory tests carried out on products intended for the market have so far provided conflicting results regarding the sterility of these products. The identification of microorganisms has not yet been completed. Consequently, the sterility of the products cannot be fully guaranteed at the current time point.

The recall covers all products placed on the market as listed in Annex 1.
It is possible that the affected lots may be further narrowed down once the investigations have been completed.

Risk assessment:
With regard to the products already on the market, it has been confirmed that none of the affected production lots were irradiated with less than 27.7 kGy. According to the literature, the identified microorganisms are inactivated by the actual radiation dose of at least 27.7 kGy. A literature research on *Deinococcus radiodurans*, the potentially most radiation-resistant member of the *Deinococcus* genus, revealed that 10 of the most radiation-resistant bacteria are killed with a probability of 1 in 10^6 when exposed to a dose of approximately 26 kGy.

The identified microorganisms were assessed in terms of their clinical relevance, their susceptibility to common antibiotic treatments, and the treatability of potential infections.
Infections caused by *Deinococcus s*pec. are very rare. However, as generally non-pathogenic organisms, in the unlikely event of an infection, they respond well to a range of antibiotics such as penicillin, amoxicillin, ciprofloxacin, doxycycline or gentamicin, or a combination of these antibiotics.
Bacteria of the genus *Roseomonas mucosa* belong to the group of pathogenic bacterial species. According to the literature, *Roseomonas* spec. is sensitive to aminoglycosides, carbapenems, fluoroquinolones, polymyxins, sulphonamides and tetracyclines. This means that infections caused by *Roseomonas mucosa* are treatable.
The literature indicates that the most radiation-resistant member of the *Roseomonas* genus (‘*Roseomonas radiodurans*’) exhibits only half the radiation resistance of *Deinococcus radiodurans*.
Given the non-pathogenic classification of *Deinococcus* spec., the risk of infection from this bacterial species is considered low, but cannot be entirely ruled out at this stage.

Recognition of the risk:
The hazard is not apparent from the non-implanted product itself.

Risk assessment:
With regard to products already on the market, it has been confirmed that none of the affected production lots were irradiated with less than 27.7 kGy.
However, due to the currently conflicting laboratory results, it is currently not possible to fully guarantee the sterility of the products supplied. Consequently, a serious deterioration in the health of patients, users or third parties cannot be ruled out at this stage.

Procedures:
<u>Acknowledgement of receipt:</u>
Please confirm that you have taken note of this urgent safety notice using the attached acknowledgement form (see Appendix 2) within one week of receiving this letter.

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Non-implanted products:
Please check the products currently in your possession against the items listed in Appendix 1 and set them aside for replacement. Our staff will replace the products in the consignment stock by 13 May 2026 at the latest.

Implanted products:
For patients who have already received the product, please monitor for signs of post-operative infections that may be associated with the specified microorganisms.
In this case, please test for the presence of the specified microorganisms and consider the treatment options outlined above.
Should you have identified, or should you identify in future, an increased incidence of infections associated with the use of the specified products in total hip replacements, please notify us immediately.

Sharing of the information described here:
Please ensure within your organisation that all users of the above-mentioned products and any other relevant parties are made aware of this Urgent Safety Notice. If you have supplied the products to third parties, please forward a copy of this notice or inform the contact person listed below.

Please store this information at least until the measure has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this urgent safety information.

Contact person:
If you have any specific questions regarding these safety instructions, please direct them to:

Dr. Heidrun Jablonski
Tel.: 02591 / 89 315-05
Mobile: 0151 / 27 25 31 67
E-Mail: heidrun.jablonski@artiqo.de

We apologise for any inconvenience caused.

Kind regards,
ARTIQO GmbH

Mario Frank
Responsible person

Dr. Heidrun Jablonski
Head of Quality & Regulatory Affairs

Appendix

- Appendix 1: Affected products
- Appendix 2: Acknowledgement of receipt