Aesculap AG
Quality Management

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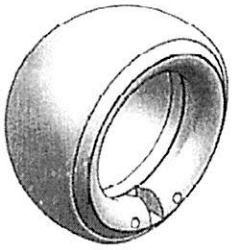
Date: 20th September 2021

Urgent Field Safety Notice

Product name: BIPOLAR CUP TRIAL HEAD
Internal reference number: FSCA 260



For the attention of users, importers and distributors of the affected products.

1. Information on affected products

1.1 Primary Intended Use

The Bipolar Cup trial heads are instruments used in orthopedic surgery with Bipolar Cup implants to determine the size of the acetabulum and for trial repositioning.

1.2 Identification of the affected medical devices

Article description	**BIPOLAR CUP TRIAL HEAD**
Article number	**Appendix 1**

2. Justification for the urgent Field Safety Notice

2.1 Description of the possible misconduct

The Bipolar Cup trial heads consist of the individual components bipolar trial head and locking ring.
During the re-validation of the sterilization process, it was determined that the mechanical pre-cleaning and cleaning/disinfection in the disassembled state, as well as the information on sterilization in the non-assembled state, are not sufficiently described in the instructions for use.

2.2 Reason for initialization this Urgent Field Safety Notice

The current description in the instructions for use could possibly lead to the reduction of the germ load during reprocessing and thus the hygiene standard for the product not being achieved.

In the unlikely event of improper reprocessing, infections may occur in patients, which could lead to a revision of the implant. According to evaluations from clinical routine, as well as the available market data and register data, there are currently no known incidents of this error pattern which led to a hazardous situation for patient, users or third parties.

3. Type of action to mitigate the risk

The Reprocessing of the Bipolar Cup trial heads is updated.
Users will be informed about this update in this urgent field safety notice.

3.1 Reprocessing of the products concerned (see Appendix 1)

In order to reduce the risk to patients, users and third parties as far as possible, the following additional reprocessing steps must be observed for the affected products with immediate effect:
Disassembly of the trial head , pre-cleaning with the brush, sterilization in disassembled state.
For a detailed description of reprocessing see Appendix 3.

3.2 Special requirements for patients already treated

There is no required follow-up for patients already treated with the affected products.

3.3 Future risk minimization measures
A new instruction for use (TA016201) is created, which contains the information for disassembly of the trial heads, pre-cleaning with brush before cleaning / disinfection, as well as disassembly before sterilization.

It is not necessary to return the affected products.

Please confirm your acknowledgement and immediate implementation of this urgent Field Safety Notice using the feedback form (Appendix 2) by email to Aesculap AG **by 01th November 2021**.

If you have any further questions, please contact the following contact persons:

For product related questions:
Dominik Kühne
Director Global Marketing
dominik.kuehne.@aesculap.de

For related questions to this safety information:
Dominik Neumeister
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The Federal Institute for Medicinal Products and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) has received a copy of this urgent field safety notice.

Please ensure in your organization that all users of the affected product and other persons to be informed are aware of this urgent field safety notice.

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

Please report all product related incidents to Aesculap AG or to your local distributor and the national Competent Authority if appropriate.

We would like to point out that all users who have received the affected products from us in the past will be informed of this urgent field safety notice.

We apologize for any inconveniences caused.

Yours sincerely

Aesculap AG

i.V.
Georg Erhard
Safety Officer
Quality Management

i.V.
Christian von der Grün
Director Post Market Surveillance
Quality Management

Appendix 1 – Affected Products
Appendix 2 – Feedback Form
Appendix 3 - Guidance for the reprocessing steps