Aesculap AG
Quality Management

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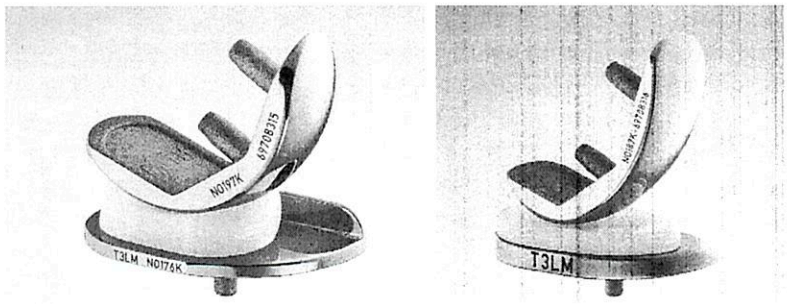
Datum: 3rd March 2021

Urgent Field Safety Notice

Product Name: univation® X system

Product: unicondylar knee endoprosthesis system

Internal Reference Number: FSCA 251



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

1. Information on affected products

1.1 Product
The univation® X system consists out of three components: - Femur component cemented (AFFECTED BY THIS FSCA) - Tibia component cemented (AFFECTED BY THIS FSCA) - Meniscal component (**NOT** AFFECTED BY THIS FSCA)
1.2 Product Name
univation® XF; univation® XM
1.3 Primary Intended Use
The univation® X system is a unicondylar knee system with a fixed or mobile platform to treat medial knee defects.
1.4 Catalogue number / product model
See Appendix 1
1.5 Associated product(s)
univation® instrument sets - see Appendix 2

2. Reason for this Field Safety Corrective Action (FSCA)

2.1 Description of the possible malfunction

A locally accumulated number of aseptic loosening has been reported in connection with the univation® X system. In the affected patients, the loosened knee endoprosthesis had to be revised or will be revised.

2.2 Reason for initialization of this FSCA

The main hazard for patients arising from the described possible malfunction is the loosening of the implant with the potential direct harm that a revision has to take place. The severity to the patient is rated as critical. We see today an occasional occurrence (0.25 % affected products).

The anticipated risk to patients is therefore rated as not acceptable.

For the reasons of health protection the competent authority proposes, in case that the meniscal component fails in well cared patients, to consider replacing the component to avoid an overall revision leading to a full implant. For this reason, the meniscal component is explicitly not affected by this recall and can continue to be used if necessary.

2.3 Root cause analysis

The result of our detailed root cause analysis showed a complex possible failure scenario. Therefore a definite root cause could not be determined.

3. Type of action to mitigate the risk

3.1 Actions to be taken by users, importers and distributors

☒ **Identify Product** ☐ Quarantine Product ☒ **Return Product** ☐ Destroy Product

☐ On-site product modification/inspection

☐ Follow patient management recommendations

☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☐ Other ☐ None

Based on the above risk scenario Aesculap AG **decided to recall the affected products** (Appendix 1) and **the associated products** (Appendix 2). Please identify the affected products at your side and return them to Aesculap AG by using the return form (Appendix 4) attached. Please take care that the return form (Appendix 4) is always returned **together with the returned products.**

Please confirm the understanding of this urgent field safety notice by returning the feedback form (Appendix 3) **until 31st March 2021**.

3.2 Special considerations for already implanted patients

We do not advise a follow-up of patients or review of patients' previous results. With a pain-free and functionally satisfactory knee endoprosthesis, revisions or additional X-ray examinations are generally not recommended.

This FSCA 251 supersedes prior FSCA 250 (if you were affected) and shall be completed within the next 6 months.

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

For product related questions:

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Product Manager Global Marketing
Orthopaedic Knee Arthroplasty
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For related questions to this security information:

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Please ensure in your organization that all users of the affected product and other persons to be informed are aware of this security information.

The Federal Institute for Medicinal Products and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) has received a copy of this security information.

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 safety information.

We apologize for any inconveniences caused.

Yours sincerely,

Aesculap AG

i.V.
Georg Erhard
Safety Officer

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

Appendix 1 – Affected Products
Appendix 2 – Associated Products
Appendix 3 – Feedback Form
Appendix 4 – Return Form

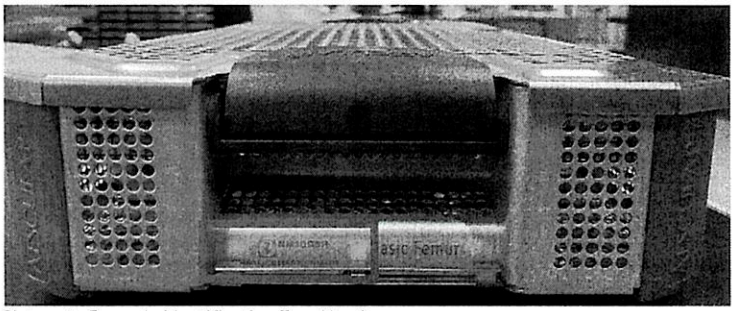
Appendix 1 – Affected Products	
NO156K	UNIVATION XF TIBIA CEMENTED T1 RM
NO157K	UNIVATION XF TIBIA CEMENTED T2 RM
NO158K	UNIVATION XF TIBIA CEMENTED T3 RM
NO159K	UNIVATION XF TIBIA CEMENTED T4 RM
NO160K	UNIVATION XF TIBIA CEMENTED T5 RM
NO161K	UNIVATION XF TIBIA CEMENTED T6 RM
NO162K	UNIVATION XF TIBIA CEMENTED T1 LM
NO163K	UNIVATION XF TIBIA CEMENTED T2 LM
NO164K	UNIVATION XF TIBIA CEMENTED T3 LM
NO165K	UNIVATION XF TIBIA CEMENTED T4 LM
NO166K	UNIVATION XF TIBIA CEMENTED T5 LM
NO167K	UNIVATION XF TIBIA CEMENTED T6 LM
NO168K	UNIVATION XM TIBIA CEMENTED T1 RM
NO169K	UNIVATION XM TIBIA CEMENTED T2 RM
NO170K	UNIVATION XM TIBIA CEMENTED T3 RM
NO171K	UNIVATION XM TIBIA CEMENTED T4 RM
NO172K	UNIVATION XM TIBIA CEMENTED T5 RM
NO173K	UNIVATION XM TIBIA CEMENTED T6 RM
NO174K	UNIVATION XM TIBIA CEMENTED T1 LM
NO175K	UNIVATION XM TIBIA CEMENTED T2 LM
NO176K	UNIVATION XM TIBIA CEMENTED T3 LM
NO177K	UNIVATION XM TIBIA CEMENTED T4 LM
NO178K	UNIVATION XM TIBIA CEMENTED T5 LM
NO179K	UNIVATION XM TIBIA CEMENTED T6 LM
NO180K	UNIVATION XF FEMUR CEMENTED F1 RM
NO181K	UNIVATION XF FEMUR CEMENTED F2 RM
NO182K	UNIVATION XF FEMUR CEMENTED F3 RM
NO183K	UNIVATION XF FEMUR CEMENTED F4 RM
NO184K	UNIVATION XF FEMUR CEMENTED F5 RM
NO185K	UNIVATION XF FEMUR CEMENTED F1 LM
NO186K	UNIVATION XF FEMUR CEMENTED F2 LM
NO187K	UNIVATION XF FEMUR CEMENTED F3 LM
NO188K	UNIVATION XF FEMUR CEMENTED F4 LM
NO189K	UNIVATION XF FEMUR CEMENTED F5 LM
NO190K	UNIVATION XM FEMUR CEMENTED F1 RM
NO191K	UNIVATION XM FEMUR CEMENTED F2 RM
NO192K	UNIVATION XM FEMUR CEMENTED F3 RM
NO193K	UNIVATION XM FEMUR CEMENTED F4 RM
NO194K	UNIVATION XM FEMUR CEMENTED F5 RM
NO195K	UNIVATION XM FEMUR CEMENTED F1 LM

Appendix 1 – Affected Products	
NO196K	UNIVATION XM FEMUR CEMENTED F2 LM
NO197K	UNIVATION XM FEMUR CEMENTED F3 LM
NO198K	UNIVATION XM FEMUR CEMENTED F4 LM
NO199K	UNIVATION XM FEMUR CEMENTED F5 LM
NO156Z	AS UNIVATION XF TIBIA CEMENTED T1 RM
NO157Z	AS UNIVATION XF TIBIA CEMENTED T2 RM
NO158Z	AS UNIVATION XF TIBIA CEMENTED T3 RM
NO159Z	AS UNIVATION XF TIBIA CEMENTED T4 RM
NO160Z	AS UNIVATION XF TIBIA CEMENTED T5 RM
NO161Z	AS UNIVATION XF TIBIA CEMENTED T6 RM
NO162Z	AS UNIVATION XF TIBIA CEMENTED T1 LM
NO163Z	AS UNIVATION XF TIBIA CEMENTED T2 LM
NO164Z	AS UNIVATION XF TIBIA CEMENTED T3 LM
NO165Z	AS UNIVATION XF TIBIA CEMENTED T4 LM
NO166Z	AS UNIVATION XF TIBIA CEMENTED T5 LM
NO167Z	AS UNIVATION XF TIBIA CEMENTED T6 LM
NO168Z	AS UNIVATION XM TIBIA CEMENTED T1 RM
NO169Z	AS UNIVATION XM TIBIA CEMENTED T2 RM
NO170Z	AS UNIVATION XM TIBIA CEMENTED T3 RM
NO171Z	AS UNIVATION XM TIBIA CEMENTED T4 RM
NO172Z	AS UNIVATION XM TIBIA CEMENTED T5 RM
NO173Z	AS UNIVATION XM TIBIA CEMENTED T6 RM
NO174Z	AS UNIVATION XM TIBIA CEMENTED T1 LM
NO175Z	AS UNIVATION XM TIBIA CEMENTED T2 LM
NO176Z	AS UNIVATION XM TIBIA CEMENTED T3 LM
NO177Z	AS UNIVATION XM TIBIA CEMENTED T4 LM
NO178Z	AS UNIVATION XM TIBIA CEMENTED T5 LM
NO179Z	AS UNIVATION XM TIBIA CEMENTED T6 LM
NO180Z	AS UNIVATION XF FEMUR CEMENTED F1 RM
NO181Z	AS UNIVATION XF FEMUR CEMENTED F2 RM
NO182Z	AS UNIVATION XF FEMUR CEMENTED F3 RM
NO183Z	AS UNIVATION XF FEMUR CEMENTED F4 RM
NO184Z	AS UNIVATION XF FEMUR CEMENTED F5 RM
NO185Z	AS UNIVATION XF FEMUR CEMENTED F1 LM
NO186Z	AS UNIVATION XF FEMUR CEMENTED F2 LM
NO187Z	AS UNIVATION XF FEMUR CEMENTED F3 LM
NO188Z	AS UNIVATION XF FEMUR CEMENTED F4 LM
NO189Z	AS UNIVATION XF FEMUR CEMENTED F5 LM
NO190Z	AS UNIVATION XM FEMUR CEMENTED F1 RM
NO191Z	AS UNIVATION XM FEMUR CEMENTED F2 RM

Appendix 1 – Affected Products	
NO192Z	AS UNIVATION XM FEMUR CEMENTED F3 RM
NO193Z	AS UNIVATION XM FEMUR CEMENTED F4 RM
NO194Z	AS UNIVATION XM FEMUR CEMENTED F5 RM
NO195Z	AS UNIVATION XM FEMUR CEMENTED F1 LM
NO196Z	AS UNIVATION XM FEMUR CEMENTED F2 LM
NO197Z	AS UNIVATION XM FEMUR CEMENTED F3 LM
NO198Z	AS UNIVATION XM FEMUR CEMENTED F4 LM
NO199Z	AS UNIVATION XM FEMUR CEMENTED F5 LM

Appendix 2 – Associated Products		
Tray Number*	**Set Name**	**Set Number**
NM1090R	Navigation Set	NM600
NM1092R + NM1095R + NM1096R (Tray insert to NM1095R)	univation XF	NM601
NM1092R + NM1095R + NM1097R (Tray insert to NM1095R)	univation XM	NM602
NM1093R	univation XF OPT	NM604
NM1094R	univation XM OPT	NM605

*the affected sets are identified by the above given tray numbers



Picture 1: Example identification Tray Number

Picture 2: Example identification Tray Number