



Aesculap AG
Quality Management

Postfach 40
78501 Tuttlingen
Deutschland

Ansprechpartner: Qun Li-Wernz

Telefon: 07461 95-31346

Fax: 07461 95-1555

E-Mail: vigilance_aag.de@aesculap.de

Internet: <http://www.aesculap.de>

Datum: 16. November 2020

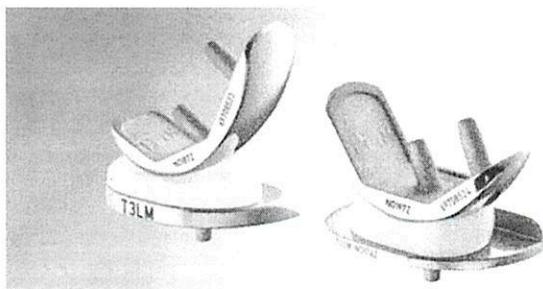
Important Security Information

Product: unicondylar knee endoprosthesis system

Product Name: univation® X system

Affected Products: see Appendix 1

Internal Reference Number: FSCA 250



Vorsitzender des Aufsichtsrates:
Prof. Dr. Heinz-Walter Große

Vorstand:
Dr. Joachim Schulz
(Vorsitzender)
Dr. Jens von Lackum
(Stellv. Vorsitzender)
Dr. Katrin Sternberg

Sitz der Gesellschaft: Tuttlingen
Reg. Gericht: Stuttgart HRB 726261
USt. Id.-Nr. DE812160059

WEEE-Reg.-Nr. DE 65109852

Bankverbindungen:
Deutsche Bank AG Tuttlingen
BLZ 653 700 75 Konto 21 22 000 00
IBAN DE 44 6537 0075 0212 2000 00
SWIFT / BIC DEUTDE33
Baden-Württembergische Bank
BLZ 600 501 01 Konto 487 1905
IBAN DE31 6005 0101 0004 8719 05
SWIFT / BIC SOLADEST

Hausanschrift:
Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
Deutschland

With this letter we would like to inform you about a possible malfunction of our product within the univation® X system.

The univation® X system is a unicondylar knee endoprosthesis system with a fixed and mobile platform. The implantation of the femoral and tibial implants takes place with bone.

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

According to the current state of knowledge and the results of the investigations carried out to date, no technical factor and no connection between the reported cases could be identified. We are currently not assuming a product-related malfunction. The possible harm to the patient is classified as critical. We are currently assuming an occasional occurrence (0.18% affected products).

Since the root cause could not yet be determined, we hereby preventively **instruct a temporary suspension of the use of the univation® X system product until January 31, 2021**. As soon as the investigations have been completed, we will inform you not later than January 31, 2021 about the next steps.

Please identify all products available at your side and make sure that these products are no longer used.

We plan to complete this field corrective action within 3 months.

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

For product related questions:

For related questions to this security information:

Brigitte Altermann**Qun Li-Wernz**

Product Manager Global Marketing
Orthopaedic Knee Arthroplasty
☎ + 49 7461 95 - 1526
brigitte.altermann@aesculap.de

Vigilance Manager
Quality Management
☎ + 49 7461 95 - 1346
vigilance_aag.de@aesculap.de

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.

In order to confirm your understanding and implementation of this security information, we ask you to return the feedback form attached to this letter (Appendix 2).

We apologize for any inconveniences caused.

Yours sincerely,

Aesculap AG

i.V. 

Georg Erhard
Safety Officer

i.V. 

Christian von der Grün
Head of Vigilance and Reporting

Appendix 1 – Affected Products

Appendix 2 – Feedback Form

Appendix 1 – Affected Products

NL470	NO161K	NO181Z	NO715
NL471	NO161Z	NO182K	NO721
NL472	NO162K	NO182Z	NO722
NL473	NO162Z	NO183K	NO723
NL474	NO163K	NO183Z	NO724
NL475	NO163Z	NO184K	NO725
NL476	NO164K	NO184Z	NO731
NL477	NO164Z	NO185K	NO732
NL478	NO165K	NO185Z	NO733
NL479	NO165Z	NO186K	NO734
NL480	NO166K	NO186Z	NO735
NL481	NO166Z	NO187K	NO741
NL482	NO167K	NO187Z	NO742
NL483	NO167Z	NO188K	NO743
NL484	NO168K	NO188Z	NO744
NL485	NO168Z	NO189K	NO745
NL486	NO169K	NO189Z	NO761
NL487	NO169Z	NO190K	NO762
NL488	NO170K	NO190Z	NO763
NL489	NO170Z	NO191K	NO764
NL490	NO171K	NO191Z	NO765
NL491	NO171Z	NO192K	
NL492	NO172K	NO192Z	
NL493	NO172Z	NO193K	
NL494	NO173K	NO193Z	
NL495	NO173Z	NO194K	
NL496	NO174K	NO194Z	
NL497	NO174Z	NO195K	
NL498	NO175K	NO195Z	
NL499	NO175Z	NO196K	
NO156K	NO176K	NO196Z	
NO156Z	NO176Z	NO197K	
NO157K	NO177K	NO197Z	
NO157Z	NO177Z	NO198K	
NO158K	NO178K	NO198Z	
NO158Z	NO178Z	NO199K	
NO159K	NO179K	NO199Z	
NO159Z	NO179Z	NO711	
NO160K	NO180K	NO712	
NO160Z	NO180Z	NO713	