import XML | fix + save

fill with test data #1

new case, keep base data

Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.7en
2012-12-03

1 Administrative information
To which NCA(s) is this report being sent? sukl (urgent@sukl.cz), sukl (ivana.justova@sukl.cz), BfArM (medizinprodukte@bfarm.de), ansm (medicaldevicesvigilance@ansm.sante.fr), sanita (dgfdm@postacert.sanita.it, vigilance@sanita.it, l.lispi@sanita.it), mhra (aic@mhra.gov.uk), aemps (sgps@aemps.es), bmgf (meddev@bmgf.gv.at), swissmedic (medical.devices@swissmedic.ch), titck (md.ivd@titck.gov.tr)
Type of report ◯ Initial report ◉ Follow-up report ◯ Final report
Date of this report 2021-01-28
Reference number assigned by the manufacturer FSCA 250
FSCA reference number assigned by NCA 19613/20
Incidence reference number assigned by NCA 16902/20 (16903/20 ff.,17521/20 ff.,17625/20 ff.)
Name of the co-ordinating NCACompetent Authority (if applicable) N/A

2 Information on submitter of the report
Status of submitter ◉ Manufacturer ◯ Authorised Representative within EEA and Switzerland ◯ Others: (identify the role)

3 Manufacturer information	new

Name Aesculap AG	
Contact Name Georg Erhard	
Address Postfach 40	
Postcode 78501	**City** Tuttlingen
Phone +49 7461 95-1062	**Fax** +49 7461 95-1555
E-mail vigilance_aag.de@aesculap.de	**Country** DE - Germany

4 Authorised Representative Information

new

Name	
Contact Name	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country** DE - Germany

5 National contact point information

new

National contact point name Aesculap AG	
Name of the contact person Georg Erhard	
Address Postfach 40	
Postcode 78501	**City** Tuttlingen
Phone +49 7461 95-1062	**Fax** +49 7461 95-1555
E-mail vigilance_aag.de@aesculap.de	**Country** DE - Germany

6 Medical device information

new

Class

- ○ AIMD Active implants
- ◉ MDD Class III
- ○ MDD Class IIb
- ○ MDD Class IIa
- ○ MDD Class I
- ○ IVD Annex II List A
- ○ IVD Annex II List B
- ○ IVD Devices for self-testing
- ○ IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	48070, 48068, 33369

Nomenclature text

Commercial name/ brand name / make

AESCULAP Univation X System

Model number	**Catalogue number**
NO711, NO712, NO713, NO714,NO715, NO721, NO722, NO723,	
Serial number(s)	**Lot/batch number(s)**
Not limited	Not limited
Device Mfr Date	**Expiry date**

Notified Body (NB) ID-number

CE0123

Accessories / associated devices (if applicable)

N/A

Software version number (if applicable)

N/A

7 Description of the FSCA

Background information and reason for the FSCA

A locally accumulated number of aseptic loosenings 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.

Description and justification of the action (corrective / preventive)

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.

Update on January 28, 2021

No definite root cause could be identified. Due to the notified body has not issued another CE certificate at this time and BfArM requested a prolongation of the application stop, we therefore extent this FSN unlimited.

Advice on actions to be taken by the distributor and the user

As soon as the investigations have been completed, we will inform you not later than January 31, 2021 about the next steps.

Update on January 28, 2021

No definite root cause could be identified. Due to the notified body has not issued another CE certificate at this time and BfArM requested a prolongation of the application stop, we therefore extent this FSN unlimited.

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

N/A

Time schedule for the implementation of the different actions

Unlimited

Attached please find

- [x] Field Safety Notice (FSN) in English
- [x] FSN in national language
- [ ] Others (please specify)

FSN Status

- ( ) Draft FSN
- (•) Final FSN

The medical device has been distributed to the following countries:

within the EEA and Switzerland

[x] AT	[ ] BE	[ ] BG	[x] CH	[ ] CY	[x] CZ	[x] DE	[ ] DK
[ ] EE	[x] ES	[ ] FI	[x] FR	[x] GB	[ ] GR	[ ] HU	[ ] IE
[ ] IS	[x] IT	[ ] LI	[ ] LT	[ ] LU	[ ] LV	[ ] MT	[ ] NL
[ ] NO	[ ] PL	[ ] PT	[ ] RO	[ ] SE	[ ] SI	[ ] SK	[x] TR

Candidate Countries

- [ ] HR

- [ ] All EEA, candidate countries and Switzerland

Others:

US, TH, IN

8 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

28. JAN. 2021

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail