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Date: 29th March 2021

Urgent Field Safety Notice

Product Group(s):
PAS-PORT Proximal Anastomosis System

Product Name:
PAS-PORT PROXIMAL ANASTOMOSIS SYSTEM
PAS-PORT PROXIMAL ANASTOMOSIS DEVICE US
PAS-PORT PROXIMAL ANASTOMOSIS DEVICE

Internal Reference Number: FSCA 255

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

[redacted]

1. Information on affected products

1.1 Product
PAS-PORT Proximal Anastomosis System
1.2 Product Name
PAS-PORT PROXIMAL ANASTOMOSIS SYSTEM PAS-PORT PROXIMAL ANASTOMOSIS DEVICE US PAS-PORT PROXIMAL ANASTOMOSIS DEVICE
1.3 Primary Intended Use
The PAS-Port System is designed to create an anastomosis between a large target vessel, such as the aorta, and a conduit, such as a venous conduit.
1.4 Catalogue number / product model
See Appendix 1
1.5 Affected batch numbers
All batches which have been placed on the market
1.6 Associated product(s)
N/A

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

2.1 Description of the possible malfunction

A significant number of complaints was reported describing issues during the deployment phase of the PAS-PORT Proximal Anastomosis System. The deployment phase is defined as the steps after loading of the venous graft until the proximal anastomosis is successfully completed.

The market feedback indicates problems at different steps during the deployment phase: Either at the aortotomy step i.e. aortotomy only or incomplete or unsuccessful, or problems with the implant formation or anastomosis were stated, i.e. the implant did not deploy successfully, was dislodged from the aorta or had to be removed because of uncontrolled bleeding from the implant site or the anastomosis was incomplete.

2.2 Reason for initialization of this FSCA

The main hazard for patients arising from the described possible malfunction is the necessity of an additional medical intervention resulting in a potential surgery delay. The severity to the patient is rated as serious. The actual occurrence rate is 1,14 %.

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

2.3 Root cause analysis

The root cause could not be determined. A systematic and cross-batch problem was identified.

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). Please identify the affected products at your side and return them to Aesculap AG by using the return form (Appendix 3) attached. Please take care that the return form (Appendix 3) is always returned together with the returned products.

Please confirm the understanding of this urgent field safety notice by returning the feedback form (Appendix 2) **until 7th June 2021**.

3.2 Special considerations for already treated patients

There are no additional follow-up measures for already treated patients required.

This FSCA 255 shall be completed within the next 15 months.

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

For product related questions:

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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 urgent field safety notice.

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 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,

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

Appendix 1 – affected products

Product Name	Catalogue number / product model
PAS-PORT PROXIMAL ANASTOMOSIS SYSTEM	FC700SU
PAS-PORT PROXIMAL ANASTOMOSIS DEVICE US	FG-000001-13
PAS-PORT PROXIMAL ANASTOMOSIS DEVICE	FG-000001-14