Aesculap AG
Quality Management

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Date: 22nd March 2021

Urgent Field Safety Notice

Product Group(s):

- Retrieval Bags
- Suction - Irrigation Instruments Single Use
- Suction - Irrigation Instruments Reusable

Product Name: see below

Internal Reference Number: FSCA 254

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

1. Information on affected products

1.1 Product

Catalogue number / product model	Product Name	Product Group
EJ022SU	RETRIEVAL BAG W/MEMORY WIRE 210ML	Retrieval Bags
EJ023SU	RETRIEVAL BAG SMALL DETACHABLE 260ML	
EJ024SU	RETRIEVAL BAG LARGE DETACHABLE 720ML	
PG032SU	MONOP.SUCT./IRRIG.HOOK L-TYPE 5/340MM	Suction - Irrigation Instruments Single Use
PG033SU	MONOP.SPATULA SUCT/IRRIG.ELECTR.5/340MM	
PG042SU	SINGLE USE SUCT.IRRIG.CANNULA 5/330MM	
PG043SU	SINGLE USE SUCT.IRRIG.CANNULA 5/450MM	
PG038R	SUCT./IRRIG.TUBE 5/330MM W.IRRIG.HOLES	Suction - Irrigation Instruments Reusable

1.2 Primary Intended Use

Retrieval Bags:
The retrieval bag is a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.

Suction - Irrigation Instruments Single Use:
The single use electrode is used during laparoscopic procedures for suction and irrigation of fluid through one instrument.
In addition monopolar current can be applied to tissue for coagulation and cutting.

Suction - Irrigation Instruments Reusable:
The reusable suction/irrigation tube is used instead of the single-use suction/irrigation tube in conjunction with the single-use suction/irrigation system PG036SU/PG037SU (TA012117) in laparoscopies for suctioning or irrigation of fluids from/into the abdomen

1.3 Catalogue number / product model

See Appendix 1

1.4 Associated product(s)

N/A

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

2.1 Description of the possible malfunction

The affected products were incorrectly marked with a CE mark from "TÜV SÜD Product Service GmbH" (CE0123) and "Aesculap AG" as the legal manufacturer.

The product functionality is not affected by this mislabeling.

2.2 Reason for initialization of this FSCA

CE mark was applied without valid declaration of conformity.
There is no potential hazard to patients due to the error described. The mislabeling only affects a limited number of batches produced (see Appendix 1).

The expected risk for patients, users and third parties is therefore rated as acceptable.

2.3 Root cause analysis

The root cause of the incorrect labeling is a manual error in the internal approval process.

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 3rd May 2021**.

3.2 Special considerations for already treated patients

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

This FSCA 254 shall be completed within the next 12 months.

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

For product related questions:

[redacted]

Senior Product Manager
Global Marketing MIS
☎+ 49 7461 95 - 2594
[redacted]

For related questions to this security information:

[redacted]

Vigilance Manager
Quality Management
☎+ 49 7461 95 - 31873
[redacted]

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,

Aesculap AG

i.V.

[redacted]
Safety Officer

i.V.

[redacted]
Director Post Market Surveillance

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

Appendix 1 – affected products

Catalogue number / product model	Batch number
EJ022SU	8252012055
	8252102049
	6252005011
	6252008057
EJ023SU	8252011035
	8252012271
	6252005012
	6252005013
	6252010055
EJ024SU	8252011058
	8252012273
	6252005014
	6252008059
PG032SU	6492006041
PG033SU	6492008001
PG038R	1372009030*
	1372011013*
PG042SU	8382011166
	8382011067
	8382011068
	8382012060
	8382012270
	8382101060
	6382006043
	6382008054
	6382009082
	6382009112
	6382009120
	6382010059
PG043SU	8382011056
	8382011165
	8382012201
	8382101100
	6382006044
	6382009113
	6382009121
	6382010060
	6382008045

* Batch number not identifiable on product packaging