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Aesculap AG
Quality Management

P.O. Box 40
78501 Tuttlingen
Germany

Contact: Manuel Hechtle

Phone: 07461 95-31948
Fax: 07461 95-1555
E-mail: vigilance_aag.de@aesculap.de
Internet: http://www.aesculap.de

Date: 18 December 2019

Security information

Product: PL730SU
Product name: CAIMAN Vessel sealing instrument, 240 mm working length, diameter 12 mm, muzzle length: 50 mm, sterile, disposable

Aesculap AG received customer feedback that a pin can loosen and fall out of the instrument for the mouth pieces of PL730SU, CAIMAN vascular sealing instrument (Figure 1). The error could be limited to the mentioned product.

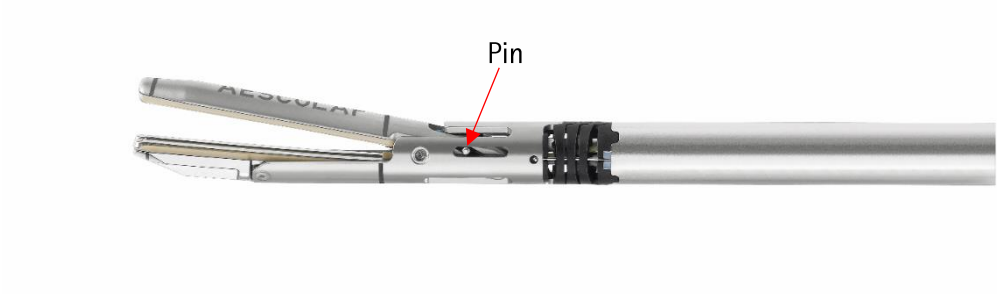

Fig. 1: Position of the affected pin.

The pin potentially dissolves only with a fully opened mouth part. A loosened pin results in the function of the instrument no longer being given. If the pin loosens during application, this can be noticed by the missing function of the instrument. Instruments that did not show any abnormalities during clinical use are not affected by the market measure. The above error pattern may also occur during transport. The pin lying loosely in the transparent packaging can be detected.

After our research, you have received articles of the affected product. Please check if such products are in your facility in the application.

If you have been able to locate an affected product in your organization, please send the product to:

Aesculap AG
LRP
Siegfried Schwarz
At Aesculap Square
D-78532 Tuttlingen

In this case, you will receive a credit from us.

You have not been able to locate an affected product:

If you **do not have** an affected product, please send us the attached **feedback form** completed.

If you have **any questions** about the **product**, please contact our product management. Please contact:

Aesculap AG
LAP
Markus Bauer
At Aesculap Square
D-78532 Tuttlingen
Phone: +49 7461 95-31266
Email: markus.bauer@aesculap.de

Please ensure that all users of the affected product are informed about this safety information in your organization. If you have distributed the products to a third party, please forward a copy of this information or inform the above mentioned contact person. The Competent Authority BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte, has received a copy of this safety information.

We apologize for any inconvenience this may cause and thank you very much for your support.

Yours sincerely

Aesculap AG

i.V.

Thorsten Barthelmes
Safety Officer Medical Devices
Director Quality Management Project

i.V.

Dr. Berenice Heid
Risk Manager
Quality Management Validation and Risk Management

REGISTRATION FORM

Field Safety Corrective Action

PL730SU – CAIMAN Vascular sealing instrument, 240 mm, inert. 12 mm, muzzle length: 50 mm, sterile, disposable

Please send back this feedback form via fax or e-mail to:

Department QMV

Fax +49 7461-95 1555

vigilance_aag.de@aesculap.de

☐ We do not have affected product(s).

☐ We will return affected product(s).

HOSPITAL _____ LOCATION _____

NAME _____ DEPARTMENT _____ PHONE _____

SIGNATURE _____ DATE _____