Safety Notice – Product Recall

PL770SU – CAIMAN MARYLAND NON ARTICULAT.D5/360MM – BATCH 52481830

During the course of post-market surveillance, Aesculap AG received feedback that during an operation with a CAIMAN MARYLAND NON ARTICULAT.D5/360MM - PL770SU no acoustic warning signal was triggered despite the fact that the coagulation cycle was not successfully completed.

The complaint analysis revealed a deviation from the product specification that occurred during the production process of a specific batch (52481830). A non-compliant component has been installed in the jaw section of the device. Due to the resulting deviation from the specification, the jaw no longer closes flush. The failure could be limited to batch 52481830.

According to internal distribution tracking you have received articles of the affected batch. Please check if such products are in use in your facility. The identification of an affected product can be clearly carried out via the label on the sterile blister (see Figure 1 REF and LOT encircled in green).

Due to the deviation from the product specification there is the possibility that insufficient coagulation might lead to intraoperative or postoperative bleeding.

Figure 1: Label sterile blister PL770SU of affected batch 52481830
In case you have located an affected product:

Please ensure that these products are no longer used.

Should you have a affected product, please return it with the attached "Product Recall Form" to:

Aesculap AG  
LRP  
Siegfried Schwarz  
Am Aesculap-Platz  
D-78532 Tuttlingen

For any product-related requests, kindly do not hesitate to contact our product manager:

Markus Bauer  
📞 + 49 7461 95 31266  
📞 + 49 151 61 31 19 44  
markus.bauer@aesculap.de

In case you could not locate any affected product:

In the case you do not have an involved product, please send us the attached "Feedback Form" and tick as appropriate.

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.

With best regards,

Aesculap AG
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 ________________
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<thead>
<tr>
<th>pos. no.</th>
<th>part no. / article no.</th>
<th>serial / lot-no.</th>
<th>quantity</th>
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**RETURN ADDRESS:**

Aesculap AG  
LRP  
Siegfried Schwarz  
Am Aesculap-Platz  
D-78532 Tuttlingen - Germany

**ADDRESS / SENDER:**

**DATE / SIGNATURE:**