

Tuttlingen, 06.10.2023

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Geschäftsführer
Peter Lazic

Gerichtsstand Tuttlingen
Amtsgericht Stuttgart
HRB 450606

Steuer-Nr. 21118/20403
USt-IdNr. DE213344752

Reportable Event – Removal

Dear ladies and gentlemen,

we would like to inform you about a reportable event.

On 20.09.2023 we have received knowledge of a complaint, which represents a reportable event.

Affected by this notification is the D-Clip applier with the article number 35.411 with the batch number W591456.

The notification to the German Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) was made on Thursday, 05.10.2023. An initial notification was made. No further investigation results are available yet.

In the present case, a D-clip was applied with the above-mentioned applier. When attempting to detach the applier from the D-clip, the jaw of the applier became entangled with the end of the clip, where the applier is positioned. This prevented the clip from being released from the applier.

This could have led to a serious deterioration in the state of health.

The appliers with the article numbers 35.410, 35.411 and 35.412 are also affected by this event. As this is a critical risk, all rigid D-Clip appliers with article numbers 35.410, 35.411 and 35.412 are being recalled.

Please inform your customers about the recall and immediately arrange the return shipment of the D-Clip appliers with the article numbers 35.410, 35.411 and 35.412.

Please check country specific regulations and/or laws if you have to report in your country as well.

Please let us know where you have to report and which further information is required.

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If you have any questions, please contact one of the PRRCs below.

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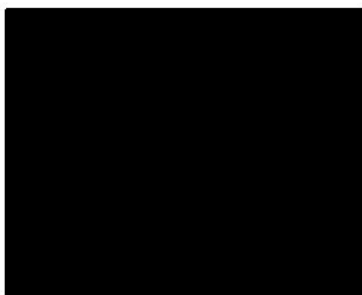
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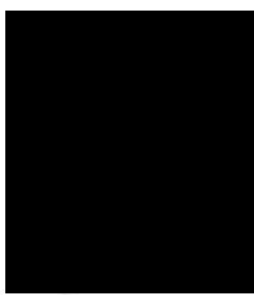
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Please return the items for the attention of one of the PRRCs to ensure quick processing and assignment to the case.



Executive Vice President
Quality Management Representative / PRRC



Quality Management / Regulatory Affairs
PRRC / Deputy Quality Management
Representative