BioBall® System
Merete® Innovative Hip Solutions

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[redacted]

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URGENT: MEDICAL DEVICE RECALL
PediatrOS RigidTack

Dear [redacted],

Purpose of this urgent notice

The purpose of this urgent notice is to advise you that Merete is voluntarily recalling a specific LOT of RigidTack Staples. PediatrOS RigidTack staples are intended to be used for pediatric patients (children/ adolescents) with leg length discrepancies.

Merete received one report from a customer that the labeling on the following product:

article number: CP20120

LOT: MS2117816

is inconsistent and could be misleading while choosing the correct implant size intraoperatively. Since the use of a wrong size staple could result in a serious injury Merete is voluntarily recalling this LOT to avoid it. According to our information you received one or more staples of the specified LOT. We therefore request you to read this urgent notice carefully and confirm its receipt via the attached Acknowledgement and Receipt Form.

Currently no serious injury by this product/ LOT is reported to Merete.

The FDA is informed about this recall.

Reason for the Voluntary Recall:

Merete has been informed by one customer that the labeling on the product is inconsistent. On the product packing two labels are affixed. One label is the product label. This product label is intended to give necessary information to identify the product (article number, LOT, UDI, size etc.) and its status (sterilization status, use by date etc.). The other label is a graphical marketing label which is intended to set a reference to the product family and give a picture of the general use area. Both labels include a size reference. For this specific LOT the product label is correct and indicates the RigidTack staple to be of size "20 mm". Other than this the marketing label indicates the product to be a size "25 mm" staple. The marketing label is incorrect. An example, showing the correct product label and the incorrect marketing label, is given in the following:

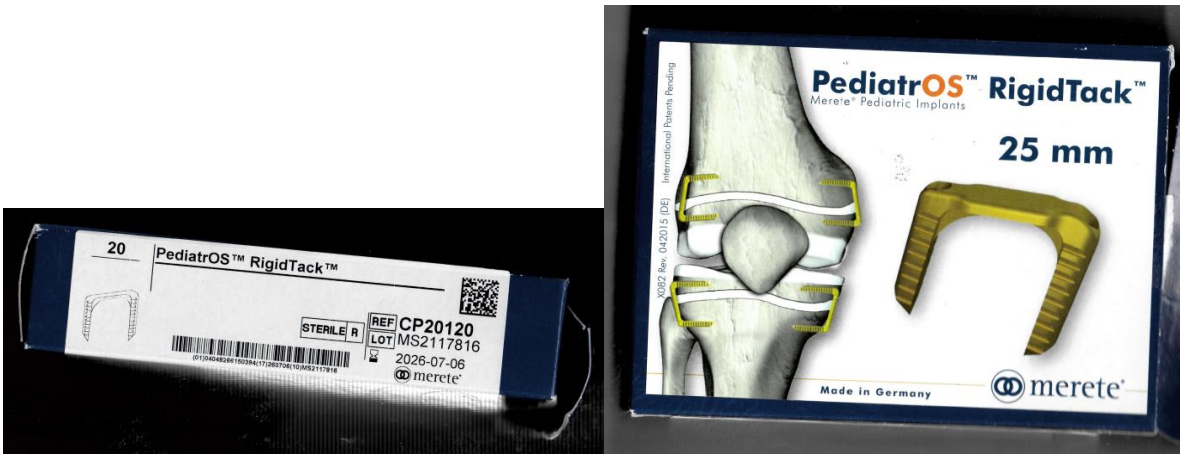

Photo of the correct product label (on the left side) and the incorrect marketing label (on the right side)

We are aware of one report including one product of this LOT. The discrepancy was identified prior to implantation and the staple was not used.

Internal checks have shown that the complete LOT is affected by this issue. Furthermore, those checks identified that this is the only affected LOT.

Consultation of users have shown that some staples of the LOT have already been implanted. In any of those cases the correct staple was used as intended (staple size 20 mm was intended and implanted).

Risk to Health:

In cases in which the user intends to implant a size 25 mm staple and choses the implant by the size given on the marketing label this would lead to implant a 20 mm staple while a 25 mm staple was intended to be used. The implantation of a wrong sized (to small (size 20 mm instead of 25 mm)) staple could damage the epiphyseal cartilage.

Actions to be taken by the Customer/User:

To avoid further use of the defective products, we request you to do the following:

1. Read this urgent notice carefully.
2. Check if the devices are in your stock .
3. Quarantine the device.
4. Send the device back to Merete while clearly indicating them with "Caution: recalled products".
5. Please make sure that all users of the products as well as any other persons within your organization who needs this information are aware of this urgent notice. In case you provided the products to third parties please forward a copy of this urgent notice.
6. Confirm the acknowledgement and receipt of this urgent notice with the attached form.

Information for end users / surgeons:

1. Read this urgent notice carefully.
2. Check if the devices are in your stock.
3. Quarantine the device.
4. Send the device back to Merete or its distributor while clearly indicating them as "Caution: recalled products".
5. If you have implanted devices of this LOT check the surgery records, if it was intended to use a RigidTack of size 20 mm. Please also verify that the staple is adequately positioned surrounding the epiphyseal cartilage.
6. Confirm the acknowledgement and receipt of this urgent notice with the attached form.

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Product and Distribution Information:

This voluntary recall includes the following products:

article number: CP20120

LOT: MS2117816

According to our information you have been provided with 17 devices of this LOT on October 14, 2021.

Type of Action by the Company:

After receiving of the products, they will be re-worked and the labels will be corrected. This will be done after receiving all devices from the LOT. Please be aware that this could take some time. If you need replacements on a short term basis please note this within the response form.

OTHER INFORMATION:

If you have any questions relating to this urgent notice, please contact us immediately. In those cases please contact:

[redacted]

Authorized by:

[redacted]

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MEDICAL DEVICE RECALL RETURN RESPONSE

Acknowledgement and Receipt Form

Response is Required

Customer Information:

[redacted]

PediatrOS RigidTack

Lot/Serial numbers: CP20120, MS2117816

I have read and understand the recall instructions provided on January 27th, 2022 urgent notice.

☐ Yes

☐ No

For distributors:

☐ We have all devices in stock and quarantined them.

☐ We have supplied products of this LOT to following customers. The Field safety Notice has been forwarded to them:

Customer	Contact data (name/ organizationadress, telephon,Fax, e-mail)	Date of delivery	quantity	Information forwarded on (date)

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For surgeons/ end-users:

☐ We have all devices in stock and quarantined them.

☐ We have ____(specify quantity) devices in stock. We have ___ (specify quantity) devices implanted

If implanted:

Any adverse events associated with recalled product?

☐ Yes

☐ No

If yes, please explain:

_____

_____

_____

_____

Name/Title	
Date	
Telephone	
Email address	
Signature	

PLEASE FAX COMPLETED RESPONSE FORM TO: +49 (0)30 77 99 80 - 177

OR MAIL TO: safety@merete.de