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Gebrüder Martin GmbH & Co. KG
Operational Product Management
Implant-Systems

19.05.2017 ts
Thomas Samyn

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Urgent safety information for users

Corrective measure

Product exchange: Ixos[®] P4 Wave | Article number: 26-914-21-09 | LOT: 61503126

Dear Sir or Madam,

In the course of global market observation, a case concerning our Ixos[®] radius plating system was reported to Gebrüder Martin GmbH & Co. KG by a user: The radius fracture plate Ixos[®] P4 Wave 26-914-21-09, LOT 61503126, was wrongly laser-marked with the incorrect article number 26-914-10-09.

In order to prevent the risk of confusion arising therefrom, the batch concerned will be recalled and exchanged as a precaution.

Measures to be taken

- Please make sure that all users of the above mentioned article and other persons to be informed will be briefed on this safety information.
- Please check your inventory immediately and close the further use of the affected article 26-914-21-09 with the batch number 61503126.
- Please return all of the affected articles 26-914-21-09 with the batch number 61503126 for free exchange to the following address:

Gebrüder Martin GmbH & Co. KG
Complaint Handling
KLS Martin Platz 3
78532 Tuttlingen
Germany

- Please submit the attached fax / e-mail response (Appendix 2) for documentation of this safety information returned to us within 14 days. This prevents us from sending you additional messages on this case unnecessarily.


1 / 2

If you have any questions, please do not hesitate to contact Ms. Anja Kohler, Operational Product Management Implant-Systems at +49 7461 706-301.

We apologize for the inconvenience caused by this action but we see it as preventative measure in the interests of patient safety. Thank you for your cooperation.

Kind regards

Gebrüder Martin GmbH & Co. KG
A Company of the KLS Martin Group

i.V. 

Thomas Samyn
Director Product Management
Implant-Systems

i.V. 

Reinhold Bücher
Head of Quality Management/
Safety Officer Medical Devices

Appendixes:

Annex 1: Overview received deliveries

Annex 2: Fax / E-Mail reply

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Annex 1

Overview received deliveries

Article 26-914-21-09 | LOT 61503126

Quantity	Delivery note - number -	Delivery note - date -
1	80859621	06.10.2016

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Annex 2

Fax reply at +49 7461 706-350 || E-Mail reply to Anja.Kohler@klsmartin.com

Customer: _____

Customer number: _____

Herewith, we confirm:

- the receipt of the letter "Urgent safety information for users" of Gebrüder Martin GmbH & Co. KG from May 2017 with the attachments 1 and 2.
- the statement below including information regarding the inventory check of the Ixos® P4 Wave plate – article number 26-914-21-09 | LOT 61503126.

Please tick the appropriate box:

The affected article 26-914-21-09 | LOT 61503126 is no longer in our inventory. Therefore, an exchange is not possible anymore.

The affected article 26-914-21-09 | LOT 61503126 is part of our inventory with the following quantity _____. We will send this quantity to the address given. We kindly ask you for an exchange free of charge.

Place, Date:	
Name / Position of the signatory:	
Company / Stamp and signature:	