

**CUSTOMER
NAME
STREET No.
ZIP-CODE, PLACE**

Urgent Safety Notice
Recall
concerning the
sterile cannulated screw

Berlin, July 27th, 2018

Reference-No.: CAPA 2018 - 015
Sender: aap Implantate AG, Lorenzweg 5, 12099 Berlin, Germany
Recipient: User, Head of Orthopedic Surgery, Head of Orthopedics; Clinical
Director, CEO, Sales Partner

Identification of medical devices affected:

Medical device: Osteosynthesis, trauma implant
Product description: Find annex A

Product number: Find annex A
Lot code: all lots

Dear customer,

we would like to inform you about particular circumstances relating to sterile cannulated screws (see annex A).

Description of the problem including the identified cause:

Background for the corrective action including the description of the product problem

The aap Implantate AG induces a recall of unused sterile packed cannulated screws with product numbers as mentioned in annex A. All batches are involved.

The concerned sterile cannulated screws have been marketed with a sterile barrier system and an outer packaging. The sterile barrier system of cannulated screws is manufactured by a combination of an inner and outer Blister and each Blister is sealed with a foil. Inside of the primary package there are inlays which lock the cannulated screw and fasten it. Within the framework of a customer complaint of sterile cannulated screws the aap Implantate AG detected, that for the sterile barrier system of the affected products a damage or deterioration of the sterile packaging (Tyvek-foil of the primary- and or secondary package) can be caused in unfavorable cases through loosen inlays and or a loose screw. A loose inlay represents a deviation from the specification, resulting in a malfunction with a change in performance. Observations show that the malfunction is due an increased force effect on the packaging. In addition, a loose inlay and or a loose cannulated screw may cause damage to the Tyvek foil, which means that the sterility of the product can no longer be guaranteed. Implantation of unsterile products can lead to infection. Infections can undesirable impair the healing process and the patient's well-being. The aap Implantate AG has decided to recall all unused sterile cannulated screws (see annex A) due to the recognition of a malfunction which is accompanied by a change in performance.

Risk for patients, users and third parties in case of further usage of the product, including evaluation of risks

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| high probability | The sterility of the outer and inner sterile barrier system is not impaired, because the products marketed are with a very high probability <u>not</u> to be exposed to the observed force. |
| Risk | No short-term health consequences (injury or illness), that result from the application of the concerning products or rather by their exposure. |
| | No long-term health consequences (injury or illness), that result from the application of the concerning products or rather by their exposure. |
| Evaluation | The manufacturer has a complaint from the market which shows a connection with the problem described. Therefore, the occurrence probability of damage to the sterile barrier systems is very low. The product associated with the complaint was not used for an implantation. |

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| Low probability | The inner sterile barrier is impaired, the outer sterile barrier is still intact. The sterility of the product stays intact during handling in the sterile surgical area. |
| Risk | No short-term health consequences (injury or illness), that result from the application of the concerning products or rather by their exposure. |
| | No long-term health consequences (injury or illness), that result from the application of the concerning products or rather by their exposure. |
| | The damaged inner barrier cannot lead to the non-sterility of the product, because the outer barrier remains intact. |
| Evaluation | Due to the intact outer sterile barrier system, the implant remains sterile. The risk of infection of the patient is therefore unlikely to be assessed. |

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| Very low probability | The inner and outer sterile barrier system is impaired. The defective sterile barrier system can transmit the sterility of the product. |
| Risk | Short-term health consequences can be wound infection, that require a treatment beyond the standards of care. |
| | Long-term health consequences can be infections, that lead to a revision surgery, unless the infection can be fought alternatively. |
| Evaluation | The probability of non-sterility of the product is classified as very low, because this sterile barrier system has been used in the market for several years and so far, there has been one complaint. Besides that, surgeons are using antibiotics during and after surgery to reduce a potential risk of infections. |

Risk for patients, that were treated with concerning products, including evaluation of risks

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| high probability | The sterility of the outer and inner sterile barrier system is not impaired, because the products marketed are with a very high probability <u>not</u> to be exposed to the observed force. |
| Risk | No short-term health consequences (injury or illness), that result from the application of the concerning products or rather by their exposure. |
| | No long-term health consequences (injury or illness), that result from the application of the concerning products or rather by their exposure. |
| Evaluation | The manufacturer has a complaint from the market which shows a connection with the problem described. Therefore, the occurrence probability of damage to the sterile barrier systems is very low. The product associated with the complaint was not used for an implantation. |

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| Low probability | The inner sterile barrier is impaired, the outer sterile barrier is still intact. The sterility of the product stays intact during handling in the sterile surgical area. |
| Risk | No short-term health consequences (injury or illness), that result from the application of the concerning products or rather by their exposure. |
| | No long-term health consequences (injury or illness), that result from the application of the concerning products or rather by their exposure. |
| | The damaged outer peel pouch can lead to unsterility of the inner peel pouch. A contamination of the sterile area can occur during transfer from unsterile area into the operating area. |
| Evaluation | Due to the intact outer sterile barrier system, the implant remains sterile. The risk of infection of the patient is therefore unlikely to be assessed. |

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| Very low probability | The inner and outer sterile barrier system is impaired. The defective sterile barrier system can transmit the sterility of the product. |
| Risk | Short-term health consequences can be wound infection, that require a treatment beyond the standards of care. |
| | Long-term health consequences can be infections, that lead to a revision surgery, unless the infection can be fought alternatively. |
| Evaluation | The probability of non-sterility of the product is classified as very low, because this sterile barrier system has been used in the market for several years and so far, there has been one complaint. Infections due to product or operation area emerge with high possibility within 3 month after implantation of the product. |

What actions does the recipient now need to implement?

Please take the following actions without delay:

1. Please immediately remove all products (see Annex A) from your stock to ensure that they can not be used.
2. With this letter you will receive a confirmation form, please complete it completely, sign it and send it back to us after receiving this information. If you do not have any affected products, please fill out the confirmation form and fax it to 0049 (0) 30 750 19 111 or mail it to incident@aap.de.
3. Please return all affected products immediately to us.

Recommendation for patients or treatment/aftercare of patients, which were treated with potentially concerned products

The general risk of non-sterility of the concerned products is considered as very low. Reasons for this are given on the one hand by using a double sterile packaging, by which sterility is still ensured even if one foil is damaged. In the extremely unlikely event of unsterile implant application this might lead to an infection of patient which, consequently, makes an appropriate treatment necessary. Infection that could be caused by unsterile implants would be at short-term visible in shape of an inflammation that ought to be immediately responded to. However, if no correlating sign emerges after 8-10 weeks clinic, the risk to patient with regards to an implant issue can be classified as very low.

Forwarding the safety notice:

1. Please ensure that all users of the specified products in your organization and all other applicable persons receive notification of this **"Urgent Safety Notice"**. If the products have been transferred to third parties, please forward a copy of this safety notice or inform the contact person specified below.
2. Please retain this information at least until all affected products have been returned to us.

The national regulators have been informed of this action.

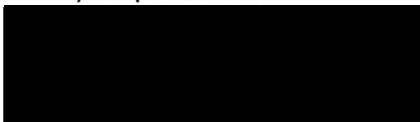
The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Notice".

Contact: Should you have any queries, please do not hesitate to contact:

aap Implantate AG
Lorenzweg 5
12099 Berlin, Germany

Robert Bednarek
Deputy Medical Device Safety Officer
incident@aap.de
Tel. +49 (0)30 750 19 197
Fax +49 (0)30 750 19 175

Yours truly,
aap Implantate AG



Robert Bednarek
QM- Manager & Deputy Director Quality Management

Confirmation of recall of sterile cannulated screws

Please return this form by fax or mail to us immediately, even if you no longer have any stock of the listed product.

- ☐ We confirm the receipt of this information. There is no stock of the product concerned. In the column "Return quantity in pieces" this was noted with the **quantity 0**.
- ☐ We confirm the receipt of this information. There is still stock of the product concerned, which will be collected from us.

Please enclose this form of confirmation of recall of the return.

| Product description | Lot-number | Quantity of <i>aap</i> supplied | Return quantity in pieces |
|---------------------|------------|---------------------------------|---------------------------|
| | all | | |
| | | | |
| | | | |

I confirm the complete examination of our stocks

Clinic: _____

Print Name: _____

Telephone number: _____

Signature/Date/Stamp _____

Please return this form to one of the following addresses:

Fax number: **030/750 19 111**

E-Mail: **incident@aap.de**

Postal address: **aap Implantate AG**
attn: Return Department
Lorenzweg 5
12099 Berlin

Annex A
to FSN sterile cannulated screws

| Model Number | EN – Title |
|---------------------|--|
| SC 7516-05-2S | Cannulated Screw 7.5, L 125, TL 16, sterile, titan |
| SC 7516-06-2S | Cannulated Screw 7.5, L 130, TL 16, sterile, titan |
| SC 7532-05-2S | Cannulated Screw 7.5, L 125, TL 32, sterile, titan |
| SC 7532-06-2S | Cannulated Screw 7.5, L 130, TL 32, sterile, titan |
| SC 7500-06-2S | Cannulated Screw 7.5, L 130, full thread, sterile, titan |
| SC 7500-05-2S | Cannulated Screw 7.5, L 125, full thread, sterile, titan |