aap Implantate AG · Lorenzweg 5 · D-12099 Berlin · Germany

CUSTOMER
NAME
STREET No.
ZIP-CODE, PLACE

Urgent Safety Notice

Recall

concerning the

VarioFit Classic cementfree hip prostheses

Berlin, March 27, 2017

Reference-No.:	CAPA 2017 - 006
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:	Orthopedic prosthesis
Product description:	VarioFit Classic cementfree
Product number:	Annex A
Lot code:	all lots

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Vorstand: Bruke Seyoum Alemu · Marek Hahn | Vorsitzender des Aufsichtsrats: Biense Visser
AG Charlottenburg HRB 64083 | VAT: DE 812 290 416 | Steuernummer: 29/532/00534
Deutsche Bank AG
Konto: 160 350 500 | BLZ: 100 700 00
IBAN: DE19 1007 0000 0160 3505 00 | BIC/SWIFT: DEUTDEBB
Commerzbank AG
Konto: 523 330 900 | BLZ: 100 400 00
IBAN: DE98 1004 0000 0523 3309 00 | BIC/SWIFT: COBADEFF

Dear customer,

we would like to inform you about particular circumstances relating to the VarioFit classic cementless hip prostheses.

Description of the problem including the identified cause:

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

aap Implantate AG induces a recall of unused sterile packed VarioFit classic cementless hip prostheses with product numbers as mentioned in annex A. The concerned VarioFit classic cementless hip prostheses have been marketed with a sterile barrier system and an outer packaging. The sterile barrier system is realized by a combination of an inner and outer sealed peel pouch. Within the framework of the revalidation of transport and single device packaging *aap* Implatate AG has discovered that with regard to the sterile barrier system of the concerning products a damage or deterioration of the sterile packaging in unfavorable cases cannot be excluded. Consequently, the sterility of product can not longer be guaranteed. Implantation of unsterile products can lead to infection. Infections could unwantedly impair the healing progress and patient well-being, which is why the *aap* Implantate AG has decided to recall all sterile VarioFit classic cementless hip prostheses.

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

high probability	Sterility of outer and inner peel pouch is not impaired, because the marketed product is not exposed to the extreme constellation of the transport and packaging validation.
Risk	**No short-term** health consequences (injury or illness), that result form the application of the concerning products or rather by their exposure.
	No long-term health consequences (injury or illness), that result form the application of the concerning products or rather by their exposure.
Evaluation	The manufacture has received no complaints or objections of the market, that indicate a link to the described problem. Therefore the probability of occurrence of sterile barrier system damage is classified as low.

Low probability	Sterility of the outer peel pouch is impaired, but sterility within the inner peel pouch is still intact. Sterility of the product persists while the product is handled and introduced into the sterile area.
Risk	**No short-term** health consequences (injury or illness), that result form the application of the concerning products or rather by their exposure.
	No long-term health consequences (injury or illness), that result form 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	On basis of an intact inner sterile barrier the implant remains sterile. Thus, the risk of a patient's infection is assessed as low. A damaged outer sterile barrier can cause an impairment of the sterile area though, which in turn increases the infection risk of the patient.

Very low probability	Sterility of the outer and inner peel pouch is impaired. The sterility of the product can be compromised by the defective packaging. Due to impairment of the sterile barriers and the handling of the product during introduction into the sterile area the sterility of the product is impaired.
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 unsterility is classified as very low, because this kind of packaging has been used on the market for many years and as yet no relating incidents have occurred. Furthermore, it should be noted that surgeons administer antibiotics intra operative as well as post operative in order to reduce the risk of infection, particularly in matters of heavy soft tissue compression, as is the case with prosthesis implantation.

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

high probability	Sterility of outer and inner peel pouch is not impaired, because the marketed product is not exposed to the extreme constellation of the transport and packaging validation.
Risk	**No short-term** health consequences (injury or illness), that result form the application of the concerning products or rather by their exposure.
	No long-term health consequences (injury or illness), that result form the application of the concerning products or rather by their exposure.
Evaluation	The manufacture has received no complaints or objections of the market, that indicate a link to the described problem. Therefore the probability of occurrence of sterile barrier system damage is classified as low.

Low probability	Sterility of the outer peel pouch is impaired, but sterility within the inner peel pouch is still intact. Sterility of the product persists while the product is handled and introduced into the sterile area.
Risk	**No short-term** health consequences (injury or illness), that result form the application of the concerning products or rather by their exposure.
	No long-term health consequences (injury or illness), that result form 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	On basis of a sterile product provided by an intact inner sterile barrier, a low risk remains that the patient will be infected, nevertheless, by the contaminated sterile area. Infections due to product or operation area emerge with high possibility within 3 month after implantation of the product.

Very low probability	Sterility of the outer and inner peel pouch is impaired. The sterility of the product can be compromised by the defective packaging. Due to impairment of the sterile barriers and the handling of the product during introduction into the sterile area the sterility of the product is impaired.
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 unsterility is classified as very low, because this kind of packaging has been used on the market for many years and as yet no relating incidents have occurred. 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 at damage of one foil, on the other hand based on the fact that no client complaint has ever occurred despite years of usage of this packaging. In the extremely unlikely event of unsterile implant application this might lead to an infection of patient which, consequently, makes an appropriate treatment necessary. Patients that were treated with the concerning products of the recall should therefore be checked in close-knit interval including the monitoring of relevant inflammation parameters, such as erythrocyte sedimentation rate (ESR), C-reaktive protein (CRP) or leucocytes. Infection that could be caused by unsterile prostheses 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 Safty Notice".

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

aap Implantate AG
Lorenzweg 5
12099 Berlin, Germany

Denis Kühn
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

[redacted]

Confirmation of recall of
VarioFit classic cementless hip prostheses

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 *aap* supplied	Return quantity in pieces
VarioFit classic cementless	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 VarioFit Classic cementfree hip prostheses

Model Number	EN
HF 3109-01	VarioFit® Classic cementfree, Size 9 R
HF 3109-02	VarioFit® Classic cementfree, Size 9 L
HF 3110-01	VarioFit® Classic cementfree, Size 10 R
HF 3110-02	VarioFit® Classic cementfree, Size 10 L
HF 3111-01	VarioFit® Classic cementfree, Size 11 R
HF 3111-02	VarioFit® Classic cementfree, Size 11 L
HF 3112-01	VarioFit® Classic cementfree, Size 12 R
HF 3112-02	VarioFit® Classic cementfree, Size 12 L
HF 3113-01	VarioFit® Classic cementfree, Size 13 R
HF 3113-02	VarioFit® Classic cementfree, Size 13 L
HF 3114-01	VarioFit® Classic cementfree, Size 14 R
HF 3114-02	VarioFit® Classic cementfree, Size 14 L
HF 3115-01	VarioFit® Classic cementfree, Size 15 R
HF 3115-02	VarioFit® Classic cementfree, Size 15 L
HF 3116-01	VarioFit® Classic cementfree, Size 16 R
HF 3116-02	VarioFit® Classic cementfree, Size 16 L
HF 3117-01	VarioFit® Classic cementfree, Size 17 R
HF 3117-02	VarioFit® Classic cementfree, Size 17 L
HF 3118-01	VarioFit® Classic cementfree, Size 18 R
HF 3118-02	VarioFit® Classic cementfree, Size 18 L