



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

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

Urgent Safety Notice
Recall
concerning the
sterile Endoprosthetics-Products and Cancellous Screw VarioCup

Berlin, March 15, 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: Annex A

Product number: Annex A
Lot code: all lots

Dear customer,

we would like to inform you about particular circumstances relating to the sterile Endoprosthetics-Products.

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 sterile Endoprosthetics-Products with product numbers as mentioned in annex A. The concerned sterile Endoprosthetics-Products 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 Implantate 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 Endoprosthetics-Products.

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	<p>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.</p>
Risk	<p>No short-term health consequences (injury or illness), that result from the application of the concerning products or rather by their exposure.</p> <p>No long-term health consequences (injury or illness), that result from the application of the concerning products or rather by their exposure.</p> <p>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.</p>
Evaluation	<p>On basis of an intact inner sterile barrier the implant remains sterile. Thus, the risk of a patient's infection is assessed as low.</p> <p>A damaged outer sterile barrier can cause an impairment of the sterile area though, which in turn increases the infection risk of the patient.</p>

Very low probability	<p>Sterility of the outer and inner peel pouch is impaired. The sterility of the product can be compromised by the defective packaging.</p> <p>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.</p>
Risk	<p>Short-term health consequences can be wound infection, that require a treatment beyond the standards of care.</p> <p>Long-term health consequences can be infections, that lead to a revision surgery, unless the infection can be fought alternatively.</p>
Evaluation	<p>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.</p>

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 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 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 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	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-reactive 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 Safety Notice".

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

aap Implantate AG
Lorenzweg 5
12099 Berlin, Germany

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Yours truly,



Denis Kühn
Director Quality Assurance & Regulatory Affairs

**Confirmation of recall of
sterile Endoprosthetics-Products and Cancellous Screw VarioCup**

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 Endoprosthetics-Products and Cancellous Screw VarioCup

Model Number	EN
Mebio Knee Femoral Component	
KE 1010-00	Mebio Knee Femoral Component, small
KE 1020-00	Mebio Knee Femoral Component, medium
KE 1030-00	Mebio Knee Femoral Component, large
KE 1040-00	Mebio Knee Femoral Component, xlarge
TSS Stem	
CS 1100-09-2	TSS Stem M5, Ø9mm, L 100mm
CS 1100-10-2	TSS Stem M5, Ø10mm, L 100mm
CS 1100-12-2	TSS Stem M5, Ø12mm, L 100mm
CS 1100-14-2	TSS Stem M5, Ø14mm, L 100mm
CS 1150-10-2	TSS Stem M5, Ø10mm, L 150mm
CS 1150-12-2	TSS Stem M5, Ø12mm, L 150mm
CS 1150-14-2	TSS Stem M5, Ø14mm, L 150mm
CS 1180-10-2	TSS Stem M5, Ø10mm, L 180mm
CS 1180-12-2	TSS Stem M5, Ø12mm, L 180mm
CS 1180-14-2	TSS Stem M5, Ø14mm, L 180mm
Ball head	
CK 4023-01	Ball head, 1 S, (23/40, short)
CK 4023-02	Ball head, 1 L, (23/40, long)
CK 4222-01	Ball head, 2 S, (22/42, short)
CK 4222-02	Ball head, 2 L, (22/42, long)
CK 4426-01	Ball head, 3 S, (26/44, short)
CK 4426-02	Ball head, 3 L, (26/44, long)
Bipolar head modular	
HA 9328-42	Bipolar head modular, Ø 42 mm, ID 28 mm
HA 9328-44	Bipolar head modular, Ø 44 mm, ID 28 mm
HA 9328-46	Bipolar head modular, Ø 46 mm, ID 28 mm
HA 9328-48	Bipolar head modular, Ø 48 mm, ID 28 mm
HA 9328-50	Bipolar head modular, Ø 50 mm, ID 28 mm
HA 9328-52	Bipolar head modular, Ø 52 mm, ID 28 mm
HA 9328-54	Bipolar head modular, Ø 54 mm, ID 28 mm
HA 9328-56	Bipolar head modular, Ø 56 mm, ID 28 mm
HA 9328-58	Bipolar head modular, Ø 58 mm, ID 28 mm
HA 9328-60	Bipolar head modular, Ø 60 mm, ID 28 mm
HA 9328-62	Bipolar head modular, Ø 62 mm, ID 28 mm
Bipolar head	
HA 9001-42	Bipolar head, self centered, Ø 42 mm, taper 12/14, short
HA 9001-44	Bipolar head, self centered, Ø 44 mm, taper 12/14, short
HA 9001-46	Bipolar head, self centered, Ø 46 mm, taper 12/14, short
HA 9001-48	Bipolar head, self centered, Ø 48 mm, taper 12/14, short
HA 9001-50	Bipolar head, self centered, Ø 50 mm, taper 12/14, short

HA 9001-52	Bipolar head, self centered, Ø 52 mm, taper 12/14, short
HA 9001-54	Bipolar head, self centered, Ø 54 mm, taper 12/14, short
HA 9001-56	Bipolar head, self centered, Ø 56 mm, taper 12/14, short
HA 9001-58	Bipolar head, self centered, Ø 58 mm, taper 12/14, short
HA 9001-60	Bipolar head, self centered, Ø 60 mm, taper 12/14, short
HA 9001-62	Bipolar head, self centered, Ø 62 mm, taper 12/14, short
HA 9002-42	Bipolar head, self centered, Ø 42 mm, taper 12/14, medium
HA 9002-43	Bipolar head, self centered, Ø 43 mm, taper 12/14, medium
HA 9002-44	Bipolar head, self centered, Ø 44 mm, taper 12/14, medium
HA 9002-45	Bipolar head, self centered, Ø 45 mm, taper 12/14, medium
HA 9002-46	Bipolar head, self centered, Ø 46 mm, taper 12/14, medium
HA 9002-47	Bipolar head, self centered, Ø 47 mm, taper 12/14, medium
HA 9002-48	Bipolar head, self centered, Ø 48 mm, taper 12/14, medium
HA 9002-49	Bipolar head, self centered, Ø 49 mm, taper 12/14, medium
HA 9002-50	Bipolar head, self centered, Ø 50 mm, taper 12/14, medium
HA 9002-51	Bipolar head, self centered, Ø 51 mm, taper 12/14, medium
HA 9002-52	Bipolar head, self centered, Ø 52 mm, taper 12/14, medium
HA 9002-54	Bipolar head, self centered, Ø 54 mm, taper 12/14, medium
HA 9002-56	Bipolar head, self centered, Ø 56 mm, taper 12/14, medium
HA 9002-58	Bipolar head, self centered, Ø 58 mm, taper 12/14, medium
HA 9002-60	Bipolar head, self centered, Ø 60 mm, taper 12/14, medium
HA 9002-62	Bipolar head, self centered, Ø 62 mm, taper 12/14, medium
HA 9003-42	Bipolar head, self centered, Ø 42 mm, taper 12/14, long
HA 9003-44	Bipolar head, self centered, Ø 44 mm, taper 12/14, long
HA 9003-46	Bipolar head, self centered, Ø 46 mm, taper 12/14, long
HA 9003-48	Bipolar head, self centered, Ø 48 mm, taper 12/14, long
HA 9003-50	Bipolar head, self centered, Ø 50 mm, taper 12/14, long
HA 9003-52	Bipolar head, self centered, Ø 52 mm, taper 12/14, long
HA 9003-54	Bipolar head, self centered, Ø 54 mm, taper 12/14, long
HA 9003-56	Bipolar head, self centered, Ø 56 mm, taper 12/14, long
HA 9003-58	Bipolar head, self centered, Ø 58 mm, taper 12/14, long
HA 9003-60	Bipolar head, self centered, Ø 60 mm, taper 12/14, long
HA 9003-62	Bipolar head, self centered, Ø 62 mm, taper 12/14, long
BIOLOX forte ceramic ball head	
HA 4001-28	BIOLOX forte ceramic ball head, Ø 28 mm, taper 12/14, short
HA 4002-28	BIOLOX forte ceramic ball head, Ø 28 mm, taper 12/14, medium
HA 4003-28	BIOLOX forte ceramic ball head, Ø 28 mm, taper 12/14, long
HA 4201-32	BIOLOX forte ceramic ball head, Ø 32 mm, taper 12/14, short
HA 4202-32	BIOLOX forte ceramic ball head, Ø 32 mm, taper 12/14, medium
HA 4203-32	BIOLOX forte ceramic ball head, Ø 32 mm, taper 12/14, long
HA 4301-36	BIOLOX forte ceramic ball head, Ø 36 mm, taper 12/14, short
HA 4302-36	BIOLOX forte ceramic ball head, Ø 36 mm, taper 12/14, medium
HA 4303-36	BIOLOX forte ceramic ball head, Ø 36 mm, taper 12/14, long
HA 4401-28	BioloX delta ceramic ball head, Ø 28 mm, taper 12/14, short
HA 4402-28	BioloX delta ceramic ball head, Ø 28 mm, taper 12/14, medium

HA 4403-28	Bilox delta ceramic ball head, Ø 28 mm, taper 12/14, long
HA 4501-32	Bilox delta ceramic ball head, Ø 32 mm, taper 12/14, short
HA 4502-32	Bilox delta ceramic ball head, Ø 32 mm, taper 12/14, medium
HA 4503-32	Bilox delta ceramic ball head, Ø 32 mm, taper 12/14, long
HA 4504-32	Bilox delta ceramic ball head, Ø 32 mm, taper 12/14, x-long
HA 4601-36	Bilox delta ceramic ball head, Ø 36 mm, taper 12/14, short
HA 4602-36	Bilox delta ceramic ball head, Ø 36 mm, taper 12/14, medium
HA 4603-36	Bilox delta ceramic ball head, Ø 36 mm, taper 12/14, long
HA 4604-36	Bilox delta ceramic ball head, Ø 36 mm, taper 12/14, x-long

Ceramic Inlay

AT 4028-35	Ceramic Inlay size 35, BioloX® delta, ball Ø 28
AT 4028-37	Ceramic Inlay Size 37, BioloX® delta, ball Ø 28
AT 4032-39	Ceramic Inlay Size 39, BioloX® delta, ball Ø 32
AT 4032-41	Ceramic Inlay Size 41, BioloX® delta, ball Ø 32
AT 4032-44	Ceramic Inlay Size 44, BioloX® delta, ball Ø 32
AT 4032-48	Ceramic Inlay Size 48, BioloX® delta, ball Ø 32
AT 4032-52	Ceramic Inlay Size 52, BioloX® delta, ball Ø 32
AT 4036-44	Ceramic Inlay Size 44, BioloX® delta, ball Ø 36
AT 4036-48	Ceramic Inlay Size 48, BioloX® delta, ball Ø 36
AT 4036-52	Ceramic Inlay Size 52, BioloX® delta, ball Ø 36

MebioKnee Tibial Component

KE 2010-00	MebioKnee Tibial Component, small
KE 2020-00	MebioKnee Tibial Component, medium
KE 2030-00	MebioKnee Tibial Component, large
KE 2040-00	MebioKnee Tibial Component, xlarge

Modular Shoulder Device

CT 1010-00-2	Modular Shoulder Device M5, standard
CT 1010-01-2	Modular Shoulder Device M5, slim

metal ball head

HA 3001-28	metal ball head Ø 28 mm, taper 12/14, short
HA 3001-32	metal ball head Ø 32 mm, taper 12/14, short
HA 3002-28	metal ball head Ø 28 mm, taper 12/14, medium
HA 3002-32	metal ball head Ø 32 mm, taper 12/14, medium
HA 3003-28	metal ball head Ø 28 mm, taper 12/14, long
HA 3003-32	metal ball head Ø 32 mm, taper 12/14, long
HA 3004-28	metal ball head Ø 28 mm, taper 12/14, x-long
HA 3004-32	metal ball head Ø 32 mm, taper 12/14, x-long
HA 3005-32	metal ball head Ø 32 mm, taper 12/14, xx-long
HA 3006-32	metal ball head Ø 32 mm, taper 12/14, xxx-long

Cancellous Screw VarioCup

SV 6500-25-2	Cancellous Screw VarioCup®, D 6.5mm, L 25mm
SV 6500-30-2	Cancellous Screw VarioCup®, D 6.5mm, L 30mm
SV 6500-35-2	Cancellous Screw VarioCup®, D 6.5mm, L 35mm
SV 6500-40-2	Cancellous Screw VarioCup®, D 6.5mm, L 40mm