aap Implantotc AG Loren,weg 5 D-12099 Berlin Germany

CUSTOMER
NAME
STREET No.
ZIP-CODE, PLACE

Urgent Safety Notice

Recall

concerning the

Varioloc, SM Straight Stem & VarioCup hip prostheses

Berlin, February 25, 2017

Reference-No.:	CAPA 2017 006_1until 006_4
Sender:	*aap* Implantate AG, Lorenzweg 5, 12099 Berlin , Germany
Recipient:	User, Head of Orthopedie Surg ery, Head of Orthopedics; Clinical Director, CEO, Sales Partner

Identification of medical devices affected:

Medical device:	Orthopedie hip prosth esis
Product description:	Variol oc, cemented Varioloc, cement less SM Straight Stem VarioCup
Product number:	Annex A
Lot code:	all lots

Dear customer,

we would like to inform you about particular circumstances relating to the products Varioloc, SM Straight Stem and VarioCup.

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 Variol oc, SM Straight Sterns and VarioCup with product numbers as mentioned in annex A. The concerned hip prosthesis 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 langer be guaranteed. Implantation of unst erile 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 Varioloc, SM Straight Sterns and VarioCups.

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 irnpaired, 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 frorn unsterile area into the operating area.
Evaluation	On basis of an intact inner sterile barrier the implant rernains 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 irnpaired. The sterility of the product can be compromised by the detective packaging Due to irnpairment 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 toa 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 detective 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 complet ely, 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 (O) 30 750 19 111 or mail it to incident@aap.de.
3. Please return all affected products immediately to us.

Forwarding the safety notice:

1. Plea se ensure that allusers of the specified products in your organization and all other applicabie 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 Not ice".

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,

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Confirmation of recall of
Varioloc, SM Straight Stem and VarioCup hip prostheses

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

D We confirm the receipt of this informat ion . There is no stock of the product concerned. In the column "Return quantity in pieces" this was noted with the **quantity 0.**

D 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	auantity of aap supplied	Return quantity in pieces
Varioloc	all		
SM Straight Stem	all		
VarioCup	all		

1 confirm the complet e examination of our stocks

Clinic: _____

Print Name: _____

Telephone number: _____

Sig n atu re/Date/Stamp _____

Please return this form to one of the following addresses:

Fax number : **030/75019 111**

E-M ail : **incident@aap .de**

Postal adres s: ***aap* Implantate AG**
attn: Return Department
Loren zweg 5
12099 Berlin

AnnexA

Item Number	Product Description
	Varioloc, cementless
HG 0406-00-2	Varioloc®, cementless, TiAl6V4 Size 1 -- 6,25mm
HG 0407-00-2	Variol oc®, cementless, TiAl6V4 Size 2 -- 7,50mm
HG 0408-00-2	Variol oc®, cementless, TiAl6V4 Size 3 -- 8,75mm
HG 0410-00-2	Variol oc ®, cementless, TiAl6V4 Size 4 -- 10,00mm
HG 0411-00-2	Varioloc®, cementless, TiAl6V4 Size 5 -- 11,25mm
HG 0412-00-2	Vario l oc ®, cementless, TiAl6V4 Size 6 -- 12,50mm
HG 0413-00-2	Vario l oc ®, cementless, TiAl6V4 Size 7 -- 13,75mm
HG 0415-00-2	Vario l oc®, cementless, TiAl6V4 Size 8 -- 15,00m m
HG 0417-00-2	Variol oc®, cementless, TiAl6V4 Size 10 -- 17,50mm
HG 0420-00-2	Variol oc®, cementless, TiAl6V4 Size 12 -- 20,00mm
Item Number	**Product Description**
	Varioloc, cemented
HG 0306-00	Variol oc®, cemented, CrNi, polished, Size 3 -- 6,25mm
HG 0307-00	Variol oc ®, cem ent ed, CrNi, polished, Size 4 -- 7,50m m
HG 0308-00	Vario l oc ®, cemented, CrNi, polished, Size 5 -- 8,75mm
HG 0310-00	Vario l oc ®, cemented, CrNi, polished, Size 6 -- 10,00mm
HG 0311-00	Vario l oc ®, cemented, CrNi, polished, Size 7 -- 11, 25mm
HG 0312-00	Vario l oc®, cemented, CrNi , polished, Size 8 -- 12,50mm
HG 0313-00	Variol oc®, cemented, CrNi , polished, Size 9 -- 13, 75m m
HG 0315-00	Variol oc®, cemented, CrNi, polished, Size 10 -- 15,00mm
HG 0317-00	Variol oc®, cemented, CrNi, polished, Size 12 -- 17,50mm
HG 0320-00	Variol oc®, cemented, CrNi, polished , Size 14 -- 20,00mm
HG 0306-40	Variol oc®, cemented, CrNi, Size 3 -- 6,25mm
HG 0307 -40	Variol oc ®, cemented, Cr Ni, Size 4 -- 7,50mm
HG 0308 - 40	Variol oc ®, cemented, Cr Ni, Size 5 -- 8,75mm
HG 0310-40	Vario l oc ®, cem ent ed, CrNi, Size 6 -- 10,00mm
HG 0311-40	Vario l oc ®, cemented, CrNi, Size 7 -- 11,25mm
HG 0312-40	Vario l oc®, cemented, CrNi, Size 8 -- 12,50mm
HG 0313-40	Vario l oc ®, cemented, CrNi, Size 9 -- 13,75mm
HG 0315-40	Vario l oc®, cemented, CrNi , Size 10 -- 15,00mm
HG 0317-40	Variol oc®, cement ed, CrNi , Size 12 -- 17,50mm
HG 0320-40	Variol oc®, cemented, CrNi , Size 14 -- 20,00mm

Item Number	Product Description
	SM Straight Stem
HG 0011-06-M	SM Straight Stem, without collar, Cone 12/14, Size 6.5, Length 125
HG 0012-07-M	SM Straight Stem, without collar, Cone 12/14, Size 7.5 , Length 125
HG 0013-10-M	SM Straight Stem, without collar, Cone 12/ 14, Size 10.0, Length 135
HG 0014-12-M	SM Straight Stem, without collar, Cone 12/14, Size 12.5, Length 145
HG 0111-06-M	SM Straight Stem, with collar, Cone 12/14, Size 6.5, Length 125
HG 0112-07-M	SM Straight Stem, with collar, Cone 12/14, Size 7.5, Length 125
HG 0113-10-M	SM Straight Stem, with collar, Cone 12/14, Size 10.0 , Length 135
HG 0114-12-M	SM Straight Stem, with collar, Cone 12/14, Size 12 .5, Length 145
HG 0211-06-M	SM Straight Stem, polished, without collar, Cone 12/14, Size 6.5 , L125
HG 0212-0 7-M	SM Straight Stem, polished, without collar, Cone 12/14, Size 7.5, L125
HG 0213-10-M	SM Straight Stem, polished, without collar, Cone 12/14, Size 10.0, L135
HG 0214-12-M	SM Straight Stem, polished, without collar, Cone 12/14, Size 12.5, L145
HG 1111-06-M	SM Straight Stem, polished, with collar, Cone 12/14, Size 6.5, L125
HG 1112-07-M	SM Straight Stem, polished, with collar, Cone 12/ 14, Size 7.5, L125
HG 1113-10-M	SM Straight Stem, polished, with collar, Cone 12/ 14, Size 10 .0, L135
HG 1114-12-M	SM Straight Stem, polished, with collar, Cone 12/ 14, Size 12 .5, L145
Item Number	**Product Description**
	VariCup
AH 4035-44	VarioCup® 0 44mm for Ceramicinlay 35mm
AH 4037-46	VarioCup® 0 46mm for Inlay 37mm
AH 4039-48	VarioCup® 0 48mm for Inlay 39mm
AH 4039-50	VarioCup ® 0 50mm for Inlay 39mm
AH 4041-52	VarioCup ® 0 52mm for Inlay 41mm
AH 4041-54	VarioCup ® 0 54mm for Inlay 41mm
AH 4044-56	VarioCup ® 0 56mm for Inlay 44mm
AH 4044-58	VarioCup ® 0 58mm for Inlay 44mm
AH 4048-60	VarioCup ® 0 60mm for Inlay 48mm
AH 4048-62	VarioCup ® 0 62mm for Inlay 48mm
AH 4052-64	VarioCup ® 0 64mm for Inlay 52mm
AH 4052-66	VarioCup ® 0 66mm for Inlay 52mm
AH 4052-68	VarioCup® 0 68mm for Inlay 52mm
AH 4052-70	VarioCup® 0 70mm for Inlay 52mm
AH 4052-72	VarioCup ® 0 72mm for Inlay 52mm