

aap Implantate AG - Lorenzweg 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, March 13, 2017

**Reference-No.:** CAPA 2017 006\_1 until 006\_4  
**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 hip prosthesis  
**Product description:** VarioLoc, cemented  
VarioLoc, cementless  
SM Straight Stem  
VarioCup

**Product number:** Annex A

**Lot code:** all lots

Dear customer,

by the letter dated Feb. 25<sup>th</sup> 2017 we have already informed you about an urgent safety notice regarding the voluntary recall of the products VarioLoc, SM Straight Stem and VarioCup hip prostheses. The recall has been initiated due to a not passed laboratory test within the scope of a transport and packaging validation.

In addition we would like to provide more information about the situation in connection with the product recall of concerned products VarioLoc, SM Straight Stem and VarioCup.

**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.

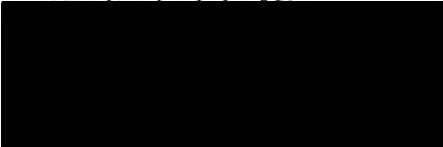
**Contact:**

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

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12099 Berlin, Germany

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Yours truly,



Denis Kühn  
Director Quality Assurance  
& Regulatory Affairs



### Annex A

Item Number	Product Description
	<b>VarioLoc, cementless</b>
HG 0406-00-2	VarioLoc®, cementless, TiAl6V4 Size 1 -- 6,25mm
HG 0407-00-2	VarioLoc®, cementless, TiAl6V4 Size 2 -- 7,50mm
HG 0408-00-2	VarioLoc®, cementless, TiAl6V4 Size 3 -- 8,75mm
HG 0410-00-2	VarioLoc®, cementless, TiAl6V4 Size 4 -- 10,00mm
HG 0411-00-2	VarioLoc®, cementless, TiAl6V4 Size 5 -- 11,25mm
HG 0412-00-2	VarioLoc®, cementless, TiAl6V4 Size 6 -- 12,50mm
HG 0413-00-2	VarioLoc®, cementless, TiAl6V4 Size 7 -- 13,75mm
HG 0415-00-2	VarioLoc®, cementless, TiAl6V4 Size 8 -- 15,00mm
HG 0417-00-2	VarioLoc®, cementless, TiAl6V4 Size 10 -- 17,50mm
HG 0420-00-2	VarioLoc®, cementless, TiAl6V4 Size 12 -- 20,00mm
Item Number	Product Description
	<b>VarioLoc, cemented</b>
HG 0306-00	VarioLoc®, cemented, CrNi, polished, Size 3 -- 6,25mm
HG 0307-00	VarioLoc®, cemented, CrNi, polished, Size 4 -- 7,50mm
HG 0308-00	VarioLoc®, cemented, CrNi, polished, Size 5 -- 8,75mm
HG 0310-00	VarioLoc®, cemented, CrNi, polished, Size 6 -- 10,00mm
HG 0311-00	VarioLoc®, cemented, CrNi, polished, Size 7 -- 11,25mm
HG 0312-00	VarioLoc®, cemented, CrNi, polished, Size 8 -- 12,50mm
HG 0313-00	VarioLoc®, cemented, CrNi, polished, Size 9 -- 13,75mm
HG 0315-00	VarioLoc®, cemented, CrNi, polished, Size 10 -- 15,00mm
HG 0317-00	VarioLoc®, cemented, CrNi, polished, Size 12 -- 17,50mm
HG 0320-00	VarioLoc®, cemented, CrNi, polished, Size 14 -- 20,00mm
HG 0306-40	VarioLoc®, cemented, CrNi, Size 3 -- 6,25mm
HG 0307-40	VarioLoc®, cemented, CrNi, Size 4 -- 7,50mm
HG 0308-40	VarioLoc®, cemented, CrNi, Size 5 -- 8,75mm
HG 0310-40	VarioLoc®, cemented, CrNi, Size 6 -- 10,00mm
HG 0311-40	VarioLoc®, cemented, CrNi, Size 7 -- 11,25mm
HG 0312-40	VarioLoc®, cemented, CrNi, Size 8 -- 12,50mm
HG 0313-40	VarioLoc®, cemented, CrNi, Size 9 -- 13,75mm
HG 0315-40	VarioLoc®, cemented, CrNi, Size 10 -- 15,00mm
HG 0317-40	VarioLoc®, cemented, CrNi, Size 12 -- 17,50mm
HG 0320-40	VarioLoc®, cemented, CrNi, Size 14 -- 20,00mm

Item Number	Product Description
	<b>SM Straight Stem</b>
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 0212-07-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
	<b>VarioCup</b>
AH 4035-44	VarioCup® Ø 44mm for Ceramic Inlay 35mm
AH 4037-46	VarioCup® Ø 46mm for Inlay 37mm
AH 4039-48	VarioCup® Ø 48mm for Inlay 39mm
AH 4039-50	VarioCup® Ø 50mm for Inlay 39mm
AH 4041-52	VarioCup® Ø 52mm for Inlay 41mm
AH 4041-54	VarioCup® Ø 54mm for Inlay 41mm
AH 4044-56	VarioCup® Ø 56mm for Inlay 44mm
AH 4044-58	VarioCup® Ø 58mm for Inlay 44mm
AH 4048-60	VarioCup® Ø 60mm for Inlay 48mm
AH 4048-62	VarioCup® Ø 62mm for Inlay 48mm
AH 4052-64	VarioCup® Ø 64mm for Inlay 52mm
AH 4052-66	VarioCup® Ø 66mm for Inlay 52mm
AH 4052-68	VarioCup® Ø 68mm for Inlay 52mm
AH 4052-70	VarioCup® Ø 70mm for Inlay 52mm
AH 4052-72	VarioCup® Ø 72mm for Inlay 52mm