Urgent Safety Information

RECALL

regarding

VarioFit® Classic (cemented)

all article numbers, all batch numbers

Recall Event ID:	CAPA 010/2014
Date:	September 5, 2014
Sent by:	aap Implantate AG, Lorenzweg 5, 12099 Berlin
Recipient:	users, operating room head of orthopedics, head of orthopedics, clinical directors, managing directors, sales partners

Products concerned.

Medical device:	orthopedic hip implant
Product description:	VarioFit® Classic (cemented)
Product number(s):	HF 3010-01, HF 3010-02 HF 3011-01, HF 3011-02 HF 3012-01, HF 3012-02 HF 3013-01, HF 3013-02 HF 3014-01, HF 3014-02 HF 3015-01, HF 3015-02 HF 3016-01, HF 3016-02 HF 3017-01, HF 3017-02
Batch code:	all batches

Description of problem, including determined cause (to date):

aap Implantate AG is initiating a voluntary recall of all batches of VarioFit® Classic (cemented) products put into circulation to date because they may not comply with all of the specifications.

A chemical analysis of a selection of representative VarioFit® Classic (cemented) hip shafts showed that the steel used in their manufacture has not been approved for implants.

The product has been introduced to the market over the last eight years and implanted in around 900 patients during this time. aap Implantate AG is not aware of any incidents regarding the product.

Reason for recall:

According to the findings to date, the material used by the supplier of the product, possibly since its market launch in 2006, is not in conformance with specifications and therefore not approved for use in surgical implants. A voluntary recall has therefore been initiated as a precautionary measure in order to prevent continued use of the product.

Scope of action:

This recall involves all batch numbers of all VarioFit® Classic (cemented) products placed on the market to date.

Clinical consequences:

According to the present status of ongoing investigations, the hip shafts manufactured with the non-compliant material meet the specified strength requirements. In addition, they do not contain any components which are also not included in materials standardized for use as implant materials.

However, the material identified is ferromagnetic. This must be taken into consideration by patients and physicians with regard to future MRI examinations.

What actions do the recipients need to take?

Immediate action must be taken to bar any existing inventories of VarioFit® Classic (cemented) and ensure that the products are not used for other implantations. In the near future, aap Implantate AG will be contacting all clinics supplied with the product to coordinate collection.

Based on current knowledge, aap Implantate AG does not feel that there is a general indication for prophylactic measures. We recommend that the surgeon contact each patient who has received such a component and discuss all the possible clinical implications and risks (e.g., limitations with regard to future MRI examinations).

Dissemination of this urgent safety information:

This information was sent to you because records indicate that your organization received the VarioFit® Classic (cemented) product concerned.
Please make sure in your organization that all users of the product mentioned above and other relevant individuals have received this **urgent safety information**. If you have provided the product to a third party, please forward a copy of this information or notify the contact person below.

Contact person:
For inquiries, please contact

aap Implantate AG
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This voluntary recall has already been registered with the proper authorities.

Sincerely yours,
aap Implantate AG

Dipl.-Ing. Marc Seegers
Director Quality Assurance
& Regulatory Affairs