CUSTOMER
NAME
STREET, No.
Postal code, TOWN

Field Safety Notice

concerning a field safety corrective action

- Product recall -

Berlin, November 28, 2019

Reference number:	Call no.: 21059783
Recipients:	Users, operators, distributors

Identification of the medical devices affected:

Product category:	Instrument
Trade name:	Soft tissue retractor, radiolucent
Model name:	N/A
Product/catalog no.:	IU 7971-00
Lot number:	All lots

Dear customer,

We are writing to inform you of a recall concerning the soft tissue retractor, radiolucent, the reason for this decision and the corrective actions being taken.

The company has become aware that the soft tissue retractor is not always removed during the sawing process. This can result in damage to the soft tissue retractor in which abrasion debris can develop and remain in vivo.

The biocompatibility of the material of the soft tissue retractor is limited to temporary use. Due to the high risk of the product being used incorrectly (during the sawing process), *aap* Implantate AG has decided to recall the product from the market.

A risk analysis has been carried out to explore and evaluate the residual risks caused by the further use of the product/part affected.

Risks to patients, users and third parties in the event that the product has already been used incorrectly

High likelihood	
Risk	Encapsulation of abrasion debris in the surrounding tissue
Assessment	It can be assumed that following cleaning of the fracture or osteotomy gap, e.g. rinsing with NaCl solution, only a small amount of PEEK material can remain in the fracture or osteotomy gap. There is currently no evidence that encapsulation of abrasion debris has a negative impact on bone healing. This is justified by the fact that, due to the fundamental biocompatibility, any PEEK material that may remain in the body does not have any known negative effects.
Decision	There is no need for action; no negative impact on healing is expected.

Very low likelihood	
Risk	Inflammatory processes caused by abrasion debris
Assessment	No cases are currently known in which inflammatory processes have occurred following the use of the soft tissue retractor. Careful rinsing and suctioning in the surgical field remove a significant proportion of the abrasion debris.
Decision	No special need for action can be derived from this. A check for inflammatory symptoms is generally carried out in the post-operative follow-up.

Please take the following actions immediately:

1. Please immediately remove all products with the catalog number in question from your warehouse or from affected trays to prevent further use.
2. A confirmation form is enclosed with this letter; please fill in, sign it and return it to us after receiving this information. If you have no affected products, **please** fill in the confirmation form **anyway** and fax it to 0049 (0) 30 750 19 111 or email it to incident@aap.de.
3. Please immediately return any products you still have in stock to us.

Forwarding the corrective action:

Please ensure that all users of the affected products within your organization and other persons who are affected receive this information via the Field Safety Notice. If products are passed on to third parties, please also send these third parties a copy of the Field Safety Notice or inform our contact.

Please retain this information until you have returned all affected products to us.

The national authorities are being informed about this FSCA. The Federal Institute for Drugs and Medical Devices has received a copy of this Field Safety Notice.

Please do not hesitate to contact us if you have any questions.

Contact:

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

aap Implantate AG
Lorenzweg 5
12099 Berlin
Germany

Thomas Batsch
Medical Device Safety Officer
incident@aap.de
Tel. +49(0)30-750 19 155
Fax +49 (0)30 750 19 111

Best wishes,

Confirmation form for the recall of the

soft tissue retractor, radiolucent

Please send this form back to us by fax or email immediately, even if you no longer have any of the products listed in stock.

☐ We confirm receipt of this information. We no longer have the product in question in stock. Mark this by writing **Quantity 0** in the "Number of items returned" column.

☐ We confirm receipt of this information. We still have some of the product in question in stock.

Please enclose this confirmation form with the return.

Product name	Lot No.	Quantity delivered by *aap*	Number of items returned
Soft tissue retractor, radiolucent, IU 7971-00			

I hereby confirm that we have checked all of our stocks:

Clinic: _____

Name in block capitals: _____

Telephone number: _____

Signature/date/stamp: _____

Please return this confirmation form to one of the following addresses:

Fax number: **+49 (0)30/750 19 111**
Email: **incident@aap.de**
Postal address: ***aap* Implantate AG, Lorenzweg 5, 12099 Berlin, FAO Goods Received (z. Hd. Wareneingang)**