

For the attention of Surgery Management:

23 March 2017

URGENT SAFETY INFORMATION

RECALL OF A MEDICAL DEVICE

Recall of 7 lots of

"drill bit f.quick coupling,Ø3.2x160,spiral ln 60,quadr.spiral,cann.,inside Ø1.75"

Dear Sir or Madam,

Königsee Implantate has started a voluntary medical device recall for the lots of the " drill bit f.quick coupling,Ø3.2x160,spiral ln 60,quadr.spiral,cann.,inside Ø1.75 " as listed below.

According to our records you may have stock of the item affected.

Identification of the medical device concerned:

This safety information relates to the "drill bit f.quick coupling,Ø3.2x160,spiral ln 60,quadr.spiral,cann.,inside Ø1.75" bearing the article number 2.905.32 in lots listed below:

Designation	Article number	LOT
drill bit f.quick coupling,Ø3.2x160,spiral ln 60,quadr.spiral,cann.,inside Ø1.75	2.905.32	168696
		172155
		172989
		177741
		183254
		186614
		188356

Description of the problem:

With the use of cannulated drill bits 2.905.32 from the LOTs listed above, fraying of the drill bit may occur. This results in an increased risk of injury to the patient and the user, in addition to which, failure of the drill bit may cause an increase in the time required for surgery.

Measures to be taken by customer:

Please make sure within your organization that all users of the a.m. products and other persons involved are informed about this Urgent Safety Information. Check whether you have stock the affected products and take the relevant measures. If the products concerned had been passed on to other institutions, please contact the latter to arrange for the return of the product and make this letter available to them.

If you hold the medical devices concerned, take the following steps:

- Make sure that all employees of your organization involved get informed about the measure.
- Identify and isolate the relevant medical devices to prevent further use.
- Please keep a copy of this letter. Attach a copy of it to the returned goods.
- Fill in the confirmation form (sheet 3 of this letter) and tick that the relevant products have been identified and indicate the relevant lots in the letter. Please add your name, title, address, telephone number and signature. Return this form to us.
- Get in touch with your contact at Königsee Implantate to arrange for the return of the medical devices concerned.

If none of the a.m. products is held by you, please take the following steps:

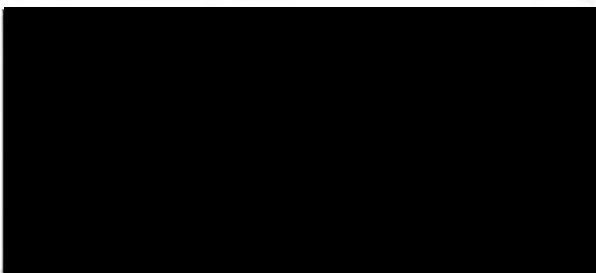
- Fill in the confirmation form (sh. 3 of this letter) and tick that you have got in stock none of the products concerned. Add your name, title, address, telephone number and signature.
- Return this form to us.

The competent authorities have been informed about this measure.

We apologize for the inconvenience caused by this recall and thank you for your cooperation and support.

If you have any questions, please ask your contact of Königsee Implantate.

Königsee Implantate





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Confirmation form

Designation	Article number	LOT
drill bit f.quick coupling, Ø3.2x160, spiral ln 60, quadr.spiral, cann., inside Ø1.75	2.905.32	168696
		172155
		172989
		177741
		183254
		186614
		188356

- We have localized the article concerned at our store. The quantity returned is indicated below. A copy of this letter is kept for our records.
- We no longer have this product. The quantity returned is "0" (zero). A copy of this letter is kept for our records.

RETURNED ITEMS (incl. quantity) and/or COMMENTS:

Clinic /customer no.: _____

Name / Title: _____

Phone number: _____

email address: _____

Date / Signature: _____

Please return this confirmation form to the following address:

Fax number: +49 (0) 36738 498-559

Email: horst.lindner@koenigsee-implantate.de

Postal address: Königsee Implantate GmbH
Herr Horst Lindner
Am Sand 4 / OT Aschau
D-07426 Allendorf