Litos/ GmbH

Urgent Safety Information

Recall

for

core hole drill, midi, Ø=3.3mm, AO

and

core hole drill, maxi/FFS/PFS, Ø=4.3mm, AO

May 19, 2016

From: Litos/ GmbH
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To: Surgeons and Sterilization Departments

Identification of the affected medical devices:

Affected are core hole drills with following article / lot numbers:

- MFK3.3, Lot-number: 2017659
- PFK4.3, Lot-number 2018980

Problem description incl. root cause:

- It may occur that the core hole drills appear to the users as blunt; drilling is possible but progress is slower than comparable drills. The cause is that the tip does not meet specifications.
- The bluntness of the drill can lead to an increased application of drill-pressure. A too high drill pressure can lead to a heat-necrosis at the bone or surrounding tissue.
- It can be assumed that experienced surgeons will notice the reduced cutting/drilling function of the core hole drill; but this cannot be ensured by litos.
- Generally, the drilling procedure is conducted with sufficient cooling water; this has a positive effect regarding the reduced drilling performance of the affected drills; according to these two matters it can be assumed that no patient harm has occurred.
- According to our quality standards we are committed us to deliver our customers products of the highest quality. Since the affected products do not meet this obligation, the litos company has decided to recall the drills.

What actions should be taken by the users?

- Application **stop** of the drills with the relevant lot numbers.
- For the patients where the affected drills have been used, specific recommendations are **not** necessary.
- Please return the drills with the corresponding batches processed back to us by 3rd July 2016.

Disclosure of the information described herein:

Please make sure within your organization, that all users and other relevant persons who use the above mentioned products are aware of this urgent safety information. If you have passed the products to third parties, please forward a copy of this information or inform the below mentioned contact person.

Please keep this information at least until the action has been completed.

The Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this „Important Safety Information".

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