



HEINZ KURZ GMBH
MEDIZINTECHNIK

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Urgent Safety Information

Recall of the medical device

KURZ-PRECISE Cartilage Cutter – Cutting Block REF 8000110 with LOT-No. B21705034

Dusslingen, 13th September 2018

Sender:

Heinz Kurz GmbH, Tuebinger Strasse 3, 72144 Dusslingen, Germany

Recipient:

Ear surgeons / ENT doctors / Otologists / surgical operation assistants

Identification of affected medical devices:

REF	Name	LOT-No.	Note
8000110	KURZ Precise Cutting Block	B21705034	
8000155	KURZ Precise - SET	B21705026	Only REF 8000110 KURZ Precise Cutting Block with LOT-No. B21705034 is affected

Description of the issue and identification of root cause:

Dear customers,

In some KURZ Precise Cutting Blocks REF 8000110 with LOT-No. B21705034 the recess for placing the distance plates is too narrow. This results in an angulated position of the distance plates inside the cutting block. Therefore, the harvested cartilage that is placed on top of those distance plates cannot be cut evenly in thickness and in some cases cutting the cartilage might not be possible at all as the cutting blade could be blocked by the angulated distance plate.

If cartilage is placed and cut on top of an angulated distance plate the resulting piece of cartilage will most likely be wedge-shaped, respectively will not be parallel.

There is no medical risk for patients as the piece of cartilage can be trimmed manually after using the cartilage cutter.

There is no increased risk of injury to users of this product.

Which measures have to be taken by the recipient of this letter?

We kindly ask you to take the following action:

1. Please do no further use the KURZ-PRECISE Cutting Blocks with REF 8000110 and LOT-No. B21705034.
2. Please return all affected KURZ precise cutting blocks, cleaned and sterilized, to Heinz Kurz GmbH via your responsible distributor.

You will receive a replacement device free of charge as soon as possible.

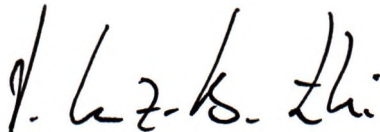
Disclosure of above-mentioned information:

Please ensure that all users of the above-mentioned products and relevant personnel within your organisation are made aware of this urgent safety information.

Should you have provided the product to third parties, please forward a copy of this note to those responsible or contact below mentioned contact person.

Please store this information at least until all measures have been completed.

We apologize for any inconvenience this may cause.



Traute Kurz – Butzki
CEO / Safety officer
Heinz Kurz GmbH

Contact person:

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