

Fuhrmann GmbH · Bövingen 139 · D-53804 Much

Addressee

Contact person:

Name

phone. +49 2245-91 96-33

fax +49 2245-91 96-60

qw@fuhrmann.de

SRN Nummer: CZ-PR-000003742

Date

Urgent safety information– 340425-3 Cartilage Regeneration Accessories Kit

Dear Sir or Madam,

for reasons of patient safety, we have to inform you about the following corrective actions.

Description of the problem

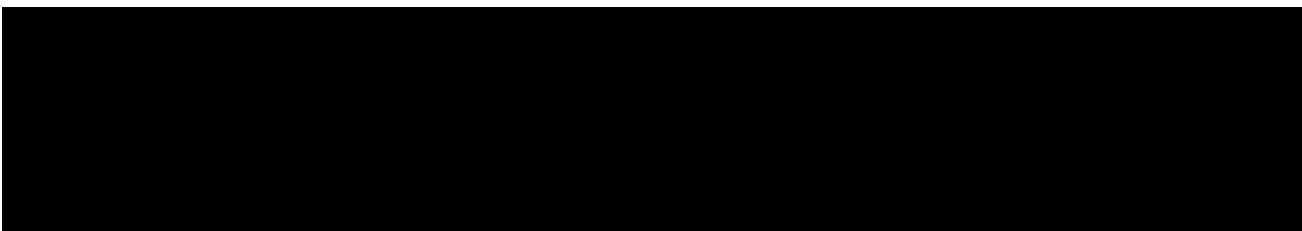
The label of the above mentioned procedure pack (LOT 30130634) indicates a shelf life (02-2024) that is longer than the actual shelf life (10-2022).

Potential hazards and possible risks for patients, users (operators) or third persons

At present there are no risks for patients, because the actual shelf life (31.10.2022) has not exceeded yet and the product can be used until this date. If the procedure packs are used until this date there are no risks for patients, users (operators) or third persons.

The following products that have been delivered to you are affected:

REF	Name	LOT	UDI	quantity delivered
340425-3	Cartilage Regeneration Accessories Kit	30130634	-	



What measures are to be taken by the addressee

1. Please immediately check your stock and immediately isolate the product listed above.
If you have continued to distribute the product that is the subject of this safety information, please identify your other customers and inform the affected customer(s) of this safety information immediately. **If it can be ensured** that the customers concerned have received this safety information and the product will be used before 31.10.2022, it is not mandatory to return the products.
We would like to ask you to monitor and follow up the measures with your customers!
2. Complete the enclosed reply form in full and send it to the above address by post, e-mail, or fax by **Date**.
Please note: Please return the completed reply form even if you no longer have any remaining stocks of the product concerned. Due to legal requirements, we must ensure and document that you have received this information, and your reply serves as proof of this.

Upon receipt of your reply form, you will be contacted by our customer service team to arrange the return and, if necessary, replacement of the affected goods. We will only take back goods from the affected batch (see table above).

Pass on this safety information!

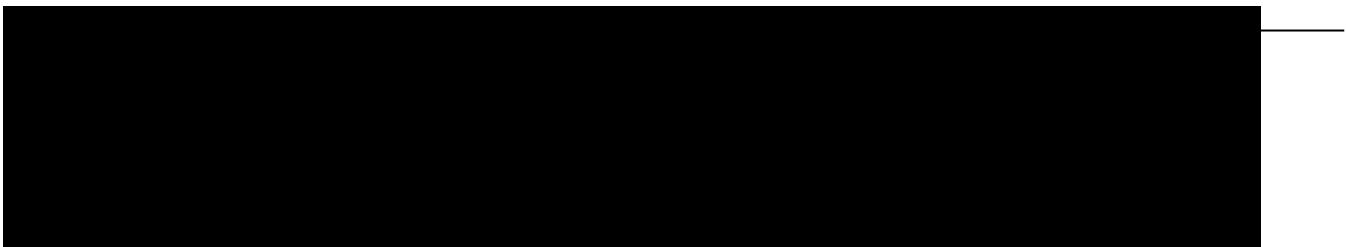
Please ensure that all relevant persons in your organisation are aware of this safety information. After a final assessment, the competent supervisory authority may also be informed about this measure.

We apologise for any inconvenience caused to you in connection with this safety information and thank you in advance for your support to enable this measure to be implemented quickly and effectively.

With best regards

Contact

Person Responsible for Regulatory Compliance according to article 15 MDR



Annex

Urgent safety information– 340425-3 Cartilage Regeneration Accessories Kit

Affected REF/batches see cover letter.

Reply form

Upon receipt of your reply form, you will be contacted by our customer service team to arrange the return and, if necessary, replacement of the affected goods.

(Please tick!)

- We do not have any remaining stocks of the product concerned in stock.
- We have the following number of items in stock (please enter in the table below).
Only goods from the affected batches that are affected by this recall will be taken back or exchanged. Please do not return any goods unsolicited.

REF	LOT	Quantity (please specify number of pieces)

Name of the institution	
Street	
Postcode/ City	
Name of contact person (in block capitals)	
Email	

