



Ortho Select GmbH
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Ortho Select GmbH | Eisenbahnstrasse 100 | 78573 Wurmlingen | Germany

Wurmlingen, 14.11.2019

Urgent Field Safety Notice – RECALL OF MEDICAL DEVICES: Instruments for application on the dura

Dear Sir or Madam,
Dear Customer,

A Our records indicate that you may be affected by this urgent safety information. Therefore, we contact you directly.

As part of an internal audit, we have found that we have sold instruments for use on the dura, with false labeling.

Therefore, we will recall all "Taylor Dura Scissors", "Cushing Dura Hooks", "Frazier Dura Hooks", and "Dura Dissectors" from the market.

With this letter we want to inform you about the following points:

- Identification of affected products and batches
- Description of the problem
- Risks for users and patients
- Corrective Actions of Ortho Select GmbH

If you discover that you have a subsequent product, we kindly ask you to follow the following instructions of this safety information notice.

If you discover that you have forwarded the product(s) to third parties, we kindly ask you to forward this safety information accordingly.

Alternatively, you can inform the below listed contact person in this regard.

Identification of affected medical devices:

Art. No.	Designation
2008-6-1917	SCHMIEDEN TAYLOR Dura Scissors
2018-2-1314	CUSHING Dura Hook 14 cm
2018-2-1413	FRAZIER Hooks (Dura) sharp 13cm
2018-2-1418	FRAZIER Hooks (Dura) sharp
6900-4-1061	Dura Dissectors, double, 22 cm

Affected batches: ALL BATCHES**Description of the problem**

The listed instruments are mislabelled (laser marked) and placed on the market.

This is recognizable by the missing number behind the "CE" sign.

This does not comply with the requirements of the Medical Device Directive 93/42/EEC.

Risks for users and patients

The listed instruments have no other known technical errors that pose a risk for users, patients or third parties.

Corrective Actions of Ortho Select GmbH

As the products listed above are not 100% compliant with the applicable product labeling regulations, we hereby recall all products mentioned which are still on the market.

For this process we ask for your support with the following steps:

1. Please confirm the receipt of the letter by **December 13th, 2019**.
For this purpose, we have prepared an acknowledgment of receipt for you in the attachment.
2. Please check if you have any of the above-mentioned products in possession.
3. If you are in possession of one of the affected instruments, we kindly ask you to note this on the acknowledgement letter with appropriate contact details and to prepare the instruments for pick-up. We arrange the collection and regulate the commercial transaction afterwards.
4. Please keep a copy of the completed form (acknowledgement letter) for your records.



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If you have any questions about the process, please contact the following contact person:

Contact person:

Ortho Select GmbH
Eisenbahnstrasse 100
78573 Wurmlingen
Germany

Mr. Oskar Doering
qm@ortho-select.de
TEL.: +49 (0) 7461-9336 666

We hereby apologize for any inconvenience caused by us and thank you for your cooperation.

Best regards,

Oskar Doering
Manager Quality & Regulatory Affairs
Safety Officer for medical devices

CUSTOMER ACKNOWLEDGMENT

Contact details

Name Customer / Company / Clinic / User	
Contact person E-Mail / Phone	
Address Street, place, country	

I hereby confirm that I have received the urgent field safety notice of Ortho Select GmbH and that I have read, checked and understood all the provided information.

Signature	Name (block letters)	Date
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- a. This is to certify, that NONE of the mentioned instruments are available**
- b. This is to certify, that a listed instrument exists (in my possession)**

Pickup address (only if **b.** is applicable)

Name Customer / Company / Clinic / User	
Address Street, place, country	
Contact person	
Phone No.	
E-Mail Address	

Bitte schicken Sie das vollständig ausgefüllte Formular ELEKTRONISCH an:

incidents@ortho-select.de

Die Ortho Select GmbH bedankt sich für Ihre Unterstützung.