TUTOGEN Medical GmbH • Industriestraße 6 • D-91077 Neunkirchen am Brand

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TUTOGEN Medical GmbH
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Datum: 30.05.2018

Urgent safety information

Type of action:
Checking of stock and return of affected medical devices

Article:
CopiOs Cancellous Particulate Xenograft
LOT: K18796
Date of manufacture 28.02.2018, expiry date 31.01.2023

05/30/2018

Dear user,

We are writing to inform you that some of the “CopiOs Cancellous Particulate Xenograft” that we have delivered to you may be packaged in a folding box with the imprint “Puros Allograft”. This imprint on the folding box therefore does not match the actual contents of the package (“CopiOs Cancellous Particulate Xenograft”). The external label on the folding box, however, does show the correct product name “CopiOs Cancellous Particulate Xenograft”, together with all product-relevant information.

Affected medical device

This issue affects one batch of the “CopiOs” product:

Article number REF	Designation	Batch number LOT
97200	CopiOs Cancellous Particulate Xenograft	K18796 (35 packages)

According to the records available to us, **35** of the “CopiOs Cancellous Particulate Xenograft” product were delivered to you from affected batch K18796.

Description of the problem including the determined cause

In batch K18796 of the “CopiOs Cancellous Particulate Xenograft” product, some folding boxes with the imprint “Puros Allograft” were accidentally used during final processing. The investigation showed that only one batch, batch K18796, is affected. Only the imprint on the folding box is incorrect. The external label on the folding box, however, does correctly show the product name “CopiOs Cancellous Particulate Xenograft”, together with all product-relevant information. The primary packaging also correctly identifies the product as a xenogeneic product, together with all of the relevant and regulatory product information. The documentation sticker to be inserted by you as the user into the patient’s file is also correctly labelled with “CopiOs Cancellous Particulate Xenograft”. The package leaflet is also for the xenogeneic product and is therefore the correct one.

Consequences and risks for users and/or patients

As all other product information is correct, we can assume that the imprint error will be detected before the product is used on the patient.

However, if the correct product-specific label and the label on the primary packaging are overlooked, the fact that the xenogeneic “CopiOs” product is packaged in a folding box imprinted with “Puros Allograft” could lead to a xenogeneic product being used for implantation on the patient instead of the intended allogeneic product. This type of mistake is therefore possible if the user fails to correctly read the correct external label on the folding box, the label on the primary packaging, the instructions for use and the documentation sticker for the patient’s file, and therefore does not realise that the product in the packaging is actually a xenogeneic product. The consequences of an incorrectly used xenogeneic product could be an allergic reaction by the patient in the event of an allergy to bovine collagen. In this case, the corresponding medically indicated measures will need to be taken.

We are absolutely determined to pre-empt any problems such as the above. Therefore, RTI Surgical/Tutogen Medical GmbH has decided to trigger a Field Safety Notice as a precautionary measure, together with a Field Safety Corrective Action (call for a check of stock and product replacement).

This measure only affects the aforementioned batch K18796 of the “CopiOs Cancellous Particulate Xenograft” product.

What actions need to be taken by you, the user?

1. Stop using the “CopiOs Cancellous Particulate Xenograft” product with batch number K18796.

2. Check your stock to see whether you have received any folding boxes with batch number K18796 where there is a discrepancy between the imprint on the folding box (“Puros Allograft”) and the external label on the folding box (product name “CopiOs Cancellous Particulate Xenograft”).

3. If you find products in stock with this discrepancy, please contact our Director of Regulatory Affairs & Compliance Management Dr. Andreas Batna immediately, and send the product with the incorrect imprint on the folding box back to us.

4. If you establish that you have implanted a xenogeneic product instead of the intended allogeneic product as a result of the incorrect imprint on the folding box, observe the patient for any allergic reactions and decide on any further medically indicated treatment measures.

5. Please fill in the confirmation form and send it to the following contact person:

   Tutogen Medical GmbH
   Dr. Andreas Batna
   Tel: +49 (0) 9134 9988-850
   Fax: +49 (0) 9134 9988-55850
   E-Mail: vigilance@rtix.com

Passing on the information in this letter

Within your organisation, please make sure that all users of the products mentioned above and all other persons who need to be informed are made aware of this **“urgent safety information”**. If you have passed on the products to third parties, please forward a copy of this information or inform the contact person specified below.

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

The wording of this “urgent safety information” has been agreed with the German Federal Institute for Drugs and Medical Devices. The German Federal Institute for Drugs and Medical Devices has received a copy of this “urgent safety information”. The relevant regulatory authorities in your country have also been informed about this Field Safety Corrective Action.

Contact person
Our Director of Regulatory Affairs & Compliance Management will be happy to help you in relation to this matter.

Dr. Andreas Batna
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Tel: +49 (0) 9134 9988-850
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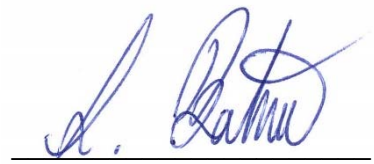
We would like to apologise for any inconvenience that may arise or that has already arisen as a result of this matter, and we hope to continue our successful collaboration despite this.

Yours sincerely,

RTI Surgical/Tutogen Medical GmbH

Neunkirchen am Brand, 30.05.2018



Tutogen Medical GmbH is a subsidiary of RTI Surgical

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Dr. Andreas Batna
Director Regulatory Affairs & Compliance Management
Sicherheitsbeauftragter für Medizinprodukte
TUTOGEN MEDICAL GmbH

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User Confirmation Form

Instructions
Fill in form and send by fax to: +49 (0) 9134 9988-55850

Date: 05/30/2018

Our records show that you have received the following affected products:
“CopiOs Cancellous Particulate Xenograft”

Quantity: 35

Article no.: 97200

Batch no.: K18796

Section to be filled in by user

___ I have received the **“urgent safety information”** regarding “CopiOs Cancellous Particulate Xenograft”, batch no. K18796.

___ I have checked my stock and found none of the discrepancies described in the Field Safety Notice.

___ I have checked my stock and found __ packages with the described discrepancy. I have sent these __ packages back to Tutogen Medical GmbH in Neunkirchen am Brand.

___ I have used the “CopiOs Cancellous Particulate Xenograft” product with the affected batch number K18796 and a discrepancy between the imprint on the outer packaging (folding box) and the label, and would like to arrange a consultation with the relevant contact partner at Tutogen Medical GmbH.

[redacted]

Signature of the user

Name of the user in block capitals

Date