
Urgent safety instruction

Recall

regarding

Gubisch Osteotom 20cm 2mm REF 67.30.52

Gubisch Osteotom 20cm 3mm REF 67.30.53

20.11.2024

1 Sender:

Medicon eG

Gänsäcker 15

D- 78532 Tuttlingen

Contact:

PRRC: Jörg Treu / Peter Großmann

Tel.: +49 7462 2009 680 / +49 7462 2009 630

Fax: +49 7462 2009 50

E-Mail: joerg.treu@medicon.de / peter.grossmann@medicon.de

Quality Management Representative:

Name Jörg Treu

Tel.: +49 7462 2009 680

Fax: +49 7462 2009 50

E-Mail: joerg.treu@medicon.de

2 Receiver:

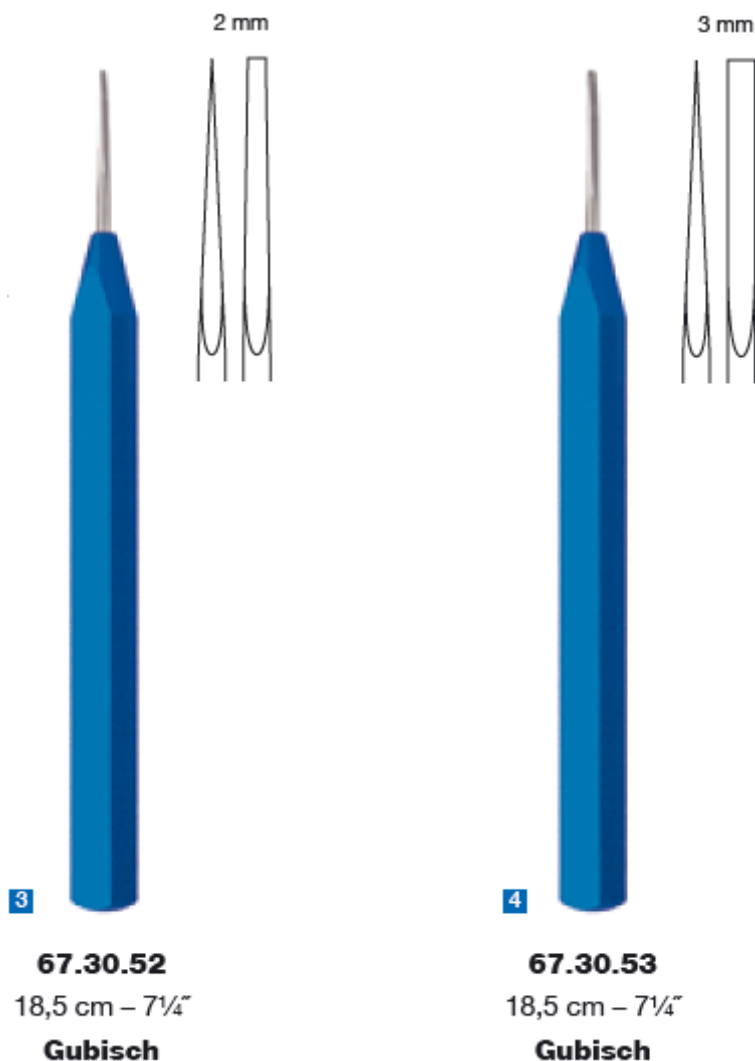
3 Identification of the medical devices concerned:

Item no. **67.30.52** Gubisch Osteotom 20cm 2mm

LOT RDIS2-0023, RLIS4-0023, REIS2-0023, FFIS4-0023, RSIC2-0023, RCIC5-0023, RAIC3-0023

Item no. **67.30.53** Gubisch Osteotom 20cm 3mm

LOT RDIS2-0023, REIS5-0023, FFIS3-0023, RIIC5-0023, RCIC4-0023



4 Description of the problem including the identified cause:

In the course of a complaint, it was discovered that the end tip and the handle could be screwed, but not glued. In the worst case scenario, the two components could come loose..

5 What measures are to be taken by the addressee?

With delivery bill no. XXXXXX dated XXXXXXXX we delivered you XXXX piece of the defective products with the LOT XXXXXX

Please sort out the product and send them back to us. We will deliver an adequate faultless free replacement as soon as possible.

6 Disclosure of the information described herein:

Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Safety Instruction. If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.

Please keep this instruction at least until the measure has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Instruction".

7 Contact:

Name: Jörg Treu

Datum: 20.11.2024

Unterschrift

Customer Response Form

Attachment 1 to the sent safety information

67.30.52 - Gubisch Osteotom 20cm 2mm
 67.30.53 - Gubisch Osteotom 20cm 3mm

Please fill in the empty fields and send this response form back to us as soon as possible!

Name	
Address	
Country	

According to our records your company received the above-mentioned product.

By completing and returning this form, I confirm that I have received and read the safety information and that I have acted according to the mentioned instructions.

- We do not have physical stock of the affected product

- We hold the following unused, affected products ready for the return to Medicon

Medicon REF	Description	LOT-Number	Quantity of units which will sent back
67.30.52	Gubisch Osteotom 20cm 2mm		
67.30.53	Gubisch Osteotom 20cm 3mm		

- The affected product was sold to a customer and has already been used.

Name	
Title	
Phone	
Date	
Signature	

Please send the response form to:

Medicon eG
Herrn Jörg Treu
Gänsäcker 15
78532 Tuttlingen
Fax: 07462 2009-680
e-Mail: joerg.treu@medicon.de