

---

**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**

[Redacted]  
[Redacted]

**Contact:**

[Redacted]  
[Redacted]  
[Redacted]

E-Mail: [Redacted]

**Quality Management Representative:**

[Redacted]  
[Redacted]  
[Redacted]

E-Mail: [Redacted]

**2 Receiver:**

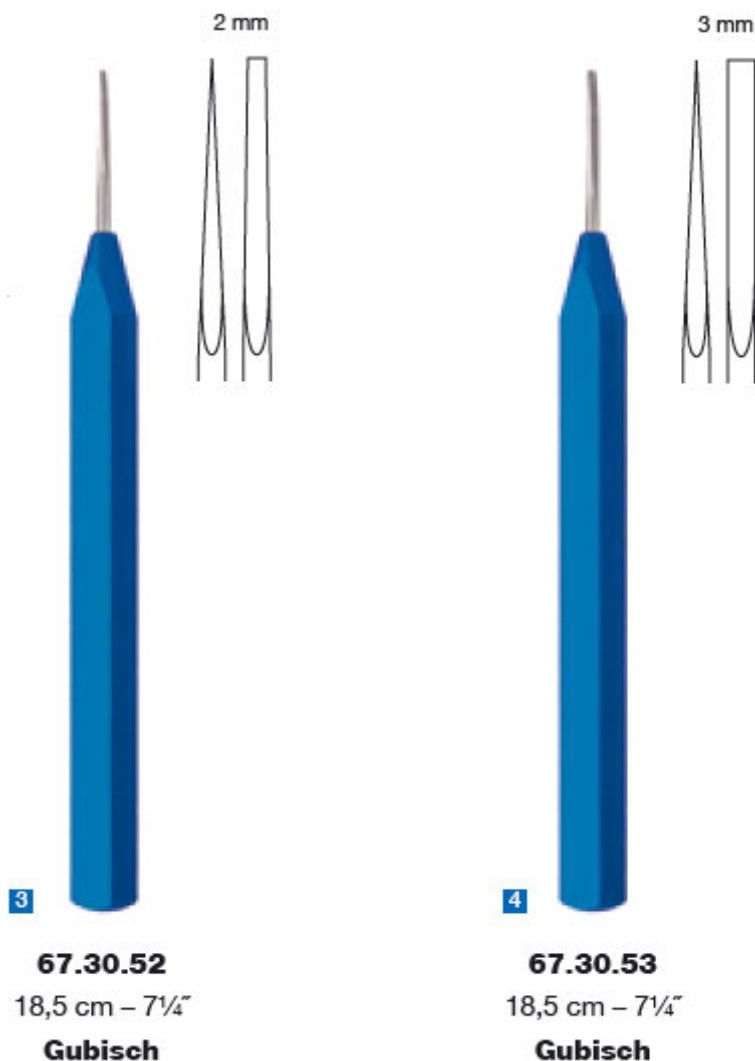
**3 Identification of the medical devices concerned:**

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:

[REDACTED]

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!

<b>Name</b>	
<b>Address</b>	
<b>Country</b>	

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.

<b>Name</b>	
<b>Title</b>	
<b>Phone</b>	
<b>Date</b>	
<b>Signature</b>	

Please send the response form to:

**Medicon eG**

  
 Gänsäcker 15  
 78532 Tuttlingen  
 Fax: 07462 2009-680  
 e-Mail: 