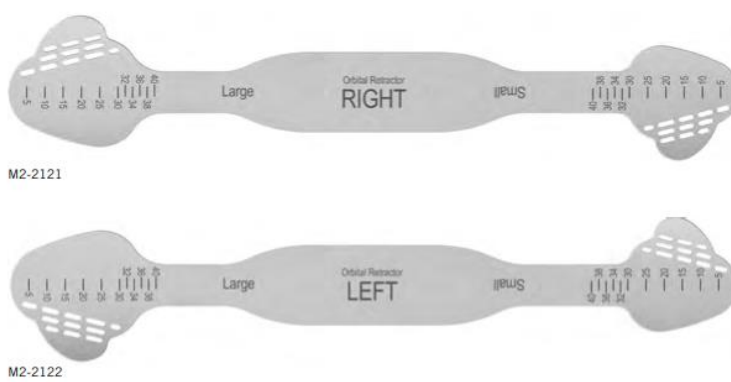
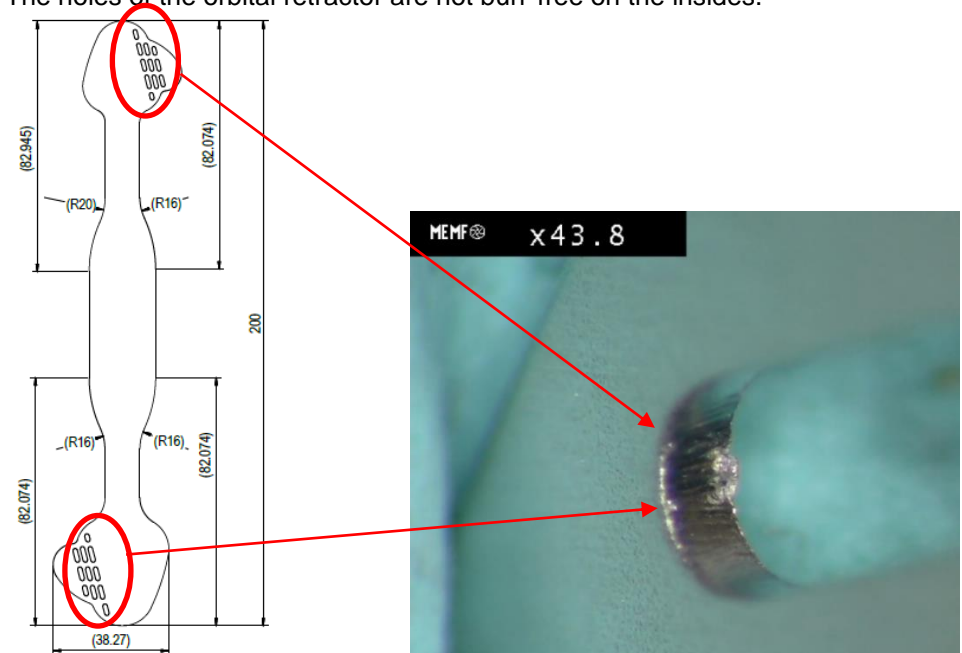


| Place/Date: **Basel, 03.04.2023**| Reference: **Urgent Field Safety Notice****URGENT: Field Safety Notice**

Dear Sir or Madam,

On March 27th, Medartis AG has initiated a lot specific product Field Safety Corrective Action (FSCA) for the Orbital Retractor, Right (M2-2121) and Orbital Retractor, Left (M2-2122).

Field Safety Action on: Orbital Retractor, Left; Orbital Retractor, Right			
Date	27.03.2023		
Contact Detail	Legal Manufacturer Medartis AG Hochbergerstrasse 60E 4057 Basel Switzerland return@medartis.com PRRC: Axel Maltzen +41 79 209 60 62	Authorized Representative Medartis GmbH Am Gansacker 10 79224 Umkirch Deutschland return@medartis.com PRRC: Andrea Rogalla +49 7665 9824 223	
Part Name	A) Orbital Retractor, Right B) Orbital Retractor, Left	Part No.	A) M2-2121 B) M2-2122
Lot No.	A) 19200836, 20231588 B) 19200838, 20231589	UDI-DI (GTIN)	A) 07630037874317 B) 07630037874324
Device Type and Purpose	The orbital retractors are designed to protect the orbital soft tissue and to determine the size of the defect.  M2-2121 M2-2122		
FSCA	FSCA 01-2023		

<p>Failure description</p>	<p>The holes of the orbital retractor are not burr-free on the insides.</p>  <p>The technical drawing shows a vertical component with two holes. The top hole has a diameter of (82.945) and a radius of (R20). The bottom hole has a diameter of (82.074) and a radius of (R16). The total height of the component is 200. A magnified photo on the right shows the inner edge of a hole with a burr, labeled 'MEMF' and 'x43.8'.</p>
<p>Results of the Risk Assessment</p>	<p>The burr can jump of the orbital retractor during surgery, what can lead to a permanent injury of soft tissues in the area of application. →Risk is not acceptable</p>
<p>Corrective Action From Medartis:</p>	<ul style="list-style-type: none"> • Field Safety Corrective Action (FSCA): Recall by the legal manufacturer (Medartis AG) • Sorting out the defect products • CAPA triggered via the internal CAPA system (reference: Critical 01-2023)
<p>Medartis Contact Person</p>	<p>Marius Hohmann Tel: +41 61 633 37 08 E-Mail: return@medartis.com Medartis AG Hochbergerstrasse 60E 4057 Basel</p>

Customer Acknowledgment and Inventory

**Hospital / Clinic /
User Information**

Contact Name:

Adress:

Postcode:

City:

Country:

Phone:

Email:

**Number of affected
products at customer**

Quantity	Article	LOT

Product Recall:

For the above mentioned products a field safety corrective action is initiated. Please confirm that all affected products under your control have been identified and please document below the amount being :

- Discarded
- Returned to Medartis

Lot	Qty	Disposition	
		Discarded: <input type="checkbox"/> _____	Returned to Medartis: <input type="checkbox"/> _____
		Discarded: <input type="checkbox"/> _____	Returned to Medartis: <input type="checkbox"/> _____
		Discarded: <input type="checkbox"/> _____	Returned to Medartis: <input type="checkbox"/> _____
		Discarded: <input type="checkbox"/> _____	Returned to Medartis: <input type="checkbox"/> _____
		Discarded: <input type="checkbox"/> _____	Returned to Medartis: <input type="checkbox"/> _____

Information to user:

I confirm with this document that I am aware of the field safety corrective action initiated by Medartis and that this information has been forwarded to all potentially affected divisions in-house.

	FIRST NAME – NAME - FUNCTION	DATE	SIGNATURE
Filled in by			

Important Informations

- **Please fill in this form and return it within 24h at the following address: return@medartis.com**
- **Please block all affected products (do not use the products)**
- **Please return all affected products immediately to Medartis AG.:**

Medartis AG
Hochbergerstraße 60E
4057 Basel
Schweiz
Attention: Deviation Management

- **Replacement of the products affected will be arranged as soon as possible after the products have been returned.**

We kindly apologize for all inconveniences this could cause and remain at your complete disposal for further inquiry.

Kind Regards,

Medartis AG