Xxxxxxxxxx Customer Adress and Contact xxxxxxxxxxxxxxxxxx

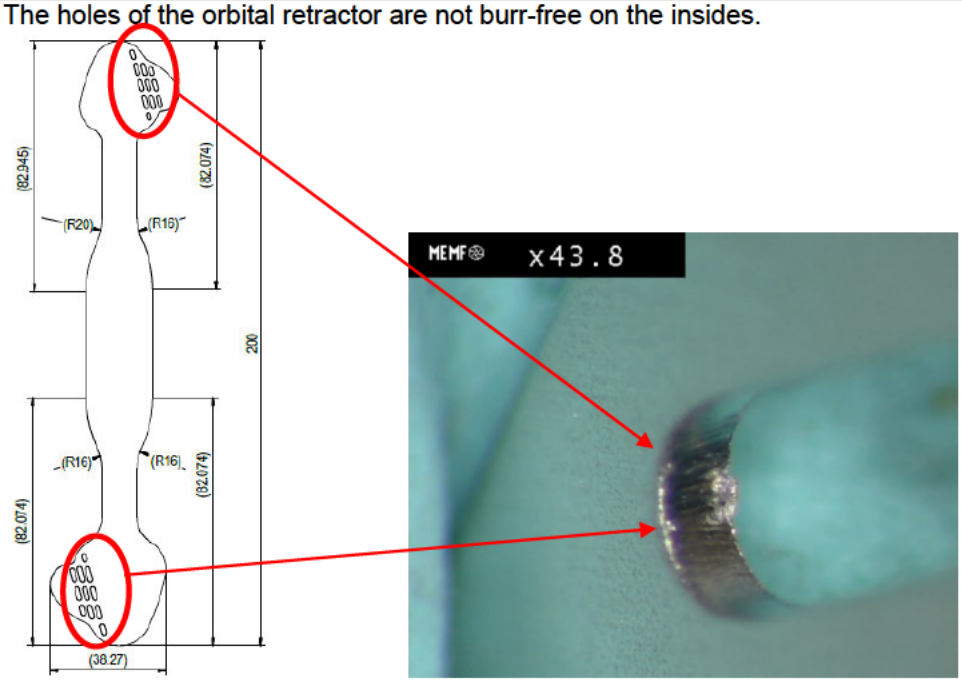
| Place/Date: **Basel, 28.03.2023** | Reference: **Urgent Field Safety Notice**

**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**<br>Medartis AG<br>Hochbergerstrasse 60E<br>4057 Basel<br>Switzerland<br>return@medartis.com<br><br>PRRC: [redacted] | **Authorized Representative**<br>Medartis GmbH<br>Am Gansacker 10<br>79224 Umkirch<br>Deutschland<br>return@medartis.com<br><br>PRRC: [redacted] | |
| **Part Name** | A) Orbital Retractor, Right<br>B) Orbital Retractor, Left | **Part No.** | A) M2-2121<br>B) M2-2122 |
| **Lot No.** | A) 19200836, 20231588<br>B) 19200838, 20231589 | **UDI-DI (GTIN)** | A) 07630037874317<br>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.<br>  <br><br>M2-2121<br>  <br><br>M2-2122 | | |
| **FSCA** | FSCA 01-2023 | | |

| | |
|---|---|
| **Failure description** | The holes of the orbital retractor are not burr-free on the insides.<br>  |
| **Results of the Risk Assessment** | 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.<br>→Risk is not acceptable |
| **Corrective Action From Medartis:** | • Field Safety Corrective Action (FSCA): Recall by the legal manufacturer (Medartis AG)<br>• Sorting out the defect products<br>• CAPA triggered via the internal CAPA system (reference: Critical 01-2023) |
| **Medartis Contact Person** | Marius Hohmann<br>Tel: +41 61 633 37 08<br><br>E-Mail: return@medartis.com<br><br>Medartis AG<br>Hochbergerstrasse 60E<br>4057 Basel |

## Customer Acknowledgment and Inventory

| | |
|---|---|
| **Hospital / Clinic / User Information** | Contact Name:<br>Adress:<br>Postcode:<br>City:<br>Country:<br>Phone:<br>Email: |

| | Quantity | Article | LOT | Order No. |
|---|---|---|---|---|
| **Number of affected products at customer** | x | x | x | x |
| | x | x | x | x |
| | x | x | x | x |

**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 | |
|---|---|---|---|
| x | x | Discarded: ☐ _____ | Returned to Medartis: ☐_____ |
| x | x | Discarded: ☐ _____ | Returned to Medartis: ☐_____ |
| x | x | Discarded: ☐ _____ | Returned to Medartis: ☐_____ |
| x | x | Discarded: ☐ _____ | Returned to Medartis: ☐_____ |
| x | x | Discarded: ☐ _____ | Returned to Medartis: ☐_____ |

**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 GmbH.:**

Medartis GmbH
Am Gansacker 10
79224 Umkirch
Deutschland
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