# URGENT FIELD SAFETY NOTICE

# Stemcup Trunnion handle/woodpecker

07 March 2023 FSN: FSN CZV-00590-001

***Attention: Distributors and users of Stemcup Trunnion handle/woodpecker (60.160.71, 60.160.72, 60.160.73)***

**Dear Customer,**

The purpose of this communication is to inform you of a product Field Safety Corrective Action (FSCA) initiated by Stemcup Medical Products AG, involving Stemcup Trunnion handle/woodpecker that cannot be assembled with IMT machine.

**Affected devices**

| REF | Description | UDI | LOT |
|---|---|---|---|
| 60.160.71 | Trunnion single offset broach handle/woodpecker | 07640121434419 | A2 |
| 60.160.72 | Trunnion double offset broach handle/left/woodpecker | 07640121434426 | A2 |
| 60.160.73 | Trunnion double offset broach handle/right/woodpecker | 07640121434433 | A2 |

**Problem description**

The trunnion handle/woodpecker from batch A2 cannot be assembled with the IMT machine due to a geometrical problem on the connection side.

**Potential health risks**

The surgery time could be longer (more as 30 minutes longer than the standard time).

**Root Case**

Due to an error in production phase, the connection side of instruments has been produced with a wrong parameter.

**Actions to be taken by the manufacturer**

- Stemcup Medical Products AG will inform with this FSN all affected distributors.
- Stemcup Medical Products AG will recall the batch A2 of REF 60.160.71, 60.160.72, 60.160.73 from market.
- Stemcup Medical Products AG will rework the batch A2 of REF 60.160.71, 60.160.72, 60.160.73.
- Stemcup Medical Products AG will collect and follow up on all response forms and the execution and completion of this corrective action.

**Actions to be taken by the distributors**

- Notify immediately all affected end-users by providing them with the FSCA package containing this FSN and FORM Field Safety Corrective Action (FSCA) End-User Response.
- Identify any affected devices by batch number using the List in this FSN.
- Return all affected products to Stemcup Medial Products AG.

**Actions to be taken by the users**

- Check receipt and contents of the FSCA package (this FSN and the FORM Field Safety Corrective Action (FSCA) End-User Response.
- If affected devices are transferred to another location or organization, make sure to forward the complete FSCA package to the respective users accordingly.
- All users of the affected products shall read and take into consideration all instructions and information provided in this FSN.
- Identify any affected devices by batch number using the List in this FSN.
- Return all affected products to Stemcup Medial Products AG or distributors.

**Contact Information**

For questions, concerns or any events that reasonably suggest being related to the subject of this FSCA or to related Forms, please email administration@stemcup.ch

The undersigned confirms that this FSN has been notified to the appropriate Regulatory Agencies.

Sincerely

[redacted]

[redacted]
CEO
Aargauerstrasse 180
Zurich
Switzerland
E-Mail: [redacted]@stemcup.ch

# Field Safety Corrective Action (FSCA) End User Response Form

## FSCA-590

**Details of affected parts and products:**

**Affected products according to the Field Safety Notice FSN CZV-00590-001**

| REF | Description | UDI | LOT |
|---|---|---|---|
| 60.160.71 | Trunnion single offset broach handle/woodpecker | 07640121434419 | A2 |
| 60.160.72 | Trunnion double offset broach handle/left/woodpecker | 07640121434426 | A2 |
| 60.160.73 | Trunnion double offset broach handle/right/woodpecker | 07640121434433 | A2 |

**End User Declaration**

| | | | |
|---|---|---|---|
| **Number of affected devices (total)** | | | |
| **Part Number** | | **Lot Number / pcs.** | |

Please verify the following by checking the appropriate boxes below.

| | |
|---|---|
| ☐ | I have received the FSCA package, comprising the Field Safety Notice (FSN CZV-00590-001) and FSCA End User Response Form, and understood the content and will follow and implement the instructions accordingly. |
| ☐ | I confirm that all users of the affected devices were or will be informed about the FSCA immediately and the FSCA package was/will be provided. |
| ☐ | I have identified all affected products and have entered them on or attached them to this response form |
| ☐ | I have removed the affected product(s) from use as indicated in the Field Safety Notice (FSN CZV-00590-001) |
| ☐ | I confirm that affected devices were transferred to another location/organization and the complete FSCA package was forwarded to the respective users accordingly.<br><br>List contact detail of recipients |

**End User Detail**

| | | | |
|---|---|---|---|
| **Contact person (name)** | | | |
| **Hospital (address)** | | | |
| **Country** | | | |
| **Email address** | | | |
| **Date** | | **Signature** | |

**PLEASE SEND THIS RESPONSE FORM TO THE FOLLOWING EMAIL ADDRESS:** administration@stemcup.ch

**Contact Information**

For questions, concerns or any events that reasonably suggest being related to the subject of this FSCA or to related Forms, please email administration@stemcup.ch

Sincerely


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