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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.

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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 Medical Products AG.

Actions to be taken by the users

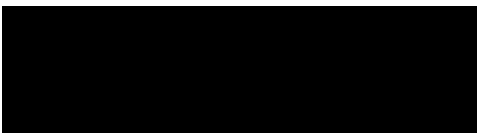
- Check receipt and contents of the FSCA package (this FSN and the FORM Field Safety Corrective Action (FSCA) End-User Response).
- If affected devices are transferred to another location or organization, make sure to forward the complete FSCA package to the respective users accordingly.
- All users 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 Medical 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



CEO

Aargauerstrasse 180

Zurich

Switzerland

E-Mail: @stemcup.ch

 <i>Medical products in motion</i>	End User Response	Dok. Nr. EUR CZV-00590-001
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FSCA End User Response		

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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