| Place/Date: **Basel, 07.03.2024** | Reference: **Urgent Field Safety Notice**

URGENT: Field Safety Notice to FSCA 01-2024

Dear Sir or Madam,

On 16.02.2024, Medartis AG has initiated a lot specific product Field Safety Corrective Action (FSCA) for the radius plate A-4750.105, Lot 23371369.

In the meantime the same error pattern was detected on the following two plates as well as on one template:

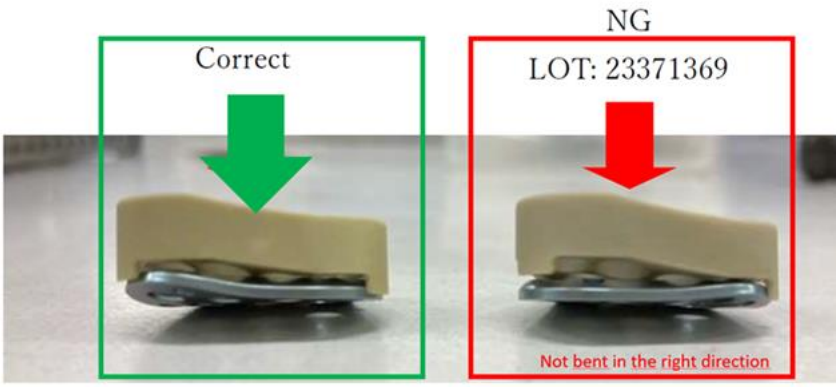
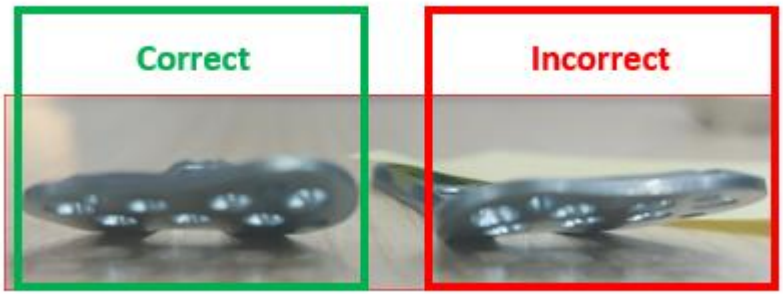
A-4750.106	Lot 23371373
A-4750.124	Lot 23364417
A-4750.124TP	Lot 23348819

For this reason, the original Field Safety Notice was expanded to include these three articles.

This safety information cancels and replaces the one sent on February 19th, 2024.

If you haven't received the initial FSN dated 19th February 2024 because you were not affected from the recall of A-4750.105, Lot 23371369 this FSN is the initial notification for you.

Field Safety Action on: radius plate / template for radius plate			
Date	07.03.2024		
Contact Detail	**Legal Manufacturer** Medartis AG Hochbergerstrasse 60E 4057 Basel Switzerland return@medartis.com PRRC: Axel Maltzen +41 79 209 60 62	**Authorized Representative EU** Medartis GmbH Am Gansacker 10 79224 Umkirch Germany andrea.rogalla@medartis.com PRRC: Andrea Rogalla +49 7665 9824 223	
Part Name	2.5 ADAPTIVE II TriLock DistRad.Pl Vol L	**Part No.**	A-4750.105
	2.5ADAPTIVE II TriLock DistRad.pl,pal re		A-4750.106
	2.5 TriLock Dist.Rad.FPL.pl, palmar re		A-4750.124
	Template for A-4750.124		A-4750.124TP
Lot No.	23371369	**UDI-DI (GTIN)**	07630037896654
	23371373		07630037896661
	23364417		07630037896746
	23348819		07630894815065
Device Type and Purpose	Osteosynthesis plate for the treatment of radius fractures. Template for osteosynthesis plate.		

FSCA	FSCA 01-2024
Failure description	The FSCA was initiated due to an error on the radius plate A-4750.105. Medartis received a customer complaint that the plate was not bent correctly. The radius plate A-4750.105 was bent not according to specification “Left” but with the setting of the bending machine as intended for a “Right” plate. This results in an incorrect anatomical shape of the plate.  The same error pattern has now also been discovered in plates A-4750.106 and A-4750.124 with the aforementioned lot numbers. All plates identified as incorrect have been bent with the same widget. The radius plates A-4750.106 / A-4750.124 were bent in the fixture for “Left” instead of according to the specification “Right”. This results in an incorrect anatomical shape of the plate. The same error pattern was also detected in the template A-4750.124TP, Lot 23348819. 
Results of the Risk Assessment	Due to the incorrect radial shape of the plate, there is an increased risk of contact with the FPL (flexor policius longus). This is difficult or almost impossible to determine radiologically. In the worst case scenario, it can therefore be assumed that the risk of tendon irritation or rupture is increased. Increased risk of tendon irritation or rupture. →Risk is not acceptable **Recommendations for patients who have already received an implant (not template as this is not being implanted):** In addition to the recommendations according to the IFU, regular examination by ultrasound or similar, in particular of the flexor tendon, is recommended in addition to the usual radiological imaging. If tendon irritation is recognisable, there is a risk of asymptomatic tendon rupture, which is why the implant should be removed and replaced with a new implant. An additional operation carries the risk of wound healing disorders, wound infections, injury to vessels or nerves, as well as risks due to the necessary anaesthesia.

Corrective Action From Medartis	• 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 01-2024)
Medartis Contact Person	Cenan Djukatani Tel: +41 61 633 37 12 E-Mail: return@medartis.com Medartis AG Hochbergerstrasse 60E 4057 Basel

Customer Acknowledgment and Inventory

Hospital / Clinic / User Information	Contact Name: Adress: Postcode: City: Country: Phone: 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 :

- Already used
- Discarded
- Returned to Medartis

Lot	Qty	Disposition		
x	x	Used: ☐ _____	Discarded: ☐ _____	Returned to Medartis: ☐_____
x	x	Used: ☐ _____	Discarded: ☐ _____	Returned to Medartis: ☐_____
x	x	Used: ☐ _____	Discarded: ☐ _____	Returned to Medartis: ☐_____
x	x	Used: ☐ _____	Discarded: ☐ _____	Returned to Medartis: ☐_____
x	x	Used: ☐ _____	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 Information

- **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
CH-4057 Basel

OR

Medartis GmbH
Am Gansacker 10
DE - 79224 Umkirch

- **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