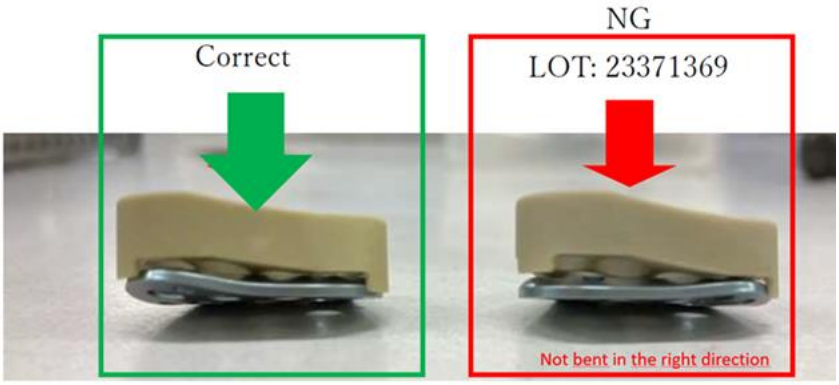
| Place/Date: **Basel, 16.02.2024** | Reference: **Urgent Field Safety Notice**

URGENT: Field Safety Notice

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.

Field Safety Action on: radius plate			
Date	16.02.2024		
Contact Detail	**Legal Manufacturer** Medartis AG Hochbergerstrasse 60E 4057 Basel Switzerland return@medartis.com PRRC: Axel Maltzen +41 79 209 60 62		**Authorized Representative** Medartis GmbH Am Gansacker 10 79224 Umkirch Germany return@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
Lot No.	23371369	**UDI-DI (GTIN)**	07630037896654
Device Type and Purpose	Osteosynthesis plate for the treatment of radius fractures.		

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. In this case, the plate was bent incorrectly as the left wing was bent higher than the right wing. Medartis immediately quarantined the affected products and initiated a stock check. To date, no further defects have been identified. 
Results of the Risk Assessment	Due to the incorrect radial shape, 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:** 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: DEV1327)
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