| Place/Date: **Basel, 27.01.2025** | Reference: **Urgent Field Safety Notice**

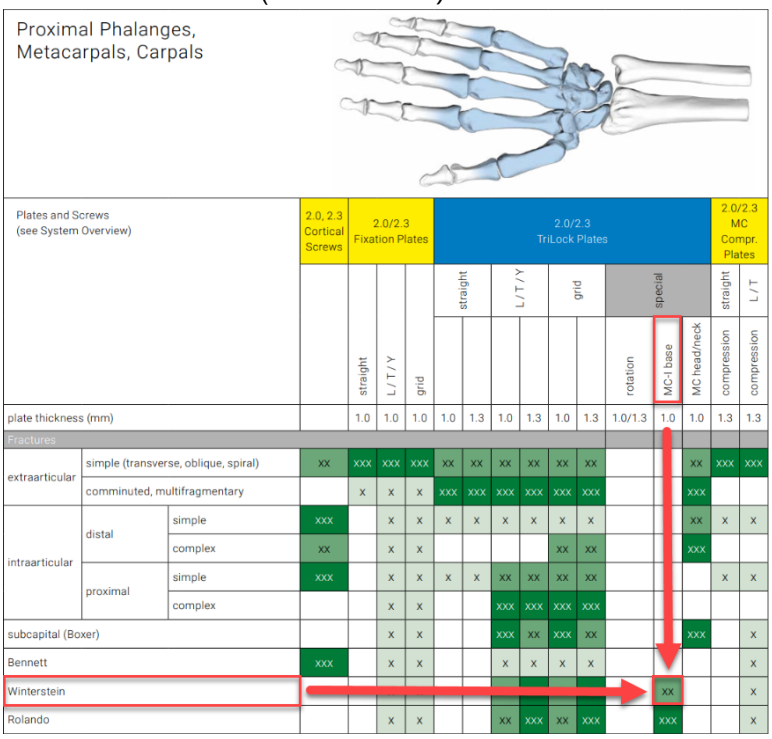
URGENT: Field Safety Notice

Dear Sir or Madam,

On 27.01.2025, Medartis AG has initiated a lot specific product Field Safety Corrective Action (FSCA) for “2.0/2.3 TriLock Plate MC I Base, t1.0” (A-4650.90S).

1. Field Safety Notice (FSN)

Field Safety Action on:	**A-4650.90S**		
Date	27.01.2025		
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	2.0/2.3 TriLock Plate MC I Base, t1.0	**Part No.**	A-4650.90S
Lot No.	24390415	**UDI-DI (GTIN)**	7630894813306
Device Type and Purpose	APTUS Hand Plate Intended Purpose: The APTUS fixation systems are intended for temporary fixation, correction or stabilization of bones. Indications: Fractures, osteotomies and arthrodesis of the bones of the hand - fractures of the distal, middle and proximal phalanges - fractures of the metacarpals - osteotomies of the hand - arthrodeses in the hand  		

FSCA reference	FSCA 01-2025
Failure description	In the surgical technique the plate A-4650.90S is also recommended for the indication “Winterstein” fracture (see red boxes):  *“XXX” means “Primary recommendation”* *“XX” means “Recommendation”* *“X” means “Possible”* Patients with “Winterstein” fractures were treated with this plate and post-operatively the plate has bent.
Results of the Risk Assessment	Failure of ORIF fixation and potential reoperation leading to an unsuccessful treatment, need for a second operation to implant the correct product. →Risk is not acceptable
Corrective Action From Medartis	• Field Safety Corrective Action (FSCA): Recall by the legal manufacturer (Medartis AG) • CAPA triggered via the internal CAPA system (reference: Critical 01-2025)
Medartis Contact Person	Marius Hohmann Tel: +41 61 633 37 08 E-Mail: return@medartis.com Medartis AG Hochbergerstrasse 60E 4057 Basel
Actions from Medartis	• Reporting to authorities • Information of all affected customers • Internal investigation and corrective measures
Actions for affected Customers	• Blocking of the affected products • Send the affected products back to the manufacturer • Fill out this form and return it to Medartis (see chapter “2. Customer Reply”)
Recommendation if the article is already implanted	As the manufacturer, we recommend that surgeons contact the affected patients for a re-concilation visit in their post-operative care.

2. Customer Reply

Customer Details	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
E-Mail*	

Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.			
☐	I blocked all affected products.			
☐	The information and required actions have been brought to the attention of all relevant users and executed.			
☐	I have returned affected devices and included a copy of this form to the shipment - enter number of devices returned and date complete.	Qty:	Lot Number:	Date Returned (DD/MM/YY):
		☐ N/A	Comments:	
☐	I have discarded affected devices – enter number discarded and date complete.	Qty:	Lot Number:	Date Discarded (DD/MM/YY):
		☐ N/A	Comments:	
☐	I have implanted affected devices – enter number implanted and date complete.	Qty:	Lot Number:	Date Discarded (DD/MM/YY):
		☐ N/A	Comments:	
☐	I do not have any affected devices.			
Name*				
Date*				
Signature*				

Return acknowledgement to sender	
E-mail	Quality.DE@medartis.com
Postal Address	Medartis GmbH Am Gansacker 10 79224 Umkirch Germany
Deadline for returning the customer reply form	10.02.2025

Mandatory fields are marked with *

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