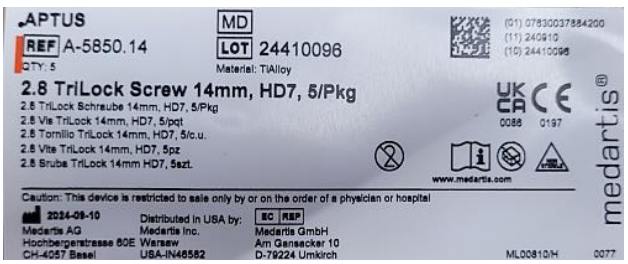
| Place/Date: **Basel, 17.12.2024** | Reference: **Urgent Field Safety Notice**

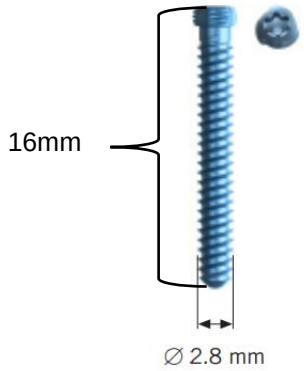
URGENT: Field Safety Notice

Dear Sir or Madam,

On 16.12.2024, Medartis AG has decided to execute a lot specific product Field Safety Corrective Action (FSCA) for the **2.8 TriLock Screw 14mm, HD7, 5/Pkg** (**A-5850.14**).

1. Field Safety Notice (FSN)

Field Safety Action on: A-5850.14			
Date	17.12.2024		
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	2.8 TriLock Screw 14mm, HD7, 5/Pkg	**Part No.**	A-5850.14
Lot No.	24410096	**UDI-DI (GTIN)**	76300378022PA
Device Type and Purpose	The APTUS fixation systems are used for fractures, osteotomies and arthrodesis of the hand, forearm, shoulder and foot   		

Field Safety Corrective Action reference(FSCA)	FSCA 05-2024
Failure description	Screw is 16mm long instead of 14mm. 
Results of the Risk Assessment	Worst Case: Wrong product chosen for the treatment due to wrong labeling, leading to soft tissue irritation, and/or nerve damage.
Corrective Action from Medartis	Internal investigation (reference: Critical 14-2024)
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	• Field Safety Corrective Action (FSCA): Recall by the legal manufacturer (Medartis AG) • Reporting to authorities and Notified Body • Directly inform all affected customers
Actions for affected Customers	• Review this notification and ensure that affected personnel are aware of the contents. • If you have affected products that are still in their original packaging at your facility quarantine all affected product. Medartis will inform you about how to proceed with the product. • If the screws with Lot no. 24410096 have already been taken out of the packaging and have been placed into a set, please ensure that the screws with a length of 16mm are placed in the designated area. The screws with Lot no. 24410096 are within the specification for 2.8 TriLock screw length 16mm and can be used without patient risk as such. • If the product has been further distributed, provide your customers with the FSN and ensure documentation. • Complete chapter 2 “Customer Reply” and send to the e-mail address mentioned in “Return acknowledgement to sender”.
Recommendation if the device is already implanted	Post-operative routine examination is sufficient. No additional follow-up is needed.

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 Implanted (DD/MM/YY):
		☐ N/A	Comments:	
☐	The affected devices have been placed into sets and are used as 16mm screws within a set.	Qty:	Lot Number:	Date (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
Deadline for returning the customer reply form	03.01.2025

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