| Place/Date: **Basel, 09.01.2026** | Reference: **Urgent Field Safety Notice**

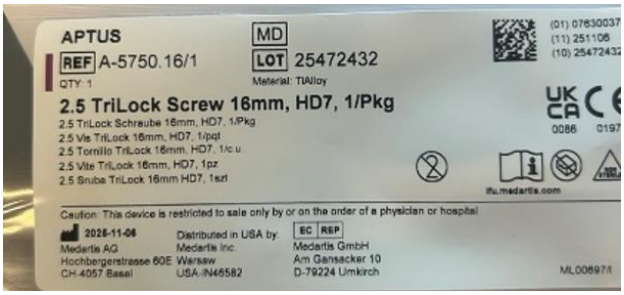
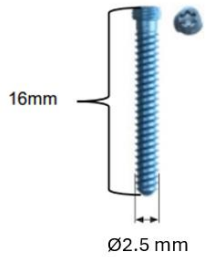
URGENT: Field Safety Notice

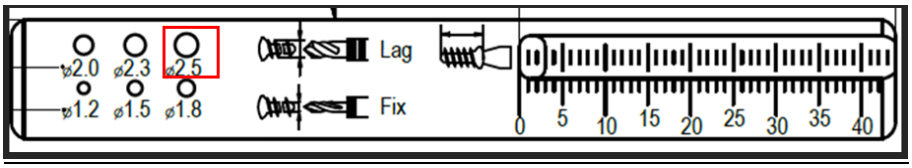
Dear Sir or Madam,

On 09.01.2026, Medartis AG has initiated a lot specific product Field Safety Corrective Action (FSCA) for the product, which is listed in the following.

1. Field Safety Notice (FSN)

Field Safety Action			
Date	09.01.2026		
Contact Detail	**Legal Manufacturer** Medartis AG Hochbergerstrasse 60E 4057 Basel Switzerland complaints@medartis.com PRRC: Ms. Claudia Zurbuchen-De Santis +41 61 633 37 23	**Authorized Representative** Medartis GmbH Am Gansacker 10 79224 Umkirch Germany quality.de@medartis.com PRRC: Ms. Andrea Rogalla +49 7665 9824 223	
Part Name	2.5 TriLock Screw 16mm, HD7, 1/Pkg 2.8 TriLock-Schraube 16mm, HD7, 1/Pkg	**Part No.**	A-5750.16/1 A-5850.16/1
Lot No.	25472432 (A-5750.16/1) 25467933 (A-5850.16/1)	**UDI-DI (GTIN)**	07630037882053 07630037802167
Device Type and Purpose	The APTUS fixation systems are intended for fractures, osteotomies and arthrodesis.		

FSCA	FSCA 01-2026
Failure description	A mix-up has been identified between the items “A-5750.16/1 2.5 TriLock Screw 16 mm, HD7, 1/Pkg” and “A-5850.16/1 2.8 TriLock Screw 16 mm”. The packaging for A-5850.16/1 contains an A-5750.16/1 2.5 TriLock Screw 16 mm, HD7, 1/Pkg, and conversely, the packaging for A-5750.16/1 contains an A-5850.16/1 2.8 TriLock Screw 16 mm. A picture of the label and screw A 5750.16/1 can be found here:  
Results of the Risk Assessment	The use of a 2.8 mm diameter screw, as opposed to a 2.5 mm diameter screw that can be locked in the corresponding plate, may increase the risk of intra-operative bone splitting, since greater force is required during drilling into the bone. The use of a 2.5 mm diameter screw, as opposed to a 2.8 mm diameter screw in the patient, may lead to prolonged procedure or healing phase, or health deterioration which leads in worst case to secondary loss of reduction. This risk is not acceptable for the user and/or patient.
Corrective Action From Medartis	• Field Safety Corrective Action (FSCA): Recall by the legal manufacturer Medartis AG • Stock hold at headquarter and subsidiaries
Medartis Contact Person	Ms. Claudia Zurbuchen-De Santis Tel: +41 61 633 37 23 E-Mail: complaints@medartis.com Medartis AG Hochbergerstrasse 60E 4057 Basel Switzerland
Actions from Medartis	• Field Safety Corrective Action (FSCA): Partial recall by the legal manufacturer Medartis AG • Reporting to national competent authorities • Inform all affected customers • Internal investigation for root cause
Actions for affected Customers	**<u>Actions for A-5750.16/1:</u>** Scenario A: Article packaged 1. Identify the article of the affected batch in your warehouse 2. Place it in quarantine 3. Dispose of the item or return it to Medartis 4. Fill out this form and return it to Medartis (see chapter “2. Customer Reply”) Scenario B: Article set in container 1. Identify the article of the affected batch in your container 2. Check all screws in the screw module of size 2.5 mm for their outer diameter using

	the Ø2.5 inspection hole provided in the container Example: Ø2.5 inspection hole in your container  3. Segregate any screws that do not fit into the Ø2.5 control hole and place them under quarantine. 4. Either dispose of the article or return it to Medartis 5. Fill out this form and return it to Medartis (see chapter “2. Customer Reply”). **Actions for A-5850.16/1:** 1. Identify the article of the affected batch in your warehouse 2. Place it in quarantine 3. Return item to Medartis 4. Fill out this form and return it to Medartis (see chapter “2. Customer Reply”)
Recommendation if the article is already implanted	**For A-5750.16/1:** Should bone splitting occur intra-operatively, then this should be managed immediately according to standard clinical procedure, and reported to Medartis. Post-operatively no change is needed in the standard follow-up protocol as long as no further clinical peculiarities occur. **For A-5850.16/1:** Should secondary loss of reduction occur post-operatively, then this should be managed immediately according to standard clinical procedure, and reported to Medartis. Patient follow-up is essential.

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 (01-2026) 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):
		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):
		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 Implantation (DD/MM/YY):
		Qty:	Lot Number:	Date Implantation (DD/MM/YY):
		☐ N/A	Comments:	

☐	I do not have any affected devices.
Name*	
Date*	
Signature*	

Return acknowledgement to sender	
E-mail	
Postal Address	
Deadline for returning the customer reply form	29.01.2026

Mandatory fields are marked with *

Replacement of the products affected will be arranged as soon as possible after the filled out FSN is received and/or 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