

| Place/Date: **Basel, 29.04.2026**

| Reference: **Urgent Field Safety Notice**


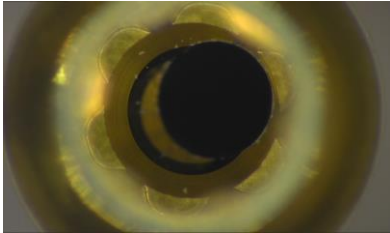
URGENT: Field Safety Notice – Recall

Dear Sir or Madam,

On 24.04.2026, Medartis AG has initiated a lot specific product Field Safety Corrective Action (FSCA) for the 5.0 headedCCS Long Thread 50/20mm, 1/Pkg (A-8216.50/1).

1. Field Safety Notice (FSN)

Field Safety Action on: A-8216.50/1			
Date	24.04.2026		
Contact Detail	Legal Manufacturer Medartis AG Hochbergerstrasse 60E 4057 Basel CH-Switzerland complaints@medartis.com PRRC: Mr. Mario Della Casa +41 61 633 35 65	Authorized Representative	Medartis GmbH Am Gansacker 10 79224 Umkirch DE-Germany Quality.DE@medartis.com PRRC: Ms. Andrea Rogalla +49 7665 9824 223
Part Name	5.0 headedCCS Long Thread 50/20mm, 1/Pkg	Part No.	A-8216.50/1
Lot No.	25444702 24425542 24404471 25441997	UDI-DI (GTIN)	07630037887706
Device Type and Purpose	The CCS screws as part of the APTUS fixation systems are intended for temporary fixation, correction or stabilization of bones.		

FSCA	FSCA 02-2026	
Failure description	The cannulation of the CCS is not centered.	
		
	Lateral view	Topic view on the head
Results of the Risk Assessment	<p><u>Intraoperatively:</u></p> <p>Off-centric cannulation in the screw may result in</p> <ul style="list-style-type: none"> a) a breakage of the screw. This can result in a delay of more than 30 minutes, as it may be necessary to organize a replacement screw or, in the worst case, to stop the surgery altogether. b) pushing the K-wire deeper than usual through the bone, which could injure the surrounding soft tissue or nerves. <p><u>Postoperatively:</u></p> <p>Off-centric cannulation may result in screw breakage during healing phase, which could lead to internal injuries to the surrounding soft tissue and as worst case, to a revision surgery.</p> <p>→ Risk is not acceptable</p>	
Corrective Action From Medartis	<ul style="list-style-type: none"> • Field Safety Corrective Action (FSCA): Recall by the legal manufacturer (Medartis AG) • Quarantined internal stock • CAPA triggered via the internal CAPA system 	
Medartis Contact Person	<p>Mr. Mario Della Casa Tel: +41 61 633 35 65 E-Mail: complaints@medartis.com Medartis AG Hochbergerstrasse 60E 4057 Basel CH-Switzerland</p>	
Actions from Medartis	<ul style="list-style-type: none"> • Field Safety Corrective Action (FSCA): Recall by the legal manufacturer (Medartis AG) • Reporting to national competent authorities • Information of all affected customers • CAPA triggered via the internal CAPA system 	
Actions for affected Customers	<p>Scenario A: Article packaged</p> <p>1. Identify the product of the affected batch in your warehouse via the article and batch number (see picture below)</p>	

Name

APTUS (01) 07630037887708
 (11) YYMMDD
 (10) XXXXXXXXXXXXXXX

REF | A-8216.50/1
 LOT | XXXXXXXXXXXXXXX

5.0 headed CCS Long Thread 50/20mm, 1/Pkg
 5.0 headed CCS langes Gew. 50/20mm, 1/Pkg
 5.0 headed CCS Filet long 50/20mm, 1/lot
 5.0 headed CCS Rosica larga 50/20mm, 1/cu
 5.0 headed CCS Filet larga 50/20mm, 1/pc
 5.0 headed CCS Dlugi gwint 50/20mm, 1szt

UK CA CE 0086 0197
 www.medartis.com

Caution: This device is restricted to sale only by or on the order of a physician or hospital

Medartis AG Hochpeterstrasse 60E, Warsaw, CH-4057 Basel
 Distributed in USA by Medartis Inc, USA-IN46582
 Medartis GmbH Am Glasacker 10, D-75224 Umkirch

ML15110/F 0001

2. Place the product in quarantine
3. Return the product to Medartis
4. Fill out this form and return it to Medartis (see chapter "2. Customer Reply")

Scenario B: Article placed in container

1. Identify the product in your container: "5.0 A-8216.xx" and the length "50" (please see picture below)



2. Identify the product of the affected batch with the marked LOT (please see picture below)



3. Place the product in quarantine
4. Return the product to Medartis
5. Fill out this form and return it to Medartis (see chapter "2. Customer Reply")

Recommendation if the article is already implanted

If an affected product has been implanted, it is recommended that, during the routine follow-up visits before the physiological bone healing has taken place, the patient is specifically asked about any symptoms that could indicate implant failure. If these symptoms are confirmed, please contact us immediately via complaints@medartis.com.

In addition, a more conservative progression of weightbearing is advised, particularly in high-risk patients.

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			
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice (02-2026) and that I read and understood its content.		
<input type="checkbox"/>	I blocked all affected products.		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.		
<input type="checkbox"/>	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):	
		<input type="checkbox"/> N/A	Comments:
<input type="checkbox"/>	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):	
		<input type="checkbox"/> N/A	Comments:
<input type="checkbox"/>	I have implanted affected devices – enter number implanted and date complete.	Qty:	Lot Number:
		Date Implanted (DD/MM/YY):	
		Qty:	Lot Number:
		Date Implanted (DD/MM/YY):	
		<input type="checkbox"/> N/A	Comments:

Field Safety Notice	medartis
Name	

<input type="checkbox"/>	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 DE - Germany
Deadline for returning the customer reply form	30.06.2026

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