| Place/Date: **Basel, 05.12.2025** | Reference: **Urgent Field Safety Notice**

URGENT: Field Safety Notice

Dear Sir or Madam,

On 05.12.2025, Medartis AG has initiated a lot specific product Field Safety Corrective Action (FSCA) for several products, which are listed in the following.

1. Field Safety Notice (FSN)

Field Safety Action				
Date	05.12.2025			
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 andrea.rogalla@medartis.com PRRC: Ms. Andrea Rogalla +49 7665 9824 223		
Article description	**Part Name**	**Part No.**	**Lot. No**	**UDI-DI (GTIN)**
	Twist Drill Ø1.6mm x 25mm, L81mm, AO	A-3430S	25465083	07630037865346
	1.7 CCS Fully Threaded 16mm	A-5282.16/1S	25468397	07630037867173
	3.0 CCS Fully Threaded 34mm	A-5882.34/1S	25467908	07630894809965

FSCA	FSCA 02-2025
Failure description	On 26. November 2025 our sterilization provider informed us that certain limits for bioburden were exceeded in the water used for the final cleaning of sterile products. This has been discovered in the frame of quarterly monitoring. After heat treatment during the cleaning and drying process, gramnegative germs can result in endotoxins. These endotoxins can remain on the final product as no treatment is applied after the final cleaning.
Results of the Risk Assessment	The 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): Recall by the legal manufacturer Medartis AG • Reporting to national competent authorities • Inform all affected customers • Testing of samples
Actions for affected Customers	• Blocking of the affected products • Discard the affected products • Fill out this form and return it to Medartis (see chapter “2. Customer Reply”)
Recommendation if the article is already implanted	An implanted product may have been exposed to elevated endotoxin levels. While many patients will remain asymptomatic, endotoxin residues on implant surfaces can lead to inflammatory reactions. We recommend the surgeon to monitor the affected patient for the following potential signs: • Fever • Redness, warmth, swelling, or persistent inflammation • Delayed or impaired wound healing • Pain that does not follow the expected postoperative course • Radiographic changes suggestive of osteolysis If such findings occur, the surgeon should evaluate and monitor the patient and manage according to standard clinical practice. In cases where symptoms persist despite appropriate management, reassessment of the treatment, including the possibility of removing the implant, may be warranted. The patient should be informed of these potential symptoms and advised to get in contact promptly should they occur.

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):
		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 Discarded (DD/MM/YY):
		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 Deutschland
Deadline for returning the customer reply form	16.01.2026

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