| Place/Date: **Basel, 30.07.2024** | Reference: **Urgent Field Safety Notice**

URGENT: Field Safety Notice (Product Recall)

Dear Sir or Madam,

On 30.07.2024, Medartis AG has decided to execute a lot specific product Field Safety Corrective Action (FSCA) for the **1.2 K-Wire, Lancet, 150mm** (**A-5042.21/2S**).

Affected lot: 24384824 / 22323924

1. Field Safety Notice (FSN)

Field Safety Action on: 1.2 K-Wire, Lancet, 150mm (**A-5042.21/2S**)			
Date	30.07.2024		
Contact Detail	**Legal Manufacturer** Medartis AG Hochbergerstrasse 60E 4057 Basel Switzerland return@medartis.com PRRC: Axel Maltzen +41 79 209 60 62	**Authorised Representative** Medartis GmbH Am Gansacker 10 79224 Umkirch Germany return@medartis.com PRRC: Andrea Rogalla +49 7665 9824 223	
Part Name	1.2 K-Wire, Lancet, 150mm	**Part No.**	A-5042.21/2S
Lot No.	24384824 22323924	**UDI-DI (GTIN)**	76300378022PA
Device Type and Purpose	The K-wire is intended temporary fixation, correction or stabilization of bones.		

Field Safety Corrective Action reference(FSCA)	FSCA 04-2023
Failure description	The FSCA was initiated due to an label error of the K-wire A-5042.21/2S. Medartis detected that the main label on the packaging has a yellow colour coding instead of a white one.
Results of the Risk Assessment	**1.** Screw is not optimally guided, which can inadvertently injure anatomical structures **2. a)** K-wire is entrained during insertion and can unintentionally injure anatomical structures **2. b)** Screw's insertion behaviour deteriorates and compression cannot take place as a result **3**. Screw is selected 50 mm too short and cannot be inserted correctly
Corrective Action From Medartis	Internal investigation (reference: Critical 05-2024)
Medartis Contact Person	Julie Moore Tel: +44 (0) 7817 360710 E-Mail: recall.uk@medartis.com Medartis Ltd. 3 Pinnacle Way Pride Park, Derby DE24 8ZS, UK
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 any packaged K-wires from lots 24384824 & 22323924 in stock, please quarantine the product. • If you have any K-wire from lots 24384824 & 22323924 in a set, please quarantine the affected product. • The Medartis sales representative responsible for you will contact you about how the return and replacement of the products will work. • 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	As the K-wire is not implanted and therefore does not remain in the patient, there is no need to check the patient's previous results.

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

Return acknowledgement to sender	
E-mail	Andrea.rogalla@medartis.com
Postal Address	Medartis GmbH Am Gansacker 10 79224 Umkirch
Deadline for returning the customer reply form via e-mail	09.08.2024

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