| Place/Date: **Basel, 06.03.2024** | Reference: **Urgent Field Safety Notice**

URGENT: Field Safety Notice

Dear Sir or Madam,

On 06/03/2024, Medartis AG initiated a field safety corrective action (FSCA) for the K-wire A-5042.21/2S.

Affected lots:

Lot 21237870
Lot 22280285
Lot 22297081
Lot 22324029

Field Safety Action on: K-wire			
Date	06/03/2024		
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 return@medartis.com PRRC: Andrea Rogalla +49 7665 9824 223
Part Name	1.2 K-Draht, Lanzette, 150mm	**Part No.**	A-5042.21/2S
Lot No.	21237870 22280285 22297081 22324029	**UDI-DI (GTIN)**	07630037864165 07630037864165 07630037864165 07630037864165
Device Type and Purpose	The K-wire is intended for implantation for temporary fixation, correction or stabilization of bones.		

FSCA	FSCA 02-2024
Failure description	The FSCA was initiated due to an error with the K-wire A-5042.21/2S. Medartis received a customer complaint regarding Lot 22324029 that the main label on the packaging has the yellow colour coding instead of the white one. The root cause analysis revealed that since the change to the master label on 22.12.2022, the wrong colour coding has been printed on the label for this item. This means that all batches produced after this date are affected by this error.
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)** The 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	Field Safety Corrective Action (FSCA): Recall by the legal manufacturer (Medartis AG) Sorting out the defect products CAPA triggered via the internal CAPA system (reference: Critical 02-2024)
Medartis Contact Person	Cenan Djukatani Tel: +41 61 633 37 12 E-Mail: return@medartis.com Medartis AG Hochbergerstraße 60E 4057 Basel

Customer Acknowledgment and Inventory

Hospital / Clinic / User Information	Contact Name: Adress: Postcode: City: Country: Phone: Email:

Number of affected products at customer

Quantity	Article	LOT	Order No.
x	x	x	x
x	x	x	x
x	x	x	x

Product Recall:

For the above mentioned products a field safety corrective action is initiated. Please confirm that all affected products under your control have been identified and please document below the amount being :

- Already used
- Discarded
- Returned to Medartis

Lot	Qty	Disposition		
x	**x**	Used: ☐ _____	Discarded: ☐ _____	Returned to Medartis: ☐_____
x	**x**	Used: ☐ _____	Discarded: ☐ _____	Returned to Medartis: ☐_____
x	**x**	Used: ☐ _____	Discarded: ☐ _____	Returned to Medartis: ☐_____
x	**x**	Used: ☐ _____	Discarded: ☐ _____	Returned to Medartis: ☐_____
x	**x**	Used: ☐ _____	Discarded: ☐ _____	Returned to Medartis: ☐_____

Information to user:

I confirm with this document that I am aware of the field safety corrective action initiated by Medartis and that this information has been forwarded to all potentially affected divisions in-house.

	FIRST NAME – NAME - FUNCTION	*DATE*	*SIGNATURE*
Filled in by			

Important Information

- **Please fill in this form and return it within 24h at the following address: return@medartis.com**
- **Please block all affected products (do not use the products)**
- **Please return all affected products immediately to Medartis AG:**

Medartis AG
Hochbergerstrasse 60E
CH-4057 Basel
z.H. Deviation Management

or

Medartis GmbH
Am Gansacker 10
DE - 79224 Umkirch
z.H. Deviation Management

- **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