



# PARADIGM SPINE

AN XTANT MEDICAL COMPANY

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## FIELD SAFETY CORRECTIVE ACTION - RECALL

REC 2024-01

### IMMEDIATE ACTION REQUIRED

Recipient:	Customers, Distributors and Sales Department		
Affected Product:	HPS 2.0 Rod coupler, S=25N/mm, 27mm		
Manufacturer	Paradigm Spine GmbH		
Date of Recall	17.07.2024		
Type of Recall	Field Safety Corrective Action (FSCA)		
Item, lot and UDI number:	<b>Item Number</b>	<b>LOT Number</b>	<b>UDI Number</b>
	HBI92527	1321000344	(01)04260148891649(17)290731(10)1321000344
	HBI92527	1321000352	(01)04260148891649(17)290731(10)1321000352
	HBI92527	1322000026	(01)04260148891649(17)300430(10)1322000026
	HBI92527	1322000072	(01)04260148891649(17)300531(10)1322000072
	HBI92527	1322000073	(01)04260148891649(17)300531(10)1322000073
	HBI92527	1322000074	(01)04260148891649(17)300531(10)1322000074
	HBI92527	1322000075	(01)04260148891649(17)300630(10)1322000075
Reason for FSCA	It has been determined that the internal thread of the rod coupler within the specified batches was manufactured out of the specified tolerances. This may result in the corresponding rod not being able to be fully screwed in.		
Clinical Effect	If the case described above occurs, the surgery may be delayed until the defective rod coupler has been replaced. If no replacement is available, it is necessary to deviate from the planned procedure and perform a fusion.		
Action Required	We would like you to identify all affected products in your warehouse as well as in your field inventory in the hospitals and return them immediately for inspection and quarantine. These items must not be sold or used. Please fill in the attached form to confirm that you have inspected your inventory and that the affected parts will be returned or have been already used.		
Transmission of this Recall	This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (If appropriate).		

Further Information For further questions related to this Field Safety Corrective Action (FSCA) do not hesitate to contact our customer sales department at:

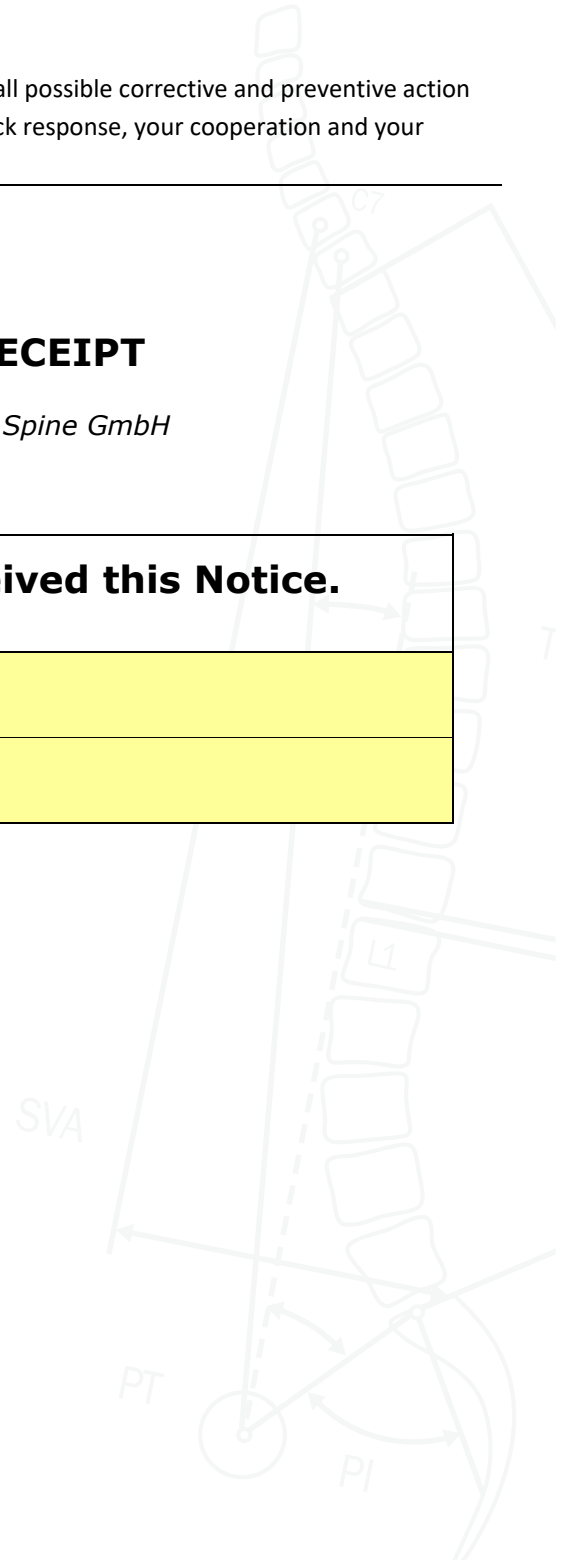
**Paradigm Spine GmbH**  
**Eisenbahnstraße 84**  
**78573 Wurmlingen / Germany**  
**psg-service@paradigmspine.com**  
**Tel.: +49(0)7461 963599-0**

We deeply regret the inconvenience and will take all possible corrective and preventive action to avoid this in the future. We appreciate your quick response, your cooperation and your understanding.

## **CONFIRMATION OF RECEIPT**

*Please sign and return to Paradigm Spine GmbH*

<b>I hereby confirm that I have received this Notice.</b>	
<b>Date:</b>	
<b>Signature:</b>	





## Confirmation of Inventory

Please return this form to Paradigm Spine by fax or email.

Fax: +49(0)7461 963599-20 / Email: [psg-service@paradigmspine.com](mailto:psg-service@paradigmspine.com)

According to our traceability records you have received items of the recalled lots. Please check your inventory and your accounts in your territory.

Item number	Lot number	Qty.	Delivery date	In inventory or accounts yes/no	Will be returned yes/no	Already implanted yes/no

Please complete the table above and sign below to confirm that you checked your inventory, your accounts in your territory and that you informed your customers, if applicable.

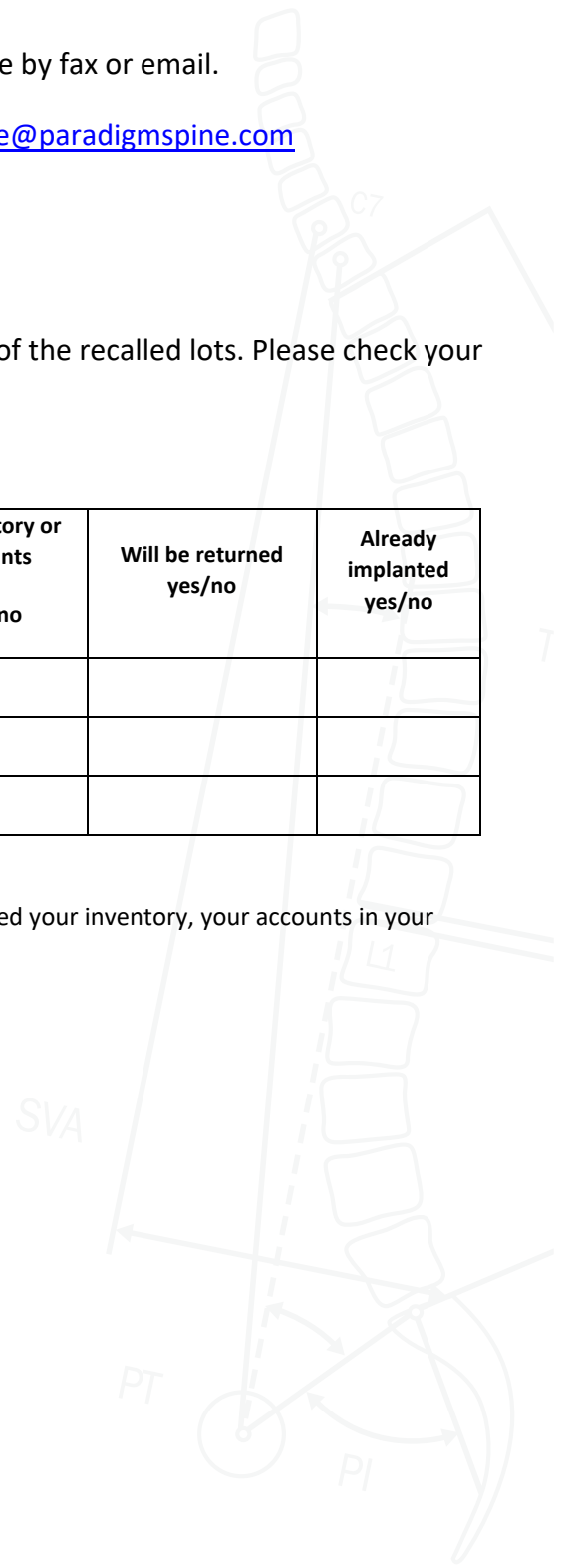
Company: \_\_\_\_\_

Print Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Position/title: \_\_\_\_\_

Date: \_\_\_\_\_





Please send the affected items separately (not mixed with other products) to the following address using recall number REC 2024-01.

Paradigm Spine GmbH  
Eisenbahnstraße 84  
78573 Wurmlingen  
Germany  
Attn: QA Department / Recall 2024-01

You will receive replacement implants immediately.

