NATIONAL COMPETENT AUTHORITY REPORT

This form should be used for the exchange of medical device information between NCAR participants only.

Completed forms should not be released to the public.

1. Is this report confidential? *Yes [ ] No [**X**]*

Reference and Reporter Data

2. NCA report ref. no.: **DE-BfArM-2024-07-30-4754**	3. Local NCA reference no.: **23795/24**	4. Related NCA report nos.: (if any)
5. Manufacturer Ref/Recall no.: **REC 2024-01**	6. Sent by: (Name and Organization) **BfArM, Division Medical Devices**	7. Contact person: (if different from 6) **Rainer Harhammer**
8. Tel: **+49 228 207 - 5390**	9. Fax: **+49 228 207 - 5300**	10. E-mail: **md-vigilance@bfarm.de**

Device Data

11. Generic name/ kind of device**: Spinal dynamic-stabilization system**		20. CAB/Notified Body no.: **0123**
12. Nomenclature id: **GMDN**	13. No.: **58446**	
14. Trade Name and Model / Catalogue: **HPS 2.0 Rod coupler, S=25N/mm, 27mm ; N/A / HBI92527**		21a. Device approval status:
15. Software version: **N/A**		
16. Serial no.: **N/A**	17. Lot/batch no.: **Please see REC 2024-01 Product List**	21b. Risk Class: **MDD Class IIb**
18. Manufacturer: **Paradigm Spine GmbH** Country: **DE** Full Address: **Eisenbahnstrasse 84** **78573** **Wurmlingen** Contact: **Camilla-Noémi Sommer** Tel: **07461963599-0** Fax: **07461963599-20** E-mail: **csommer@paradigmspine.com**	19. Authorized rep: Country: Full Address: Contact: Tel: Fax: E-mail:	22. Action taken: [ ] None [ ] Safeguard Action [**X**] Field Safety Corrective Action [ ] Other (specify)

Event Data

23a. Background information and reason for this report:
The manufacturer has informed BfArM about a corrective action concerning the above mentioned device.

23b. Is the investigation of the report complete? Yes [**X**] No [ ]

24a. Conclusions:
The manufacturer issued the enclosed FSN.

24b. Have the manufacturer's actions been made public? Yes [**X**] No [ ]
24c. The originator of this NCAR will take the lead and co-ordinate the investigation - Yes [**X**] No [ ]

25a. Recommendation to receivers of this report:
For your information and be aware of the problem.

25b. Device known to be in the market in (include copy of manufacturer's letter):
AT, DE, GB, IT

25c. Device also marketed as (trade name):

Report Distribution

26a. This report is being distributed to:
[ ] The NCAR Secretariat for further distribution to FULL NCAR PARTICIPANTS.

[ ] The NCAR Secretariat for further distribution to ALL NCAR PARTICIPANTS.
[**X**] EEA states, EC, and EFTA
[ ] The following targeted NCAs:
[**X**] The manufacturer / authorized rep.: **Paradigm Spine GmbH /**