

Field Safety Notice (FSN) – Madita-fun integrative therapy chair

FSN-2026A

2nd April 2026

For the attention of: All users, carers, prescribers, healthcare organisations, and distributors of the Madita-fun integrative therapy chair.

1. Products affected

Madita-fun integrative therapy chair

The **madita-fun.** therapy chair is designed for children and youths who cannot sit or stand unaided however whose limited torso posture does not require permanent sitting in a seat pan.



Product codes: 7900000/UK, 7900200/UK, 7901000/UK, 7901200/UK, 7901300/UK, 7902000/UK, 7902100/UK

Basic UDI-DI – 425104020000400740XXXXC5

2. Reason for Field Safety Action

Schuchmann were informed of an incident where a user was secured in a Madita-fun chair with a chest harness in conjunction with a 4 point lap belt. The user slipped through the lap belt and choked, resulting in a serious medical event.

3. Actions taken by the manufacturer

The use of a number of belts and harnesses available as accessories with Madita-fun had previously been assessed by risk management. Following the incident, the risk was re-analysed and, as a measure, a more detailed description of the assessment, including new warnings was added to the instructions for use. Included in Attachment 1 - see section 4.12, page 24.

4. Actions to be taken by the user/user's representative

The product is safe to continue to use if used in accordance with the current IFU, however please incorporate the additional information provided in this FSN into your risk assessment to determine the suitability for individual users of the belts and harnesses used. In particular please consider the use of a T shaped groin harness in conjunction with a chest harness. Without proper pelvic positioning there is risk that the user may slip downward.

Ensure regular reviews of the equipment by healthcare professionals to identify any change in needs of the user and to ensure that the user is able to remain correctly positioned in the chair.

Please contact us immediately if you have any concerns with the use of the belts and harnesses or need any additional accessories.

5. Actions to be taken by organisations and distributors

Increased awareness and vigilance is important to ensure the IFU are understood and followed. Distribute this FSN to any person within your organisation and/or to any customer where the product may have been allocated or sold.

Please report all device-related incidents to the manufacturer, distributor or local product specialist, and the national Competent Authority if appropriate, as this provides important feedback

6. Acknowledgement

Please fill the attached reply form - Attachment 2 and return to the following email address: vb@schuchmann.co.uk. Deadline for returning the reply form 8th May 2026.

7. Contact details

Schuchmann LLP info@schuchmann.co.uk 01733 561885

Manufacturer Contact Reference Person

Victoria Bignell – Director

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vb@schuchmann.co.uk

To confirm this notice has been forwarded to the appropriate Regulatory Agencies for and on behalf of Schuchmann.



Attachments

Attachment 1 : IFU

Attachment 2 : Acknowledgement form