

URGENT: Instructions For Use

Field Safety Notice (FSN) FSCA-02-2026

February, 27th 2026

Customer

Adress

<u>Product Information</u>	<u>Manufacturer</u>
Manosplint Cushionfoam	Kinetec SAS Zone industrielle de Tournes Rue Maurice Périn 08090 Tournes France
<u>References :</u> M300000027 M300000028 M300000029 M300000030	Contact: DAVAL Frédéric Email: quality@kinetec.fr

All batches already on the market that have not expired are affected by this safety information.

➤ Intended Use:

Manosplint[®] Cushion Foam is a foam used in the design of removable immobilisation splints. It acts as an interface between the skin and the splint, positioned at bony protrusions or the contours of the splint to prevent bone crushing or friction.

➤ Contraindications:

Manosplint[®] Cushion foam should not be used to create a closed circular immobilization or any type of enclosed environment for the skin. Do not apply cream, ointment, or perfume to the immobilized limb.

➤ Description of the incident that led to the action:

This action is being taken following the use of Manosplint Cushionfoam to create an airtight bandage. This may cause skin reactions.

➤ Risk analysis:

With a circular bandage, there is a risk of skin reaction, particularly if Manosplint[®] Cushion foam is used to create a closed circular immobilisation or any type of enclosed environment for the skin. The risk analysis has been reviewed to include the use of an inappropriate bandaging technique. The causes of the hazardous event have been identified:

- User side: Prolonged contact with the patient in an oxygen-free environment. No visibility of the immobilised area.
- Kinetec[®] side: No clear instructions for use to avoid the use of an airtight bandaging technique. Solutions to reduce the risk: Update the instructions for use. Explain the intended use. Specify contraindications. Communication of the FSN to the Scandinavian distributor following the three incidents in 2025 (in Sweden and Denmark: only these two countries use Manosplint Cushionfoam to create an airtight bandage).

The residual risk has been reduced as much as possible and assessed as acceptable by Kinetec. The benefit/risk ratio is favourable for the patient.

➤ Advice from Kinetec[®] regarding the use of Manosplint Cushionfoam:

A risk assessment has been undertaken. To reduce the risk of skin reactions to an acceptable level, the following instructions must be followed:

Manosplint[®] Cushionfoam should only be used for the design of removable immobilization splints.

The splint must be removable by the patient to allow them to air the skin daily, especially in case of sweating.

The immobilized limb must be dry before the splint is applied and at all times thereafter.

Do not attempt to clean or wet the Cushion Foam, use a new one.

The leaflet (Instruction For Use) have been updated accordingly.