

URGENT: Instructions For Use

Field Safety Notice (FSN) FSCA-02-2026

February, 27th 2026

Client

Adresse

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

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.

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➤ 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.

➤ Potential risks associated :

With circular bandage there is a risk of skin reaction, especially if Manosplint® Cushion foam is used to create a closed circular immobilization or any type of enclosed environment for the skin.

➤ 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.

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