U.S. SURGITECH
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SurgyPad
Mattress Overlay
Instructions for Use

Product Description

The SurgyPad mattress overlay is a modular, single-use patient positioning system designed to optimize patient comfort, and safety during prolong surgical procedures by providing extra cushioning to the pressure points.



Clinical Benefits

The device aids healthcare facilities in providing a safe and effective method for managing patients to prevent pressure ulcers during lateral patient positioning.

Intended User

This device is intended for use by qualified surgeons, doctors, or trained healthcare professionals with adequate knowledge of surgical positioning procedures.

Inspections

Before use, the product must be inspected for the following:

- Visible damage to the exterior, such as wearing, tearing, residuals, or cracks.
- Presence of sharp edges or burrs.
- Uniformity of the product, checking for unwanted bending or compression.
- Do not use the product if it fails any of the above inspections.

Patient Population

The SurgyPad Matteress overlay is designed for adults of all genders.

Single-Use/ Disposable Product

This device is designed and sold for single use only. Reprocessing, reuse, or re-sterilization is strictly prohibited, as it may compromise structural integrity or lead to cross-contamination and patient infection. After the procedure, dispose of the device in accordance with hospital protocols for used medical devices.

Disposal

Following use, discard the Surgypad in accordance with applicable hospital policies and local regulations.

Shelf Life, Storage, and Transportation

- **Shelf Life:** Indefinite
- **Storage:** Store in a clean, cool, and dry area
- **Handling:** Protect from mechanical damage and direct sunlight. Ensure the pad remains flat during handling and storage; do not roll or fold the pad.

Performance Claims

- Prevents pressure-related injuries.
- Easy to setup and remove.
- High-density, latex-free, and water-wicking foam construction.
- Single-use design eliminates cross-contamination risk.

Undesirable Side Effects

There are no known side effects associated with the SurgyPad Matteress overlay when used by a professional for its intended purpose.

Adverse event

Any serious incident or adverse event that occurs in relation to the use of the device should be reported to U.S. Surgitech, Inc. at the contact details provided in this IFU and to the relevant competent authority or regulatory authority, as applicable.

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V5: 17/10/2026

Contraindications

Do not use if the patient exceeds the O.R. table weight limit.

Warnings

- **Single Use Only:** Do not reuse or reprocess.
- **Professional Use:** Only to be used by qualified medical staff.
- **Weight Limits:** Consult the O.R. table manufacturer regarding weight limits.
- **Patient Habitus:** Higher BMI may necessitate modified positioning strategies to ensure safety.
- **Steep Positioning:** The product does not support steep trendeleburg or reverse trendelenburg positioning

Preparation for Use

Place the SurgyPad Matteress Overlay in the optimal location on the table so that the patient's sacrum and scapula rest directly on the pad.

Symbols	Meaning
	Latex Free
	Single Use
	European Conformity
	The medical device/ product has not undergone a sterilization process
	See Instructions For Use
	Date of Manufacturing
	Reference Number
	Batch Number