

SurgyPad Flex

Patient Positioning System

Instructions for Use

Product Description

The SurgyPad flex is a modular, single-use patient positioning system designed to optimize patient stability, comfort, and safety during robotic and laparoscopic surgical procedures. Engineered for use across a variety of surgical specialties, the SurgyPad flex system helps maintain proper anatomical alignment and reduces the risk of pressure injuries, nerve damage, and intraoperative shifting.

Clinical Benefits

The device aids healthcare facilities in providing a safe and effective method for managing patients to prevent pressure ulcers and ensure non-movement while in steep Trendelenburg positions. It helps mitigate clinical hazards and reduces the occurrence of "never-events" related to 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 Flex 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 Flex when used by a professional for its intended purpose.

Contraindication

- There are no device-specific contraindications known for SurgyPad Flex when used as intended. The device should not be used where Trendelenburg, Reverse Trendelenburg, lateral tilt positioning, robotic/laparoscopic positioning, or patient immobilization is contraindicated based on the patient's clinical condition or physician judgment.

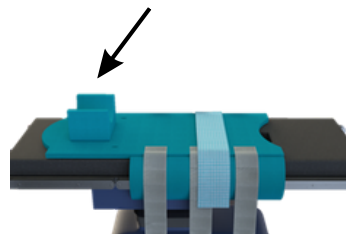
Adverse event

- Any serious incident or adverse event that occurs in relation to the use of SurgyPad Flex 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.

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.
- **Preparation Solutions:** Care should be taken to safeguard the pad from exposure to prep solutions.

Note: Headrest sold separately



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

► Precautions

- Use the SurgiPad Flex only by qualified surgeons, doctors, or trained healthcare professionals familiar with surgical positioning procedures.
- Inspect the device before use for visible damage, wear, tears, cracks, sharp edges, burrs, unwanted bending, compression, or contamination. Do not use the device if any damage or defect is observed.
- Ensure the SurgiPad Flex is correctly positioned on the operating room table and securely fastened using the strap system before positioning the patient.
- Ensure the patient's sacrum and scapula are in direct contact with the pad and that no sheets, devices, or other materials interfere with patient-to-pad contact unless specifically required by the procedure.
- Protect the pad from excessive exposure to preparation solutions, fluids, direct sunlight, mechanical damage, or elevated temperatures.
- Do not roll, fold, reuse, reprocess, or re-sterilize the device.

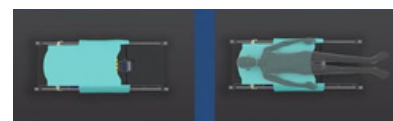
► Preparation for Use

1. Position the SurgiPad on the Operating Room Table

a. Lithotomy Positioning: Align the perineal cutout of the SurgiPad flex approximately 1 inch below the perineal cutout of the surgical mattress.

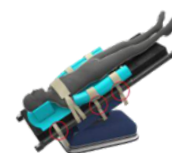
b. All Other Positions: Place the SurgiPad in the optimal location on the table so that the patient's sacrum and scapula rest directly on the pad.

c. NOTE: During this step, arm protectors should remain attached.



2. Secure SurgiPad to Table Using the 6-Strap System

a. Loop each strap around the surgical rail, then bring it up through the small D-ring and fasten the Velcro ends downward (nappy side to tacky side) toward the rail.



i. Double wrap method: Wrap the strap around the rail twice before passing it through the D-ring.

If a post is present, loop the strap once on either side of the post for additional stability.

Ideal for thin O.R. mattresses or gaps in the rail to prevent strap slippage



i. Around the post method: Loop the strap around the post behind the table rail, bring it up through the D-ring, and fasten Velcro back onto itself.

1. This technique is preferred by many, as it leaves the rail free for clamps and accessories like stirrups or the Bookwalter system.



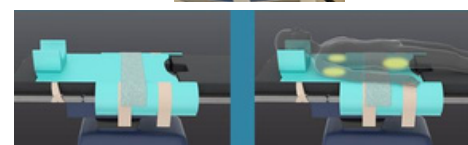
3. Position the Patient on SurgiPad

a. Lift sheet may be removed after re-positioning patient (optional).

b. If lift sheet will be utilized during the procedure, keep folded, and place in center of SurgiPad where small/lumbar of patient's back will lay.

i. Keep sheet width to 10 inches or less to maintain maximum direct skin contact with the pad, especially in sacral and scapular areas.

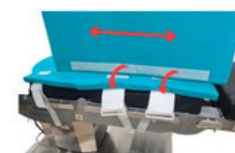
c. Allow patient to position self, aligning sacrum directly above perineal cutout. Ensure nothing is between patient's sacrum or scapula and SurgiPad.



4. Adjust Arm Protectors (if needed)

a. If repositioning is needed, adjust arm protector so that the patient's ulnar nerve, elbow, and hands are properly covered and protected.

b. Velcro strip on bottom of arm protectors affix to wide, plush, white D-ring straps below.



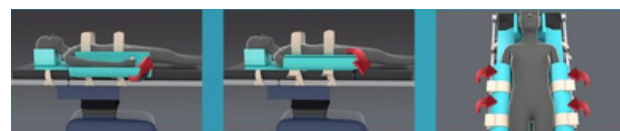
5. Wrap Patient's Arms with Arm Protectors

a. Place the patient's arm along the crease between the arm protector flaps, with the hand in a neutral position.

i. Optional: Use item 780-427 SurgiGrip for hand positioning.)

b. Fold the bottom flap up and over the arm, then bring the top flap down to wrap securely.

c. Fasten at least 2/3 of the arm safety straps through the large D-rings and secure back onto themselves.

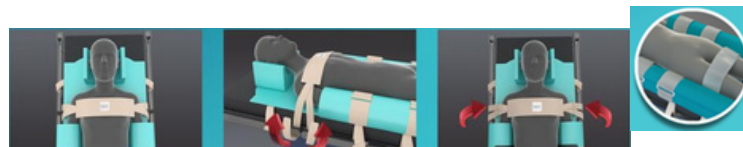


6. Secure Patient Using the Universal Body Strap

a. Place the body strap across the patient's chest, with the SurgiPad logo centered and facing up.

b. Loop the Y-connection Velcro straps through the bed rails and secure them back onto the body strap as shown.

c. Note: Dependent on location (if applicable), unused arm protector strap may be utilized as leg or chest strap for added security.



7. Post-Procedure Removal

a. After the procedure, carefully release the arm protectors and body strap before transferring the patient.

b. The SurgiPad is free from harmful or toxic materials and may be disposed of in accordance with hospital protocols for used medical devices. For efficient SurgiPad removal, table straps may be cut with scissors if needed.