STS-BodyPad™ XL Plus by NinoMed, LLC

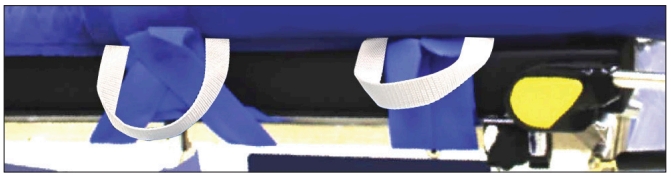
Instructions for Use (IFU)

US Patent: 10512578, 29588893
European Patent: 2988717
Additional Patents Pending

STS-BodyPad™ XL Plus

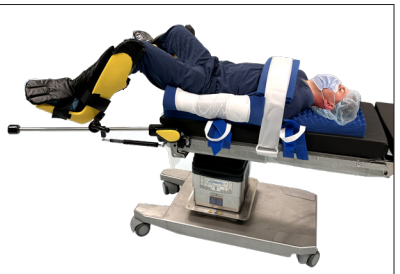
Intended use: This device is intended for patient positioning and to prevent possible injury during surgery.

1. Remove foam from plastic packaging by opening one end with scissors.
2. Place the non-woven lift sheet centered and at 90 degrees to the longitudinal axis of the OR table.
3. Then place **STS-BodyPad™ XL Plus** on operating table with short blue Velcro straps facing down towards the floor.
4. Align the curve of the perineal cutout of **STS-BodyPad™ XL Plus** with the perineal cutout of the operating table mattress.
5. Firmly secure **STS-BodyPad™ XL Plus** to the horizontal metal side rails of the operating table by looping each of the FOUR side Velcro straps between the operating table mattress and the side rail, then tightly pulling on the Velcro strap, and finally attaching the ends to the complementary piece of Velcro.



NOTE: If a connector from the side rail to the operating table falls at the location where the blue Velcro strap attaches, the strap is longitudinally slit to allow for half of the Velcro strap to be placed towards the head and half to be placed towards the feet relative to the connector or break in the siderail. Confirm the Velcro straps are secure.

6. Position the patient supine on the **STS-BodyPad™ XL Plus** to facilitate intubation.
7. Use the Velcro body strap and protective foam to secure the patient while on the operating table.
8. Position the legs and feet in stirrups or other appropriate leg holders if in lithotomy.
9. After intubation/induction of anesthesia,
   a. Lift and position the patient to the desired location in relation to the perineal cut out if necessary and according to the surgeon's preference.
   b. Two white handles are included on each side to help facilitate moving/shifting a patient on **STS-BodyPad™ XL Plus** cephalad/superiorly or caudal/inferiorly on the operating table. The side handles and **STS-BodyPad™ XL Plus** should NOT be used for lateral transfers. Confirm that the patient's perineum is aligned with the perineal cutout if access to the perineum is necessary.
10. Wrap the arms and hands with the included foam arm protectors carefully tucking any IV tubing or monitor wires. Use additional padding if necessary.
11. While an assistant rolls the patient's body towards the contralateral side, hold the non-woven white sheet and wrap the sheet around the **STS-BodyPad™ XL Plus** arm foam. Then tuck the white sheet under the patient's back holding it taut. Have the assistant gently roll the patient back keeping the sheet firmly under the patient. The patient's weight will serve to hold the sheet in place.
12. Confirm that the arm and hand are safely wrapped and secured.
13. Repeat steps 10-12 on the contralateral side. Again, confirm that the arm and hand are safely wrapped and secured.
14. Next, the body/chest Velcro straps should each be looped around the siderails and through the attached D-rings on each side of the operating table. The body/chest Velcro straps and protective foam should be used to secure the patient's chest or torso by overlapping the Velcro with the appropriate amount of tension. Confirm the protective body/chest foam is present between the patient and the Velcro and that the anesthesiologist can adequately ventilate the patient.
15. If Trendelenburg positioning is required, confirm that the patient is securely positioned.



Kit contains: 21" x 40" STS BodyPad™ XL Plus with sewn-on handles to assist with moving the pad plus patient down to the desired location, lift sheet, white velcro strap w/ protective foam, perineal protective sheet, and blue arm protectors.

Description: OR table pad designed for Trendelenburg and lithotomy. Has a perineal protective sheet. Includes body strap with protective foam, arm protectors, and lift sheet.

⚠ Warnings:

- Visually inspect every device before use to ensure the device is still in good condition and not contaminated before use.
- The device is intended only for single patient use only.
- Do not reuse or reprocess this device. Reuse or reprocessing of this device may lead to its failure or subsequent injury or patient infection.
- Store the device in a clean, dry location at room temperature prior to use.
- Ensure that the device is securely attached to the operating table.
- Monitor the patient according to usual practice and facility's policies and guidelines.
- Ensure that any alcohol-based preps are dry and not spilled on the positioners.
- Only trained licensed medical personnel should use the device.

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Symbol	Description
REF	Device Catalogue/Reference Number
LOT	Batch Code
	Date of Manufacture of Device
	Caution/Warning
	Consult Instructions for Use
MD	Medical Device
	Non-Sterile Medical Device
	Do Not Reuse
UDI	Represents the Unique Identification (UDI)
	Importer
EC REP	Authorized Representative in the European Community
	Manufacturer
CE	CE Mark

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For order fulfillment, distribution, issues or feedback, reach us at:
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CE

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