

Safe-T-Secure® by NinoMed, LLC

Instructions for Use (IFU)



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

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 **Safe-T-Secure®** on operating table with short blue Velcro straps facing down towards the floor.
3. Align the curve of the perineal cutout of **Safe-T-Secure®** with the perineal cutout of the operating table mattress. The bottom (distal) edge of the **Safe-T-Secure®** should extend 4-6 inches beyond the bottom of the operating table.



4. Firmly secure **Safe-T-Secure®** 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

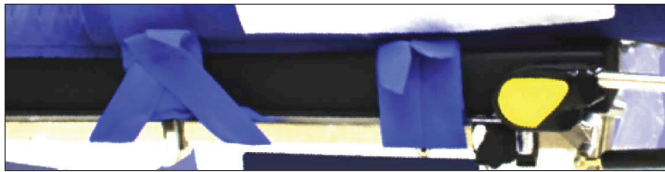
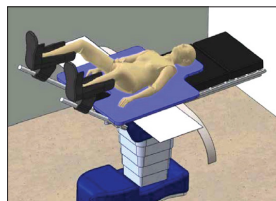
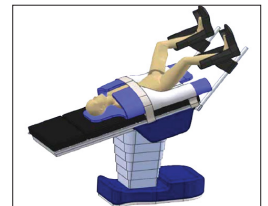
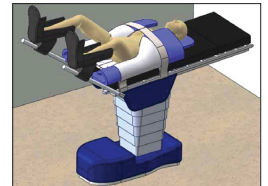
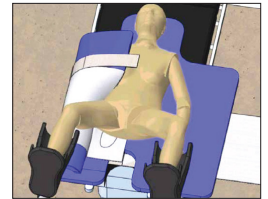


table falls at the location where the blue Velcro strap attaches, the strap is longitudinally slit to allow for half of the Velcro strap to be placed towards the head and half to be placed towards the feet relative to the connector or break in the siderail. Confirm the Velcro straps are secure.

5. Position the patient supine on the **Safe-T-Secure®** to facilitate intubation.
6. If the Velcro chest straps are loosely applied during intubation, the use of arm boards is optional.
7. Position the legs and feet in stirrups or other appropriate leg holders.
8. After intubation/induction of anesthesia,
 - a. Loosen the chest strap.
 - b. 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.
 - c. Confirm that the patient's perineum is aligned with the perineal cutout.



9. Use the specially designed egg crate configuration to tuck any IV tubing or monitor wires. Use additional padding if necessary.
10. While an assistant rolls the patient's body towards the contralateral side, wrap the **Safe-T-Secure®** foam around the patient's arm and hand keeping the "thumbs up" orientation. Then tuck the attached and integrated 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.
11. Confirm that the arm and hand are safely wrapped and secured.
12. Repeat steps 9-11 on the contralateral side. Again, confirm that the arm and hand are safely wrapped and secured.
13. Next, bring the integrated chest foam together in the midline. Use the longer Velcro straps to secure the patient's chest by overlapping the Velcro with the appropriate amount of tension. Confirm that the integrated chest foam is present between the patient and the Velcro and that the anesthesiologist can adequately ventilate the patient.
14. Place the patient in Trendelenburg as required and confirm that the patient is securely positioned.



Warnings:

- Visually inspect every device before use to ensure the device is still in good condition and not contaminated before use.
- Do not use with patients weighing more than 400 pounds.
- 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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For order fulfillment, distribution, issues or complaints, reach us at:

Phone: +1-919-818-7311 | Fax: +1-919-869-2012 | Email: orders@ninomed.com | www.ninomed.com



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

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NinoMed, LLC.
241 Parker Road
Chapel Hill, NC 27517

Made in USA



MedEnvoy Global BV
Prinses Margrietplantsoen
33 Suite 123
2595 AM The Hague
The Netherlands