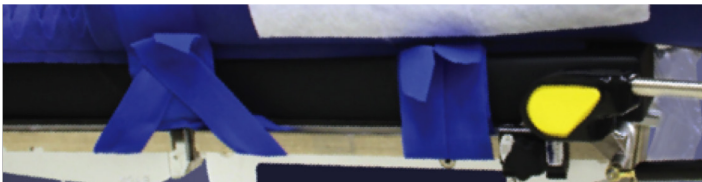


Safe-T-Secure® by NinoMed, LLC Instructions For Use (IFU)



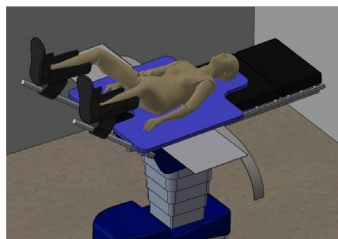
1. Intended for patients up to 400 pounds
2. Remove foam from plastic packaging by pulling on slit at head end or opening with scissors.
3. Place **Safe-T-Secure®** on operating table with short blue Velcro straps facing down towards the floor.
4. Align the curve of the perineal cutout in the Safe-T-Secure® with the perineal cutout in 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.
5. Firmly secure the **Safe-T-Secure®** to the horizontal metal side rails of the operating table by looping each of the FOUR Velcro straps attached to



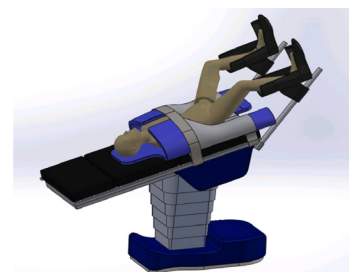
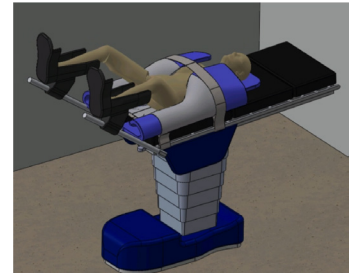
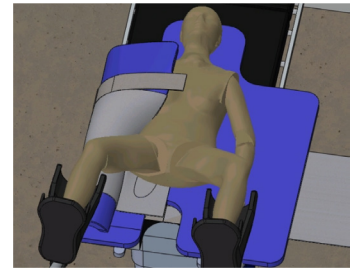
the undersurface of the device, between the operating table mattress and the side rail, then tightly pulling on the Velcro strap, and finally attaching the ends to the complementary piece of Velcro.

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 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 **Safe-T-Secure®** to facilitate intubation.
7. If the Velcro chest straps are loosely applied during intubation, the use of arm boards is optional.
8. Position the legs and feet in Allen Stirrups or other appropriate leg holders.
9. 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.



10. Use the specially designed egg crate configuration to tuck any IV tubing or monitor wires. Use additional padding if necessary.
11. Using the lateral arm wings of the **Safe-T-Secure®**, wrap one of the patient's arms and hands as an assistant rolls the patient's body towards the contralateral side.
12. While the patient's body and torso are being rolled towards the contralateral side and while the patient's arm and hand are wrapped with the **Safe-T-Secure®** foam, 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.
13. Confirm that the arm and hand are safely wrapped and secured.
14. Repeat steps 7-9 on the contralateral side. Again, confirm that the arm and hand are safely wrapped and secured.
15. 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.
16. Place the patient in Trendelenburg as required and confirm that the patient is securely positioned.



Prior to beginning surgery:

- Confirm that the **Safe-T-Secure®** is securely attached to the operating table.
- Monitor the patient according to usual practice and facility's policies and guidelines.
- Confirm that any alcohol-based preps are dry.
- **Safe-T-Secure®** is only intended to be used by licensed medical personnel.

Safe-T-Secure by NinoMed

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