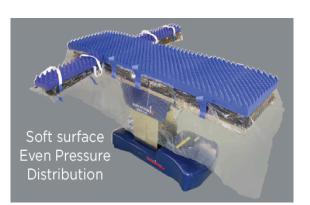


Instructions For Use (IFU)



Pressure Distribution Head-to-Toe[®]

SAFETY STRAP



- 1. Intended for patients up to 400 pounds
- 2. Remove foam from plastic packaging by pulling on slit or cutting plastic wrap.
- 3. Place the BODY FOAM SECTION of **Pluma-Soft™** on the operating table with the short blue Velcro straps facing down towards operating table.
- 4. Align the curve of the perineal cutout of the **Pluma-Soft™** with the perineal cutout on the operating table mattress.
- 5. Allow the clear plastic apron to drape around the OR table and over the foot section of the OR table and mattress.
- 6. Firmly secure the **Pluma-Soft™** to the horizontal metal side rails of the operating table by looping each of the Velcro straps attached to the BODY SECTION around the side rails and securing the strap to the complementary piece of Velcro.
- 7. Place the <u>Pluma-Soft™ Bottom Foam Section</u> over the inferior (foot) portion of the OR table and mattress and plastic apron and secure the foam section to the siderails using the Velcro straps as described above in #6.
- 8. Attach the <u>Pluma-Soft™ Foam Arm Board Cover</u> by stretching the elastic mouth and slipping the transparent arm board sleeve over the padded arm board. Secure the <u>Pluma-Soft™ Foam Arm</u> <u>Board Cover</u> to the OR Table arm board using the overlapping Blue Velcro Straps along the bottom surface of the transparent <u>Pluma-Soft™ Foam Arm Board Cover</u>.
- 9. Position the patient supine on the **Pluma-Soft™** to facilitate intubation.
- 10. Attach the <u>Pluma-Soft™ Patient Safety Strap</u> to the right and left side rails using the D-Rings allowing the complementary hook-and-loop fasteners to overlap for at least 6 inches.
- 11. Place the included rectangular foam transversely between the <u>Pluma-SoftTM Patient Safety Strap</u> and the patient's skin to secure the patient to the OR table and protect the skin.
- 12. Position the OR table arm boards according to surgeon preference and facilities guidelines using the soft WHITE Velcro straps to secure the patient's upper extremity/extremities while not compressing the skin or fastening tightly which could reduce blood flow to the extremities.
- 13. After intubation/induction of anesthesia, loosen the chest strap and re-position the patient, if appropriate, according to surgeon's preference or institutional guidelines.

тор-то-воттом

GentleTouch easily converts to Top-to-Bottom for lithotomy positioning by removing the foot section and adding stirrups.





- 14. If the patient's lower extremities are to be positioned in stirrups or other leg holders, the <u>Pluma-Soft™ Bottom</u>
 <u>Foam Section</u> can be removed and the FOOT section of the OR table can be lowered or removed.
- 15. The patient may be lifted and positioned to the desired location in relation to the perineal cut out if necessary and according to the surgeon's preference.
- 16. Confirm that the patient's perineum is aligned with the perineal cutout.
- 17. If patient's body habitus or anatomy creates uneven pressure distribution or significant contact with equipment whether attached to the OR table or not, use of additional padding should be considered and may be necessary.
- 18. Re-position the OR table arm boards according to surgeon preference and facilities guidelines confirming that the WHITE Velcro straps are not compressing the patient's upper extremity/extremities.
- 19. Confirm that the arm and hand are safely positioned and secured.

PRIOR TO BEGINNING SURGERY:

- 1. Confirm that the $Pluma-Soft^{TM}$ is securely attached to the operating table.
- 2. Monitor the patient according to usual practice and facility's policies and guidelines.
- 3. Confirm that any alcohol-based preps are dry.
- 4. **Pluma-Soft™** is only intended to be used by licensed medical personnel.

Placing an Order
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