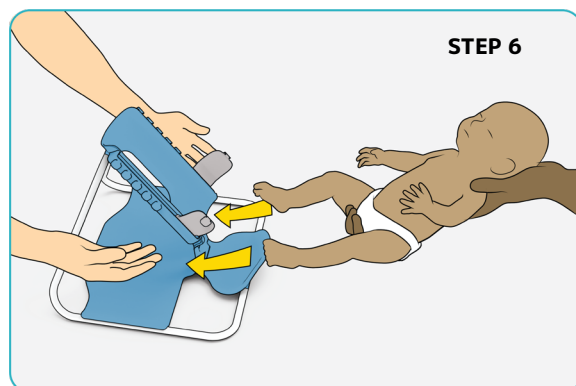


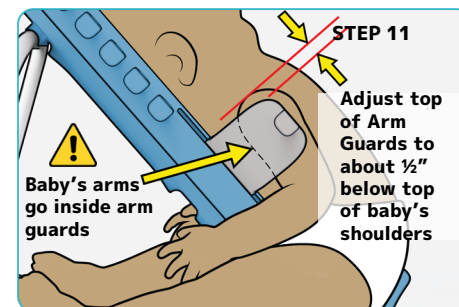
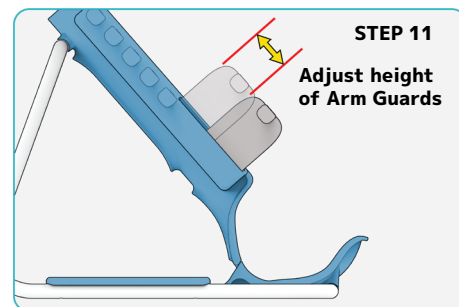
SMöLTAP™ Application Instructions

1. Make sure room is warm to ensure comfort of the baby, bring device into the room before procedure to be warmed up to room temperature.
2. Place **Cradle** on a clean, leveled surface, away from edges of the surface. Verify device will not fall off the surface.
3. Take 2 **Straps** out of the plastic packaging. Place **Straps** in easy reach.
4. ***Optional but Recommended:** Prepare sucrose solution to feed the baby while the baby is secure in device.
5. Undress the baby, leaving the diaper on so the baby does not leave waste on device.
6. Practitioner to hover the baby into the device, while assistant slides baby's legs through leg openings and onto the device **Floor**.



7. Rest the baby's upper body towards the **Upper Opening**. The baby's arms must be within the **Arm Guards**.
8. Assistant should gently hold the baby's head against the **Upper Opening** until baby is completely secured.
9. Verify that the baby's mouth is within the **Upper Opening**. If the baby can't breathe correctly through the **Upper Opening**, remove the baby from device.

10. Place pulse oximeter on the baby's toe to verify the baby is at a good oxygen level.
11. Adjust the height of the **Arm Guards** so the top edges of the **Arm Guards** are about ½" (i.e. one finger's width), below the top of the baby's shoulders.

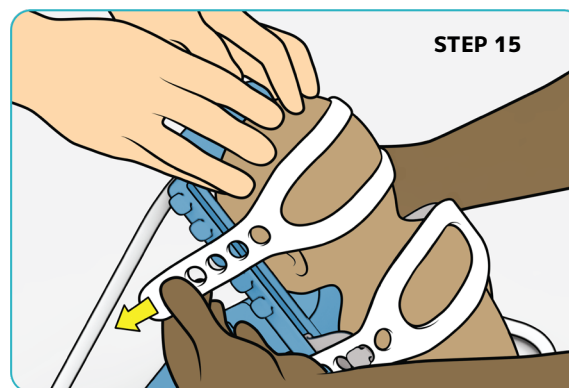


12. Without tightening, place, and center one **Strap** across the baby's shoulders and one **Strap** across baby's head

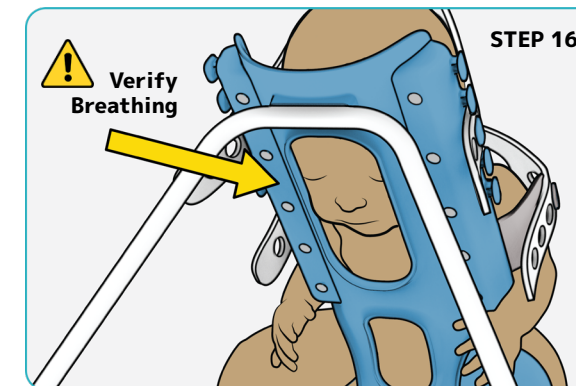


13. ***Never leave the baby unattended while in the Cradle.**

14. Gently tighten the **Back Strap**, onto one hook on each side of the **Cradle**, based on practitioner's judgement. Verify that the baby is breathing.
15. Gently tighten the **Head Strap**, onto one hook on each side of the **Cradle** so the baby's head is stable.

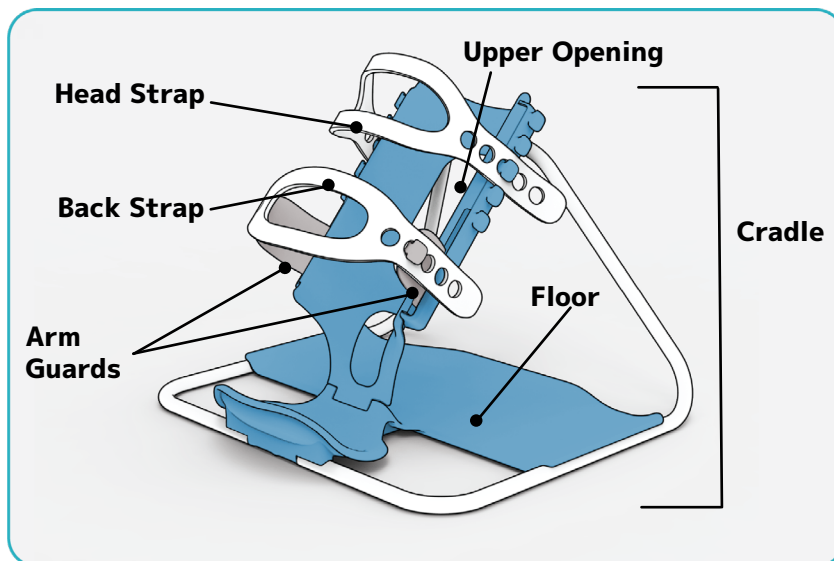


16. **Verify that the baby is breathing through the Upper Opening.** If the baby can't breathe correctly through the **Upper Opening**, remove the baby from the device.



17. ***Optional but Recommended:** Assistant may wish to feed the baby sucrose solution throughout the procedure. If physician decides to do so, use the **Upper Opening** for access.
18. At any time, if the baby desaturates, remove the baby from **Cradle**.
19. Pull diaper down so that it is well below spinal tapping area.
20. Perform the spinal tap procedure.
21. When procedure is finished, remove **Head Strap** while ensuring the baby is breathing.
22. Remove the **Back Strap**.
23. Lean the baby away from the **Cradle**.
24. Hover the baby out of the **Cradle**.
25. Clean the baby per healthcare institution policy.
26. Dispose of the Straps per healthcare institution policy.
27. Remove any fluid on the device.
28. Clean Cradle with disinfectant wipes per healthcare institution policy.

SMöLTAP™



Product Description

- 1 adjustable Cradle and 2 soft Straps for use during infant spinal tap procedures.
- Cradle, catalog number: STCR1
- Single-Use Strap, catalog number STSTR1
- Dimensions: 14" x 13" x 12"

Indications for Use

For use during spinal tap procedures to gently hold a baby in position. The Upper Opening is to ensure unobstructed breathing and optional feeding of dextrose solution.

Only use device under supervision of qualified medical practitioner.

Recommended to be used with at least one assistant.

Only use for infants sized between 45-57 cm, head to toe length.



WARNING

Use of **non-SMöLTAP Straps** is not recommended and may lead to product failure. Damage resulting from using **Straps** purchased from other manufacturers is not covered by the product warranty.

Straps are one-time use only, not to be reused. Dispose of the **Straps** after use per healthcare institution policy.

Not made with natural rubber latex.



Contraindications

NEVER USE:

- If patient cannot breathe correctly through mouth **Upper Opening** on the device.
- If patient is precluded from receiving a spinal tap procedure.
- Non-SMöLTAP straps.
- If the goal is to get an opening pressure.
- As a babysitter.

Adverse Reactions

Not for long-term use. Severe emotional, psychological, or physical problems may occur if the applied device is uncomfortable or if it severely limits movement. If symptoms of these problems appear for any reason, get help from a qualified medical authority and find an alternative intervention.

Rx Only. Caution: Federal law restricts this device to sale by or on the order of a physician.



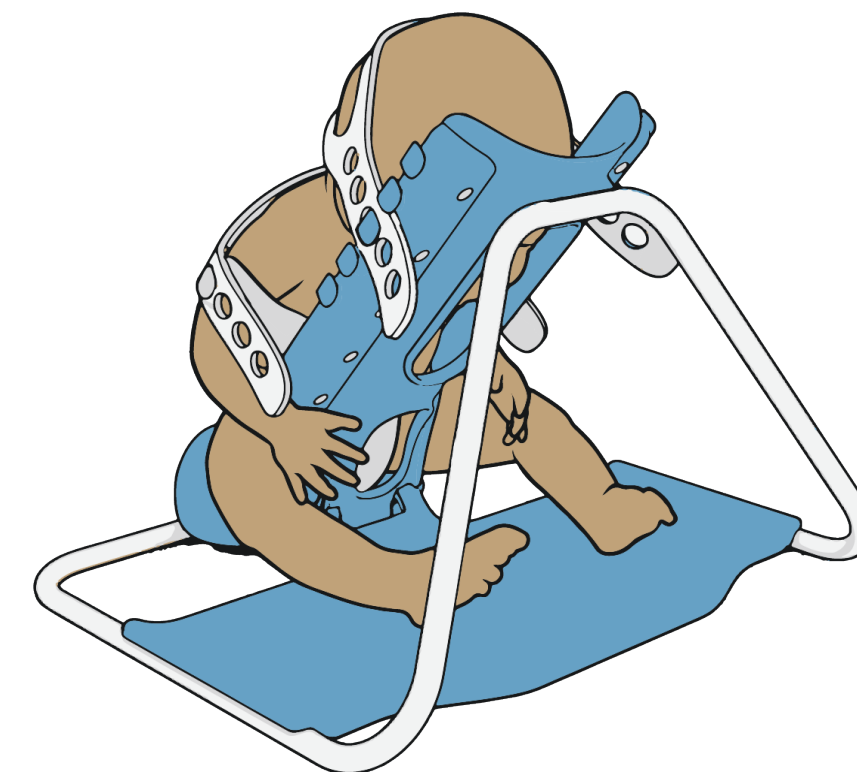
CAUTION

- **Handling and Storage:** Before use, check device for damage. DO NOT use if you have any questions about patient safety. Contact SMöLTAP Inc. for product replacement. Do not dispose of the Cradle.
- It is the practitioner's discretion to determine whether the baby is safe in the device. If the baby is not safe, alternatives should be sought.
- DO NOT leave the baby unattended during procedure.
- Do not transport or move the cradle while the baby is positioned within.
- NEVER use device sideways. Only use device in the upright position.
- DO NOT heat sterilize the cradle. Do not use cleaning agents containing ketones, ether, or plastic solvents as they will damage the cradle.
- **The device should be replaced every two years.**
- The baby may have temporary impressions left on face
- For information or replacement ordering, contact SMöLTAP Inc.

30 Day Warranty: SMöLTAP warranties products are free from material defects in materials and workmanship.

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Revision Number: Rev 0001
Date: 09/01/2022

SMöLTAP™



INSTRUCTIONS FOR USE FOR THE SMöLTAP INFANT POSITIONING PRODUCT



WEBSITE
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