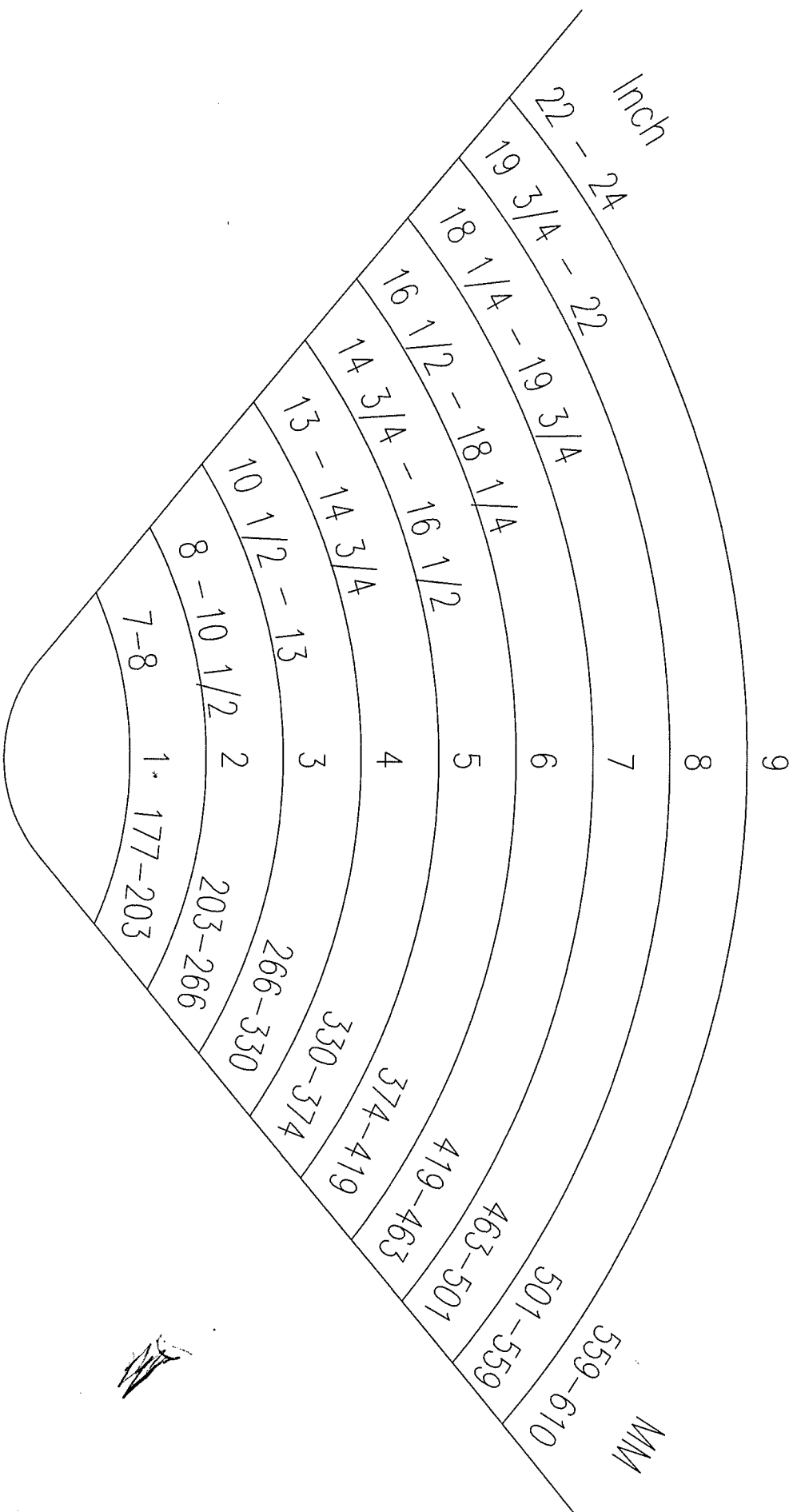
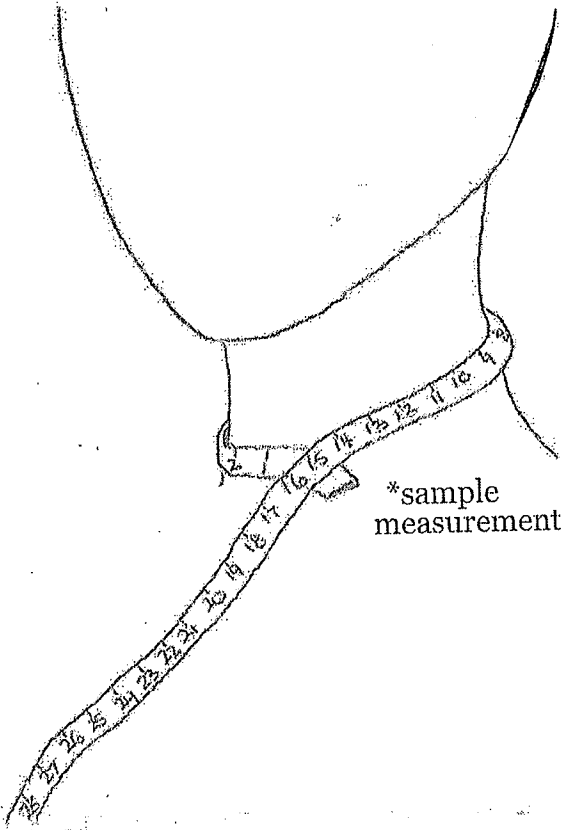


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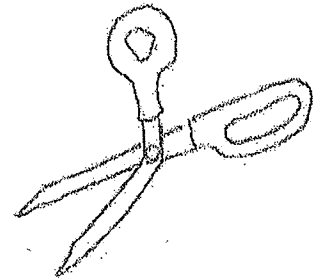
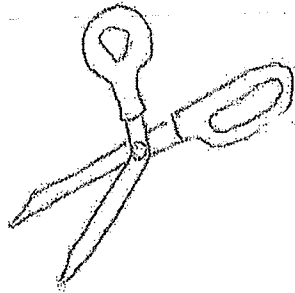
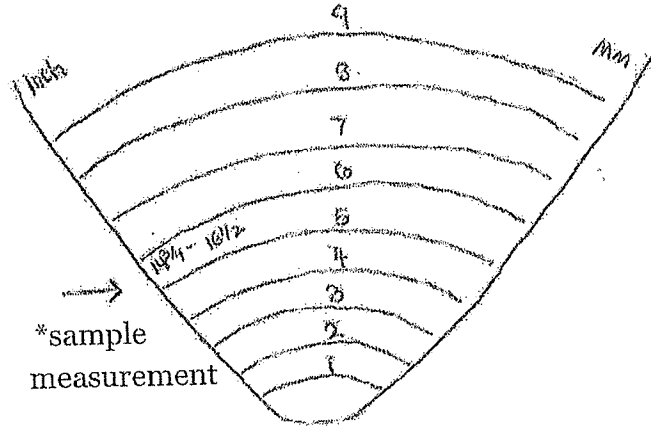


[Handwritten mark]

1. Measure patient's neck with the provided tape measure

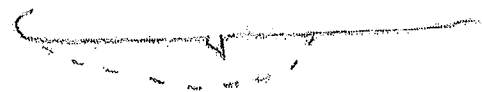
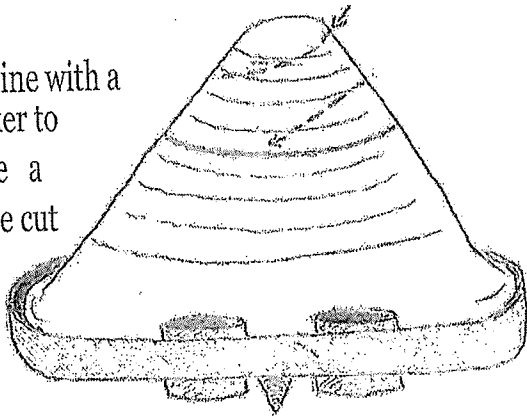


2. Use provided cut-chart to determine which line to cut on the Neckseal



Tip:

Mark line with a marker to ensure a precise cut



NOTE: To avoid splitting Neckseals, smoothly cut around small tears, cuts, or jagged edges

3. Start at the top of the Neckseal and use the "spiral-cut"* method to reach the desired line. Then follow the line around the neckseal until the circle is completely cut out.

*for more information on the "spiral-cut" see our instructional video at: <https://vimeo.com/sealong/hooddemo>

Device Life

The Sea-Long Neckseal Assembly is strictly for single patient, multi-use only. The Sea-Long HTAs (Head Tent Assembly) are multi-patient devices.

Directions

1. Remove HTA Set from plastic bag. (Save bag for storage)
2. Wash and sterilize HTA Set as required by your facility.
3. Cut the Neckseal to fit patient's neck using the Sizing Instructions to the right.
4. Place the Neckring over patient's head in the following manner:
 - a. Turn the Neckring so the silver label is right side up and in front of the patient.
 - b. Fold the cut edge of the Neckseal under about one inch (2cm) before stretching. This prevents tearing and should be done each time the Neckseal is seated or removed. See diagram to right.
 - c. Holding the folded edge, grasp the Neckseal and stretch the opening over the patient's head.
 - d. Adjust as necessary for clothing or hair obstructions. The Neckseal should be air-tight, wrinkle-free and comfortable.
 - e. Two Technicians may be required if the patient has special needs.
5. Unfold HTA and turn so visor is facing the front of patient. If the HTA does not have (2) Ports, proceed to Step 6. If it does have ports, you have a 4-port delivery option available; two on the Neckring and two on the HTA.

NOTE: The Port closest to the ring on the HTA is an INTAKE PORT ONLY (see diagram on back). Determine which two ports are best suited and connect standard 22mm corrugated tubing to each. Use Port Caps to block the additional two ports. Proceed to Step 7.

6. If using a No Port HTA, connect standard 22mm corrugated tubing to each of the Ports on the Neckring.
7. Once desired depth has been reached, seat the HTA with the Neckring by inserting the Ports on the Neckring first. Work evenly around toward the back of the HTA until the two are tightly assembled. Begin therapeutic gas flow according to your facility's protocol.
8. Insert the inlet flow ventilation tube (inspiration limb) coming from the ventilator into the connector set in the lower part of the tent "Flow inlet".
9. Start the ventilator in Pressure Support Ventilation with a PEEP of 5-7 cmH₂O at least, switching off the alarms for 2 minutes.
10. Remove the plug from the connector in the high part of the tent "flow outlet".
11. Attach HTA to Neckring, fix it behind first and then in front, verify it is correctly fixed.
12. Insert the outlet flow ventilation tube (expiration limb) of the ventilator in the connector "flow outlet".
13. Verify the pressurization inside the HTA (no leakages).
14. Set the value of Pressure Support Ventilation on the ventilator, switch on the alarms and verify the compensation of the leakages.

Warnings

- a. This HTA does not include an anti-asphyxiation valve that would allow a patient to breathe if the gas supply fails.
- b. This HTA must be used with a gas supply which has adequate alarms and safety systems for gas supply.
- c. This HTA should not be used on patients who are uncooperative, obtunded, unresponsive, or unable to remove the HTA.
- d. Any unusual chest discomfort, shortness of breath, stomach distention, belching or severe headache during or after use should be immediately reported to physician.
- e. If the patient experiences skin irritation, consult the physician.
- f. The HTA will not remain sterile between treatments. Cleaning, disinfection and sterilization procedures are included as part of the Directions for Use and should be followed between patient treatment.
- g. HTAs should not be placed over open wounds that are prone to infection.
- h. To prevent the growth and spread of infectious microbes, replace the HTA if it cannot be properly cleaned.
- i. Discontinue use of the HTA if patient skin or mucous membrane irritation or allergic reaction develops due to the HTA.

- j. The HTA should not be worn unless the gas supply device is connected and operating properly.
- k. Do not use this HTA to connect a patient to a gas supply device that does not have a built-in anti-suffocation mechanism.

- l. The patient under ventilation therapy must be always monitored by medical personnel
- m. Use the device only with devices and appliances suitable to the Non Invasive Ventilation (NIV) and Pressure Support Ventilation (PSV)

Sizing Instructions

Measure the distance around the patient's neck (circumference), then refer to the Trim Chart for the appropriate rib line. Trimming below the chosen line is suggested. Cut as smoothly as possible to avoid jagged edges and prevent tearing.

Cleaning Instructions

The Neckseal has been manufactured with a medical grade material and can be disinfected using a hospital grade disinfectant, such as Sanizide, or warm, soapy water and rinsed well.

The HTA may be gas sterilized or cleaned with a hospital approved germicidal disinfectant such as Sanizide and rinsed well.

Make sure Neckseal and HTA have been dried thoroughly before storing in plastic bag. The Neckseal can be used for multiple treatments by the SAME patient.

General Care, Storage and Maintenance

The Neckseal O-Ring has been slightly coated with an oxygen compatible, non-toxic lubricant to aid mating of the Neckseal Assembly and HTA Ring. It may be necessary to re-apply lubricant when the Neckseal Ring becomes difficult to insert or remove from the HTA and after cleaning.

Examine all parts for proper fitting and wear to ensure optimum treatment performance. The Head Tent assembly should be disassembled, cleaned, and dried after each treatment. Parts for assembly or other items should not be stored inside the HTA. Storage of Head Tent Assembly should be in a moderately cool and dry location until next use.

Contraindications

The HTA will not remain sterile between repeated uses and should not be placed over open wounds that are prone to infection. Cleaning, disinfection and sterilization procedures are included as part of the directions for use. The Series 500 HTA may not be suitable for use on patients with the following conditions:

1. Unconsciousness
2. Patient unable to remove HTA
3. Open Wounds that are prone to infection
4. Hemodynamic or cardiorespiratory instability
5. Excessive reflux, GI blood, or other secretions
6. Claustrophobia, anxiety, or other discomfort with HTA.
7. Patients requiring immediate intubation
8. Barotrauma
9. Patients under medication with a drug that may cause vomiting
10. Impaired cough reflex, hiatal hernia, or inability to swallow or clear secretions.

Complications

These HTA Sets are non-invasive devices. The Neckseal surfaces applied directly to the patient's skin are soft, pliable and biocompatible material. The following are some possible minor to moderate complications:

1. Infection due to improper use over open wounds
2. Eye irritation or conjunctivitis
3. Nasal or dental pain or deformity
4. Drying of pharyngeal and nasal mucous
5. Skin irritation from Neckseal after prolonged use. (Non-Latex Neckseals are available for patients with an allergy to Natural Latex)
6. Gastric distention and abdominal pain or flatulence from ingested air.
7. Aspiration of secretions
8. Decreased secretion clearance, especially during upper respiratory tract infections.

