

Description	Material
1 Hood Assembly	PVC & PVC Vinyl
2 Neckseal Ring	Polysulfone
3 Neckseal - Latex	Natural Latex
4 Port Caps	Polysulfone
5 Accessory Ports	Thermoplastic Elastomer

Contact Information

SEA-LONG Medical Systems, Inc.
 1983 South Park Road
 Louisville, Kentucky 40219 USA
 Phone: 011-1-502-969-4949
 Fax: 011-1-502-969-0494
 Email: sales@sea-long.com
 Website: www.sea-long.com

European Authorized Representative
 Advena Ltd.
 13 North Parade, Milnwood
 Horsham, West Sussex
 RH12 2BT, UK
 Phone: [44] 011-44-1-403243114



SEA-LONG

MEDICAL SYSTEMS, INC.

Series 500 Replaceable Neckseal Assembly

Directions for Use and Recommendations for Cleaning, Disinfection, Sterilization and Maintenance



The following instructions describe the use of the Series 500 Replaceable Neckseal and Oxygen Head Tent. Read all instructions carefully before using. There is an illustrated diagram on the backside.

INDICATIONS FOR USE: The treatment hood is intended for any place that a clinician would normally use a mask for medical purposes of supplying gas/oxygen/air.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING: The Oxygen Head Tent is to be administered to a patient under the direct supervision of a physician. See additional warnings.

CLASS I (FDA) and CLASS IIA MEDICAL DEVICE - CE

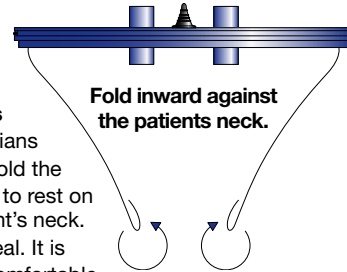


Device Life

The Sea-Long Neckseal Assembly is strictly for single patient multi-use only. The Sea-Long Oxygen Hoods are multi-patient devices. The Sea-Long Neckseal Assembly is a single patient device only and therefore may be purchased separately to accompany the Hoods which are multi-patient devices.

Directions

1. Remove Neckseal Ring or Hood from plastic bag. (Save bag for storage)
2. Wash and sterilize Neckseal Assembly and Hood as required. The O-ring has been lubricated with Christo-Lube (PN1000).
3. Cut the Neckseal to fit patient's neck. (See Sizing Instructions on next page) **NOTE:** Ensuring a smooth, **non-jagged** cut made on the Neckseal will reduce potential for tears. Trim for comfortable fit and allow quick removal if necessary.
4. Place Neckseal Ring over patient's head with label and control numbers facing up: Insert hands under Neckseal, Grasp Neckseal at the cut opening. **Fold cut edge over by one inch (2cm) before stretching over patient's head. This will help to prevent tearing.** Two technicians should stretch the opening to fit over the patients head. Fold the Neckseal inward and release grasp allowing the Neckseal to rest on the patient's neck. Adjust back of Neckseal Ring on patient's neck. No clothing or hair should be under or obstructing Neckseal. It is important that the Neckseal is air-tight, wrinkle free and comfortable for the patient.
5. Connect Hood to oxygen delivery system in chamber:
 - The control label on the hood ring signifies the front of the hood.
 - Face patient: Attach standard 22mm corrugated hosing directly to the hood or Neckseal Assembly ports. The port on the hood closest to the Hood ring is an intake port **ONLY**.
(See illustrated diagram on the backside)
6. Place 22mm cap over the two ports not in use.
7. Seat patient in chamber.
8. Pressurize chamber to prescribed depth.
9. Turn on oxygen supply to hood assembly, according to facility protocol.
10. Place Hood over patient's head and mate Neckseal Assembly to the inside of the Hood ring.
11. When the Hood inflates, open exhaust valve to establish exhaust flow.



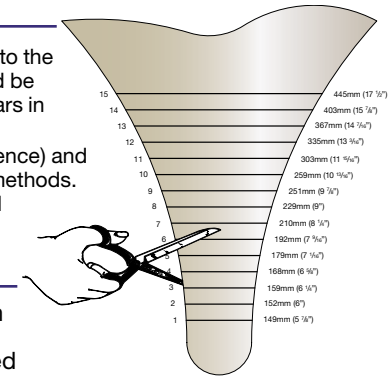
Warnings

- a. This hood does not include an anti-asphyxiation valve that would allow a patient to breathe if the gas supply fails.
- b. This hood must be used with a gas supply which has adequate alarms and safety systems for gas supply.
- c. This hood should not be used on patients who are uncooperative, obtunded, unresponsive, or unable to remove the hood.
- d. Any unusual chest discomfort, shortness of breath, stomach distention, belching or severe headache during or immediately after use should be immediately reported to your physician.
- e. If the patient experiences skin irritation, consult the physician.
- f. The hood will not remain sterile between repeated single-patient uses. Cleaning, disinfection, and sterilization procedures are included as part of the Directions for Use.
- g. Hoods should not be placed over open wounds that are prone to infection.
- h. To prevent the growth and spread of infectious microbes, replace the hood if it is uncleanable.
- i. Discontinue use of the hood if patient skin or mucous membrane irritation or allergic reaction develops due to the hood.
- j. The hood should not be worn unless the gas supply device is connected and operating properly.
- k. Do not use this hood to connect a patient to a gas supply device that does not have a built-in anti-suffocation mechanism.

Sizing Instructions

Please see chart diagram to assist in cutting the Neckseal to the proper neck size. **Please Note:** The trimmed edge should be smooth, avoiding any jagged edges which could lead to tears in Neckseal. Trimming below the chosen rib line is suggested.

Measure the distance around the patients neck (circumference) and cut the Neckseal smaller according to your normal sizing methods. See the chart diagram for guidance on associated ribs and circumference sizes.



Cleaning Instructions

The Neckseal Assembly has been manufactured with a latex medical grade material. The Hood may be **gas sterilized** or cleaned with a hospital approved germicidal disinfectant. If cleaned with a disinfectant, be sure to rinse and dry completely. The Neckseal, even though it is a single patient device, may be cleaned between uses if desirable. 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 (PN1000) to aid mating of the Neckseal Assembly and Hood Ring. It may be necessary to re-apply lubricant when the Neckseal Ring becomes difficult to insert or remove from the Hood 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 hood. Storage of Head Tent Assembly should be in a moderately cool and dry location until next use.

Contraindications

The hood will not remain sterile between repeated single-patient 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 Hood may not be suitable for use on patients with the following conditions:

1. Unconsciousness
2. Patient unable to remove hood
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 hood.
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

The Series 500 Hoods are non-invasive devices. The Latex surface which is applied directly to the patient's skin is a soft, pliable and biocompatible material. The follow 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 after prolonged use caused by neckseal.
6. Gastric distention and abdominal pain or flatulence from ingested air.
7. Some slight discomfort after prolonged use
8. Aspiration of secretions
9. Decreased secretion clearance especially during upper respiratory tract infections.