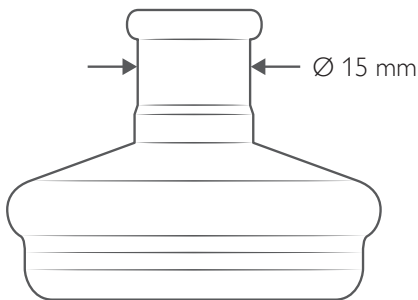


# Newborn Mask

## Snap Design

### User Guide



846156 - Size 0, 10 pack

846157 - Size 1, 10 pack



# Clinical Indications

---

## **Device Description**

Laerdal Newborn Mask (LNM) is a mask that can be connected to a resuscitator.

## **Indication for Use**

The Newborn Masks are indicated for use for patients requiring ventilation

## **Intended Use**

LNM is intended to be used for ventilation of patients.

LNM is available in two sizes:

- Size 0 is suitable for small newborn patients.
- Size 1 is suitable for newborn patients.

## **Intended Users**

LNM is intended to be used by healthcare professionals trained in delivering ventilatory support and in the use of manual resuscitators.

## **Clinical Benefits**

Positive impact on clinical outcome, by respiratory support that reduces probability of adverse outcomes, such as morbidity and mortality caused by hypoxia.

## **Clinical Outcome**

Desired outcome of ventilation is oxygenation of the patient, often evaluated using  $\text{SpO}_2$ ,  $\text{EtCO}_2$ , blood gas analysis or other method of analysis.

## **Known Side Effects**

Facial damage due to pressure

## **Contraindications**

No known contraindications for use.

# Important Information

---

Read this User Guide and become familiar with the operation of the product prior to use. Use the product only as described in this User Guide. This User Guide covers both size 0 and size 1 models.

## Warning and Cautions

A Warning states a condition, hazard, or unsafe practice that can result in serious personal injury or death.

A Caution states a condition, hazard, or unsafe practice that can result in minor personal injury or damage to the mask.

## Notes

Important information about the product or its operation.

## Warnings

- *Care should be taken when using the LNM on patients with severe anomalies or when applying other medical devices which may conflict with the mask as mask leakage may occur. If mask face sealing is not possible to achieve consider using alternative airway device.*
- *Care should be taken when applying pressure to the mask to avoid facial damage, especially in the case of pediatric patients, infants, pre-terms.*
- *Care should be taken when choosing the right size mask for the patient to ensure proper fit. Alternative mask sizes should be readily available.*

## Caution

*The mask may be reused provided proper cleaning and sterilization/ disinfection procedures are followed between each patient use. It must be cleaned and sterilized/disinfected before first patient use.*

## Notes

- The mask fits with standard 15 mm inner-diameter conical connectors, as defined by ISO 5356-1.*
- Check fit before use with your 15 mm connector. When used with Upright Newborn Bag-Mask the mask attaches with a snap fit when pressed completely into place.*
- Should any serious malfunction, undesirable incident with, or deterioration in the functionality or performance of the device occur, contact Laerdal promptly. The competent authority where the incident took place and/or the device was used should also be notified.*

# Cleaning and Disinfection

---

## Cautions

- *The mask is not provided sterile. The mask must be cleaned and disinfected prior to initial use.*
- *It is recommended that the highest level of disinfection/sterilization possible is used for patients that may have compromised immune defense, such as a pre-term baby or in the case of outbreaks of highly transmissible pathogens.*
- *The mask must be cleaned and disinfected before next patient use.*
- *The use of cleaning and disinfection procedures not described in this section may have adverse effects on the material and/or performance and may not be effective for disinfecting the Mask.*

To reduce the risk of cross-contamination, follow these instructions after each use.

## 1. Manual Cleaning

1. Wash in a clean tray with clean water and mild soap.
2. Use a scrub or brush to remove any soil.
3. Rinse in clean water to remove all soil and soap.
4. Repeat above steps until clean.

## 2. Sterilization/ High-level Disinfection

Sterilize or disinfect the mask by one of these methods:




- Sterilization - Gravity Displacement Steam Autoclaving  
136 °C (276 °F), 2.0 kg/cm<sup>2</sup>, 10-20 minutes
- Disinfection - Boiling in clean water\*  
100 °C (212 °F), 10 minutes.  
\*Validated at approximately sea-level pressure.

## 3. Dry and Inspect

1. Allow the mask to air dry.
2. Visually inspect for damage and cleanliness/mineral deposits.
3. Remove damaged or unclean masks from service.

# Specifications

---

Symbol Glossary	
	Medical Device
	This medical device complies with the general safety and performance requirements of Regulation (EU) 2017/745 for medical devices.
	Not made with natural rubber latex



Technical Information	
Material	Silicone rubber
Mass	17g (size 0), 37g (size 1)
Outer diameter	49 mm (size 0), 64 mm (size 1)
Operating environmental conditions	-18 °C to 50 °C (-0.4 °F to 122 °F)
Storage environmental conditions	-40 °C to 60 °C (-40 °F to 140 °F)
<p>Newborn Mask - Snap design is designed to fit with 15 mm inner diameter female conical connectors, but deviates from ISO 5356-1:2015 Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets.</p>	
Lifetime Parameters	
Shelf-life	5 years
Expected Service Life	100 cycles of reprocessing

## Warranty

Refer to the Laerdal Global Warranty for terms and conditions. For more information visit [www.laerdal.com](http://www.laerdal.com)





© 2023 Laerdal Medical AS, All rights reserved.

Protected by US and International design registrations.  
Laerdal® is a registered trademark of Laerdal Medical AS.



Manufactured in China for:  
Laerdal Medical AS  
P.O. Box 377, Tanke Svilandsgate 30,  
4002 Stavanger, Norway  
Tel : +47 51 51 17 00



20-19673 Rev A

---

[www.laerdalglobalhealth.com](http://www.laerdalglobalhealth.com)



**Laerdal**  
helping save lives