

Passy-Muir®



Passy-Muir, Inc.
Irvine, CA 92614-6813 USA
Tel: 949.833.8255 • 800.634.5397
Fax: 949.833.8299
website: www.passymuir.com
email: info@passymuir.com

Made in USA

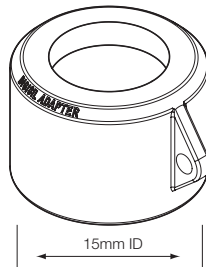
Patent pending
© Passy-Muir, Inc. All rights reserved.

IB OCLN/R0622

Passy-Muir®

15mm **DigiSil**™

Digital (Finger) Occlusion Adapter

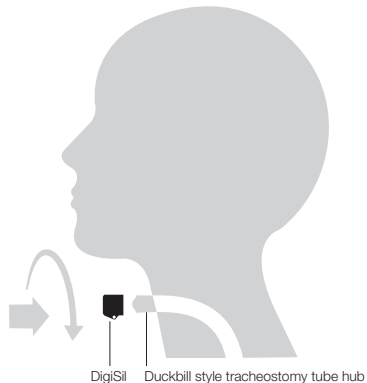


For use with duckbill style tracheostomy tubes

INSTRUCTIONS FOR USE



Passy Muir®
DigiSil™ Digital (Finger) Occlusion Adapter
REF PM-OCLN (15mm I.D.)



INSTRUCTIONS FOR USE

Intended Use:

The DigiSil is a non-sterile, lightweight, single patient use, stretch-to-fit adapter intended for placement on the 15mm hub of a tracheostomy tube with a duckbill designed inner cannula to allow finger occlusion.

Indications for Use:

For non-mechanically ventilated tracheostomy patients who have a tracheostomy tube with a duckbill designed inner cannula, where finger occlusion is desired.

Environment of Use:

Clinical settings that include hospital, sub-acute, rehabilitation, outpatient, skilled nursing, long-term care, and in the home setting. Professional use only. Not intended for use by neonatal or infant patients. Non-sterile. Not made with natural rubber latex.

WARNINGS

- ⚠ **SINGLE PATIENT USE ONLY. USE ON MORE THAN ONE PATIENT COULD CAUSE CROSS-CONTAMINATION AND LEAD TO INFECTION.**
- ⚠ **NOT FOR USE WITH A VENTILATOR, AS THE VENTILATOR CIRCUITRY WILL NOT CONNECT APPROPRIATELY.**
- ⚠ **NOT FOR USE AS A CONNECTOR FOR STANDARD 15MM TUBING, ADAPTERS, ACCESSORIES, OR OTHER CONNECTIONS TO THE HUB OF THE TRACHEOSTOMY TUBE, AS THE CONNECTION WILL NOT BE SECURE.**
- ⚠ **DO NOT USE IF THE DIGISIL IS DIRTY OR OBSTRUCTED WITH MUCUS OR OTHER PARTICULATES.**

CAUTIONS

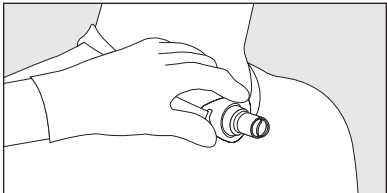
- ⚠ Discard when worn or damaged.
- ⚠ *DO NOT* clean, autoclave, or sterilize the DigiSil.
- ⚠ Finger occlusion is a potential source of bacterial or viral pathogens. It is recommended to follow universal precautions, including use of a gloved hand or appropriate hand sanitizer and washing procedures.
- ⚠ Do not force the DigiSil onto the tracheostomy tube hub.
- ⚠ Do not use with a suction catheter as the catheter will not connect properly.
- ⚠ Only for use with finger occlusion.

CONTRAINDICATIONS

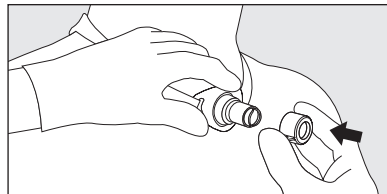
- **Do not use** on patients who are on any form of mechanical ventilation.
- **Do not use** while a patient is receiving medicated aerosol treatments.

PLACEMENT

The following instructions are for the placement of the DigiSil.

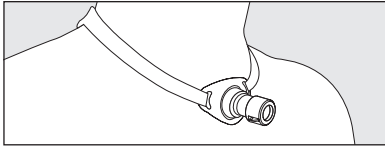


Step 1: Using universal precautions and appropriate PPE, stabilize the patient's tracheostomy tube.

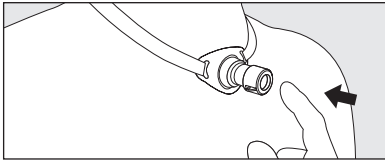


Step 2: While stabilizing the tracheostomy tube, place the DigiSil by gently pushing it onto the 15mm hub of the tracheostomy tube. The DigiSil should be placed completely onto the hub with the outer rim of the adapter resting on the edge of the tracheostomy tube hub. Ensure that the DigiSil is placed in a manner that covers the upper exposed edges of the duckbill designed inner cannula.

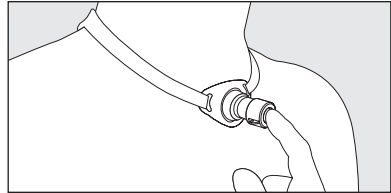
⚠ CAUTION: Do not force the DigiSil onto the tracheostomy tube hub.



Step 3: Monitor the patient's respiratory status and assess for changes from baseline parameters.



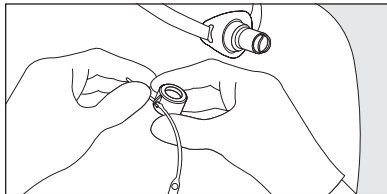
Step 4: When using with finger occlusion, monitor the patient's respiration. Instruct the patient to take a breath in or observe an inspiratory breath. The patient or the healthcare provider should then gently place the tip of a finger over the opening immediately following inspiration.



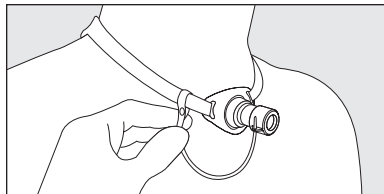
Step 5: To check for airflow out the mouth and nose, have the patient say "ah" or count to five.

Attaching PMV Secure-It®

The PMV Secure-It attaches to the tracheostomy tie to help prevent the loss of the DigiSil. Use of the PMV Secure-It is optional.



Step 1: Thread the tapered end of the PMV Secure-It through the small hole provided in the side of the DigiSil and pull it through until it rests between the two notches on the Secure-It.



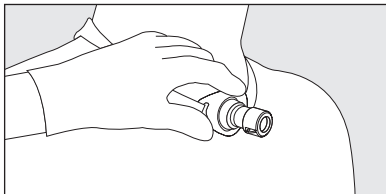
Step 2: Place the other end of the PMV Secure-It around the patient's tracheostomy tie near the tracheostomy tube neckplate and fasten the button hole.

Removing the PMV Secure-It

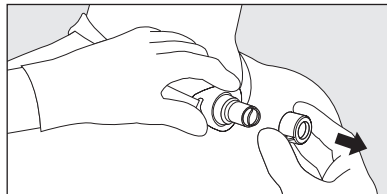
The PMV Secure-It should be removed from the patient's tracheostomy tie prior to removal of the Secure-It from the DigiSil. To remove the PMV Secure-It, unbutton the fastener and then gently remove the Secure-It from the tracheostomy tube tie. The Secure-It can be removed from the DigiSil by gently pulling it out of the small hole in the side of the adapter.

REMOVAL

The following instructions are for the removal of the DigiSil.



Step 1: Using universal precautions and appropriate PPE, stabilize the patient's tracheostomy tube.



Step 2: Remove the DigiSil with a quarter turn clockwise (to the right) while gently removing the DigiSil from the tracheostomy tube hub.

PRODUCT LIFE AND DISPOSAL

The DigiSil should be discarded when dirty.

 **CAUTION:** DO NOT clean, autoclave, or sterilize.

Store at room temperature and away from direct sunlight.

Dispose of the DigiSil following facility policy and procedures.

SYMBOLS



Single patient multiple use



Non-sterile



Medical device



Product reference number



Caution



Instructions for use



Manufacturer