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NEO-fit™ Neonatal Endotracheal Tube Holder 42-2540



Instructions for Use • English

DEVICE DESCRIPTION

Includes one plastic tube grip with adjustable hook and loop strap and adhesive foam foot pads, two foam "lollipop" securing tapes. Adjustable hook and loop strap allows rapid release and adjustment of ET tube. This product is non-sterile.

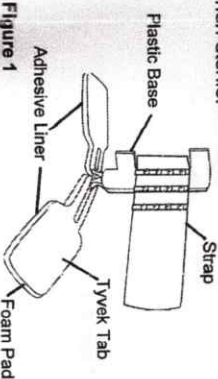


Figure 1

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

INTENDED USE

For stabilizing a 2.5 mm to 4.0 mm ID Neonatal ET tube.

CONTRAINDICATIONS

None known.

WARNINGS

- Separation of the plastic base foot from the adhesive foam pad may result in potential ET tube extubation. If signs of delamination are observed, replace with a new NEO-fit™.
- Usage of ointments or oils may adversely affect the adhesion properties of the adhesive foam pad.
- Excessive salivation may adversely affect the attachment of this device or cause the device to fall during use.
- Discontinue use immediately if skin irritation occurs.

- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.

Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Dispose of in accordance with all applicable Federal, State, and local Medical/Hazardous waste practices.

PRECAUTIONS

- Not for use with 2.0 mm ID or smaller ET tube.
- Do not use as sole method of support for ventilator tubes; use a tubing support device.
- Patient must be under professional supervision while intubated.
- Do not wrap the tube holder too tightly or the ET tube may be deformed and prevent suction catheter passage.
- Do not wrap the tube holder too loosely or the ET tube may move in the tube holder.

ADVERSE EVENTS

- Skin irritation
- ET tube extubation

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NEO-fit™ Neonatal Endotracheal Tube Holder 42-2540 Instructions for Use • English (Continued)

INSTRUCTIONS FOR USE

1. Trial fit the NEO-fit™ on patient prior to removing the adhesive liner, (adhesive pad should not overlap the mouth or eyes). Usage of a pectin-based skin preparation may minimize the risk of contact dermatitis.

2. Remove the adhesive liners from the bottom of the adhesive pads.
See *Figure 2*.

Caution: Do not peel the adhesive pad away from the plastic base during removal of the adhesive liner or the adhesive may be adversely affected. Use a new NEO-fit if this occurs.

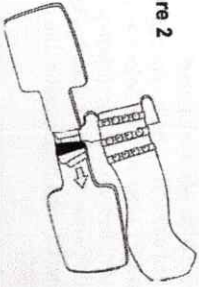


Figure 2

3. Affix the adhesive pads to the patient adjacent to the ET tube. See *Figure 3*.

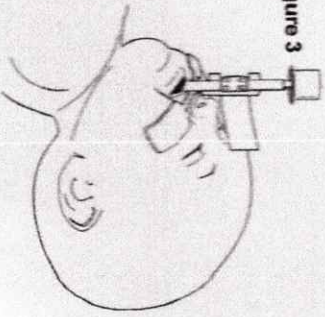


Figure 3

4. Wrap the tube holder strap snugly around the ET tube by pulling from the end of the strap. Pushing the strap around the tube may not secure the tube adequately. Do not wrap too tightly as this may interfere with the passage of a suction catheter through the ET tube.
See *Figure 4*.

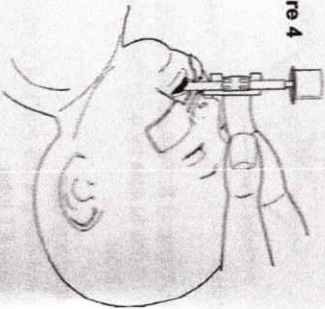


Figure 4

5. Secure the strap using the hook and loop material of the strap. If needed, secure using "lollipop" foam adhesive tape, included, or other tape as appropriate. See *Figure 5*.

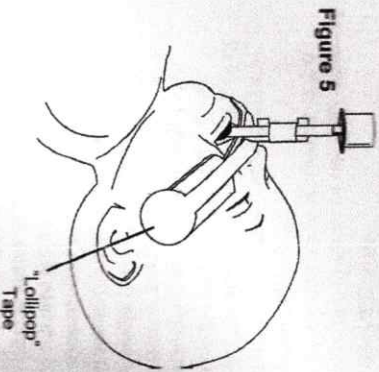


Figure 5

NEO-fit™ Neonatal Endotracheal Tube Holder 42-2540 Instructions for Use • English (Continued)

EXPLANATION OF SYMBOLS

	Reorder Number		Consult instructions for use	
	Batch Code		Do not use if package is damaged	
	Use By		Not made with natural rubber latex	
	Do not re-use		Caution	
	Non-sterile			

MR Conditional

The Neo-fit™ Neonatal Endotracheal Tube Grip/Holder was determined to be MR-conditional.

Non-clinical testing demonstrated that the Neo-fit Neonatal Endotracheal Tube Grip/Holder is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

Static Magnetic Field

MR-Related Heating
In non-clinical testing, the Neo-fit Neonatal Endotracheal Tube Grip/Holder produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HD, Software 14X.MS, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change +1.7°C (35.06 °F)

Therefore, the MRI-related heating experiments for the Neo-fit Neonatal Endotracheal Tube Grip/Holder at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 -W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.7°C (35.06 °F).

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Neo-fit Neonatal Endotracheal Tube Grip/Holder. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 20-mm relative to the size and shape of the Neo-fit Neonatal Endotracheal Tube Grip/Holder.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	1,980-mm ²	1,453-mm ²	4,381-mm ²	3,678-mm ²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

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