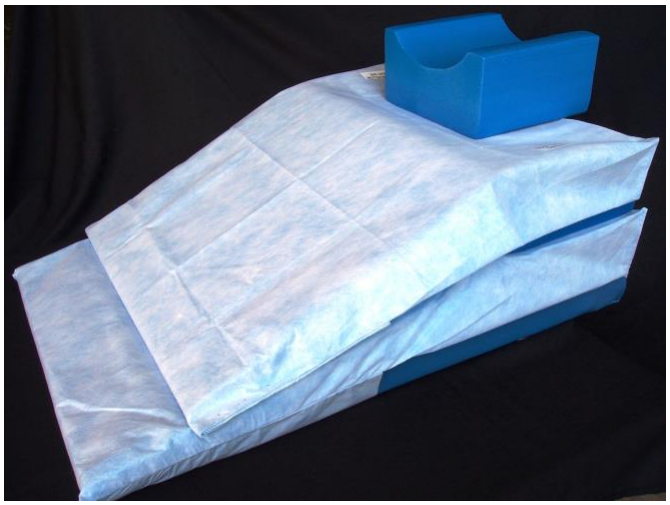
Troop Elevation Pillow Addition: **Instructions for Use and Care**

Description

The Troop Elevation Pillow Addition (TEPA) or the ***Addition*** is a wedge- shaped positioner that is designed to be used with the Troop Elevation Pillow. The Addition is placed on top of the Troop Elevation Pillow and a head cradle or standard intubating pillow is placed on top of the flat / plateau part of the Addition to help improve airway management of morbidly obese patients.

Use



Intended Users: Trained airway management medical providers.

The Troop Elevation Pillow (TEP) + the Addition (TEPA) + the Head Cradle (H.C.) are designed for ***positioning the super morbidly obese patient in the H.E.L.P. position*** (head elevated laryngoscopy position). As a general guideline, the TEP + TEPA + H.C. is recommended for patients weighing 450 to 500 pounds or more or patients whose ***BMI is greater than 50***. The patient's height and weight distribution are important observations when considering the clinical indication to use the TEPA. For example, a super morbidly obese patient whose weight is mainly in the abdomen and upper chest area (verses the waist and hip area) is more likely to receive the most benefit.

The ***Troop Elevation Pillow Addition (TEPA)*** is available as a disposable or reusable vinyl covered product designed to be placed on top of the vinyl covered Troop Elevation Pillow. ***A disposable surgical barrier cover (sold separately) is recommended to cover and protect the vinyl TEPA and the vinyl Troop Elevation Pillow.***

Care

Cleaning Instructions:

Virex, Fantastik or Formula 409 are the recommended cleaning agents for the Troop Elevation Pillow product line. Each positioner must be cleaned after every patient use.

1. Remove the disposable surgical barrier cover from the Troop Elevation Pillow and dispose of as clinical medical waste.

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2. Apply the cleaning fluid liberally to the top, sides and underside of the Elevation Pillow and wipe with a clean lint-free cloth. Use a clean cloth dampened with water to remove any cleaning solution. Then use a final clean cloth to remove any remaining residue.
3. Position the Troop Elevation Pillow so that it can thoroughly air dry.
4. Repeat the cleaning procedure for the Head Cradle, Troop Addition, and Arm Board Pads if they are used as well. Discard the Velcro straps – they are single use only.

A hydrogen peroxide cleaning solution such as Virex may discolor the vinyl or (overtime) change the 'feel' of the vinyl. We do not recommend our product line be machine washed, machine dried, gas sterilized or autoclaved. Our positioners should never be soaked in cleaning solution as it might seriously compromise the integrity of the product.

Storage and Handling:

The following storage conditions are recommended to maintain the integrity of the Troop Pillow Products such that hardening, softening, cracking or surface degradation can be avoided:

Heat: The storage temperature should preferably be between 4°C and 25°C. Direct contact with sources of heat should be avoided.

Humidity: The relative humidity in the storeroom should be between 30% and 70%. Very moist or very dry conditions should be avoided.

Light: It is best to avoid exposure to direct sunlight for long periods of time. Our products are designed for use in normal indoor environments.

Do not make contact with sharp edges or any surface that could puncture, tear, cut or pinch the positioner. Handle the positioners carefully to avoid any damage.

Disposal Procedures:

The Troop Elevation Pillow product line does not consist of any medicinal substances. The vinyl positioners should be disposed as general medical waste. The surgical barrier covers should be disposed of as clinical waste and can either be heat treated or incinerated.

Construction

Materials used are a vinyl surface with polyester substrate and polyurethane foam. Velcro straps are polypropylene hook and nylon loop.

Fire Code Compliance:

All materials are compliant with fire code regulations: The State of California Department of Consumer Affairs Technical Bulletin #117-2013 and TB129. This includes all covers and foam fillers. All materials are compliant with The Boston Fire Code Flammability Requirements.

The vinyl covering has antimicrobial protection and is mildew resistant. All materials are anti-static, phthalate free and not made with natural rubber latex.

Warranty:

Warranted to be free of defective materials and workmanship at the time of purchase and are serviceable for a period of two years excepting misuse, negligence, abuse or failure to follow the Care and Use Guidelines provided herein. A

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disposable surgical barrier cover must be used to cover the Troop Elevation Pillow and Addition for protection with every use for the warranty to be valid.

Bone Foam, Inc. reserves the right to determine if a pad is repairable and whether or not it has suffered misuse, negligence or abuse. The customer accepts full cost of return shipping charges. Proof of purchase is required for all warranty inquiries. All specific warranty questions and serious incidents should be directed to Bone Foam Inc. in Corcoran, Minnesota: 763-559-1830 and the competent authority of the member state in which the user is established.

Cautions, Warnings and Precautions: To prevent injury, all parts of the Troop Elevation Pillow (TEP) should be placed securely on the hospital bed in use. The user is instructed to place the pre-formed barrier cover or impermeable surgical cover over the TEP. Never wrap the TEP in plastic during patient use. Discontinue use if signs of material degradation.

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Made in the USA

CE PHT DEHP NON STERILE

"Not made with natural rubber latex"

Symbols used on labels:

Symbol	Symbol Ref No.	Title of Symbol	Symbol Description
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU MDR 2017/745.
EC REP	5.1.2	Authorized representative in the European Community	Indicates the authorized representative in the European Community.
	5.1.3	Date of Manufacture	Indicates the date when the medical device was manufactured.
LOT	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.
NON STERILE	5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
%	5.3.8	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
i	5.4.3	Consult instructions for use or Consult electronic instructions for use	Indicates the need for the user to consult the instruction for use.
MD	5.7.7	Medical device	Indicates the item is a *medical device*