TECHNICAL SUMMARY SHEET

BLUperc™ Percutaneous Dilation Tracheostomy Procedural Kit with or Without BLUselect™ Tracheostomy Tube

Product Description

BLUperc is a percutaneous dilation tracheostomy procedural kit that allows the percutaneous insertion of a tracheostomy tube using a one-stage circumferential dilational Seldinger guidewire technique.

Kits are supplied with or without a BLUselect or BLUselect Suctionaid™ tracheostomy tube in sizes 7.0 mm, 8.0 mm, and 9.0 mm internal diameter.

Kits are intended for use in a controlled setting such as an intensive care unit or operating room with the assistance of trained personnel. A minimum of two operators are required: one operator is to maintain the patient's airway, provide anesthesia, assist in breathing, and monitor circulation; the other operator is to perform the procedure.

The single-stage dilator has a lubricious hydrophilic coating to improve ease of insertion when wetted.

Refer to included Instructions for Use for tracheostomy tube if applicable.

Product is designed and provided as sterile, single use – DO NOT REUSE.

The sale, distribution, and use of this device is restricted to prescription use.

KITS MUST ONLY BE USED BY CLINICIANS TRAINED TO PERFORM PERCUTANEOUS DILATIONAL TRACHEOSTOMY.

Indications

Controlled, elective, subcricoid percutaneous insertion of a tracheostomy tube for airway management using a Seldinger guidewire dilation technique

Precautions

Once the needle and cannula assembly or introducer needle has entered the trachea, it must be held in place so that the tip does not drift out of the trachea.

Once the needle has been partially or completely withdrawn from the cannula, never reinsert it as this could result in the cannula being cut and left in the trachea.

If the guidewire is damaged during the procedure, it may be difficult to continue. In these cases, proceed only if the damaged section can be advanced into the trachea, and there is sufficient length of undamaged guidewire remaining.

If the guidewire cannot be salvaged, it is necessary to use a new kit or a new guidewire.

Care must be exercised to ensure the needle, guidewire, guiding catheter, and single-stage dilator do not perforate the posterior tracheal wall.

Care must be taken not to cause trauma to the carina with single-stage dilator/introducer in small/short/low weight patients.

Do not insert the maximum insertion depth mark on the single-stage dilator beyond the level of the skin to prevent damage to the trachea and/or carina.

Do not use an excessive twisting motion when dilating the stoma to avoid trauma to the trachea.

The soft introducer must only be used for the introduction of tracheostomy tubes, not dilation of the stoma.

The dedicated introducer must only be used with the correct size of tracheostomy tube included with the kit or tray.

Avoid application of excessive rotational or linear force on the tube during and after attachment of the breathing system to the tracheostomy tube connector to prevent accidental disconnection, decannulation, or occlusion.

Passage of a bronchoscope through the Peep-Keep™ cap may result in loss of delivered tidal volume.

Adequately humidify the air delivered to patients to minimize mucous and encrustation of the tracheostomy tube and/or inner cannula lumen.

Precautions Continued

Guard against contact of the tube and/or tracheostomy cuff with sharp edges to avoid tracheostomy tube cuff damage.

Syringes used to inflate the cuff must be clean and free from all foreign matter. The syringe should be removed from the inflation valve immediately after use and the dust cap fitted.

Cuff pressures should be monitored and adjusted routinely. Overinflation of the cuff may result in permanent damage to the trachea.

Avoid repositioning of the in-situ tracheostomy tube while the cuff is inflated.

Ensure secretions are suctioned from above the cuff immediately before deflating the cuff of the tracheostomy tube in order to minimize secretions entering the lungs after cuff deflation.

Prior to the removal of cuffed tracheostomy tubes, all air must be completely removed from the cuff to prevent damage to the trachea and stoma.

Where an inner cannula is used, ensure that it is both the correct diameter and length for the tracheostomy tube in use.

The inner cannula should be routinely checked, cleaned, or replaced at regular intervals to avoid blockage or reduction in lumen of the airway.

Do not try to forcibly remove the inner cannula from the tracheostomy tube; both the inner cannula and tracheostomy tube should be removed together and replaced with a new tracheostomy tube and inner cannula.

If tracheostomy tubes are used outside the hospital, the patient must be instructed by a healthcare professional in the safe use and handling of the product.

Product Components				
All kits include (101/562/000)	Additional components in 101/561/--- includes a cuffed tube 101/596/--- includes a Suctionaid tube	Additional components in 101/595/--- includes a cuffed tube 101/596/--- includes a Suctionaid tube	Additional components in 101/573/---	Additional components in 101/561/--- includes a cuffed tube 101/563/--- includes a Suctionaid tube
› Lubricating jelly (2) › Gauze sponges (10) › Split tracheostomy dressing › Safety scalpel › 5 mL syringe › 10 mL syringe › Introducer cannula and needle assembly › Introducer needle (5 cm) › J-tip guidewire preloaded in single-handed feeder › 14 FR short dilator › Single-stage dilator preloaded with guiding catheter › Curved hemostatic forceps › Dedicated or soft introducer › Needle safety device › Tracheostomy tube holder with brush › Disconnection wedge › IFU percutaneous kits	› BLUselect tracheostomy tube › Inner cannulas (2) › If Suctionaid tube, vacuum control valve › Obturator › Patient labels › Dedicated introducer	› BLUselect tracheostomy tube › Inner cannulas (2) › Needle driver › Polypropylene sutures › Peep-Keep swivel adapter › If Suctionaid tube, vacuum control valve › Obturator › Patient labels › ChloraPrep™ applicators (2) › 5 mL lidocaine and epinephrine 1.5% (2) › Filter straw › Fenestrated drape › Hypodermic needles › Dedicated introducer	› Needle driver › Polypropylene sutures › Peep-Keep swivel adapter › ChloraPrep applicators (2) › 5 mL lidocaine and epinephrine 1.5% (2) › Filter straw › Fenestrated drape › Hypodermic needles	› Tracheostomy tube › Inner cannula (2) › If Suctionaid tube, vacuum control valve › Obturator › Patient labels › IFU tracheostomy tube

Component Composition	
Description	Material
Syringe	Polypropylene, polyisoprene
Safety scalpel	Stainless steel
S-shaped dilator	Polyurethane
Guiding catheter	Polyether Block Amide
Soft introducer	Polyvinyl chloride
Lubricating jelly	See Vendor Biological Safety Data in VAL-10007497-002, Attachment A for composition
Gauze sponges	Cotton
Split tracheostomy dressing	70% polyester-rayon, 30% terylene
Curved hemostatic forceps	Stainless steel
14 FR pre-dilator	Low-density polyethylene
Introducer cannula & needle assembly	› Needle hub - polycarbonate › Catheter hub - polypropylene › Stopper - stainless steel (SUS-304) › 14G cannula › 16G needle - stainless steel (SUS-304) › Needle guard - polyethylene
J-tip guidewire	AISI 304 stainless steel core per ASTM A313 Coating: green polytetrafluoroethylene (PTFE) with white PTFE markings.
	AISI 304 stainless steel core per ASTM A313 Coating: green PTFE
Dedicated introducer	› Handle - polypropylene › Shaft - thermoplastic polyurethane › Insert - stainless steel
Obturator	High-density polyethylene
Tracheostomy tube holder with brush (neck strap)	› Cotton › Polyester foam › Nylon › Elastic
Single-handed guidewire feeder	Polypropylene
Needle safety device	› Cup - polycarbonate › Insert - polyethylene foam
Disconnection wedge	Acrylic
Vacuum control valve	Acrylic
Tracheostomy tube	Polyvinyl Chloride, acetal
Inner cannula	Polyethylene

Manufacturing Site Names and Addresses

ICU Medical, Inc.
6000 Nathan Lane North,
Minneapolis, MN 55442, USA

ICU Medical, Inc.
Olomoucká 306, Hranice 1 - Město,
753 01 Hranice, Czech Republic

Countries of Origin

USA and Czech Republic

Sterilization Method

The BLUperc percutaneous dilation tracheostomy procedural kit or tray is ethylene oxide sterilized and provided to the end user in a sterile package. The device remains sterile as long as the package integrity has not been compromised and/or the Use by Date is not exceeded. The Use by Date and integrity of the outer tray/lid should be verified prior to use; if the “use by date” has expired or the packaging is compromised, the kit or tray must not be used. The BLUperc percutaneous dilation tracheostomy procedural kit or tray must not be resterilized by the end user.

Shelf Life

5 years.

Labeling and Packaging

Packaging Dimensions			
Container type	Length	Width (breadth)	Height (depth)
Unit pack	317.5 mm	419.1 mm	65.15 mm
Shelf carton (1 unit)	320 mm	425 mm	70 mm
Transit carton (5 units)	330 mm	434 mm	376 mm

A product in the BLUperc portfolio is always contained in an E flute shelf box, a PETG outer tray sealed with High Density Polyethylene, an inner tray wrapped with CSR, and various procedural components placed into the interior of the inner tray compartments. The specific configuration of components depends on the product family, tube type (BLUselect or BLUselect Suctionaid), and tube size (7.0 mm, 8.0 mm, or 9 mm).

The unit pack lid is printed with product specific information and color coded to aid identification of the product size.

One (1) unit pack is packed into a solid broad shelf carton along with one Instructions for Use booklet. Size and color coding is also on the shelf carton label. Five (5) shelf cartons are placed in one fluted corrugated transit carton (total of 5 units). Product is supplied sterile unless package is open, wet, or damaged.

The lot number, manufacturing date, and expiry date are located on the unit pack, on the shelf carton, and on the transit carton labels.

For more information, visit www.icumed.com

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℞ Only For safe and proper use, refer to the Instructions for Use.

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