By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 669121**

Issued To: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2017-07-20** Date: **2018-05-09** Expiry Date: **2023-03-18**

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Certificate No: CE 669121

Certificate Scope:

The design, development and manufacture of:

Sterile Disposable infusion kits including cassette, tubes, connectors, needles

Patient warming units

Blood and Fluid Warmers units

Sterile Blood and Fluid Warmers disposables sets

Sterile Central Implantable Access Systems

Sterile Peripheral Implantable Access Systems

Those aspects of Annex II concerned with securing and maintaining sterile conditions of convective warmers blankets.

First Issued: **2017-07-20** Date: **2018-05-09** Expiry Date: **2023-03-18**

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 669121**
Date:	**2018-05-09**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
CarTika Medical Inc 6551 Wedgwood Rd N Suite 300 Maple Grove Minnesota 55311 USA	**Manufacture**
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis MN 55433 USA	**ETO Sterilization**
Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	**ETO Sterilization**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 43425 Business Park Drive Temecula California 92590 USA	**ETO Sterilization**
Isomedix Operations, Inc. 23 Elizabeth Drive Chester New York 10918 USA	**Gamma Sterilization**
Minnetronix, Inc. 1635 Energy Park Drive St Paul Minnesota 55108 USA	**Design** **Manufacture**

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Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexico	**Manufacture**
Smiths Medical ASD Inc. 1265 Grey Fox Road St Paul Minnesota 55112 USA	**Regulatory Compliance**
Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale Minnesota 55128 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Certificate No:	**CE 669121**
Date:	**2018-05-09**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Smiths Medical International Limited 1500 Eureka Park Lower Pemberton Ashford Kent TN25 4BF United Kingdom	**EU Representative**
Sterigenics US, LLC 10811 Withers Cover Park Drive Charlotte North Carolina 28278 USA	**ETO Sterilization**
Sterigenics US, LLC 1700 College Boulevard West Memphis AR 72301 USA	**Gamma Sterilization**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Date:	**2018-05-09**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	**Gamma Sterilization**
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA	**ETO Sterilization**
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 669121**

Date: **2018-05-09**

Issued To: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

Date	Reference Number	Action
20 July 2017	8691798	First issue, transferred from another notified body.
Current	8893340	Renewal, scope rewording, scope reduction, subcontractor removal, correction of subcontractor address and activities

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

Certificate Number:
119-04 C

Initial Certification Date:
08 June 2004

Date of Certification Decision:
25 June 2018

Issuing Date:
25 June 2018

Valid Until:
24 June 2021

This is to certify that the management system of:

SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn, Germany

See appendix for additional sites and additional site scopes

has been registered by Intertek as conforming to the requirements of:

EN ISO 13485:2016

The management system is applicable to:

Design, manufacture, inspection, storage and distribution of Pressure Monitoring, Infusion Disposables, Interventional Imaging, Neurosurgery, Vascular Access.

The Servicing of active medical devices.

UKAS MANAGEMENT SYSTEMS
061

Calin Moldovean
President, Business Assurance

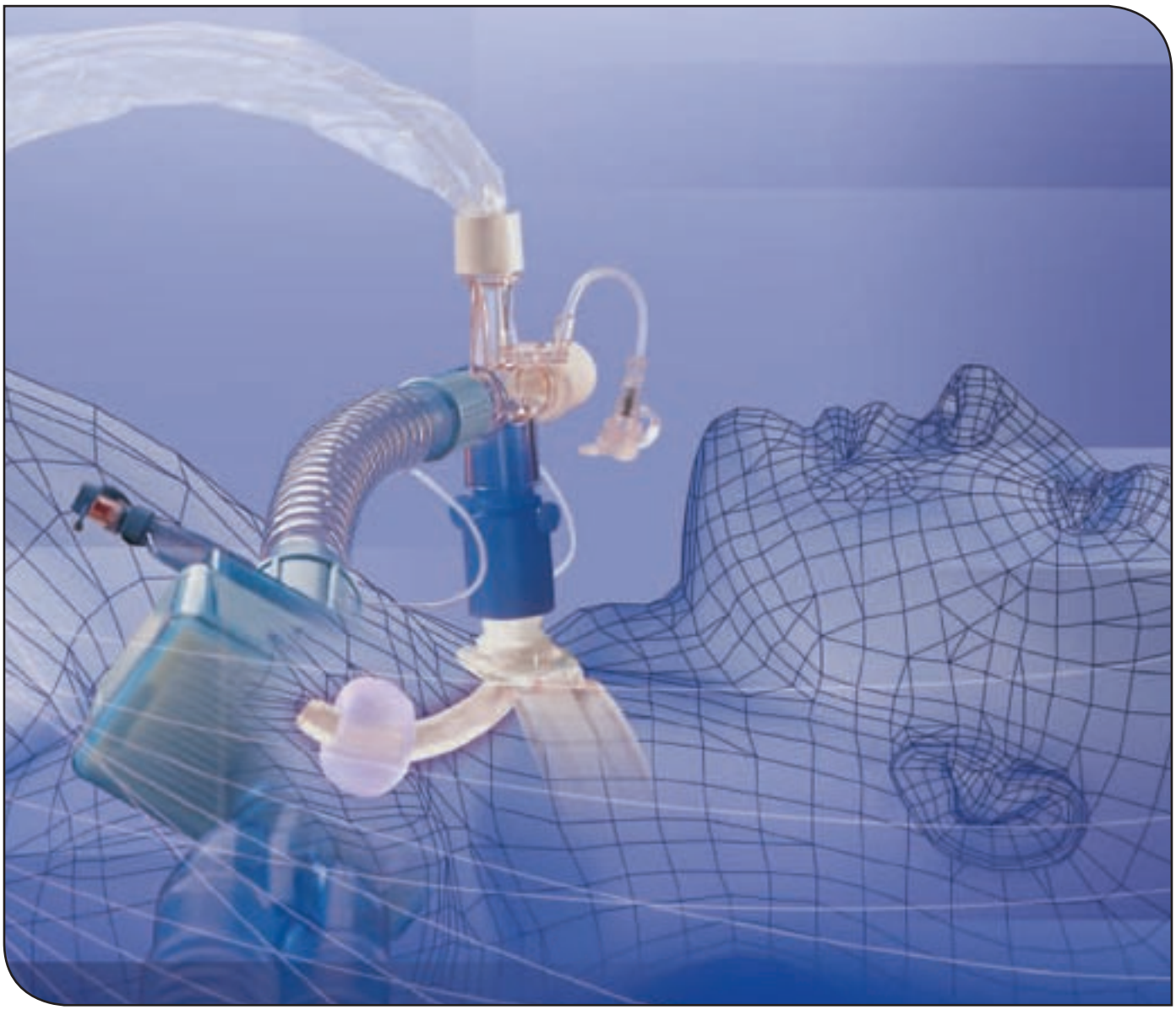
AMTAC Certification Services Limited, T/A Intertek;
Milton Keynes, UK

"This certificate is the property of AMTAC Certification Services Ltd a wholly owned subsidiary of Intertek Holdings Ltd"

Intertek Certification Limited is a UKAS accredited body under schedule of Accreditation No. 061

smiths medical
bringing technology to life

Tracheostomy Supplement
Helping you sustain life



AIRWAY MANAGEMENT

PORTEX™

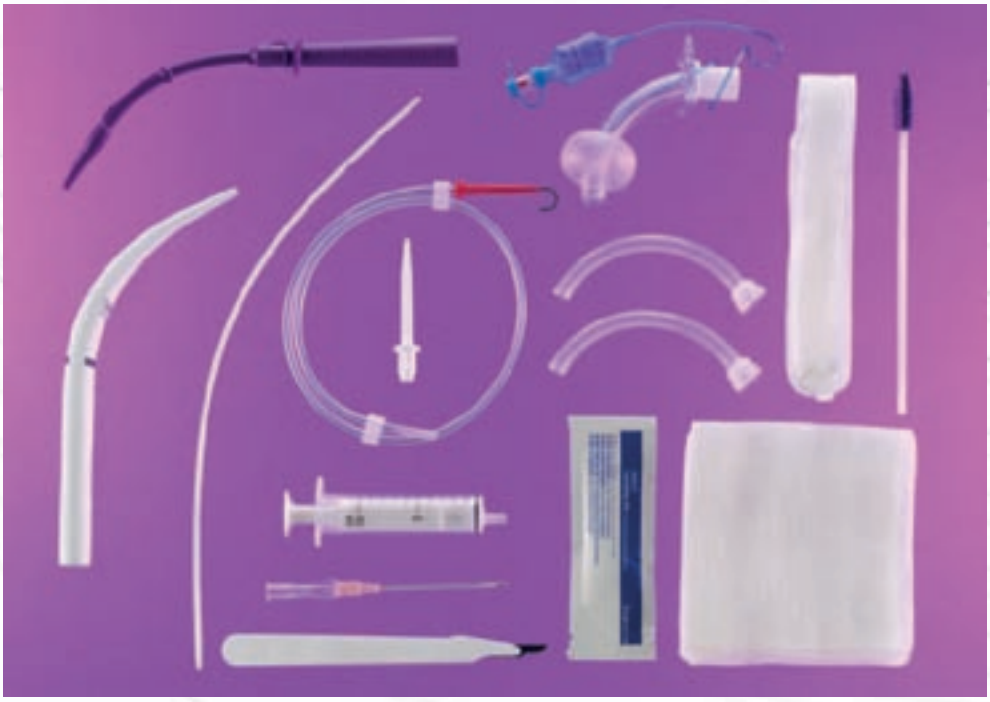
New ULTRAperc kits for percutaneous dilational tracheostomy

ULTRAperc provides the clinician with a range of totally integrated procedural kits for percutaneous dilational tracheostomy for use in Intensive Care or theatre.

Only ULTRAperc kits include every component required from initial incision to final tube insertion using a purpose designed introducer. Also, because ULTRAperc kits are available with Blue Line Ultra, by using ULTRAperc you will gain all the added benefits of this innovative and popular range of tracheostomy tubes.

ULTRAperc is produced with the meticulous attention to detail and quality you expect from Smiths Medical, and offers the clinician:

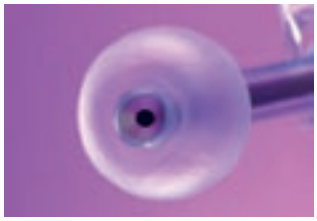
- Totally integrated components, with unique introducer
- The advantages of Blue Line Ultra
- A wide choice of kits to meet individual requirements
- A convenient package including everything required for the procedure
- Ergonomic design for ease of use
- Cost-effective kits



ULTRAperc

PERCUTANEOUS TRACHEOSTOMY KITS

A close fit - the ULTRAperc introducer is tailor made for Blue Line Ultra tracheostomy tubes. The tapered tube tip fits the introducer to minimise trauma on insertion.



A convenient package - Only Smiths Medical ULTRAperc PDT kits can offer the option of the unique introducer and Blue Line Ultra tracheostomy tube all in one kit, avoiding the compromise of mis-matched components.

An ergonomic design - the handle of the ULTRAperc single stage dilator has a chevron-style design, giving a good grip when use of lubricant jelly makes for slippery handling.

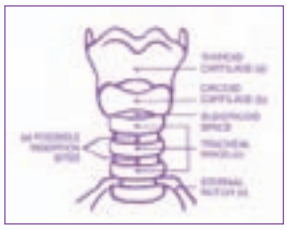
The benefits of Blue Line Ultra - ULTRAperc PDT kits with Blue Line Ultra include all the advantages of this tube range: Soft-Seal cuff, flexible flange, tapered tip, thermo-sensitive PVC material for patient comfort and is suitably radio-opaque for x-ray visualisation.

Also available - Smiths Medical has produced supporting educational material for users of the ULTRAperc kit. The 'How To Guide: Percutaneous Tracheostomy' is produced in association with Care of the Critically Ill. The educational video demonstrates the technique for inserting Blue Line Ultra tubes using the ULTRAperc system.

ULTRAperc kits for percutaneous dilational tracheostomy

Using Ultraperc single dilation technique

1. With the patient in the supine position, hyperextend the neck using a suitable support.



2. Locate and mark the anatomical landmarks. Prepare patient for surgery. Suction pharynx and (if present) re-establish airway with the tracheal tube cuff above the vocal cords to avoid the risk of damaging the tube. If appropriate, inject the site with local anaesthetic.

3. Make a horizontal incision (1.5-2cm) at the chosen insertion site.

4. Insert the needle and cannula (with the syringe attached). Advance the needle until aspiration of air confirms entry into the trachea.

5. Ease the guidewire introducer out from its sheath and straighten the 'J' tip, leaving a sufficient length of exposed guidewire (2-3cm) to enable its dispensing with the forefinger and thumb.

6. Using the introducer, feed the guidewire into the trachea.

7. Pass the dilator over the guidewire towards the trachea and push the dilator forward to penetrate the tracheal wall and at the same time dilate both the tissues and the tracheal wall.

8. Pass the long guiding catheter over the guidewire into the trachea in the direction of the arrow marked on the catheter (safety stop end first) until the safety stop on the guiding catheter is located at the skin. Align the proximal end of the guiding catheter with the proximal band mark on the guidewire to determine the depth of insertion.

9. Immediately prior to insertion, immerse the distal end of the "single stage" dilator in sterile water or saline to activate the lubricious coating on the dilator. Pass the dilator over the guiding catheter until it reaches the "safety stop". In this position, the proximal mark on the guiding catheter will just be visible at the handle end of the dilator.

10. Whilst stabilising the guidewire and guiding catheter to ensure they remain stable and in position in the trachea, insert and partially remove the dilator several times in order to slightly over-dilate the trachea to a size appropriate for the tracheostomy tube to be inserted. The dilator is marked, for guidance, with 38FR and maximum insertion depth.

11. Insert the lubricated tracheostomy tube located on its lubricated introducer over the guiding catheter through the stoma with a slight twisting motion.

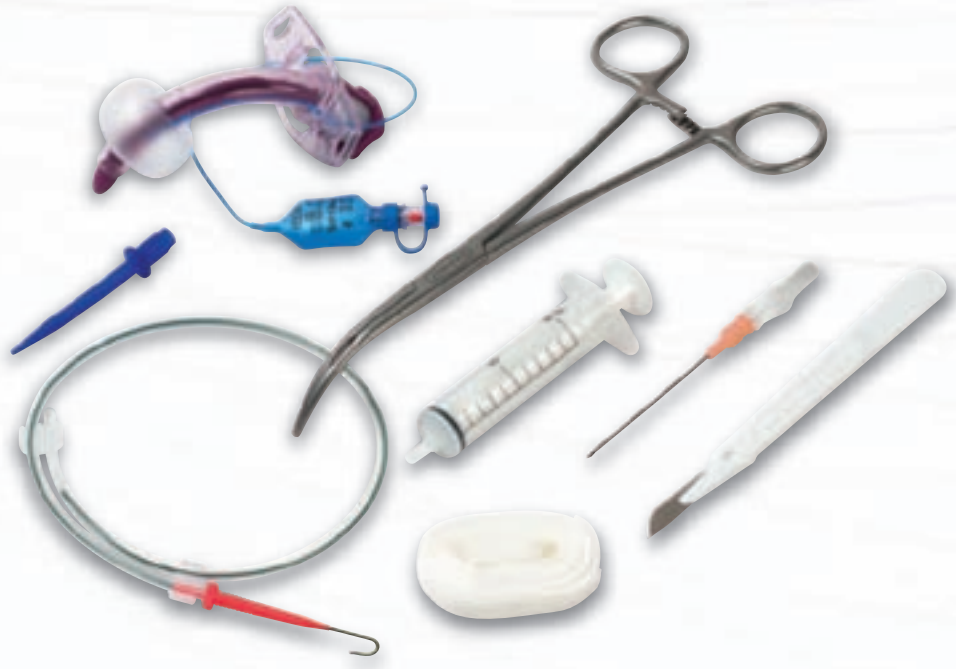
Griggs dilating forceps kits for percutaneous tracheostomy

Based on the widely accepted Seldinger guidewire technique, these kits incorporate the unique and patented Griggs guidewire dilating forceps.

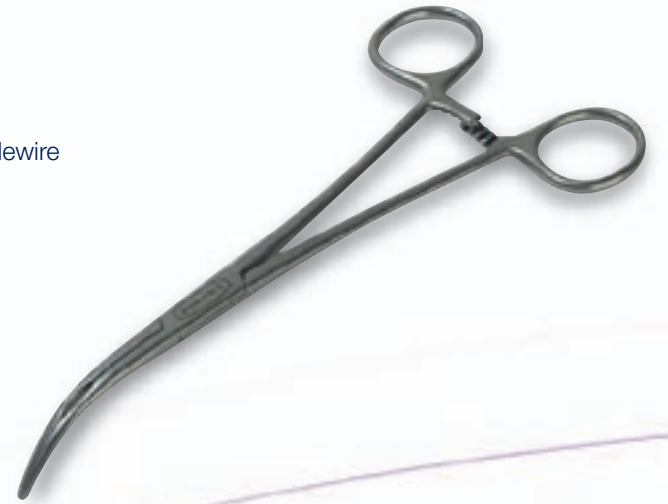
The design of the Griggs forceps permits:

- Single step dilation
  - No need for repeated insertions
  - Minimises tracheal trauma
  - One instrument for a wide range of adult sizes
- Retention of guidewire in situ throughout procedure
  - Maintains accuracy and safety

Smiths Medical kits for Griggs technique percutaneous tracheostomy provide the option for immediate minimally invasive and minimally disruptive treatment, at the bedside or in theatre, which has been shown to have lower complications and morbidity rates versus the traditional surgical technique. [1,2]



References:
1: Griggs WM, Myburgh JA, Worthley LIG. A prospective comparison of a percutaneous tracheostomy technique with standard surgical tracheostomy. Int Care Med 1991; **17**: 261-263.
2: Leinhardt DJ, Mughal M, Bowles B, Glew R, Kishen R et al. Br J Surg 1992; **79**: 255-258.



Only Smiths Medical kits include the unique, patented Griggs guidewire dilating forceps:

- Lock over guidewire for easy, atraumatic insertion
- Allow single step dilation
- Minimise tracheal trauma
- Re-usable to ensure cost-effectiveness

Smiths Medical kits provide what you need:

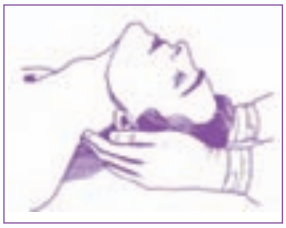
- Full procedure pack (excluding drapes) - avoids delay and inconvenience
- Kits available with or without guidewire dilating forceps - for flexible economy
- Include a Smiths Medical tracheostomy tube with unique guidewire obturator - to ensure convenience and compatibility
- Choice of three tracheostomy tube sizes - to suit a wide range of patients

Kits are also available with the Adjustable Flange Tracheostomy Tube:

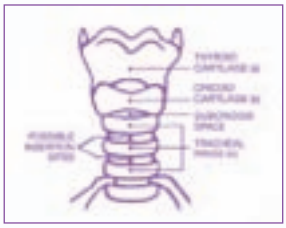
- Moveable flange to facilitate stoma hygiene
- Suitable for patients with deep-set tracheas
- Tapered tube tip and tapered obturator which clips onto bonded connector aid tube insertion
- Siliconised PVC eases passage of suction catheter

Kits for Griggs technique percutaneous tracheostomy

Using the Griggs technique



1. With the patient in the supine position, hyperextend the neck using a suitable support.



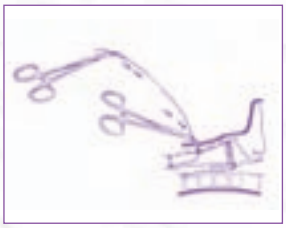
2. Locate and mark the anatomical landmarks. Prepare patient for surgery. Suction pharynx and (if present) re-establish airway with the tracheal tube cuff above the vocal cords to avoid the risk of damaging the tube. If appropriate, inject the site with local anaesthetic.

3. Make a horizontal incision (1.5-2cm) at the chosen insertion site.

4. Insert the needle and cannula (with the syringe attached). Advance the needle until aspiration of air confirms entry into the trachea.

5. Using the introducer, feed the guidewire into the trachea.

6. Pass the dilator over the guidewire towards the trachea and push the dilator forward to penetrate the tracheal wall and at the same time dilate both the tissues and the tracheal wall.



7. Thread the guidewire through the clamped Guidewire Dilating Forceps and advance the forceps until the anterior tracheal wall is reached. Dilate the pre tracheal tissues by opening the forceps and remove the forceps in the open position.

8. Re-thread the forceps as described and now advance through the tracheal wall. Raise forceps handles into the vertical position so that the forceps jaws further penetrate the tracheal wall and lie longitudinally in the trachea. Dilate the trachea by opening forceps. Remove forceps in the open position.

9. Thread the guidewire through the obturator of the tracheostomy tube and advance both into the trachea. Remove obturator and guidewire.

Ordering information

Smiths Medical **Blue Line Ultra** Percutaneous Tracheostomy kit with Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/541/070
Kit with 8mm I.D. tracheostomy tube	100/541/080
Kit with 9mm I.D. tracheostomy tube	100/541/090

Smiths Medical **Blue Line Ultra Suctionaid** Percutaneous Tracheostomy kit with Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/891/070
Kit with 8mm I.D. tracheostomy tube	100/891/080
Kit with 9mm I.D. tracheostomy tube	100/891/090

Smiths Medical **Blue Line Ultra** Percutaneous Tracheostomy kit without Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/543/070
Kit with 8mm I.D. tracheostomy tube	100/543/080
Kit with 9mm I.D. tracheostomy tube	100/543/090

Smiths Medical **Blue Line Ultra Suctionaid** Percutaneous Tracheostomy kit without Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/893/070
Kit with 8mm I.D. tracheostomy tube	100/893/080
Kit with 9mm I.D. tracheostomy tube	100/893/090


100/541


100/543


100/891


100/893

Smiths Medical **Blue Line** Percutaneous Tracheostomy kit with Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/540/070
Kit with 8mm I.D. tracheostomy tube	100/540/080
Kit with 9mm I.D. tracheostomy tube	100/540/090

Smiths Medical **Adjustable Flange** Tracheostomy kit with Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/545/070
Kit with 8mm I.D. tracheostomy tube	100/545/080
Kit with 9mm I.D. tracheostomy tube	100/545/090

Smiths Medical **Blue Line** Percutaneous Tracheostomy kit without Guidewire Dilating Forceps

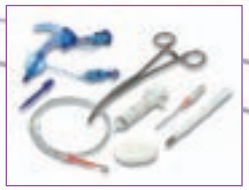
Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/542/070
Kit with 8mm I.D. tracheostomy tube	100/542/080
Kit with 9mm I.D. tracheostomy tube	100/542/090

Smiths Medical **Adjustable Flange** Tracheostomy kit without Guidewire Dilating Forceps

Description	Product Code
Kit with 7mm I.D. tracheostomy tube	100/546/070
Kit with 8mm I.D. tracheostomy tube	100/546/080
Kit with 9mm I.D. tracheostomy tube	100/546/090


100/540


100/542

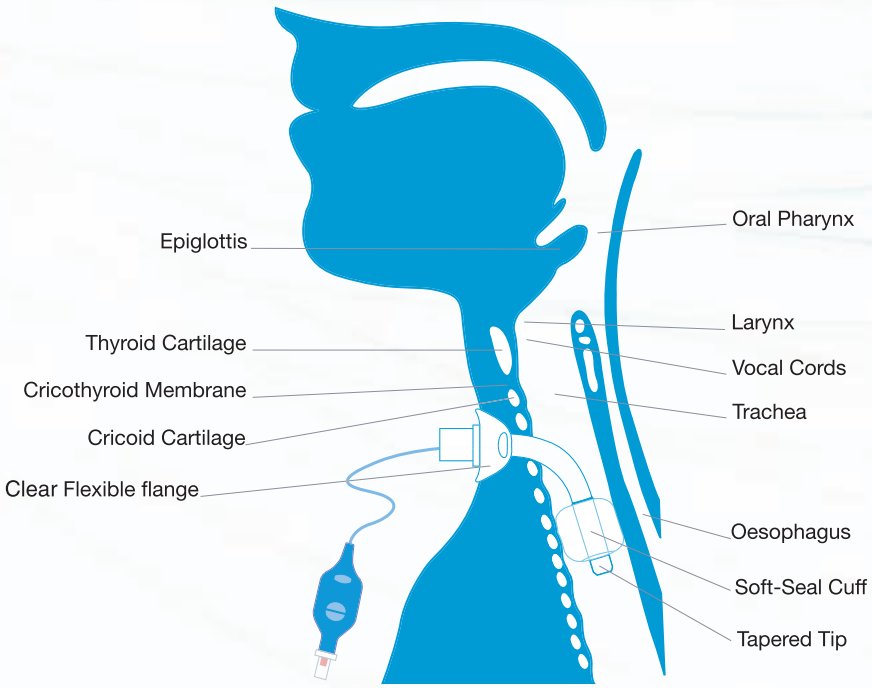

100/545


100/546

Blue Line Ultra with inner cannula

The benefits of the Blue Line Ultra inner cannula system

- Inner cannula designed to be robust and easy to use. Clicks into place to confirm correct insertion. Can be used for up to 30 days
- Ring-pull design aids smooth insertion and removal from tube, minimising patient trauma
- Size of inner cannula indicated to avoid errors in use
- 15mm ISO termination is permanent part of the tube, patient can be ventilated with or without inner cannula in place
- A cleaning brush is supplied for cleaning inner cannula. Brush features soft nylon filaments and smooth brush tip
- Fenestrated inner cannula is coloured red for ease of identification of use
- Multiple fenestrations match those of tracheostomy tube and minimise risk of blockages
- Provided with two reusable inner cannulae and tube holder to secure tube



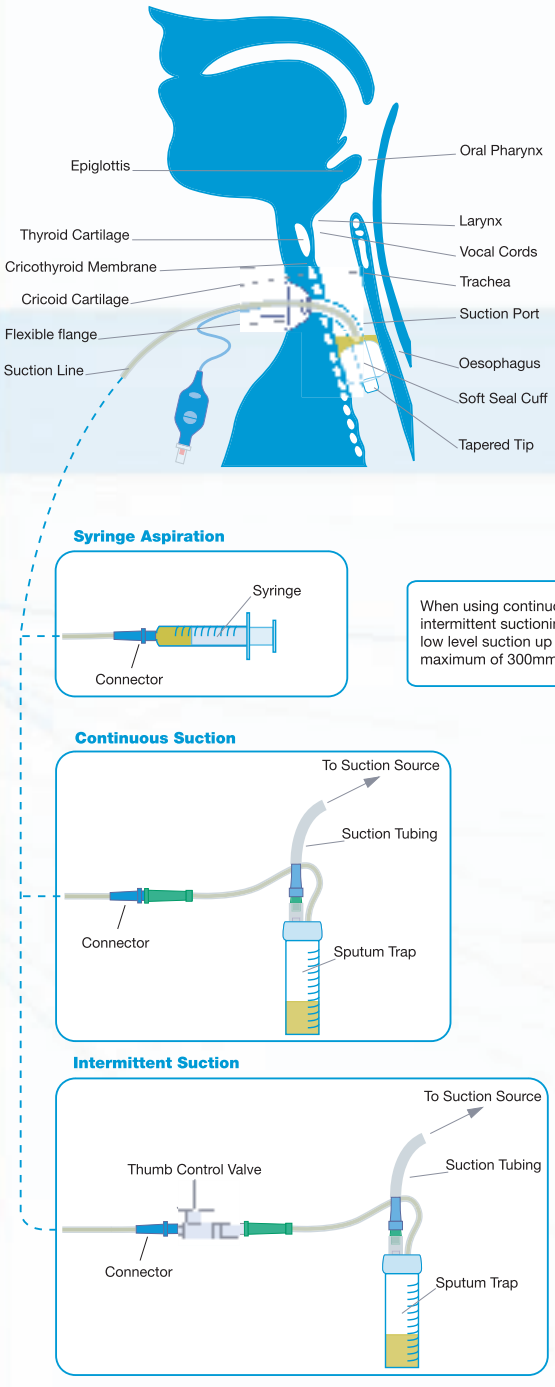
Blue Line Ultra tracheostomy tubes

When caring for a patient with a tracheostomy, you need to choose the tracheostomy tube that best suits the specific clinical need. The Blue Line Ultra range has many benefits:

- Comprehensive range - available with or without inner cannula, cuffed or uncuffed, rigid or thermosensitive, fenestrated or unfenestrated
- Thermosensitive PVC tubes provides sufficient rigidity for initial insertion, and then softens at body temperature to accommodate individual patient anatomy
- Soft-Seal cuff - low pressure, high volume cuff for minimal trauma whilst providing an effective seal. When deflated, cuff relaxes smoothly to tube minimising discomfort on insertion and removal. Velvet soft material with larger cuff resting diameter
- Clear markings on pilot balloon provide relevant information
- Flange is soft for maximum patient comfort, and clear to ensure aesthetic acceptability
- Tube material is suitably radio-opaque to enable confirmation of tube position
- Multiple fenestrations to minimise risk of occlusions
- Obturator provides rigidity for tube insertion. Rounded obturator tip for insertion with minimal trauma
- Special clip design minimises obturator tip movement during tube insertion

New Blue Line Ultra Suctionaid

A new addition to the Blue Line Ultra range, the Blue Line Ultra Suction Aid is ideal for improving patient well-being by maintaining a clean, hygienic and unobstructed airway and having the ability to remove secretions from above the cuff.

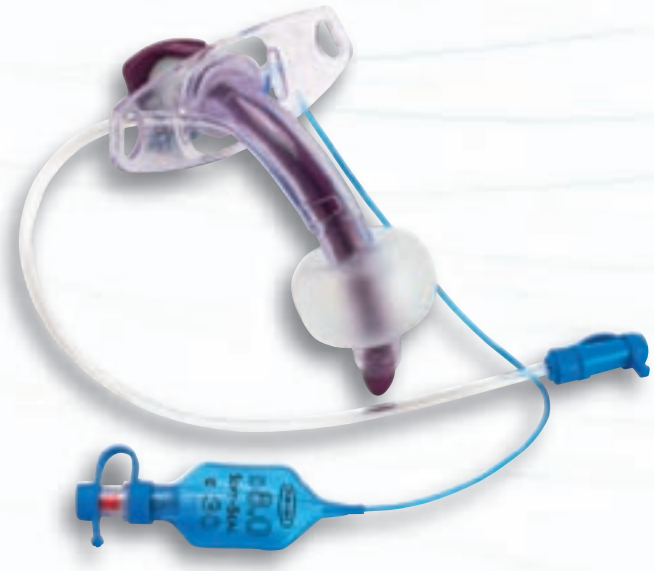


Reducing the potential risk of infection

Accumulation and stasis of contaminated mucus and subglottic secretions above the cuff of tracheostomy tubes can be uncomfortable for patients and provides an ideal growth medium for pathogens. The integral suction lumen of Blue Line Ultra Suctionaid allows removal of these pooled secretions.

Reducing the risk of aspiration

However good the cuff, microaspiration of contaminated material can potentially lead to pulmonary infection. Maintaining tracheostomy hygiene and regular removal of secretions with Blue Line Ultra Suctionaid can help reduce this aspiration.



Blue Line tracheostomy tubes

The comprehensive range of Blue Line tracheostomy tubes meets the varying needs of different departments and different patients.

In Surgery the primary requirement is for ventilation, which needs an atraumatic tube with a good cuff seal against air and liquid. These needs are met by Blue Line cuffed, thermosensitive tubes.

In Intensive Care the patient also needs to be weaned off ventilation, and to restart vocalisation. Tubes for this setting, as well as being atraumatic with a good cuff seal against air and liquid, need to permit airflow to the larynx. Blue Line cuffed, thermosensitive, fenestrated tubes fulfil this requirement.

On the Ward spontaneous breathing obviates the need for the cuff, while vocalisation demands airflow to the larynx. For these patients Blue Line uncuffed thermosensitive tubes are ideal.

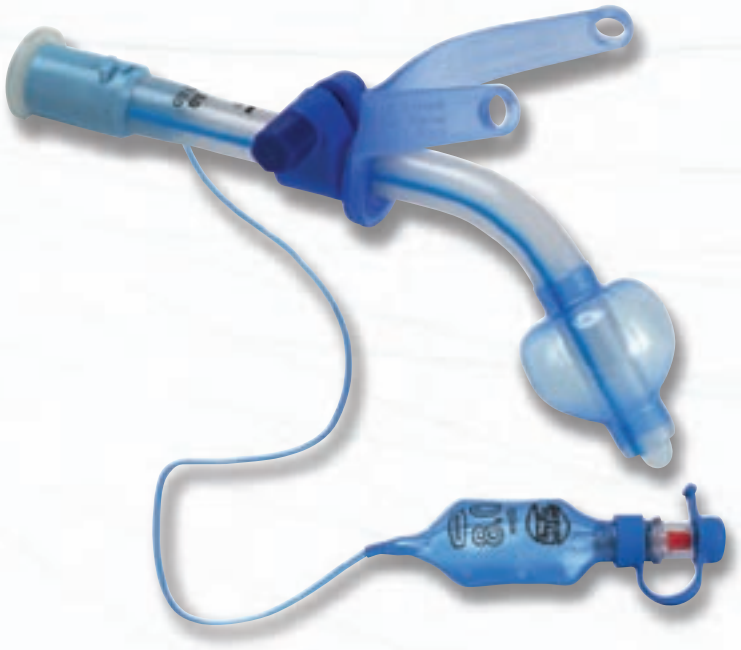
In the Home, patients who still require a tracheostomy although they are breathing spontaneously and vocalising want a tube which is unobtrusive, as well as atraumatic and permitting a good airflow to the larynx. For them the solution is a Blue Line uncuffed, thermosensitive, fenestrated tube with no 15mm connector.

The Blue Line range is also broad and flexible enough to cover the enormous variation in individual patient anatomy by offering customised tubes (see pages 56-62).

Blue Line tracheostomy tubes

Blue Line tubes are designed to meet all your needs.

- Thermosensitive material
  - Initial rigidity for easy intubation
  - Flexibility at body temperature to adapt to the individual patient's anatomy
- Atraumatic design
  - Anatomical tube shape
  - Smooth contours for maximum comfort
  - Non-toxic siliconised PVC tube
  - Low pressure, high volume Profile cuff
- Large choice of tubes
  - Cuffed or uncuffed, fenestrated or unfenestrated, with or without 15mm connector
  - Specialised products for specific needs



Blue Line tracheostomy tubes

Ordering information

Cuffed tubes

Product	Sizes (I.D.mm)	Pack size	Product Codes
Profile cuff tube	6-10	10	100/518/060 - 100/518/100
Double cuff tube	7-10	10	100/512/070 - 100/512/100
Vocalaid tube	6-10	10	100/517/060 - 100/517/100

Uncuffed tubes

Product	Sizes (I.D.mm)	Pack size	Product Codes
Uncuffed tube	3-10	10	100/506/030 - 100/506/100
Uncuffed single fenestrated tube	3-10	10	100/536/030 - 100/536/100
Uncuffed double fenestrated tube	6-10	10	100/537/060 - 100/537/100

Uncuffed tubes without 15mm connector

Product	Sizes (I.D.mm)	Pack size	Product Codes
Uncuffed tube	3-10	10	100/505/030 - 100/505/100
Uncuffed fenestrated tube	3-10	10	100/535/030 - 100/535/100

Adjustable flange tubes

Product	Sizes (I.D.mm)	Pack size	Product Codes
Profile cuff tube	6-10	2	100/523/060 - 100/523/100
Uncuffed tube	6-10	2	100/526/060 - 100/526/100

The last 3 digits indicate the correct tube size e.g. for a size 8.0mm I.D. tube, the product code is 100/518/080

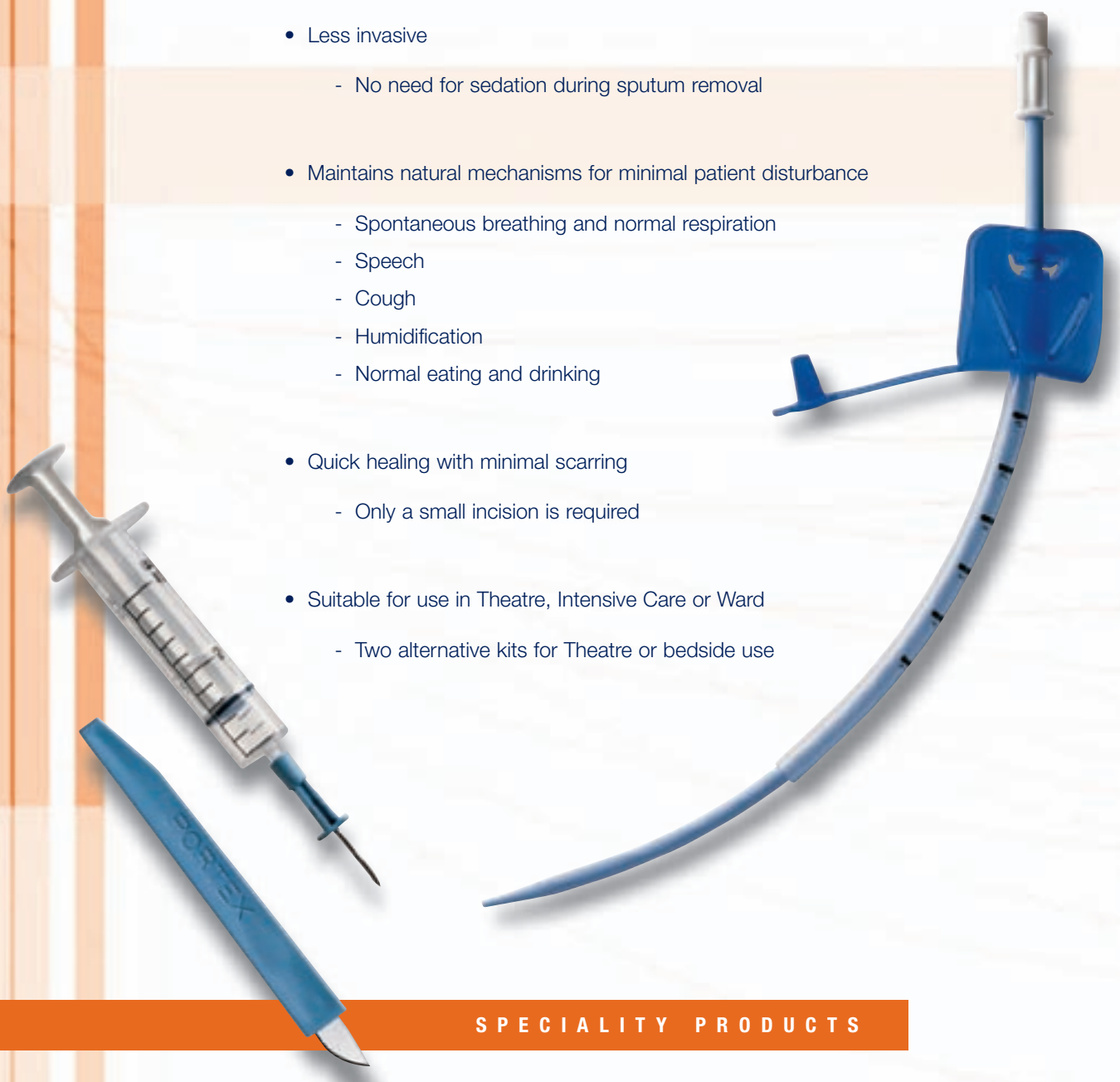
No inner cannulae are available for these products.

100/505 products are available single packed. To order replace '0' with '1' - e.g. 100/505/130.
Code for size 10mm tube as single item is 100/505/110.

Mini-Trach II minitracheotomy kits

After surgery, infection or injury, sputum retention can be a real problem which, if not effectively treated can lead to significant morbidity and even death. When there is the risk that natural sputum removal by coughing, with or without physiotherapy, will not be adequate, prophylactic minitracheotomy can prevent the problem arising and offers many advantages over conventional techniques for managing sputum retention: [4,5,6,7]

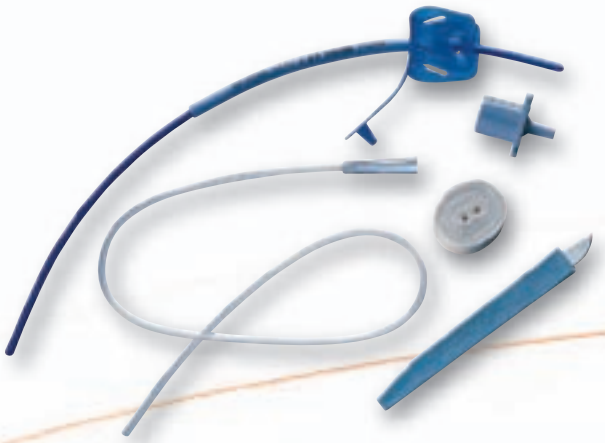
- Constant tracheal access
  - No need for tracheal intubation or tracheostomy
- Less invasive
  - No need for sedation during sputum removal
- Maintains natural mechanisms for minimal patient disturbance
  - Spontaneous breathing and normal respiration
  - Speech
  - Cough
  - Humidification
  - Normal eating and drinking
- Quick healing with minimal scarring
  - Only a small incision is required
- Suitable for use in Theatre, Intensive Care or Ward
  - Two alternative kits for Theatre or bedside use



4: HR Matthews, RB Hopkinson "Treatment of sputum retention by mini tracheostomy" Brit J Surg 1984: 71: 147-150
5: Mini tracheostomy and the control of sputum, HR Matthews. Surgeon Annual 1998. Appleton & Lange, USA P39-59
6: P Bonde, I Papachristos, A McCraith, B Kelly, C Wilson, JA McGuigon, K McManus, "Sputum Retention after Lung Operation: Randomised trial shows superiority of prophylachc minitracheostomy in high-risk patients" Ann Thoracic Surg 2002; 74: 196-203
7: P Bonde, K McManus, M McMnespie, J MuGuigon "Lung Surgery: identifing the subgroup at risk for sputum retention" European Journal of Cardio-Thoracic Surgery 22(2002) 18-22

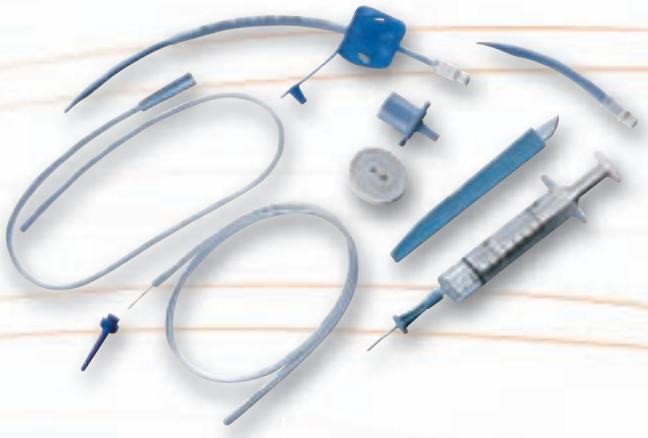
Mini-Trach II kit for surgical insertion in Theatre

- Guarded scalpel allows the correct incision to be made without risk of damage to the posterior wall of the trachea
- Introducer guides the cannula into the trachea
- 4.0mm ID soft PVC cannula provides access to the trachea both as an airway and for suctioning
- 15mm connector allows standard connection to breathing systems. 10F low friction suction catheter allows immediate initial suctioning following cannulation



Mini-Trach II Seldinger kit for therapeutic insertion in Theatre, Intensive Care or Ward

- Guarded scalpel to make initial midline skin incision
- 16G bevelled needle allows simple puncture of the cricothyroid membrane
- Aspirating syringe allows confirmation of correct needle placement
- Flexible tipped guidewire helps introduction of dilator without trauma to posterior tracheal wall
- Curved dilator expands the opening to permit smooth insertion of the Mini-Trach cannula
- Introducer guides the cannula into the trachea
- 4.0mm ID soft PVC cannula provides access to the trachea both as an airway and for suctioning
- 15mm connector allows standard connection to breathing systems
- 10F low friction suction catheter allows immediate initial suctioning following cannulation



Mini-Trach II minitracheotomy kits

Using the Mini-Trach II Seldinger kit

1. The patient is positioned supine with head, neck and chin fully extended. The operator stands above the patient's head facing the patient's feet.

2. The skin is cleansed and the position of the cricothyroid membrane located by palpation and marked.

3. A midline vertical 1cm skin incision is made using the guarded scalpel.

4. The 16G bevelled needle is fitted to the syringe. With the trachea immobilised the bevelled needle is inserted vertically (with the opening of the needle facing caudally) through the cricothyroid membrane. Correct placement is confirmed by aspiration of air.

5. The syringe is removed carefully, keeping the needle in position. The flexible tip of the guidewire is inserted through the bevelled needle into the trachea.

6. The bevelled needle is removed carefully while holding the guidewire to ensure that the guidewire is not moved out of position.

7. The curved dilator is fed onto the guidewire and passed through the cricothyroid membrane.

8. The dilator is removed carefully while holding the guidewire to ensure that the guidewire is not moved out of position. The curved introducer with the premounted Mini-Trach cannula is then fed onto the guidewire and introduced into the trachea with firm pressure.

9. The introducer and guidewire are removed holding the cannula flange in place against the skin.

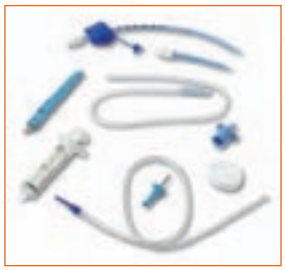
10. The cannula is fixed in place with neck tapes.

11. The suction catheter is passed immediately to remove any existing blood and secretions.

Ordering information

Mini-Trach II

Description	Pack Size	Product Code
Seldinger kit	5	100/461/000
Non-Seldinger kit	10	100/462/000



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