

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Smiths Medical ASD Inc.
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

Holds Certificate Number:

MD 669191

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Please see scope page.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2017-08-16

Latest Revision Date: 2019-02-28

Effective Date: 2017-08-16

Expiry Date: 2020-08-15

Page: 1 of 6



003

...making excellence a habit.™

Certificate No: **MD 669191**

Registered Scope:

The design, development and manufacturing of:

- Sterile Disposable infusion kits including cassette, tubes, connectors, needles
- Sterile Blood and Fluid Warmers disposables sets
- Sterile Central Implantable Access Systems
- Sterile Peripheral Implantable Access Systems
- Sterile and non-sterile vital sign monitoring probes
- Sterile Needles and Introducer for Implantable Access
- Sterile Catheters and accessories
- Sterile Blood Sampling Devices
- Sterile Respiratory Therapy Devices and positive airway pressure therapy
- Sterile Catheter Connectors,
- Loss of Resistance Devices Syringes, Epidural Filters
- Epidural Needles,
- Hypodermic Needles and
- Introducer Needles
- Sterile Spinal and combined spinal/epidural needles including correct inject spinal needles Devices
- Sterile Positive expiratory pressure therapy systems
- Sterile and non-sterile Breathing Systems and Circuits including
- Sterile and non-sterile Applications for patient Intubation
- Sterile Tracheostomy Tubes and Kits
- Sterile and non-sterile Oxygen and Humidity Management,
- Non-Sterile Resuscitation,
- Non-Sterile filter,
- And Sterile and Non-Sterile tracheostomy accessories
- Sterile Disposable Pressure Monitoring tubes, connectors and transducers
- Sterile Suction Catheters
- Sterile Drainage Devices
- Sterile Feeding devices
- Sterile Cardiothoracic Catheters
- Patient warming units
- Blood and Fluid Warmers units
- Infusion Pumps for hospital and home use
- Infusion Application Software
- Sterile and non sterile convective warmers blankets and accessories
- Medical Gas Administration Accessories
- Gas Powered Emergency and Transport Ventilators and Resuscitators
- Anesthetic Ventilators
- Monitors and Related Equipment
- Non-Sterile Nebulizers

Original Registration Date: 2017-08-16

Latest Revision Date: 2019-02-28

Effective Date: 2017-08-16

Expiry Date: 2020-08-15

Page: 2 of 6

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Certificate No: **MD 669191**

Registered Scope:

Sterile Regional Anesthesia Devices

Sterile Needle safety devices and cough sampling devices and catheters securing devices and kit for applying local anesthesia

Interventional Imaging Devices

Sterile Pain Management Devices

Document Control, Post Market Risk Management, Customer Complaints, Global Sourcing, Regulatory Affairs, Servicing, distribution.



Original Registration Date: 2017-08-16

Latest Revision Date: 2019-02-28

Effective Date: 2017-08-16

Expiry Date: 2020-08-15

Page: 3 of 6

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **MD 669191**

Location

Smiths Medical ASD Inc.
3350 Granada Avenue North
Oakdale
Minnesota
55128
USA

Registered Activities

The manufacture of:
Sterile Catheters and Accessories
Sterile and non sterile convective warmers blankets and accessories
Patient warming units
Sterile and non sterile vital sign monitoring probes
Blood and Fluid Warmers units
Sterile Blood and Fluid Warmers disposables sets
Infusion Application Software
Infusion Pumps for hospital and home use
Sterile Disposable infusion kits including cassette, tubes, connectors, needles
Medical Gas Administration Accessories
Servicing, distribution



Original Registration Date: 2017-08-16

Latest Revision Date: 2019-02-28

Effective Date: 2017-08-16

Expiry Date: 2020-08-15

Page: 4 of 6

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **MD 669191**

Location

Smiths Medical ASD Inc.
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

Registered Activities

The design, development and manufacturing of:
Sterile Disposable infusion kits including cassette, tubes, connectors, needles
Sterile Blood and Fluid Warmers disposables sets
Sterile Central Implantable Access Systems
Sterile Peripheral Implantable Access Systems
Sterile and non-sterile vital sign monitoring probes
Sterile Needles and Introducer for Implantable Access
Sterile Catheters and accessories
Sterile Blood Sampling Devices
Sterile Respiratory Therapy Devices and positive airway pressure therapy
Sterile Catheter Connectors,
Loss of Resistance Devices Syringes, Epidural Filters
Epidural Needles,
Hypodermic Needles and
Introducer Needles
Sterile Spinal and combined spinal/epidural needles including correct inject spinal needles Devices
Sterile Positive expiratory pressure therapy systems
Sterile and non-sterile Breathing Systems and Circuits including
-Sterile and non-sterile Applications for patient Intubation
-Sterile Tracheostomy Tubes and Kits
-Sterile and non-sterile Oxygen and Humidity Management,
-Non-Sterile Resuscitation,
-Non-Sterile filter,
-And Sterile and Non-Sterile tracheostomy accessories
Sterile Disposable Pressure Monitoring tubes, connectors and transducers
Sterile Suction Catheters
Sterile Drainage Devices
Sterile Feeding devices
Sterile Cardiothoracic Catheters
Patient warming units
Blood and Fluid Warmers units
Infusion Pumps for hospital and home use
Infusion Application Software
Sterile and non sterile convective warmers blankets and accessories
Medical Gas Administration Accessories
Gas Powered Emergency and Transport Ventilators and Resuscitators
Anesthetic Ventilators
Monitors and Related Equipment
Non-Sterile Nebulizers
Sterile Regional Anesthesia Devices

Original Registration Date: 2017-08-16

Effective Date: 2017-08-16

Latest Revision Date: 2019-02-28

Expiry Date: 2020-08-15

Page: 5 of 6

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Certificate No: **MD 669191**

Location

Registered Activities

Sterile Needle safety devices and cough sampling devices and catheters securing devices and kit for applying local anesthesia
Interventional Imaging Devices
Sterile Pain Management Devices
Document Control, Post Market Risk Management, Customer Complaints, Global Sourcing, Regulatory Affairs, Servicing, distribution.



Original Registration Date: 2017-08-16

Effective Date: 2017-08-16

Latest Revision Date: 2019-02-28

Expiry Date: 2020-08-15

Page: 6 of 6

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

EC Certification



EC DESIGN EXAMINATION CERTIFICATE Directive 93/42/EEC for Medical Devices, Annex II (4)

We hereby declare that a design examination has been carried out on the device(s) listed hereafter following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II Section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed hereafter conforms with the relevant provisions of Annex II Section 4 of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products*.

SMITHS MEDICAL DEUTSCHLAND GmbH

Bretonischer Ring 3, D-85630 Grasbrunn, Germany

Central venous catheters:

- standard sets
- standard kits
- custom sets

*For CE marking the class III devices covered by this certificate, an EC certificate according to Annex II (3) is also required.

Certificate Number: 119-05 B DE
Initial Certification Date: 01 September 2006
Certificate Effective Date: 07 March 2017
Certificate Expiry Date: 06 March 2022

Barry A. Fitch
AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

The certificate remains the property of Intertek, to whom it must be returned upon request.

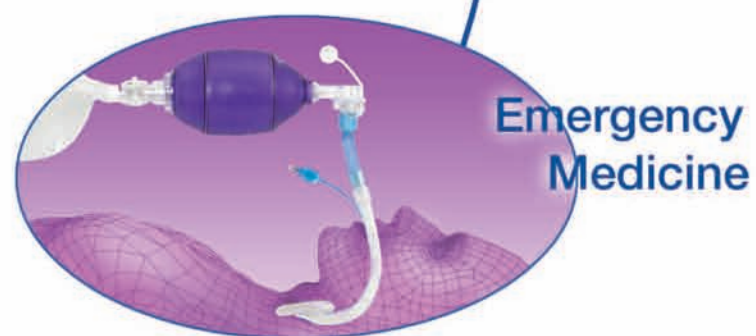
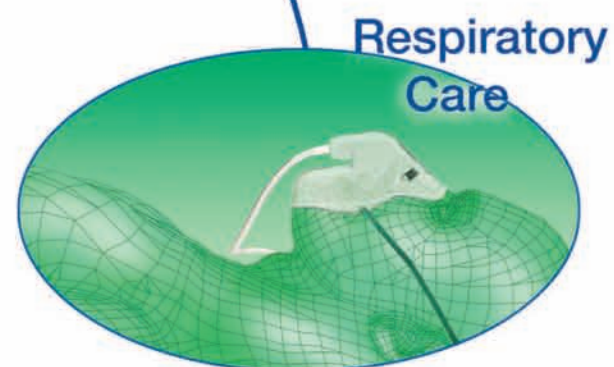
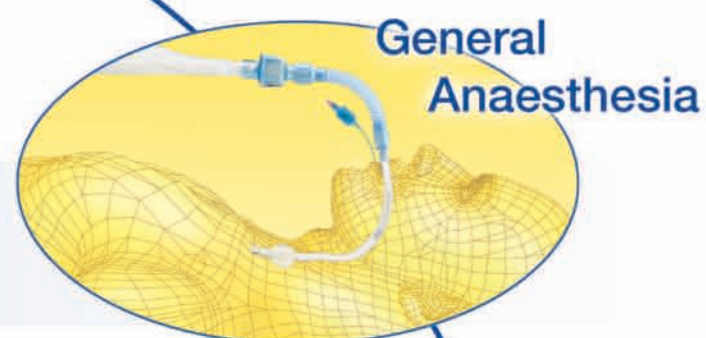
The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

contents

4	Percutaneous tracheostomy kits	—
	ULTRAperc dilational kits	
	Griggs dilating forceps kits	
14	Tracheostomy tubes	—
	Blue Line Ultra with inner cannula	
	Blue Line	
	Bivona Adult	
	Paediatric and Neonatal	
32	Speciality products	—
	Mini-Trach II minitracheotomy kits	
	Emergency cricothyrotomy kits	
	Orator speaking valve	
	Voice restoration	
	Special tubes	
44	Associated products	—
	Suction catheters	
	HEPA	
	Thermovent T	
	HME's	
	Catheter mounts	
48	Accessories	—
52	Educational materials	—
56	Customisation	—
63	Index	

Smiths Medical Airway Management



UK Customers Services

Customers in the UK with queries on any product in this supplement should contact:

Tel: 0870 6016789

Fax: 01303 265560

International Customer Services

Customers outside the UK with queries on any product in this supplement should contact:

Tel: +44 (0) 1303 260551

Fax: +44 (0) 1303 236899

We will be happy to put you in touch with your nearest distributor.

Additional information is available at
www.smiths-medical.com

1

Percutaneous Tracheostomy Kits

Percutaneous tracheostomy provides a convenient and rapid method of tracheostomy tube insertion which can be performed at the bedside, making it ideal for use in Intensive Care.

With the introduction of the new ULTRAperc dilational percutaneous kits Smiths Medical can now offer kits for the three major techniques: Single dilation, Serial dilation or Griggs dilating forceps.

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:

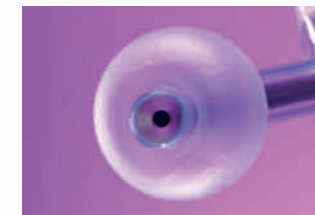
- Totally integrated components, with unique introducer
- The advantages of Blue Line Ultra
- A wide choice of kits to meet individual requirements
- A convenient package including everything required for the procedure
- Ergonomic design for ease of use
- Cost-effective kits



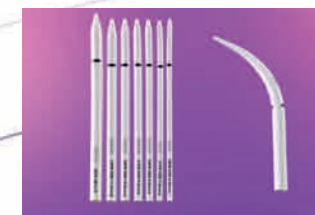
ULTRAPerc

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 wide choice - with the range of single stage or serial PDT kits, an ULTRAPerc solution is available whatever your preferred technique - each option is designed for a safe, rapid and controlled procedure either by the bedside or in theatre.



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.

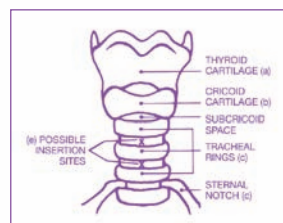


ULTRAperc kits for percutaneous dilational tracheostomy

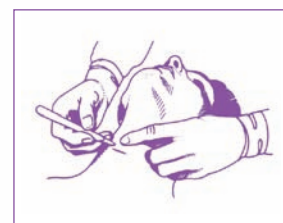
Using Ultraperc single dilation technique



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



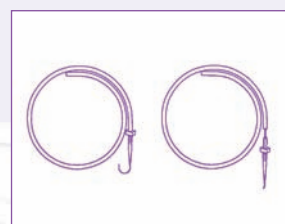
2. Locate and mark the anatomical landmarks. Prepare patient for surgery. Suction pharynx and (if present) re-establish airway with the tracheal tube cuff above the vocal cords to avoid the risk of damaging the tube. If appropriate, inject the site with local anaesthetic.



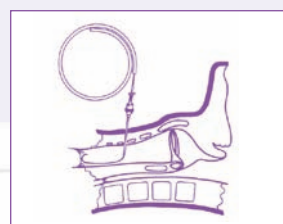
3. Make a horizontal incision (1.5-2cm) at the chosen insertion site.



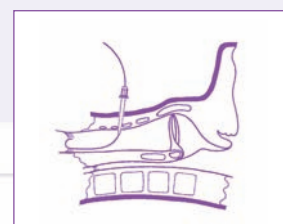
4. Insert the needle and cannula (with the syringe attached). Advance the needle until aspiration of air confirms entry into the trachea.



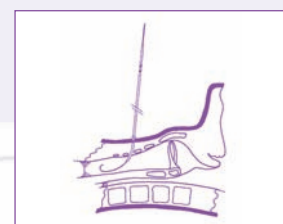
5. Ease the guidewire introducer out from its sheath and straighten the 'J' tip, leaving a sufficient length of exposed guidewire (2-3cm) to enable its dispensing with the forefinger and thumb.



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



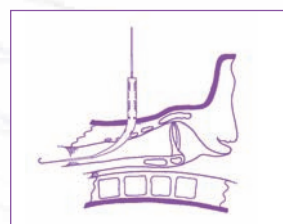
7. Pass the dilator over the guidewire towards the trachea and push the dilator forward to penetrate the tracheal wall and at the same time dilate both the tissues and the tracheal wall.



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.

Single Stage Dilator

Ordering information

Percutaneous Dilation Tracheostomy Kit with Single Stage Dilator

Description	Product Code
With Blue Line Ultra Tracheostomy Tube (7mm) and Introducer	100/561/070
With Blue Line Ultra Tracheostomy Tube (8mm) and Introducer	100/561/080
With Blue Line Ultra Tracheostomy Tube (9mm) and Introducer	100/561/090



Percutaneous Dilation Tracheostomy Kit with Single Stage Dilator and Soft Introducers for 7, 8 & 9mm Tubes Only

Description	Product Code
Without Tracheostomy Tube	100/562/000



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 LG. 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.

PERCUTANEOUS TRACHEOSTOMY KITS

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

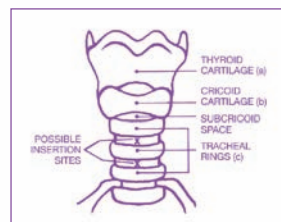


Kits for Griggs technique percutaneous tracheostomy

Using the Griggs technique



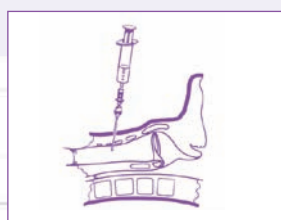
1. With the patient in the supine position, hyperextend the neck using a suitable support.



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.



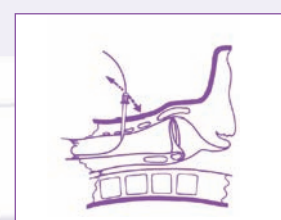
3. Make a horizontal incision (1.5-2cm) at the chosen insertion site.



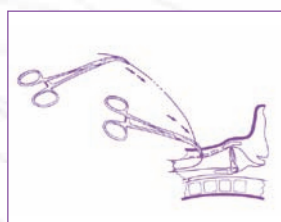
4. Insert the needle and cannula (with the syringe attached). Advance the needle until aspiration of air confirms entry into the trachea.



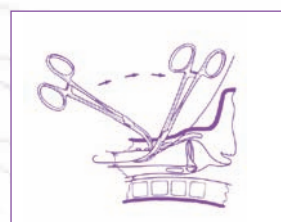
5. Using the introducer, feed the guidewire into the trachea.



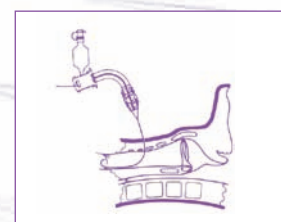
6. Pass the dilator over the guidewire towards the trachea and push the dilator forward to penetrate the tracheal wall and at the same time dilate both the tissues and the tracheal wall.



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 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 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 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



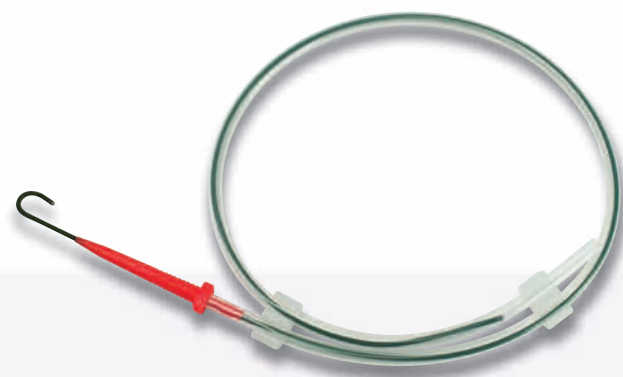
100/546

Guidewires

Spare guidewires for use with either the Dilational or Griggs technique percutaneous tracheostomy kits.

Ordering information

Description	Pack Size	Product Code
Spare guidewires	5	100/544/000



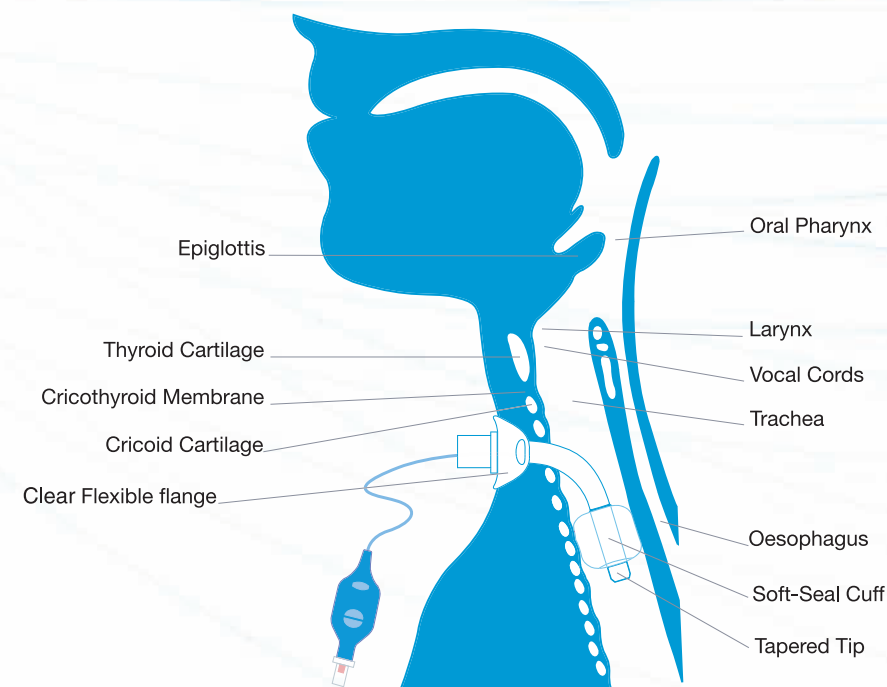
2 Tracheostomy tubes

Smiths Medical have been experts in the production of tracheostomy tubes for over quarter of a century. We offer an extensive choice of tracheostomy tubes, from the traditional Blue Line range to our next generation of Blue Line Ultra tubes which, because we know that clinicians have different requirements for their own clinical procedures, offer the ultimate in choice and flexibility. Smiths Medical now also offers the complete range of Bivona tracheostomy tubes including paediatric and neonatal tubes.

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

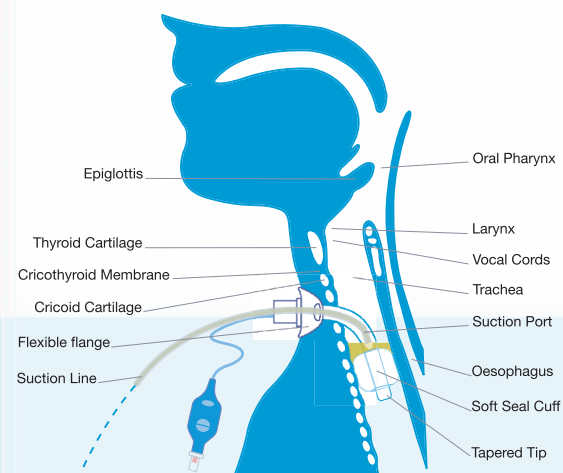
When caring for a patient with a tracheostomy, you need to choose the tracheostomy tube that best suits the specific clinical need. The Blue Line Ultra range has many benefits:

- 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.



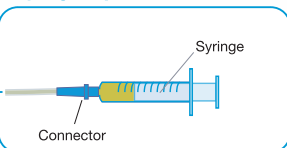
Reducing the potential risk of infection

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

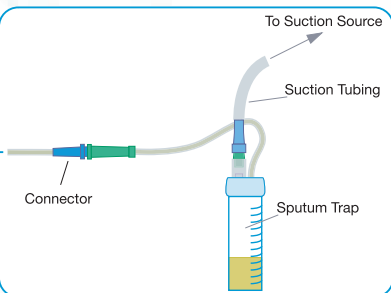
However good the cuff, microaspiration of contaminated material can potentially lead to pulmonary infection. Maintaining tracheostomy hygiene and regular removal of secretions with Blue Line Ultra Suctionaid can help reduce this aspiration.

Syringe Aspiration

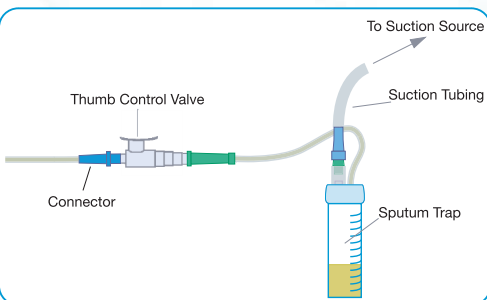


When using continuous or intermittent suctioning, use low level suction up to a maximum of 300mmHg

Continuous Suction



Intermittent Suction



Blue Line Ultra tracheostomy tubes

Ordering information

Blue Line Ultra tube with Profile Soft-Seal cuff			
Sizes (Tube I.D.mm)	Pack size	Product Code	Fenestrated Product Code
6.0	10	100/800/060	100/802/060
7.0	10	100/800/070	100/802/070
7.5	10	100/800/075	100/802/075
8.0	10	100/800/080	100/802/080
8.5	10	100/800/085	100/802/085
9.0	10	100/800/090	100/802/090
10.0	10	100/800/100	100/802/100



Blue Line Ultra tube kit with inner cannulae					
Sizes (Tube I.D.mm)	Pack size	Cuffed Product Code	Uncuffed Product Code	Cuffed Fenestrated Product Code	Uncuffed Fenestrated Product Code
6.0	1 unit	100/810/060	100/811/060	100/812/060	100/813/060
7.0	1 unit	100/810/070	100/811/070	100/812/070	100/813/070
7.5	1 unit	100/810/075	100/811/075	100/812/075	100/813/075
8.0	1 unit	100/810/080	100/811/080	100/812/080	100/813/080
8.5	1 unit	100/810/085	100/811/085	100/812/085	100/813/085
9.0	1 unit	100/810/090	100/811/090	100/812/090	100/813/090
10.0	1 unit	100/810/100	100/811/100	100/812/100	100/813/100



Blue Line Ultra tube change kit with Inner cannulae					
Sizes (Tube I.D.mm)	Pack size	Cuffed Product Code	Uncuffed Product Code	Cuffed Fenestrated Product Code	Uncuffed Fenestrated Product Code
7.0	1 unit	100/820/070	100/821/070	100/822/070	100/823/070
7.5	1 unit	100/820/075	100/821/075	100/822/075	100/823/075
8.0	1 unit	100/820/080	100/821/080	100/822/080	100/823/080
9.0	1 unit	100/820/090	100/821/090	100/822/090	100/823/090



Blue Line Ultra tube Orator speaking valve kit with Inner cannulae				
Sizes (Tube I.D.mm)	Pack size	Uncuffed Product Code	Cuffed Fenestrated Product Code	Uncuffed Fenestrated Product Code
7.0	1 unit	100/831/070	100/832/070	100/833/070
7.5	1 unit	100/831/075	100/832/075	100/833/075
8.0	1 unit	100/831/080	100/832/080	100/833/080
9.0	1 unit	100/831/090	100/832/090	100/833/090



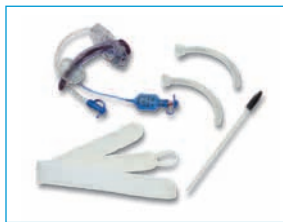
When a fenestrated tube kit is ordered, it will be provided with one fenestrated and one plain inner cannula.

Blue Line Ultra Suctionaid tube with Profile Soft-Seal Cuff

Sizes (Tube I.D.mm)	Pack size	Product Code
6.0	10	100/860/060
7.0	10	100/860/070
7.5	10	100/860/075
8.0	10	100/860/080
8.5	10	100/860/085
9.0	10	100/860/090
10.0	10	100/860/100

**Blue Line Ultra Suctionaid tube with Profile Soft-Seal Cuff and inner cannulae**

Sizes (Tube I.D.mm)	Pack size	Product Code
6.0	1	100/870/060
7.0	1	100/870/070
7.5	1	100/870/075
8.0	1	100/870/080
8.5	1	100/870/085
9.0	1	100/870/090
10.0	1	100/870/100

**Blue Line Ultra Suctionaid tube change kit with Profile Soft-Seal Cuff and inner cannulae**

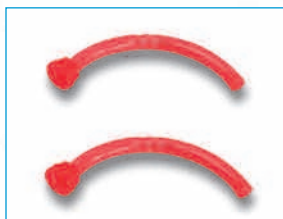
Sizes (Tube I.D.mm)	Pack size	Product Code
6.0	1	100/880/060
7.0	1	100/880/070
7.5	1	100/880/075
8.0	1	100/880/080
8.5	1	100/880/085
9.0	1	100/880/090
10.0	1	100/880/100

**Inner Cannulae****Replacement inner cannulae, plain**

Sizes (Tube I.D.mm)	Pack size	Product Code
6.0	2	100/850/060
7.0	2	100/850/070
7.5	2	100/850/075
8.0	2	100/850/080
8.5	2	100/850/085
9.0	2	100/850/090
10.0	2	100/850/100

**Replacement inner cannulae, fenestrated**

Sizes (Tube I.D.mm)	Pack size	Product Code
6.0	2	100/851/060
7.0	2	100/851/070
7.5	2	100/851/075
8.0	2	100/851/080
8.5	2	100/851/085
9.0	2	100/851/090
10.0	2	100/851/100

**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.

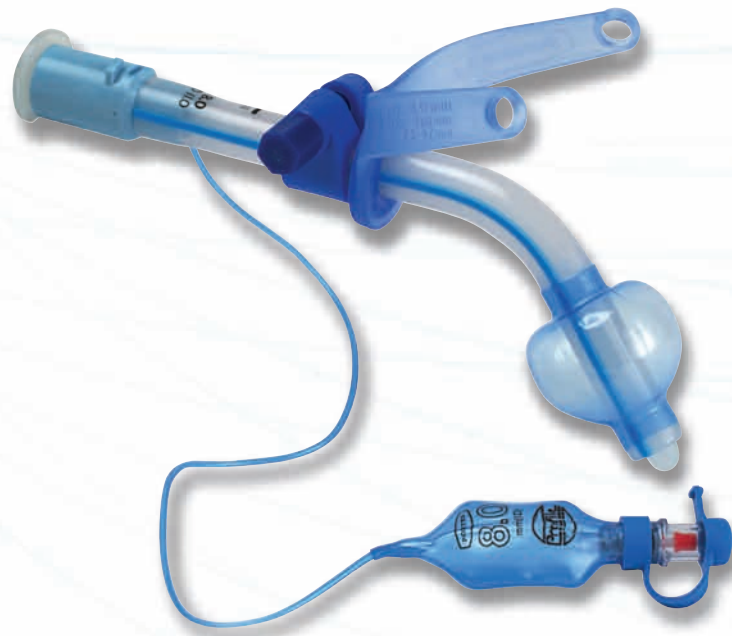
The Blue Line range is also broad and flexible enough to cover the enormous variation in individual patient anatomy by offering customised tubes (see pages 56-62).



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.

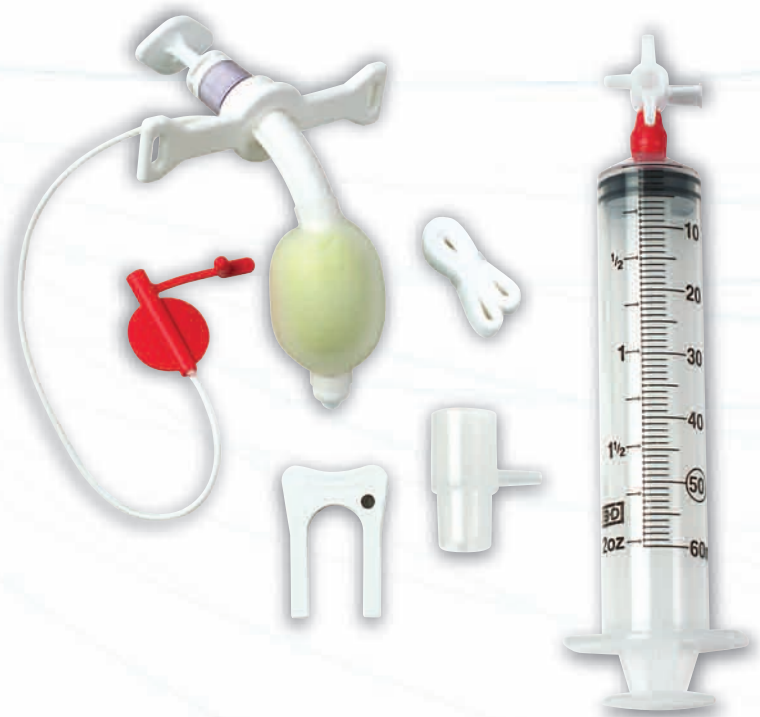
Bivona Adult tracheostomy tubes

Bivona adult tracheostomy tubes provide a range of steam autoclavable silicone products which provide a high level of comfort.

This range provides you with tubes that offer:

- High level of protection from aspiration in Fome-Cuf® products³
- Reduced risk of tracheal dilation
- The flexibility of adjustable neck flanges and flexible reinforced shafts
- A range of cuff designs to suit individual clinician preference

All Bivona tubes are designed to ensure optimal patient comfort and safety.



3: BJA 1990; 65: 433-437

TRACHEOSTOMY TUBES

Bivona tracheostomy tubes incorporate an advanced design to ensure that the needs of your patients are exactly met.

These special features include:

- Fome-Cuf®
 - Auto-expanding foam filled cuff that conforms to the contours of each individual patient's trachea
- TTS™ (Tight to Shaft) cuff
 - Offers the benefits of a cuff with the profile of an uncuffed tube
 - Can be partially or completely inflated to meet varying needs
 - Provides exceptional versatility
- Aire-Cuf® tubes
 - For those who prefer a more traditional design
- Hyperflex™ wire reinforced shafts
 - Flexible to conform to unusual anatomy or pathology
 - Available with either adjustable or fixed neck flange and TTS™ cuff
- CMD™ cuff maintenance device
 - Allows monitoring of cuff volume and simplifies routine cuff maintenance
- SidePort™ and DryPort™ AutoControl™ airway connectors



Bivona Adult tracheostomy tubes

Ordering information

Fome-Cuf® kit with SidePort™ AutoControl™ airway connector and CMD™

Size (I.D.mm)	Sizes (O.D.mm)	Length (mm)	Pack Size	Product Code
5.0	7.3	60	1	850150
6.0	8.7	70	1	850160
7.0	10.0	80	1	850170
8.0	11.0	88	1	850180
9.0	12.3	98	1	850190
9.5	13.3	98	1	850195



Fome-Cuf® StomaSeal™ kit with DryPort™ AutoControl™ airway connector and CMD™

Size (I.D.mm)	Solid Silicone StomaSeal™ (O.D.mm)	Compressed Fome Cuff® (O.D.mm)	Shaft (O.D.mm)	Length (mm)	Pack Size	Product Code
5.0	12.5	13.0	7.3	60	1	851550
6.0	13.5	14.0	8.7	70	1	851560
7.0	15.5	16.0	10.0	80	1	851570
8.0	16.5	18.0	11.0	88	1	851580
9.0	18.5	19.0	12.3	98	1	851590
9.5	18.5	19.0	13.3	98	1	851595



TTS™ tracheostomy tube

Size (I.D.mm)	Sizes (O.D.mm)	Length (mm)	Pack Size	Product Code
5.0	7.3	60	1	670150
6.0	8.7	70	1	670160
6.5	9.4	70	1	670165
7.0	10.0	80	1	670170
7.5	10.4	80	1	670175
8.0	11.0	88	1	670180
8.5	11.8	88	1	670185
9.0	12.3	98	1	670190
9.5	13.3	98	1	670195



Mid-range Aire-Cuf® tracheostomy tube

Size (I.D.mm)	Sizes (O.D.mm)	Length (mm)	Pack Size	Product Code
5.0	7.3	60	1	750150
6.0	8.7	70	1	750160
7.0	10.0	80	1	750170
8.0	11.0	88	1	750180
9.0	12.3	98	1	750190
9.5	13.3	88	1	750195



Uncuffed adult tracheostomy tube

Size (I.D.mm)	Sizes (O.D.mm)	Length (mm)	Pack Size	Product Code
5.0	7.3	60	1	60A150
6.0	8.7	70	1	60A160
7.0	10.0	80	1	60A170
8.0	11.0	88	1	60A180
9.0	12.3	98	1	60A190
9.5	13.3	88	1	60A195



Mid-range Aire-Cuf® adjustable neck flange Hyperflex™ tracheostomy tubes kit

Size (I.D.mm)	Sizes (O.D.mm)	Length (mm)	Pack Size	Product Code
6.0	8.7	110	1	75HA60
7.0	10.0	120	1	75HA70
8.0	11.0	130	1	75HA80
9.0	12.3	140	1	75HA90



TTS™ adjustable neck flange Hyperflex™ tracheostomy tubes kit

Size (I.D.mm)	Sizes (O.D.mm)	Length (mm)	Pack Size	Product Code
6.0	8.7	110	1	67HA60
7.0	10.0	120	1	67HA70
8.0	11.0	130	1	67HA80
9.0	12.3	140	1	67HA90



TTS™ fixed neck flange Hyperflex™ tracheostomy tubes

Size (I.D.mm)	Sizes (O.D.mm)	Length (mm)	Pack Size	Product Code
6.0	8.7	70	1	67FH60
7.0	10.0	80	1	67FH70
8.0	11.0	88	1	67FH80
9.0	12.3	98	1	67FH90



Fome-Cuf® tracheostomy tube with talk attachment

Size (I.D.mm)	Sizes (O.D.mm)	Length (mm)	Pack Size	Product Code
5.0	7.3	60	1	855150
6.0	8.7	70	1	855160
7.0	10.0	80	1	855170
8.0	11.0	88	1	855180
9.0	12.3	98	1	855190
9.5	13.3	98	1	855195



Mid-range Aire-Cuf® tracheostomy tube with talk attachment

Size (I.D.mm)	Sizes (O.D.mm)	Length (mm)	Pack Size	Product Code
5.0	7.3	60	1	755150
6.0	8.7	70	1	755160
7.0	10.0	80	1	755170
8.0	11.0	88	1	755180
9.0	12.3	98	1	755190
9.5	13.3	88	1	755195



Paediatric and neonatal tracheostomy tubes

While many of the tracheostomy tube needs of neonatal or paediatric patients are the same as for adults, this patient group has special additional requirements.

Bivona paediatric and neonatal tracheostomy tubes

The Bivona range of neonatal and paediatric tracheostomy tubes offers a number of features which make them leaders in this field.

The tubes provide high flexibility, to conform to the wide anatomical variation found in these patients, coupled with kink resistance and atraumatic design for maximum patient comfort.

FlexTend Plus™ tubes, with:

- Flexible one piece, kink resistant, wire reinforced silicone shaft
- Independently flexing proximal and distal shafts
- Atraumatic neck flange

Improved tube access for children in the prone position, while minimising the risk of tube occlusion associated with head flexion. Ideal for patients with minimal chin to stoma distances, they reduce excoriation from tracheostomy tube connections.

Both cuffed and uncuffed standard neonatal and paediatric tubes are kink resistant yet soft, flexible and compliant and feature an atraumatic contoured neck flange.

The Cuffless Adjustable Neck Flange Hyperflex™ tube is in effect "instantly customisable" to accommodate unusual anatomy or pathology, assuring these patients a secure airway.



Smiths Medical paediatric and neonatal tracheostomy tubes

Smiths Medical paediatric tubes maximise comfort and safety and are designed to conform to the individual child's trachea for short and long term ventilation. The Smiths Medical infant tracheostomy tube is designed to conform closely to the infant's anatomy to provide maximum comfort.



Paediatric tracheostomy tubes



Neonatal tracheostomy tube

Paediatric tracheostomy tubes

Ordering information

Product	Size (I.D.mm)	Size (O.D.mm)	Length (mm)	PackSize	Product Code
Fome-Cuf® Paediatric tracheostomy tube with Tracheostoma seal	2.5	4.0	38	1	85P025
	3.0	4.7	39	1	85P030
	3.5	5.3	40	1	85P035
	4.0	6.0	41	1	85P040
	4.5	6.7	42	1	85P045
	5.0	7.3	44	1	85P050
	5.5	8.0	46	1	85P055



Product	Size (I.D.mm)	Size (O.D.mm)	Length (mm)	PackSize	Product Code
TTS™ Paediatric tracheostomy tube	2.5	4.0	38	1	67P025
	3.0	4.7	39	1	67P030
	3.5	5.3	40	1	67P035
	4.0	6.0	41	1	67P040
	4.5	6.7	42	1	67P045
	5.0	7.3	44	1	67P050
	5.5	8.0	46	1	67P055



Product	Size (I.D.mm)	Size (O.D.mm)	Length (mm)	PackSize	Product Code
Aire-Cuf® Paediatric tracheostomy tube	2.5	4.0	38	1	65P025
	3.0	4.7	39	1	65P030
	3.5	5.3	40	1	65P035
	4.0	6.0	41	1	65P040
	4.5	6.7	42	1	65P045
	5.0	7.3	44	1	65P050
	5.5	8.0	46	1	65P055



Product	Size (I.D.mm)	Size (O.D.mm)	Length (mm)	PackSize	Product Code
Uncuffed Paediatric tracheostomy tube	2.5	4.0	38	1	60P025
	3.0	4.7	39	1	60P030
	3.5	5.3	40	1	60P035
	4.0	6.0	41	1	60P040
	4.5	6.7	42	1	60P045
	5.0	7.3	44	1	60P050
	5.5	8.0	46	1	60P055



Product	Size (I.D.mm)	Size (O.D.mm)	Length (mm)	PackSize	Product Code
FlexTend Plus™ paediatric tubes	3.5	5.3	40	1	60PFP35
	4.0	6.0	44	1	60PFP40
	4.5	6.7	48	1	60PFP45
	5.0	7.3	50	1	60PFP50
	5.5	8.0	52	1	60PFP55



Product	Size (I.D.mm)	Size (O.D.mm)	Length (mm)	PackSize	Product Code
FlexTend Plus™ standard paediatric tubes	2.5	4.0	38	1	60PFS25
	3.0	4.7	39	1	60PFS30
	3.5	5.3	40	1	60PFS35
	4.0	6.0	41	1	60PFS40
	4.5	6.7	42	1	60PFS45
	5.0	7.3	44	1	60PFS50
	5.5	8.0	46	1	60PFS55



Product	Size (I.D.mm)	Size (O.D.mm)	Length (mm)	PackSize	Product Code
Uncuffed adjustable neck flange Hyperflex™ tubes	2.5	4.0	55	1	60HA25
	3.0	4.7	60	1	60HA30
	3.5	5.3	65	1	60HA35
	4.0	6.0	70	1	60HA40
	4.5	6.7	75	1	60HA45
	5.0	7.3	80	1	60HA50
	5.5	8.0	85	1	60HA55



Product	Size (I.D.mm)	Size (O.D.mm)	Length (mm)	PackSize	Product Code
Smiths Medical Tracheostomy Tube, Paediatric with clear angled 15mm connector	2.5	4.5	30	1	555025
	3.0	5.2	36	1	555030
	3.5	5.8	40	1	555035
	4.0	6.5	44	1	555040
	4.5	7.1	48	1	555045
	5.0	7.7	50	1	555050
	5.5	8.3	52	1	555055



All Bivona products are packaged individually sterile with obturator, twill tape ties and 15mm disconnect wedge.

Adjustable neck flange tracheostomy tubes (60HA codes) are intended for temporary use until the proper length fixed neck flange tube can be obtained. **Not for home care use.**

Neonatal tracheostomy tubes

Ordering information

Product	Size (I.D.mm)	Size (O.D.mm)	Length (mm)	PackSize	Product Code
Fome-Cuf® Neonatal tracheostomy tube with Tracheostoma seal	2.5	4.0	30	1	85N025
	3.0	4.7	32	1	85N030
	3.5	5.3	34	1	85N035
	4.0	6.0	36	1	85N040



Product	Size (I.D.mm)	Size (O.D.mm)	Length (mm)	PackSize	Product Code
TTS™ Neonatal tracheostomy tube	2.5	4.0	30	1	67N025
	3.0	4.7	32	1	67N030
	3.5	5.3	34	1	67N035
	4.0	6.0	36	1	67N040



Product	Size (I.D.mm)	Size (O.D.mm)	Length (mm)	PackSize	Product Code
Aire-Cuf® Neonatal tracheostomy tube	2.5	4.0	30	1	65N025
	3.0	4.7	32	1	65N030
	3.5	5.3	34	1	65N035
	4.0	6.0	36	1	65N040



Product	Size (I.D.mm)	Size (O.D.mm)	Length (mm)	PackSize	Product Code
Uncuffed Neonatal tracheostomy tubes	2.5	4.0	30	1	60N025
	3.0	4.7	32	1	60N030
	3.5	5.3	34	1	60N035
	4.5	6.0	36	1	60N045



Product	Size (I.D.mm)	Size (O.D.mm)	Length (mm)	PackSize	Product Code
FlexTend Plus™ neonatal tubes	2.5	4.0	30	1	60NFP25
	3.0	4.7	32	1	60NFP30
	3.5	5.3	34	1	60NFP35
	4.0	6.0	36	1	60NFP40



Product	Size (I.D.mm)	Size (O.D.mm)	PackSize	Product Code
Smiths Medical Tracheostomy Tube, Infant G.O.S design without 15mm connector	3.0	4.5	10	100/501/450



All Bivona products packaged individually sterile with obturator, twill tape ties and 15mm disconnect wedge.

Customised tracheostomy tubes

On occasions your patients may have special requirements which cannot be met from our comprehensive range of tracheostomy tubes.

For these occasions, Smiths Medical can offer customised tracheostomy tubes based on either the Blue Line or Bivona ranges.

The Bivona customised tube service allows you to select the tube shaft style, curvature, length, internal and external diameter, cuff design, cuff position and neck flange that best meets your patient's needs.

Templates for tube customisation may be found at the back of this supplement pgs 56-62.

For further information please contact:

International Customer Services - Tel: +44 (0) 1303 260 551 Fax: +44 (0) 1303 236 899

UK Customer Services - Tel: 0870 601 6789 Fax: 01303 265 560

INTERNATIONAL CUSTOMIZED - CUFFLESS TRACHEOSTOMY TUBE TEMPLATE

☐ 3-4 WEEKS (STERILE)

☐ EXPRESS SERVICE (NON STERILE)

NECK FLANGE TYPE:

FIXED NECK FLANGE

AVAILABLE SIZES: 2.5 - 9.5mm

☐ WITH ISO CONNECTOR OR

☐ WITHOUT ISO CONNECTOR

FIXED NECK FLANGE

AVAILABLE SIZES: 2.5 - 9.5mm

☐ WITH ISO CONNECTOR OR

☐ WITHOUT ISO CONNECTOR

FIXED NECK FLANGE

AVAILABLE SIZES: 2.5 - 9.5mm

☐ WITH ISO CONNECTOR OR

☐ WITHOUT ISO CONNECTOR

FIXED NECK FLANGE

AVAILABLE SIZES: 2.5 - 9.5mm

☐ WITHOUT ISO CONNECTOR

SHAFT: I.D. _____ mm

(OR) O.D. _____ mm

SHAFT STYLE:

☐ STANDARD SILICONE

☐ HYPERFLEX™

☐ FENESTRATION

(ADULT SIZES, STANDARD SILICONE ONLY)

DISTANCE FROM NECK FLANGE _____ mm

SHAFT LENGTH AT CENTRE LINE _____ MM

3mm MIN. DISTANCE TO OPTIONAL FENESTRATION

DISTRIBUTOR:

DISTRIBUTOR CONTACT NAME:

TEMPLATE REF. NO.:

DATE:

BIVONA USE ONLY

BIVONA ENGRG. APPROVAL:

REORDER:

BIVONA

TMPLATE1A-INTL REV. 0

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

NOTE: PLEASE PRINT CLEARLY. BIVONA STAFF CANNOT MAKE ANY ALTERATIONS TO THE COMPLETED TEMPLATE.

3

Speciality products

Tracheostomy is only one of the procedures which may be required to provide tracheal access in Theatre or Intensive Care. Smiths Medical also cater for those patients who require minitracheotomy, emergency cricothyrotomy or laryngectomy with a range of products from initial incision to long term voice restoration.

TRACHEOSTOMY TUBES

31

32

Mini-Trach II minitracheotomy kits

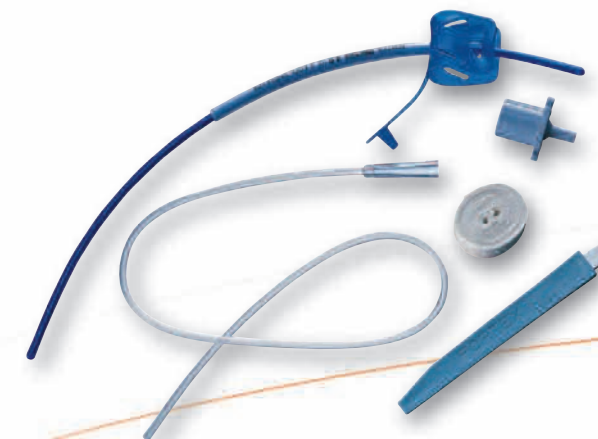
After surgery, infection or injury, sputum retention can be a real problem which, if not effectively treated can lead to significant morbidity and even death. When there is the risk that natural sputum removal by coughing, with or without physiotherapy, will not be adequate, prophylactic minitracheotomy 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

SPECIALITY PRODUCTS

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



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 McGuigan, K McManus, "Sputum Retention after Lung Operation: Randomised trial shows superiority of prophylactic minitracheostomy in high-risk patients" Ann Thoracic Surg 2002; 74: 196-203
 7: P Bonde, K McManus, M McManespie, J MuGuigan "Lung Surgery: identifying the subgroup at risk for sputum retention" European Journal of Cardio-Thoracic Surgery 22(2002) 18-22

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.



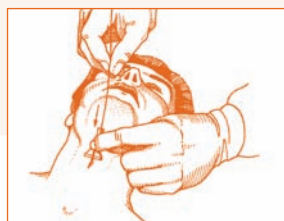
2. The skin is cleansed and the position of the cricothyroid membrane located by palpation and marked.



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



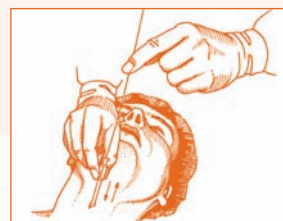
4. The 16G bevelled needle is fitted to the syringe. With the trachea immobilised the bevelled needle is inserted vertically (with the opening of the needle facing caudally) through the cricothyroid membrane. Correct placement is confirmed by aspiration of air.



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.



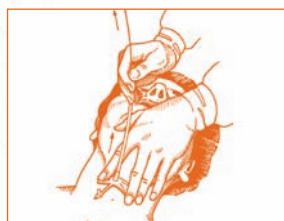
6. The bevelled needle is removed carefully while holding the guidewire to ensure that the guidewire is not moved out of position.



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



100/461

Nu-Trake®, Pedia-Trake™

For emergency airway restoration

Nu-Trake®: adult cricothyrotomy device

A complete cricothyrotomy system for emergency airway access, Nu-Trake®:

- Rapidly establishes up to 7.2mm airway
- Allows immediate ventilation through integral 15mm connector
- Allows introduction of a suction catheter through the airway
- Provides a user-friendly system



Pedia-Trake™: emergency airway system for paediatric applications

When you need to establish an emergency airway in paediatric patients Pedia-Trake™ gives you:

- Fast restoration of air flow
- Minimal bleeding
- Simplicity in use



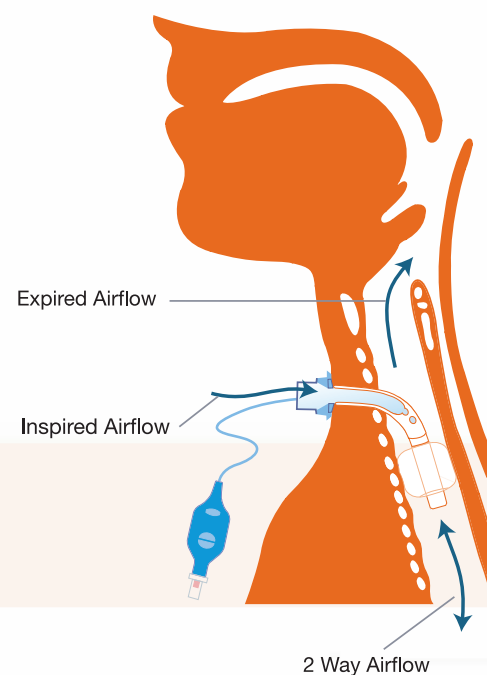
Ordering information

Nu-Trake® cricothyrotomy device		
Description	Pack Size	Product Code
Adult	1 unit	B10100

Pedia-Trake™ emergency airway system		
Description	Pack Size	Product Code
Paediatric	1 unit	B20100

Orator Speaking Valve

Orator allows the patient with a tracheostomy to communicate, by ensuring that expelled air is re-directed to the larynx.

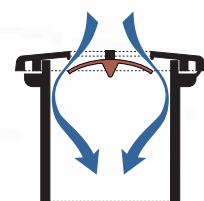


Orator provides:

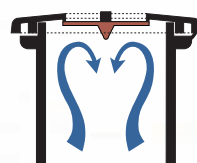
- A simple but effective one-way valve
- Quiet operation
- Attachable to supplementary oxygen supply
- Compatibility with standard ISO 15mm connectors
- Flip-top cap for easy cleaning
- Cosmetic cap and oxygen supply cap

Which offer your patients:

- Comfortable and effective speech
- Easier communication between users and listeners
- Unobtrusive and cosmetically acceptable design
- Simplicity in use



Inspired airflow directed to lungs



Expired airflow directed to larynx



Ordering information

Orator Speaking Valve		
Description	Pack Size	Product Code
With cosmetic cap & oxygen supply cap	2	Code: 100/550/000

Voice restoration

OptiVox Plus Electrolarynx kit

The Optivox Electrolarynx is a complete artificial speech aid kit including everything needed for immediate post laryngectomy voice production.



- Tonal purity and clarity without harsh background noise
- Functions as either a neck or intra-oral device
- Simple pitch adjustment

Ordering information

OptiVox Plus Electrolarynx kit		
Product	Pack Size	Product Code
Electrolarynx Kit	1	OPTIVEXP
Replacement Oral tubes		
Standard silicone	3	OPTISOFT
Plastic	5	OPTIORAL

Ultra Low™ and Duckbill voice prostheses

- Large variety of sizes to fit varying patient requirements
- Rounded tip and thin retention collar for easy insertion
- Auxiliary airflow port available



Ordering information

Length	Ultra Low™ Resistance Product codes		Duckbill Product codes	
	16 Fr	20 Fr	16 Fr	20 Fr
1.4	B614UO	B214UO	BRVO614	BRVO214
1.6	B616UO	B216UO	BRVO616	BRVO216
1.8	B618UO	B218UO	BRVO618	BRVO218
2.0	B620UO	B220UO	BRVO620	-
2.2	B622UO	B222UO	BRVO622	BRVO222
2.6	B626UO	B226UO	BRVO626	BRVO226
3.0	B630UO	B230UO	BRVO630	BRVO230
3.3	-	-	BRVO633	BRVO233

All products supplied individually non-sterile with insertion device

Voice restoration

Bivona-Colorado™ voice prostheses

Available in either Duckbill or Ultra Low™ resistance, in a wide range of sizes.

Ordering information

Button O.D.(mm)	Valve Stem Length (mm)	Duckbill		Ultra Low™ Resistance	
		Product codes		Product codes	
		16 Fr	20 Fr	16 Fr	20 Fr
15.0	15.0	B51615	B52015	B5U615	B5U215
	20.0	B51620	B52020	B5U620	B5U220
	25.0	B51625	B52025	B5U625	B5U225
	30.0	B51630	B52030	B5U630	B5U230
17.5	15.0	B71615	B72015	B7U615	B7U215
	20.0	B71620	B71020	B7U620	B7U220
	25.0	B71625	B72025	B7U625	B7U225
	30.0	B71630	B72030	B7U630	B7U230
20.0	15.0	B21615	B22015	B2U615	B2U215
	20.0	B21620	B22020	B2U620	B2U220
	25.0	B21625	B22025	B2U625	B2U225
	30.0	B21630	B22030	B2U630	B2U230

All products supplied individually, non-sterile

Dummy Prosthesis Depth Gauge

For rapid, accurate determination of required Bivona prosthesis length:

- Easy to read markings
- Thin retention collar for easy insertion
- Maintains puncture site
- Radio-opaque

Ordering information

Product Code	16Fr BDDG16	20Fr BDDG20
--------------	-------------	-------------

Products supplied individually, non-sterile

Dummy Prosthesis

A stent to maintain the puncture site.

- Prevents puncture from closing
- Radio-opaque

Ordering information

Dummy prostheses		
Length	Product codes	
	16 Fr	20 Fr
2.2	DRC622	DRC222
2.6	DRC626	DRC226
3.0	DRC630	DRC230
3.3	DRC633	DRC233
3.6	DRC636	DRC236
4.0	DRC640	DRC240
4.3	DRC643	DRC243

All products supplied individually, non-sterile

Voice restoration

Bivona-Colorado™ accessories

Available in either duckbill or ultra low resistance, in a wide range of sizes.

Ordering information

Bivona-Colorado™ accessories				
Description	Button O.D. (mm)	(12 Fr)	Product codes (16 Fr)	(20 Fr)
Template	15.0		BTMP15	
	17.5		BTMP17	
	20.0		BTMP20	
Button	15.0		BTNO15	
	17.5		BTNO17	
	20.0		BTNO20	
Dummy prosthesis	15.0	B1512S	B1516S	B1520S
	17.5	B1712S	B1716S	B1720S
	20.0	B2012S	B2016S	B2020S
Sizing device			BCSD16	BCSD20

All products supplied individually, non-sterile

Tracheostoma Valve

- Special fitting kit allows evaluation of adaptability, comfort and size for the individual patient

Ordering information

Tracheostoma Valve				
Product	Product codes			
Professional fitting kit	BPFKT4			
	Ultra light	Light	Medium	Firm
Patient kit	BPATUL	BPATLL	BPATMM	BPATFF
Valve only	BVNLYU	BVNLYL	BVNLYM	BVNLYF

Fitting kit contains 4 valve assemblies, 4 valve housings, 4 packages of adhesive discs, 1 bottle of silicone adhesive and an instruction manual. Patient kit contains one valve assembly, 2 valve housings, 2 packages of adhesive discs, 1 bottle of silicone adhesive and an instruction manual

Tracheostoma Valve II

- Reliable performance
- Valve performance not affected by temperature or humidity
- Integral cough band reduces valve blowout

Ordering information

Tracheostoma Valve II		
Product	Product codes	
	Complete kit	Valve only
Tracheostoma Valve II	BTSVK2	BTSVO2
Tracheostoma Valve II Large	BTSVKL	BTSVOL

Complete kits contain 1 assembled valve, a set of 4 interchangeable springs, 2 valve housings, spare parts and adhesive materials. Valve only contains 1 assembled valve, 4 interchangeable springs and 1 spare parts kit

Voice restoration

Tracheostoma Vent

Ordering information

Tracheostoma Vent					
Size	(I.D./O.D. mm)	18(mm)	Product Code		
			27(mm)	36(mm)	55(mm)
8	(9.5/12.0)	BV0818	BV0827	BV0836	BV0855
9	(10.5/13.5)	BV0918	BV0927	BV0936	BV0955
10	(12.0/15.0)	BV1018	BV1027	BV1036	BV1055
12	(13.5/17.0)	BV1218	BV1227	BV1236	BV1255
14	(16.5/20.0)	BV1418	BV1427	BV1436	BV1455
16	(20.5/24.0)	BV1618	BV1627	BV1636	BV1655
Kit: Includes one each of all Size 8, 9, 10 and 12 codes					BV0KIT

All products supplied individually, non-sterile



Bivona HME System for the Laryngectomee

- Replaces the functions of the nose and upper airway bypassed by laryngectomy
- Provides resistance, filtration, heat and humidity to the inspired air
- Enhances pulmonary function



HME101

Ordering information

Bivona HME System		
Description	Pack size	Product code
HME Cartridge	10	HME101
Self-Adhesive Housing	10	SAH101

Special Tubes

Sleep Apnea Tracheostomy Tube

- Non-wetting silicone surface facilitates suctioning and resists encrustation
- Easily capped and concealed low-profile design
- Steam autoclavable



Ordering information

Sleep Apnea Tracheostomy Tube				
I.D. (mm)	O.D. (mm)	Length (mm)	Pack size	Product Code
6.0	9.0	68	1	SAT605
6.5	10.0	73	1	SAT656
7.5	11.0	79	1	SAT757

Packed non-sterile with twill tape tie and (2) plugs

Laryngectomy Tube

- Longer shaft lengths
- Wider neck flanges
- Soft and compliant silicone design for patient comfort



Ordering information

Laryngectomy Tube				
I.D. (mm)	O.D. (mm)	Shaft Length (mm)	Pack size	Product Code
9.5	12.0	85	1	BOSL1L
9.5	12.0	55	1	BOSL1S
11.0	14.0	105	1	BOSL3L
11.0	14.0	55	1	BOSL3S
13.0	16.0	85	1	BOSL5L
13.0	16.0	55	1	BOSL5S

Packed non-sterile with twill tape tie

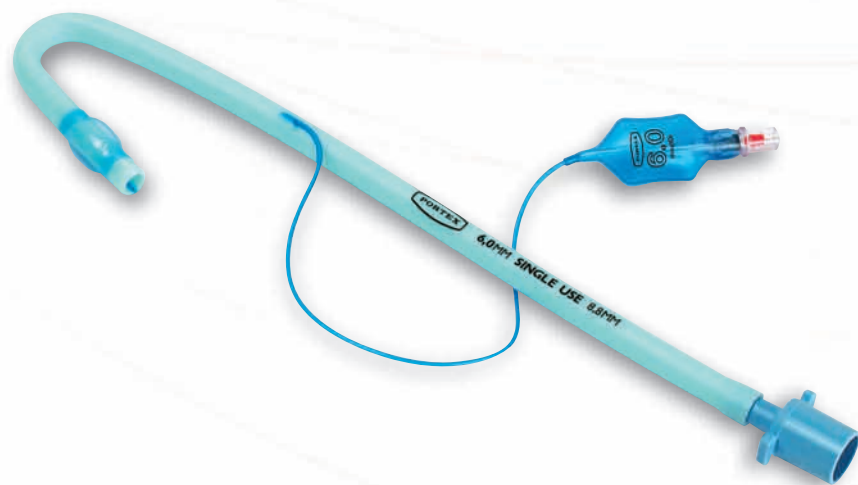
Special tubes

'Montandon' Tracheostomy Tube

- Extended tube design locates breathing system away from operative field for easier access
- Non-toxic, implant tested, kink resistant, soft ivory PVC protects delicate mucosal tissues
- Small volume traditional cuff on adult sizes ideal for intubation through delicate stomas while maintaining good short term seal
- Sterile and single use to avoid the risk of cross infection

Ordering information

Montandon tube			
I.D. (mm)	O.D. (mm)	Pack size	Product Code
6.0	8.8	2	100/509/060
7.0	10.2	2	100/509/070
8.0	11.6	2	100/509/080
9.0	13.0	2	100/509/090
10.0	14.2	2	100/509/100



SPECIALITY PRODUCTS

4

Associated products

As the producers of one of the most advanced and comprehensive range of tracheostomy products available, Smiths Medical are aware that care of these patients is not completed by intubation. The Smiths Medical range of associated products are all designed and manufactured to the same exacting standards to ensure total compatibility.

For full details of all these products please see the General Anaesthesia Supplement or main Airway Catalogue.

Stericath

A closed ventilation suction system which allows simple and safe maintenance of pressures during suctioning of the critically ill patient, while also reducing the risk of cross contamination. Available in single and dual lumen.

- Single lumen
 - The whole of the lumen diameter is available as a suction pathway. Ideal if an irrigation channel is not required. Available with catheter mount in pack.
- Dual lumen
 - Ideal if saline installation is indicated. The integral irrigation line delivers fluid from the tip for effective bronchial lavage.



Ordering information

Description	Sizes (F)/O.D. (mm)	Length (mm)	Pack size	Product Code
Single Lumen	14F/4.7	300	20	6109-14
Single lumen with catheter mount	14F/4.7	300	20	6109-14FE
Dual Lumen	14F/4.7	300	20	6111-14

Suction Catheters

The comprehensive range of endobronchial suction catheters with Terminal or Terminal and Lateral Eye offer quality, safety and economy in response to all suctioning requirements.



Ordering information

Sizes (F)	O.D. (mm)	Length (mm)	Pack size	Suction Catheter Terminal eye	Suction Catheter Terminal eye & 2 Lateral eyes
4	1.3	380	50	100/360/040	
5	1.7	380	50	100/360/050	
6	2.0	460	50	100/360/060	100/361/060
8	2.7	460	50	100/360/080	100/361/080
10	3.3	460	50	100/360/100	100/361/100
12	4.0	610	50	100/360/120	100/361/120
14	4.7	610	50	100/360/140	100/361/140
16	5.3	610	50	100/360/160	100/361/160
18	6.0	610	50	100/360/180	100/361/180
20	6.7	610	50	100/360/200	100/361/200

Thermovent T

A 15mm female connector, single use Heat & Moisture Exchanger (HME) which captures heat and moisture on expiration and returns it to the patient on inspiration. It is suitable for spontaneously breathing patients with a tracheostomy tube.



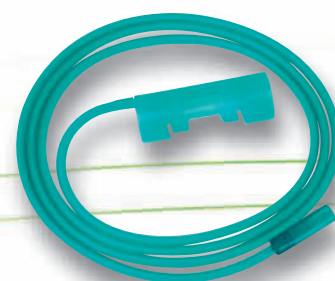
- Low-profile design ensures maximum comfort and minimal protrusion
- High performance, double paper element reduces the risk of blockage with minimal resistance to flow
- Lightweight. Minimises the drag on tracheostomy tube
- Convenient oxygen therapy - can easily accommodate Thermovent O₂
- Sterile and single use. Avoids risk of cross infection

Ordering information

Description	Pack Size	Product Code
Thermovent T	50	100/570/015

Thermovent O₂ Delivery Aid

A specifically designed oxygen delivery aid for Thermovent T, provides the easiest and most comfortable way of supplying oxygen enriched humidified air.



Ordering information

Description	Pack Size	Product Code
Thermovent O ₂	10	100/575/010

Thermovent HEPA

- Low deadspace bacterial and viral filter with HME properties offering optimum hydrophobic filtration performance
- Hydrophobic filter medium provides protection against liquid and airborne contamination
- Even-pleated filter medium allows maximum filtration efficiency with minimal resistance to flow
- Gas sampling port, centrally located to ensure accuracy of readings



Ordering information

Description	Pack Size	Product Code
Thermovent HEPA	50	100/585/000

Thermavent 600 and Thermavent 1200

- High efficiency HME paper elements recover approximately 75% of energy and moisture
- Low resistance to flow minimises pressure build and reduces the work of breathing
- Small dead space
- Lightweight



Ordering information

Description	Pack Size	Product Code
Thermavent 600	10	100/580/015
Thermavent 1200	10	100/582/000

Catheter mounts

- Single use lightweight design minimises the drag upon anaesthetic breathing equipment
- Transparent material allows identification of blockages or fluid accumulation within the device
- Low deadspace, minimises re-breathing
- Non-conductive
- Available with Double Swivel Connector and Gas Sampling Elbow



100/590

Ordering information

Description	Pack Size	Product Code
Without Double Swivel Connector:	20	100/590/000
With Double Swivel Connector:	10	100/594/000
Plain	50	2837
With Gas Sampling Elbow	50	2838

5

Accessories

Smiths Medical provide a number of accessories to further enhance the ease of use of their tubes for both clinician and patient.

Tracheostomy tube holder - Velcro™ fastening

- Velcro tabs for quick, easy and secure fastening
- Elastic section combines with Velcro fastening to ensure a comfortable and reliable fit
- Soft absorbent lining for minimum chafing
- Wide band to prevent twisting and constriction

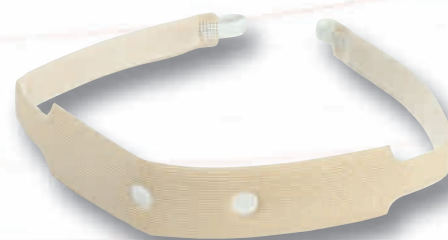


Ordering information

Description	Pack Size	Product Code
Width 25mm	10	100/503/200

Tracheostomy tube holder - Foam

- Strong, soft, lightweight, fabric covered foam increases patient comfort
- Available in adult, paediatric and infant sizes



Ordering information

Description	Pack Size	Product Code
Adult	100	520000
Paediatric	100	520001
Infant	100	520002

Cuff Inflator Pressure Gauge

- Controlled initial cuff inflation
- Intermittent monitoring with instant visual confirmation of intra-cuff pressure

Ordering information

Description	Pack Size	Product Code
Cuff Inflator & Pressure with Gauge Connecting Tube	1	100/568/000*
Separate Connecting Tubes	10	100/569/000

*Product 100/568/000 contains latex

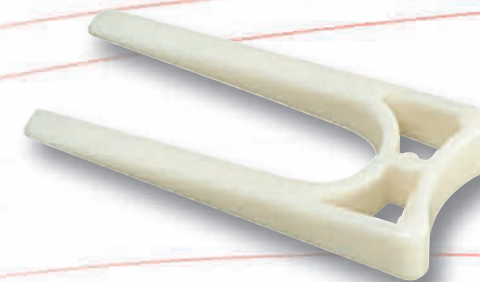


Tracheostomy tube Disconnection Wedge

- Facilitates disconnection of circuit from tracheostomy tube

Ordering information

Description	Pack Size	Product Code
Tube Disconnection Wedge	20	100/555/100



Brushes

- For cleaning re-usable inner cannulae

Ordering information

Description	Pack Size	Product Code
Brushes	40	100/855/000

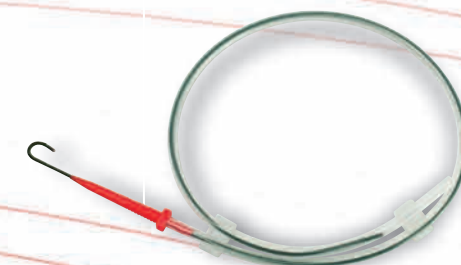


Guidewires

- Spare guidewires for use with either the Dilational or Griggs technique percutaneous tracheostomy kits

Ordering information

Description	Pack Size	Product Code
Spare guidewires	5	100/544/000



Tracheostomy mask and connectors

Ordering information

Description	Pack Size	Product Code
Tracheostomy mask, vinyl, adult.	50	2400
Venturi Aerosol tracheostomy mask, adult, 24-50%	25	2640
Tracheostomy Y-assembly, drainage bag	50	1573
Tracheostomy T-piece, 15mm I.D./22mm O.D.	50	1575
Tracheostomy elbow, 15mm I.D./22mm O.D., with cap	50	1577



2400

Stoma button

- Prevents narrowing of the stoma during intermittent use of tracheostomy or laryngectomy tubes.

Ordering information

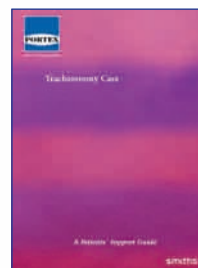
Description	Size O.D. (mm)	Pack Size	Product Code
Size 1	8	10	109/530/010
Size 2	10	10	109/530/020
Size 3	12	10	109/530/030
Size 4	14	10	109/530/040



6 Educational Materials

Smiths Medical also produces a range of support materials for all those involved in the care of the tracheostomy patient, as well as for the patient.

Educational literature



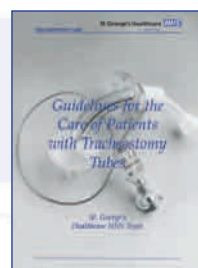
Tracheostomy Patient Support Guide - Booklet to help patients and relatives to understand physical effects and implications of having a tracheostomy.

Available from your local Smiths Medical distributor
or Smiths Medical on **+44 (0) 1303 260551**



Tracheostomy Educational Support Guide - Booklet to help Nurses and ward staff understand what is a tracheostomy, types of tracheostomy tubes and basics of tracheostomy care.

Available from your local Smiths Medical distributor
or Smiths Medical on **+44 (0) 1303 260551**



'Guidelines for the care of patients with tracheostomy tubes'. Second edition of tracheostomy care policy as practiced at St Georges Hospital in London, UK. The aim of the policy is to set out standards necessary to provide the basis of high quality patient care.

Available from your local Smiths Medical distributor
or Smiths Medical on **+44 (0) 1303 260551**



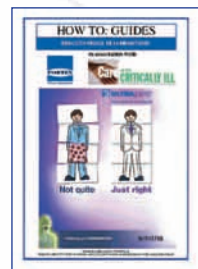
'How To Guide: Tracheostomy tube management. Produced in association with Care of the Critically Ill, these guides are specifically aimed at those working in intensive care. This guide looks at the management of patients with tracheostomy tubes.

Available from your local Smiths Medical distributor
or Smiths Medical on **+44 (0) 1303 260551**



How To Guide: 'Pitfalls in tracheostomy care'. Produced in association with Care of the Critically Ill, these guides are specifically aimed at those working in intensive care. This guide looks at the management of complications occurring in patients with tracheostomy tubes.

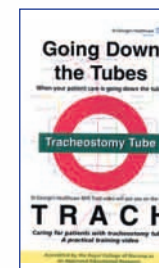
Available from your local Smiths Medical distributor
or Smiths Medical on **+44 (0) 1303 260551**



How To Guide: 'Percutaneous Tracheostomy'. Produced in association with Care of the Critically Ill, these guides are specifically aimed at those working in intensive care. This guide looks at the advantages of using ULTRAPerc for percutaneous tracheostomy.

Available from your local Smiths Medical distributor
or Smiths Medical on **+44 (0) 1303 260551**

Educational Videos



"Going Down The Tubes" is a practical training video for healthcare practitioners who undertake to care for patients with tracheostomies.

Available from St Georges Medical Television.

Telephone: **+44 (0) 208-725-2701**



Single Dilator Percutaneous Technique Video

Educational video demonstrating the technique for inserting Blue Line Ultra tracheostomy tubes using the new 'ULTRAPerc' percutaneous dilational tracheostomy kits from Smiths Medical.

Available from your Smiths Medical distributor
or Smiths Medical on **+44 (0) 1303 260551**



Griggs Percutaneous Technique Video

Educational video demonstrating the technique for inserting Blue Line tracheostomy tubes using the Griggs forceps percutaneous tracheostomy kits from Smiths Medical.

Available from your Smiths Medical distributor
or Smiths Medical on **+44 (0) 1303 260551**



Fome-Cuf® Video

A short in-service training tape for teaching the function and applications of the Fome-Cuf® tracheostomy systems.

Available from your Smiths Medical distributor
or Smiths Medical on **+44 (0) 1303 260551**



Nu-Trake™/Pedia-Trake™ Cricothyrotomy Video

Educational video demonstrating the techniques for utilising the Nu-Trake™ and Pedia-Trake™ Cricothyrotomy devices.

Available from your Smiths Medical distributor
or Smiths Medical on **+44 (0) 1303 260551**

Demonstration Heads

The Smiths Medical Tracheostomy Head is a multifunctional mannequin, which presents an anatomical challenge to the user, but also offers a realistic feel particularly when using the Smiths Medical Percutaneous Dilatational Tracheostomy Products. The unique design provides an ideal simulation mannequin for:

- Practicing the Percutaneous Tracheostomy procedure using the ULTRAperc Single or Serial Dilator methods or the Griggs Dilating Forceps method
- Patient demonstration and education of tracheostomy tube change, care and management
- Support during nurse training and education
- Practicing the Cricothyroidotomy procedure using Mini-Trach II Seldinger kit

Up to 16 procedures can be performed on a single trachea, which is replaceable along with the highly realistic skin.



Ordering information

Description	Pack Size	Product Code
Tracheotomy Trainer & Case	1	TOT100*
Trauma Kit (2 Tracheas & 4 Skins)	1	TOT101
Replacement Thyroid	1	TOT102
Replacement Carina with balloons	1	TOT103*
Black Carry Case	1	TOT104

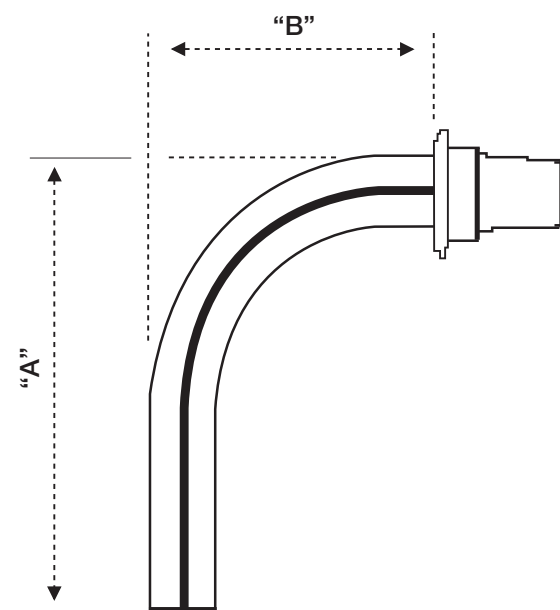
*Product codes TOT100 and TOT103 contains latex.

7 Customisation Templates

Smiths Medical endeavour to produce a product range to suit the widest variation among patients. For those patients whose needs cannot be met by our normal range, these templates will enable us to provide you with a product made to their precise requirements and your exact specification.

To order, complete the details on the required template and fax to the appropriate number.

Smiths Medical Special Tracheostomy Tube Guides Standard Product Dimensions



A = Measurement "bend to tip"
B = Measurement "bend to flange"

If you require a longer tube, from bend to tip and/or bend to flange; add the additional length in Millimetres to those for a tube with the same I.D. as described below.

If you require a shorter tube, from bend to tip and/or bend to flange; subtract the additional length in Millimetres to those for a tube with the same I.D. as described below.

TUBE SIZE (i.d.)	STANDARD PRODUCT "A" Dimension (Bend to Tip)	STANDARD PRODUCT "B" Dimension (Bend to Flange)
3.0mm	29.0mm	17.0mm
3.5mm	31.0mm	19.0mm
4.0mm	33.0mm	22.0mm
4.5mm	35.0mm	24.0mm
5.0mm	37.0mm	26.0mm
6.0mm	43.0mm	28.0mm
7.0mm	51.0mm	33.0mm
7.5mm	55.0mm	36.0mm
8.0mm	59.0mm	39.0mm
9.0mm	67.0mm	44.0mm
10.0mm	76.0mm	50.0mm

Smiths Medical Special Tracheostomy Tube Request

PLEASE COMPLETE THE FOLLOWING IN **BLOCK CAPITALS**

Requested By: _____ Prescribing Clinician

For: _____ Patient

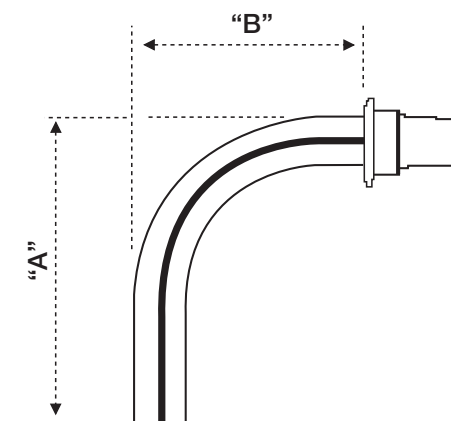
Ward/Unit: _____

Hospital Address: _____

Post Code: _____

Telephone: _____ Ext: _____ Fax: _____

Order Number: _____ Purchasing Contact: _____



See reference sheet
for measurements of
standard products

Product Type: _____
(Cuffed or uncuffed)

Size: (I.D.): _____

"A" Dimension: _____ mm

"B" Dimension: _____ mm

Flange Type: _____
(Plain or 15mm Termination)

Quantity Required: _____

A = Measurement "bend to tip"
B = Measurement "bend to flange"

Design Approved _____ / /
(Signature of prescribing clinician) Date

Special Requirements

International customers fax to +44 (0) 1303 236899
UK customers fax to +44 (0) 1303 265560

Customisation Templates

Patient's Name: _____ Patient's Date of Birth: _____
Hospital: _____ Dept: _____
Consultant: _____ Tel No: _____
Nurse/Coordinator: _____ Fax No: _____
Hospital Purchase Order No: _____ Smiths Medical Internal Order No: _____

INTERNATIONAL CUSTOMIZED ADJUSTABLE NECK FLANGE HYPERFLEX™

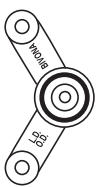
SELECT TYPE SERVICE

☐ 3-4 WEEKS (STERILE)

☐ EXPRESS SERVICE (NON STERILE)

NECK FLANGE TYPE:

A



ADJUSTABLE NECK FLANGE
AVAILABLE SIZES:
2.5 - 9.5mm

B



ADJUSTABLE NECK FLANGE
AVAILABLE SIZES:
5.0 - 9.5mm

C

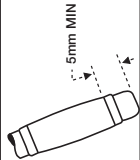


ADJUSTABLE NECK FLANGE
AVAILABLE SIZES:
5.0 - 9.5mm

CUFF TYPE(S):

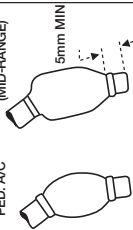
☐ UNCUFFED

☐ TTS™ TIGHT TO SHAFT



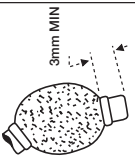
5mm MIN

☐ AIRE-CUF®
ADULT A/C
(MID-RANGE)
PED. A/C

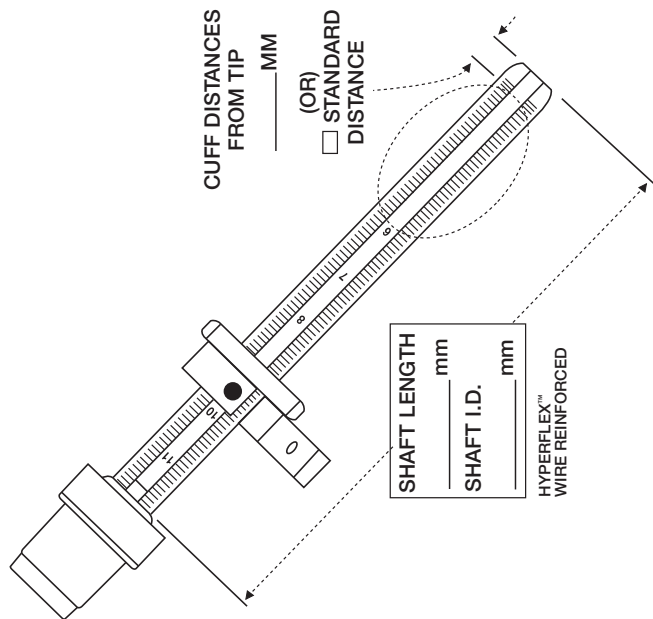


5mm MIN

☐ FOME-CUF®



3mm MIN



CUFF DISTANCES FROM TIP _____ MM
(OR)
☐ STANDARD DISTANCE

SHAFT LENGTH _____ mm

SHAFT I.D. _____ mm

HYPERLEX™ WIRE REINFORCED

DISTRIBUTOR:

DISTRIBUTOR CONTACT NAME:

TEMPLATE REF. NO. :

BIVONA USE ONLY

BIVONA ENGRG. APPROVAL:

REORDER:

DATE:

TMP.LATE2-INTL REV. 0

SR.03A

(NOT INTENDED FOR LONG TERM USE: FOR TEMPORARY USE ONLY.)

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

NOTE: PLEASE PRINT CLEARLY. BIVONA STAFF CANNOT MAKE ANY ALTERATIONS TO THE COMPLETED TEMPLATE.

Customisation Templates

Patient's Name: _____ Patient's Date of Birth: _____
Hospital: _____ Dept: _____
Consultant: _____ Tel No: _____
Nurse/Coordinator: _____ Fax No: _____
Hospital Purchase Order No: _____ Smiths Medical Internal Order No: _____

INTERNATIONAL CUSTOMIZED - CUFFLESS TRACHEOSTOMY TUBE TEMPLATE

SELECT TYPE SERVICE

☐ 3-4 WEEKS (STERILE)

☐ EXPRESS SERVICE (NON STERILE)

NECK FLANGE TYPE:

A



B



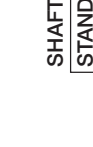
C



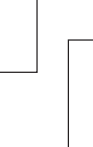
SHAFT: I.D. _____ mm
(OR) O.D. _____ mm

SHAFT STYLE:

☐ **STANDARD SILICONE**



☐ **HYPERFLEX™**



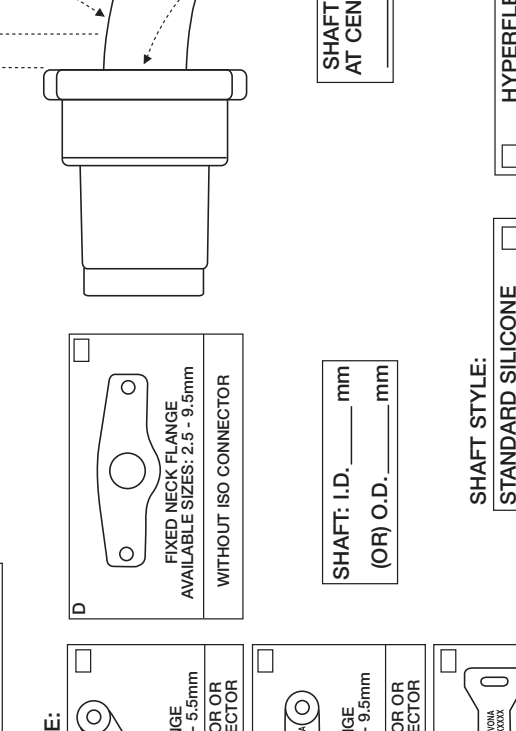
**WIRE REINFORCED
CAN NOT BE FENESTRATED**

**IF FENESTRATION
(ADULT SIZES, STANDARD SILICONE ONLY)
DISTANCE FROM NECK FLANGE _____ mm**

**SHAFT LENGTH
AT CENTRE LINE _____ MM**

**3mm MIN. DISTANCE TO
OPTIONAL FENESTRATION**

D



BIVONA USE ONLY

BIVONA ENGRG. APPROVAL:

REORDER:

DISTRIBUTOR:

DISTRIBUTOR CONTACT NAME:

TEMPLATE REF. NO. :

DATE:

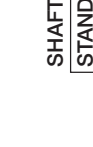
3-4 WEEKS (STERILE)

EXPRESS SERVICE (NON STERILE)

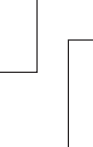
SHAFT: I.D. _____ mm
(OR) O.D. _____ mm

SHAFT STYLE:

☐ **STANDARD SILICONE**



☐ **HYPERFLEX™**



**WIRE REINFORCED
CAN NOT BE FENESTRATED**

BIVONA USE ONLY

BIVONA ENGRG. APPROVAL:

REORDER:

DISTRIBUTOR:

DISTRIBUTOR CONTACT NAME:

TEMPLATE REF. NO. :

DATE:

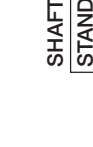
3-4 WEEKS (STERILE)

EXPRESS SERVICE (NON STERILE)

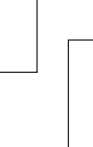
SHAFT: I.D. _____ mm
(OR) O.D. _____ mm

SHAFT STYLE:

☐ **STANDARD SILICONE**



☐ **HYPERFLEX™**



**WIRE REINFORCED
CAN NOT BE FENESTRATED**

BIVONA USE ONLY

BIVONA ENGRG. APPROVAL:

REORDER:

DISTRIBUTOR:

DISTRIBUTOR CONTACT NAME:

TEMPLATE REF. NO. :

DATE:

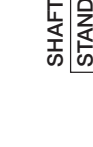
3-4 WEEKS (STERILE)

EXPRESS SERVICE (NON STERILE)

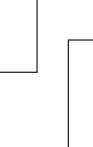
SHAFT: I.D. _____ mm
(OR) O.D. _____ mm

SHAFT STYLE:

☐ **STANDARD SILICONE**



☐ **HYPERFLEX™**



**WIRE REINFORCED
CAN NOT BE FENESTRATED**

BIVONA USE ONLY

BIVONA ENGRG. APPROVAL:

REORDER:

DISTRIBUTOR:

DISTRIBUTOR CONTACT NAME:

TEMPLATE REF. NO. :

DATE:

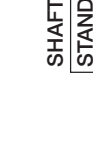
3-4 WEEKS (STERILE)

EXPRESS SERVICE (NON STERILE)

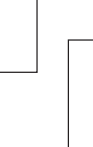
SHAFT: I.D. _____ mm
(OR) O.D. _____ mm

SHAFT STYLE:

☐ **STANDARD SILICONE**



☐ **HYPERFLEX™**



**WIRE REINFORCED
CAN NOT BE FENESTRATED**

BIVONA USE ONLY

BIVONA ENGRG. APPROVAL:

REORDER:

DISTRIBUTOR:

DISTRIBUTOR CONTACT NAME:

TEMPLATE REF. NO. :

DATE:

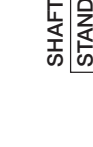
3-4 WEEKS (STERILE)

EXPRESS SERVICE (NON STERILE)

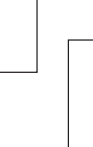
SHAFT: I.D. _____ mm
(OR) O.D. _____ mm

SHAFT STYLE:

☐ **STANDARD SILICONE**



☐ **HYPERFLEX™**



**WIRE REINFORCED
CAN NOT BE FENESTRATED**

BIVONA USE ONLY

BIVONA ENGRG. APPROVAL:

REORDER:

DISTRIBUTOR:

DISTRIBUTOR CONTACT NAME:

TEMPLATE REF. NO. :

DATE:

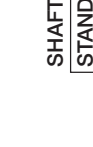
3-4 WEEKS (STERILE)

EXPRESS SERVICE (NON STERILE)

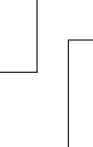
SHAFT: I.D. _____ mm
(OR) O.D. _____ mm

SHAFT STYLE:

☐ **STANDARD SILICONE**



☐ **HYPERFLEX™**



**WIRE REINFORCED
CAN NOT BE FENESTRATED**

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
NOTE: PLEASE PRINT CLEARLY. BIVONA STAFF CANNOT MAKE ANY ALTERATIONS TO THE COMPLETED TEMPLATE.

Index - Alpha

Accessories, Bivona	51	Educational Literature	53
Accessories, Smiths Medical	48	Educational Videos	54
Adjustable Flange Tracheostomy Tubes, Bivona Adult	23	Fixed Neck Flange Hyperflex™ Adult Tracheostomy Tubes	23
Adjustable Flange Tracheostomy Tubes, Blue Line	22	Flextend Plus™ Neonatal Tracheostomy Tubes	27
Adjustable Flange Tracheostomy Tubes, Paediatric	27	Flextend Plus™ Paediatric Tracheostomy Tubes	27
Adult Tracheostomy Tube Holders	49	Flextend Plus™ Standard Paediatric Tracheostomy Tubes	2
Aire-Cuf® Adult Tracheostomy Tubes	23	Fome-Cuf® Adult Tracheostomy Tubes	23
Aire-Cuf® Neonatal Tracheostomy Tubes	27	Fome-Cuf® Adult Tracheostomy Tubes with Talk Attachment	23
Aire-Cuf® Paediatric Tracheostomy Tubes	27	Fome-Cuf® Stoma-Seal™ Adult Tracheostomy Tubes	23
Artificial Speech Aid Kit	38	Fome-Cuf® Stoma-Seal™ Neonatal Tracheostomy Tubes	27
Associated Products	44	Fome-Cuf® Stoma-Seal™ Paediatric Tracheostomy Tubes	27
Bivona-Colorado™ Accessories	40	Griggs Forceps Percutaneous Tracheostomy Kits	9
Bivona-Colorado™ Voice Prostheses	39	Guidewires	13/50
Blue Line Tracheostomy Tubes	20	HEPA	46
Blue Line Ultra Inner Cannulae	19	HME System for Laryngectomee	41
Blue Line Ultra Suctionaid Tracheostomy Tubes	17	Hydrophobic Filter	46
Blue Line Ultra Tracheostomy Tube Change Kits	18	Hyperflex™ Adjustable Flange Adult Tracheostomy Tubes	23
Blue Line Ultra Tracheostomy Tube Kits	18	Hyperflex™ Adjustable Flange Paediatric Tracheostomy Tubes	27
Blue Line Ultra Tracheostomy Tubes	15	Hyperflex™ Fixed Neck Flange Adult Tracheostomy Tubes	23
Brushes	50	Inner Cannulae Cleaning Brushes	50
Catheter Mounts	47	Inner Cannulae, Blue Line Ultra	19
Cleaning Brushes	50	Laryngectomy HME System	41
Closed Suction Systems, Steri-Cath	45	Laryngectomy Tubes, Bivona	42
Cricothyrotomy Devices	36	Laryngectomy Tubes, Blue Line	22
Cuff Inflator Pressure Gauge	50	Literature	53
Cuff Inflator Pressure Gauge Connecting Tubes	50	Mini-trach II Non-Seldinger Kit	33
Cuffed Bivona Adult Tracheostomy Tubes	23	Mini-trach II Seldinger Kit	33
Cuffed Blue Line Tracheostomy Tubes	20	Montandon Tracheostomy Tubes	43
Cuffed Blue Line Ultra Tracheostomy Tubes	18	Neonatal Tracheostomy Tube Holders	49
Cuffed Neonatal Tracheostomy Tubes	27	Neonatal Tracheostomy Tubes	27
Cuffed Paediatric Tracheostomy Tubes	27	Nu-Trake® Cricothyrotomy Device	36
Customised Tracheostomy Tubes	31/56	Optivox Electrolarynx Kits	38
Demonstration Heads	55	Optivox Replacement Oral Tubes	38
Disconnection Wedge	50		
Duckbill Voice Prostheses	38		
Dummy Prostheses	39		
Dummy Prosthesis Depth Gauge	39		

Orator Speaking Valve	37	Tracheostomy T-piece	51
Orator Speaking Valve Tracheostomy Tube Kits	18	Tracheostomy Tube Holders	49
Paediatric Tracheostomy Tube Holders	49	Tracheostomy Tubes, Bivona Adult	23
Paediatric Tracheostomy Tubes	27	Tracheostomy Tubes, Blue Line	20
Pedia-Trake™ Emergency Airway System	36	Tracheostomy Tubes, Blue Line Ultra	15
Percutaneous Techniques Demonstration Heads	55	Tracheostomy Tubes, Customised	31/56
Percutaneous Tracheostomy Kits	4	Tracheostomy Tubes, Neonatal	27
Percutaneous Tracheostomy Kits, Adjustable Flange	9	Tracheostomy Tubes, Paediatric	27
Percutaneous Tracheostomy Kits, Blue Line Ultra Suctionaid	9	Tracheostomy Tubes, Rigid Blue Line Ultra	18
Percutaneous Tracheostomy Kits, Griggs Forceps Dilation	9	Tracheostomy Wedges	50
Percutaneous Tracheostomy Kits, Single Dilation	5	Tracheostomy Y-assembly	51
Percutaneous Trachesostomy Guidewires	13	TTS™ Cuff Adult Tracheostomy Tubes	23
Replacement Inner Cannulae	19	TTS™ Cuff Neonatal Tracheostomy Tubes	27
Replacement Oral Tubes, Optivox	38	TTS™ Cuff Paediatric Tracheostomy Tubes	27
Rigid Blue Line Ultra Tracheostomy Tubes	18	Tube Change Kits, Blue Line Ultra	18
Single Dilation Percutaneous Tracheostomy Kits	5	Ultralow™ Voice Prostheses	38
Sleep Apnea Tubes	42	ULTRAperc Percutaneous Tracheostomy Kits	5
Speaking Valves	37	Uncuffed Bivona Adult Tracheostomy Tubes	23
Special Tubes	42	Uncuffed Blue Line Tracheostomy Tubes	20
Speciality Products	32	Uncuffed Blue Line Tracheostomy Tubes, No 15mm Connector	22
Steri-Cath Closed Suction Systems	45	Uncuffed Neonatal Tracheostomy Tubes	27
Stoma Button	51	Uncuffed Paediatric Tracheostomy Tubes	27
Suction Catheters	45	Vents, Tracheostoma	41
Suctionaid, Blue Line Ultra	17	Venturi Aerosol Tracheostomy Masks	51
Thermovent 1200	47	Videos	54
Thermovent 600	47	Vocalaid Tracheostomy Tubes	22
Thermovent HEPA+	46	Voice Prostheses, Bivona-Colorado	39
Thermovent O ₂ Oxygen Adaptor	46	Voice Prostheses, Duckbill	38
Thermovent T HME	46	Voice Prostheses, Ultralow™	38
Tracheostoma Valve	40	Voice Restoration Products	38
Tracheostoma Valve II	40		
Tracheostoma Vents	41		
Tracheostomy Disconnection Wedge	50	Fome-Cuf, Aire-Cuf, TTS, SidePort, AutoControl, Flex Tend Plus, Hyperflex, DryPort, CMD, StomaSeal, Bivona Colorado, Ultralow, Nu-Trake, Pedia-Trake are trademarks of Smiths Group plc.	
Tracheostomy Elbow	51		
Tracheostomy Mask	51		
Tracheostomy Mask, Venturi Aerosol	51	Velcro™ is a trademark of the Velcro Companies	

Index - Numerical

Code No.	Page No.	Code No.	Page No.	Code No.	Page No.	Code No.	Page No.
100/360	45	100/590	47	555	29	B20162	40
100/361	45	100/594	47	60A1	25	B2020S	40
100/461	33	100/800	18	60HA	29	B214UO	38
100/462	33	100/802	18	60NFP	30	B21615	39
100/501	30	100/810	18	60N	30	B21620	39
100/503	49	100/811	18	60PFP	29	B21625	39
100/505	22	100/812	18	60PFS	29	B21630	39
100/506	22	100/813	18	60P	29	B216UO	38
100/509	43	100/820	18	6109-14	45	B218UO	38
100/512	22	100/821	18	6109-14FE	45	B22015	39
100/517	22	100/822	18	6111-14	45	B22020	39
100/518	22	100/823	18	65N	30	B22025	39
100/523	22	100/831	18	65P	29	B22030	39
100/526	22	100/832	18	670	25	B220UO	38
100/535	22	100/833	18	67FH	26	B222UO	38
100/536	22	100/850	19	67HA	26	B226UO	38
100/537	22	100/851	19	67N	30	B230UO	38
100/540	12	100/855	50	67P	29	B2U215	39
100/541	12	100/860	19	750	25	B2U220	39
100/542	12	100/870	19	75HA	26	B2U225	39
100/543	12	100/880	19	755	26	B2U230	39
100/544	50	100/891	12	850	25	B2U615	39
100/545	12	100/893	12	85N	30	B2U620	39
100/546	12	109/509	22	85P	29	B2U625	39
100/550	37	109/530	51	851	25	B2U630	39
100/555	50	1573	51	855	26	B51615	39
100/561	8	1575	51	B10100	36	B51620	39
100/562	8	1577	51	B1512S	40	B51625	39
100/568	50	2400	51	B1516S	40	B51630	39
100/569	50	2640	51	B152OS	40	B52015	39
100/570	46	2837	47	B1712S	40	B52020	39
100/575	46	2838	47	B1716S	40	B52025	39
100/580	47	520000	49	B1720S	40	B52030	39
100/582	47	520001	49	B20100	36		
100/585	46	520002	49	B2012S	40		