performance and comfort with a personal touch

Bivona®
Customized Tracheostomy Tubes

Smiths Medical is a leading manufacturer of airway management devices. Our Portex® and Bivona® lines comprise one of healthcare's most complete tracheostomy product ranges:

- PVC standard tubes for pediatric and adult patients
- D.I.C.® Laryngectomy Tubes
- Blue Line® and Blue Line Ultra® Tracheostomy Tubes
- Portex® specialty tubes
- ULTRAperc® percutaneous tubes and kits
- UniPerc® tubes and percutaneous kits for patients with large necks
- Griggs® percutaneous kits featuring guidewire dilating forceps
- Bivona® silicone tubes for neonates, pediatrics and adults

Customization Services
In addition to our wide selection of standard offerings, we provide Customization Services for our Bivona® silicone tracheostomy tubes. Technicians in our Customization Lab craft thousands of tubes each year to fit the unique requirements of patients, based on clinicians' orders.

VAP Solutions
Smiths Medical's eVAPorate™ Program is an implementation-based program that combines a broad selection of products with patient care and education components to help reduce the incidence of ventilator-associated pneumonia.

Professional Services
Smiths offers evidence-based programs and services to promote best practices, optimize patient outcomes and enhance cost-effectiveness.

A Smiths Medical representative can help you select the products best suited to the exact needs of your patients.

Smiths Medical ASD, Inc.
Norwell, MA 02061, USA
Phone: 1-214-618-0218
Toll-Free USA: 1-800-258-5361
www.smiths-medical.com

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Find your local contact information at:
www.smiths-medical.com/customer-support
Why choose a Bivona®
Why choose a custom tube when a standard tube might do?

A custom tracheostomy tube can address anatomical problems that a standard tube can’t –

- Abnormal tracheal length
- Unusual tracheal curvature
- Irregular stoma

Tube components can be arranged to match up with anatomy and help alleviate complications such as –

- Tracheal irritation
- Ventilation bypass
- Stoma leakage
- General discomfort

A custom tube made of silicone can fit better, be more comfortable and be less damaging when compared to a standard tube made of PVC and designed for normal anatomy.

custom tracheostomy tube?

Treating a patient with difficult or unusual anatomy can be a challenge; getting that patient a proper fitting tracheostomy tube shouldn’t be.

A Bivona® lab technician can hand-craft a tube of soft, durable silicone to conform to the patient’s neck, stoma and trachea. Whether it’s a customized tube of prefabricated components or a custom-made tube fashioned to dimensions you provide, a Bivona® custom tube is your best choice.

Because your patients deserve the very best.
Options

set Bivona® Customized Tubes above the rest

Problem
- Severe tracheal malacia
- Fear of developing a tracheal esophageal fistula

Problem
- Unusual tracheal curve
- Nocturnal ventilatory support
- Raw and swollen stoma

Problem
- Chin excoriation from tracheostomy tube connections
- Junctional epidermolysis bullosa
- Tip of the tube shaft digging into the posterior wall of the trachea

Customized Solution
- Increased length of tube
- Fome-Cuf® tracheostomy cuff
- Adult silicone neck flange

Customized Solution
- Heperflex® silicone shaft
- TTS™ tracheostomy cuff
- Proximal Fome-Cuf® stoma seal

Customized Solution
- Standard silicone shaft
- TTS™ tracheostomy cuff
- Proximal Fome-Cuf® cushion
**Problem**
- High bifurcation of the trachea and severe tracheal malacia
- High airway resistance

**Problem**
- Unusual tracheal length
- Nocturnal ventilatory support
- Cuff volume diffusion noted over time

**Customized Solution**
- Hyperflex™ shaft for tracheal stent
- Fome-Cuf® proximal double cuff
- Talk attachment

**Customized Solution**
- Silicone shaft, length determined by chest x-ray
- TTS™ Cuff filled with sterile water

A custom-made tube, designed by you, is a completely unique solution.

A Bivona® tube technician can mold silicone to any shape, thickness, contour and curvature for optimal fit and comfort.

**Customization Options**

**Tube Shaft Style**
- Standard Silicone
- Hyperflex™ Wire Reinforced Silicone
- Fenestrations
- Proximal Stoma Cushions

**Curvature**
- Standard Anatomical Pre-curve Shaft
- Hyperflex™ Wire Reinforced Flexible

**Length**
- Standard Extensive Range

**I.D. / O.D.**
- Comprehensive range

**Cuff Design**
- Fome-Cuf® Proximal Cuff
- Aire-Cuf® Proximal Cuff
- TTS™ Proximal Cuff
- Cuffless
- Multi-Cuff Configurations
- Stoma Cushion Cuff

**Cuff Position**
- To your specification

**Neck Flange**
- Adult
- Neonatal ("V" and Straight)
- Pediatric ("V" and Straight)
- Fixed
- Adjustable
Customization Services
performance and comfort with a personal touch

Convenient and Efficient
Designing and ordering a customized tracheostomy tube from Smiths Medical is easy. First, we provide you with convenient order templates, and you:

- Select components
- Provide critical dimensions
- Choose the level of service
- Fax the completed template

Second, a Bivona® specialist is assigned to work with you to review and evaluate the unique needs of each patient.

Third, once we receive written approval of the final design, the customized tracheostomy tube is made to order and shipped directly to you or your patient.

Turnaround time from receipt of a signed order template to shipment is seven days (for non-sterile tubes that can be steam-autoclaved). We also offer a variety of options for higher priority service and faster delivery.

<table>
<thead>
<tr>
<th>Service</th>
<th>Timeframe</th>
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</thead>
<tbody>
<tr>
<td>Standard Service (sterile)</td>
<td>3-4 weeks</td>
</tr>
<tr>
<td>Standard Service (non-sterile)</td>
<td>5-7 working days</td>
</tr>
<tr>
<td>Express Service (non-sterile)</td>
<td>3 working days</td>
</tr>
<tr>
<td>Next-Day Service (non-sterile)</td>
<td>Shipped same day</td>
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<tr>
<td></td>
<td>(Order must be received by 10 a.m. CST)</td>
</tr>
<tr>
<td>NEW Extended Next-Day Service (non-sterile)</td>
<td>Shipped same day</td>
</tr>
<tr>
<td></td>
<td>(Order must be received by 12 noon CST)</td>
</tr>
<tr>
<td></td>
<td>Maximum 2 units per order</td>
</tr>
</tbody>
</table>

An RRT at the Bivona® Customization Lab in Gary, Indiana, examines an X-ray to determine the optimal solution.

Working from a completed design template, a Bivona® Customs Specialist develops a customized tube.

Shipped anywhere in the world - to you or right to the patient.
Why choose a Bivona® performance and comfort with a personal touch

Bivona® Customized Tracheostomy Tubes

Templates for Designing and Ordering a Bivona® Customized Tracheostomy Tube

Visit us online at BivonaCustom.com
Smiths Medical is a leading manufacturer of airway management devices. Our Portex® and Bivona® lines comprise one of healthcare’s most complete tracheostomy product ranges:

- **PVC standard tubes for pediatric and adult patients**
  - D.I.C.® Laryngectomy Tubes
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- **Professional Services**
  Smiths offers evidence-based programs and services to promote best practices, optimize patient outcomes and enhance cost-effectiveness.

A Smiths Medical representative can help you select the products best suited to the exact needs of your patients.
Bivona® Customized FlexTend™ Tracheostomy Tube Template

PORTEX® NEW easy-to-read template
Just follow steps 1-9. Please specify:

1. Shaft Length:
   □ 1a: Shaft Length ______mm (5mm min.; 60mm max.)
   □ 1b: Shaft Length ______mm (30mm min.; 140mm max.)

2. Shaft:
   □ Shaft: I.D.____mm (2.5-9.5mm) or □ Shaft: O.D.____mm

3. Connector:
   □ 3a. Swivel 2.5-9.5mm □ 3b. Fixed 2.5-6.0mm

4. Neck Flange:
   □ 4a. 2.5-6.0mm
   □ 4c. 5.0-9.5mm
   □ 4d. 6.5-9.5mm
   □ 4e. 2.5-4.0mm
   □ 4f. 2.5-6.0mm

5. Cuff:
   □ 5a. TTS™ Tight to Shaft 2.5-9.5mm
   □ 5b. Aire-Cuf® Pedi 2.5-5.5mm
   □ 5b. Aire-Cuf® Adult 5.0-9.5mm
   □ 5c. Fome-Cuf® 2.5-9.5mm
   □ 5d. Cuffless 2.5-9.5mm

6. Specialty Shaft:
   □ 6a. Std. Curved 2.5-6.0mm
   □ 6b. Hyperflex™ Neo / Pedi
       Reinforced – Straight
   □ Adult 5.0-9.5mm
       2.5-9.5mm

7. Optional:
   □ 7a. Proximal (TOP) Cuff
       □ TTS® Cuff
       □ Aire-Cuf®
       □ Fome-Cuf®
   □ 7b. Stoma seal
       □ Solid Silicone
       □ ______ mm OD
       □ ______ mm Length
   □ 7c. Distal (BOTTOM) Cuff
       □ Cuff distance from tip of shaft ______mm
       □ Note: Cuff distance from tip cannot be less than the minimum standard distance listed below:
       a. Pediatric TTS, Aire & Fome – 3mm
       b. Adult Aire & Fome – 5mm
       c. Adult TTS – 9mm
   □ 7d. Talk Attachment
       □ Tapered
       □ Non Tapered
   □ NOTE: 5.0mm I.D. Adult shaft or above only.

8. Approval: NOTE: Please print clearly. Smiths Medical will review the completed template for compliance. Any required modifications will be made with the approval of a clinician.

HOSPITAL/CLINIC

DATE

P.O. NUMBER

CLINICIAN SIGNATURE/CREDS

PATIENT/CLIENT ID

(Smiths Medical Use Only) Approval:_________________ Reorder:_________________

9. Select Type of Service:

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

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### Bivona® Customized Fixed Tracheostomy Tube Template

**PORTEX® NEW easy-to-read template**
Just follow steps 1-9. Please specify:

1. **Shaft Length:**
   - [ ] 1a: Shaft Length _____ mm (30mm min.; 140mm max.)
   - [ ] 1b: Extra Horizontal Length _____ mm

2. **Shaft:**
   - [ ] Shaft: I.D. _____ mm (2.5-9.5mm) or [ ] Shaft: O.D. _____ mm

3. **Connector:**
   - [ ] 3a. Swivel 2.5-9.5mm
   - [ ] 3b. No ISO Connector
     - Note: Product cannot be connected to any circuit or adapter.

4. **Neck Flange:**
   - [ ] 4a. 2.5-5.5mm
   - [ ] 4b. 2.5-9.5mm
   - [ ] 4c. 2.5-9.5mm
   - [ ] 4d. 2.5-9.5mm
     - No ISO connector (Cuffless only)
   - [ ] 4e. 2.5-4.0mm
     - No ISO connector (Cuffless only)

   - Neck Flange Length: 60mm
   - Neck Flange Length: 67mm
   - Neck Flange Length: 83mm
   - Neck Flange Length: 67mm
   - Neck Flange Length: 47mm

5. **Cuff:**
   - [ ] 5a. TTS™ Tight to Shaft
     - 2.5-9.5mm
   - [ ] 5b. Aire-Cuf® Pedi
     - 2.5-5.5mm
   - [ ] 5b. Aire-Cuf® Adult
     - 5.0-9.5mm
   - [ ] 5c. Fome-Cuf®
     - 2.5-9.5mm
   - [ ] 5d. Cuffless
     - 2.5-9.5mm

6. **Specialty Shaft:**
   - [ ] 6a. Std. Curved
     - 2.5-9.5mm
   - [ ] 6b. Hyperflex™
     - Reinforced-Straight
     - 2.5-9.5mm

7. **Optional:**
   - [ ] 7a. Proximal (TOP) Cuff
     - TTS™ Cuff
     - Aire-Cuf®
     - Fome-Cuf®
     - Pediatric
     - Adult

   - Cuff position from Neck Flange _____ mm

   - [ ] 7b. Stoma seal
     - Solid Silicone
     - _____ mm OD
     - _____ mm Length
     - Tapered
     - Non Tapered

   - [ ] 7c. Distal(BOTTOM) Cuff
     - Cuff distance from tip of shaft _____ mm

     - Note: Cuff distance from tip cannot be less than the minimum standard distance listed below:
     - a. Pediatric TTS, Aire & Fome - 3mm
     - b. Adult Aire & Fome - 5mm
     - c. Adult TTS - 9mm

   - [ ] 7d. Talk Attachment

   - NOTE: 5.0mm I.D. Adult shaft or above only.

8. **Approval:**
   - NOTE: Please print clearly. Smiths Medical will review the completed template for compliance. Any required modifications will be made with the approval of a clinician.

### Hospital/Clinic

<table>
<thead>
<tr>
<th>HOSPITAL/CLINIC</th>
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</table>

### Clinician Signature/Credentials

<table>
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<tr>
<th>PATIENT/CLIENT ID</th>
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<tbody>
<tr>
<td>[Smiths Medical Use Only] Approval: ________________ Reorder: ________________</td>
</tr>
</tbody>
</table>

9. **Select Type of Service:**
   - [ ] 3-4 weeks (Sterile)  [ ] Standard Service (NON-Sterile)
   - [ ] Express Service (NON-Sterile)  [ ] Same Day Service (NON-Sterile) – USA Only

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

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Bivona® Customized Adjustable Tracheostomy Tube Template

PORTEX® NEW easy-to-read template
Just follow steps 1-9. Please specify:

1. Shaft Length:
   - Shaft Length ___ mm [30 mm min., 200 mm max.]

2. Shaft:
   - Shaft: I.D. ___ mm [2.5-9.5 mm] or Shaft: O.D. ___ mm

3. Connector:
   - 3a. Swivel 2.5-9.5 mm
   - 3b. Fixed 2.5-6.0 mm

4. Neck Flange:
   - 4a. 2.5-5.5 mm
   - 4c. 5.0-9.5 mm

   Neck Flange Length: 60 mm  Neck Flange Length: 83 mm

5. Cuff:
   - 5a. TTS™ Tight to Shaft
   - 5b. Aire-Cuf® Pedi
   - 5b. Aire-Cuf® Adult
   - 5c. Fome-Cuf®
   - 5d. Cuffless

6. Specialty Shaft:
   - 6b. Hyperflex™

   Reinforced - Straight

   2.5-9.5 mm

   Not intended for long term use. This tube provides temporary airway access for a tracheostomized patient when determining the optimal tube length for the patient. This tube must be replaced with a fixed neck flange tracheostomy tube when the optimal length is determined.

7. Optional:
   - 7a. Distal (Bottom) Cuff
   - Cuff distance from tip to shaft ___ mm

   Note: Cuff distance from tip cannot be less than the minimum standard distance listed below:
   a. Pediatric TTS, Aire & Fome - 3 mm
   b. Adult Aire & Fome - 5 mm
   c. Adult TTS - 9 mm

8. Approval: NOTE: Please print clearly. Smiths Medical will review the completed template for compliance. Any required modifications will be made with the approval of a clinician.

   HOSPITAL/CLINIC __________________________ DATE __________________________ P.O. NUMBER __________________________

   CLINICIAN SIGNATURE/CREDS/ENDS __________________________ PATIENT/CLIENT ID __________________________

9. Select Type of Service:
   - 3-4 weeks [Sterile]
   - Standard Service [NON-Sterile]
   - Express Service [NON-Sterile]
   - Same Day Service [NON-Sterile] - USA Only

   [Smiths Medical Use Only] Approval: __________________________ Reorder: __________________________

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