

EC Declaration of Conformity

Name of Products: Face Masks

Product Codes: See **Attachment A**

UMDNS Code: 12458 (Masks, Surgical)

GMDN Code: 35177 (Surgical face mask, Single Use)

Legal Manufacturer (Place of Issue): Halyard Health, Inc.
5405 Windward Parkway
Alpharetta, Georgia (GA) 30004, USA

EU Authorized Representative: Halyard Belgium BVBA
Leonardo Da Vincilaan 1
1930 Zaventem
Belgium

Product Standards: BS EN 14683 (excepted for products with * which comply to Bacterial Filtration Efficiency requirements only)

Start of CE: See **Attachment A**

Conformity Assessment Route: Annex VII

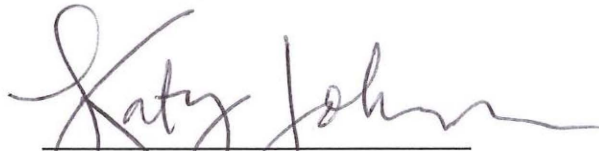
Device Classification, Rules: I, non sterile and non-measuring, Rule 1 per Annex IX

CE certificate number: N/A

I, the undersigned, hereby declare that the specified medical device(s) meet(s) the applicable provisions of European Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices.

All supporting documentation that contains proof of compliance to the aforementioned Directive(s) is retained under the premises of Halyard Health, Inc. This declaration applies to all devices on the attached product list from the signature date forward.

Authorized Signature:



Name: Katy Johnson
Title: Regulatory Affairs Technical Leader
Halyard Health, Inc.
Date: 02-Nov-2016

Attachment A (Product List)

This attachment specifies the products included in the above referenced Declaration of Conformity.

Stock Code	Description	Start of CE
146	FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops	03-June-2015
148	FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops	03-June-2015
152	Standard Cone Mask	03-June-2015
10729	Surgical Face Mask	03-June-2015
37525	Duckbill Surgical Mask	03-June-2015
46727*	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining	03-June-2015
46767*	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and SO SOFT* Lining	03-June-2015
46827*	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining	03-June-2015
46867*	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and SO SOFT* Lining	03-June-2015
47080	Procedure Mask with SO SOFT* Earloops	03-June-2015
47081	Procedure Mask with SO SOFT* Earloops	03-June-2015
47085	Procedure Mask with SO SOFT* Earloops	03-June-2015
47090	Procedure Mask with SO SOFT* Earloops	03-June-2015
47095	Procedure Mask with SO SOFT* Earloops	03-June-2015
47116	Procedure Mask with SO SOFT* Earloops	03-June-2015
47117	Procedure Mask with SO SOFT* Earloops	03-June-2015
47127	Child's Face Mask with SO SOFT* Earloops	03-June-2015
47137	FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops	03-June-2015
47295	Teddy Bear Procedure Mask with SO SOFT* Earloops	03-June-2015
47297	FLUIDSHIELD* 3 Teddy Bear Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops	03-June-2015
47298	FLUIDSHIELD* 3 Teddy Bear Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops	03-June-2015
47500	SOFT TOUCH II* Surgical Mask	03-June-2015
47625	High Filtration Surgical Mask	03-June-2015
47650	High Filtration Fog-Free Surgical Mask	03-June-2015
47700	Pouch Style Mask with SO SOFT* Lining	03-June-2015
47717	Pouch Style Mask with SO SOFT* Lining	03-June-2015
48100	THE LITE ONE* Surgical Mask	03-June-2015
48105	THE LITE ONE* Surgical Mask	03-June-2015
48201	Surgical Mask	03-June-2015
48210	Surgical Mask	03-June-2015
48220	Duckbill Surgical Mask	03-June-2015
48247	FLUIDSHIELD* 3 Fog-Free Surgical Mask with SO SOFT* Lining (ASTM F2100-EN 14683 Type II R)	03-June-2015
48248	FLUIDSHIELD* 3 Surgical Mask with SO SOFT* Lining (ASTM F2100-EN 14683 Type II R)	03-June-2015
48296	Teddy Bear Surgical Mask	03-June-2015
48297	FLUIDSHIELD* 3 Teddy Bear Surgical Mask with SO SOFT* Lining	03-June-2015
48390	Surgical Mask with SO SOFT* Lining	03-June-2015

Stock Code	Description	Start of CE
49214	Fog-Free Surgical Mask	03-June-2015
49215	Anti-Fog Surgical Mask	03-June-2015
49216	Duckbill Fog-Free Surgical Mask	03-June-2015
49235	Anti-Fog Surgical Mask	03-June-2015
49310	ULTI-MASK* Fog-Free Surgical Mask	03-June-2015
49700	Standard Procedure Mask	03-June-2015
49701	Standard Surgical Mask	03-June-2015
59928	THE FRIENDLY* Surgical Mask	03-June-2015
62113	FLUIDSHIELD* 2 Fog-Free Surgical Mask	03-June-2015
62114	FLUIDSHIELD* 2 Fog-Free Surgical Mask	03-June-2015
62115	FLUIDSHIELD* 2 Procedure Mask with SO SOFT* Earloops	03-June-2015
62116	FLUIDSHIELD* 2 Fog-Free Procedure Mask with SO SOFT* Earloops	03-June-2015
62126*	FLUIDSHIELD* 2 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining	03-June-2015
62355*	FLUIDSHIELD* 2 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining	03-June-2015
62356	THE LITE ONE* Procedure Mask with SO SOFT* Earloops	03-June-2015
62357	THE LITE ONE* Procedure Mask with SO SOFT* Earloops	03-June-2015
62362	Fog-Free Procedure Mask with SO SOFT* Earloops	03-June-2015
62363	Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops	03-June-2015
62367	THE LITE ONE* Surgical Mask	03-June-2015
28804	FLUIDSHIELD* 3 Fog-Free Surgical Mask/WrapAround Anti-Glare Visor (ASTM F2100-EN 14683 Type II R)	04-May-2016
28820	FLUIDSHIELD* 3 Fog-Free Surgical Mask (ASTM F2100-EN 14683 Type II R)	04-May-2016
25867*	FLUIDSHIELD* 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops (ASTM F2100-EN 14683 (BFE))	03-June-2015
25869*	FLUIDSHIELD* 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops (ASTM F2100-EN 14683 (BFE))	03-June-2015
28802*	FLUIDSHIELD* 1 Surgical Mask with SO SOFT* Lining (ASTM F2100-EN 14683 (BFE))	03-June-2015
28806*	FLUIDSHIELD* 1 Fog-Free Surgical Mask with SO SOFT* Lining (ASTM F2100 –EN 14683 (BFE))	03-June-2015
28808	FLUIDSHIELD* 2 Fog-Free Surgical Mask (ASTM F2100-EN 14683 Type II R)	03-June-2015
28809	FLUIDSHIELD* 2 Fog-Free Surgical Mask (ASTM F2100-EN 14683 Type IIR)	03-June-2015
28810	FLUIDSHIELD* 2 Procedure Mask with SO SOFT* Earloops (ASTM F2100-EN 14683 Type IIR)	03-June-2015
28821	FLUIDSHIELD* 2 Fog-Free Procedure Mask with SO SOFT* Earloops (ASTM F2100-EN 14683 Type IIR)	03-June-2015
47107	3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops (ASTM F2100-EN 14683 Type IIR)	03-June-2015
47147	FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops (ASTM F2100-EN 14683 Type IIR)	03-June-2015
48207	FLUIDSHIELD* 3 Fog-Free Surgical Mask with SO SOFT* Lining (ASTM F2100-EN 14683 Type IIR)	03-June-2015
48208	FLUIDSHIELD* 3 Surgical Mask with SO SOFT* Lining (ASTM F2100-EN 14683 Type IIR)	03-June-2015

Stock Code	Description	Start of CE
48237	FLUIDSHIELD* 3 Fog-Free Surgical Mask with SO SOFT* Lining (ASTM F2100-EN 14683 Type IIR)	03-June-2015

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

O & M Halyard, Inc.
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Holds Certificate No:

FM 697013

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

The design and development, manufacture and distribution of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-12-09

Latest Revision Date: 2020-01-08

Effective Date: 2020-01-09

Expiry Date: 2023-01-08

Page: 1 of 3



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Certificate No: **FM 697013**

Location	Registered Activities
O & M Halyard, Inc. 9120 Lockwood Blvd Mechanicsville Virginia 23116 USA	Headquarter management activities.
O & M Halyard, Inc. 5405 Windward Parkway Alpharetta Georgia 30004 USA	The design and development of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.
Halyard North Carolina, LLC 389 Clyde Fitzgerald Rd. Linwood North Carolina 27299 USA	The manufacture of nonwoven materials for medical devices, Sterilization wrap, and infection control products including disposable gowns and linens.
La Ada de Acuna 14 Finegan Road Del Rio Texas 78840 USA	Receiving and Incoming Inspection, Warehouse and Distribution.
O&M Halyard Honduras S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	The manufacture and distribution of disposable sterile and non-sterile surgical gowns.
La Ada de Acuna Avenida Hidalgo #16 Parque Industrial San Carlos Nogales Sonora 84092 Mexico	Receiving and incoming inspection. Manufacturer/Conversion of nonwoven materials.

Original Registration Date: 2014-12-09

Latest Revision Date: 2020-01-08

Effective Date: 2020-01-09

Expiry Date: 2023-01-08

Page: 2 of 3

This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory

To be read in conjunction with the scope above or the attached appendix.

Certificate No: **FM 697013**

Location	Registered Activities
La Ada de Acuna Kim. 4.5 Carreterra Presa La Amistad Ciudad De Acuna Coahuila 26220 Mexico	The manufacture of non-sterile face masks (surgical isolation, industrial and respirator), non-surgical gowns, cold therapy products, and sterilization wrap.
La Ada de Acuna S.De. R.L. De C.V AV. Hidalgo #6 Esq., Blvd., Luis Donaldo Colosio, Col. Educativa Nogales Sonora 84093 Mexico	The manufacture of disposable products including sterile and non sterile surgical packs, gowns and components. The manufacture of temperature management systems for areas of general surgery.
Safeskin Medical & Scientific (Thailand) Ltd. 200 Moo 8, Kanchanavanich Road, Tambol Prik, Amphur Sadao, Songkhla 90120 Thailand	The design and development, production and distribution of industrial gloves, sterile and non-sterile examination gloves.

Original Registration Date: 2014-12-09

Latest Revision Date: 2020-01-08

Effective Date: 2020-01-09

Expiry Date: 2023-01-08

Page: 3 of 3

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To be read in conjunction with the scope above or the attached appendix.

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.

CE 540596

Issued To:

**Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland**

In respect of:

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of non-active respiratory, non-active gynaecological, non-active regional anaesthesia, non-active surgical and non-active urology devices.

Those aspects of manufacturing relating to obtaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.

The manufacture of non-active and active surgical devices for adult and paediatric intraosseous infusion, bone marrow aspiration, bone marrow biopsy, bone lesion biopsy and non-active sterile urology catheters.

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

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-01-13**

Date: **2020-06-09**

Expiry Date: **2024-05-26**

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Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

EC Certificate - Production Quality Assurance

Supplementary Information to CE 540596

Issued To:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0102	Sterile Intraosseous Vascular Access System	--
MD 1104	Non-sterile Intraosseous Vascular Access System	
MD 0102	Sterile Powered Bone Access	--
MD 1104	Non-sterile Powered Bone Access	
MD 0102	Sterile Sternal Intraosseous Device	--
MD 0101	Sterile Silicone Foley Catheter	--

First Issued: **2009-01-13**Date: **2020-06-09**Expiry Date: **2024-05-26**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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Supplementary Information to CE 540596

Issued To:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
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Ireland

Number	Device Name	Intended purpose per IFU
Class Is		
MD 0301	Intraosseous Vascular Access System Stabilizer	--
MD 0102	Powered bone access connector	--
MD 0101	Tracheostomy Tube Accessories	--
MD 0102	Tuohy Borst Adaptor	--
MD 0102	Syringe	--
MD 0101	Urology Dilator	--
MD 0101	Guedel Airway	--
MD 0101	Intrauterine Catheter Set	--
MD 0101	Sterile Container	--
MD 0101	Neckband	--
Sterility aspects only		
---	Procedure Packs under article 12	---

First Issued: **2009-01-13**

Date: **2020-06-09**

Expiry Date: **2024-05-26**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No: **CE 540596**
 Date: **2020-06-09**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
ArcRoyal Virginia Road Kells, Co. Meath Ireland	Manufacture
Arriol International Corporation Carretera San Isidro KM 17 Zona Franca San Isidro Santo Domingo Este Dominican Republic	ETO Sterilization Manufacture
Arrow International CR, a.s. Jamska 2359/47 Zdar Nad Sazavou 59101 Czech Republic	Manufacture
BBF Sterilisationsservice GmbH Willy-Rüsch-Straße 10/1 71394 Kernen Germany	Radiation (Gamma Sterilization)

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Directive 93/42/EEC on Medical Devices, Annex V

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Subcontractor:	Service(s) supplied
CeMed GmbH Im Oberdorf 41 72419 Neufra Germany	Assembly Packaging
China Biotech Corporation No. 10, 33 rd., Road, Taichung Industrial Park Taichung Taiwan	Radiation (Gamma Sterilization)
Degania Silicone Limited Kibbutz 1513000 Degania Bet Israel	Manufacture
Donatelle Plastics, Inc. 501 County Road E-2 Extension New Brighton MN 55112 USA	Manufacture

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Subcontractor:	Service(s) supplied
Foremount Enterprise Co., Ltd. No. 17, Alley 15, Lane 5 Shenan Street Shengang Dist 42944 Taichung City Taiwan	Manufacture
Iotron Industries USA 4394 East Park 30 Drive Columbia City Indiana 46725 USA	Radiation (E Beam Sterilization)
Medical Service GmbH Luisenstraße 8 75378 Bad Liebenzell/Unterhaugstett Germany	Assembly Packaging

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Subcontractor:	Service(s) supplied
Medioplast Israel Ltd. 7 Hayarkon St. P.O. Box 13214 Industrial Zone Yavne 8122710 Israel	ETO Sterilization
Rose GmbH für Medizintechnik Gottbillstraße 25-30 54294 Trier Germany	ETO Sterilization
sfm medical devices GmbH Brückenstraße 5 63607 Wächtersbach Germany	ETO Sterilization Manufacture

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Subcontractor:	Service(s) supplied
Sparton Onyx, LLC 2920 Kelly Avenue Watertown South Dakota 57201-7249 USA	Manufacture
Sterigenics Germany GmbH Kasteler Straße 45 Wiesbaden 65203 Germany	ETO Sterilization
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	ETO Sterilization

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Ireland

Subcontractor:	Service(s) supplied
Steritec, Inc. P.O. Box 1969 1705 Enterprise Street Athens, TX 75751 United States of America	ETO Sterilization
Synergy Health Sterilisation UK Ltd 1 Alpha Court Capitol Park Thorne Doncaster DN8 5TZ United Kingdom	ETO Sterilization
Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	ETO Sterilization

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Subcontractor:	Service(s) supplied
Teleflex Medical Sdn. Bhd. Lot PT 2577, Jalan Perusahaan 4 34600 Kamunting Perak Malaysia	ETO Sterilization Manufacture
Viant San Antonio, Inc. 7027 Fairgrounds Parkway San Antonio TX 78238 United States of America	Manufacture
Viant Upland, Inc. a.t.a. (formerly) Lake Region Medical 2052 West 11th Street Upland CA 91786 USA	Manufacture
Willy Rüschi GmbH Willy-Rüsch-Straße 4-10 71394 Kernen i.R., Germany	Manufacture

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EC Certificate - Production Quality Assurance

Certificate History

Certificate No: **CE 540596**
 Date: **2020-06-09**
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IDA Business and Technology Park
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Date	Reference Number	Action
13 January 2009	7245725	First issue.
17 March 2009	7325720	Company address amended. Extension to scope. Addition of Willy Rüsç, Germany as subcontractor for design and manufacture.
25 August 2009	7399908 7439096	Addition of SFM as significant subcontractor for manufacture. Addition of 'design' services supplied by Teleflex Medical, Malaysia, Arrow International CR, a.s. and Arrow International, Inc., Czech Republic. Correction of History page header. Intrauterine catheter added to scope.
08 September 2010	7558507	Scope reworded in accordance with generic device groups. Activity of 'Design' removed from all subcontractors and 'Control of Sterilisation' added. Certificate renewal.

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Page 1 of 5

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Date	Reference Number	Action
23 February 2011	7635647	Scope extended to include, 'Those aspects of manufacturing relating to securing and maintaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.' Addition of subcontractor, 'ArcRoyal Ltd., Virginia Road, Kells, Co. Meath, Ireland' for Manufacture and Control of Sterilization activities.
23 May 2012	7778468	Correction of significant subcontractor address.
04 February 2013	7932595	The addition of significant subcontractors Foremount Enterprise Co Ltd and Bidoia SAS Di Gianfranco Didia EC.
13 July 2015	8334933	Extension to scope to include 'The manufacture of non-active and active surgical devices for adult and paediatric intraosseous infusion, bone marrow aspiration, bone marrow biopsy and bone lesion biopsy.' Significant subcontractor changes: Addition of Vidacare LLC, Lake Region Medical, Arriol International Corporation, Coastal Life Technologies, Inc & Sparton Onyx. LLC.

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Page 2 of 5

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Date	Reference Number	Action
28 August 2015	8406492	Certificate renewal. Removal from scope of 'those aspects of Annex V relating to securing and maintaining sterility in the manufacture of non-active digestive tract devices' and 'Those aspects of Annex V related to metrology in the manufacture of non-active respiratory devices'.
10 February 2016	8455693	Removal of Vidacare LLC from list of significant subcontractors. Service(s) supplied for Arriol International Corporation, Coastal Life Technologies Inc. and Lake Region Medical changed from crucial suppliers to Control of Sterilization, Manufacture. Service(s) supplied for Sparton Onyx. LLC changed from crucial supplier to Manufacture. Removal of repeated use of word 'devices' from scope.
28 July 2017	8762518	Change of address for Coastal Life Technologies. Addition of Donatelle Plastics Inc., 55112 New Brighton to list of significant subcontractors.
04 March 2019	7779566	Traceable to NB 0086.

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Ireland

Date	Reference Number	Action
Current	3124053	<p>Certificate renewal.</p> <p>Addition of supplementary product information table.</p> <p>Update to scope to include non-active sterile urology catheters.</p> <p>Name change from Coastal Life Technologies to Viant San Antonio, Inc., Name change from Lake Region Medical to Viant Upland, Inc</p> <p>Removal of Control of Sterilization from Service(s) supplied for ArcRoyal Ltd., Arrow International CR, a.s. (Zdar), Viant San Antonio, Inc., Donatelle Plastics, Inc., Foremount Enterprise Co., Ltd., Viant Upland, Inc., sfm medical devices GmbH, Teleflex Medical Sdn. Bhd., and Willy Rüsç GmbH.</p> <p>Addition of ETO Sterilization to Service(s) supplied for sfm medical devices GmbH and Teleflex Medical Sdn. Bhd.</p> <p>Administrative correction of details for ArcRoyal, Arriol International Corporation, Arrow International CR, a.s., Donatelle Plastics, Inc., Foremount Enterprise Co., Ltd., Sparton Onyx. LLC, sfm medical devices GmbH, Teleflex Medical Sdn. Bhd. and Willy Rüsç GmbH.</p> <p>Removal of Arrow International CR a.s. (Hradec Kralove) and Bidoia SAS Di Gianfranco Didoia E.C.</p> <p>Addition of CeMed GmbH and Medical Service GmbH for Assembly and Packaging.</p>

...making excellence a habit.™

Page 4 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Production Quality Assurance

Certificate History

Certificate No: **CE 540596**
Date: **2020-06-09**
Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
	3124053	Addition of Degania Silicone Limited for Manufacture Addition of Steritec, Inc., Sterigenics US, LLC, Rose GmbH für Medizintechnik, Synergy Health Sterilisation UK Ltd, Sterigenics Germany GmbH, Medioplast Israel Ltd., and Synergy Sterilisation (M) Sdn Bhd. for ETO Sterilization Addition of Iotron Industries USA for E-beam Sterilization Addition of China Biotech Corporation and BBF Sterilisationsservice GmbH for Gamma Sterilization.

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Page 5 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

The management system of

Teleflex Medical

2917 Weck Drive, Research Triangle Park, NC, 27709, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 11 September 2018 until 14 July 2023
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 27 May 2021

Issue 29. Certified since 26 September 2000

Certification is based on reports numbered WWW/MC/06866

Multiple certificates have been issued for this scope
The main certificate is numbered US97/10879.00

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

2026 Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

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Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 29

Detailed scope

Sterile Hem-o-lok Ligation Clips.
Sterile Deknatel® PTFE pledgets.
Sterile Polyester Nonabsorbable Surgical Sutures (POLYLENE/ "cottony"™ II, "silky" II POLYDEK®, TEVDEK® II, NextSitch®, Capio™, Fx®, NiceLoop™, TEVDEK®).
Sterile DEKLENE® II, DEKLENE® MAXXTM, CAPIOTM and FIXT® polypropylene non-absorbable surgical sutures.
Sterile BONDEK® and BONDEK® Plus Polyglycolic Acid Synthetic Absorbable Surgical Sutures.
Sterile Polyglytone 6211™ Monofilament Absorbable Surgical Sutures.
Sterile MONODEK® Polydioxanone Absorbable Surgical Sutures.
Sterile Hem-o-lok Automatic Clip Appliers.
Metal Ligation System.

Sterile External stapling system (including stainless steel staples, staplers and removers), Sterile, Efx endo fascial closuresystem (abdominal access), Sterile, Efx shield fascial closure system (abdominal access), Sterile, Efx classic fascial closuresystem (abdominal access)

Sterile stainless steel surgical Sutures
Sterile FORCE FIBER® surgical sutures.
Sterile Chest drainage and autotransfusion systems,
Sterile Thoracic Catheters,
Sterile and Non-sterile Aortic Punch,
Non-sterile Self Retaining Tissue retractor/blades

Non-sterile Anaesthesia and respiratory Circuits including breathing bags and water traps,
Non-sterile Heated Humidifiers, Non-sterile Non-Pre-filled Humidifiers and Nebulizers, Non-sterile Small Volume Nebulizers, Sterile Pre-filled Humidifiers and Nebulizers (saline or water) with adaptors, Sterile Pre-filled unit dose vial /solution for nebulisation, Non-sterile Respiratory therapy Adaptors and connectors, Sterile Column and Reservoirs including adaptors, Non-sterile Nasal cannula (including gas sampling), Non-sterile Cannula and Supply Tubing, Nonsterile CPAP Cannula System, Non-sterile Manual resuscitators and PEEP valves, Non-sterile Respiratory and anaesthesia masks, Non-sterile Gas scavenging mask, Sterile Endotracheal tubes, Sterile Endobronchial tubes, Non-sterile Suction and Aspirating Tubes, Sterile Ventilated Thoracic Chest Seal, Sterile Operative Cholangiogram Catheters, Sterile Abdominal Access and Insufflation devices, Sterile Capillary drains, Sterile Percutaneous Surgical System (MiniLap and Grip graspers), Sterile Percutaneous Surgical System (Mini Polar electrosurgical probe and MiniGrip Bipolar Graspers), Percutaneous surgical System (Interchangeable electrosurgical tool tips) for laparoscopic surgery, Non-sterile Heat and Moisture Exchangers

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market





Certificate US97/10878.00

The management system of

Teleflex Medical

3015 Carrington Mill Blvd., Morrisville, NC, 27560, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016



For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 11 September 2018 until 14 July 2021
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 27 May 2021

Issue 20. Certified since 26 September 2000

Multiple certificates have been issued for this scope

The main certificate is numbered US97/10878.00

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by



0005

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

Page 1 of 2



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Teleflex Medical

ISO 13485:2016
EN ISO 13485:2016



Issue 20

Detailed scope

Design, development, manufacture and distribution of reusable medical and surgical instruments for general and specialty use; sterile and non-sterile disposable surgical, urology, anaesthesia and respiratory medical devices, sterile disposable electrosurgical medical devices. Design of Non-Sterile Nasal and Oral Mucosal Devices. Design and development of sterile single use absorbable and non-absorbable sutures, pledgets and suture guides and manufacturing of non-sterile absorbable and non-absorbable suture material. Manufacturing of sterile single use absorbable and non-absorbable sutures.

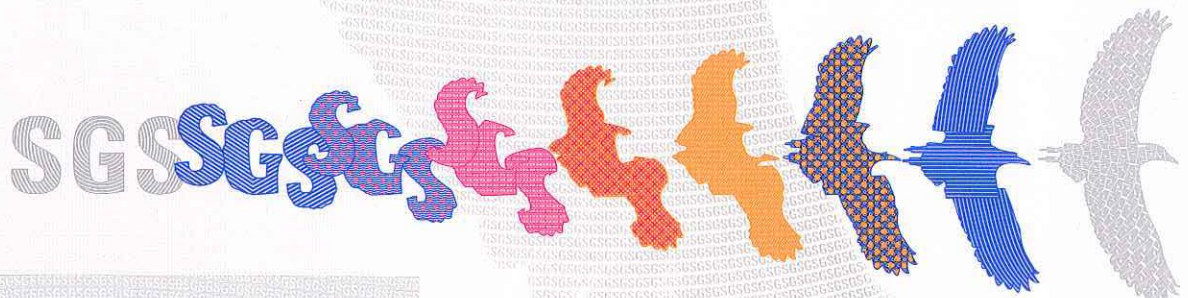
Distribution of sterile single use absorbable and non-absorbable sutures and non-sterile suture material. Distribution of medical devices for endoscopy; fiber optic illuminators; sterile single use instruments for cardiovascular and general surgical procedures.

Additional facilities

375 Forbes Blvd, Mansfield, MA, 02048-1805, United States
2917 Weck Drive, Research Triangle Park, NC, 27709, United States



0005



FLUIDSHIELD* Level 1

Surgical & Procedure Masks

ASTM F2100-11 Level 1 Compliant



SOFTNESS AND BREATHABILITY
FOR COMFORTABLE FLUID
PROTECTION

FLUID-RESISTANT PROTECTION



For assured Level 1 fluid protection
look for this symbol on the package!



FLUIDSHIELD* Level 1

Surgical & Procedure Masks

ASTM F2100-11 Level 1 Compliant

CHOOSE THE MASK THAT FITS THE TASK

In protecting against infection, face masks are perhaps the most personal of equipment choices. HALYARD* Level 1 Surgical and Procedure Masks deliver both comfort and protection. When you're involved in any task with any possibility of low fluid exposure, you'll breathe easier knowing these masks meet the new ASTM F2100-11 Level 1 standard. Level 1 Procedure and Surgical Masks feature an inner layer of SO SOFT* bicomponent fabric technology for comfort.

Level 1 Surgical and Procedure Masks

Test Method	Test Description	ASTM F2100-11 Requirement Level 1	Level 1 Mask*
ASTM F1862	Fluid Resistance with synthetic blood	80 mm Hg	80 mm Hg
MIL-M-36954C	Delta P	< 4.0 mm H ₂ O	2.7 mm H ₂ O
ASTM F2101	Bacterial Filtration Efficiency (BFE)	≥ 95%	99.9%
ASTM F2299	Submicron Particle Filtration (PFE)	≥ 95% @ 0.1 micron	99.8%
16 CFR Part 1610	Flammability	Class 1	Class 1

*Based on the calculated median

EN14683

EU Standard Class	Bacterial Filtration Efficiency	Breathing Resistance (Pa)	Splash Resistance (kPa)	Microbial Cleanliness (cfu/g)
Type I	95 %	< 29.4	NA	≤ 30
Type II	98 %	< 29.4	NA	≤ 30
Type IIR	98 %	< 49.0	≥ 120	≤ 30

HALYARD* ASTM face masks are designed to meet industry standards and regulations, including EN14683. Some masks in the facial protection range designed for specific clinical applications meet EN 149:2001.

LEVEL 1

FEATURE AN INNER LAYER OF SO SOFT* BICOMPONENT FABRIC TECHNOLOGY FOR ADDED COMFORT.



Procedure Mask



Fog-Free
Surgical Mask



Surgical Mask



ASTM F2100-11
LEVEL 1



LOW FLUID PROTECTION

FLUIDSHIELD* Level 1 Surgical and Procedure Masks

Item #	ASTM F2100-11 LEVEL 1 Product Description	Colour	Packaging
25867	Procedure Mask with earloops	Yellow	50 masks/box 10 boxes/case
25869	Procedure Mask with earloops	Blue	50 masks/box 10 boxes/case
28802	Surgical Mask with ties	Blue	50 masks/box 6 boxes/case
28806	Fog-Free Surgical Mask with ties	Green	50 masks/box 6 boxes/case

For ordering information, please contact
your Halyard Health customer services team:
Tel: 0800 917 6585 (from UK)
Fax: 0800 169 0235 (from UK)
Tel: +32 2 711 2660 (from other countries)
Email: customerservice.uk.ie@hyh.com

Sensitive Skin Comfort



Surgical and Procedure Masks Fluid-Resistant Protection

THE MASKS YOU'VE BEEN WAITING FOR ARE HERE

Halyard has always offered the best in facial and respiratory protection. Now, with our new line of Level 1 fluid-resistant face masks designed for sensitive skin, you can have the comfort you've always wanted, without sacrificing protection.

Introducing three new Level 1 Surgical and Procedure Masks.

- Feature an inner lining made of our exclusive SO SOFT* fabric, a unique bicomponent material that was rated softest and silkiest among leading masks tested.¹
- Provide ASTM F2100-11 Level 1 protection, for procedures with risk of low fluid exposure.
- Dye-free inner lining, designed specifically for those with sensitive skin.



For assured Level 1, 2, or 3 fluid protection.

Look for the symbol on the package!

LEVEL 1

Test Method	Test Description	ASTM F2100-11	Masks
ASTM F1862	Fluid Resistance with synthetic blood, in mm Hg	80 mm Hg	80 mm Hg
MIL-M-36954C	Delta P Differential pressure, mm H ₂ O/cm ²	<4.0 mm H ₂ O	2.7
ASTM F2101	Bacterial Filtration Efficiency (BFE), %	≥ 95%	99.9%
ASTM F2299	Submicron Particle Filtration (PFE) @ 0.1 µ, %	≥ 95%	98.8%
16 CFR Part 1610	Flammability	Class 1	Class 1

[†] Based on the calculated median.





41802

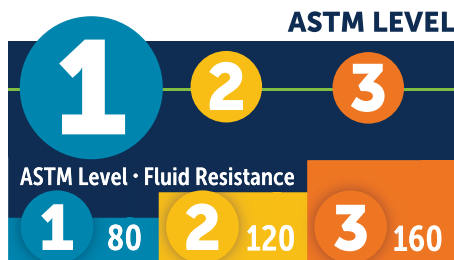


41803



41805

Halyard Level 1 Surgical and Procedure Masks feature the silky feel of our dye-free SO SOFT* inner lining designed for sensitive skin. Offers ASTM F2100-11 Level 1 fluid protection, for low fluid exposure situations.



HALYARD* SURGICAL AND PROCEDURE MASKS

Code	Description	Masks/Box	Boxes/Case	Case Count
41802	Fog-Free Procedure Mask, with SO SOFT* Lining, Earloops, White, ASTM Level 1 Fluid-Resistant	50	10	500
41803	Fog-Free Procedure Mask, with WrapAround Visor, SO SOFT* Lining, Earloops, White, ASTM Level 1 Fluid-Resistant	25	4	100
41805	Surgical Mask, with SO SOFT* Lining, Ties, White, ASTM Level 1 Fluid-Resistant	50	6	300

TRY OUR COMPLETE LINE OF ASTM F2100-11 LEVEL 1 FLUID-RESISTANT MASKS

Code	Description	Masks/Box	Boxes/Case	Case Count
25867	Procedure Mask with SO SOFT* Lining, Earloops, Yellow	50	10	500
25868	Procedure Mask with SO SOFT* Lining, Earloops, Lavender	50	10	500
25869	Procedure Mask with SO SOFT* Lining, Earloops, Blue	50	10	500
28802	Surgical Mask with SO SOFT* Lining, Ties, Blue	50	6	300
28806	Fog-Free Surgical Mask with SO SOFT* Lining, Ties, Green	50	6	300

For more information, visit our website at www.halyardhealth.com, or contact your Halyard representative.



KNOWLEDGE NETWORK* Accredited Education
In-Service Training and Technical Support
Credentialed Sales Representatives
Tools & Best Practices
Clinical Research
Commitment to Excellence

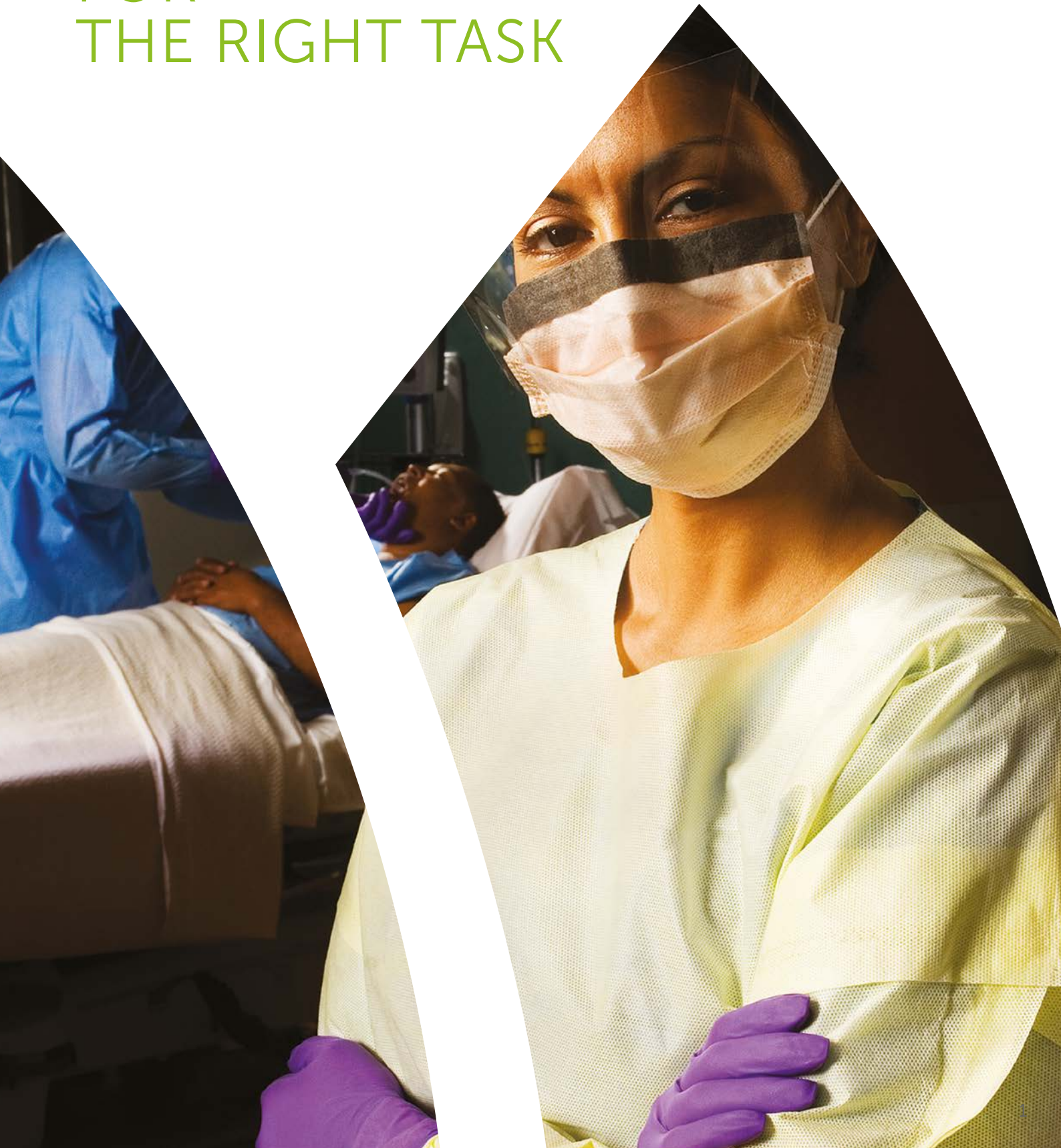
www.halyardhealth.com



¹ Kimberly-Clark Sensory Panel Study. 2013

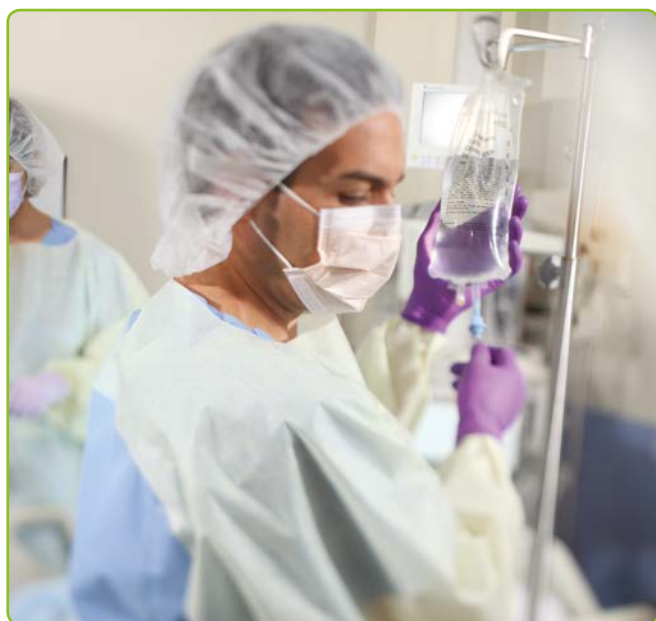
*Registered Trademark or Trademark of Halyard Health, Inc. or its affiliates. © 2014 HYH. All rights reserved.
IP52 C14169

THE RIGHT MASK FOR THE RIGHT TASK



THE PERFECT BALANCE BETWEEN PROTECTION & COMFORT

Halyard Health is a leading provider of infection control, surgical, and VAP solutions that help prevent Healthcare Associated Infections (HAIs), contributing to a safer environment for both healthcare workers and patients. HALYARD* Face Masks offer a very broad range of styles, features, and levels of protection.



DEFINING YOUR NEEDS IN A FACE MASK

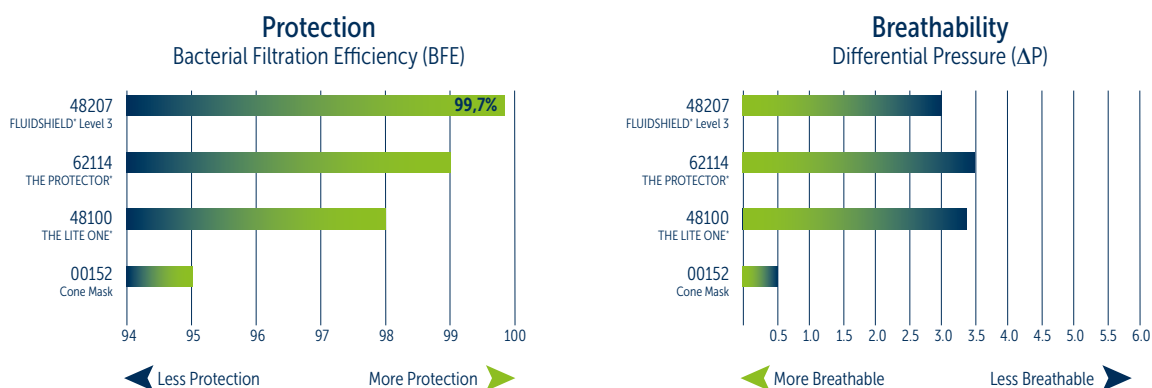
When selecting a face mask, consider the following:

- Protection
- Procedure
- Personal Comfort and Preference

TWO-WAY PROTECTION

The most important element in selecting a face mask is the confidence that comes from knowing that both the patient and the healthcare worker are adequately protected. When addressing facial protection, consider the following:

- What are the airborne infection risks?
- Is there a risk of contact with bodily fluids?
- Is eye protection required?
- Does the patient have respiratory symptoms?
- Is there a potential exposure to laser or cautery plume?



These charts illustrate the protection and breathability of several of our face masks and show the correlation between protection and breathability.

PROCEDURE: WHAT AND WHERE

Selecting an appropriate face mask requires careful examination of the types of procedures that will be routinely conducted and where they will be performed.

- How long are the procedures?
- Is the procedure fluid intensive and is there a risk for splashing and spraying?
- Is it an aerosol generating procedure?
- Does your facility or professional organisation have policies or standards associated with the procedures?

Just as procedures and environments vary, so do individual needs and preferences. The single most important factor in determining whether a mask is comfortable to a wearer is whether the mask's features put the wearer at ease. We all have our own styles, likes and dislikes, and a face mask is one of the most personal products a healthcare professional wears.

PERSONAL COMFORT AND PREFERENCE

"Breathability" is measured by differential pressure, or ΔP (the difference in air pressure on the inside of the mask vs. the outside of the mask during air exchange). The lower the ΔP , the more "breathable" the mask. Cool, easy breathing comfort encourages healthcare worker compliance – a key component in personal protection.

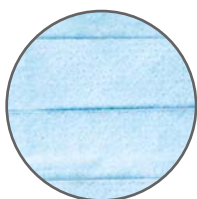
- How "breathable" is a mask?
- From what materials is the mask constructed?

HALYARD HEALTH: THE RIGHT MASK FOR THE RIGHT TASK



Halyard Health offers facial protection products designed to meet industry standards and regulations, such as EN14683:2014 and EN 149:2001, for specific clinical applications. The materials and donning attachments are sonically bonded, and all masks¹ have enclosed nosepieces to assist in conforming to the contours of the face. All face masks are natural rubber latex & DEHP (di-2-ethylhexyl phthalate) free.

PRODUCT PORTFOLIO



STANDARD FACE MASKS

Protection for General Patient Care.

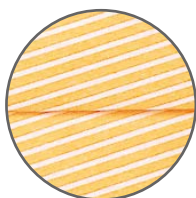
- Protective three-layer construction
- Exposure to blood and/or bodily fluids is not a risk
- Appropriate for general patient care and isolation



SPECIALTY FACE MASKS

Unique Features to Accommodate a Vast Range of Individual Performance Needs and Clinical Requirements.

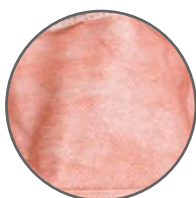
- Fog reduction
- Larger breathing chambers for increased comfort
- Patented designs to enhance facial fit



FLUID RESISTANT FACE MASKS

A Complete Family of Fluid Resistant Facial Protection Products. FLUIDSHIELD* Level 2 & Level 3 products meet EN14683:2014 Type IIR standards for facial protection against the penetration of blood and bodily fluids.

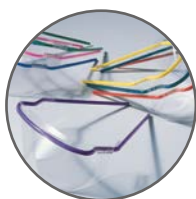
- Constructed with a patented combination of materials to resist fluid penetration upon impact
- Features POWERGUARD* equipped filter media
- Some feature anti-glare visors
- Offered in a wide variety of styles and features



RESPIRATOR FACE MASKS

Tested and approved according to the EN 149:2001 norm on Particle Filtration Half Masks. The HALYARD* P1, P2 and P3 respirators are designed to provide an effective facial fit, as required for proper respiratory protection against airborne pathogens.

- Features a large breathing chamber
- Tight facial fit with soft inner facing



EYEWEAR AND FACE SHIELDS

Designed for use in situations where risk of exposure to blood and/or bodily fluids through splashing is possible.

- Lightweight eyewear with colorful frames
- Single-use lenses easily replaced into reusable frames
- Face Shields equipped with a foam band and headband
- Can be worn with glasses or goggles



HALYARD* STANDARD FACE MASKS

PROTECTION FOR GENERAL PATIENT CARE IN ANY SETTING

	Surgical Masks			
	TYPE	CODE	ITEMS/BOX	BOXES/ CASE
 SOFT TOUCH* II SURGICAL MASK, BLUE Description: Pleat-Style with Horizontal Ties	II	47500	50	6
 THE LITE ONE* SURGICAL MASK, BLUE	II	48100	50	6
THE LITE ONE* SURGICAL MASK, GREEN	II	48105	50	6
THE LITE ONE* SURGICAL MASK, WHITE Description: Pleat-Style with Ties	II	62367	50	6
 CLASSIC* SURGICAL MASK, BLUE Description: Pleat-Style with Ties	I	48201	50	6
 NURSES' SURGICAL MASK, BLUE Description: Pleat-Style with Ties	II	48210	50	6
 TEDDY BEAR* SURGICAL MASK Description: Pleat-Style with Ties, Pink and Blue Teddy Bear Print	II	48296	50	6
 THE FRIENDLY* SURGICAL MASK, WHITE Description: Pleat-Style with Ties	I	59928	50	6
 DUCKBILL* SURGICAL MASK, BLUE Description: Pouch-Style with Ties	I	48220	50	6
 STANDARD SURGICAL MASK, BLUE Description: Pleat-Style with Ties	II	49701	50	6



HALYARD*

FACIAL PROTECTION



Procedure Masks

	TYPE	CODE	ITEMS/BOX	BOXES/ CASE
PROCEDURE MASK, BLUE	I	47080	50	10
PROCEDURE MASK, BLUE	II	47081	50	10
PROCEDURE MASK, GREEN	II	47085	50	10
PROCEDURE MASK, WHITE	II	47090	50	10
PROCEDURE MASK, PINK	II	47095	50	10
PROCEDURE MASK, YELLOW	II	47116	50	10
PROCEDURE MASK, YELLOW	I	47117	50	10

Description: Pleat-Style with Earloops



TEDDY BEAR* PROCEDURE MASK

Description: Pleat-Style with Earloops, Pink and Blue Teddy Bear Print

II	47295	50	10
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DISNEY® SO-SOFT* CHILD FACE MASK

Description: Pleat-Style with Earloops, Disney® Characters Print

I	47127	75	10
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THE LITE ONE* PROCEDURE MASK, BLUE

THE LITE ONE* PROCEDURE MASK, GREEN

Description: Pleat-Style with Earloops

II	62356	50	10
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II	62357	50	10
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STANDARD PROCEDURE MASK, BLUE

Description: Pleat-Style with Earloops

II	49700	50	10
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Cone Masks

CONE MASK, BLUE

Description: Molded Cone-Style with Headband

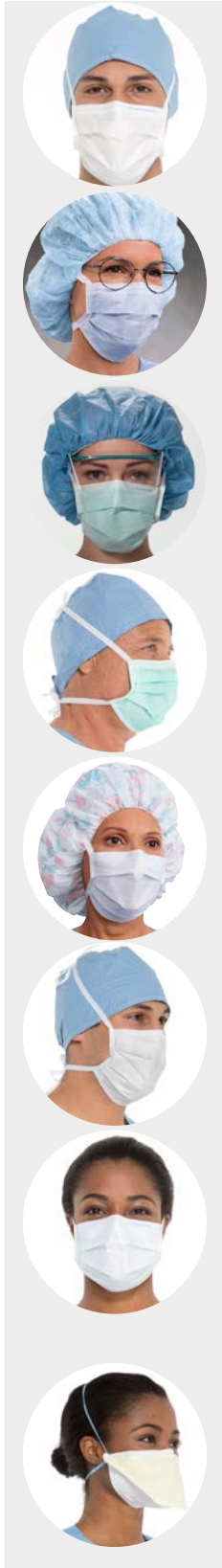
TYPE	CODE	ITEMS/BOX	BOXES/ CASE
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-	00152	50	6
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HALYARD* SPECIALTY FACE MASKS

UNIQUE FEATURES TO ACCOMMODATE A VAST RANGE OF INDIVIDUAL PERFORMANCE NEEDS AND CLINICAL REQUIREMENTS



Surgical Masks	TYPE	CODE	ITEMS/BOX	BOXES/ CASE
FOG-FREE ULTI-MASK* SURGICAL MASK, FOAM BAND, WHITE	II	49310	50	6

Description: Pleat-Style with Ties

FOG-FREE SURGICAL MASK, FOAM BAND, BLUE	II	49214	50	6
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Description: Pleat-Style with Ties

ANTI-FOG SURGICAL MASK W/ DERMA-TOUCH* TAPE, GREEN	II	49215	50	6
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Description: Pleat-Style with Ties

ANTI-FOG SURGICAL MASK, FILM STRIP, GREEN	II	49235	50	6
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Description: Pleat-Style with Ties

SO SOFT* SURGICAL MASK, WHITE	II	48390	50	6
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Description: Pleat-Style with Ties

SURGICAL MASK	II	47625	35	6
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FOG-FREE SURGICAL MASK, FOAM BAND	II	47650	35	6
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Description: Pleat-Style with Ties, Silver

FOG-FREE Procedure Masks	TYPE	CODE	ITEMS/BOX	BOXES/ CASE
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FOG-FREE PROCEDURE MASK, FOAM BAND, BLUE	II	62362	50	10
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SO SOFT* FOG-FREE PROCEDURE MASK, FOAM BAND, WHITE	II	62363	50	10
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Description: Pleat-Style with Earloops

PCM2000* Masks	TYPE	CODE	ITEMS/BOX	BOXES/ CASE
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PCM2000* MASK, REGULAR SIZE, BLUE	II	47700	50	6
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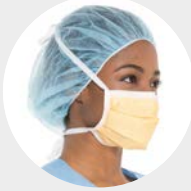
PCM2000* MASK, REGULAR SIZE, YELLOW	II	47717	50	6
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Description: Pouch-Style with Polyurethane Headbands



HALYARD* FLUID RESISTANT FACE MASKS

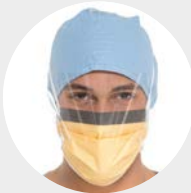
A COMPLETE FAMILY OF FLUID RESISTANT FACIAL PROTECTION



FLUIDSHIELD* LEVEL 3* Surgical Masks

	TYPE	CODE	ITEMS/BOX	BOXES/ CASE
SO SOFT* FLUIDSHIELD* FOG-FREE SURGICAL MASK, FOAM BAND	IIR	48207	50	6
SO SOFT* FLUIDSHIELD* SURGICAL MASK	IIR	48208	50	6

Description: Pleat-Style with Ties, Orange



SO SOFT* FLUIDSHIELD* FOG-FREE SURGICAL MASK W/ SPLASHGUARD* VISOR, FOAM BAND	IIR	48237	25	4
SO SOFT* FLUIDSHIELD* FOG-FREE SURGICAL MASK W/ WRAPAROUND SPLASHGUARD* ANTI-GLARE VISOR, FOAM BAND	IIR	48247	25	4
SO SOFT* FLUIDSHIELD* SURGICAL MASK W/ WRAPAROUND SPLASHGUARD* VISOR	IIR	48248	25	4

Description: Pleat-Style with Ties, Orange



FLUIDSHIELD* LEVEL 3* Procedure Masks

	TYPE	CODE	ITEMS/BOX	BOXES/ CASE
SO SOFT* FLUIDSHIELD* FOG-FREE PROCEDURE MASK, FOAM BAND	IIR	47107	40	10
SO SOFT* FLUIDSHIELD* FOG-FREE PROCEDURE MASK W/ SPLASHGUARD* VISOR, FOAM BAND	IIR	47137	25	4
SO SOFT* FLUIDSHIELD* FOG-FREE PROCEDURE MASK W/ WRAPAROUND SPLASHGUARD* VISOR, FOAM BAND	IIR	47147	25	4

Description: Pleat-Style with Earloops, Orange



SO SOFT* FLUIDSHIELD* PROCEDURE MASK W/WRAPAROUND SPLASHGUARD* VISOR	IIR	00146	25	4
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Description: Pleat-Style with Earloops, Blue



FLUIDSHIELD* LEVEL 2* Surgical Masks

	TYPE	CODE	ITEMS/BOX	BOXES/ CASE
FLUIDSHIELD* FOG-FREE SURGICAL MASK, FOAM BAND	IIR	28808	50	6
FLUIDSHIELD* FOG-FREE SURGICAL MASK W/WRAPAROUND VISOR	IIR	28809	25	4

Description: Pleat-Style with Ties, Blue with Orange Cross Hatch



FLUIDSHIELD* LEVEL 2* Procedure Masks

	TYPE	CODE	ITEMS/BOX	BOXES/ CASE
FLUIDSHIELD* PROCEDURE MASK	IIR	28810	50	10
FLUIDSHIELD* FOG-FREE PROCEDURE MASK W/WRAPAROUND VISOR	IIR	28821	25	4

Description: Pleat-Style with Earloops, Blue



FLUIDSHIELD* LEVEL 1* Surgical Masks

	TYPE	CODE	ITEMS/BOX	BOXES/ CASE
FLUIDSHIELD* SURGICAL MASK, BLUE	-	28802	50	6
FLUIDSHIELD* SURGICAL MASK, GREEN	-	28806	50	6

Description: Pleat-Style with Ties



HALYARD* FLUID RESISTANT FACE MASKS

A COMPLETE FAMILY OF FLUID RESISTANT FACIAL PROTECTION



FLUIDSHIELD* LEVEL 1* Procedure Masks

TYPE	CODE	ITEMS/BOX	BOXES/ CASE
-	25867	50	10
-	25869	50	10

Description: Pleat-Style with Earloops



FLUIDSHIELD* SPECIALTY Surgical Masks

TYPE	CODE	ITEMS/BOX	BOXES/ CASE
IIR	48297	50	6

Description: Pleat-Style with Ties, Pink and Blue Teddy Bear Print



FLUIDSHIELD* SPECIALTY Procedure Masks

TYPE	CODE	ITEMS/BOX	BOXES/ CASE
IIR	47297	40	10
IIR	47298	25	4

FLUIDSHIELD* TEDDY BEAR* PROCEDURE MASK
FLUIDSHIELD* FOG-FREE TEDDY BEAR* PROCEDURE MASK W/ WRAPAROUND SPLASHGUARD* VISOR, FOAM BAND

Description: Pleat-Style with Earloops, Pink and Blue Teddy Bear Print



FLUIDSHIELD* PCM SPECIALTY Masks

TYPE	CODE	ITEMS/BOX	BOXES/ CASE
IIR	47707	50	6

FLUIDSHIELD* PCM2000* MASK, ORANGE
Description: Pouch-Style with Polyurethane Headbands, Regular Size



THE PROTECTOR* Surgical Masks

TYPE	CODE	ITEMS/BOX	BOXES/ CASE
IIR	62113	50	6

THE PROTECTOR* FOG-FREE SPLASH RESISTANT SURGICAL MASK
Description: Pleat-Style with Ties, Blue with Orange Diamond Print



TYPE	CODE	ITEMS/BOX	BOXES/ CASE
IIR	62114	25	4

THE PROTECTOR* FOG-FREE SPLASH RESISTANT SURGICAL MASK W/ WRAPAROUND SPLASHGUARD* VISOR, FOAM BAND
Description: Pleat-Style with Ties, Blue with Orange Diamond Print



THE PROTECTOR* Procedure Masks

TYPE	CODE	ITEMS/BOX	BOXES/ CASE
IIR	62115	50	10

THE PROTECTOR* SPLASH RESISTANT PROCEDURE MASK, BLUE
Description: Pleat-Style with Earloops

TYPE	CODE	ITEMS/BOX	BOXES/ CASE
IIR	62116	25	4

THE PROTECTOR* FOG-FREE SPLASH RESISTANT PROCEDURE MASK W/ WRAPAROUND SPLASHGUARD* VISOR, FOAM BAND, BLUE
Description: Pleat-Style with Earloops



HALYARD* RESPIRATOR FACE MASKS EYEWEAR & FACE SHIELDS



Respirator Face Masks (EN149: 2001)

	CODE	ITEMS/BOX	BOXES/ CASE
PFR P1*, FILTERING HALF MASK FFP1, WHITE	62354	50	6
PFR P2*, FILTERING HALF MASK FFP2, YELLOW	62408	50	6
PFR P3*, FILTERING HALF MASK FFP3, W/VALVE, WHITE	62360	20	12



SAFEVIEW* Eyewear

	CODE	ITEMS/BOX	BOXES/ CASE
50 Assembled Glasses	SV50A	10	5

Description: 50 Assembled Glasses, Assorted Colours

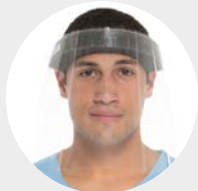


Frames	SV100F	10	10
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Description: 100 Frames, Assorted Colours

Replacement Lenses	SV250L	25	10
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Description: 250 Replacement Lenses, Clear



GUARDALL SHIELD* Face Shields

	CODE	ITEMS/BOX	BOXES/ CASE
GUARDALL SHIELD*	41204	40	1

Description: Full Length Visor (no Mask)

GUARDALL SHIELD*	41205	40	1
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Description: 3/4 Length Visor (no Mask)

Reference: 1. With the exception of cone-style masks.



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HALYARD



Rüsch

Tracheostomy

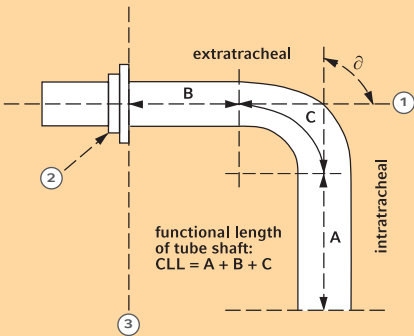
Effectively supporting Tracheostomy Therapy



Teleflex

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Dimensions acc. to
ISO 5366-1 & 5366-3

- ① midline
- ② fixation flange
- ③ reference level



The Optimum Tube for all Applications

Teleflex's large and diverse range of Rüsch tracheostomy tubes caters for the majority of needs associated with creating and maintaining a healthy neck stoma. The optimised ratio between inner and outer diameter is characteristic of all Rüsch tubes and helps to support patient comfort and good work of breathing. High-grade materials, that have been exhaustively tested according to medical criteria, reflect our understanding of high quality.

The Right Solution

With its comprehensive Rüsch tracheostomy portfolio, Teleflex offers solutions for the changing needs of tracheotomy patients. From acute care through to the demands of long-term tracheostomy, Rüsch provides coordinated options for adult and paediatric patients. Accessories can be ordered separately for the economical benefit of the hospital budgets.

	Acute area	ENT	Long-term application	Paediatrics
Crystal Suction	x	x		
CrystalClear Plus	x	x		x
CrystalClear	x	x		x
TracheoFix	x	x	x	
TracFlex Plus	x	x	x	x
TracFlex Plus Subglottic	x	x		
Ultra TracheoFlex	x	x	x	
TracheoFlex	x	x	x	x
TracheoFlex S	x	x	x	x
PercuQuick	x	x		
PercuTwist	x	x		



Paediatric sizes available in several of the ranges

Safety at a glance

Atraumatic tips and rotating connectors, for example in our single use fixed flange range, have been designed for patient comfort and effective stoma care.

Product options

Tracheostomy tubes from Rüsch are available in numerous versions: with or without low-pressure cuff, with or without fenestration and a wide range of flexible reinforced tubes with adjustable flange.

Flexible and adaptable

The innovative adaptation and attachment mechanism of the TracheoFix tubes allows multiple attachments to be added, supporting long term tracheotomy care.

1 Single Use Fixed Flange Tracheostomy Tubes

The design of R sch single use tracheostomy tubes endeavours in reducing the incidence of the most common complications related to a new tracheostomy stomas. Although the reported rate of accidental decannulation is low (0.35 – 2.6%), it carries one of the highest mortality rates (25 – 100%) of any tracheostomy complication.⁸

The combination of a swivel on the 15 mm connector to reduce torque on the ventilator circuit, the acute angle of the tube (95 to 98 degrees) and the colour-coded flexible flange, helps to facilitate a secure fit in new stomas which minimises the movement of the devices in situ.

Crystal Subglottic Suction Tube

Critically ill patients in the Intensive Care Unit (ICU) are at high risk from infections that are associated with increased morbidity, mortality, and healthcare costs.^{1,2} The clearly identifiable suction line moulded into the length of the 98 degree tube enables intermittent and continuous suction from above the cuff where there is potential for oropharyngeal or gastric secretions to pool. The evacuation hole is placed close to the cuff and designed to reduce the microaspiration of secretions, and subsequent bacterial colonisation of the respiratory tract, which is one of the leading causes of VAP.⁷

CrystalClear Plus Tube

The CrystalClear Plus tracheostomy tube set from R sch is an advanced tube system with a colour coded flexible inner cannula system. The thermosensitive, soft plastic material adapts to the patient's anatomy. Secretions are removed simply and efficiently at an early stage of accumulation inside of the tube through frequent changes of the inner cannula, while protecting the inner tube lumen against contamination. Including an open and transparent fixation flange and an integrated rotating connector, this system assists in supporting safety and comfort during use.

The CrystalClear Plus tracheostomy tube is for single use only. The tubes are available with and without low-pressure cuffs and in full and intermediate sizes.

CrystalClear Tube

The single-use R sch CrystalClear tracheostomy tube portfolio from Teleflex is comprised of cuffed, uncuffed or fenestrated (cuffed and uncuffed) tracheostomy tubes that are ideally suited for 'first tube in' situations. Manufactured from thermo-sensitive PVC tubing, and with a thin, flexible, PVC flange, R sch CrystalClear tracheostomy tubes have been designed to assist in patient comfort and effective stoma care.

The flexibility of the flange enables it to conform to the anatomy, with minimal skin contact when a stoma dressing is not required; helping to minimise tube movement during care, and providing ease of access to the stoma site for cleaning, to help reduce the risk of infection.

R sch CrystalClear tracheostomy tubes are available in a full range of paediatric and adult sizes.

- integrated rotating 15 mm connector
- with cuffed versions:
 - valve for Luer and Luer-lock syringe tips
 - blue pilot balloon
 - low-pressure cuff starting from size 6
- continuous X-ray marker along the tube shaft
- latex-free
- sterile
- single use

1.1 Crystal Subglottic Suction

Subglottic Suction Tracheostomy Tube

Set components

- Tracheostomy tube
- Suitable for use with Rüsch flexible Crystal Clear Plus inner cannula
- Soft neck band
- Insertion aid (obturator)
- Patient card



Crystal Subglottic Suction Tracheostomy Tube

REF.	SIZE / I.D. (MM)	O.D. (MM)	LENGTH (MM)	ANGLE θ APPROX.	CUFF Ø (MM)	INNER CANNULA	QTY
20103065	6.5	8.7	64.0	98°	24.0	6.5	10
20103070	7.0	10.0	70.0	98°	26.0	7.0	10
20103075	7.5	10.7	75.5	98°	26.0	7.5	10
20103080	8.0	11.3	81.0	98°	28.0	8.0	10
20103085	8.5	11.3	81.0	98°	28.0	8.5	10
20103090	9.0	12.7	87.0	98°	30.0	9.0	10
20103095	9.5	12.7	87.0	98°	30.0	9.0	10
20103100	10.0	14.0	95.5	98°	30.0	10.0	10

Inner cannula
available separately. See page 7

References:

1. Girou E, Stephan F, Novara A, Safar M, Fagon JY. *Am J Respir Crit Care Med.* 1998;157(4 Pt 1):1151-1158.
2. Bueno-Cavanillas A, Delgado-Rodriguez M, Lopez-Luque A, Schaffino-Cano S, Galvez-Vargas R. *Crit Care Med.* 1994;22(1):55-60.
3. Vincent JL, Bihari DJ, Suter PM, et al. *JAMA.* 1995;274(8):639-644.
4. Kerver AJ, Rommes JH, Mevissen-Verhage EA, et al. *Intensive Care Med.* 1987;13(5):347-351.
5. Rello J, Quintana E, Ausina V, et al. *Chest.* 1991;100(2):439-444.
6. Jimenez P, Torres A, Rodriguez-Roisin R, et al. *Crit Care Med.* 1989;17(9):882-885.
7. Souza CR, Santana VT. *Rev Bras Ter Intensiva.* 2012;24(4):401-406
8. Cipriano A, Mao ML, Hon HH, et al. An overview of complications associated with open and percutaneous tracheostomy procedures. *Int J Crit Illn Inj Sci.* 2015;5(3):179-188..

1.2 CrystalClear Plus

Advanced tube system with a flexible inner tube, made of thermosensitive PVC

CrystalClear Plus Set with cuff

Set components

- Tracheostomy tube
- 2 flexible inner cannulas with colour-coded stopper (\geq size 6)
- Soft neck band
- Insertion aid (obturator) (\geq size 6)
- Water-soluble lubricating jelly, 3 g sachet
- Patient card



REF.	ORDER SIZE / I.D.	QTY
121303	3.5–10.0	5

CrystalClear Plus Set without cuff

Set components

- Tracheostomy tube
- 2 flexible inner cannulas with colour-coded stopper (\geq size 6)
- Soft neck band
- Insertion aid (obturator) (\geq size 6)
- Water-soluble lubricating jelly, 3 g sachet



REF.	ORDER SIZE / I.D.	QTY
121300	3.5–10.0	5

Crystalclear Plus Tubes

	ORDER SIZE / I.D.	O.D.	TOTAL LENGTH (CLL=A+B+C)	DIM. A	DIM. B	DIM. C	ANGLE θ (APPROX.)	CUFF \emptyset	INNER CANNULA*
Paediatrics	● 3.5	5.3 mm	47 mm	17 mm	0	30 mm	95°	11 mm	–
	○ 4.0	5.9 mm	54 mm	18 mm	0	36 mm	95°	12 mm	–
	● 4.5	6.5 mm	54 mm	19 mm	0	35 mm	95°	14 mm	–
	● 5.0	7.0 mm	57 mm	20 mm	0	37 mm	95°	14 mm	–
	● 5.5	7.5 mm	58 mm	20 mm	0	38 mm	95°	15 mm	–
	● 6.0	8.7 mm	64 mm	25.5 mm	0	38.5 mm	95°	19 mm	6.0
Adult	● 6.5	8.7 mm	64 mm	25.5 mm	0	38.5 mm	95°	19 mm	6.5
	● 7.0	10.0 mm	70 mm	29.2 mm	0	40.8 mm	95°	21 mm	7.0
	● 7.5	10.7 mm	75.5 mm	30 mm	0	45.5 mm	95°	25 mm	7.5
	● 8.0	11.3 mm	81 mm	35.5 mm	0	45.5 mm	95°	28 mm	8.0
	● 8.5	11.3 mm	81 mm	35.5 mm	0	45.5 mm	95°	28 mm	8.5
	● 9.0	12.7 mm	87 mm	39.9 mm	0	47.1 mm	95°	28 mm	9.0
	● 9.5	12.7 mm	87 mm	39.9 mm	0	47.1 mm	95°	28 mm	9.5
	● 10.0	14.0 mm	95.5 mm	48.4 mm	0	47.1 mm	95°	30 mm	10.0

* only for 121303 CrystalClear Plus Set




Crystal Clear Plus Inner Cannula

REF.	ORDER SIZE	I.D.	O.D.	QTY
121310	6.0	5.0 mm	5.7 mm	10
	6.5	5.0 mm	5.7 mm	10
	7.0	6.0 mm	6.7 mm	10
	7.5	6.5 mm	7.3 mm	10
	8.0	7.0 mm	7.7 mm	10
	8.5	7.0 mm	7.7 mm	10
	9.0	8.0 mm	8.7 mm	10
	9.5	8.0 mm	8.7 mm	10
	10.0	8.8 mm	9.7 mm	10



- colour coded stopper
- sterile
- single use

Crystal Clear Plus Accessories

	REF.	O.D.	QTY
	121311	shower cap for CrystalClear Plus tubes, acting as a splash guard to prevent the entry or inhalation of water droplets during bathing or showering	4
	121312	cough cap for CrystalClear Plus tubes, to channel expelled secretions downwards	4
	121313	sealing cap for CrystalClear Plus tubes (for weaning therapy)	4

- single use

1.3 CrystalClear

Tracheostomy Tube with or without cuff

Set components

- Tracheostomy Tube
- Neck ties
- Insertion Obturator (from size 6)



CrystalClear Tubes

	REF.*	REF.**		COLOUR CODE	SIZE / I.D. (MM)	O.D. (MM)	LENGTH (MM)	ANGLE Ø APPROX.	CUFF Ø (MM)	INNER CANNULA	QTY
Paediatrics	121710-000035	121610-000035	—	—	3.5	5.3	47.0	95°	11.0	—	5
	121710-000040	121610-000040	—	—	4.0	5.9	54.0	95°	12.0	—	5
	121710-000045	121610-000045	—	—	4.5	6.5	54.0	95°	14.0	—	5
	121710-000050	121610-000050	—	—	5.0	7.0	57.0	95°	14.0	—	5
	121710-000055	121610-000055	—	—	5.5	7.5	58.0	95°	15.0	—	5
	121710-000060	121610-000060	🟠	Orange	6.0	8.7	64.0	95°	19.0	6.0	5
Adult	121710-000065	121610-000065	🟤	Maroon	6.5	8.7	64.0	95°	19.0	6.5	5
	121710-000070	121610-000070	🟡	Blue	7.0	10.0	70.0	95°	21.0	7.0	5
	121710-000075	121610-000075	🟡	Yellow	7.5	10.7	75.5	95°	25.0	7.5	5
	121710-000080	121610-000080	🟣	Lilac	8.0	11.3	81.0	95°	28.0	8.0	5
	121710-000085	121610-000085	🟢	Green	8.5	11.3	81.0	95°	28.0	8.5	5
	121710-000090	121610-000090	🟤	Brown	9.0	12.7	87.0	95°	28.0	9.0	5
	121710-000095	121610-000095	🟦	Navy	9.5	12.7	87.0	95°	28.0	9.0	5
	121710-000100	121610-000100	🔴	Red	10.0	14.0	95.5	95°	30.0	10.0	5

* Without cuff ** With cuff

2 Curved Tracheostomy Tubes with 15 mm connection system

Semiflexible, transparent, made of thermosensitive PVC with “arctic air” surface to assist with tube insertion. Independent 15 mm connection system also facilitates a choice of inner cannula and accessories.

Good ID to OD ratio – resulting in low breathing resistance

and ideal conditions for both artificial ventilation and spontaneously breathing patients.

Curved tube and shape of the tip allows smooth tube exchanges, especially important for carers and patients alike.

2.1 TracheoFix

Tracheostomy Tube made of thermosensitive PVC

The Rüsch TracheoFix tracheostomy tubes have size-specific colour-coded inner cannulas (available with or without a 15 mm connector) that correspond to the matching coloured information on the flange. Moreover, the inner cannula can be removed and cleaned or replaced, helping to prevent the accumulation of biofilm and secretions, which could occlude the cannula and restrict ventilation. The flexibility of the flange enables it to conform to the anatomy and provides ease of access to the stoma site for cleaning and dressing changes, while the curved tube is designed to be easy to insert, supporting carers in the community setting.

Accessories

Accessories for TracheoFix Set available separately. See page 10

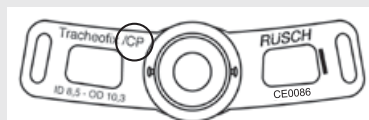
Special feature

TracheoFix Set for PDT. See page 23

- With cuffed versions:
 - valve for Luer and Luer-lock syringe tips
 - blue pilot balloon
 - low-pressure cuff
- With or without phonation window
- Multifunctional connector set with rotary locking mechanism (depending on version with phonation valve, cough cap, sealing cap, 15 mm connector etc.)
- Soft fixation flange, flexible in all directions, with letter coding
- Fixation flange and inner cannula colour-coded according to size
- Innovative connection mechanism for inner cannula systems (rotary locking)
- Continuous X-ray marker along the tube shaft
- Latex-free
- Sterile
- Single patient use

Simple and safe identification

- 1) Marking letters on the fixation flange:
 - C = Tube with cuff (without phonation)
 - P = Tube with phonation (without cuff)
 - CP = Tube with cuff and phonation
 - = Tube without cuff and phonation



- 2) Coloured circle on the inner cannula and colour-code according to size:



Interrupted coloured circle
with phonation



Closed coloured circle
without phonation

TracheoFix TFC Set with cuff, without phonation window



Set components

- Tracheostomy tube
- 2 colour-coded inner cannulas with 15 mm connector, premounted fixation ring, (long)
- Comfort neck band
- Insertion aid (obturator)

REF.	ORDER SIZE/I.D.	QTY
121400	7.0 – 11.0	5

TracheoFix TFP Set without cuff, with phonation window



Set components

- Tracheostomy tube
- 4 colour-coded inner cannulas
 - 1 inner cannula with 15 mm connector, premounted fixation ring, (long)
 - 1 inner cannula with low-profile connector, (short)
 - 1 inner cannula with 15 mm connector, phonation, premounted fixation ring, (long)
 - 1 inner cannula with low-profile connector, phonation, (short)
- Fixation ring
- Cough cap
- Phonation valve with O₂-adapter
- Comfort neck band
- Insertion aid (obturator)

REF.	ORDER SIZE/I.D.	QTY
121420	7.0 – 11.0	5

TracheoFix TF Set without cuff and phonation window



Set components

- Tracheostomy tube
- 2 colour-coded inner cannulas
 - 1 inner cannula with 15 mm connector, premounted fixation ring, (long)
 - 1 inner cannula with low-profile connector, (short)
- Fixation ring
- Cough cap
- Comfort neck band
- Insertion aid (obturator)

REF.	ORDER SIZE/I.D.	QTY
121415	7.0 – 11.0	5

TracheoFix TFCP Set with cuff and phonation window



Set components

- Tracheostomy tube
- 4 colour-coded inner cannulas
 - 1 inner cannula with 15 mm connector, premounted fixation ring (long)
 - 1 inner cannula with low-profile connector, (short)
 - 1 inner cannula with 15 mm connector, phonation, premounted fixation ring, (long)
 - 1 inner cannula with low-profile connector, phonation, (short)
- Fixation ring
- Cough cap
- Phonation valve with O₂-adapter
- Comfort neck band
- Insertion aid (obturator)





REF.	ORDER SIZE/I.D.	QTY
121410	7.0 – 11.0	5

TracheoFix Tube

ORDER SIZE	I.D.	O.D.	TOTAL LENGTH (CLL=A+B+C)	DIM. A	DIM. B	DIM. C	ANGLE θ (APPROX.)	CUFF Ø
7.0	7.2 mm	9.0 mm	70.0 mm	–	–	70.0 mm	102°	27.0 mm
8.5	8.7 mm	10.3 mm	78.0 mm	–	–	78.0 mm	94°	27.0 mm
10.0	10.2 mm	12.3 mm	86.0 mm	–	–	86.0 mm	90°	32.0 mm
11.0	11.2 mm	13.3 mm	86.0 mm	–	–	86.0 mm	92°	35.0 mm

Tracheofix Inner Cannula







Tracheofix Inner Cannula

	REF.	ORDER SIZE	DESCRIPTION	I.D.	O.D.	QTY
	121425	7.0	<ul style="list-style-type: none"> 15 mm connector Premounted fixation ring 	5.5 mm	6.7 mm	10
		8.5		7.0 mm	8.2 mm	10
		10.0		8.5 mm	9.7 mm	10
		11.0		9.5 mm	10.7 mm	10
	121430	7.0	<ul style="list-style-type: none"> Low-profile connector Fixation ring 	5.5 mm	6.7 mm	10
		8.5		7.0 mm	8.2 mm	10
		10.0		8.5 mm	9.7 mm	10
		11.0		9.5 mm	10.7 mm	10
	121435	7.0	<ul style="list-style-type: none"> 15 mm connector Premounted fixation ring Phonation 	5.5 mm	6.7 mm	10
		8.5		7.0 mm	8.2 mm	10
		10.0		8.5 mm	9.7 mm	10
		11.0		9.5 mm	10.7 mm	10
	121440	7.0	<ul style="list-style-type: none"> Low-profile connector Fixation ring Phonation 	5.5 mm	6.7 mm	10
		8.5		7.0 mm	8.2 mm	10
		10.0		8.5 mm	9.7 mm	10
		11.0		9.5 mm	10.7 mm	10

• Latex-free • Sterile • Single use

Tracheofix Accessories

Tracheofix Accessories

	REF.	ORDER SIZE	DESCRIPTION	QTY
	121475	7.0	Insertion aid	1
		8.5		1
		10.0		1
		11.0		1
	121445	–	Sealing cap for • weaning	4
	121450	–	Phonation valve • for 15 mm connectors with SoftMembrane technology • with O ₂ -adapter	2
	121455	–	Phonation valve • with SoftMembrane technology • with O ₂ -adapter	2
	121460	–	Cough cap	4
	121465	–	Fixation ring to secure the TracheoFix inner cannula to low-profile connector	4

3 Reinforced Tracheostomy Tubes

3.1 TracFlex Plus

Armoured tube made of thermosensitive PVC, DEHP-free

The RÜSCH TracFlex Plus product line boasts of reinforced tracheostomy tubes, providing a broad range of products in today's critical and acute care arena.

Sophisticated designs and flexible material, assists in providing comfort for the patient.

The flexible inner cannula system, as well as the distinct colour code feature, facilitates easy maintenance and increases efficiency and safety.

For individual patient care we offer a broad range of accessories.

TracFlex Plus Cuffed & Uncuffed

The tapered atraumatic tip of the tracheostomy tube and the insertion aid, supports easy, gentle and safe tube insertion, which helps to preserve the patient's tracheostoma and tracheal mucosa. Widescope low pressure cuff creates a positive seal.

The adjustable fixation flange system with its effective locking mechanism enables accurate adjustment and secure positioning of the tracheostomy tube to the patient's neck. In addition, fine graduation marks on the tube's shaft facilitates proper alignment, preadjustment and documentation of the position of the fixation flange.

TracFlexPlus Subglottic Suction

Effective subglottic secretion removal as part of a protocol providing a confident strategy to help protect against VAP. During mechanical ventilation, secretions from the upper respiratory tract accumulates above the tube cuff.

Drainage of the subglottic secretions has been proven as an effective strategy in helping to reduce the incidence of VAP when used as part of a VAP bundle.

This tracheostomy tube with integrated suction line is characterized by features to optimise the effectiveness of removing the secretions from above the cuff.

TracFlex Plus Phonation

The innovative combination of an adjustable fixation flange and multiple fenestrations assists in optimal positioning ensuring alignment of the tracheostomy tube is easily and safely achieved.

TracFlex Plus Tube

- Siliconised
- Atraumatic tip
- With cuffed versions:
 - valve for Luer and Luer-lock syringe tips
 - blue pilot balloon
 - low-pressure cuff
- Fixed 15 mm connector
- Soft, movable fixation flange
- Radiopaque
- Latex-free
- Sterile
- Single patient use

TracFlex Plus Subglottic Tube

- Set components
- Tracheostomy tube
 - Comfort neck band
 - Insertion aid (holed obturator)



REF.	ORDER SIZE / I.D.	QTY
121905	7.0–11.0	2

TracFlex Plus Subglottic Tube

ORDER SIZE / I.D.	O.D.	TOTAL LENGTH (CLL=A+B+C)	DIM. A	DIM. B	DIM. C	ANGLE θ (APPROX.)	CUFF Ø
7.0	11.1	67.8 mm	37.0 mm	8.0 mm	22.8 mm	100°	23 mm
8.0	12.6	85.8 mm	40.0 mm	20.5 mm	25.4 mm	100°	27 mm
9.0	13.8	116.8 mm	44.0 mm	46.4 mm	26.4 mm	100°	30 mm
10.0	15.4	119.8 mm	44.0 mm	41.8 mm	34.0 mm	100°	32 mm
11.0	16.7	127.8 mm	47.0 mm	47.7 mm	33.1 mm	100°	34 mm

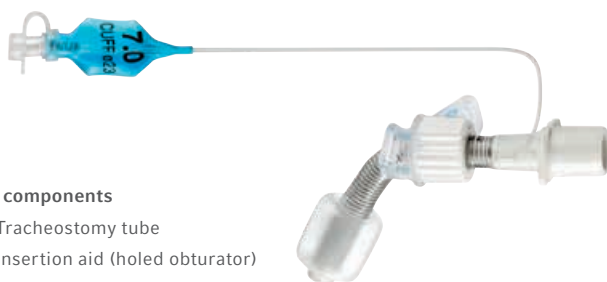
Our Flexible Inner Cannula:
Effective Secretion Management
Made Easy

Our flexible single-use inner cannula is designed to enable a good fit to the inner diameter of the tracheostomy tube facilitating a quick and hygienic removal of secretions. The flexibility of the inner cannula supports a low torque on the tube during cannula changes, simplifies maintenance, and protects the inner lumen of the tracheostomy tube against contamination reducing the risk of infection.



TracFlex Plus Inner Cannulas				
REF.	ORDER SIZE / I. D.	O.D.	TOTAL LENGTH (CLL=A+B+C)	QTY
121910	6.0	5.0	5.7	10
	7.0	5.5	6.2	10
	8.0	6.5	7.2	10
	9.0	7.8	8.3	10
	10.0	8.8	9.4	10
	11.0	9.8	10.4	10

TracFlex Plus Set with cuff



Set components

- Tracheostomy tube
- Insertion aid (holed obturator)
- Comfort neck band
- Tracheostomy tube patient card



REF.	ORDER SIZE / I.D.	QTY
121903	5.0–11.0	5

TracFlex Plus Set without cuff



Set components

- Tracheostomy tube
- Insertion aid (holed obturator)
- Comfort neck band
- Tracheostomy tube patient card



REF.	ORDER SIZE / I.D.	QTY
121900	3.0–11.0	5

TracFlex Plus Tube

ORDER SIZE / I.D.	O.D.	TOTAL LENGTH (CLL=A+B+C)	DIM. A	DIM. B	DIM. C	ANGLE θ (APPROX.)	CUFF Ø *	INNER CANNULA
● 3.0	5.3 mm	45.2 mm	21.1 mm	6.2 mm	17.9 mm	105°	–	–
○ 4.0	6.1 mm	55.2 mm	20.7 mm	8.2 mm	26.3 mm	105°	–	–
● 5.0	7.6 mm	59.2 mm	24.0 mm	7.2 mm	28.0 mm	105°	14 mm	–
● 6.0	8.6 mm	64.2 mm	27.9 mm	7.2 mm	29.1 mm	105°	18 mm	6.0
● 7.0	10.1 mm	67.8 mm	37.0 mm	8.0 mm	22.8 mm	100°	23 mm	7.0
● 8.0	11.1 mm	85.8 mm	40.0 mm	20.4 mm	25.4 mm	100°	27 mm	8.0
● 9.0	12.1 mm	116.7 mm	44.0 mm	46.3 mm	26.4 mm	100°	30 mm	9.0
● 10.0	13.1 mm	119.7 mm	44.0 mm	41.7 mm	34.0 mm	100°	32 mm	10.0
● 11.0	14.2 mm	126.7 mm	47.0 mm	46.6 mm	33.1 mm	100°	34 mm	11.0

* only for 121903

TracFlex Plus Accessories, single use

	REF.	DESCRIPTION	QTY
	121911	Shower cap for TracFlex Plus tubes, acting as a splash guard to prevent the entry or inhalation of water droplets during bathing or showering	4
	121912	Cough cap for TracFlex Plus tubes, to channel expelled secretions downwards	4
	121913	Sealing cap for TracFlex Plus tubes, for weaning therapy	4
	121915 **	Insertion aid for safe and atraumatic introduction of the TracFlex Plus tracheostomy tube	1

** when ordering, please also indicate tube size

TracFlex Plus Phonation Set with cuff



Set components

- Tracheostomy Tube with premounted valve sealing cap
- 2 flexible inner cannulas with colour-coded stopper
- Insertion aid (obturator) with guide wire channel (can also be ordered separately)
- Comfort neck band
- Speaking valve with O₂-adapter (can be ordered separately)

REF.	ORDER SIZE/I.D.	QTY
121902	7.0–11.0	2

TracFlex Plus Phonation Set without cuff



Set components

- Tracheostomy Tube with premounted valve sealing cap
- 2 flexible inner cannulas with colour-coded stopper
- Insertion aid (obturator) with guide wire channel (can also be ordered separately)
- Comfort neck band
- Speaking valve with O₂-adapter (can be ordered separately)

REF.	ORDER SIZE/I.D.	QTY
121901	7.0–11.0	2

TracFlex Plus Phonation Tube

ORDER SIZE / I. D.	O.D.	TOTAL LENGTH (CLL=A+B+C)	DIM. A	DIM. B	DIM. C	ANGLE θ (APPROX.)	CUFF Ø **	INNER CANNULA
● 7.0	10.1 mm	67.8 mm	37.0 mm	8.0 mm	22.8 mm	100°	23 mm	7.0
● 8.0	11.1 mm	85.8 mm	40.0 mm	20.4 mm	25.4 mm	100°	27 mm	8.0
● 9.0	12.1 mm	116.7 mm	44.0 mm	46.3 mm	26.4 mm	100°	30 mm	9.0
● 10.0	13.1 mm	119.7 mm	44.0 mm	41.7 mm	34.0 mm	100°	32 mm	10.0
● 11.0	14.2 mm	126.7 mm	47.0 mm	46.6 mm	33.1 mm	100°	34 mm	11.0

REF.	DESCRIPTION	QTY
121450	Phonation valve with O ₂ -adapter	2

** only for 121902

Inner cannulas & accessories

available separately, see page 12 & 13

3.2 TracheoFlex

Flexible reinforced Tracheostomy tubes made of thermosensitive PVC

The TracheoFlex tubes are soft and flexible. TracheoFlex, tubes for acute use in the ENT area and intensive therapy, are extremely flexible and adaptable. They have a thin-walled (low pressure) cuff, which seal the trachea securely.

The TracheoFlex S range is the right choice for the long-term care of tracheostomy patients and during weaning from the ventilator as supported by a separate 15mm connection system.

The flexible material of the two tracheostomy systems enables them to be introduced atraumatically. The armoring renders the tubes very stable and reduces kinking or compression.

The Extra TracheoFlex tubes are longer in length, curved for ease of insertion and incorporate the secure Rüschi adjustable flange system. Ideal for when distal or proximal extra length is required, especially for patients with unusual anatomy.

TracheoFlex Tube

- Siliconised
- Atraumatic tip
- With cuffed versions:
 - valve for Luer and Luer-lock syringe tips
 - blue pilot balloon
 - low-pressure cuff
- Fixed 15 mm connector
- Soft, movable fixation flange
- Radiopaque
- Latex-free
- Sterile
- Single patient use

Ultra Tracheoflex Set with cuff

Set components

- Tracheostomy tube
- Comfort neck band
- Insertion aid (catheter)



REF.	ORDER SIZE/I.D.	QTY
120304	7.0–11.0	5

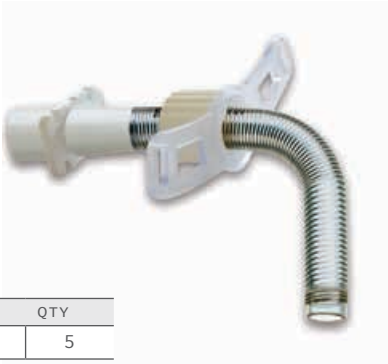
Ultra TracheoFlex Tube

ORDER SIZE/ I.D.	O.D.	TOTAL LENGTH (CLL=A+B+C)	DIM. A	DIM. B	DIM. C	ANGLE θ (APPROX.)	CUFF Ø
7.0 mm	10.4 mm	63.0 mm	32.0 mm	3.0 mm	28.0 mm	90°	22 mm
8.0 mm	11.4 mm	88.0 mm	32.0 mm	21.0 mm	35.0 mm	90°	24 mm
9.0 mm	12.4 mm	117.0 mm	42.0 mm	40.0 mm	35.0 mm	90°	25 mm
10.0 mm	13.4 mm	117.0 mm	46.0 mm	36.0 mm	35.0 mm	90°	26 mm
11.0 mm	14.4 mm	116.0 mm	43.0 mm	34.0 mm	39.0 mm	90°	28 mm

TracheoFlex Set
without cuff

Set components

- Tracheostomy tube
- Comfort neck band
- Insertion aid



a) Movable fixation flange with
unique locking mechanism
in sizes I.D. 7.0 – 12.0 mm



b) Fixation flange with screw
threaded ring
in sizes I.D. 3.0 – 6.0 mm

REF.	ORDER SIZE/I.D.	QTY
120502	3.0–11.0	5

TracheoFlex Tube

	ORDER SIZE/ I.D.	O.D.	TOTAL LENGTH (CLL=A+B+C)	DIM. A	DIM. B	DIM. C	ANGLE θ (APPROX.)	FIXATION FLANGE TYPE
Paediatrics	3.0 mm	5.0 mm	45.0 mm	11.0 mm	15.0 mm	19.0 mm	90°	b
	4.0 mm	6.0 mm	55.0 mm	14.0 mm	21.0 mm	20.0 mm	90°	b
	5.0 mm	7.0 mm	59.0 mm	18.0 mm	19.0 mm	22.0 mm	90°	b
	6.0 mm	8.4 mm	64.0 mm	21.0 mm	19.0 mm	24.0 mm	90°	b
Adult	7.0 mm	10.4 mm	63.0 mm	32.0 mm	3.0 mm	28.0 mm	90°	a
	8.0 mm	11.4 mm	88.0 mm	32.0 mm	21.0 mm	35.0 mm	90°	a
	9.0 mm	12.4 mm	117.0 mm	42.0 mm	40.0 mm	35.0 mm	90°	a
	10.0 mm	13.4 mm	117.0 mm	46.0 mm	36.0 mm	35.0 mm	90°	a
	11.0 mm	14.4 mm	116.0 mm	43.0 mm	34.0 mm	39.0 mm	90°	a
	12.0 mm	15.4 mm	116.0 mm	41.0 mm	34.0 mm	41.0 mm	90°	a

Extra TracheoFlex Set
with cuff

Set components

- Tracheostomy tube
- Comfort neck band
- Insertion aid (catheter)



- In the form of an arc

REF.	ORDER SIZE/I.D.	QTY
120204	7.5–10.5	2

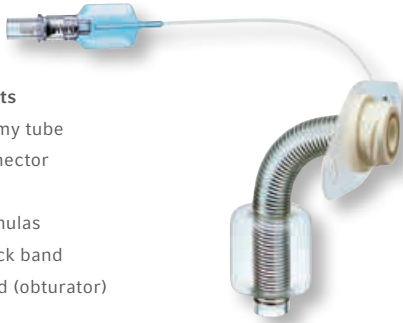
Extra Tracheoflex Tube

I.D.	O.D.	TOTAL LENGTH (CLL=A+B+C)	CUFF Ø
7.5 mm	10.3 mm	155.0	22 mm
8.5 mm	11.3 mm	155.0	24 mm
9.5 mm	12.3 mm	155.0	25 mm
10.5 mm	13.3 mm	155.0	26 mm

TracheoFlex S Set with cuff, without phonation window

Set components

- Tracheostomy tube
- 15 mm connector
- Cough cap
- 2 inner cannulas
- Comfort neck band
- Insertion aid (obturator)



REF.	ORDER SIZE/I.D.	QTY
120000	6.0–11.0	2

TracheoFlex S Set with cuff, with phonation window

Set components

- Tracheostomy tube with phonation window
- Phonation valve
- Sealing cap
- 15 mm connector
- Cough cap
- 2 inner cannulas
- Comfort neck band
- Insertion aid (obturator)



REF.	ORDER SIZE/I.D.	QTY
120001	6.0–11.0	2

TracheoFlex S Set without cuff, without phonation window

Set components

- Tracheostomy tube
- 15 mm connector
- Cough cap
- 2 inner cannulas
- Comfort neck band
- Insertion aid (obturator)



REF.	ORDER SIZE/I.D.	QTY
120100	6.0–11.0	2

TracheoFlex S Set without cuff, with phonation window

Set components

- Tracheostomy tube with phonation window
- Phonation valve
- Sealing cap
- 15 mm connector
- Cough cap
- 2 inner cannulas
- Comfort neck band
- Insertion aid (obturator)



REF.	ORDER SIZE/I.D.	QTY
120101	6.0–11.0	2

Caution: When using tracheostomy tubes without a phonation window, the phonation valve should not be attached when the cuff is blocked (airway obstruction).

When using a phonation valve or a sealing cap, only use tracheostomy tubes with a phonation window and deflate any cuffs prior to use. Also remove the inner cannula, if present, from the tube first.

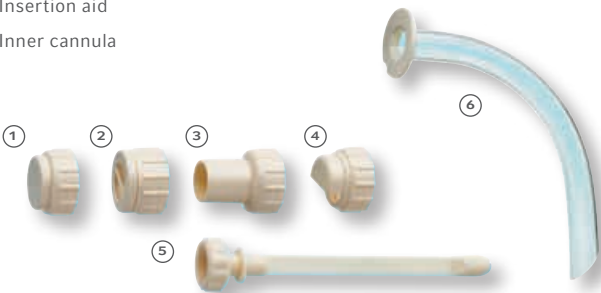
Tracheoflex S Tube

- Siliconised
- Atraumatic tip
- With or without phonation window
- With cuffed versions:
 - valve for Luer and Luer-lock syringe tips
 - blue pilot balloon
 - low-pressure cuff
- Soft fixation flange
- Radiopaque
- Latex-free
- Sterile
- Single patient use


Set components

Multifunctional connector set with screw cap

- ① Sealing cap
- ② Phonation valve
- ③ 15 mm connector
- ④ Cough cap
- ⑤ Insertion aid
- ⑥ Inner cannula



TracheoFlex S Tube								
	ORDER SIZE/ I.D.	O.D.	TOTAL LENGTH (CLL=A+B+C)	DIM. A	DIM. B	DIM. C	ANGLE θ (APPROX.)	CUFF Ø
Paed.	6.0 mm	9.4 mm	61 mm	26.7 mm	7.4 mm	26.7 mm	106°	18 mm
Adult	7.0 mm	10.4 mm	66.5 mm	27.8 mm	8.7 mm	29.8 mm	101°	22 mm
	8.0 mm	11.4 mm	76.6 mm	32.5 mm	12.7 mm	31.4 mm	95°	24 mm
	9.0 mm	12.4 mm	76.6 mm	30.5 mm	11.5 mm	34.5 mm	95°	25 mm
	10.0 mm	13.4 mm	87.6 mm	36.5 mm	15.0 mm	36.1 mm	95°	26 mm
	11.0 mm	14.4 mm	87.6 mm	34.5 mm	13.8 mm	39.2 mm	95°	28 mm



Tracheoflex S inner cannula

- Without phonation window
- Atraumatic tip
- With low-profile connector
- Sterile
- Single patient use

Fixation through accessories, such as the 15 mm connector or the cough cap.

TracheoFlex S inner cannula

REF.	ORDER SIZE	I.D.	O.D.	QTY
858135	6.0	4.0 mm	5.0 mm	1
	7.0	5.0 mm	6.0 mm	1
	8.0	6.0 mm	7.0 mm	1
	9.0	7.0 mm	8.0 mm	1
	10.0	8.0 mm	9.0 mm	1
	11.0	9.0 mm	10.0 mm	1

4 Tracheostomy Tubes for Paediatrics

The atraumatic tip is gentle to the mucosa and facilitates gentle introduction while the thermoplastic material conforms optimally to the child's anatomy. As a result of

years of experience in the development of "small" tubes, Rüsch helps to make tracheostomy as pleasant and safe as possible for children.

4.1 TracFlex Plus

Armoured tube made of soft thermosensitive PVC, DEHP-free

The tube angle of 105° helps to support good fit, as well as an easy and gentle application. The flexible V-shaped fixation flange compensates the sloping pull of the neck band to help facilitate stress-free use.

- atraumatic tip
- with cuffed versions:
 - valve for Luer and Luer-lock syringe tips
 - with valve sealing cap
 - blue pilot balloon
 - low-pressure cuff
- fixed 15 mm connector
- soft, movable, colour-coded fixation flange
- with unique safe locking mechanism
- radiopaque
- latex-free, DEHP-free
- sterile
- single patient use

Inner cannulas & accessories
available separately, see page 13

TracFlex Plus Set with cuff

Set components

- Tracheostomy tube
- Insertion aid (obturator)
- Comfort neck band
- Patient card



REF.	ORDER SIZE/I.D.	QTY
121903	5.0 – 6.0	2

TracFlex Plus Set without cuff

Set components

- Tracheostomy tube
- Soft neck band
- Insertion aid (obturator) (≥ size 6)
- Water-soluble lubricating jelly, 3 g sachet



REF.	ORDER SIZE/I.D.	QTY
121900	3.0 – 6.0	5

TracFlex Plus Tube

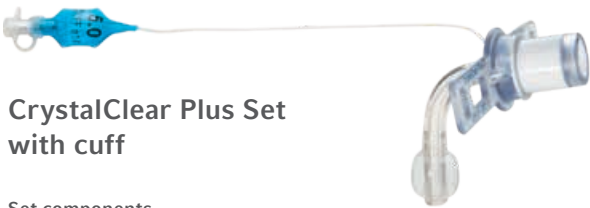
ORDER SIZE / I.D.	O.D.	TOTAL LENGTH (CLL=A+B+C)	DIM. A	DIM. B	DIM. C	ANGLE θ (APPROX.)	CUFF Ø *	INNER CANNULA
● 3.0	5.3 mm	45.2 mm	21.1 mm	6.2 mm	17.9 mm	105°	–	–
○ 4.0	6.1 mm	55.2 mm	20.7 mm	8.2 mm	26.3 mm	105°	–	–
● 5.0	7.6 mm	59.2 mm	24.0 mm	7.2 mm	28.0 mm	105°	14 mm	–
● 6.0	8.6 mm	64.2 mm	27.9 mm	7.2 mm	29.1 mm	105°	18 mm	6.0

4.2 CrystalClear Plus

Advanced tube system with a flexible inner cannula system made of thermosensitive PVC

- Integrated rotating 15 mm connector
- With cuffed versions:
 - valve for Luer and Luer-lock syringe tips
 - blue pilot balloon
 - low-pressure cuff
- Colour-coded tube neckplate
- Continuous X-ray marker along the tube shaft
- Latex-free
- Sterile
- Single use

Inner cannulas & accessories
available separately, see page 7

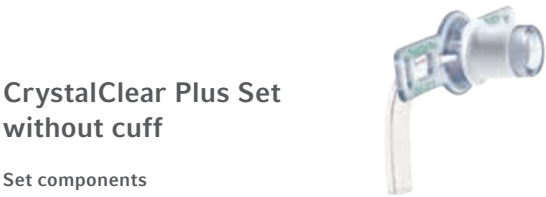


CrystalClear Plus Set
with cuff

Set components

- Tracheostomy tube
- 2 flexible inner cannulas with colour-coded stopper (≥ size 6)
- Soft neck band
- Insertion aid (obturator) (≥ size 6)
- Water-soluble lubricating jelly, 3 g sachet

REF.	ORDER SIZE/I.D.	QTY
121303	3.5–6.5	5



CrystalClear Plus Set
without cuff

Set components

- Tracheostomy tube
- 2 flexible inner cannulas with colour-coded stopper (≥ size 6)
- Soft neck band
- Insertion aid (obturator) (≥ size 6)
- Water-soluble lubricating jelly, 3 g sachet

REF.	ORDER SIZE/I.D.	QTY
121300	3.5–6.5	5

CrystalClear Plus Tube

ORDER SIZE / I.D.	O.D.	TOTAL LENGTH (CLL=A+B+C)	DIM. A	DIM. B	DIM. C	ANGLE θ (APPROX.)	CUFF Ø *	INNER CANNULA
● 3.5	5.3 mm	47 mm	17 mm	0	30 mm	95°	11 mm	–
○ 4.0	5.9 mm	54 mm	18 mm	0	36 mm	95°	12 mm	–
● 4.5	6.5 mm	54 mm	19 mm	0	35 mm	95°	14 mm	–
● 5.0	7.0 mm	57 mm	20 mm	0	37 mm	95°	14 mm	–
● 5.5	7.5 mm	58 mm	20 mm	0	38 mm	95°	15 mm	–
● 6.0	8.7 mm	64 mm	25.5 mm	0	38.5 mm	95°	19 mm	6.0
● 6.5	8.7 mm	64 mm	25.5 mm	0	38.5 mm	95°	19 mm	6.5

4.3 TracheoFlex

Armoured tube made of thermosensitive PVC

- Siliconised
- Atraumatic tip
- Fixed 15 mm connector
- Radiopaque
- Latex-free
- Sterile
- Single patient use

TracheoFlex Set without cuff

- Set components**
- Tracheostomy tube
 - Comfort neck band
 - Insertion aid (catheter)
 - Movable fixation flange with screw threaded ring



movable fixation flange with screw threaded ring



REF.	ORDER SIZE/I.D.	QTY
120502	3.0 – 6.0	2

Tracheoflex Tube

I. D.	O. D.	TOTAL LENGTH (CLL=A+B+C)	DIM. A	DIM. B	DIM. C	ANGLE θ (APPROX.)
3.0 mm	5.0 mm	45.0 mm	11.0 mm	15.0 mm	19.0 mm	90°
4.0 mm	6.0 mm	55.0 mm	14.0 mm	21.0 mm	20.0 mm	90°
5.0 mm	7.0 mm	59.0 mm	18.0 mm	19.0 mm	22.0 mm	90°
6.0 mm	8.4 mm	64.0 mm	21.0 mm	19.0 mm	24.0 mm	90°

5 Percutaneous Tracheostomy (PDT)

All methods facilitate endoscopic monitoring and continuous ventilation. For each method we can offer you well-matched sets as well as an extensive range of set components which can be ordered separately.

Depending on their intended use, the sets can be freely combined. The PercuQuick and PercuTwist sets are pre-configured; with the “Solo set” you choose the tube.

The high-quality tracheostomy tubes come with tips especially adapted to the corresponding dilators.

Thanks to the use of thermosensitive materials, a hydrophilic coating and flexible fixation flanges, these tracheostomy tubes, in connection with the introduction dilators specifically developed for PDT, are a good option.

The revolutionary method: PercuTwist One-Step Dilator

The patented single step dilator lifts the tracheal rings during insertion to help prevent accidental tracheal ring trauma during the percutaneous tracheotomy procedure.

The conventional method: PercuQuick Multi-Step Dilator Set

The traditional step by step dilator system gives you a cost effective choice of which tube and components you can use to best meet the patient needs.

The all-in-one method: PercuQuick One-Step Dilator

Dilation is carried out with only one instrument. As with all of our PDT options, you can select from 4 types of tubes to use with this kit.

PercuTwist One-Step method



PercuTwist Solo set

Ref. 121557

PercuQuick Multi-Step method



PercuQuick dilator set

Ref. 121553



PercuQuick replacement set

Ref. 121551

PercuQuick One-Step method



PercuQuick One-Step set

Ref. 121560



PercuQuick

Ref. 121550



TracFlex Plus

Ref. 121904



TracheoFix

Ref. 121501



CrystalClear Plus

Ref. 121304

5.1 Tracheostomy Tube Kits for use with PDT

PercuQuick Kit

Set components

- Tracheostomy tube with low-pressure cuff
- Movable fixation flange, with simple and safe locking mechanism
- Comfort neck band
- Introduction dilator
- Sterile
- Single use

REF.	ORDER SIZE/I.D.	QTY
121550	7.0/8.0/9.0	1



PercuQuick PDT

I.D. (MM)	O.D. (MM)	TOTAL LENGTH (CLL=A+B+C)	DIM. A (MM)	DIM. B (MM)	DIM. C (MM)	ANGLE θ (APPROX.)	CUFF Ø (MM)
7.0	10.7	81.0 mm	42.0	47.0	28.0	90°	27
8.0	11.7	98.0 mm	42.0	57.0	35.0	90°	32
9.0	12.7	117.0 mm	42.0	77.0	35.0	90°	32

TracheoFix Kit

Set components

- Tracheostomy tube with low-pressure cuff
- Flexible fixation flange
- Comfort neck band
- Introduction dilator
- Sterile
- Single use

REF.	ORDER SIZE/I.D.	QTY
121501	7.0/8.5/10.0	1



TracheoFix PDT

I.D. (MM)	O.D. (MM)	TOTAL LENGTH (CLL=A+B+C)	DIM. A (MM)	DIM. B (MM)	DIM. C (MM)	ANGLE θ (APPROX.)	CUFF Ø (MM)
7.0	9.0	70.0 mm	–	–	70.0	102°	27
8.5	10.3	78.0 mm	–	–	78.0	94°	27
10.0	12.3	86.0 mm	–	–	86.0	90°	32

TracFlex Plus Kit

Set components

- Tracheostomy tube with low-pressure cuff, armoured
- Movable fixation flange, with simple and safe locking mechanism
- Comfort neck band
- Introduction dilator
- Sterile
- Single use

REF.	ORDER SIZE/I.D.	QTY
121904	7.0/8.0/9.0	1



TracFlex Plus PDT

I.D. (MM)	O.D. (MM)	TOTAL LENGTH (CLL=A+B+C)	DIM. A (MM)	DIM. B (MM)	DIM. C (MM)	ANGLE θ (APPROX.)	CUFF Ø (MM)
7.0	10.1	67.8 mm	37.0	8.0	22.8	100°	23
8.0	11.1	85.8 mm	40.0	20.4	25.4	100°	27
9.0	12.1	116.7 mm	44.0	46.3	26.4	100°	30

CrystalClear Plus Kit

Set components

- Tracheostomy tube with low-pressure cuff
- Flexible fixation flange
- 2 colour coded inner cannula
- Comfort neck band
- Introduction dilator
- Sterile
- Single use

REF.	ORDER SIZE/I.D.	QTY
121304	7.0/8.0/9.0	1



CrystalClear Plus PDT

I.D. (MM)	O.D. (MM)	TOTAL LENGTH (CLL=A+B+C)	DIM. A (MM)	DIM. B (MM)	DIM. C (MM)	ANGLE θ (APPROX.)	CUFF Ø (MM)
7.0	10.0	70.0 mm	29.2	–	40.8	95°	21
8.0	11.3	81.0 mm	35.5	–	45.5	95°	28
9.0	12.7	87.0 mm	39.9	–	47.1	95°	28

5.2 PercuTwist One-Step Dilator

Safe, Intuitive and Cost Effective

The Rüsch PercuTwist from Teleflex is a patented single-step dilator for use in percutaneous tracheostomy procedure; using a controllable twist technique to achieve dilation.

The Percutwist technique which is surprisingly simple and gentle. Enhanced cosmetic results are often achieved using the percutaneous tracheostomy in comparison with a surgical tracheotomy, as the access site requires an incision of less than 2 cm. Its innovative design with a dilating thread makes it possible to lift the tracheal anterior wall while simultaneously dilating through simple rotation. The hydrophilic coating reduces friction and allows smoother access into the trachea.

Available in a choice of 3 sizes to enable the device to be used most effectively for a wide range of adult patients.

An unrestricted endoscopic view of the dilation process inside of the trachea is possible, not cutting off the airflow during the procedure.



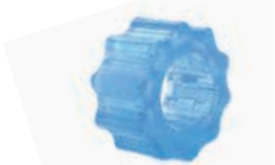
Free Choice

The PercuTwist Solo Set allows you choose the tube to meet your patient's clinical need.


PercuTwist Accessories

All products are in individual sterile packaging.

PercuTwist XXL Handle

	REF.	DESCRIPTION	QTY
	121558	Handle to be attached to the PercuTwist dilator to increase the torque • Sterile, single use	2

First-Step dilator

	REF.	DESCRIPTION	QTY
	121503	Dilator for initial dilation of the trachea O.D. 2.2–6 mm • Sterile, single use	5

PercuTwist complete sets

PercuTwist Set with PercuQuick PDT kit

Set components

- PercuTwist dilator
- PercuQuick tracheostomy tube with introduction dilator
- Guide wire with J-tip and insertion aid
- Puncturing cannula 17G x 70mm/14G x 52mm
- Scalpel
- Luer-lock syringe



- Latex-free
- Sterile
- Single use



REF.	ORDER SIZE/I.D.	QTY
121555	7.0/8.0/9.0	1

PercuTwist Set with CrystalClear Plus PDT kit

Set components

- PercuTwist dilator
- CrystalClear tracheostomy tube with introduction dilator
- Guide wire with J-tip and insertion aid
- Puncturing cannula 17 G x 70 mm/14 G x 52 mm
- Scalpel
- Luer-lock syringe
- Neck band



- Latex-free
- Sterile
- Single use



REF.	ORDER SIZE/I.D.	QTY
121556	7.0/8.0/9.0	1

Combination Possibilities

PercuTwist Solo Set

Set components

- PercuTwist dilator
- guide wire with J-tip and insertion aid
- puncturing cannula
- scalpel
- Luer-lock syringe
- neck band
- latex-free
- sterile
- single use



REF.	ORDER SIZE/I.D.	QTY
121557	7.0/8.0/9.0	1

+



Ref. 121550
Sizes: I.D. 7.0/8.0/9.0 mm



Ref. 121904
Sizes: I.D. 7.0/8.0/9.0 mm



Ref. 121501
Sizes: I.D. 7.0/8.0/9.0 mm



Ref. 121304
Sizes: I.D. 7.0/8.0/9.0 mm

The sizes indicated always correspond to the size of the tracheostomy tube used (see page 23)

5.3 PercuQuick Multi-Step

The conventional method: PercuQuick Multi-Step Dilator Set

The PercuQuick Multi-Step set with its first-step dilator and a further seven dilators that are staggered in size, the tips of which are equipped with a hydrophilic coating, to assist during introduction.

- the hydrophilic coating of the tip facilitates dilation and reduces the forces needed for penetration



PercuQuick Set

Set components

- Complete set with dilators and yellow guide sleeve
- Application set with First-Step dilator, puncturing cannula, scalpel, Luer-lock syringe, neck band and guidewire with J-tip
- PercuQuick tracheostomy tube with low-pressure cuff and introduction dilator
- Sterile
- Single use

REF.	ORDER SIZE/I.D.	QTY
121549	7.0/8.0/9.0	1

The sizes indicated always correspond to the size of the tracheostomy tube used (see page 23)

Combination Possibilities

PercuQuick Replacement Set

Set components

- Application set with First-Step dilator, puncturing cannula, scalpel, Luer-lock syringe, neck band and guidewire with J-tip
- Sterile
- Single use

REF.	QTY
121551	1



+



Ref. 121550
Sizes: I.D. 7.0/8.0/9.0 mm



Ref. 121904
Sizes: I.D. 7.0/8.0/9.0 mm



Ref. 121501
Sizes: I.D. 7.0/8.0/9.0 mm



Ref. 121304
Sizes: I.D. 7.0/8.0/9.0 mm

PercuQuick Dilator Set

Set components

- Set with 7 dilators and yellow guide sleeve
- Sterile
- Single use

REF.	QTY
121553	1



5.4 PercuQuick One-Step

The all-in-one method: PercuQuick One-Step Dilator

Dilation is carried out with only one instrument. The PercuQuick One-Step dilator offers optimum dilation properties thanks to its hydrophilic coating.

- the special shape of the One-Step tip enables dilation in just one step
- now with stopper – for increased safety and better handling



PercuQuick One-Step Set

Set components

- Application set with First-Step dilator, puncturing cannula, scalpel, Luer-lock syringe and guidewire with J-tip yellow guide sleeve
- PercuQuick One-Step dilator
- Sterile
- Single use

REF.	ORDER SIZE/I.D.	QTY
121560	7.0/8.0/9.0	1



PercuQuick One-Step Dilator

REF.	ORDER SIZE/O.D.	QTY
121565	7.0/8.0/9.0 mm	1

6 Speciality Products

EasyCric, the emergency cricothyrotomy set, contains everything needed for rapid intervention in the case of obstruction of the upper respiratory tract, when intubation or ventilation is not possible using the trusted Seldinger technique. The alternative Crocothyrotomy kits TracheoQuick is a faster stab technique kit that is pre-assembled for speed of use.

The unique double-lumen TracheoPart tracheostomy tubes

enable the two sides to be ventilated separately.

The flexible LaryngoFlex tracheostomy tube is the safe and proven solution for tracheostomy patients during anaesthesia.

TPS Multiflex is used to gently shorten the weaning phase of tracheostomy patients.

The tracheostoma retainer is characterised by high patient tolerability as well as simple and safe handling.

6.1 EasyCric

Seldinger based Emergency Cricothyrotomy Set

An intuitive ready to use cricothyrotomy procedure kit, to save precious time when it is needed most

Premounted EasyCric tube and dilator, complete set for adults (size 5)

- Hydrophilic coated
- Anatomically shaped
- Fixed, transparent neck-plate, premounted on the blue insertion dilator
- Ergonomical grip
- 15 mm connector
- Latex-free
- Sterile
- Single use



EasyCric Set

Set components

- Application set with First-Step dilator, puncturing cannula, scalpel, Luer-lock syringe and guidewire with J-tip yellow guide sleeve
- PercuQuick One-Step dilator
- Sterile
- Single use



REF.	ORDER SIZE/I.D.	QTY
120605	5.0	1

EasyCric Emergency Cricothyrotomy Tube

ORDER SIZE	ID BEHIND NECKPLATE	ID AT TIP	OD BEHIND NECK PLATE	OD AT TIP	L (CENTRE LINE)	TOTAL LENGTH	ANGLE IN DEGREE°
5.0	6.0 mm	5.0 mm	8.5 mm	5.8 mm	70.0 mm	95.0 mm	113.5°

Insertion Dilator

ID AT GRIP	ID AT TIP	OD AT TIP	LENGTH BEHIND GRIP TO TIP	TOTAL LENGTH	ANGLE
3.0 mm	1.5 mm	2.0 mm	125.0 mm	130.0 mm	113.5°

6.2 TracheoQuick

Emergency Coniotomy Set

- Alternative method for Cricothyrotomy emergency procedures
- Pre-assembled coniotomy set, ready to use
- Conical introduction dilator made of stainless steel
- Coniotomy tube made of plastic
- 15 mm connector
- Fixation plate
- Mounted stopper
- Latex-free
- Sterile
- Single use

TracheoQuick Coniotomy Tube

ORDER SIZE/I.D.	O.D.
2.0 mm	2.8 mm
4.0 mm	4.8 mm

TracheoQuick plus Coniotomy Tube

ORDER SIZE/I.D.	O.D.
4.0 mm	5.0 mm

TracheoQuick Set without cuff

Set components

- Coniotomy tube
- Flexible tube extension made of silicone with connectors
- Scalpel
- One-way syringe and comfort neck band pre-assembled with tube

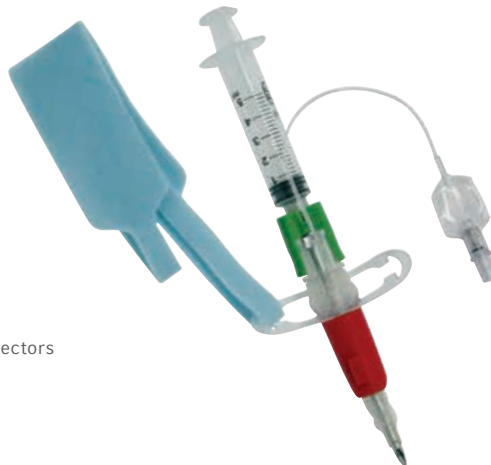


REF.	ORDER SIZE/I.D.	QTY
120600	2.0, 4.0	1

TracheoQuick Plus Set with cuff

Set components

- Coniotomy tube
- Flexible tube extension made of silicone with connectors
- Scalpel
- One-way syringe and comfort neck band pre-assembled with tube



REF.	ORDER SIZE/I.D.	QTY
120604	4.0	1

6.3 TracheoPart

Double-lumen Tracheostomy Bronchial Tube for laterally separated Ventilation made of thermosensitive PVC

- Valve for Luer and Luer-lock syringe tips
- Integrated rotary 15 mm connector
- Open transparent fixation flange
- Continuous X-ray marker
- Latex-free
- Sterile
- Single use

TracheoPart Set for left-sided bronchial intubation

Set components

- Tracheostomy tube
- 2 suction catheters
- 2 angled connecting pieces with extension and closable openings for bronchoscopy
- Y-connector
- Comfort neck band



REF.	ORDER SIZE/I.D.	QTY
116400	7.5 – 9.5	1

TracheoPart Set for right-sided bronchial intubation

Set components

- Tracheostomy tube
- 2 suction catheters
- 2 angled connecting pieces with extension and closable openings for bronchoscopy
- Y-connector
- Comfort neck band



REF.	ORDER SIZE/I.D.	QTY
116401	7.5 – 9.5	1

6.4 LaryngoFlex

Armoured flexible Tracheostomy Tube, for Laryngectomies made of thermosensitive PVC

- Valve for Luer and Luer-lock syringe tips
- Integrated rotary 15 mm connector
- Open transparent fixation flange
- Continuous X-ray marker
- Latex-free
- Sterile
- Single use



LaryngoFlex without Fixation Flange

- With valve for Luer and Luer-lock syringe tips

REF.	ORDER SIZE/I.D.	DESCRIPTION	QTY
121181	7.0–11.0	w/o fixation flange	2

LaryngoFlex Tube

ORDER SIZE/I.D.	O.D.	TOTAL LENGTH (CLL=A+B+C)	DIM. A	DIM. B	DIM. C	ANGLE θ (APPROX.)	CUFF Ø
7.0 mm	10.4 mm	270.0 mm	30.0 mm	173.0 mm	67.0 mm	180°	22 mm
8.0 mm	11.4 mm	270.0 mm	34.0 mm	164.0 mm	72.0 mm	180°	24 mm
9.0 mm	12.4 mm	280.0 mm	42.0 mm	161.0 mm	77.0 mm	180°	25 mm
10.0 mm	13.4 mm	290.0 mm	41.0 mm	167.0 mm	82.0 mm	180°	26 mm
11.0 mm	14.4 mm	290.0 mm	41.0 mm	167.0 mm	82.0 mm	180°	28 mm

6.5 TPS Multiflex



Armoured Tracheostomy Retainer

- Armoured retainer with intratracheal disc, made of silicone
- Evenly spaced armoured sections to allow for length alteration
- Latex-free
- Sterile
- Single patient use

TPS Multiflex Set

Set components

- Tracheostomy retainer
- Sealing cap made of silicone
- 15 mm connector
- Movable fixation flange
- Comfort neck band



a) Movable fixation flange with unique locking mechanism in sizes I.D. 8.0 and 10.0 mm



b) Fixation flange with screw threaded ring in size I.D. 6.0 mm

TPS MultiFlex



	REF.	ORDER SIZE/I.D.	O.D.	TOTAL LENGTH	FIXATION FLANGE TYPE
<i>Paed.</i>	120460	6.0 mm	8.3 mm	110.0 mm	b
<i>Adult</i>		8.0 mm	11.4 mm	110.0 mm	a
		10.0 mm	13.4 mm	110.0 mm	a




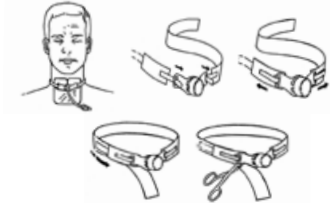
Size 6 available especially for paediatrics

7 Accessories



Comfort Neck Band

	REF.	DESCRIPTION	QTY
 	507900	<ul style="list-style-type: none"> Fits all tracheostomy tubes Single use 	10
	507800	Comfort neck band for paediatric use (not illustrated) <ul style="list-style-type: none"> Extra small version Single use 	10



Comfort Neck Band, Size L

	REF.	DESCRIPTION	QTY
 	507906	<ul style="list-style-type: none"> 2-piece neck band for tracheostomy tubes Progressively adjustable and easily positioned Velcro fastener, secure and easy to fix Non-irritant with cotton exterior and moisture-transporting soft inner layer Specially designed for prolonged use and patients with sensitive skin Latex-free Ready to use Single use Individually packed 	20





TrachFit Neck Band, fits adults and children

	REF.	DESCRIPTION	QTY
 	968671	<ul style="list-style-type: none"> Beige coloured 3-piece neck band for tracheostomy tubes Progressively adjustable and easily positioned Velcro™ fastener, secure and easy to fix Latex-free Sterile Single use Individually packed 	10


Wound Dressing for Tracheostoma

	REF.	DESCRIPTION	QTY
 	503090	<ul style="list-style-type: none"> Special oblique slit to fit optimally around the tracheostomy tube Three-layer highly absorbent material composition Does not stick to the wound Latex-free Sterile, individually packed 	25


SPIRO

	REF.	DESCRIPTION	QTY
	121800	Spiro phonation valve set consisting of: <ul style="list-style-type: none"> • Housing with phonation valve and filter • Housing with filter, without phonation valve • Deflector • Connectors for silver cannulas • Tweezers <ul style="list-style-type: none"> • With oxygen port • Single patient use 	1
	121801	Spiro filter housing with phonation valve <ul style="list-style-type: none"> • Single patient use 	5
	121802	Spiro filter housing without phonation valve <ul style="list-style-type: none"> • Single patient use 	5
	121803	Spiro filter for Spiro filter housing 121800/121801/121802 <ul style="list-style-type: none"> • Single use 	100




Soft Membrane Phonation Valve

	REF.	DESCRIPTION	QTY
	121450	<ul style="list-style-type: none"> • For 15 mm connectors • Soft Membrane technology and O₂-adapter • Single patient use 	2



Cleaning Brushes

	REF.	DESCRIPTION	QTY
	968675	<ul style="list-style-type: none"> • Size 6 mm for tube I.D. 3–6 mm • Size 10 mm for tube I.D. 7–9 mm • Size 15 mm for tube I.D. 10–13 mm 	10


Trach-Vent

	REF.	DESCRIPTION	QTY
	41111	<ul style="list-style-type: none"> Heat and moisture exchanger Suitable for adults and children for tidal volume (TV) > 50 ml Sterile 	50
	41112	<ul style="list-style-type: none"> Heat and moisture exchanger Suitable for adults and children from tidal volume (TV) > 50 ml Clean packed 	50
	61112	<ul style="list-style-type: none"> Holder for artificial nose Trach-Vent 	30
	41172	<ul style="list-style-type: none"> Starter kit Contains 3 Trach-Vents, 1 Trach-Vent holder and 1 Oxy-Vent with tubing 	6


Oxy-Vent

	REF.	DESCRIPTION	QTY
	49912	<ul style="list-style-type: none"> For oxygen supply 	10
	45512	<ul style="list-style-type: none"> For oxygen supply With tubing 	20


Trach-Vent+

	REF.	DESCRIPTION	QTY
	41311U	<ul style="list-style-type: none"> Excellent humidification performance Suitable for adults and children for tidal volume (TV) > 50 ml Sterile 	50
	41312U	<ul style="list-style-type: none"> Excellent humidification performance Suitable for adults and children from tidal volume (TV) > 50 ml Clean packed 	50


Trachjell Lubricating Jelly

	REF.	DESCRIPTION	QTY
	556100	<ul style="list-style-type: none"> Water soluble lubricating gel 8.5 g Sterile 	25



Humid-Vent Mini

	REF.	DESCRIPTION	QTY
	10011	<ul style="list-style-type: none"> Heat and moisture exchanger For tidal volume (TV) 15–50 ml Sterile 	30
	10012	<ul style="list-style-type: none"> Heat and moisture exchanger For tidal volume (TV) 15–50 ml Clean packed 	30


Aqua+ TS

	REF.	DESCRIPTION	QTY
	41574	<ul style="list-style-type: none"> Safety valve O₂-port For tidal volume (TV) 75–1000 ml 	30


Tracheostomy Mask

	REF.	DESCRIPTION	QTY
	1075	<ul style="list-style-type: none"> Adult For aerosol therapy with adults Swivel connector 	50
	41076	<ul style="list-style-type: none"> Paediatric For aerosol therapy with children Swivel connector 	50

Endotest

	REF.	DESCRIPTION	QTY
	112700	<ul style="list-style-type: none"> Apparatus for filling and monitoring the pressure of low-pressure cuffs on tracheal, tracheostomy and bronchial tubes With connecting tube 	1

Connecting Tube made of PVC

	REF.	DESCRIPTION	QTY
	230100	<ul style="list-style-type: none"> Transparent, latex-free, with Luer adapter (male and female) Approx. 100 cm long, 2.0 x 3.0 mm 	1

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Teleflex is the home of Arrow, Deknatel, Hudson RCI, LMA, Pilling, Rüsch, UroLift, and Weck – trusted brands united by a common sense of purpose.

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