

The management system of

Intersurgical Ltd.

Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, UK

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 24 May 2021 until 26 November 2023
and remains valid subject to satisfactory surveillance audits.

Issue 8. Certified since 11 January 1995

Certification is based on reports numbered GB/PC 04303

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by



Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium

t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4 EN rev. 02

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Intersurgical Ltd. Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

Issue 8

Detailed scope

Sterile and Non-Sterile medical devices for respiratory care, in the areas of airway management, anaesthesia, critical care, oxygen and aerosol therapy:

Sterile and Non-Sterile Anaesthetic Breathing Systems

Aerosol and Oxygen Face Masks

Anaesthetic Face Masks

Sterile Endotracheal Tube Introducer and Sterile Airway Stylets

Sterile and Non-Sterile Breathing Systems

Non-Heated Respiratory Bubble Humidifier

Sterile and Non-Sterile Catheter Mounts

Sterile and Non-Sterile Breathing System Connectors

Sterile and Non-Sterile Respiratory Filters

Breathing System Flexible Tubing

High Concentration Oxygen Face Masks

Sterile and Non-Sterile Heat and Moisture Exchangers

Sterile and Non-Sterile HME Filters

Sterile and Non-Sterile Inspiratory Line Humidification Chambers

Sterile I-gel Supraglottic Airways

Sterile Laryngeal Airways

Gas Sampling/Monitoring Respiratory Tubing

Sterile and Non-Sterile Heated Wire Breathing Systems,

Heated Wires and attachments (electrical adaptor leads)

Electrically Powered Moisture Condenser, Nasal Cannulae

Nebulising System Delivery Sets

Suction and Irrigation Oral Care Toothbrush

Oxygen Administration Tubing

Repeated Use Breathing Systems

Breathing Systems Reservoir Bags

Manual Pulmonary Resuscitation Systems

Carbon Dioxide Absorbents

Sterile and Non-Sterile Tracheal Suction Systems

Sterile Endotracheal Tubes

Venturi Valves and Venturi Valve Face Mask Kits

Wall Humidifier Nebuliser

Breathing System Water Traps

CPAP Bi-level Nasal Masks and NIV Face Masks

Pressure Limiting Valves

Peep Valves One Way Directional Valves

Infant Nasal CPAP Breathing System

Oxygen Recovery Kits

Endoscopy Molar Bite Block

Carbon Dioxide Cuvette

Class I sterile: Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile Guedel Airways

Certificate GB19/964232 continued



Intersurgical Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 8

Detailed scope

Additional facilities

Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, UK

Unit 3, Molly Millars Bridge, RG41 2WY, UK

Dray House, Molly Millars Lane, RG41 2PX, UK

Brook House, Molly Millars Bridge,, RG41 2WY, UK

Unit 1, Molly Millars Lane, RG41 2QZ, UK

Circuit House, Pitronnerie Road, Industrial Estate, St Peter Port,
Guernsey, GY1 2RL, UK

UAB Intersurgical Arnionių g.60, LT-18170 Pabradė, Lithuania

Arnionių g. 60A, Pabradė, LT-18170, Lithuania

Arnionių g. 45, Pabradė, LT-18170, Lithuania

Duksto kelias 84A, Visaginas, LT-31146, Lithuania



Certificate GB95/4313

The management system of

Intersurgical Ltd

Crane House, Molly Millars Lane, Wokingham, RG41 2RZ, UK

Brook House, Molly Millars Bridge, Wokingham, Berkshire, RG41 2WY, UK

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

The design, manufacture, and supply of medical respiratory products.

This certificate is valid from 08 August 2021 until 08 August 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date. Issue 27. Certified since 11 January 1995

Authorised by



SGS United Kingdom Ltd

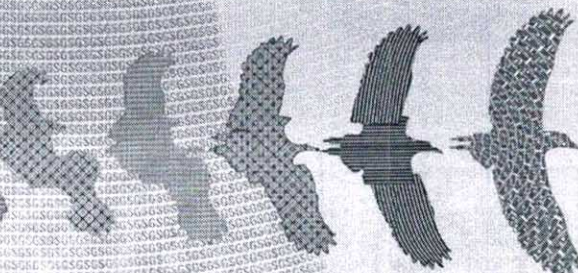
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t+44 (0)151 350-6666 f+44 (0)151 350-6600 www.sgs.com

21HC 9001 2015 0421

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0005



Certificate GB06/70658

SGS

The management system of

Intersurgical Ltd

Crane House, Molly Millars Lane, Wokingham, RG41 2RZ, UK

Brook House, Molly Millars Bridge, Wokingham, Berkshire, RG41 2WY, UK

has been assessed and certified as meeting the requirements of

ISO 14001:2015

For the following activities

The design, manufacture, and supply of medical respiratory products.

This certificate is valid from 08 August 2021 until 08 August 2024 and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 9. Certified since 12 December 2006



0005

Authorised by

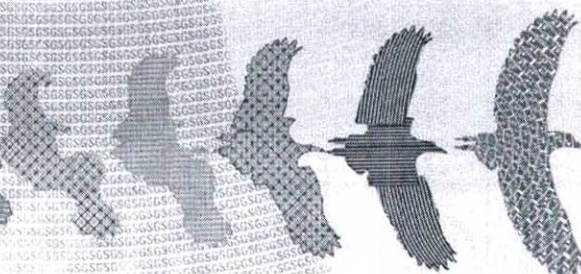
SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 14001:2015_0421

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SGS



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Manufacturer's Authorization

Date: 01.08.2022

To Whom It May Concern

We Intersurgical Ltd, located at Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, United Kingdom are the registered legal manufacturer of medical device for respiratory support. We have factories located at UAB Intersurgical, Arnoniu, g.60, LT-18170 Pabrade, Lithuania, and Intersurgical Ltd., Circuit House, Pitronnerie Road, Industrial Estate, St Peter Port, Guernsey, GY1 do hereby declare that

ECHIPAMED PLUS SRL
str. Valea Trandafirilor 24 "B", of. 2-7
MD-2001, Chisinau
Republic of Moldova

is our official distributor and local representative for the complete range of Intersurgical products, , in the territory of the Republic of Moldova.

We declare that above mentioned company is authorized to quote, sell, subsequently negotiate and sign contracts, perform installation and after sales service, as well as to perform all the procedures required for the expertise process at state registration (re-registration, etc.) of All Intersurgical Product Range of Medical Devices for Respiratory Support in the Republic Moldova, manufactured by us.

We hereby extend our full warranty with respect to the Goods offered by the above company.

This authorization letter will remain valid until 31.12.2027 and all terms and conditions are as per the Distributor Agreement signed by both parties.

Yours sincerely

INTERSURGICAL LTD.

Crane House
Molly Millars Lane
Wokingham, Berks.
RG41 2RZ

Stephen Williams
Global Sales Director



i-gel® supraglottic airway



For use in anaesthesia and resuscitation

i-gel is a truly unique, single use, latex and PVC free second generation supraglottic airway management device that represents the culmination of years of extensive research and development. Made from a medical grade thermoplastic elastomer, i-gel has been designed to create a non-inflatable, anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures whilst avoiding compression trauma.

The i-gel® supraglottic airway is supplied in a fully recyclable protective cradle or cage pack. This unique packaging protects the i-gel in transit and ensures that it maintains its anatomical shape. i-gel is available in seven sizes.

www.i-gel.com

Video available at www.intersurgical.com



15mm connector

Reliable connection to any standard catheter mount or connection

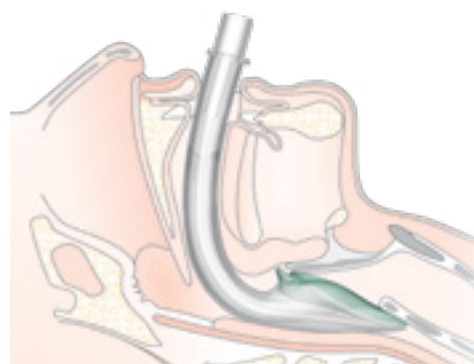
Proximal end of gastric channel

Clearly displayed product information

For quick easy reference. Includes confirmation of size and weight guidance

Position guide (adult sizes only)

Easy confirmation of optimum insertion depth



Gastric channel

The i-gel incorporates a gastric channel (except size 1). It provides an early warning of regurgitation, allows for the passing of a nasogastric tube to empty stomach contents and facilitates venting

Integral bite block

Reduces the possibility of airway channel occlusion

Buccal cavity stabiliser

Aids insertion and eliminates the potential for rotation

Epiglottic rest

Reduces the possibility of epiglottic 'down folding' and airway obstruction

The non-inflatable cuff

Made from a unique soft gel-like material allowing ease of insertion and reduced trauma

Distal end of gastric channel



Code	Description	Size	Weight	Box Qty.
8205000	i-gel, supraglottic airway	5 Large adult	90+kg	25
8204000	i-gel, supraglottic airway	4 Medium adult	50–90kg	25
8203000	i-gel, supraglottic airway	3 Small adult	30–60kg	25
8225000	i-gel, supraglottic airway	2.5 Large paediatric	25–35kg	10
8202000	i-gel, supraglottic airway	2 Small paediatric	10–25kg	10
8215000	i-gel, supraglottic airway	1.5 Infant	5–12kg	10
8201000	i-gel, supraglottic airway	1 Neonate	2–5kg	10



Make an enquiry

OptiLube™ sachets of lubricant

For use with supraglottic airways, endotracheal tubes and naso/oropharyngeal airways

To complement our wide range of airway devices, we are delighted to announce the addition of sachets of lubricant to our product portfolio as a service to our customers.

OptiLube sachets of lubricant contain 5g of water soluble lubricating jelly for use in the preparation of airway devices such as supraglottic airways, endotracheal tubes and naso/oropharyngeal airways. It can also be used to prime the gastric channel of second generation airway devices such as the i-gel® or lubricate suction and orogastric tubes.

OptiLube sachets are harmless to human tissue and will not injure rubber, metal appliances, instruments and natural or synthetic textiles.



Code	Description	Box Qty.
5469000	OptiLube, sachets of lubricant, 5g	150

Make an enquiry

OptiLube is a trademark of Optimum Medical Solutions.

Compact™ extendable anaesthetic breathing systems providing a versatile solution

Optimum compression

Designed for economy, the unique Compact extendable anaesthetic breathing system can be compressed to almost one fifth of its extended length. Supplied in compressed form increasing the number of systems per box, there can be significant space and cost savings compared with other breathing systems. A standard box of Compact systems could provide a hospital with an extra three weeks supply.

- More Compact systems per box
- Lower storage requirements
- Lower freight volume costs
- Improved disposal

Low resistance to flow

Designed with a shallow profile resulting in more laminar gas flow and lower resistance to flow. At 60 L/min, resistance to flow of the extended tube is 1.0 cm H₂O per metre.

Lightweight system

Lighter than other extendable systems ensuring that the 'pull' on the patient's airway device is kept to a minimum.

Low compliance

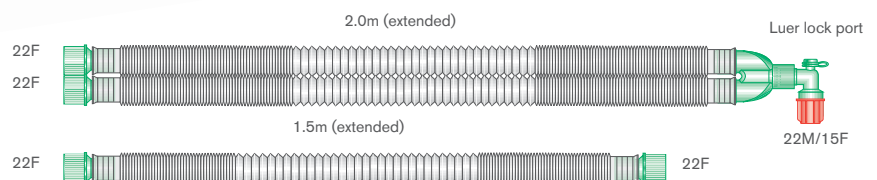
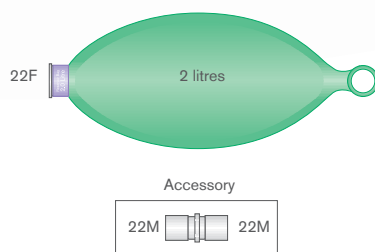
The compliance of the Compact system tube when extended is 4.4ml/kpa per metre of tube, which is less than that required in the ISO 5367:2000 standard.

Adjustable length

Packed and supplied in the shortest length for simple extension to the length required for clinical use.

Easy positioning

The nature of the Compact system tube allows for it to be set in any position required. This results in multiple positioning possibilities, ideal for head and neck surgery where the system can be positioned away from the patient, and does not require any additional patient connections.



👁 system illustrated

Code	Description	Box Qty.
2150000	22mm Compact, extendable breathing system with luer elbow, ≥1.5m	70
2151000 (S*)	22mm Compact, extendable breathing system with luer elbow, ≥2.0m	70 (30*)
2152000	22mm Compact, extendable breathing system with 3L bag and limb, ≥2.0m	35
2153000	22mm Compact, extendable breathing system with 3L bag and filter and limb, ≥2.0m	35
👁 2154000 (S*)	22mm Compact, extendable breathing system with 2L bag and limb, ≥2.0m	35 (20*)
2155000	22mm Compact, extendable breathing system with two re-sealable water traps and limb, ≥3.0m	12
2156000	22mm Compact, extendable breathing system with 2L bag and limb, ≥3.0m	25
2157000	22mm Compact, extendable breathing system with 2L bag and limb, ≥3.0m	25
2158000	22mm Compact, extendable breathing system with luer elbow, ≥3.0m	40
1526000	Compact, extension tube ≥2.0m	100

Make an enquiry

🅈 Sterile option available

(S*) Add an S to the seven digit code number for the sterile version of this product eg. 5000000S (sterile box quantity is shown in brackets).



Contact us

info@intersurgical.com ▪ www.intersurgical.com

Patient spirometry connectors

Replacement spirometry connectors for both our adult and paediatric spirometry kits.

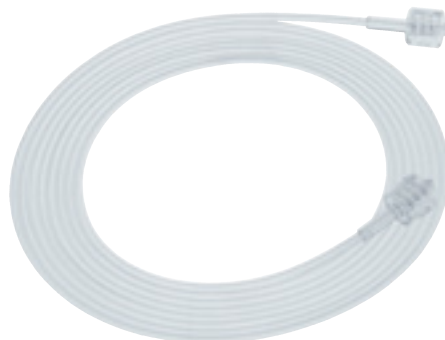


Code	Description	Box Qty.
2742000	Adult, patient spirometry sensor	25
2743000	Paediatric, patient spirometry sensor	25

[Make an enquiry](#)

Respiratory gas monitoring lines

Respiratory gas monitoring lines in various lengths designed to fit between the patient end of the breathing system, via a suitable luer lock connection, and the anaesthesia machine respiratory gas monitor connection. Manufactured from PVC, internally lined with LDPE.



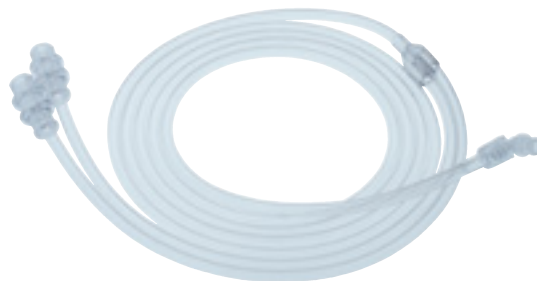
system illustrated

	Code	Description	Length	Box Qty.
	2734000	Respiratory gas monitoring line, 1.2mm ID, male luer lock/male luer lock	≥3.0m	30
	2732000	Respiratory gas monitoring line, 1.2mm ID, male luer lock/male luer lock	≥2.45m	20
	2725000	Respiratory gas monitoring line, 1.2mm ID, male luer lock/male luer lock	≥1.8m	20
	2731000	Respiratory gas monitoring line, 1.2mm ID, female luer lock/male luer lock	≥1.8m	20
	2737000	Respiratory gas monitoring line, 1.2mm ID, male luer lock/male luer lock	≥0.7m	40

[Make an enquiry](#)

Pressure monitoring line kits for use with standard 7.6mm ports

Pressure monitoring kits for anaesthesia machines, which have a separate monitor for measuring airway pressure. They are available as basic kits with standard luer tapers, or with 6mm port connectors. Manufactured from PVC.



system illustrated

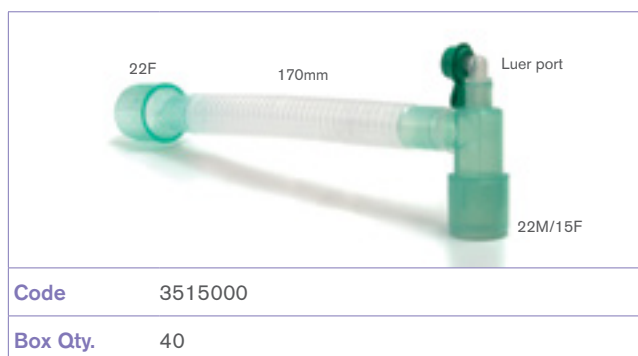
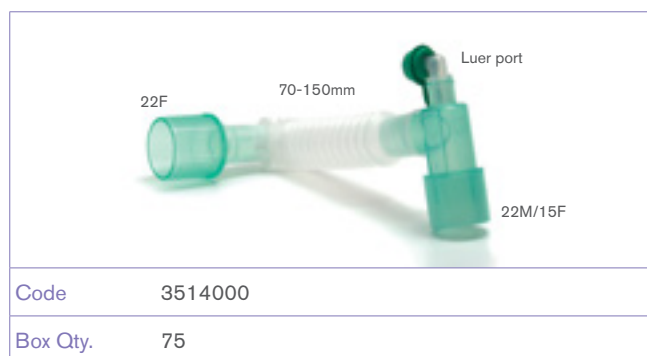
	Code	Description	Length	Box Qty.
	2720000	Pressure monitoring line kit, 3.6mm ID, male luer taper/male luer port	≥1.8m	10
	2721000	Pressure monitoring line kit, 3.6mm ID, 2 x 6mm connectors/male luer port	≥1.8m	10
	2722000	Pressure monitoring line kit, 3.6mm ID, male luer taper and normal line/male luer port	≥1.8m	10
	2723000	Pressure monitoring line kit, 3.6mm ID, 6mm connector/male luer port	≥1.8m	10

[Make an enquiry](#)



Monitoring line connectors

This range of various luer ports and connections are for use in breathing systems that do not include a respiratory monitoring port connection. A hydrophobic filter can be fitted to the monitor connection to protect the monitor.



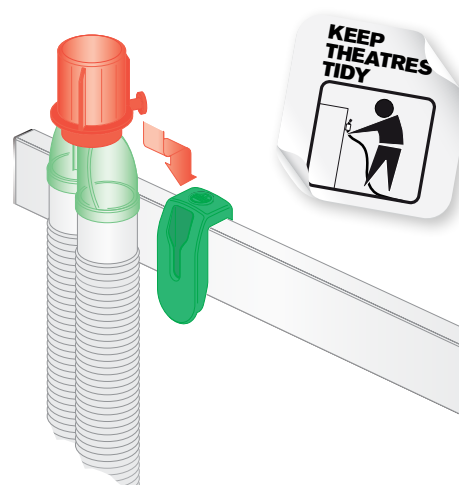
[Make an enquiry](#)

Tube management clip system

Don't trip – Clip

Breathing systems that drag across the floor are unhygienic and can cause accidents. Our new tube management clip system comprises two U-shaped brackets, a single tube clip and a double tube clip to keep bagging limbs and tubes secure. The U-shaped bracket is self adhesive and can be used with the red safety cap supplied with our systems or tube clips.

Video available at www.intersurgical.com



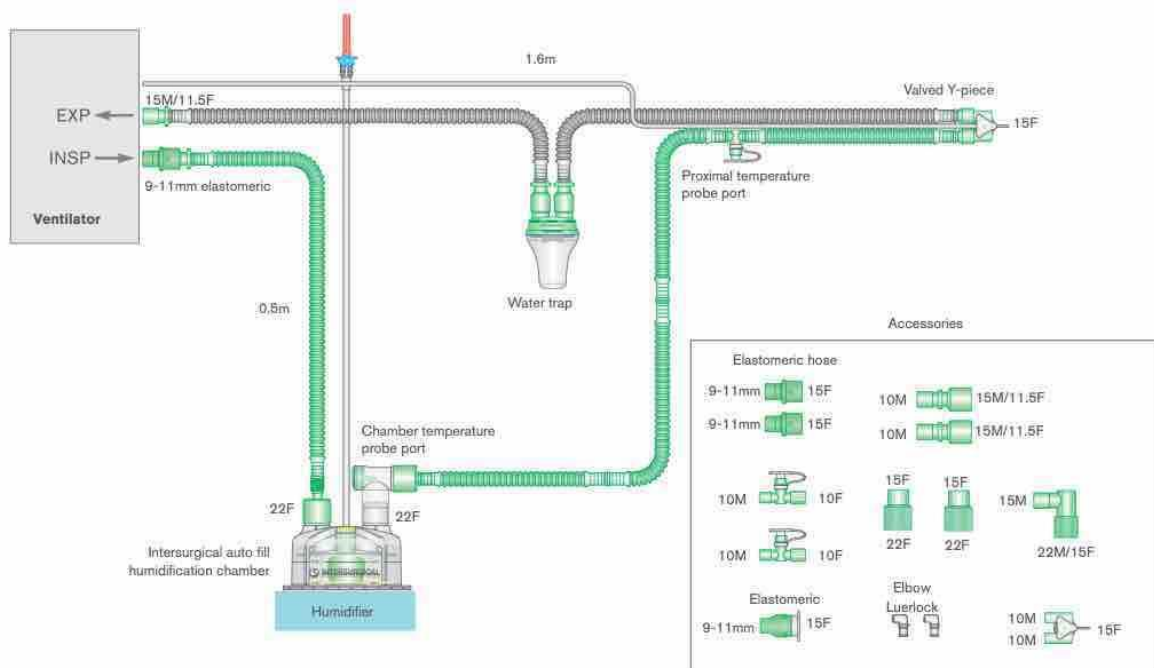
Code	Description	Box Qty.
2316000	Tube management clip system	12

[Make an enquiry](#)

Universal breathing systems for neonatal/paediatric ventilators with 15M and non-standard machine connections

10mm and 15mm Flextube™ breathing systems for active humidification

A range of 10mm and 15mm Flextube single and dual heated wire breathing system for active humidification, set up for ventilators not covered in the previous pages. However, if you do not find a breathing system to suit your requirements please contact us.



Dual heated wire

👁 system illustrated

Code	Description	Box Qty.
4540810	10mm Flextube dual heated wire breathing system universal with Nitric Oxide adaptors, monitor line, auto-fill chamber and extra limb. $\geq 1.6\text{m}$	7
4538810	10mm Flextube dual heated wire breathing system universal with Nitric Oxide adaptors, monitor line, auto-fill chamber and extra limb. $\geq 1.6\text{m}$	8
6393810	10mm Flextube dual heated wire breathing system universal with Nitric Oxide adaptors, monitor line, auto-fill chamber and limb. $\geq 1.2\text{m}$	7
4525850	15mm Flextube dual heated wire breathing system with extra limb. $\geq 1.6\text{m}$	15

Single heated wire

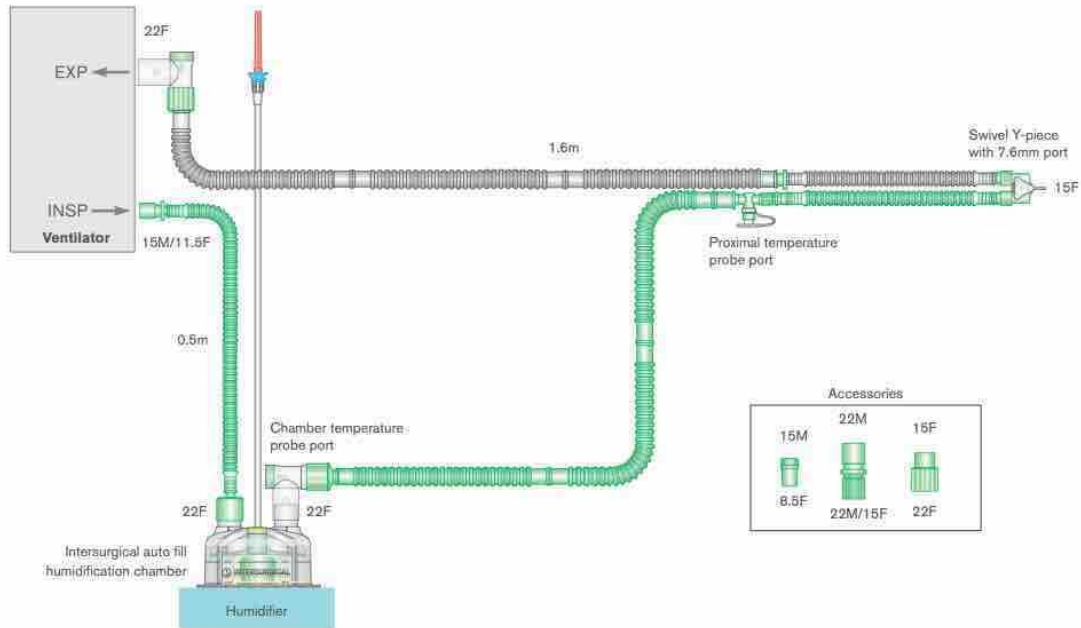
Code	Description	Box Qty.
👁 4519810	10mm Flextube single heated wire breathing system universal with water trap, monitor line, auto-fill chamber and extra limb. $\geq 1.6\text{m}$	7
4523850	15mm Flextube single heated wire breathing system with water trap, monitor line and extra limb. $\geq 1.2\text{m}$	10

Make an enquiry

Universal breathing systems for paediatric/adult ventilators with 22M/15F machine connections

10mm and 15mm Flextube™ breathing systems for active humidification

A range of Flextube dual and single heated wire breathing systems for active humidification, set up for use with adult ventilators with 22mm machine connectors. However, if you do not find a breathing system to suit your requirements please contact us.



Dual heated wire

system illustrated

Code	Description	Box Qty.
6392850	10mm Flextube dual heated wire breathing system with extra limb. $\geq 1.6\text{m}$	15
6392810	10mm Flextube dual heated wire breathing system with auto-fill chamber and extra limb. $\geq 1.6\text{m}$	7
4504018	15mm Flextube dual heated wire breathing system with auto-fill chamber and extra limb. $\geq 1.2\text{m}$	7

Single heated wire

Code	Description	Box Qty.
6091850	10mm Flextube single heated wire breathing system with neonatal water trap and extra limb. $\geq 1.6\text{m}$	15
6091810	10mm Flextube single heated wire breathing system with neonatal water trap, auto-fill chamber and extra limb. $\geq 1.6\text{m}$	20
4504850	15mm Flextube single heated wire breathing system with water trap and extra limb. $\geq 1.2\text{m}$	10

Make an enquiry



Contact us

info@intersurgical.com • www.intersurgical.com

Reservoir bags – single-use

We offer a range of single-use reservoir bags that have excellent compliance characteristics for use in various clinical applications. Available in a range of sizes and bag neck fittings, they are totally latex-free.

The range also includes two bags with our 'Baggins the Bear' symbol for use with paediatric systems. Please see our website for support material for paediatrics.



www.intersurgical.com/info/bagginsbear

Code	Description	Box Qty.
2810000	Reservoir bag, 1L with anti occlusion cage mount, 22F neck	10
2811000	Reservoir bag, 1L with anti occlusion cage mount, 15F neck	10
2812000	Reservoir bag, 1L with anti occlusion cage mount and Baggins the Bear design, 15F neck	10 
2805000	Reservoir bag, 0.5L with anti occlusion cage mount, 15F neck	10
2806000	Reservoir bag, 0.5L with anti occlusion cage mount and Baggins the Bear design, 15F neck	10 

[Make an enquiry](#)


Alterna™ reservoir bags with loop – reprocessable

A latex-free solution for those requiring reliable, high performing, synthetic products in the area of anaesthetic consumables. The bags are manufactured from chloroprene, a synthetic material with similar attributes to natural rubber (NRL), but without the associated danger of Type 1 (protein) allergies. The bags are autoclavable up to temperatures of 134 °C.



Code	Description	Box Qty.
8911000	Alterna, reprocessable reservoir bag, 1L with loop, 22F neck	1
8910000	Alterna, reprocessable reservoir bags, 0.5L with loop, 15F neck	1

[Make an enquiry](#)

 Baggins the Bear design



Contact us

info@intersurgical.com • www.intersurgical.com