i-gel®

The supraglottic airway with a non-inflatable cuff

Airway Management ▪ Airway Devices

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Airway management has evolved

Introducing the i-gel®: a revolutionary single use supraglottic airway from Intersurgical.

i-gel® and natural airway management

The i-gel® is a truly unique single use, latex and PVC free airway device, representing the culmination of years of extensive research and development. Everything about the i-gel® has been designed to work in perfect unison with the anatomy; the i-gel® design was inspired by the physiology of the perilaryngeal framework itself – airway management as nature might have intended.

i-gel® mirrors the anatomy

The shape, softness and contours accurately mirror the perilaryngeal anatomy to create the perfect fit.
This innovative concept means that no cuff inflation is required. The i-gel® works in harmony with the patient's anatomy so that compression and displacement trauma are significantly reduced or eliminated.

The non-inflatable cuff

i-gel® gets its name from the soft gel-like material from which it is made. It is the innovative application of this material that has enabled the development of a unique non-inflatable cuff. This key feature means insertion of i-gel® is easy, rapid and consistently reliable.

The simple, safe and rapid solution

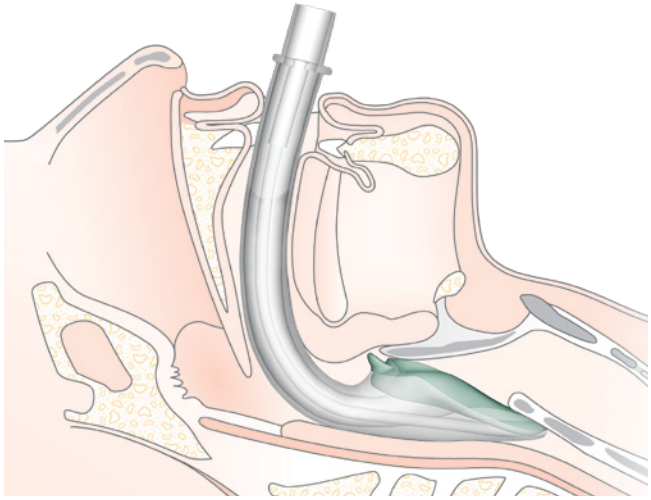
i-gel® is incredibly easy to use. A proficient user can achieve insertion of the i-gel® in less than 5 seconds. With no inflatable cuff, i-gel® provides a safe and rapid airway management solution.

Adults

Adult i-gel® is indicated for securing and maintaining a patient airway in routine and emergency anaesthetics of fasted patients, during spontaneous or intermittent positive pressure ventilation (IPPV), during resuscitation of the unconscious patient, and as a conduit for intubation under fibreoptic guidance in a known or unexpectedly difficult intubation, by personnel who are suitably trained and experienced in the use of airway management techniques and devices.

Accurate and natural positioning

The i-gel® accurately and naturally positions itself over the laryngeal framework, providing a reliable perilaryngeal seal without the need for an inflatable cuff.



Paediatrics

i-gel® is now available in four paediatric as well as three adult sizes, making it applicable for use with patients between 2–90+kg. Paediatric i-gel® is indicated for securing and maintaining a patient airway in routine and emergency anaesthetics for operations of fasted patients during spontaneous or intermittent positive pressure ventilation (IPPV).

Additional information available

An i-gel® user guide, clinical study material and other support documentation is available to download from the i-gel® website at **www.i-gel.com**.

Video available at www.intersurgical.com

Features and benefits

The i-gel® has a host of features that provide significant benefits to the patient and the clinician.

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 the stomach contents and facilitates venting

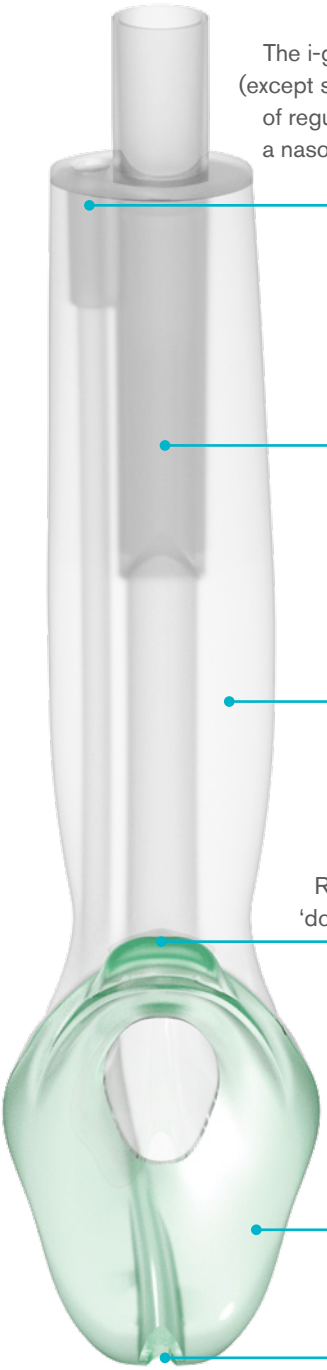
Integral bite block
Reduces the possibility of airway channel occlusion

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



The adult sizes of i-gel® can be used as a conduit for intubation under fibreoptic guidance in a known or unexpectedly difficult intubation

Innovative packaging

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.

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

Make an enquiry

Visit the i-gel® website www.i-gel.com

S Sterile

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INTERSURGICAL® COMPLETE RESPIRATORY SYSTEMS

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The manufacturer Intersurgical Ltd is certified to ISO 9001:2015, ISO 13485:2016 and ISO 14001:2015

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EC Declaration of Conformity

We, Intersurgical Ltd (address: Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, United Kingdom) as manufacturer, hereby declare under the sole responsibility of that the below mentioned devices comply with European Medical Devices Directive 93/42/EEC with all amendments and transposing legislation.

Authorised Representative in the European Economic Area (EEA):
UAB Intersurgical (address: Arnioniu g. 60, Pabradė, LT-18170, Lithuania)

I-gel Supraglottic Airways
These are class IIA medical devices, in accordance with rule 5 of Annex IX of the Medical Devices Directive 93/42/EEC (classification.doc)
Essential requirements checklist is on IQR139.
Internally manufactured components master data is on EFACS (Parts Master) and design drawings are on IQR69 (Product and Mould Drawing List).
Internally manufactured finished products master data, production drawings and Master Product Formulae are on EFACS (Master Product Formula, Parts Master) and IQR69 (Product and Mould Drawing List).
Externally manufactured materials, components, design drawings and products are on EFACS (Parts Master), IQR98 (Incoming Product Specification) and IQR69 (Product and Mould Drawing List).
Instructions for use, pack inserts and labels are as detailed on EFACS (Master Product Formula) and IQR107 (Index of Controlled Artworks).
Label content is on EFACS (Master Product Formula) and Labels Printing System.
Product realisation processes are referenced in IQM section 7.1

Product Codes
As listed in EFACS MPF Details under group DCIGEL.DOC.

This range is subject to the procedure set out in Annex 2 excluding section 4 of Directive 93/42/EEC as amended by 2007/47/EC, under the supervision of Notified Body Number 1639, SGS Belgium NV, SGS House Noorderlaan 87-2030, Antwerpen, Belgium

EC Certificate Full Quality Assurance System GB19/964232 has been issued for the management system of Intersurgical Ltd, which has been assessed and certified according to the requirements of Annex 2 excluding section 4 of Directive 93/42/EEC as amended by 2007/47/EC.

Ivan Seniut
Group Quality and Regulatory Affairs Director
Duly authorised for and on behalf of Intersurgical Ltd
Crane House, Molly Millars Lane, Wokingham,
Berkshire, RG41 2RZ, United Kingdom

Issue 11
Valid from 1 January 2021
DCIGEL.DOC

Appendix for EU Declaration of Conformity Group: DCIGEL.DOC

Product Codes:

8201000	8202000	8203000	8204000	8205000
8215000	8225000	8603000	8604000	8605000
8703000	8703030	8704000	8704030	8705000
8705030	8800000			