




Product Name	Intersurgical EcoLite™, paediatric, medium concentration oxygen mask with tube, 2.1m			
Reference number	1196015			
Product Type	Oxygen Mask Kit			
Manufacturer	Intersurgical			
Materials	  PP PVC TPE Elastic			
Packaging	Unit Packaging Individually packaged Box quantity 40 Pallet quantity 1280			
Instructions for Use	Instructions for use with product No Instructions for use with each box Yes			
Applicable Standards	BS EN ISO 13485: Medical devices — Quality management systems — Requirements for regulatory purposes BS EN ISO 9001: Quality Management Systems - Requirements BS EN ISO 15223-1: Medical Devices - Symbols to be Used with Medical Device Labels, Labelling, & Information to be Supplied BS ISO 18190: Anaesthetic and respiratory equipment - General requirements for airways and related equipment BS EN 13544-2: Respiratory therapy equipment. Tubing and connectors			
Sterile	No			
Shelf life	5 Years			
Disposal Methods	Following use, the product must be disposed of in line with local healthcare hygiene and waste disposal protocols and regulations			
Re-use	 Single use only			

Product characteristics
Technical information – Mask

Patient	Paediatric
Approximate weight (g)	10
Height (mm)	89
Width (mm)	78

Technical information – Oxygen tube

Approximate weight (g)	27
Length (m)	2.1

Technical information - Oxygen concentration

Approximate oxygen concentration (%)	At 3 L/min	41
	At 4 L/min	47
	At 5 L/min	50
	At 6 L/min	56
	At 7 L/min	61

The values are based upon a breathing pattern of 15 breaths per minute, Tidal Volume: 350 ml, and I:E ratio 1:2

Approximate oxygen concentration (%)	At 2 L/min	38
	At 3 L/min	65
	At 4 L/min	72

The values are based upon a breathing pattern of 20 breaths per minute, Tidal Volume: 150 ml, and I:E ratio 1:2

Oxygen concentration is affected by the patient's tidal volume, breathing pattern, the fit of the mask, and the oxygen flow rate used.



**Material
Abbreviations**

ABS	Acrylonitrile Butadiene Styrene
AL	Aluminium
Cu	Copper
EPDM	Ethylene Propylene Terpolymer Rubber
EVA	Ethylene-vinyl acetate
HDPE	High Density Polyethylene
HIPS	High Impact Polystyrene
LDPE	Low Density Polyethylene
LSR	Liquid Silicone Rubber
MBS	Methacrylate Butadiene Styrene
NRL	Natural Rubber Latex
PA	Polyamide (Nylon)
PC	Polycarbonate
PE	Polyethylene
PIR	Polyisoprene rubber
POM	Polyoxymethylene
POP	Ethylene based plastomer
PP	Polypropylene
PPTA	Poly (p-phenylene terephthalamide)
PS	Polystyrene
PSU	Polysulfone
PU	Polyurethane
PVC	Poly Vinyl Chloride
SB	Styrene Butadiene
Si	Silicone
SS	Stainless Steel
TPE	Thermoplastic Elastomer
SBC	Styrene Butadiene Copolymer
SEBS	Styrene-Ethylene-Butadiene-Styrene

