air-Q®sp3G Intubating Laryngeal Airway

air-Q®sp3G with Self Pressurizing Cuff and Gastric Access					
Reference Number	60105 (size 1.0)	60155 (size 1.5)	60205 (size 2		
	60305 (size 3)	60405 (size 4)	60505 (size 5		
Manufacturer	SunMed LLC/Cookgas LLC				
FDA Classification	Class I Medical Device				
FDA Product Code	CAE – Airway, Oropharyngeal, Anesthesiology				
Classifications – EU	Class II, Rule 5 EU MDD 93/42/EEC Annex IX				
CE Mark/Notified Body	CE0482 / Medcert GmbH				
GMDN Code	42424 Oropharyngeal Airway, Single Use				
UMDNS Code	10059 Airways, Oropharyngeal				
Usage	Disposable, Single Patie	nt Use			
Sterile	EO Sterilization				
Patient Population	Infant, Pediatric, Adult				
Packaging	Individually Packaged, 10/case				

Description: A curved tube used in inhalational anesthesia and resuscitation to facilitate and secure airway patency for the delivery and exchange of gases in spontaneously breathing and ventilated patients.

Intended use: To provide an unobstructed airway for gas delivery.

Area of use: Hospitals, pre-hospital, home, surgical centers.

Contraindications: In patients at high risk for regurgitation and/or aspiration.

Device Specifications

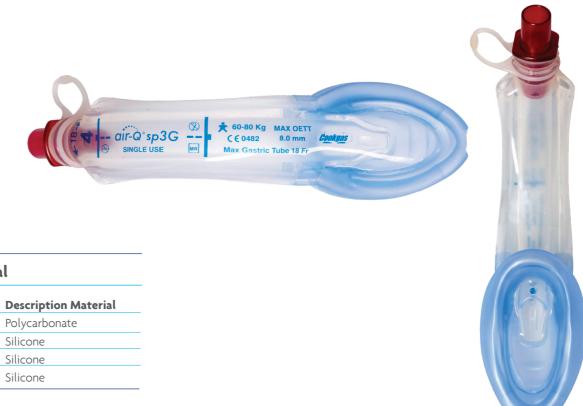
Size	Ideal Body	Maximum	Mouth	Length	Maximum	ET Tube
	Weight (kg)	OETT (mm)	Opening (mm)	of Tube (cm) OG Tube (Fr)	Connector (mm)
0	< 2.0	3.0	5	6.0	6	15
0.5	2 – 4	4.0	8	7.0	6	15
1.0	4 - 7	4.5	11	9.0	8	15
1.5	7 - 17	5.0	14	11.0	10	15
2	17 - 30	5.5	17	14.0	12	15
3	30 - 60	7.0	20	16.0	16	15
4	60 - 80	8.0	23	18.0	18	15
5	> 80	9.0	25	20.0	18	15



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Latex: SunMed® does not utilize latex or latex-containing material to manufacture products. To the best of our knowledge latex does not contact components or finished goods during the manufacturing process.

Phthalates: The selected materials are Non-DEHP; DEHP was not intentionally added as part of the manufacturing process.

Mercury-Lead: The selected materials do not contain lead or mercury.

Biocompatible per device classification in ISO 10993. SunMed manufactures product from medical grade materials in compliance with Good Manufacturing Practices (GMP's) as listed in 21 C.F.R. (U.S. code of Federal Regulations).

Product material						
Part Number	Size	UOM	GTIN			
60005	0	Case	0081495402026			
60055	0.5	Case	0081495402027			
60105	1.0	Case	0081495402028			
60155	1.5	Case	0081495402029			
60205	2	Case	0081495402030			
60305	3	Case	0081495402031			
60405	4	Case	0081495402032			
60505	5	Case	0081495402033			

Product material

Airway Connector

Airway Tube Inflation Tube

Part