

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 Patient 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 Weight (kg)	Maximum OETT (mm)	Mouth Opening (mm)	Length of Tube (cm)	Maximum OG Tube (Fr)	ET Tube 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



Product material

Part	Description	Material
Airway Connector		Polycarbonate
Mask		Silicone
Airway Tube		Silicone
Inflation Tube		Silicone

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