TRACHEOSTOMY TUBE

STERILE | DISPOSABLE | SINGLE USE | LATEX FREE

DEVICE MANUFACTURING SPECIFICATIONS	
Product Family	Tracheostomy Tubes
Company	AirLife
Company Address	SunMed LLC 2710 Northridge Dr. NW, Suite A Grand Rapids, MI 49544 USA
Country of Origin/Made In	China
Classification – US/510k #	Class II K042684
FDA Product Code	BTO (Tube Tracheostomy and Tube Cuff)
Classification – Canada	Class II
Classification – IMDRF (GHFT)	Rule 5, Class B
GMDN Code	35404 Tracheostomy Tube, Non-Reinforced, Non-Customized, Single-Use
UMDNS Code	14096 Tubes, Tracheostomy
UNSPSC Code	42271904 Tracheostomy Tube
Duration of Use	Single Use, Disposable
Patient Population	Pediatric, Adult
Sterility	Sterile, Ethylene Oxide
Packaging Material	Individually Packaged, 10/Case
Shelf Life	5 Year
Storage Conditions	Store at a temperature that does not exceed 49°C. Exposure to elevated temperatures and ultraviolet light should be avoided during storage.
Disposal Instruction	Dispose device and device packaging in accordance to hospital practices and applicable state, federal and other regulations.



DEVICE MATERIAL

COMPONENT	MATERIAL
Tracheostomy Tube	Composed of medical grade PVC which does not contain latex
Obturator	Polyethlylene (PE)
Tube	Polyvinyl Chloride (PVC)
Swivel Adaptor	Polyvinyl Chloride (PVC)
Flange	Polyvinyl Chloride (PVC)
Cuff	Polyvinyl Chloride (PVC)
Pilot Balloon	Polyvinyl Chloride (PVC)
Inflation Line	Polyvinyl Chloride (PVC)

Description: The tracheostomy tube is a hollow, curved tube with or without a cuff which is made from medical grade PVC. consists of main tube, cuff, inflation line, valve, pilot balloon, obturator, neck plate, connector, and tube ties. SunMed® Tracheostomy Tubes are available uncuffed or cuffed. Tubes are supplied with compatible cuff, a one-way luer-lock valve, a responsive pilot balloon and radiopaque line.

Intended Purpose: Tracheostomy Tubes (cuffed or uncuffed) are indicated for airway management.

Contraindications: Use of Tracheal Tubes in procedures which will involve the use of a laser beam or electrosurgical active electrode in the immediate area of the device.

Biocompatibility: Material: Non-irritating, Non-sensitizing, Non-cytotoxic. The subject devices do not contain natural rubber latex. The selected materials are formulated with DEHP.

PART	DESCRIPTION	SIZE	FR SIZE	LENGTH	EACH GTIN	CASE GTIN
1-7390-30	Tracheostomy Tube Uncuffed	3.0 mm	12 Fr	34 mm	10889483002025	20889483002022
1-7390-35	Tracheostomy Tube Uncuffed	3.5 mm	14 Fr	37 mm	10889483002032	20889483002039
1-7390-40	Tracheostomy Tube Uncuffed	4.0 mm	16 Fr	41 mm	10889483002049	20889483002046
1-7390-45	Tracheostomy Tube Uncuffed	4.5 mm	18 Fr	43 mm	10889483002056	20889483002053
1-7390-50	Tracheostomy Tube Uncuffed	5.0 mm	20 Fr	47 mm	10889483002063	20889483002060
1-7393-50	Tracheostomy Tube Cuffed	5.0 mm	20 Fr	47 mm	10889483002087	20889483002084
1-7393-55	Tracheostomy Tube Cuffed	5.5 mm	22 Fr	50 mm	10889483002094	20889483002091
1-7393-60	Tracheostomy Tube Cuffed	6.0 mm	24 Fr	62 mm	10889483041437	20889483041434
1-7393-65	Tracheostomy Tube Cuffed	6.5 mm	26 Fr	67 mm	10889483041444	20889483041441
1-7393-70	Tracheostomy Tube Cuffed	7.0 mm	28 Fr	69 mm	10889483041451	20889483041458
1-7393-75	Tracheostomy Tube Cuffed	7.5 mm	30 Fr	75 mm	10889483041468	20889483041465
1-7393-80	Tracheostomy Tube Cuffed	8.0 mm	32 Fr	79 mm	10889483041475	20889483041472
1-7393-85	Tracheostomy Tube Cuffed	8.5 mm	34 Fr	83 mm	10889483041482	20889483041489
1-7393-90	Tracheostomy Tube Cuffed	9.0 mm	36 Fr	87 mm	10889483041499	20889483041496
1-7393-95	Tracheostomy Tube Cuffed	9.5 mm	38 Fr	91 mm	10889483041505	20889483041502
1-7393-10	Tracheostomy Tube Cuffed	10.0 mm	40 Fr	96 mm	10889483002070	20889483002077

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