BALLARD™ TURBO-CLEANING CLOSED SUCTION SYSTEMS FOR ADULTS – T-PIECE

STERILE | DISPOSABLE | SINGLE USE | MR CONDITIONAL

DEVICE MANUFACTURING SPECIFICATIONS	
Product Family	Ballard Turbo-Cleaning Closed Suction Systems for Adults – T-Piece
Manufacturer	Avanos Medical, Inc.
Manufacturer Address	5405 Windward Parkway, Alpharetta, GA 30004, USA
Country of Origin/Made In	Mexico
Classification – US/510k #	Class I, 510(k) Exempt
FDA Product Code	BSY (Catheters, Suction, Tracheobronchial)
Classification – Australia	Class IIa
Classification – Canada	Class II
Classification – EU	Class IIa
CE Mark/Notification Body	CE 2797 / BSI Group
EU Authorized Representative	Avanos Medical Belgium BVBA, Leonarda da Vincilaan 1, 1930 Zaventem, Belgium
EMDN Code	R050101 – Respiratory and Anesthesia Devices, Respiratory
GMDN Code	34923 – Suction System Catheter General Purpose
UMDNS Code	10749 – Catheters, Suction
UNSPSC Code	42144403 – Artificial Airway Tube Suction Catheters
Duration of Use	Do Not Use More Than 72 Hours
Patient Population	Adult
Area of Use	Clinical Procedure Environment, Home Environment
Sterility	Products are Sterilized by Gamma Radiation (R)
Magnetic Resonance	MR Conditional
Packaging	Individually Packaged in Film Pouch, 20/Case
Shelf Life	5 Years from Date of Manufacture
Storage Conditions	Store in a dry and cool place, away from sources of heat and radiation
Disposal Instruction	Dispose of all materials in accordance with local, state, and federal regulations. Decontaminate and dispose of all potentially biohazardous material.

Description: A closed suction catheter is a product that enables maintaining the patency of a patient's artificial airway without breaking the ventilation circuit during suctioning. It is a protected suction catheter inside a sterile plastic sleeve.

Intended Purpose: The Ballard™ closed suction catheter is a product that enables maintaining the patency of a patient's artificial airway without breaking the ventilation circuit during suctioning.

Contraindications: No known contraindications

TECHNICAL SPECIFICATIONS

PART	OUTER DIAMETER	LENGTH	ADDITIONAL DESCRIPTION	ISO COLOR
227105-5	10 Fr / 3.3 mm	54 cm	Endotracheal Length	Black
2271053-5	10 Fr / 3.3 mm	30.5 cm	Tracheostomy Length	Black
227135-5	12 Fr / 4.0 mm	30.5 cm	Tracheostomy Length	White
22715-5	12 Fr / 4.0 mm	54 cm	Endotracheal Length	White
2270135	14 Fr / 4.6 mm	30.5cm	Tracheostomy Length	Green

DEVICE MATERIAL

COMPONENT	MATERIAL
Sleeve Collar	Polypropylene (PP)
Sleeve	Polyurethane (PU)
Seal cartridge	Acrylic, Acrylonitrile Butadiene Styrene (ABS), Silicone
Manifold Assembly	Polypropylene (PP), Acrylic, Silicone, Polyamide, Polycarbonate
MDI Port	Acrylic, Polyvinyl Chloride (PVC)
Catheter Assembly	Polyvinyl Chloride (PVC), Acrylonitrile Butadiene Styrene (ABS)
Irrigation Assembly	Copolymer, Stainless Steel, Acrylonitrile Butadiene Styrene (ABS), Polyvinyl Chloride (PVC)
Thumb Valve Assembly	Low Density Polyethylene (LDPE), Acrylonitrile Butadiene Styrene (ABS), Kraton

Biocompatability: The closed suction catheters are not made of natural rubber latex. The selected materials are not formulated with DEHP. These devices do not contain blood derivatives or materials derived from animal or human tissue.

PART	EACH GTIN	CASE GTIN
227105-5	00609038982533	10609038982530
2271053-5	00609038982540	10609038982547
227135-5	00609038989730	10609038989737
22715-5	00609038989754	10609038989751
2270135	00609038947013	10609038947010

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