

BALLARD™ TURBO-CLEANING CLOSED SUCTION SYSTEMS FOR ADULTS – DOUBLE SWIVEL ELBOW AND WETPAK

STERILE | DISPOSABLE | SINGLE USE | MR CONDITIONAL

DEVICE MANUFACTURING SPECIFICATIONS

Product Family	Ballard Turbo-Cleaning Closed Suction Systems for Adults – Double Swivel Elbow and WetPak
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). Saline Vials are Aseptically Filled.
Magnetic Resonance	MR Conditional
Packaging	Individually Packaged in High Density Polyethylene (HDPE) Pouch, 20/Case
Shelf Life	Maximum 3 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



DEVICE MATERIAL

COMPONENT	MATERIAL
Saline Solution	Sodium Chloride 09%
Sleeve Collar	Polypropylene (PP) Sleeve
Polyurethane 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

Biocompatibility: 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.

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TECHNICAL SPECIFICATIONS

PART	OUTER DIAMETER	LENGTH	ADDITIONAL DESCRIPTION	ISO COLOR
227166-5	12 Fr / 4.0 mm	54 cm	Endotracheal Length	White
22716036-5	12 Fr / 4.0 mm	30.5 cm	Tracheostomy Length	White
22712186-5	12 Fr / 4.0 mm	54 cm	Endotracheal Length, MDI Port	White
227121863-5	12 Fr / 4.0 mm	30.5 cm	Tracheostomy Length, MDI Port	White
2276-5	14 Fr / 4.6 mm	54 cm	Endotracheal Length	Green
227036-5	14 Fr / 4.6 mm	30.5 cm	Tracheostomy Length	Green
22714186-5	14 Fr / 4.6 mm	54 cm	Endotracheal Length, MDI Port	Green
227141863-5	14 Fr / 4.6 mm	30.5 cm	Tracheostomy Length, MDI Port	Green
2271616-5	16 Fr / 5.3 mm	54 cm	Endotracheal Length	Orange
22716186-5	16 Fr / 5.3 mm	54 cm	Endotracheal Length, MDI Port	Orange
227161863-5	16 Fr / 5.3 mm	30.5 cm	Tracheostomy Length, MDI Port	Orange

PART	DESCRIPTION	EACH GTIN	CASE GTIN
227166-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 12 F, DSE, WetPak	00609038989815	10609038989812
22716036-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 12 F, DSE, WetPak	00609038989792	10609038989799
22712186-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 12 F, DSE, MDI, WetPak	00609038988825	10609038988822
227121863-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 12 F, DSE, MDI, WetPak	00609038988832	10609038988839
2276-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 14 F, DSE, WetPak	00609038989839	10609038989836
227036-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 14 F, DSE, WetPak	00609038989709	10609038989706
22714186-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 14 F, DSE, MDI, WetPak	00609038980904	10609038980901
227141863-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 14 F, DSE, MDI, WetPak	00609038988849	10609038988846
2271616-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 16 F, DSE, WetPak	00609038980942	10609038980949
22716186-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 16 F, DSE, MDI, WetPak	00609038988856	10609038988853
227161863-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 16 F, DSE, MDI, WetPak	00609038988863	10609038988860