

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

STERILE | DISPOSABLE | SINGLE USE | MR CONDITIONAL

## DEVICE MANUFACTURING SPECIFICATIONS

Product Family	Ballard Turbo-Cleaning Closed Suction Systems for Adults – Double Swivel Elbow
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 High-Density Polyethylene (HDPE) 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.



## 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 (PC)
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. 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
227101-5	10 Fr / 3.3 mm	54 cm	Endotracheal Length	Black
2271018-5	10 Fr / 3.3 mm	54 cm	Endotracheal Length, MDI Port	Black
22716-5	12 Fr / 4.0 mm	54 cm	Endotracheal Length	White
2271603-5	12 Fr / 4.0 mm	30.5 cm	Tracheostomy Length	White
2271218-5	12 Fr / 4.0 mm	54 cm	Endotracheal Length, MDI Port	White
227-5	14 Fr / 4.6 mm	54 cm	Endotracheal Length	Green
22703-5	14 Fr / 4.6 mm	30.5 cm	Tracheostomy Length	Green
2271418-5	14 Fr / 4.6 mm	54 cm	Endotracheal Length, MDI Port	Green
22714183-5	14 Fr / 4.6 mm	30.5 cm	Tracheostomy Length, MDI Port	Green
227161-5	16 Fr / 5.3 mm	54 cm	Endotracheal Length	Orange
2271613-5	16 Fr / 5.3 mm	30.5 cm	Tracheostomy Length	Orange
2271618-5	16 Fr / 5.3 mm	54 cm	Endotracheal Length, MDI Port	Orange
22716183-5	16 Fr / 5.3 mm	30.5 cm	Tracheostomy Length, MDI Port	Orange

PART	DESCRIPTION	EACH GTIN	CASE GTIN
227101-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 10 Fr, DSE	00609038982519	20609038982513
2271018-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 10 Fr, DSE, MDI	00609038982595	20609038982599
22716-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 12 Fr, DSE	00609038989778	20609038989772
2271603-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 12 Fr, DSE	00609038989785	20609038989789
2271218-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 12 Fr, DSE, MDI	00609038982618	20609038982612
227-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 14 Fr, DSE	00609038989655	20609038989659
22703-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 14 Fr, DSE	00609038989693	20609038989697
2271418-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 14 Fr, DSE, MDI	00609038982632	20609038982636
22714183-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 14 Fr, DSE, MDI	00609038982649	20609038982643
227161-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 16 Fr, DSE	00609038982557	20609038982551
2271613-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 16 Fr, DSE	00609038982564	20609038982568
2271618-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 16 Fr, DSE, MDI	00609038982656	20609038982650
22716183-5	Ballard Turbo-Cleaning Closed Suction System for Adults, 16 Fr, DSE, MDI	00609038982663	20609038982667