

# BALLARD™ TURBO-CLEANING CLOSED SUCTION SYSTEMS FOR ADULTS – T-PIECE 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	42144402 – Artificial Airway Suction Kits
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	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

## TECHNICAL SPECIFICATIONS

PART	OUTER DIAMETER	LENGTH	ADDITIONAL DESCRIPTION	ISO COLOR
2271516-5	12 Fr / 4.0 mm	54 cm	Endotracheal Length, WetPak	White
22701356-5	14 Fr / 4.6 mm	30.5 cm	Tracheostomy Length, WetPak	Green
2270156-5	14 Fr / 4.6 mm	54 cm	Endotracheal Length, WetPak	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

**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.

PART	EACH GTIN	CASE GTIN
2271516-5	00609038989877	1609038989874
22701356-5	00609038989679	1609038989676
2270156-5	00609038989686	1609038989683