BALLARD™ CLOSED SUCTION SYSTEMS FOR NEONATES/PEDIATRICS – Y ADAPTER

STERILE | DISPOSABLE | SINGLE USE | MR CONDITIONAL

DEVICE MANUFACTURING SPECIFICATIONS	
Product Family	Ballard Closed Suction Systems for Neonates/Pediatrics – Y Adapter
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 24 Hours
Patient Population	Neonate, Pediatric
Area of Use	Clinical Procedure Environment, NICU/PICU
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
Catheter Assembly	Polyvinyl Chloride (PVC), Acrylonitrile Butadiene Styrene (ABS)
Luer Irrigation	Polyvinyl Chloride (PVC)
Check Valve Irrigation	Polyvinyl Chloride (PVC), Acrylonitrile Butadiene Styrene (ABS), and Stainless Steel
Thumb Valve Assembly	Low Density Polyethylene (LDPE), Acrylonitrile Butadiene Styrene (ABS), and 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.

PART	EACH GTIN	CASE GTIN
195-5	00609038983837	20609038983831
196-5	00609038983844	20609038983848
197-5	00609038983851	20609038983855
198-5	00609038983868	20609038983817
1910-5	00609038983813	20609038983817
1912-5	00609038983820	20609038983824

TECHNICAL SPECIFICATIONS

DESCRIPTION	SPECIFICATION					
	195-5	196-5	197-5	198-5	1910-5	1912-5
Outer Diameter	5 Fr / 1.6 mm	6 Fr / 2.0 mm	7 Fr / 2.3 mm	8 Fr / 2.6 mm	10 Fr / 3.3 mm	12 Fr / 4.0 mm
Length	30.5 cm	30.5 cm	30.5 cm	30.5 cm	40.5 cm	40.5 cm
Endotracheal Length, Y-Adapter	2 / 2.5 mm	2.5 / 3 / 3.5 mm	3 / 3.5 / 4 mm	3 / 3.5 / 4 mm	4.5 / 5 / 5.5 mm	5.5 / 6 / 6.5 mm
ISO Color	Grey	Light Green	Ivory	Light Blue	Black	White

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