BALLARD™ ACCESSORIES FOR CLOSED SUCTION SYSTEMS FOR ADULTS

STERILE | DISPOSABLE | SINGLE USE

DEVICE MANUFACTURING SPECIFICATIONS	
Product Family	Ballard Accessories for Closed Suction Systems for Adults
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	111, 112, 113, 119, 1115 – Class of the Device: IIa 118 – Class of the Device: I sterile
Classification – Canada	Class II
Classification – EU	111, 112, 113, 119, 1115 – Class of the device: IIa 118 – Class of the device: I sterile
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	46115 – General Purpose Catheter Connector 37207 – Surgical/Medical Procedure Irrigation Fluid
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	Adult
Area of Use	Hospital
Sterility	111, 112, 113, 119, 1115 – Sterilized by Gamma Radiation (R) 118 – Non-Sterile, Aseptically filled
Packaging	111, 112, 113, 119, 1115 – All units are placed within 1 shipping case. Each unit of Closed Suction System Accessories is in a peelable pouch. 118 – 24 units are placed within 1 dispenser, 6 dispensers are placed within 1 shipping case.
Shelf Life	111, 112, 113, 119, 1115 – 5 Years from Date of Manufacture 118 – 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.

DEVICE MATERIAL

PART	MATERIAL
113	Copolymer
114	Polyvinyl Chloride (PVC), Acrylic
118	09% Sodium Chloride Solution, Polyethylene
1115	Copolymer
111	Acrylic, Polypropylene (PP) (PP)
112	Polyethylene
119	Polyvinyl Chloride (PVC), Acrylic

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

PART	EACH GTIN	CASE GTIN
113	00609038938028	1609038938025
118	00609038938066	1609038970216
1115	00609038938769	1609038938766
111	00609038938004	1609038938001
112	00609038938011	1609038938018
119	00609038938073	1609038938070

Description: Ballard™ closed suction accessories are connectors, adapters intended to enable the mobility of Ballard closed suction catheters. Saline vials are used to irrigate the tip of the Ballard closed suction catheters after suction. The MDI Adapter is a channel for the delivery of solutions from a metered dose inhaler.

Intended Purpose: This family of products are utilized as accessories for airway management by connecting patients to a respiratory circuit or a resuscitator to an endotracheal tube, to enable increased mobility at the patient end of the circuit or connections. Saline dispensed from saline vials may be used with the closed suction system to rinse or clean the system suction catheter, aid in clearing pulmonary secretions, and mechanically loosen thick secretions.

Contraindications: No known contraindications.

TECHNICAL SPECIFICATIONS

SPECIFICATION	PARAMETER					
Item	111	112	113	118	119	1115
Reference	Swivel Adapter, 15 mm x 22 mm	Adapter, 15 mm x 22 mm	Flex Tube, LD 22 mm x Length 101 mm	Single Dose Saline Vials, 15 mL, Pink	Metered Dose Inhaler (MDI) Adapter	Flex Connector, 15 mm x 22 mm
Packaging	50 Each	50 Each	50 Each	144 Each	20 Each	50 Each

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