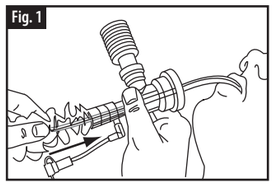
Material Specification:7DayCatheter.INIFU

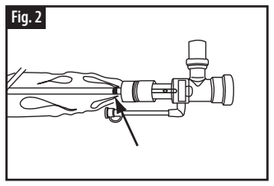
Material Specification	7DayCatheter.INIFU	**Style**	Flat with 4 x 1/4” rounded corners (RC), machine trim; Aqueous coating (STARKOTE AQ-705) on front side of Insert
Revision	1	**Size (mm) (OD) (W)**	N/A
Description	IFU - BALLARD 7DAY Closed Suction System	**Size (mm) (OD) (D)**	N/A
Item Number	7DayCatheter.INIFU	**Size (Inches) (OD) (D)**	N/A
Previous item number	N/A	**Size (mm) (OD) (L)**	N/A
SAP Number	7130020	**Size (Inches) (OD) (W)**	N/A
Published Date	DCR-17047	**Size (Inches) (L)**	4.875
Item Description	IFU - BALLARD 7DAY Closed Suction System	**Other Requirements**	N/A
Material Type	IFU / MANUAL / BOOKLET	**Primary Vendor**	Litho Flexo Graphics Inc / Salt Lake City, UT
OS Size (Inches) (OD) (W)		**Alternate Vendor**	N/A
OS Size (Inches) (OD) (D)	N/A	**Size (Inches) (ID) (W)**	N/A
OS Size (Inches) (OD) (L)	N/A	**Size (Inches) (ID) (D)**	N/A
Printing Details	N/A	**Flute**	N/A
Roll Core Size	N/A	**Size (Inches) (ID) (L)**	N/A
Size (mm) (L)	123.825	**Size (mm) (W)**	323.85
Target Min. Compression	N/A	**Size (mm) (D)**	N/A
Size (Inches) (W)	12.75	**Size (mm) (ID) (D)**	N/A
Manufacturer's Joint	N/A	**Size (Inches) (OD) (L)**	N/A
Size (Inches) (D)	N/A	**Size (mm) (ID) (W)**	N/A
ECT	N/A	**Master Text**	(EN) English - United States
Material Description	100 # Bookgloss White Paper	**Translation Language(s)**	N/A
Printing Colors	Process Black	**Size (mm) (ID) (L)**	N/A
Roll Diameter	N/A	**PDF Viewable Files**	DayCatheter.INIFU, IFU - BALLARD 7DAY Closed Suction System.pdf
Bar Code	N/A	**Latest Revision**	Initial release per DCR-17047
Mill Part Number	N/A	**UPC**	N/A
Label Shell Available	N/A	**Percentage (%) of Post-Consumer Recycled Content**	N/A
Dieline Available	N/A	**Material Contains the Following Synthetics**	N/A
Primary Vendor Location	Salt Lake City, UT	**Percentage (%) of Pre-Consumer Recycled Content**	N/A
Primary Vendor Contact	Paulette Camden	**Is Material Compostable?**	N/A
Dieline	N/A	**Is Material Biodegradable?**	N/A
Adhesive	N/A	**Is Material Laminated?**	N/A
Board Grade	N/A	**Is Material Coated with Plastic?**	N/A
Alternate Vendor Contact	N/A	**Is Material Labelled with Recycling Information?**	N/A
Primary Vendor Name	Litho Flexo Graphics Inc	**Is Material Recyclable?**	N/A
Alternate Vendor Location	N/A	**Market Clearance Number**	N/A
Primary Vendor Phone	801-994-1130	**Weight (g)**	N/A
Alternate Vendor Phone	N/A	**Thickness Unit**	N/A
Revision History	New per DCR-17047	**Thickness (Pts)**	N/A
Drawing Number	N/A	**Special Considerations**	N/A
UKCA	No	**Master Specification**	N/A
EUR24	No		

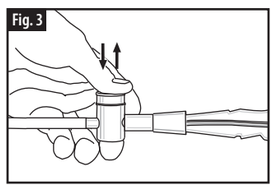
12.75″

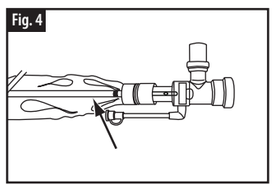
4.875″

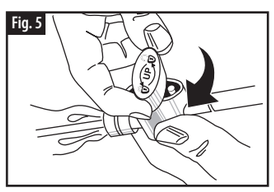
BALLARD™ 7DAY CLOSED SUCTION SYSTEM











These instructions apply to the following families of BALLARD products:
- Double Swivel Elbow
- T-Piece

These instructions also apply to the following configurations of the above families of products:
- Endotracheal Length
- Tracheostomy Length

Device 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 Use:
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.

Indications for Use:
The BALLARD Closed Suction Catheter is intended to suction a patient's artificial airway without breaking the ventilation circuit to allow for a patent airway. The target population includes adult patients with artificial airways.

Environment:
- Hospital
- Home

MR Safety:
- MRI Safe

Patient Target Group:
- Adult

Intended User:
The BALLARD 7Day Closed Suction Catheter devices are intended to be used by trained medical professionals, or trained caregivers.

Contraindications:
None known.

⚠ Warnings:
1. Cap on BALLARD T-Piece prevents continuous flow therapy. Remove cap before starting continuous flow therapy. Failure to remove cap prior to continuous flow therapy may result in serious injury or death.
2. Do not trim or cut the endotracheal tube (not supplied) while the BALLARD catheter is attached, otherwise the BALLARD catheter may also be cut and that portion of the catheter may be aspirated into the lower respiratory tract of the patient and may cause death or serious injury.
3. Do not reuse, reprocess, or resterilize this medical device. Reuse, reprocessing, or resterilization may 1) adversely affect the known biocompatibility characteristics of the device, 2) compromise the structural integrity of the device, 3) lead to the device not performing as intended, or 4) create a risk of contamination and cause the transmission of infectious diseases resulting in patient injury, illness, or death.

⚠ Cautions:
1. Inspect the BALLARD 7Day catheter package before opening. Do not use product if packaging has been compromised. Non-sterile contents may cause infection.
2. Excess fluid in heat and moisture exchanger (HME) may increase gas flow resistance. When introducing fluid into T-Piece, ensure that fluid does not enter HME.
3. Always place the thumb valve in the locked position when not in use to prevent inadvertent activation.
4. Single patient use only.
5. The BALLARD 7Day catheter is intended to be used for 7 days before changing. Change more frequently if catheter becomes heavily soiled during use.
6. Remove red wedge plug from BALLARD 7Day catheter prior to use.
7. Inspect sodium chloride vial prior to opening. Do not use product if vial has been compromised. Compromised contents may cause infection.
8. Do not use 54 cm (21.3 inch) catheters on tracheostomy patients. Mucosal damage may result.
9. Select the appropriate size BALLARD 7Day catheter. Most experts suggest that the catheter selected should occupy no more than one half of the internal diameter of the artificial airway.
10. Do not leave the catheter within the airway. Always pull back until the black stripe is visible within the sleeve. Any catheter left extended into the airway will cause increased airway resistance.
11. Use appropriate regulated vacuum levels. Most experts suggest -80 to -120 mm/Hg (-10.7 to -15.9 kPa).
12. Use appropriate suction technique. Most experts suggest that the entire suction procedure should last no longer than 10 to 15 seconds and that actual duration of negative pressure should be no longer than 5 to 8 seconds per episode.
13. Always use caution and good clinical judgement no matter what ventilator mode is in use. If the clinician notes any signs of suction intolerance such as oxygen desaturation, negative ventilator system pressures, patient stress or excessive discomfort, adjustments to the ventilator settings may need to be made. These adjustments (please refer to the ventilator's instructions for use) may include manipulation of the inspiratory trigger sensitivity, inspiratory volume or flowrate, and selection of a different ventilator mode; or may require the use of an alternate suction technique. Failure to follow the above precautions may increase the risk of positive and negative barotrauma.

Necessary User Qualifications:
Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.

Instructions for Use:

Setup:
1. Select appropriate size BALLARD 7Day catheter.
2. Attach thumb control valve to suction tubing.
3. Depress and hold thumb valve and simultaneously adjust vacuum regulator to desired level.
4. Release thumb control valve and attach BALLARD 7Day catheter between patient and the ventilator circuit.

Suggested Suction Procedure:
1. Stabilize BALLARD 7Day catheter and endotracheal (ET) adapter with one hand then push the catheter into the endotracheal tube with the thumb and forefinger of the opposite hand (**Fig. 1**).
2. Advance BALLARD 7Day catheter to desired depth.
3. Depress and hold thumb control valve, then gently withdraw catheter. Stop withdrawal when black marking ring is visible inside sleeve (**Fig. 2**).
4. Release thumb control valve.
5. Repeat steps 1 through 4 above as necessary.

Catheter Irrigation Instructions:
1. Be sure the black marking ring is visible in the sleeve (**Fig. 2**). Open the cap on the irrigation port.
2. Introduce fluid slowly into the port, simultaneously depress the thumb control valve (**Fig. 3**).
3. Continue to irrigate until the BALLARD 7Day catheter is clear (**Fig. 4**).
4. Close the cap on the port.
5. Lift and turn the thumb control valve 180 degrees to lock in position (**Fig. 5**).
6. Place the BALLARD 7Day catheter and suction tubing alongside the breathing circuit.

Control Depth Suction: (Endotracheal length catheters printed with numerical markings only):
1. Align any printed depth number on the catheter with the similar number printed on the endotracheal tube, or
2. Observe the printed number on the endotracheal tube closest to the endotracheal tube adapter. Add 8 cm to this number. Advance catheter until the sum (depth plus 8) appears in the window directly across from irrigation port connector.
3. Catheter tip will be within 1 cm of the end of the artificial airway.

Thumb Control Valve Operation:
1. The thumb control valve can be locked to prevent inadvertent or accidental suction. To lock, lift white part of thumb control valve and rotate 180 degrees. To unlock, repeat this action (**Fig. 5**).

Day Sticker Usage:
1. Apply the appropriate day sticker to the thumb control valve.

These instructions also apply to the following configurations of the above families of products:
- Tracheostomy Length

Tracheostomy Patients:
1. Use tracheostomy 30 cm (12 inch) BALLARD 7Day catheter for patients with tracheostomy artificial airway only, per hospital policy. If 30 cm BALLARD 7Day catheter is used on endotracheal artificial airway, ineffective suction may result.
2. Do not use 54 cm (21.3 inch) catheter on tracheostomy patients. Mucosal damage may result.

Table 1: Internal Manifold Volume

Patient End Adaptor Manifold	Internal Volume (mL)
BALLARD 7DAY Catheter Double Swivel Elbow	12
BALLARD 7DAY Catheter T-Piece	19

$\dot{V}_D$ Interval volume · Diameter · Length · Single use only · STERILE R · Do not use if package is damaged · Do not resterilize · Not made with natural rubber latex · Product is NOT made with DEHP · R_x ONLY · ⚠ Caution · MR MRI Safe · Endotracheal Length · Tracheostomy Length · -20°C 50°C

SunMed, LLC,
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Made in Mexico

7DayCatheter.INIFU Rev 1 2025/08

Aug 19, 2025
Preprinted Insert-Instructions for use
12.750" (W) x 4.875" (L)
7DayCatheter.INIFU

Prints 1/c Process Black