Symbols Legend

STERILE EO	Sterilised using Ethylene Oxide in a single sterile barrier system		Non-Pyrogenic
	For Single Use Only		Do Not Re-sterilise
	Fragile and handle with care		Do Not Use If Package Is Damaged
LATEX	Contains natural rubber or latex		Keep From Direct Sunlight
	Temperature Limitation		Keep Dry
	Use by date		Humidity Limitation
	Manufacturer and date of manufacture	MD	Medical Device
	Importer information	EC REP	Authorised Representative in the European Community
REF	Catalogue number		Distributor information
UDI	Unique Device Identifier	LOT	Lot Number
	Consult Instruction for Use	CE 0344	CE conformity marking per European Council Directive 93/42/ EEC
Rx Only	Federal (USA) law restricts this device to sale by or on the order of a physician	PHT DEHP	Contains or Presence of Phthalate

CE 0344

51-000006-01 Rev. F2
23 May 2023

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Bioptimal™

INSTRUCTIONS FOR USE OF
PULMONARY ARTERY MONITORING CATHETER AND KITS

READ ALL INSTRUCTIONS, WARNINGS AND PRECAUTIONS CAREFULLY PRIOR TO USE.

Generic Models

TD1502N	TD1602N	TD1702N	TD1603N	TD1703N
TD2502N	TD2602N	TD2702N	TD2603N	TD2703N

DEVICE DESCRIPTION

BIOPTIMAL Balloon-Tipped Right Heart Pressure Monitoring Catheters are extruded polyvinylchloride (PVC) or polyurethane (PU) tubing with a French Size of 5Fr, 6Fr or 7Fr, connected to a hub carrying 2 or 3 lumens with a total length of 90 or 110 cm. Each catheter is marked every 10 centimeters to indicate distance from the distal tip. Narrow bands represent 10 centimeter markings while wide bands represent 50-centimeter markings. The extension tubings comprise a proximal and distal extension of 5Fr or 7Fr, and an inflation extension of 6Fr.

Monitoring catheters are available in double and triple-lumen models. Triple-lumen catheters contain a distal PA lumen, balloon lumen and a proximal lumen while Double-lumen monitoring catheters offer the same capabilities as triple-lumen catheters but without a Proximal (CVP) lumen.

- Distal PA lumen: This lumen terminates at the catheter tip. Its usage is to monitor the pulmonary artery and capillary wedge pressures and to sample mixed-venous blood.
- Balloon lumen: This lumen terminates in a latex balloon near the catheter tip. It provides a means for inflating and deflating the balloon to facilitate catheter placement and to measure pulmonary capillary wedge pressure.
- Proximal (CVP) lumen: This lumen terminates 29 centimeters proximal to the catheter tip. It is used for measuring right atrial or central venous pressure, and to infuse solutions.

Kits's alternate name is Biotray. Biotray is a more comprehensive procedure pack with an extended list of accessories and a catheter. This IFU only reflects the operation instructions related to Pulmonary Artery monitoring catheter, and the operation instructions releated to the accessory of Biotray can refer to IFU 51-000019-00.

INDICATIONS AND INTENDED USE

BIOPTIMAL Pulmonary Artery Monitoring Catheter and Kits are designed for use in patients as a diagnostic tool. Catheter models are available to allow the physician to measure intracardiac pressures, sample mixed-venous blood, and infuse solution in adult or pediatric patients. These catheters are designed for use at the bedside and in the cardiac catheterization laboratory, surgical suite, post-anesthesia recovery unit, and other specialized critical care units.

These catheters are designed for bedside diagnostic procedures and do not normally require the use of fluoroscopy for insertion. However, they are radiopaque, so fluoroscopy can be used to guide insertion and to verify position following insertion. Device is intended to be used by trained clinicians who are aware of the benefits and risks of the catheter usage.

CONTRAINDICATION

1. Catheter with natural latex balloon is contraindicated for patient with known or suspected allergy to natural rubber latex.
2. Absolute contraindications to cardiac catheterization include tricuspid or pulmonary valvular Stenosis, right atrial or right ventricular masses (tumor or thrombus) and Tetralogy of fallot.
3. Relative contraindications to cardiac catheterization include unstable ventricular rhythm, heart block and temporary transvenous pacemaker (wire dislodgement).

PRECAUTIONS

1. This product is designed for single use only. Do not reuse or resterilize the catheter.
2. Do not use catheter after indicated expiration date printed on the tyvek lid of the package.
3. Do not use catheter or components if package is opened or damaged as contents may lose sterility.
4. To avoid damage to the catheter or balloon when a cut-down is used, it is recommended that a vessel dilator or disposable vein guide be used. NEVER use forceps on the catheter.
5. Always deflate the balloon by removing the syringe, and always deflate the balloon prior to withdrawing the catheter.
6. Never use liquid for balloon inflation. Liquid within the balloon inflation lumen may cause the balloon to stay inflated even after removal of the inflation syringe.
7. To minimize infection, it is generally recommended that the catheter should not be left in the patient for longer than three days.
8. Do not advance the catheter after it has been set in place; the portion of the catheter left outside the body may not be sterile. If a catheter sterility sheath is used, the catheter may be repositioned as needed.
9. To determine wedge pressure, inflate balloon slowly, stopping when PA waveform changes to wedge pressure waveform. Deflate balloon after completing measurement.
10. Use filtered CO_2 for balloon inflation in any situation where balloon rupture may result in air embolus entering the arterial circulation, as in a right-to-left shunt.
11. To minimize ventricular irritation, always inflate the balloon before the catheter reaches the right ventricle.
12. To avoid balloon rupture during inflation, do not exceed the recommended balloon inflation volume (1.5cc for 7F, 1.00cc for 6F and 0.75cc for 5F).
13. Initial placement of the catheter in the pulmonary artery should always be made with the maximum recommended balloon inflation volume. An under-deflated balloon will be smaller, allowing the catheter to be positioned in a narrower portion of the pulmonary artery. This may increase the likelihood of spontaneous wedging.
14. A flow directed catheter may migrate into the distal pulmonary artery, and spontaneous wedging may occur. To detect the occurrence of spontaneous wedging, the PA pressure waveform should be monitored continuously or at short intervals.
15. The biological activity of the thrombo-resistant coating used on the latex balloon is initiated by blood contact, therefore the efficiency of the coasting is guaranteed for one patient use only.
16. Used catheter must be properly disposed as biohazard material and processed according to facility protocol.
17. The package is designed to prevent kinking to the catheter. A damaged catheter cannot be repaired. The catheter balloon is fragile; therefore, reasonable care should be employed when removing the catheter from the package.
18. Ensure that sampling/distribution devices are connected to the right extension of the catheter.

WARNINGS

1. Please use product with contamination shield.
2. This device is intended for single patient use only.
3. **DO NOT** resterilize and/ or reuse this device, as this can compromise its performance and can lead to device failure and procedure complications with severe injury or patient death. Reuse and resterilisation bear the risk of cross contamination and patient infection and may also cause transmission of infectious diseases from patient to patient.

INSTRUCTIONS FOR USE

Read carefully your hospital's policies, rules and procedures relating to the use of thermodilution catheters, if any.

Preparation and Use of Catheter:

1. Remove Catheter from the package using sterile technique.
2. Test the balloon by placing it in sterile water and injecting 1.5cc of air for 7F, 1.00cc for 6F and 0.75cc for 5F. If bubbles appear around the balloon, do not use the catheter. Deflate the balloon by removing the syringe.

CAUTION: REMOVE THE BALLOON COVER BEFORE CONDUCTING THE BALLOON INFLATION TEST. NEVER USE LIQUID FOR BALLOON INFLATION. LIQUID WITHIN THE BALLOON LUMEN MAY CAUSE THE BALLOON TO REMAIN INFLATED. SPECIAL CARE MUST ALWAYS BE TAKEN TO PREVENT MOISTURE FROM ENTERING THE LUMEN.

3. Evacuate all air from injected administration solution bags by inserting a large-bore needle into medication port and squeezing the air through the needle. Remove the needle.

Note: Eliminating the air from the solution bag will prevent air from entering the tubing system when the solution is exhausted or the solution bag is inverted.

4. Connect stopcocks to the end of the PA distal lumen and CVP lumen, if applicable. Flush and fill the catheter lumens with the sterile solution.

Catheter Insertion:

Insertion of the catheter should follow the basic procedures recommended below. However, catheter usage must always conform to your hospital policies procedures. A thorough understanding of the cautions listed at the end of the procedure is necessary before using these catheters.

1. Monitor the ECG continuously during catheter insertion.
2. Insert the catheter either percutaneously or via a cutdown without prewiping the catheter. Typical insertion sites include the, median basilica, jugular, femoral, and subclavian veins.
3. Advanced the catheter into the vena cava and partially inflate the balloon to 1.00cc for 7F, 0.75cc for 6F and 0.5cc for 5F. Filtered CO_2 is recommended for inflation because of its rapid absorption into blood in case of balloon rupture. However, air is frequently used if there is no left-to-right shunt or pulmonary arterial venous fistula. Introduction of an air embolus into the arterial system can cause serious complications. The risk of balloon rupture and the likelihood of air entering the arterial system must be considered when selecting air as balloon inflation medium.
4. Determine the length of the catheter inserted by referring to catheter markings at the 10-centimeter intervals. Follow the pressure waveforms as the catheter is advanced (Reference Figure 1).
5. When the pressure waveform indicates that the tip of the catheter is in right atrium (Figure 1-A), inflate the balloon to full capacity of 1.5cc for 7F, 1.00cc for 6F and 0.75cc for 5F.
6. Advanced the catheter through the right atrium and into the right ventricle (Figure 1-B). If a right ventricular pressure tracing is not recorded after the catheter has been advanced beyond the right atrium, deflate the balloon, pull the catheter back slowly, reinflate and advance the catheter. Advance the catheter in the pulmonary artery (Figure 1-C). Observe the pressure artery, remove the syringe to deflate the balloon and withdraw the catheter until the tip is in the right atrium. Then reinflate the balloon and repeat steps 4, 5, and 6.

Note: If the balloon has been inflated for more than four or five minutes during the insertion, the inflated balloon volume may have decreased due to diffusion of the inflation medium. Remove the syringe to deflate the balloon and then reinflate if necessary.

7. Continue advancing the catheter slowly into the pulmonary artery until a pulmonary capillary wedge pressure is measured (Figure 1-D)
8. Test that the catheter is properly positioned in the pulmonary artery by deflating the balloon completely (removing the syringe) and observing the change from a wedge pressure tracing to a pulmonary artery pressure tracing. (Figure 1-E). Gradually reinflate the balloon until a wedge is obtained and recorded the volume of air required. It should take 1.25 to 1.5 cc for 7F, 0.75 to 1.00cc for 6F and 0.5 to 0.75cc for 5F. If less than 1.25cc for 7F or 0.75cc for 6F or 0.5cc for 5F is required, the catheter may be too far advanced, increasing the likelihood of distal migration and spontaneous wedging. Pull the catheter back two or three centimeters and recheck inflation volume.

Note: Always deflate the balloon by removing the syringe after measurement of pulmonary capillary wedge pressure. Never attempt to aspirate air from the balloon using the syringe. The balloon may be damaged by this procedure.

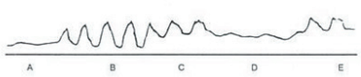

Figure 1 (A-E). Pressure Waveforms During Catheter Insertion and Positioning. (Chart speed: 25mm/sec)

Maintenance and Use in situ

The Catheter should remain indwelling only as long as is required by the patient's condition. However, physician should note that the incidences of complications increase significantly with indwelling periods longer than 72 hours (Ref 12).

COMPLICATIONS

All invasive procedures inherently involve some patient risks. Although serious complications associated with Thermodilution and pulmonary artery catheters are relatively uncommon, the physician is advised to weigh the potential benefits and risks associated with the use of the catheter against alternative procedures before deciding to use the catheter.

Strict adherence to the given instructions and awareness of the possible risks reduces the incidences of the complications. Several known complications described in literatures are as follows:

Perforation of the Pulmonary Artery

Causes of pulmonary artery rupture during the use of the flow-directed balloon-tipped catheters are pulmonary hypertension, advance age and distal tip migration (Ref 8 and 14). Factors that predispose to ventricular perforation during catheterization include small chamber size, stiff catheter, outflow tract obstruction, and myocardial infarction (Ref 6).

Pulmonary Infarction

Over-inflation of balloon and tip migration with spontaneous wedging, air embolism, and thromboembolism are factors of this complication (Ref 4, 9 and 13).

Cardiac Arrhythmias

Cardiac arrhythmias may occur during catheter insertion and removal but are usually associated with transient hypotension (Ref 1). Ventricular arrhythmias are the most commonly observed. Predisposing factors of ventricular arrhythmias are myocardial infarction or ischemia, shock, acidosis, hypoxia and electrolyte disturbances (Ref 3 and 10). Use of prophylactic lidocain should be considered to reduce the incidence of ventricular arrhythmias during catheter catheterization (Ref 11).

Kinking, Looping and Knotting

Soft flexible and excessive length catheters are often reported to have looped or knotted. Loose knot can be untied by a radiologist using guide wires under fluoroscopy control. Alternatively, knot can be gently tightened and withdraw the catheter percutaneously together with the introducer sheath through the entry site (Ref 2 and 5).

Sepsis/Infection

Catheter infections have been reported due to poor aseptic technique at the time of insertion or during subsequent use, contamination infusion fluids and devices used in the cardiac surgery, ingrown of organisms from the skin along the catheter as well as hematogenous spread from remote foci (Ref 7 and 9). Preventive measures are recommended to guard against all possible infections, including the practice of aseptic technique, application of topical antibiotics ointment, and frequent sterile dressing changes.

Air Embolism

Air embolism is an uncommon but potentially catastrophic event which occurs as a consequence of the entry of air into the vasculature. Efforts should be made to reduce the risk of air embolism during mechanical ventilation and central line placement.

Other Complications

Other complications include right bundle branch block, complete heart block, pneumothorax, venous thrombosis thrombophebitis and triscupid valve injury (Ref 4, 5,8 and 9). In addition, allergic reactions to latex have been reported. Before using catheter, physicians should identify latex sensitive patients and prepare to treat the allergic reactions promptly.

PACKAGING AND STERILITY

Product is supplied sterile and non-pyrogenic if package is undamaged or unopened. Do not use if package is opened or damaged. Catheters are for single use only. Do not clean or resterilized a used catheter.

STORAGE

BIOPTIMAL Pulmonary Artery Monitoring Catheter and Kits should be stored unopened in its original packaging in dark, cool dry places.

SHELF-LIFE

The recommended shelf-life is indicated on each package. Storage beyond the stated time may result in balloon deterioration, since the balloon is acted upon and deteriorated by the atmosphere.

SPECIFICATIONS for BIOPTIMAL Pulmonary Artery Monitoring Catheter

MODEL	TD1502	TD1602	TD1702	TD1603	TD1703	TD2502	TD2602	TD2702	TD2603	TD2703
Usable Length (cm)	90	110	110	110	110	90	110	110	110	110
Catheter Body French Size	5F	6F	7F	6F	7F	5F	6F	7F	6F	7F
Body Color	White	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Required Introducer Size	6F	7F	8F	7F	8F	6F	7F	8F	7F	8F
Balloon inflation Capacity (cc)	0.75	1.00	1.50	1.00	1.50	0.75	1.00	1.50	1.00	1.50
Proximal Port Location (cm from tip)	NA	NA	NA	29	29	NA	NA	NA	29	29
Distance between Length Marking	10	10	10	10	10	10	10	10	10	10
External Catheter Body	Polyvinylchloride Material					Polyurethane Material				

WARRANTY

BIOPTIMAL warrants all its products free from defect in workmanship and materials under proper use and handling. This warranty is in lieu of all other warranties, whether expressed or implied, including any warranty of merchantability, suitability or fitness for a particular purpose since handling, storage as well as factors relating to the patient, his diagnosis, treatment, surgical procedures, and other matters beyond BIOPTIMAL'S control, directly affect BIOPTIMAL'S products and the results obtained from their use. BIOPTIMAL shall not be liable for any incidental or consequential loss, damage, or expense directly arising from the use of its products. BIOPTIMAL neither assumes, nor authorizes any other person to assume for it, any other additional liability or responsibility in connection with its products.

ADVERSE EVENT REPORTING

While Bioptimal strives to produce quality Critical Care Products that are free of workmanship and product defects, the possibility of adverse events that may happen to the user due to unintended product failures, use-errors and/or user non-conformance to product information in the IFU cannot be fully mitigated. For any adverse event that may happen, please report to the manufacturer and authorized representative indicated in the IFU or product labels. Similarly, please also report any adverse event to the competent authorities of EU member states.

Federal (USA) law restricts this device to sale by or on the order of a physician.

TECHNICAL ASSISTANCE

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