Bioptimal™

INSTRUCTIONS FOR USE OF BIOTRAY

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

DEVICE DESCRIPTION:

Biotray is a more comprehensive procedure pack with an extended list of accessories and a catheter. It contains the essential components for the introduction of temporary pacing leads, balloon catheters, closed end catheter or angiographic catheters into the vasculature.

This IFU only reflects the operation instructions for the accessory of Biotray, and the operation instructions of Catheters can refer to the IFU of TD and PA.

INDICATIONS AND INTENDED USE

This kit is intended to assist introduction of temporary pacing leads, balloon catheters, closed end catheter or angiographic catheters into the vasculature.

PRECAUTIONS

1. Rx only.
2. Do not use the product after indicated expiration date.
3. Inspect packaging and product for damage prior to use. Do not use components if package is opened or damaged as contents may lose sterility.
4. Physician should be familiar with Seldinger or modified Seldinger techniques of introducing using a guide wire.
5. Do not withdraw the guide wire back through the needle as this may shear the guide wire.
6. Do not leave percutaneous introducer sheaths remain indwelling without internal support of the sheath wall.
7. Care should be exercised during insertion, manipulation and withdrawal of the catheter through the hemostasis valve. Excessive force or rapid withdrawal may compromise the integrity of the hemostasis valve. If resistance is encountered, remove the catheter and introducer as a unit. DO NOT USE FORCE.
8. When using Tuohy-Borst Introducer, do not tighten the adapter without internal support.
9. During repositioning of the sheath suture tab, avoid twisting the sheath by inserting a vessel dilator prior to insertion to provide internal support to the sheath.
10. Upon removal of a catheter or other medical device, it is recommended that an obturator be immediately placed in the sheath.
11. Upon removal of a device and before the insertion of another medical device, the sideport should be aspirated to remove any clotted material that may have accumulated.

WARNINGS

1. Care should be exercised during insertion, use or removal of the device to prevent aspiration of air into the vasculature.
2. Rapid withdrawal of the catheter or dilator through the hemostasis valve may cause misalignment of the valve gasket assembly, causing bleedback through the valve. Should this happen, reinsert the vessel dilator tip or catheter slowly to realign the valve and stopping bleedback.
3. Avoid contacting the introducer hub with acetone solution or isopropyl alcohol. Such solution could weaken the hub and cause possible leakage.
4. Tighten all connections prior to use. Do not over tightening as this may cause damage to components.
5. Periodically check all connections for tightness.
6. This device is intended for single patient use only.
7. **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

The following instructions are supplied solely for information about the techniques of percutaneous catheter insertion. Physician may alter the procedural detail in accordance to institutional protocol.

1. Prepare and drape the skin at the intended puncture site, achieve local anesthesia as necessary.
2. Locate vessel with an appropriate sized needle and syringe.
3. Enter vessel using thin-walled needle or OTN catheter. Remove locator needle. If OTN catheter is used, advanced catheter over needle into vessel and remove needle when good flow verifies placement of catheter tip within the vessel.

   CAUTION: If insertion is unsuccessful, withdraw the complete assembly as a unit.

   CAUTION: Do not advance needle into catheter or attempt to withdraw catheter backwards over the needle while catheter is in the patient.
4. Straighten “J” tip of the guide wire with plastic insertion sleeve.
5. Insert guide wire into the OTN catheter or thin walled needle and gently advance it to the desired length. It may be necessary to gently rotate the “J” tip for successful advance of the guide wire. Maintain firm grip on guide wire at all times.

   CAUTION: Avoid vigorous manipulation to prevent damage to vessel or shearing of guide wire tip.
6. If an obstruction is met that cannot be passed, remove needle and guide wire together and select another introducer site.

   CAUTION: Do not attempt to withdraw guide wire backwards through needle or catheter as this may result in shearing guide wire or damaging catheter.
7. When guide wire is advanced to the desired location, remove OTN catheter or needle proximally.
8. Thread assembled sheath/dilator over the guide wire and advance to puncture site. Enlarging puncture site with a small skin nick if needed, insert the sheath/dilator unit into vessel with a slight rotary motion.
9. Remove the dilator and guide wire together leaving sheath in vessel.
10. Suture sheath in place using tab or hub.

    CAUTION: Do not place suture on sheath tubing as this may restrict flow or damage tubing.
11. When utilizing an introducer with removable valve, connect hemostasis valve securely to sheath.
12. To allow adequate flow through introducer side-port, a catheter one-half to one French size smaller than introducer sheath is recommended.
13. Tuohy-Borst adapters should be gently hand-tightened to prevent blood reflux and/or catheter migration. Over tightening may compromise indwelling catheter lumen.

14. Follow hospital protocol for puncture site dressing and maintenance.
15. Care should be exercised not to pull the guide wire or catheter to extreme angles while the device is through the hemostasis valve, as it will distort the valve leaflets.

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. The kit is for single use only. Do not clean or resterilized used components of the kit.

STORAGE

Product should be stored in a cool dark place to avoid exposure to fluorescent or sunlight, which will cause material deterioration.

SHELF-LIFE

The recommended shelf-life is indicated on each package.

WARRANTY

BIOPTIMAL warrants all its products free from defects in workmanship and material 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 or indirectly arising from the use of its products. BIOPTIMAL neither assumes, nor authorises any other person to assume for it, any other or 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

PRODUCT INFORMATION

For further information or assistance relating to the BIOPTIMAL products, please contact:

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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	PHT DEHP	Contains or Presence of Phthalate
MR	MR Unsafe		Keep From Direct Sunlight
	Temperature Limitation		Keep Dry
	Use by date		Humidity Limitation
	Manufacturer and date of manufacture		Importer information
	Distributor information	EC REP	Authorised Representative in the European Community
MD	Medical Device	REF	Catalogue number
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		