LIVE Catheter Kit

Lungpacer IntraVenous Electrode Catheter Kit
A component of the Lungpacer Diaphragm Pacing Therapy System

Instructions for Use

℞ Only

The LIVE Catheter is a component of the Lungpacer Diaphragm Pacing Therapy System (DPTS). This Diaphragmatic Pacing Stimulator has not been FDA cleared or approved.

This Diaphragmatic Pacing Stimulator has been authorized by FDA under an Emergency Use Authorization (EUA).

This Diaphragmatic Pacing Stimulator is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of Diaphragmatic Pacing Stimulator Systems under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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CAUTION:

For use only with the Lungpacer Diaphragm Pacing Therapy System (DPTS).

The LIVE Catheter has not been evaluated for safety when used with cardiac pacemakers or defibrillators.

Remove the LIVE Catheter prior to Magnetic Resonance (MR) imaging. The LIVE Catheter has not been evaluated for safety and compatibility in the MR environment. Scanning a patient who has this device may result in MR image artifact or patient injury due to heating or migration of the device.

Do not place the LIVE Catheter (or allow it to remain) in the right atrium or right ventricle.

1. DEVICE DESCRIPTION

The LIVE Catheter (Lungpacer IntraVenous Electrode Catheter) Kit contains one LIVE Catheter and accessories that may be used for deployment of the LIVE Catheter. The contents of the LIVE Catheter Kit are listed below.

- LIVE Catheter (19, 21, or 23 cm length)
- Guidewire, J-tip, 0.032in (0.81mm) x 70cm
- Scalpel, #11
- Dilator, 10Fr x 4in
- Needle, 18G x 2.75in (70mm), XTW
- Syringe, 5ml, Luer Slip (x2)
- Syringe, 3ml, Luer Lock, with 25G x 1in Needle
- Introducer Catheter, 18G x 2.50in
- Gauze, 4in x 4in (x5)
- Suture, 3-0 Silk, C7 Reverse Cutting Needle
- Catheter Clamp
- Catheter Clamp Fastener
- Needle-Free Male Luer Lock Injection Site
- Dressing, Tegaderm, 4in x 4.75in
- Drape, Full Body, with 4in Fenestration
- Sharps Receptacle

The LIVE Catheter is shown below in Figure 1.

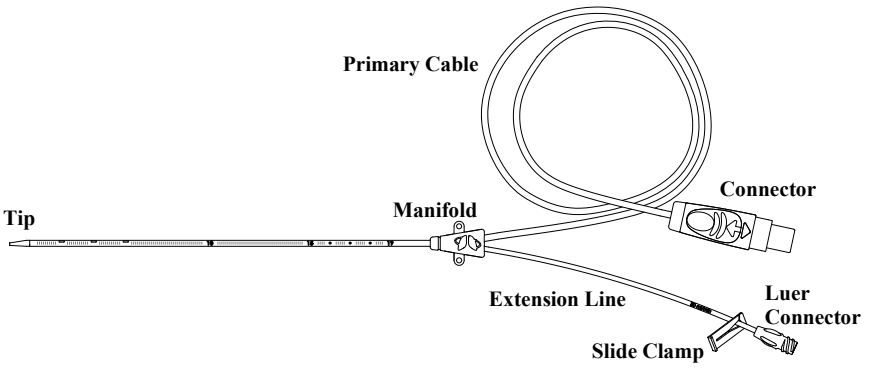

Figure 1 – LIVE Catheter

The LIVE Catheter is a component of the Lungpacer Diaphragm Pacing Therapy System (DPTS).

The Lungpacer DPTS has been authorized for emergency use in healthcare settings for treatment of patients on invasive mechanical ventilation who are at high risk of weaning failure, including COVID-19 patients, during the COVID-

19 pandemic. The purpose of the device is to stimulate the phrenic nerves and activate the diaphragm in adult patients who have been mechanically ventilated and are unable to sustainably breathe without assistance from the mechanical ventilator due to diaphragmatic dysfunction. Treatment is for a maximum of 30 days.

The LIVE Catheter is inserted percutaneously into the left subclavian vein and activated via the Lungpacer Control Unit (LCU) to stimulate the left and right phrenic nerves causing the diaphragm to contract. The Connector component of the LIVE Catheter at the end of the Primary Cable is intended only for connection to the Intermediate Cable.

The LIVE Catheter is manufactured from medical grade, flexible polyurethane and is equipped with electrodes to deliver electrical stimulation and a single lumen to be used for guidewire insertion and subsequently for fluid delivery.

The LIVE Catheter is sterilized by exposure to ethylene oxide (EO) gas and is intended for single use. The LIVE Catheter is provided in three lengths to accommodate dimensional differences in patient anatomy. The available lengths are shown in Table 1 along with nominal dimensions.

Table 1– LIVE Catheter Lengths and Nominal Dimensions

LIVE Catheter Kit Part Number	Nominal Effective Length (cm)	Outside Diameter (mm)
000-0007	19	3.2
000-0008	21	3.2
000-0009	23	3.2

The LIVE Catheter is marked to indicate distance in centimeters from the tip and to indicate the orientation of the catheter during insertion and placement. See Figure 2 below.

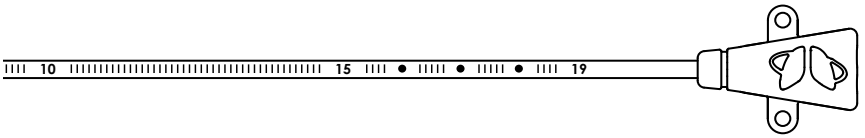

Figure 2 - LIVE Catheter Depth Markings

The flowrate for the injection lumen is 30 mL/min.

The LIVE catheter is not rated for high pressure/Power Injection. Do not use excessive pressure during fluid delivery through the injection lumen.

The maximum guidewire diameter to be used with the LIVE Catheter is 0.81 mm (0.032 inches).

Do not use the LIVE Catheter if its packaging is damaged. Discard the LIVE Catheter Kit if there is visible damage to the packaging.

Verify the LIVE Catheter use-by date before use. Do not use the LIVE Catheter beyond the use-by date on the LIVE Catheter Kit label.

The LIVE Catheter Extension Tubing, Slide Clamp or Luer may be cleaned using chlorhexidine (2% in 70% alcohol) or povidone-iodine (Betadine) (10% solution) while in use.

2. INTENDED USE

The Lungpacer Diaphragm Pacing Therapy System (DPTS) is a temporary, percutaneously-placed, transvenous, phrenic nerve-stimulating device intended to stimulate the diaphragm in conjunction with a mechanical ventilator. Treatment is for a maximum of 30 days.

The Lungpacer Diaphragm Pacing Therapy System (DPTS) is for treatment of patients on invasive mechanical ventilation who are at high risk of weaning failure, including COVID-19 patients, over the duration of the emergency use authorization. The Lungpacer DPTS may improve inspiratory muscle strength and weaning success in patients ages 18 years or older who have failed to wean from mechanical ventilation.

The Lungpacer Diaphragm Pacing Therapy System is intended for use in hospitals and hospital-type facilities by qualified, trained personnel under the direction of a physician.

3. LIVE CATHETER - WARNINGS AND PRECAUTIONS

Do not place the catheter into or allow it to remain in the right atrium or right ventricle (refer to Figure 3)

Figure 3 – LIVE Catheter Warning

4. GENERAL WARNINGS AND PRECAUTIONS:

4.1 WARNINGS:

- Read all package insert warnings, cautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.

- Practitioners must be aware of complications associated with the LIVE Catheter, including, but not limited to:

- Adverse tissue response
- Allergic reaction
- Arrhythmia (including, but not limited to ventricular fibrillation, ventricular tachycardia, atrial fibrillation, atrial fibrillation/flutter, pulseless electrical activity, asystole)
- Atrial or ventricular perforation
- Bleeding / Hemorrhage
- Bradycardia
- Bruising or swelling at insertion site
- Cardiac tamponade
- Central Line-associated Blood Stream Infection (CLABSI)
- Cerebrovascular event
- Diaphragm injury
- Embolism (device, air, or thrombus)
- Hematoma
- Hemothorax
- Hypertension
- Hypotension
- Inadvertent arterial puncture
- Lung injury (e.g., pleural effusion)
- Mediastinal injury
- Pain or discomfort during stimulation
- Pain, tenderness, discomfort at access site
- Phrenic nerve damage or injury
- Pneumohematoma
- Pneumomediastinum
- Pneumothorax
- Pseudo aneurysm at access site
- Sepsis
- Skin irritation
- Syncope
- Thoracic duct laceration
- Tissue damage
- Vessel occlusion
- Vessel wall damage / perforation
- Wound infection

- Do not place the LIVE Catheter into or allow it to remain in the right atrium or right ventricle. X-ray, or other method in compliance with hospital/institutional practices or current guidelines, must confirm appropriate catheter placement and absence of pneumothorax or hemothorax. The LIVE Catheter tip must be located in the right side of the mediastinum in the Superior Vena Cava (SVC) above its junction with the right atrium and parallel to the vessel wall, and its distal tip positioned at a level above either the azygous vein or the carina of the trachea, whichever is better visualized. Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it. Improper advancement of the guidewire into the heart has been implicated in causing cardiac perforation and tamponade. Do not allow the guidewire to be placed in or remain in the right atrium as this may lead to arrhythmia.
- Ensure the LIVE Catheter tip has not entered the heart by performing placement assessment in compliance with hospital/institutional practices or

current guidelines. If catheter position has changed, immediately re-evaluate.

- Practitioners must be aware of the potential for entrapment of the guidewire by any implanted device in the circulatory system (i.e., vena cava filters, stents, catheters). Review the patient's history before the catheterization procedure to assess for possible implants. Care should be taken regarding the length of the guidewire inserted. It is recommended that if the patient has a circulatory system implant then the catheterization procedure should be performed under direct visualization to minimize the risk of guidewire entrapment.
- The LIVE Catheter tip must be located in central circulation when administering >10% glucose solution, total parenteral nutrition, continuous vesicant therapy, infusates with an osmolality above 600 mOsm/L, or any medication known to be irritating to vessels proximal to the vena cava.
- Do not leave open needles or uncapped/unclamped catheters in the central venous puncture site. Air embolism can occur with these practices.
- Use only securely tightened luer-lock connections to guard against any inadvertent disconnection.
- Use luer-lock connectors to help guard against air embolism and blood loss.
- Pulsatile flow is usually an indicator of inadvertent arterial puncture during the insertion procedure.
- Implanted parts of the LIVE Catheter should not be exposed to therapeutic levels of ultrasound energy, as the device may inadvertently concentrate the ultrasound field and cause harm.
- The LIVE Catheter has not been evaluated for safety and compatibility to be used with any implanted stimulators, diathermy, electrocautery, and electrosurgical equipment.
- If the patient is subsequently given any medical treatment in which an electrical current is passed through his/her body from an external source the Lungpacer DPTS should first be deactivated by disconnecting the Intermediate Cable from the LIVE Catheter.
- Remove the LIVE Catheter prior to Magnetic Resonance (MR) imaging. The LIVE Catheter has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the LIVE Catheter in the MR environment is unknown. Scanning a patient who has this device may result in MR image artifact or patient injury due to heating or migration of the device.

CAUTIONS:

- The LIVE Catheter and accessories provided in the LIVE Catheter Kit are designed for single use only.

- Reuse of LIVE Catheter Kit components intended for single use may result in infection.
- Do not re-sterilize or reuse the sterile components. Reuse or re-sterilization, where applicable, of the single-use components may impair the structural integrity and/or performance of the system.
- Use of a non-sterile LIVE Catheter poses the risk of infection.
- Failure to adhere to aseptic catheter insertion technique may result in infection.
- Improper vein access technique may result in vessel wall damage or perforation.
- Improper handling of the LIVE Catheter extension line and/or the insertion site may result in infection.
- Use of the LIVE Catheter beyond its recommended use period may result in infection.
- Connecting LIVE Catheter to anything other than the Lungpacer Diaphragm Pacing Therapy System as intended may pose serious risk of adverse health consequences or death.
- The use of the Lungpacer DPTS incurs the following risks: phrenic nerve damage, and diaphragmatic fatigue.
- Placement of the LIVE Catheter's electrodes in the atrium may result in cardiac arrhythmia.
- Placement of the LIVE Catheter's electrodes too close to the heart may result in cardiac arrhythmia.
- Touching the contacts of the Primary Cable connector of the LIVE Catheter may result in cardiac arrhythmia in the patient.
- Movement of the catheter after placement and mapping may result in overstimulation of the diaphragm.
- Damage to the LIVE Catheter or occlusion of the lumen may pose the risk of embolism.
- Use of the LIVE Catheter may result in an adverse tissue response.
- Ensure that the LIVE Catheter is connected to the LCU via the Intermediate Cable as described in the Diaphragm Pacing Therapy System instructions for use prior to initiating therapy.
- After LIVE Catheter placement, remove any guidewire prior to electrical stimulation.
- Excessive bending, torqueing or kinking of the LIVE Catheter may cause damage to the device including damage to the internal wires.
- Please ensure LIVE Catheter connector pin(s) does not contact with operator or other active or ground surface.
- After use, the LIVE Catheter may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws.

5. PROCEDURE

5.1 PRE-LIVE CATHETER INSERTION & PATIENT ASSESSMENT ACTIVITIES

1) Clinical assessment of the patient must be completed to ensure no contraindications exist e.g. allergies, other existing devices. This device is not recommended for use in the presence of device-related infections or previous/current thrombosis.

(A suggested procedure)

***Warning**: Read all package insert warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.*

2) Perform hand hygiene as required.
3) Verify physician order:
    - Confirm correct patient
    - Confirm correct procedure
4) Physician order must include post-placement assessment of LIVE Catheter tip location (direct visualization technique or other method in compliance with hospital/institutional practices or current guidelines).
5) Educate the patient, or the patient's legally authorized representative, where applicable. Explain the procedure and make sure information is presented at the appropriate level of understanding, culture and language.
6) Select the appropriate length LIVE Catheter for the patient's anatomical dimensions.
    - Sizing is dependent upon the relative position of the right and left phrenic nerves with respect to the right and left electrode arrays on LIVE Catheter. The 21cm length LIVE Catheter will be appropriate for most patients. The depth of insertion of LIVE Catheter should be such that the tip is placed in the distal SVC.
    - The Placement Confirmation sequence on the LCU confirms the recruitment of left phrenic nerve. This is described in the Catheter Insertion Instructions provided below. If the left phrenic nerve is not recruited during the Placement Confirmation sequence, adjust the LIVE Catheter insertion depth to position the left electrode array in proximity to the left phrenic nerve.
    - Assess the placement of the LIVE Catheter, in compliance with hospital/institutional practices or current guidelines, after successful Placement Confirmation to evaluate the need for a longer (23 cm), or a shorter (19 cm) LIVE Catheter before performing Mapping on

the LCU. Placement Confirmation is described in the Catheter Insertion Instructions provided below.

- After successful Placement Confirmation, if the distal end of the LIVE Catheter is placed in the right atrium or right ventricle, retract the LIVE Catheter such that the tip is placed in the distal SVC and run the Placement Confirmation sequence again. If the Placement Confirmation sequence yields no left phrenic recruitment, a shorter (19 cm) LIVE Catheter will be required.
- After successful Placement Confirmation, if the LIVE Catheter tip is not placed in the distal SVC a longer (23 cm) LIVE Catheter may be required to recruit the right phrenic nerve.

7) Identify the insertion site:

- The vein for LIVE Catheter insertion is the left subclavian.

***Caution**: Do not use a right-side venous access point or left jugular access point for LIVE Catheter insertion as this will adversely impact the likelihood of phrenic nerve capture.*

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a) Select the insertion site as lateral as possible.
b) Using direct ultrasound may help to visualize the location of the left subclavian vein.

8) Position the patient as appropriate for insertion site:

a) Place patient in slight Trendelenburg position as tolerated to reduce the risk of air embolism and enhance venous filling.

9) Prepare work area.

5.2 PREPARE FOR LIVE CATHETER INSERTION

1) Perform hand hygiene as required.

- Before and immediately after all clinical procedures
- Before and after donning and removal of gloves

***Caution**: Use universal blood and body-fluid precautions in the care of all patients due to the risk of exposure to COVID-19 (Coronavirus Disease-2019), HIV (Human Immunodeficiency Virus) or other blood-borne pathogens.*

***Caution**: Properly handle and dispose of sharps in sharps container in accordance with US OSHA or other governmental standards for blood-borne pathogens and/or hospital/institutional policy.*

***Warning**: Ensure there is no damage to the LIVE Catheter packaging that could compromise sterility of the device.*

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2) Clinicians should use sterile technique, maximal sterile barrier precautions throughout the procedure, and dress in protective clothing: mask, sterile gown, hair cover, eye protection, and sterile gloves.

3) Flush Catheter:

   a) Flush the lumen of the LIVE Catheter with sterile saline solution to establish patency and prime the lumen.

4) Prepare Puncture Site:

   a) Prepare puncture site with appropriate antiseptic agent.
   b) Position and secure the sterile drape to the skin at the intended insertion site to maintain the sterile field.
   c) Perform skin wheal using desired needle and local anesthetic.
   d) Dispose of needle.

***Warning**: Do not cut the LIVE Catheter to alter length.*

***Warning**: Ensure there are no leaks from the hub or near the extension line connection. Such leaks may contribute to infection.*

5.3 CATHETER INSERTION INSTRUCTIONS

1) Gain and Verify Initial Venous Access

   a) Using ultrasound may help locate the left subclavian vein from the intended insertion site.

***Warning**: Do not leave open needles or uncapped, unclamped catheters in central venous puncture site. This can cause air embolism.*

   b) Insert introducer needle percutaneously into the vein and confirm access.
   c) Insert guidewire through the needle and into the vein.

***Caution**: Maintain firm grip on guidewire at all times. Keep sufficient guidewire length exposed at hub for handling purposes. A non-controlled guidewire can lead to wire embolism.*

***Caution**: Do not reinfuse blood to minimize the risk of blood leakage from rear (cap) of syringe.*

***Warning:** Do not use excessive force to advance or withdraw guidewire as this can lead to vessel damage.*

***Warning**: Do not aspirate with guidewire in place or air may enter syringe.*

***Warning**: Do not withdraw the guidewire against the needle bevel to minimize the risk of severing or damaging the guidewire.*

d) Remove the introducer needle while ensuring the guidewire is still in the vein.

e) Make a small incision in the skin where the guidewire enters.

***Warning**: Do not cut guidewire to alter length.*

***Warning**: Take care not to cut guidewire with scalpel.*

f) Insert the dilator over the guidewire and dilate the incision as needed.

***Warning**: Do not leave the tissue dilator in place as an indwelling catheter to minimize the risk of possible vessel wall perforation.*

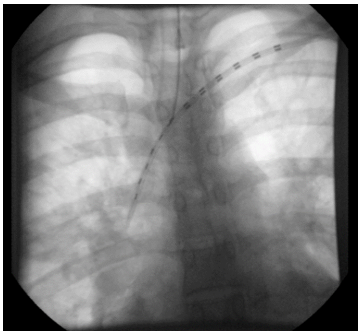
g) Remove the dilator while ensuring the guidewire is still in the vein.

2) LIVE Catheter Advancement

***Caution**: Do not apply excessive force while advancing or retracting the LIVE Catheter.*

The target placement of the LIVE Catheter distal tip is within the distal Superior Vena Cava (SVC), above the cavoatrial junction, as shown in Figure 4.

Figure 4- Target Placement of LIVE Catheter Distal Tip



a) Insert the LIVE Catheter by railing it over the guidewire, ensuring the guidewire is fed back proximally.

b) While advancing the LIVE Catheter, ensure that the **Orientation Stripe** (see Figure 5 below) is visible on top (180° from skin).

Figure 5 – LIVE Catheter Orientation Stripe

c) Position LIVE Catheter to the target depth with the tip placed in the distal SVC by advancing, retracting, and rotating as needed, while ensuring the orientation stripe is visible on top (radially 180 degrees from patient skin).

***Caution**: Ensure that the heart rate is not affected when the catheter is being advanced. If an atrial arrhythmia is detected that could be produced by the LIVE Catheter tip having entered the atrium, retract the catheter tip back into the SVC.*

d) Hold catheter at desired depth and remove the guidewire.

***Warning**: Do not attach catheter clamp until the guidewire is removed.*

***Caution**: If resistance is encountered when attempting to remove the guidewire after LIVE Catheter placement, the guidewire may have kinked around the tip as shown in Figure 6 below.*

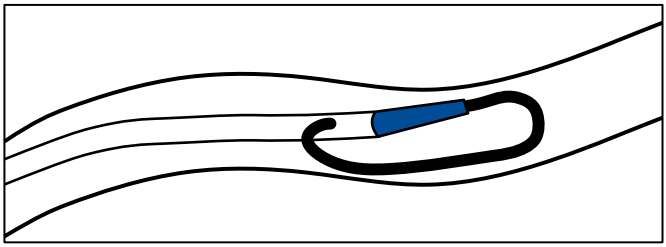


Figure 6 – Kinked Guidewire

- In this circumstance pulling back on the guidewire may result in undue force being applied to guidewire resulting in guidewire breakage.
- If resistance is encountered, withdraw the LIVE Catheter relative to the guidewire about 2-3 cm and attempt to remove the guidewire.
- If resistance is again encountered remove the guidewire and the LIVE Catheter simultaneously.

***Warning**: Do not apply undue force to minimize the risk of possible breakage.*

e) Verify entire guidewire is intact upon removal.

3) Complete LIVE Catheter Insertion:

a) Check placement by attaching a syringe to the extension line and aspirate until free flow of venous blood is observed.

b) Flush the lumen with sterile saline to completely clear blood from the LIVE Catheter.

c) Ensure that the LIVE Catheter is still oriented with the Orientation Stripe and Lungpacer logo on the hub facing away from the patient's skin.

d) To maintain patency of the LIVE Catheter, a heparin lock must be created in the catheter lumen before clamping the extension line. Follow hospital protocol for heparin concentration.

e) Secure the Needle-Free Male Luer Lock Injection Site (included in the LIVE Catheter Kit) or cath-lock, as applicable, using standard hospital/institutional practices or current guidelines. A slide clamp is provided on the extension line to occlude flow through the lumen during line and injection cap changes.

***Warning:** Take care not to position slide clamp directly adjacent to luer fitting.*

***Warning**: Open slide clamp prior to infusion of fluid through lumen to minimize the risk of damage to the extension line from excessive pressure.*

4) LIVE Catheter Placement Confirmation

Steps to be completed by non-sterile operator.

a) Connect the Intermediate Cable to the connector at the end of the Primary Cable component of the LIVE Catheter.

b) Perform Placement Confirmation and verify that the left phrenic nerve can be recruited by the LIVE Catheter as placed.

c) If the left phrenic nerve cannot be recruited during Placement Confirmation, assess the placement of the LIVE Catheter in compliance with hospital/institutional practices or standards.

d) Upon confirmation of successful placement proceed to the next step.

5) Secure LIVE Catheter in place

a) Secure catheter manifold to the patient's skin with sutures or other preferred fixation device.

***Warning**: Do not tie sutures directly around the catheter shaft. Use the suture tabs provided on the catheter manifold.*

b) Secure the catheter using additional catheter clamp and fastener as needed.

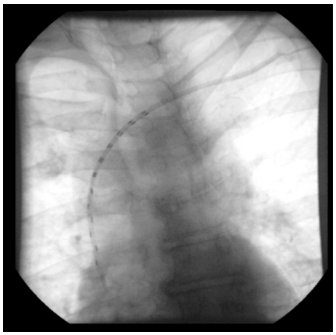
***Caution**: Minimize LIVE Catheter manipulation throughout the procedure to maintain proper tip position.*

c) Ensure insertion site is dry before applying dressing. Apply skin protectant as needed.

***Caution**: Do not routinely apply prophylactic topical antimicrobial or antiseptic ointment or cream to the insertion site because of the potential risk of promoting fungal infections and antimicrobial resistance and because of potential damage to the LIVE Catheter materials.*

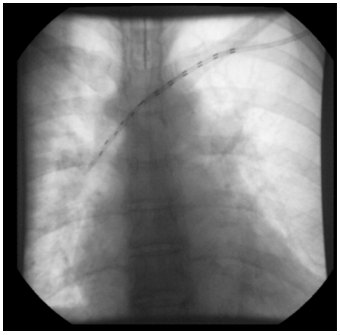
d) Dispose of single-use accessories.
e) Remove sterile drape.
f) Assess placement of catheter tip in compliance with hospital/institutional practices or current guidelines.
g) After successful Placement Confirmation, if the distal end of the LIVE Catheter is malpositioned in the right atrium or right ventricle as shown in Figure 7, retract the LIVE Catheter such that tip is placed in the distal SVC and run Placement Confirmation again. If the Placement Confirmation sequence yields no left phrenic recruitment, a shorter (19 cm) LIVE Catheter will be required.

Figure 7- Malpositioning of LIVE Catheter: Distal Tip Placed Too Deep



h) After successful Placement Confirmation, if the LIVE Catheter tip is not placed in the distal SVC as shown in Figure 8, a longer (23 cm) LIVE Catheter may be required to recruit the right phrenic nerve.

Figure 8- Malpositioning of LIVE Catheter: Distal Tip Not Placed In Distal SVC



***Warning**: Do not run Mapping on the LCU without assessing the placement of the LIVE Catheter in compliance with hospital/institutional practices or current guidelines.*

***Warning**: Do not place the LIVE Catheter into or allow it to remain in the right atrium or right ventricle. Placement assessment in compliance with hospital/institutional practices or current guidelines must show the LIVE Catheter tip located in the right side of the mediastinum in the Superior Vena Cava (SVC) above its junction with the right atrium and parallel to the vessel wall and its distal tip positioned in the distal Superior Vena Cava (SVC), above the cavoatrial junction. Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it. Improper advancement of the guidewire into the heart has also been implicated in causing cardiac perforation and tamponade.*

i) If the LIVE Catheter tip is malpositioned, reposition the catheter using standard sterile techniques, redress, and re-verify proper placement in compliance with hospital/institutional practices and current guidelines.

The LIVE Catheter, once inserted as described above, is ready for use as part of the Lungpacer Diaphragm Pacing Therapy System.

Refer to the Instructions for Use for the Lungpacer Diaphragm Pacing Therapy System before proceeding further. For LIVE Catheter removal from the patient, follow the steps described below.

5.4 REMOVAL OF LIVE CATHETER

1) Disconnect the LIVE Catheter from Intermediate Cable if it is connected.

2) Stop the drip or infusion pump, as applicable.
3) Don sterile gloves.
4) Tighten the slide clamp and remove the drip/infusion pump line.
5) Remove the dressing and any fixation devices used to secure the LIVE Catheter.
6) Place sterile gauze at the insertion site and remove the LIVE Catheter when there is positive intrathoracic pressure.
7) Apply pressure to the gauze and remove the LIVE Catheter.
8) Apply a pressure dressing per standard procedure.
9) Ensure bleeding has stopped and apply a sterile dressing to the wound.
10) Adhere to local procedures for disposal of the LIVE Catheter as biohazardous waste.

6. SYMBOL GLOSSARY


Manufacturer


Date of manufacture

Catalogue number

Batch code


Use by


Caution


Consult instructions for use

MR Unsafe


Do not re-use

Do not re-sterilize


Keep dry


Keep away from sunlight


Do not use if package is damaged

Sterilized using ethylene oxide

Prescription only