AeroPace™ Catheter Kit

For use only with compatible Lungpacer Systems

Rx Only.

CAUTION:

Investigational device. Limited by United States law to investigational use.

Exclusively for clinical investigations. To be used by qualified investigators only.

Instrument de recherche. Réservé uniquement à l'usage de chercheurs compétents.

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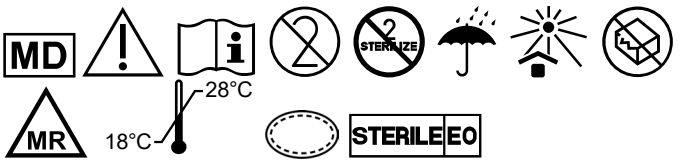

650-0211 Rev G 2024-09-17

DEVICE DESCRIPTION

The AeroPace Catheter Kit contains one AeroPace Catheter and accessories that may be used for deployment of the Catheter. The AeroPace Catheter is a component of compatible Lungpacer Systems.

Refer to the Lungpacer System instructions for use compatibility information and indications for use.

The AeroPace Catheter is supplied sterile for single use up to 30 days. The AeroPace Catheter can be inserted into either the left subclavian vein or the left jugular vein using an over-the-wire procedure and is marked with numerals to indicate the distance from the tip of the Catheter in centimeters. The integrated electrodes are activated via the Lungpacer Neurostimulation Console to stimulate the left and right phrenic nerves, causing the diaphragm to contract.

The AeroPace Catheter contains one distal lumen for the guidewire, for over-the-wire insertion of the Catheter. The maximum guidewire diameter is 0.81 mm (0.032 inches). After guidewire removal, three lumens are available for fluid and/or medication delivery. The distal lumen is rated for high-pressure injection.

		Using maximum viscosity media 12.1 cP at 37° C					
		At **300 psi (2070 kPa)** Injection Pressure Setting		At **400 psi (2760 kPa)** Injection Pressure Setting Max Indicated Catheter Rating			
Catheter Lumen	Flow Rate	Maximum Pressure Injection Flow Rate	Maximum Catheter Pressure During Max. Flow Rate	Maximum Indicated Pressure Injection Flow Rate	Maximum Catheter Pressure During Max. Flow Rate	Average Static Burst Pressure*	Range of Static Burst Pressures*
Distal	42 ml/min	5 ml/s	74 psi (510 kPa)	5 ml/s	78 psi (540 kPa)	212 psi (1460 kPa)	139 – 272 psi (960 – 1875 kPa)
Medial	17 ml/min	Not rated for high-pressure power injection					
Proximal	17 ml/min	Not rated for high-pressure power injection					
	* Static burst pressure is the pressure at the failure point of the Catheter. When Catheter was occluded failure occurred at these pressures.						

The AeroPace Catheter Kit is sterilized by exposure to ethylene oxide (EO) gas. The accessories provided in the Catheter Kit are designed for single use only.

Non-sterile portions of the AeroPace Catheter may be cleaned after insertion using chlorhexidine (2% in 70% alcohol) or povidone-iodine (Betadine) (10% solution).

INTENDED USE

The AeroPace Catheter is a temporary, percutaneously placed, transvenous, phrenic-nerve-stimulating medical device intended to stimulate the diaphragm.

Refer to the Lungpacer System instructions for use for the intended use.

The device is intended to be used by qualified, trained personnel under the direction of a physician.

⚠WARNINGS

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

1) The electrical connector of the AeroPace Catheter must be connected only to the Lungpacer Neurostimulation Console using the Catheter Cable. Use of unauthorized devices with the AeroPace Catheter may result in serious injury.
2) Do not use the AeroPace Catheter with any electrical device (implanted or external) that may be prone to interaction with, or interference from the Lungpacer System, including neurological pacing/stimulator devices, cardiac pacemakers and defibrillators.
3) The AeroPace Catheter is MR Conditional. A patient with the AeroPace Catheter may be safely scanned under the conditions described in the MRI Safety Information.

4) Practitioners must be aware of complications associated with the placement or use of the AeroPace Catheter, including, but not limited to:

- Adverse tissue response
- Allergic reaction
- Arrhythmia*
- Bleeding / Hemorrhage
- Bradycardia
- Bruising, swelling or seroma at insertion site
- Cardiac structure damage (e.g., atrial or ventricular perforation, tricuspid valve injury, cardiac tamponade)
- Central Line-associated Blood Stream Infection (CLABSI)
- Cerebrovascular event
- Diaphragm injury
- Discomfort
- Embolism (device, air, or thrombus including pulmonary embolism due to blood vessel blockage)
- Hematoma
- Hemothorax
- Hypercapnia / hypocapnia
- Hypertension / hypotension
- Hypoxia
- Inadvertent arterial or venous puncture
- Inappropriate stimulation
- Infection (including endocarditis)
- Liberation of mucus plug, secretions
- Lung injury (including pleural effusion)
- Lymphatic / thoracic duct injury (including chylothorax, chylopericardium, lymphocutaneous fistula)
- Mediastinal injury
- Muscle fatigue or discomfort
- Nerve injury (e.g. cervical/brachial plexus, vagus, recurrent laryngeal nerves, phrenic nerve, and sympathetic chain [Horner Syndrome])
- Pain or discomfort during stimulation
- Pain, tenderness, swelling, discomfort at access site.
- Phrenic nerve damage or injury
- Pneumohematoma
- Pneumomediastinum
- Pneumothorax
- Pseudoaneurysm or AV fistula at access site
- Sepsis
- Skin irritation
- Syncope
- Thrombosis / stenosis
- Tissue damage
- Unable to deliver therapy
- Vessel occlusion
- Vessel wall damage / perforation
- Wound healing issues
- Wound infection / phlebitis

* including, but not limited to asystole (cardiac arrest), atrial extrasystole(s), atrial fibrillation, atrial flutter, atrial tachycardia, atrioventricular (AV) block, atrioventricular nodal re-entrant tachycardia (AVNRT), atrioventricular re-entrant tachycardia (AVRT), pulseless electrical activity, supraventricular extrasystole(s), transient atrial arrhythmia lasting less than 2 seconds, transient ventricular arrhythmia lasting less than 2 seconds, ventricular extrasystole(s), ventricular fibrillation, ventricular flutter, and ventricular tachycardia.

5) Do not use the AeroPace Catheter Kit if its packaging is damaged. Discard the Catheter Kit if there is visible damage to the packaging.
6) Do not use AeroPace Catheter Kit beyond the use-by date on the label. Verify the use-by date before use.
7) Do not use a guidewire with a diameter in excess of 0.81 mm (0.032 inches).
8) Do not place the Catheter into or allow it to remain in the right atrium or right ventricle. Hospital/institutional practices or current guidelines must be used to confirm appropriate Catheter placement and the absence of pneumothorax or hemothorax. The 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.
9) Ensure the 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.
10) Practitioners must be aware of the potential for entrapment of the guidewire by any implanted device in the circulatory system (e.g., 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.
11) Assess each patient for appropriateness of a high-pressure power injection procedure through the Catheter. Pressure injection procedure must be performed by trained personnel well versed in safe technique and potential complications.
12) Confirm the Catheter tip position prior to each high-pressure power injection.
13) Ensure patency of distal lumen prior to high-pressure power injection to minimize the risk of Catheter failure and/or potential complications.
14) Discontinue high-pressure power injection at first sign of extravasation or Catheter deformation. Follow hospital/institutional protocol for appropriate medical intervention.

15) Do not exceed maximum pressure or maximum flow rate during high-pressure injection through the distal lumen to minimize the risk of Catheter failure and/or potential complications.
16) Do not use excessive pressure during fluid delivery through the injection lumen for the proximal and medial lumens. These lumens are not rated for high-pressure power injection.
17) The Catheter tip must be located in central circulation when administering >10% glucose solution, total parenteral nutrition, continuous vesicant therapy, infusates with an osmolarity above 600 mOsm/L, or any medication known to be irritating to vessels proximal to the vena cava.
18) Do not leave open needles or uncapped/unclamped catheters in the central venous puncture site. Air embolism can occur with these practices.
19) Use only securely tightened Luer lock connections to guard against any inadvertent disconnection.
20) Use Luer lock connectors to help guard against air embolism and blood loss.
21) Pulsatile flow is usually an indicator of inadvertent arterial puncture during the insertion procedure.
22) The portion of the Catheter inside the patient's tissue or veins should not be exposed to therapeutic levels of ultrasound energy, as the device may inadvertently concentrate the ultrasound field and cause harm.
23) 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 AeroPace System should first be deactivated by disconnecting it from the Catheter.

PRECAUTIONS:

1) The accessories provided in the Catheter Kit are designed for single use only.
2) The Catheter is designed for single insertion and use for up to 30 days.
3) Reuse of components intended for single use or reinsertion of the Catheter may result in infection.Do not re-sterilize or reuse the sterile components. Reuse or re-sterilization of the sterile components may impair the structural integrity and/or performance of the Catheter Kit.
5) Use of a non-sterile Catheter poses the risk of infection.
6) Failure to adhere to aseptic Catheter insertion technique may result in infection.
7) Improper vein access technique may result in vessel wall damage or perforation.

8) Improper handling of the Catheter extension lines and/or the insertion site may result in infection.
9) Use of the Catheter beyond its recommended use period may result in infection.
10) Connecting the AeroPace Catheter electrical connector to anything other than the a compatible Lungpacer System may pose serious risk of adverse health consequences or death.
11) Improper use of the Lungpacer System may result in phrenic nerve damage or overstimulation of the diaphragm. Closely follow all System instructions for use.
12) Placement of the Catheter's stimulation electrodes in the atrium may result in cardiac arrhythmia.
13) Placement of the Catheter's stimulation electrodes too close to the heart may result in cardiac arrhythmia.
14) Touching or grounding the contacts of the Catheter's electrical connector may result in cardiac arrhythmia in the patient.
15) Movement of the Catheter after placement and mapping may result in overstimulation of the diaphragm, which may result in diaphragm injury.
16) There is a risk of inability to deliver Therapy to one or both hemidiaphragms after Catheter placement if the electrodes cannot stimulate the phrenic nerve(s) due to nerve damage or distance / interference.
17) Damage to the Catheter or occlusion of the lumen may pose the risk of embolism.
18) Use of the Catheter may result in an adverse tissue response.
19) After Catheter placement, remove any guidewire prior to electrical stimulation.
20) Excessive bending, torquing or kinking of the Catheter may cause damage to the device including damage to the electrical conductors.
21) Multiple replacements of the Catheter increase the risk of vessel wall damage and perforation.
22) Ensure the Catheter connector pins do not contact the operator or other active or ground surface.
23) Ensure sharp procedure implements do not cut or damage the Catheter.
24) After use, the Catheter or Catheter Kit Components may be potential biohazards. Handle and dispose in accordance with accepted medical practice and applicable local, state, and federal laws.

RECOMMENDED PROCEDURE

PRE-INSERTION & PATIENT ASSESSMENT ACTIVITIES

1) Clinical assessment of the patient must be completed to ensure no medical conditions exist that may contraindicate use of the Catheter for the intended use:
   - Patients with any electrical device (implanted or external) that may be prone to interaction with, or interference from the Lungpacer System including neurological pacing/stimulator devices, cardiac pacemakers and defibrillators.

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

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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 the Catheter tip location (direct visualization technique or other method according to hospital/institutional practices or current guidelines).
5) Obtain informed consent.
6) Identify the insertion site:

   The AeroPace Catheter can be inserted in either the left subclavian vein or the left jugular vein.

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

⚠***Caution**: The US Centers for Disease Control and Prevention recommend catheter placement using a subclavian site rather than a jugular site in adult patients to minimize infection risk https://www.cdc.gov/infectioncontrol/guidelines/bsi/index.html.*

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   a) Use direct ultrasound to visualize the location of the left subclavian vein or left jugular vein.
7) Position the patient as appropriate for the insertion site:
   a) Place patient in slight Trendelenburg position as tolerated to reduce the risk of air embolism and enhance venous filling.
8) Prepare work area.

PREPARE FOR CATHETER INSERTION

9) Perform hand hygiene as required.

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

⚠***Caution**: Inspect the Catheter Kit expiration date before use. Use of expired product may lead to injury.*

⚠***Caution**: Use universal blood and body-fluid precautions in the care of all patients due to the risk of exposure to 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 bloodborne pathogens and/or hospital/institutional policy.*

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

⚠***Warning**: Ensure there is no damage to the Catheter prior to use.*

⚠***Caution**: Do not place the Catheter through any introducer sheath.*

10) 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.
11) Flush Catheter:
    a) Flush the lumens of the Catheter with sterile saline solution to establish patency and prime the lumen.
12) Prepare Puncture Site:
    a) Prepare and clean skin 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) Administer local anesthetic per institutional policies and procedures.
    d) Dispose of needle.

⚠***Warning**: Do not cut the 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.*

CATHETER INSERTION INSTRUCTIONS

1) Gain and Verify Initial Venous Access
    a) Using ultrasound, as needed, locate the left subclavian vein or left jugular 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.*

⚠***Caution***: *To reduce the risk of infection, consider removing any existing central venous catheter(s) in the patient's left jugular or left subclavian vein before insertion of the AeroPace catheter.*

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 the 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) Catheter Advancement

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

The target placement of the Catheter's distal tip is within the distal Superior Vena Cava (SVC), above the cavoatrial junction.

The Lungpacer Neurostimulation Console has an optional intravascular electrogram (ECG) feature that can be used during or immediately after insertion of the Catheter, which may be used to assist in placing the Catheter in its target position. The Catheter is marked with numerals to indicate distance from the tip in centimeters.

a) Insert the Catheter by advancing it over the guidewire while maintaining a grip on the guidewire.

b) Position the Catheter so that the tip is placed in the distal SVC by advancing or retracting the Catheter as needed.

c) If the optional ECG feature will be used while placing the Catheter:

- While maintaining the sterile field and sterility of the Catheter, connect the Catheter's electrical connector to the Catheter Cable.
- Refer to the Lungpacer System Instructions for Use for details on using the ECG feature for Catheter placement.

⚠***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 Catheter tip having entered the atrium, retract the Catheter tip back into the SVC.*

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

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

⚠***Caution***: *If resistance is encountered when attempting to remove the guidewire after Catheter placement, the guidewire may have kinked around the tip as shown in Figure 1 below.*

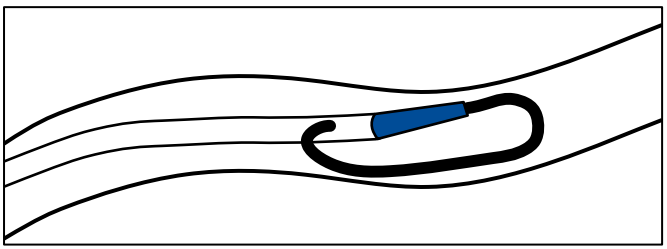

Figure 1 – Kinked Guidewire

- 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 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 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 Catheter Insertion:
   a) Check placement by attaching a syringe to the extension line and aspirate until free flow of venous blood is observed. If lumens exhibit excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flow.
   b) Flush the lumens with sterile saline to completely clear blood from the Catheter.
   c) To maintain patency of the Catheter, a heparin lock must be created in the Catheter lumens before clamping the extension lines. Follow hospital protocol for heparin concentration.
   d) Unused ports may be “locked” through luer-activated connectors using standard hospital/institutional protocol. Clamps are provided on the extension lines to occlude flow through the lumens during line and injection site changes.

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

4) Catheter Placement on Lungpacer Neurostimulation Console
   Steps to be completed by non-sterile operator.
   a) Connect the AeroPace Catheter to the Lungpacer System using the Catheter Cable.
   b) Perform Placement and verify that the left phrenic nerve can be recruited by the Catheter as placed.
   c) If the left phrenic nerve cannot be recruited during Placement, assess the placement of the Catheter in compliance with hospital/institutional practices or standards.
   d) The catheter contains radiopaque markings that indicate the start and end of the left and right electrode arrays and may be used in positioning the arrays relative to anatomical landmarks. Refer to Figure 2 below.

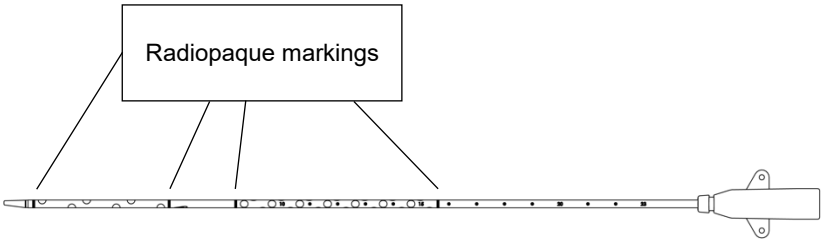

Figure 2 – Radiopaque markings

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

5) Secure Catheter in place

a) Secure the 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.*

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

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

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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 Catheter materials.*

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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) If assessment of Catheter placement indicates that the distal end of the Catheter is located in the right atrium or right ventricle, retract the Catheter such that tip is placed in the distal SVC and run Placement again.

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

⚠***Warning**: Do not place the 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 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.*

h) If the 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 AeroPace Catheter, once inserted as described above, is ready for use as part of a compatible Lungpacer System. Refer to the Instructions for Use for the Lungpacer System before proceeding further.

For Catheter removal from the patient, follow the steps described below.

REMOVAL OF CATHETER

1) Disconnect the Catheter from the Lungpacer Neurostimulation Console if it is connected.
2) Stop the drip or infusion pump, as applicable.
3) Don sterile gloves.
4) Tighten the clamps and remove the drip/infusion pump lines.
5) Remove the dressing and any fixation devices used to secure the Catheter.
6) Place sterile gauze at the insertion site and remove the Catheter when there is positive intrathoracic pressure.
7) Apply pressure to the gauze and remove the Catheter.
8) Apply a pressure dressing per standard procedure.
9) Ensure bleeding has stopped and apply a sterile dressing to the wound.
10) In cases where the Catheter or catheter kit components are to be discarded, adhere to local procedures for disposal of biohazardous waste.

CATHETER CARE AND MAINTENANCE

Catheter entry site must be prepared and maintained in a manner consistent with standard procedure for central venous catheterization.

Maintain Catheter patency according to hospital/institutional policies, procedures, and practice guidelines. All personnel who care for patients

with a central venous catheter must be knowledgeable about effective management to prolong catheter's dwell time and prevent injury. To care for the AeroPace Catheter during use:

1) Solution and frequency of flushing a venous access catheter should be performed in accordance with hospital/institutional policy.
2) Any unused lumens/ports should be maintained and/or "locked" in accordance with hospital/institutional policy.
3) Prior to using any lumen that is already "locked", lumen should be flushed with sufficient volume of saline in accordance with hospital/institutional policy.
4) Lumens should be flushed with sufficient volume of saline in accordance with hospital/institutional policy between administrations of different infusates.
5) Lumens should be flushed with sufficient volume of saline in accordance with hospital/institutional policy before reestablishing "lock."

MRI SAFETY INFORMATION

The AeroPace Catheter is MR Conditional. A patient with the AeroPace Catheter may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

⚠***Warning**: The AeroPace Catheter is MR Conditional, but the Neurostimulation Console and other System components are MR Unsafe. Always disconnect the Catheter from the Neurostimulation Console before conducting an MRI and keep the Console and other System components (including the Airway Sensor) away from MR equipment. Failure to do so may result in serious injury or death.*

Nominal Values of Static Magnetic Field (T)	1.5 T
Type of Nuclei	Hydrogen
MR Scanner Type	Cylindrical
Direction of Static Magnetic Field	Horizontal
Maximum Spatial Field Gradient (T/m and gauss/cm)	40 T/m (4,000 gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature-driven)

Operating Mode of MR System	Normal Operating Mode* *Note: Certain conditions require reducing the whole-body averaged and head SAR to values lower than the Normal Operating Mode. Refer to the information above and in **Figure 3** and **Figure 4**.
RF Conditions	1.5 T/64 MHz See information in **Figure 3** and **Figure 4.**
Maximum Head SAR	Certain conditions require reducing the head SAR to a value lower than the Normal Operating Mode. Refer to the information in **Figure 3** and **Figure 4**.
Scan Regions	Depending on the type of MRI examination to be performed, careful consideration must be given to the particular scan region (i.e., zone) and the positioning of the AeroPace Catheter in order to ensure patient safety. The WBA SAR or head SAR must not be exceeded. Refer to **Figure 3** and **Figure 4**.
Limits on Scan Duration	Maximum whole-body averaged SAR of 0.2 W/kg for 30 minutes of continuous RF exposure with a 30-minute cooling period. Under the scan conditions defined, the AeroPace Catheter is expected to produce a maximum rise of 6°C after 30 minutes of continuous scanning.
MR Image Artifact	The presence of the AeroPace Catheter produces an imaging artifact. Therefore, carefully select pulse sequence parameters to minimize artifacts if the Catheter is located in the area of interest. In non-clinical testing, the image artifact caused by the AeroPace Catheter extends approximately 6 mm from this device when imaged using a gradient echo pulse sequence and a 1.5 T MR system.

The Catheter must be positioned exactly as shown and exit the body along the B0 axis of the scanner and at the XY isocenter during an MRI.

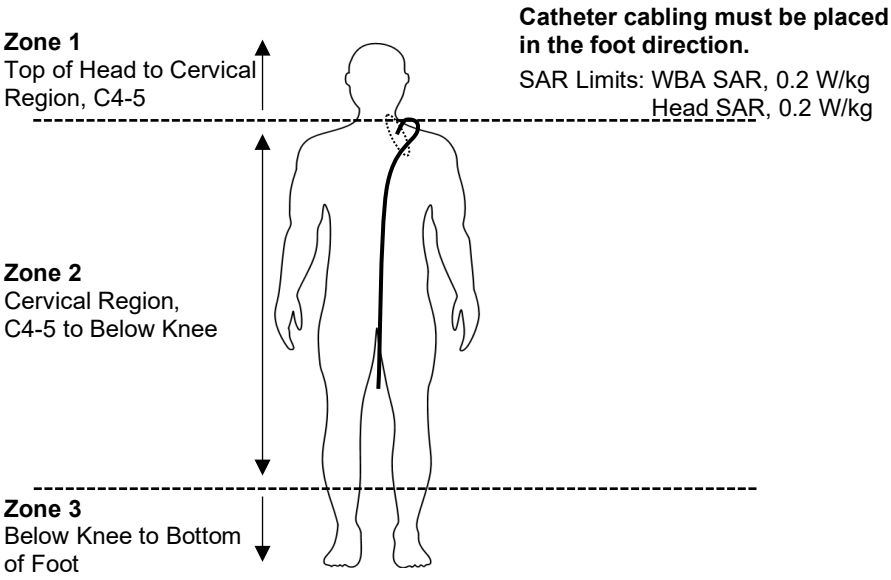

Figure 3 – MRI Exam: Zone 1, Head-First or Feet-First Patient Positioning

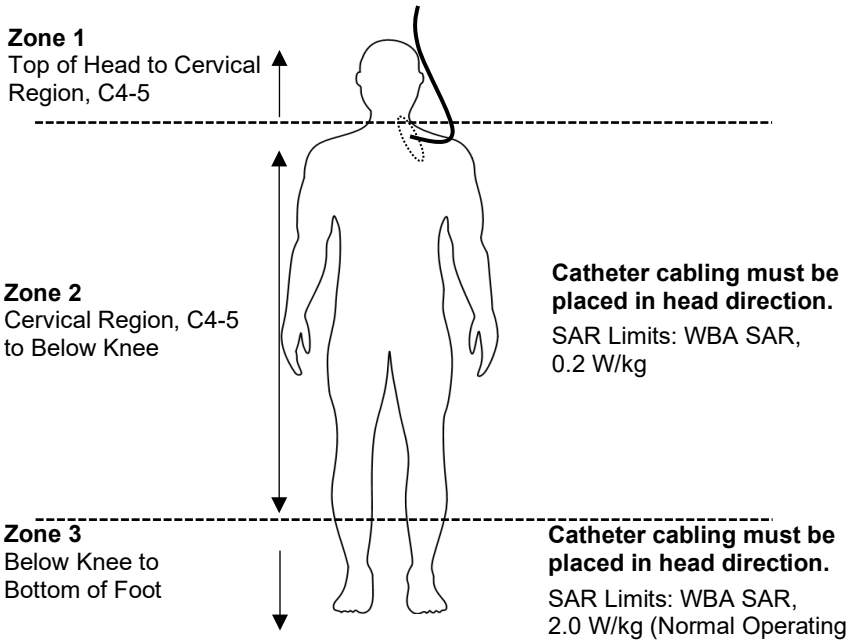

Figure 4 – MRI Exam: Zone 2 or Zone 3, Head-First or Feet-First Patient Positioning

SYMBOL GLOSSARY

Medical Device

Caution

Consult instructions for use

Do not re-use

Do not re-sterilize

Keep dry

Keep away from sunlight

Do not use if package is damaged

Temperature limit

MR Conditional

Single sterile barrier system with protective packaging inside

Sterilized using ethylene oxide

Manufacturer

Catalogue number

Batch code

Date of manufacture

Use by

Open here

Rx Only Prescription Only