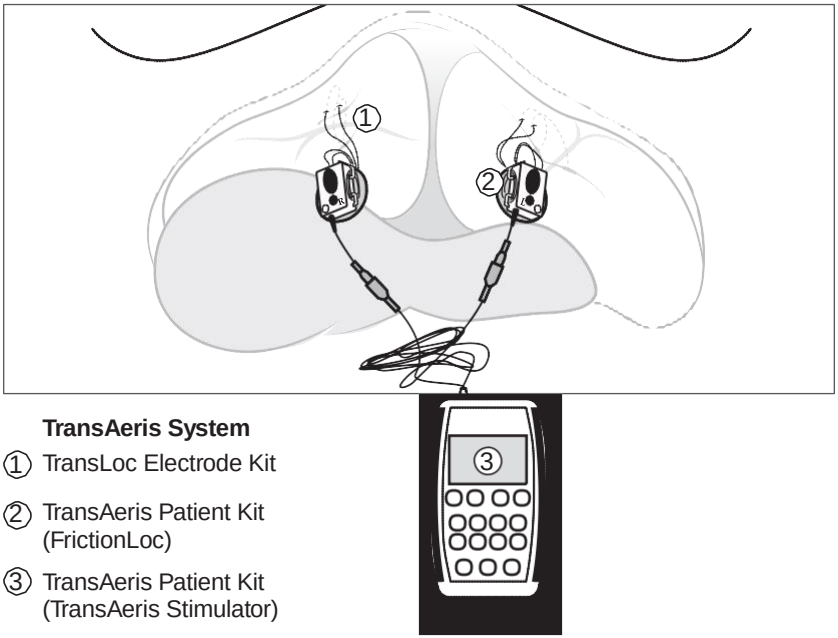
SYNAPSE
Biomedical Inc.

Surgical Procedures for

Implantation of TransLoc® Electrodes

(for TransAeris® System)



TransAeris System

① TransLoc Electrode Kit

② TransAeris Patient Kit (FrictionLoc)

③ TransAeris Patient Kit (TransAeris Stimulator)

Package Contents

The TransLoc electrodes are supplied with the following items:

- (20) TransLoc Electrodes
- (1) Surgical Manual

Re-Order # 20-1004

Authorized for emergency use during the COVID-19 pandemic

About This Manual

This manual describes the surgical procedures for implantation of TransLoc Electrodes.

TransAeris® is a percutaneous intramuscular diaphragm stimulator for temporary use in the hospital setting. The system consists of implantable stimulating TransLoc® electrode leads, disposable/single-use FrictionLoc® connectors (20-1002 Patient Kit), and a disposable/single-use portable external stimulator (20-1002 Patient Kit).

- When done prophylactically with another procedure, the implant approach to the diaphragm may be from either the inferior (abdominal) or superior (chest) aspect of the diaphragm surface.
- The system has four stimulating intramuscular TransLoc electrodes to be implanted into the diaphragm for motor point diaphragm stimulation.
- Two stimulating TransLoc electrodes shall be placed into each hemi-diaphragm.
- TransLoc electrodes are tunneled through two percutaneous exit sites on the respective lateral chest region.
- A single left and right FrictionLoc connector (Patient Kit) will provide an electrical interface from the TransLoc electrodes to a patient cable.
- The patient cable with left (blue) and right (green) identifiers (Patient Kit) is integrated into the TransAeris stimulator (Patient Kit).
- TransAeris stimulator has a user interface for clinical control.

Intended Use

For emergency use during the COVID-19 pandemic, the TransAeris is a percutaneous intramuscular diaphragm stimulator intended for patients at risk of or on prolonged positive pressure mechanical ventilation.

TransAeris is indicated for use in the prevention and treatment of ventilator-induced diaphragm dysfunction (VIDD).

Contraindications

- None

⚠Warnings

Use only under the direction of a physician. The TransAeris stimulator is electrically powered and may produce tissue damage or electrical hazard if improperly used.

- The device has accessible controls for clinical staff and NO patient-accessible controls.
- Do NOT attempt to open the TransAeris stimulator case or attempt any unintended modifications as this will cause a failure in the TransAeris stimulator functionality.

Use of TransAeris could interfere with some medical equipment. Some medical equipment could interfere with the use of TransAeris. Consult the User Manual before having any of the following:

- **Implanted cardiac pacemaker or defibrillator.** Use of the TransAeris stimulator may interfere with these devices.
- **Surgery**. Use of high-frequency surgical equipment may cause burns where the electrode leads pass through the skin. Such equipment may damage the TransAeris stimulator. Disconnect the TransAeris stimulator when high-frequency surgical equipment is in use.
- **Magnetic Resonance Imaging (MRI) test.** The TransLoc electrode is MR unsafe. Do not perform a MRI test while implanted with the TransLoc electrodes or remove the TransLoc electrodes from the patient before a MRI test.
- **Magnetic Resonance Imaging (MRI) test.** The TransAeris stimulator, FrictionLoc connector, and surface electrode are MRI Unsafe. Remove these components from the patient before a MRI test.
- **Use of external electrical stimulation such as transcutaneous electrical nerve stimulation (TENS)** should not be done in the chest area near the electrode leads. Unwanted diaphragm contraction could occur.

Clinicians should avoid accidental contact between connected but unused applied parts (cable or leads) and other conductive parts including those connected to earth ground or any device with the ground symbol.

Safety has not been established for the use of the device during pregnancy.

It should not be used in patients with epilepsy.

CARDIAC INTERFERENCE. Before conditioning, test interference with cardiac rhythm. Monitor electrocardiogram (ECG) while stimulating at maximal settings. If interference is observed, decrease stimulation settings below level of interaction, turn off identified electrodes, or remove identified electrodes.

Do NOT come in contract with TransLoc electrodes during emergency defibrillation. It may lead to electric shock to caregivers.

ELECTROMAGNETIC INTERFERENCE WARNING: Some electrically powered equipment gives off electromagnetic waves which could interfere with TransAeris systems. When using your TransAeris system around electrical equipment, check the TransAeris stimulator screen to make sure the TransAeris system is working.

Do follow the electromagnetic compatibility (EMC) information provided. The TransAeris stimulator needs special precautions regarding EMC. To reduce the possibility of interference on the TransAeris stimulator from other electrical equipment or the TransAeris stimulator effecting other electrical equipment, do not use cables or accessories with the TransAeris stimulator other than those specified.

RF COMMUNICATION WARNING: Portable and mobile RF communication equipment may affect medical electrical equipment. Ensure proper function of TransAeris when using around such equipment.

⚠Warnings Continued

ELECTRO-STATIC DISCHARGE (ESD): After the TransLoc electrode has been implanted but not connected to the FrictionLoc connector, use caution when handling the electrode leads. Before touching the electrode leads, touch the patient to equalize the electrostatic potential.

FLAMMABILITY WARNING: Do NOT use TransAeris system in an oxygen enriched environment, such as a hyperbaric oxygen chamber, or near a flammable anesthetic mixture with air, oxygen, or nitrous oxide. This could cause a fire or explosion.

⚠ Precautions

The TransLoc electrodes have been carefully designed and tested to ensure reliability during normal use. To avoid damage to the TransLoc electrodes, observe the following precautions.

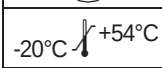
- The TransAeris system is designed for single-patient use. Dispose of the device and all components when finished using on a patient. Do NOT reuse. Reuse may lead to transmission of infection.
- TransLoc leads, improper connection, or fracture of leads may result in failure of the TransAeris stimulator. Inspect exiting electrode leads for damage before use.

Possible Adverse Effects

Possible adverse effects from the use of TransAeris system may include:

- Cardiac interaction
- Lead breakage
- Unretrieved device fragment
- Electrode dislodgement
- Skin infection
- Skin sensitivity due to adhesive
- Pain or discomfort due to stimulation

Symbols

Explanation of symbols	
	The ***Warning*** symbol precedes warning information that mitigates a risk that is not obvious to the operator. Indicates that a potentially hazardous situation which, if not avoided, could result in harm to the operator or patient. Powered equipment indicates physiological effects not obvious to the user that can cause harm.
	The ***Caution*** symbol appears next to precautionary information when the intention is solely to inform. Indicates that a potentially hazardous situation which, if not avoided, may result in minor or moderate personal injury or property damage. This word is used to also alert against unsafe practices.
	The ***Manufacturer*** symbol appears next to the manufacturer's name and address.
	The ***Reference*** symbol appears preceding the part number for the device. The part number is a unique numeric identifier for the device.
	The ***Lot*** symbol appears preceding the lot number for a device. Devices manufactured at the same time using identical material and parts will share a common lot number.
	The ***Use Until*** symbol appears on devices that have an indication of the date by which the device should be used. The date is expressed as the year and month, with the month referring to the end of the month.
	The ***Sterile*** symbol and the EO method of sterilization symbol appear on devices that have undergone an ethylene-oxide gas sterilization process and are provided sterile
	The ***Do not Re-sterilize*** symbol appears on devices that are supplied sterile to indicate that the device may not be re-sterilized.
	The ***Do not Re-use*** symbol appears on devices that are suppled sterile to indicate that the device is for single-use and may not be used again.
	The ***Temperature Limits*** symbol appears on packages of devices as an indication of the storage and transit temperature limits.
	The ***Keep Dry*** symbol appears on all packages of devices requiring to protect the packaging from potential damage.
	The ***Don't Use If*** Packing Damaged symbol appears on all packages of devices requiring to dispose of the device if the packaging has suffered damage.
	The ***Regulatory Marking of Conformity*** symbol indicates that the device meets Medical Device Directive 93/42/EEC. This has been certified by notified body number 2797.
	The ***European Community*** Representative symbol indicates the identification of the authorized representative for the distribution of devices into the European community.
	***MR Unsafe.*** A device that is known to pose hazards in all MR environments.
	***ESD sensitive device.***

Surgical Instructions

INFERIOR IMPLANT

During a laparotomy with a midline incision for patients such as Liver Transplant, Esophagectomy, Gastrectomy, or Exploratory Laparotomy from Trauma, hold a retractor up on the abdominal wall to see the left and right diaphragm. Place two electrodes into the right hemi diaphragm lateral to the central tendon. On the patient's left diaphragm two electrodes are placed lateral to the edge of the pericardium, where you can see the heart is beating as the phrenic nerve comes in laterally on the left diaphragm. To implant an electrode, use standard suture techniques. Grasp the curved needle avoiding the swage (crimp area) and pass the needle through the diaphragm. Once needle and suture are exposed, cut the needle off of the suture near the swage and remove the needle. Then grasp the blue suture and pull the electrode through the diaphragm so that the tip of the electrode is exposed. Cut the excess suture and remove. Repeat this procedure for each remaining electrode to be implanted. The electrodes are externalized by pushing the percutaneous access needles through the abdominal wall. The two electrodes implanted in the right hemi-diaphragm are externalized through the right upper quadrant. The two electrodes implanted in the left hemi-diaphragm are externalized by pushing the percutaneous access needles through the lateral aspect of the left upper abdomen below the costal margin. Adequate electrode length should remain near the diaphragm so that there is not any tension on the lead during contraction. If implantation of electrodes will be done via laparoscopic approach, use of a 10 mm or larger trocar is necessary to facilitate electrode introduction into the abdomen.

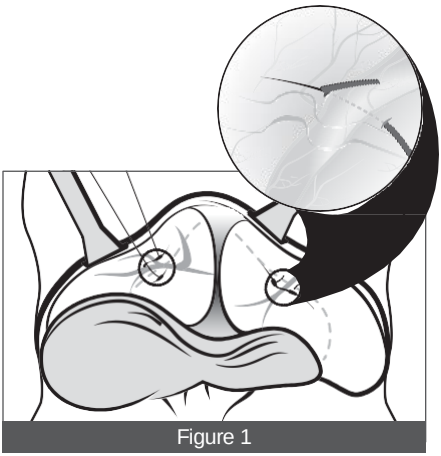


Figure 1

SUPERIOR IMPLANT

During an open median sternotomy two electrodes are implanted on the right hemi diaphragm and two electrodes on the left hemi diaphragm. They are implanted just lateral to where the phrenic nerve comes into the central tendon. To implant an electrode, use standard suture techniques. Grasp the curved needle avoiding the swage (crimp area) and pass the needle through the diaphragm. Once needle and suture are exposed, cut the needle off of the suture near the swage and remove the needle. Then grasp the blue suture and pull the electrode through the diaphragm so that the tip of the electrode is exposed. Cut the excess suture and remove. Repeat this procedure for each remaining electrode to be implanted. Each electrode is externalized so that it exits the chest in as direct a path as possible to the percutaneous exit site to allow for eventual easier removal. This is done by using the percutaneous access needle to bring the lead out through the skin in the desired location. For procedures with temporary cardiac pacing, two electrodes exit on each side above and lateral to the temporary cardiac pacing wires. Adequate electrode length should remain near the diaphragm so that there is not any tension on the lead during contraction. If implantation of electrodes will be done via thoracoscopic approach, use of a 10 mm or larger trocar is necessary to facilitate electrode introduction into the chest.

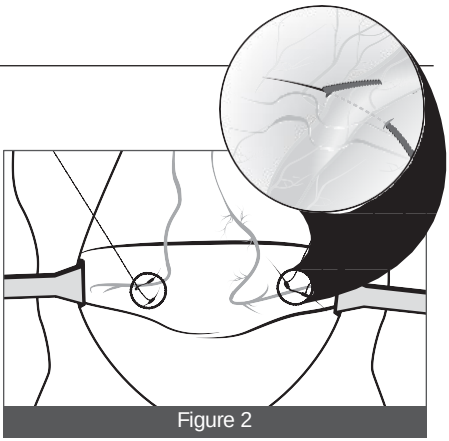


Figure 2

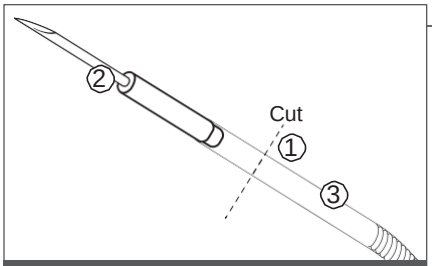


Figure 3

After the TransLoc electrodes have been implanted into the diaphragm and tunneled through the skin, the external end of the electrodes requires preparation before it can be connected to the FrictionLoc connector. The suture (1) between the tunneling needle (2) and the conductive pin (3) must be cut.

Cut the suture approximately halfway between the tunneling needle and the conductive pin, leaving the silicon protective tube covering the conductive pin.

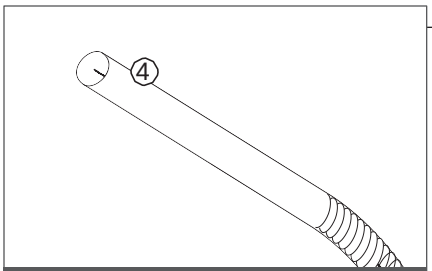


Figure 4

The silicon protective tube (4) will remain on the conductive pin until it is ready to use in the ICU.

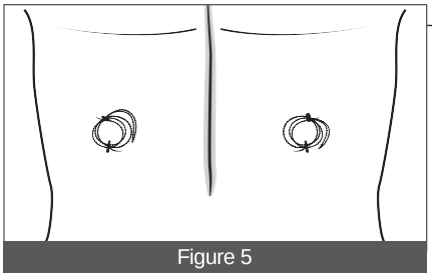


Figure 5

The external wires are fixated on the skin by looping them and suturing them.

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