TransAeris System

Temporary Diaphragm Stimulator

Designed for the prevention and treatment of VIDD (Ventilator Induced Diaphragm Dysfunction)

- Prevent, slow, or reverse diaphragm disuse atrophy
- Minimize mechanical ventilation exposure
- Enhance ability to wean from mechanical ventilation
- Implant electrodes prophylactically or as primary procedure
- Intuitive interface with built in clinical programming
- Single use and disposable, reducing risk of healthcare associated infections
- Temporary stimulation up to 30 days

The TransAeris has been authorized for the above emergency use by the FDA under an EUA.

The TransAeris™ System is a temporary 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). The primary components of the TransAeris System include the TransLoc® electrodes and the external TransAeris stimulator. Up to two TransLoc electrodes are inserted into each, right and left, hemi-diaphragm. TransAeris is used to provide neuromuscular electrical stimulation to the diaphragm while the patient is on mechanical ventilation to prevent, slow, or reverse diaphragm disuse atrophy and, more generally, to treat VIDD. Once the patient is successfully extubated after mechanical ventilation, the electrodes are removed from the patient. The entire system is disposed of after single patient use to avoid any transfer of nosocomial infections in the ICU environment.

Item	Model Number	Shelf Life	Service Life
TransAeris Stimulator Kit Multi-Pack (5 Kits)	20-1003-EUA	1 Year	30 Days
TransLoc Electrode Kit (20 Electrodes)	20-1004-EUA	1 Year	30 Days
FrictionLoc Kit (Blue and Green)	22-1005-EUA	1 Year	30 Days
Surface Electrode Kit (5 Pair – 10 total)	20-1007-EUA	1 Year	30 Days

Specifications	
Output Intensity Level	2% to 100% (0.1 µC to 5 µC)
Output Frequency	6 to 20 Hz
Cycle Rate	5 to 30 Cycles per Minute (CPM)
Cycle Time	0.5 to 1.5 sec
Dimensions (cm).	14.73 x 9.14 x 2.54
Weight	390 g

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TransAeris System:

User manual must be reviewed prior to use for detailed disclosure.

Intended use

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 known

Warnings

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. Use of TransAeris could interfere with some medical equipment. Some medical equipment could interfere with the use of TransAeris. 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. Safety has not been established for the use of the device during pregnancy. Safety has not been established for the use 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 contact with TransLoc electrodes during emergency defibrillation. It may lead to electric shock to caregivers.

Precautions

Before each use, evaluate the TransAeris stimulator for damage and observable defects. Do not use the TransAeris stimulator if the case is cracked, the controls are not functioning, the displays are not working, or if the controls, displays, or connectors are broken. The TransAeris stimulus artifact may be seen on monitored bio-potential signals such as continuous ECG monitoring. The TransAeris stimulator is designed for single-patient use. Dispose of the device when finished using on a patient. Do NOT reuse. Reuse may lead to transmission of healthcare associated infections. TransLoc leads, FrictionLoc™ connectors, and cables – Improper connection or fracture of leads or cables may result in failure of the TransAeris stimulator. Inspect exiting electrode leads and cables for damage before use. To avoid patient entanglement with the cable, keep TransAeris close to the patient at all times when in use. If you think the device is not providing enough stimulation, then consult this manual or call Synapse Biomedical Customer Service. This could mean that the TransAeris may not cause the patient's diaphragm to contract.

Other environmental factors may impact proper performance of the TransAeris in the hospital setting. Use of appropriate environmental health and safety practices will help prevent environmental damage to the TransAeris.

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

See the user manual for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Synapse at 1-888-767-3770 and/or consult the Synapse Biomedical website at www.synapsebiomedical.com

The TransAeris® Diaphragm Pacing System (DPS) has neither been cleared or approved for the indication to assist in weaning patients off ventilators in healthcare settings during the COVID-19 pandemic. TransAeris DPS has been authorized for the above emergency use by the FDA under an EUA. TransAeris DPS has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the TransAeris DPS 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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