

Temporary Transvenous Diaphragm Activation

AeroPace® System
Lungpacer Medical, Inc

ICD-10 Coordination and Maintenance Committee
Meeting

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A Critical Risk of Mechanical Ventilation (MV) – Diaphragm Atrophy

Diaphragm atrophy extends patients' weaning times and results in poor outcomes

Difficulty Weaning

- Diaphragm muscle atrophy occurs soon after MV is initiated^{1,2,3} (VIDD).
- Weakened muscles make it difficult to regain independent breathing^{4,5}

Trauma & Mortality

- Each day of MV associated with increasingly poor outcomes due to MV-associated complications affecting survival^{6,7}

Quality of Life

- Patients on MV experience isolation and anxiety, some even preferring death^{8,9}
- Many suffer from PTSD symptoms even after weaning¹⁰

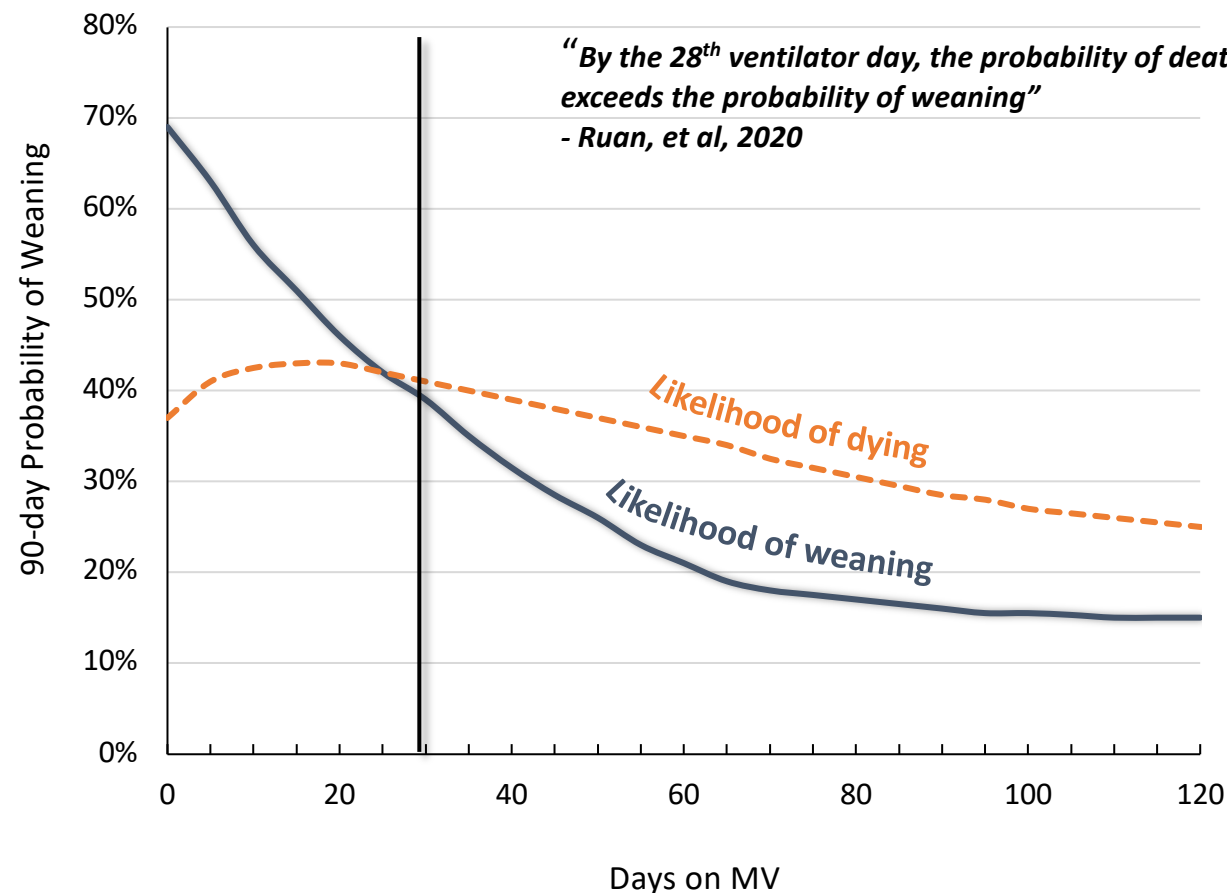
Costly

- Inability to wean patients leads to extended ICU stays^{4,5}
- Consumes valuable hospital resources¹¹

Unmet Need in MV - Rationale for Temporary Transvenous Diaphragm Activation Using the AeroPace® System

Improve diaphragm strength for earlier weaning in patients who fail to wean

90-Day Probability of Weaning or Death by Days on MV



AeroPace® System
FDA Breakthrough Device
Designation (May 2016):

“...for earlier weaning in patients 18 years or older who failed at least 2 weaning trials, the device is intended to treat a life-threatening condition... represents a breakthrough technology that provides a clinically meaningful advantage... and is in the best interest of patients.”

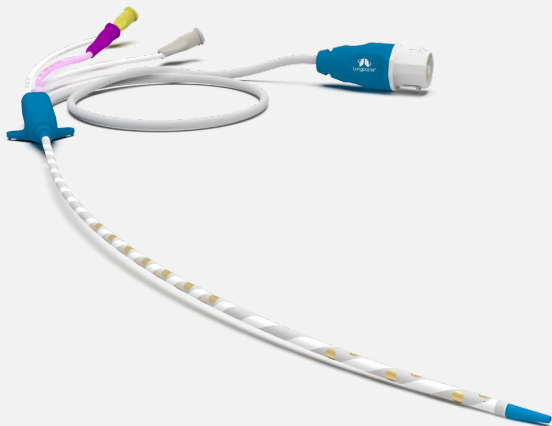
Ruan, S. Y., Teng, N. C., Huang, C. T., et al. (2020). Dynamic Changes in Prognosis with Elapsed Time on Ventilators among Mechanically Ventilated Patients. *Ann Am Thorac Soc* 17(6): 729-735. PMID: 32011907 PMCID: PMC7258420 DOI: 10.1513/AnnalsATS.201908-646OC

AeroPace® System (Temporary Transvenous Diaphragm Activation System (TT-DAS))

Key Components

AeroPace® Catheter

A proprietary temporary (30-day), catheter with **specialized electrodes** that **stimulate the phrenic nerves and activate the diaphragm.**



Neurostimulation Console

Adjustable stimulation parameters for limited number of diaphragm contractions to build diaphragmatic strength and increase weaning success.



Airway Sensor

Compatible with any ventilator for single-patient use to deliver AeroPace® Therapy with ventilator breaths.



When is the AeroPace® System Used?

Proposed Intended Use and Indication for Use

Intended Use | Intended for temporary stimulation of the phrenic nerve(s) to increase diaphragmatic strength.

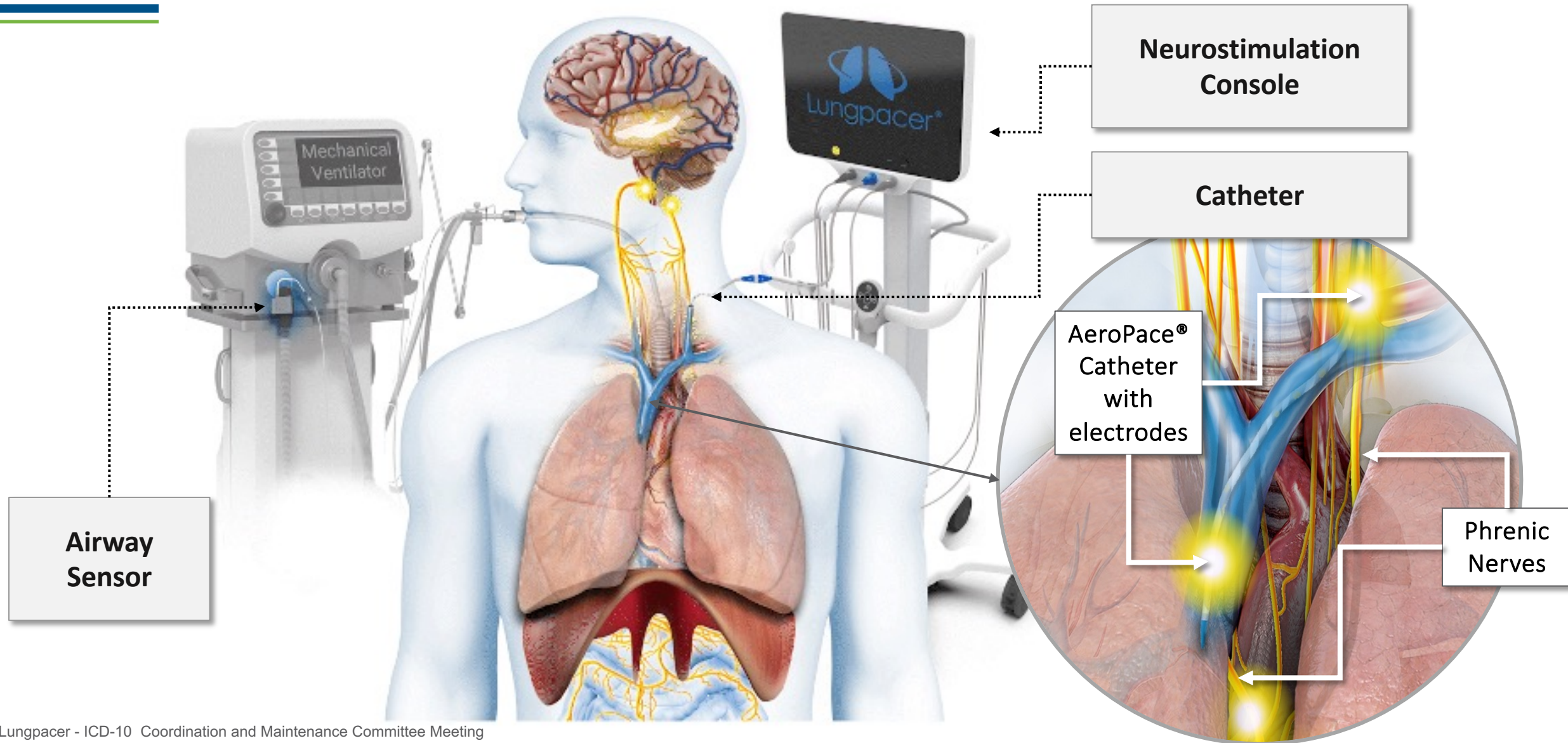
Indication for Use | Indicated to improve weaning success - *increase weaning, reduce ventilator days and reduce reintubation* – in patients ages 18 years or older on mechanical ventilation at least 96 hours and who have not weaned.

Rationale for Indicated Patient Population

- Proposed indication categorizes weaning failure by the duration of MV (i.e., ≥ 96 hours)
 - Consistent with MV treatment guidelines⁶ and Standard of Care (SoC) - weaning potential assessed by MV days
 - Allows treatment of patients on MV ≥ 96 hours for whom weaning trials cannot be conducted or tolerated
 - Patients on MV ≥ 96 hours will have diaphragm atrophy³, reduced probability to wean with SoC and high mortality^{6,11}
 - AeroPace mechanism of action and safety of diaphragm activation is the same in MV patients regardless of number of weaning failures

AeroPace® System

System Setup



AeroPace® Catheter

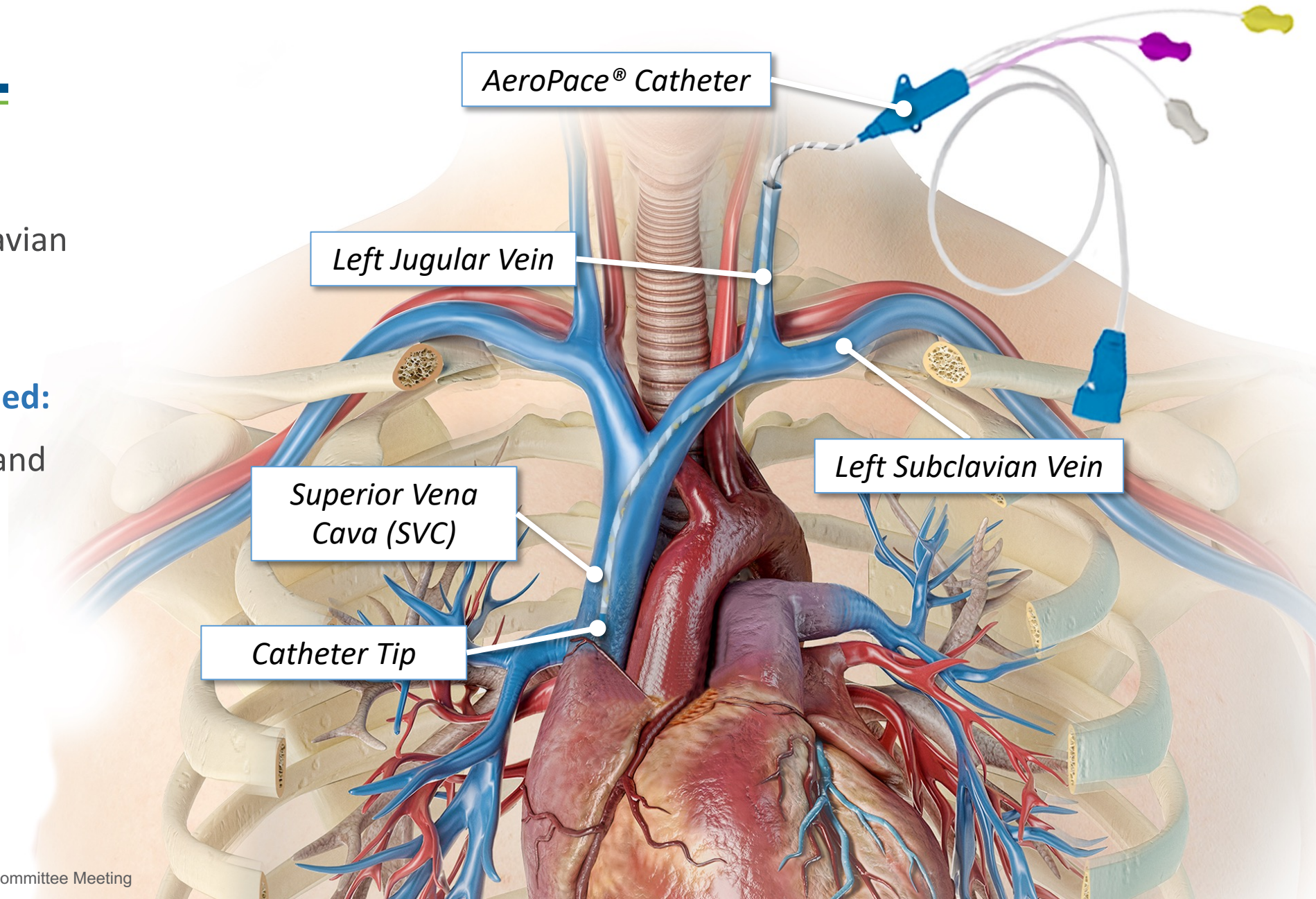
Catheter Placement

Canulation Site:

Left Jugular or Left Subclavian Vein

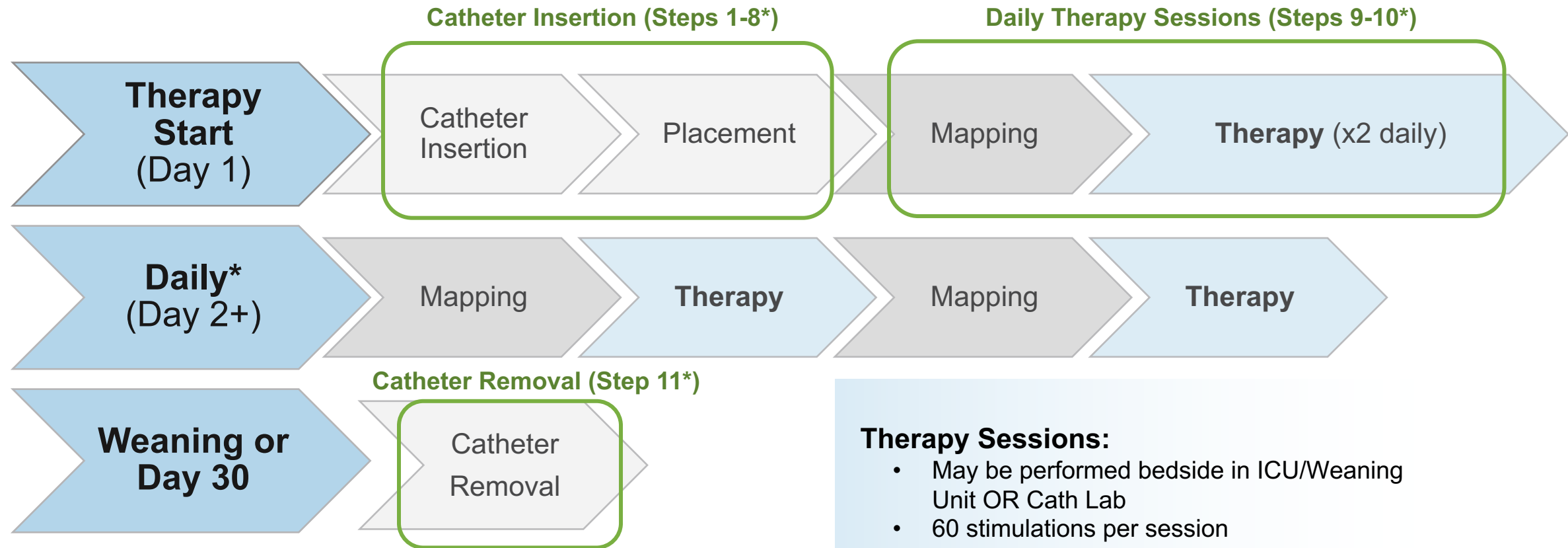
The Catheter tip positioned:

In distal third of the SVC and parallel to its wall



AeroPace® Therapy – Basic Steps

Twice daily stimulation/exercise to increase diaphragmatic strength



*Refer to Slide 9 for AeroPace®
System workflow steps 1-11.

Therapy Sessions:

- May be performed bedside in ICU/Weaning Unit OR Cath Lab
- 60 stimulations per session
- 2 sessions per day (120 stimulations/day)
- Up to 30 days
- **Up to 3600 total stimulations**

Detailed Workflow Steps

Catheter Insertion & Therapy Delivery

1. Visualize Left Subclavian Vein or Left Jugular Vein using Ultrasound
2. Obtain guidewire access using standard Seldinger Technique
3. Insert AeroPace® Catheter over the guidewire
4. Advance Catheter such that tip is placed in distal Superior Vena Cava 1-2 cm above the level of the carina; Optional: use intravascular electrogram available on AeroPace® Neurostimulation Console to assist with catheter placement
5. Run “Placement” workflow on AeroPace® Neurostimulation Console, to confirm left hemidiaphragm is contracting, adjust the depth of catheter as needed
6. Remove guidewire and confirm patency of all three lumens
7. Secure Catheter and protect insertion site using sterile dressings
8. Confirm placement of Catheter through X-ray or institutional practices
9. Deliver AeroPace® “Therapy” Sessions 2 x / day
 - a. Perform Mapping
 - b. Deliver 60 diaphragmatic exercise contractions per session
10. Use Catheter lumens as needed for fluid/drug delivery, CVP monitoring, venous blood sampling, etc.
11. Remove Catheter when patient weans, or day 30, whichever comes first

Safety Events

- No unanticipated serious adverse device effects (USADE)
- Among serious adverse events (SAEs) deemed device- or procedure-related, the most frequently reported were:
 - Infections associated with catheter use (bacteremia, catheter infection, sepsis) – 6.4% or 4.4 events/1000 catheter days
 - Cardiac disorders: arrhythmias due to inadvertent cardiac stimulation (1.8%) or were related to catheter misplacement (0.9%). These events were temporary, low incidence, and managed without sequelae.
- Two deaths were associated with device or procedure-related SAEs:
 - Acute coronary syndrome adjudicated as **possibly** related to the procedure due to undetected tension pneumothorax
 - Hypovolemic shock adjudicated as **possibly** related to the device due to a possible hemothorax/pneumothorax

Safety events noted in the study were consistent with those associated with mechanically ventilated ICU patients

Medical Record Documentation & Key Terms

Catheter Insertion & Therapy Delivery

- Medical record documentation may reference Temporary Transvenous Diaphragmatic Activation (TTDA) or Temporary Transvenous Diaphragmatic Neurostimulation (TTDN)
 - Patient admission records
 - Progress notes
 - Discharge summary notes
- Number of Therapy Sessions, Number of Stimulations delivered per session may be referenced
- Key terms include:
 - Transvenous Diaphragm Activation (TDA)
 - Temporary Transvenous Diaphragm Activation (TTDA)
 - Transvenous Electrical Phrenic Nerve Stimulation
 - Temporary Transvenous Diaphragm Pacing
 - Transvenous Diaphragm Pacing
 - Transvenous Diaphragm Pacing Therapy
 - (Lungpacer) Diaphragm Pacing
 - Diaphragm Pacing Therapy
 - Transvenous Phrenic Nerve Pacing
 - Transvenous Phrenic Neurostimulation
 - Lungpacer Therapy
 - AeroPace® System
 - AeroPace Catheter
 - Lungpacer AeroPace Catheter
 - Phrenic Nerve Stimulation Catheter
 - Diaphragm Stimulation Catheter
 - Diaphragm Activation Catheter
 - Airway Sensor
 - Neurostimulation Console

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