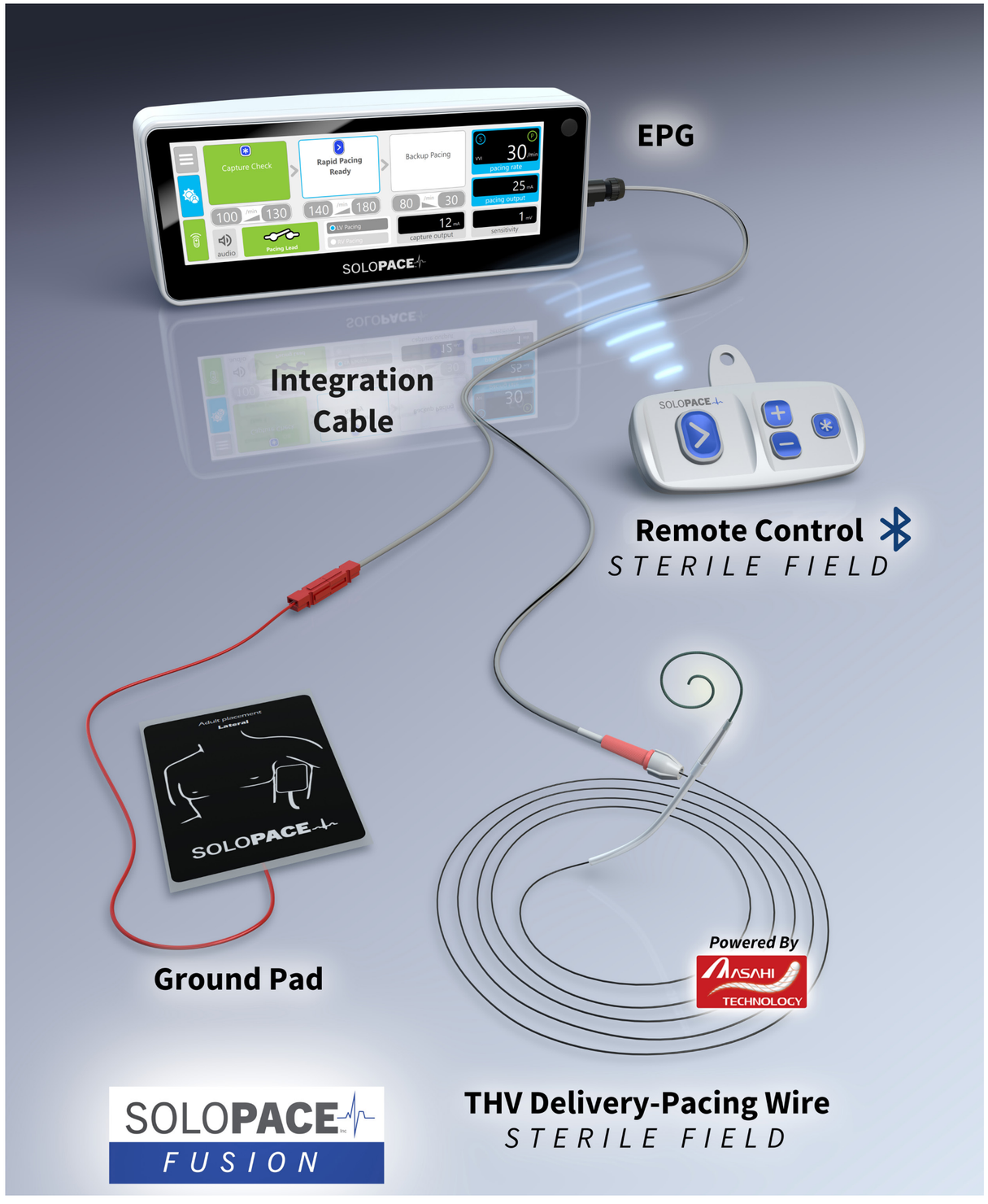

SOLOPACE Inc

FUSION

INSTRUCTIONS FOR USE

https://www.solopace.health
IFU version 100055 Rev C

Manufacturer
Solo Pace, Inc.
7125 Northland Terrace N
Minneapolis, MN 55428

408831001_001 ID 062926

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SYMBOLS

SYMBOL	SYMBOL NAME
	Do Not Re-Use
	Do Not Re-Sterilize
	Sterilized Using Ethylene Oxide
	Single Sterile Barrier System
	Batch Code
	Consult Instructions For Use
	Catalog Number
	Caution: Read all warning and precautions in instructions for use
	Use-By Date YYYY-MM-DD
	Do Not Use If Package Is Damaged
	Manufacturer
	Distributor
	Date of Manufacture
	Keep Away From Sunlight
	Keep Dry
	Cardiac Floating
	Non Pyrogenic
	USA only: Federal law restricts this device to sale by or on the order of a physician

DISCLAIMER

Carefully read all instructions prior to use. This device should only be used by physicians trained in the introduction and placement of interventional devices including those used within transcatheter aortic valve replacement procedures. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

INTENDED USE

The Solo Pace Fusion System is intended to introduce and position interventional devices within the chambers of the heart, including those used for transcatheter aortic valve replacement procedures. Additionally, the Fusion System can be used for temporary intracardiac pacing by transmitting an electrical signal from Solo Pace Control to the heart.

CONTRAINDICATIONS

The Fusion Guidewire is not intended for use in the cerebrovasculature and coronary arteries. The Fusion Guidewire is contraindicated in the absence of anticoagulation therapy.

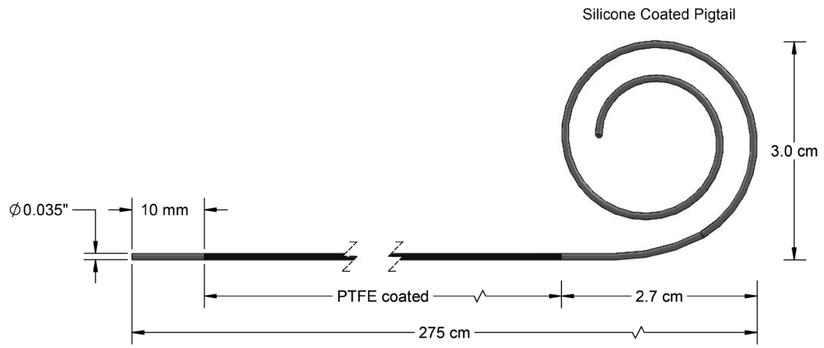
SYSTEM COMPONENTS

The Solo Pace Fusion System consists of the following components:

- Fusion Guidewire
- Fusion Ground Pad
- Fusion Integration Cable
- Solo Pace Control System, consisting of the following:
    - Solo Pace Remote Control Module (RCM), packaged with the Fusion Guidewire, Fusion Ground Pad and Fusion Integration Cable
    - Solo Pace External Pulse Generator (EPG) (sold separately)

The Fusion Guidewire is intended to deliver interventional devices into the heart and serve as the pacing conduit when used with the Solo Pace Control system.

The Fusion Guidewire is made of stainless steel and includes a pre-shaped pigtail distal tip. The Fusion Guidewire diameter is 0.035" (0.89 mm) and the length is 275 cm. The Fusion Guidewire is supplied with a tip insertion tube to help advance the guidewire into a catheter. A PTFE coating covers the shaft for lubricity. The proximal 10 mm is uncoated to allow connection of the Fusion Guidewire to the Fusion Integration Cable. The pigtail is coated with silicone for lubricity. The Fusion Guidewire is supplied sterile, non-pyrogenic and is intended for single use only.



The Fusion Ground Pad is a transcutaneous pad placed on the patient to serve as the anode terminal for unipolar pacing via a unique connection to the Fusion Integration Cable. The Ground Pad acts as the return electrode for the pacing signal delivered to the patient's heart through the Fusion Guidewire. The Ground Pad cable is 60 inches (1.5 m) long and the skin contacting surface area is approximately 350 cm^2.

The Fusion Integration Cable connects the Fusion Guidewire and the Fusion Ground Pad to the Solo Pace Control System (EPG component) in a manner that ensures proper polarity. The Fusion Integration Cable is approximately 60 inches (1.5 m) long.

The Solo Pace Control System RCM is a single use sterile device supplied with the Solo Pace Fusion System. The Solo Pace RCM connects wirelessly with the EPG to allow physician control of the EPG in the sterile field.

The Solo Pace Control System EPG is a reusable, external pulse generator described in detail in its Instructions for Use (IFU). The Solo Pace Control IFU should be reviewed, in its entirety, prior to using the Solo Pace Fusion System.

WARNINGS

- Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in a serious adverse event
- The Fusion System devices are intended for single use only. Do not resterilize and/or reuse the devices. Reuse of single use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Reprocessing may compromise the integrity of the device and/or lead to device failure.
- Do not use the Fusion System devices if any portion of a device or packaging appears damaged, if any portion of the sterile pouch has been opened or if product is expired. Return damaged units to Solo Pace per the Return Policy.
- The Fusion Guidewire should only be introduced into, and pulled out from, the heart through a catheter already positioned in the ventricle.
- Unipolar pacing with the Fusion Guidewire should only be performed using Solo Pace Control. Use of an electrical pace generator other than Solo Pace Control EPG has not been tested.
- Inadequate electrode placement during rapid pacing and valve deployment may result in valve displacement and patient injury. Always test pacing capture using the Solo Pace Control Capture Check function prior to proceeding with the intervention (i.e. transcatheter valve deployment). Additional warnings specific to Solo Pace Control can be found in the Solo Pace Control IFU. These warnings should be reviewed prior to using the Solo Pace Fusion System.

PRECAUTIONS

- The safety and effectiveness of the coated device has not been established, or is unknown, in vascular regions other than those specifically indicated.
- Confirm the compatibility of the guidewire diameter with the interventional device before actual use.
- Inspect the Fusion Guidewire, the Fusion Integration Cable, and the Fusion Ground Pad for bends, kinks or other damage prior to use.
- Inspect the Solo Pace RCM for damage prior to use.

- Do not attempt to straighten a guidewire that has been kinked.
- Proceed with care when pulling the Fusion Guidewire out of the hoop. Do not grasp the tip. The stiffness of the guidewire may cause it to uncoil unexpectedly if pulled out or manipulated abruptly.
- The Fusion Guidewire tip is pre-shaped for compatibility with ventricles. Do not manually shape the tip.
- Fusion Guidewire is not meant to be deployed in anatomy other than heart chambers.
- Avoid abrasion of the Fusion Guidewire PTFE coating. Do not withdraw or manipulate the guidewire in a metal cannula or sharp-edged object.
- Clean the Fusion Guidewire thoroughly with heparinized saline before and after each insertion or exchange of catheter.
- Always use the provided insertion tube to straighten the tip prior to inserting the Fusion Guidewire into a catheter or other device. If the Fusion Guidewire tip is pulled out of the insertion tube, slide the tube over the proximal end of the wire.
- Never advance, pull or torque a Fusion Guidewire against resistance without first determining the reason for the resistance under fluoroscopy. Excessive force against resistance may result in damage to the wire and/or to the tissue.
- The Fusion Guidewire should be observed under fluoroscopy during manipulation. Care should be taken when the Fusion Guidewire tip is positioned, moved or torqued in the ventricle.
- Use special care when positioning the Fusion Guidewire tip in small, hyperdynamic ventricles.
- Rapid pacing can induce patient discomfort or muscle contraction.
- Additional precautions specific to Solo Pace Control can be found in the Solo Pace Control IFU. These precautions should be reviewed prior to using the Solo Pace Fusion System.

USE ENVIRONMENT PRECAUTIONS

Solo Pace Fusion has not been assessed for use in emergency medical service (EMS) transport or an emergency medevac aircraft situation.

ADVERSE EVENTS

Adverse events that may result from the use of this device include, but are not limited to: access site or vessel complications, additional surgical procedure, allergic reactions, amputation, arrhythmia, bleeding, cardiac or vessel perforation/dissection, coronary obstruction, death, embolism, fibrillation, foreign body/wire fracture, heart block, hematoma, hypotension/hypertension, infection, kidney injury/failure, myocardial infarction, need for permanent pacemaker, pericardial effusion, pneumothorax, stroke or other neurologic event, spasm, tamponade, thrombus, valve dysfunction or complications, vessel occlusion, wire entrapment/entanglement.

Additional adverse events specific to Solo Pace Control can be found in the Solo Pace Control IFU. These potential adverse events should be reviewed prior to using the Solo Pace Fusion System.

INSTRUCTION FOR USE

Please review these instructions and the Solo Pace Control IFU in their entirety before using the Solo Pace Fusion System. Both contain important information regarding the safe use of the Solo Pace Fusion System.

PREPARATION

- Note: The Fusion Ground Pad is not sterile.
- Ensure the packages have not been opened or damaged.
- Open the Fusion Ground Pad and place it on the patient, typically on the lateral chest wall.
- Open the sterilized pouch and take the hoop containing the Fusion Guidewire, the Fusion Integration Cable, and the RCM out of the packaging using sterile technique and place them on the sterile field.
- Flush or wipe the Fusion Guidewire with saline.
- Keep the RCM and the Fusion Integration Cable from being submerged in fluid.
- Connect the black end of the Fusion Integration Cable to the Pacing Patient Cable Port of the Solo Pace Control EPG. This step must be performed prior to making any patient connections (i.e. Fusion Guidewire or Fusion Ground Pad).

- Connect the Fusion Ground Pad to the red Fusion Integration Cable connector. This step must be performed prior to connecting the Fusion Guidewire.

INSERTION AND EXCHANGE

- Place the Fusion Guidewire insertion tube into the catheter proximal end.
- Advance the Fusion Guidewire through the insertion tube and into the catheter.
- Carefully deploy the Fusion Guidewire pigtail tip into the desired chamber under fluoroscopic guidance.
- Withdraw the catheter used to deliver the Fusion Guidewire if an additional catheter exchange is required.
- Secure the Fusion Guidewire prior to removing or loading any catheters over the wire.
- Wipe the Fusion Guidewire with saline prior to reintroduction if the guidewire is removed from the patient.

RAPID PACING

- Insert the proximal end of the Fusion Guidewire into the orange/white Fusion Integration Cable guidewire connector and secure the wire by tightening the connector.
- Ensure the Fusion Guidewire pigtail tip is stable and maintains contact with the cardiac tissue.
- Test pacing capture using the Capture Check function of Solo Pace Control.
- Perform temporary rapid pacing according to the Solo Pace Control IFU.
- For more information on common unipolar pacing practice, refer to Blusztein D, Raney A, Walsh J, Nazif T, Woods C, Daniels D. Best Practices in Left Ventricular Pacing for Transcatheter Aortic Valve Replacement. Struct Heart. 2023 Jul 26;7(6):100213.

INTERVENTIONAL PROCEDURE

- To perform catheter exchanges during the procedure, disconnect the Fusion Guidewire from the Fusion Integration Cable by loosening and removing the orange/white guidewire connector.
- Maintain wire position and monitor the pigtail tip under fluoroscopy while advancing devices over the Fusion Guidewire.
- Reconnect the Fusion Guidewire to the Fusion Integration Cable as needed for additional pacing during intervention.
- Proceed with intervention according to manufacturer's instructions.

END OF PROCEDURE

- Advance an interventional catheter over the Fusion Guidewire to withdraw it from the heart.
- Handle and dispose of the Fusion Guidewire, Fusion Ground Pad, RCM, and Fusion Integration Cable following standard solid biohazard waste procedures and in accordance with medical practices and applicable, local, state and federal laws and regulations.

STORAGE AND HANDLING

Store in a dry and cool place.

This product, and the use thereof, may be covered by U.S. and international patents.

ADDITIONAL QUESTIONS REGARDING THIS PRODUCT SHOULD BE DIRECTED TO:

Solo Pace, Inc. 7125 Northland Terrace N Minneapolis, MN 55428

www.solopace.health

SOLOPACE Inc

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