

OneLINK™ Splitter Cable

MP4110

Non-Sterile Cable

Rx ONLY

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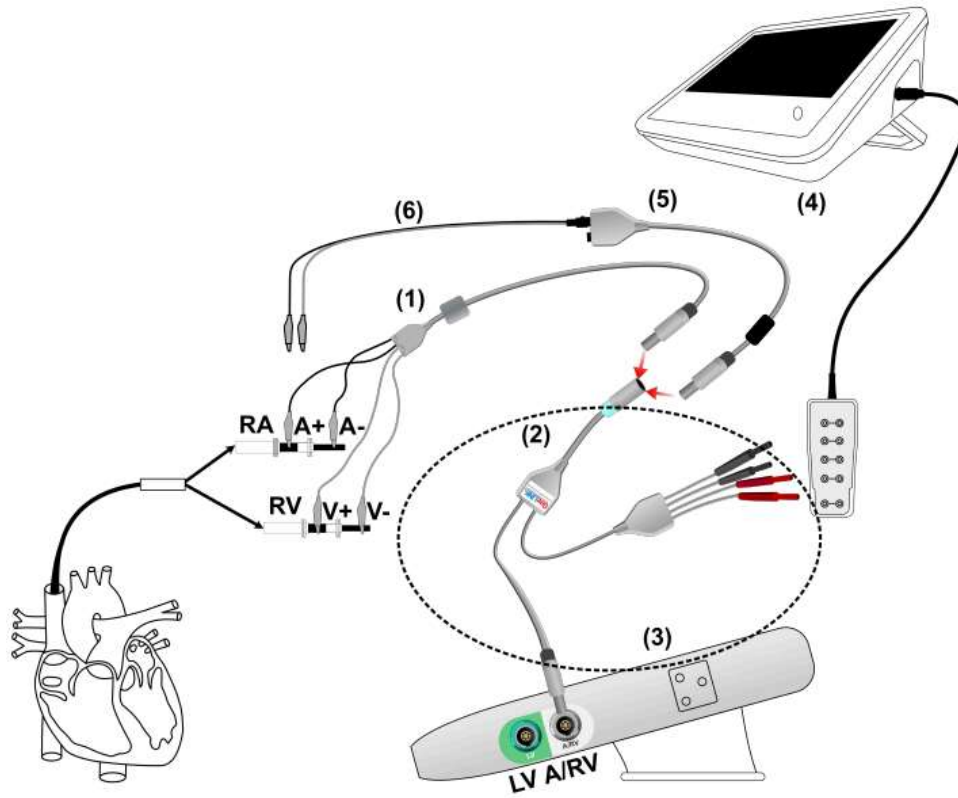


OneLINK Splitter Cable MP4110
User Instruction Manual
MP4148
Release V1.8 Date : 08/08/2024

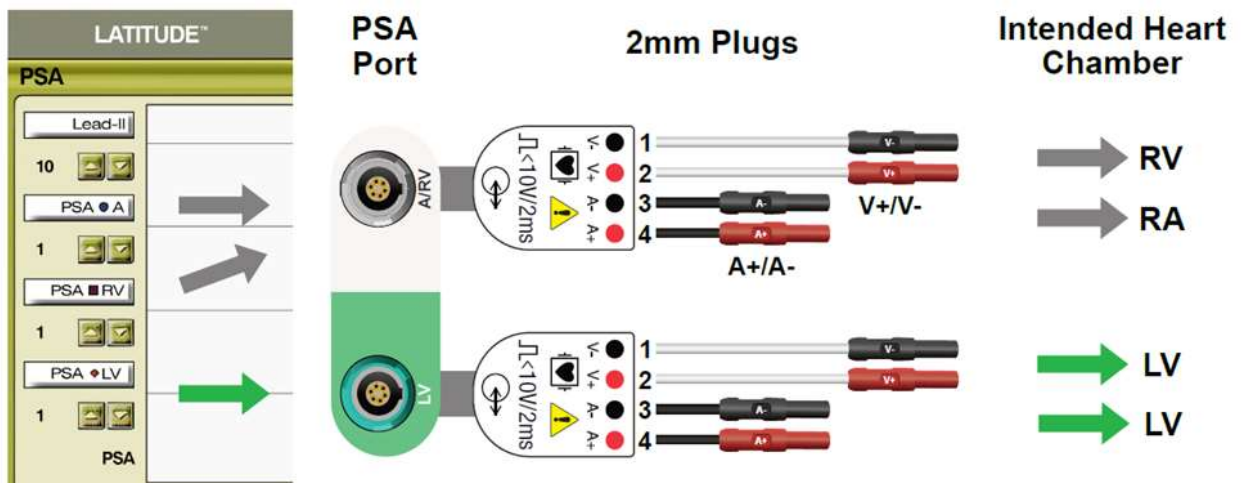
<https://micropaceep.com/product/OneLink>



USER INSTRUCTION MANUAL



F001



F002

1. Essential Prescribing Information

1.1 Device Description and compatibility

OneLink™ is a non-sterile electrical cable with custom connectors for interconnecting three devices:

1. Boston Scientific Model 3300 LATITUDE™ Programming System (LPS) / Pacing System Analyser (PSA) and
 2. Boston Scientific patient lead PSA Cables (6763) or Boston Scientific patient lead PSA Cables (6697) with Remington Cable Adaptor (6133).
 3. Electrophysiological (EP) diagnostic systems or Micropace OneStim, using four shrouded 2mm banana plugs
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1.2 Intended use

OneLINK is a non-sterile multi-use device comprising of insulated wires with connectors. It is intended to simultaneously interconnect an electrode/ evaluating lead cable from a patient to a pacing system analyser device and an electrophysiological diagnostic system for the purpose of placement by measurements of paced cardiac conduction and pacing parameters.

1.3 Indications for Use

OneLINK is indicated for use in patients undergoing permanent pacemaker lead implantation or revision for implantable pacemaker or defibrillator, where physician requires analysis of paced cardiac conduction parameters for determining optimum pacing site for cardiac performance.

1.4 Clinical Benefit Statement

The OneLINK Splitter Cable connects an electrophysiological diagnostic system to a pacing lead and pacemaker system analyser during lead implantation, giving the physician ability to use measurements of cardiac conduction, refractory periods and cardiac activation synchronicity to better characterise physiological effects of pacing locations when selecting permanent lead implant site. More physiological pacing may reduce incidence of progression of heart failure associated with traditional right ventricular pacing.

1.5 Intended User and Environment

Intended to be used by cardiologists, technicians and company representatives trained in the use and limitations of this cable and appropriately trained in permanent pacemaker implantation in hospital procedure rooms and laboratories equipped with cardiac monitoring and advanced resuscitation.

1.6 Compatibility

OneLINK integrated plug is compatible with Boston Scientific products specified in Device Description in Section 1.1. The 2mm shrouded banana plugs are compatible with standard (EP) diagnostic systems such as GE Healthcare CardioLab™ or Boston Scientific LabSystem™ Pro and Micropace OneStim-CRM™ stimulator recorder.

1.7 Contraindications

No known contraindications or constraints on age, gender, race or nature or severity of illness.

1.8 Warnings

- **Always limit stimulation pulses to < 10V / 2ms.** EP Stimulators can deliver >50 x larger pulse energies than PSA or pacemakers. In order to avoid potential damage to, or degradation of implantable pacing lead electrodes, pacing should be delivered from the PSA. If pacing from a connected EP Recorder / Stimulator, **always limit stimulation pulses to < 10V (or 10mA from current controlled EP stimulators) and < 2ms in duration.**
- **Do not pace simultaneously from PSA and EP Stimulator.** In order to avoid inadvertent induction of dangerous arrhythmias from accidental simultaneous pacing from both EP stimulator and PSA causing chaotic rapid pacing, connected EP Stimulator should always be either **temporarily disabled or set to ≤50ppm in inhibited pacing mode**, so that accidental

simultaneous pacing from both EP stimulator and PSA does not combine to cause chaotic rapid pacing.

- **Protect heart connection from leakage currents.** In order to avoid patient micro-shock and induction of dangerous cardiac arrhythmias:
 - Connect OneLINK Splitter Cable, only to equipment with connections of type CF and defibrillator proof.
 - Do not connect to any cables or equipment with exposed wires or connectors subject to human touch or contact with conductive surfaces, except for the PSA lead with alligator clips connecting directly onto pacing lead connector in the sterile area such as the Boston Scientific PSA Cable 6763.
 - Inspect cable prior to use and do not use if visibly damaged with kinks, cuts to insulation, exposed inner cables or wires or if packaging is damaged.
- In order to avoid risk of infection, do not use cable which appears soiled, contaminated or is not indicated to have been cleaned between uses according to Section 3.1 for cleaning instructions.
- Any serious incident that occurs in relation to this device should be reported to the manufacturer, and to the relevant local regulatory authority.

2. Connection and Use

Connect cable as shown in figure F001.

1. Connect OneLink (2) plug to Boston Scientific LATITUDE PSA 3300 (3) 'A/RV' or 'LV' port (As shown in figure F002).
2. Connect Boston Scientific PSA Cable 6763 (1) into OneLink (2) Socket, or connect Boston Scientific PSA Cable 6697 (6) into Remington Cable Adaptor 6133 (5) and then into OneLink (2) Socket
3. Optionally connect OneLink 4 pin plugs into EP Stimulator / recorder, such as Micropace OneStim™ connection box.
4. Connect Cable 6763 four alligator clips, or connect Boston Scientific PSA Cable 6697 two alligator clips to pacing lead electrodes as required in bipolar or unipolar mode.

3. General Instructions

3.1 Cleaning Instructions

- The cable may be cleaned using a dampened cloth in a mild, non-abrasive soap or detergent and/or isopropyl alcohol (IPA).
- Do not sterilise, immerse in liquids or use strong solvents such as acetone.

3.2 Service, Serviceable Life and Disposal

- The OneLINK Splitter Cable has no user serviceable parts.
- Dispose of OneLINK Splitter Cable separately from household waste according to EU WEEE legislation – contact the distributor or Micropace for assistance.
- Further technical and service support information is available by request at micropaceep.com.



4. OneLink Cable Specifications

- Length: 1.2m
- Patient Lead socket: Redel 6 pin socket
- PSA Plug: Redel 6 pin plug
- Insulation voltage withstand: 1000V for 1 minute
- Defibrillation Proof: 5kV Common Mode, 1000V differential mode
- Cable insulation material: TPU
- Conductor resistance: < 1 Ohm between any connections
- Applied Standards: AAMI EC53:2020 ECR trunk cables and patient lead wires
- Operating T° Range: +5°C to +35°C (30% to 80% RH)
- Storage T° Range: -10°C to +60°C (10% to 85% RH)
- Altitude (non-pressurized transport): 0m to 4,267m
- Sterilization: Non-sterile, not sterilizable

5. Warranty and Disclaimer

Use of OneLink is governed by our warranty, disclaimer of Warranty and limitation of liability, which may limit your legal rights, the details of which is provided at: <https://micropaceep.com/product/OneLink/>

6. Explanation of Symbols

For international symbols on packaging, refer to: www.MicropaceEP.com/customer-support/symbols-glossary.

Symbols on Cable (see coloured figure F002):

Symbol	Name	Meaning
	Defibrillator Proof	Limited to 380V +5% -0%
	Read Warnings in Manual (Yellow Triangle)	Read Warnings in Manual
	Signal Input / Output	Connectors for Input / Output of electrogram signals and stimulation pulses
	EP Recorder Connectors	V+ (red) / V- (black): ventricular +ve / -ve connectors A+ (red) / A- (black): atrial +ve / -ve connectors
	Limit Stimulation Energy	Cardiac stimulation pulses inputted into the OneLink and thus into the implantable pacing lead must be limited to < 10V amplitude and < 2ms in duration.