

Limited Warranty

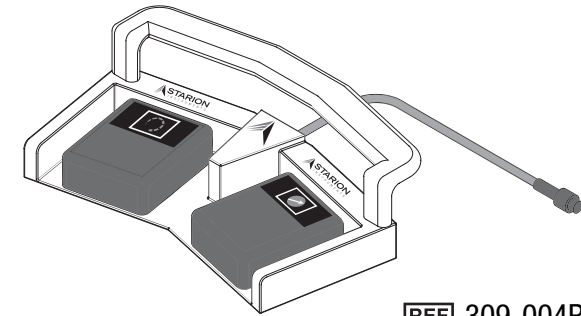
Starion Instruments Corporation warrants that the PowerPack Dual Control Footswitch will be free from defects in materials and workmanship for a period of one (1) year from shipment invoice provided that the product is used in accordance with applicable instructions. Products found to be defective during this period will be replaced at no charge. Starion Instruments Corporation makes no other warranties with respect to the product and expressly disclaims all other warranties expressed or implied, as to merchantability, fitness for any particular purpose or any other matter. In no event shall Starion Instruments Corporation be liable for consequential damages.



EMERGO EUROPE - Molenstraat 15
2513 BH, The Hague, The Netherlands



POWERPACK™ DUAL CONTROL FOOTSWITCH



REF 309-004R

INSTRUCTIONS FOR USE

For use only with

Starion Cautery Instruments, Starion PowerPack™ Universal Power Supply (UPS) (REF 200-003R) and Starion UPS (REF 200-004R, 200-006R)

Device Description

The PowerPack Dual Control Footswitch is a non-sterile, reusable unit intended to be used only with Starion Cautery Instruments and the Starion UPS. The PowerPack Dual Control Footswitch has one outlet cable which is connected to the UPS. The PowerPack Dual Control Footswitch has two power settings, variable and high. The amount of power delivered in the variable mode is determined by the knob/push button setting on the power supply. Variable power is activated by depressing the left footpedal. High power is activated by pressing on the right footpedal (see figure). The PowerPack Dual Control Footswitch should be placed on the floor or a flat surface (such as a stand) near the surgeon so that it can be activated by the surgeon's foot.

To use the different heat ranges, the operator must depress the appropriate foot pedal on the PowerPack Footswitch while activating the safety interlock of the device. Generally, lower heat ranges increase the sealing capabilities and increase the time required to divide tissue. Higher heating ranges decrease the time to divide and may decrease seal integrity. See appropriate device Instructions For Use.

Intended Use

The PowerPack Dual Control Footswitch is intended for use only with Starion Cautery Instruments and the UPS for the simultaneous cutting and coagulation of soft tissue during surgery.

Symbol Definition



Means: Attention — Read and follow indicated Instructions For Use, Precautions, Warnings, etc.



Means: Variable Power.



Means: Authorized Representative.



Means: High Power.



IFU0025E-01 ECO #2111

INSTRUCTIONS FOR USE

Note: Ultra Slim Forceps Users - See Instructions for Use.

1. Connect the PowerPack Dual Control Footswitch to the non-sterile UPS by inserting the connector of the PowerPack Dual Control Footswitch into the footswitch connector receptacle of the power supply. Ensure connector plug keys properly into receptacle.
2. Insert the connector of the Cautery Instrument power cord into the instrument connector receptacle (non-sterile) of the UPS. Ensure connector plug keys properly into receptacle.
3. Place the PowerPack Footswitch on a level surface near enough to the surgeon so that it can be activated by the surgeon's foot.
4. Refer to the appropriate Cautery Instrument and Starion UPS Instructions for Use for device-specific use instructions.
5. When using footswitch activated devices, depressing the PowerPack Dual Control Footswitch pedal will activate the heating element only after closing cautery device (see device specific Instructions For Use).
6. Activate the Cautery Instrument by first closing the device and then depressing the left or right footpedal (variable or high power respectively), depending on desired clinical result. When the heating element of the Cautery Instrument is activated, the UPS emits an audible tone that lasts until the heating element is deactivated. A low pitch tone is emitted when variable power is delivered. A high pitch tone is emitted when high power is delivered.
7. At the conclusion of the surgical procedure, disconnect the PowerPack Dual Control Footswitch from the UPS.

Note: Unlike the Cautery Instrument, which is discarded at the end of the surgical procedure, the PowerPack Dual Control Footswitch is reusable and should be moved to a safe and convenient storage location for use in future surgical procedures.

PRECAUTIONS AND WARNINGS

- Use only with Starion Cautery Instruments and UPS. Use of any other instrument/power supply may damage the instrument, the power supply and/or the PowerPack Dual Control Footswitch and could prevent it from functioning properly during use.
- Do not drop the PowerPack Dual Control Footswitch.
- Do not immerse the PowerPack Dual Control Footswitch in liquids.
- Do not sterilize PowerPack Dual Control Footswitch.
- Procedures using instruments for cutting/cauterization should be performed only by persons having adequate training and familiarity with these surgical techniques. Consult the medical literature relative to techniques, complications and hazards prior to performance of any procedure. Surgeons using this device should be familiar with the specific anatomy of the region in which they intend to perform the procedure.
- No user-serviceable parts.

Warning

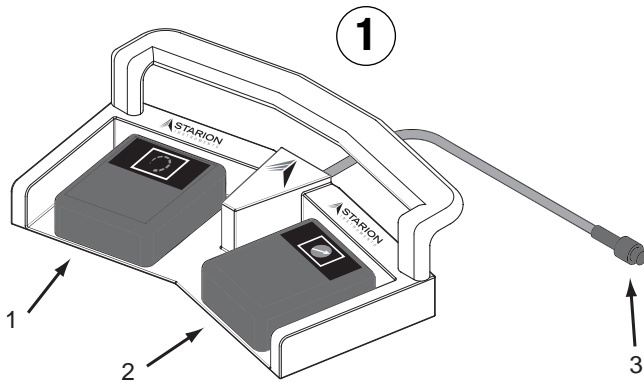
Do not use in the presence of flammable materials (e.g. alcohol, flammable anesthetics). Always disconnect the instrument before discarding; the PowerPack Dual Control Footswitch and UPS are reusable.

HANDLING, STORAGE AND CLEANING

Do not drop. Store in a cool, dry place. Avoid prolonged exposure to extreme temperatures. Exterior of the PowerPack Dual Control Footswitch may be cleaned using a soft cloth moistened with a solution of water and mild detergent or disinfectant. Do not immerse the PowerPack Dual Control Footswitch in liquids.

1 Dual Control Footswitch 1 Non Sterile

- 1- Variable Power Pedal (Left)
- 2- High Power Pedal (Right)
- 3- Power Supply Connector



2 Universal Power Supply Non Sterile

