

INSTRUCTIONS FOR USE

RE-USABLE CABLES – MONOPOLAR, BIPOLAR & DISPERSIVE

INTENDED USE.

Re-usable electrosurgery cables for use with electrosurgery generators during surgical and other medical procedures. The cables are manufactured with connectors to suit electrosurgical appliances from major manufacturers. The device is provided non-sterile and must be cleaned and sterilised before first and subsequent uses. These cables are rated for 100 uses – DO NOT EXCEED THIS AS PRODUCT FAILURE MAY RESULT.

PRODUCT CODE

All Bipolar Cables with codes P to Z and 12 to 30. All Monopolar Cables with codes A to G and 1 to 50.
All Dispersive Connecting Cables with product code prefixed 'DE', **except** DE1523 and DE1525

DESCRIPTION

Electrosurgery Bipolar Cables are for use with electrosurgery generators of up to 50 watts output.
Electrosurgery Monopolar Cables and dispersive cables for use with electrosurgery generators of up to 400 watts output.

It is the users' responsibility to validate any deviations from these recommended methods of use and cleaning. The use of alternative methods, particularly in respect of cleaning, may result in a non-sterile product or may reduce the effective life of the product. For the purpose of this document, the cable shall refer to the complete product assembly, i.e. the electrosurgery generator connector, the connecting cable and the electrosurgery instrument connector.

CABLES

Cleaning

Do not immerse the cable in any fluid within four hours after using pre-vacuum sterilisation, as damage to the product may result.

1. Wipe or rinse the cable with normal lukewarm tap water prior to cleaning.
2. Submerge the cable in lukewarm, blood-dissolving enzymatic solution. Do not force fluid or air into either end of the cable, nor introduce any other objects to the end connectors. Do not use ultrasonic cleaners. Damage to the product may result. The use of mechanical cleaners may reduce the useful life of the product.
3. Remove gross matter, i.e. blood, mucous, tissue from the outside of the cable with a soft cloth.
4. Using lukewarm tap water, rinse the cable until the enzymatic solution is removed. Allow the water to drain out of the connector ends by inverting the cable in this position for a minimum of 30 minutes, prior to sterilisation.

Cautions

Before sterilisation, inspect the cable and connector ends for breaks and cracks in the insulation, loose connections or corrosion. Do not use the cable if any of the above conditions exist.

If at any time the performance of the device changes suddenly, stop usage immediately.

RECOMMENDED STERILISATION PROCEDURES

If in doubt, the sterilisation manufacturer should be consulted for recommendation of loading instructions and drying times. All cables are guaranteed for 100 uses. Only use validated equipment and processes according to national or international standards.

A – Ethylene Oxide (EtO)

Loosely coil the cable before inserting the cable into the ETO pouch - tight bunching or wrapping of the cable may decrease the product's life.

- Temperature - 54° C (130° F)
- Concentration - EtO: 600Mg/Lt
- Humidity - 40 – 60% RH
- Exposure Time - 105 Minutes
- Aeration Time - 12 Hours at 54° C (130° F)

B – Steam (Autoclave)

Important - using an autoclave supply water with a high mineral content may reduce the effective life of the cable. Ensure the cable does not contact the metal housing of the autoclave/other metal instruments during the autoclave cycle, as this may reduce the product's effective life.

Wrapped (porous load)

- Pre-Vacuum - 134° - 137°C (274° - 279°F) for 3 to 3½ minutes
- Gravity - 132° - 136°C (270° - 277°F) for 10 minutes
- Gravity - 121°C (230°F) for 20 minutes

C – Machine Washing

Use a PH Neutral Solution at 90° for one minute followed by **steam** sterilisation in an Autoclave as described above.



Unwrapped – Flash Sterilisation

The method of sterilisation is generally gravity displacement, which is completed in the operating room.

1. In the sterilisation basket, place the sterilisation indicator with the cable before placing it in the sterilising chamber.
2. Select the appropriate cycle, depending on the type of cable:

Monopolar

Pre-Vacuum	- 132° - 137°C (270° - 279°F) for 3-3.5 minutes
Gravity Displacement	- 132° - 137°C (270° - 279°F) for 3 minutes

Bipolar/Dispersive

Pre-Vacuum	- 132° - 137°C (270° - 279°F) for 4 minutes
Gravity Displacement	- 132° - 137°C (270° - 279°F) for 3 minutes

WARNINGS

Before use, check the connection with the electrosurgery instrument to ensure proper compatibility and fit:

1. Ensure the cable is not connected to the electrosurgery generator.
2. Grasp the insulated part of the instrument and connect the connector on the instrument to the appropriate end of the cable.
3. Ensure that the connection made between the instrument and the cable connector is firmly secured with no exposed metal portions.

Fire hazards are associated with the use of electrosurgery accessories that are activated or hot from use. Do not place them in contact with or near to inflammable materials (i.e. drapes, gauze, oxygen sources). Use a holster or quiver to hold electrosurgery cables and similar accessories safely away from operating room personnel, surgical drapes and the patient.

If the electrosurgery generator plug does not fit securely into the electrosurgery generator, or there are exposed metal portions of the connector once plugged in (i.e. the plug is not firmly home), do not use the cable.

Ensure that the generator connector is plugged into the correct socket as advised by the manufacturer of the electrosurgery generator. If the insulating sleeve of the electrosurgery instrument and the connector on the cable do not fit securely and there is an exposed metal part, do not use the cable and instrument assembly. The patient or surgical personnel may receive diathermy burns or electrical shocks.

When not using active electrosurgery accessories in the operating room, ensure that they are placed in a clean, non-conductive, dry and visible area, not in contact with the patient or other equipment. Patient burns or electric shock could result from inadvertent patient contact.

Do not bend the cable tightly around towel clips or other similar clipping devices to secure the cable, damage to the cable may result.

When changing the electrosurgery instrument, ensure that the cable is not connected to the electrosurgery generator.

The cable is intended for re-use, **however** should any part of these instructions or warnings not be followed, the cable should not be used.

Confirm proper electrosurgical power setting before surgery. Use the lowest electrosurgery power settings to achieve the desired effect.

Dispose of used products safely to prevent injury to hospital personnel.

CAUTION

An incorrect connection may result in injury to the patient or operating room personnel by the action of electrosurgery current arcing at the connection between the cable connector and the electrosurgery instrument.

PRODUCT INFORMATION DISCLOSURE

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LIMITED WARRANTY

Prima Medical Limited warrants that this product will be free from material and workmanship defects. The warranty is void should Prima Medical Limited determine that damage has occurred as a result of improper handling, misuse, unauthorised repair or accident.



Prima Medical Limited, Mill 16 Bath Road Trading Estate, Bath Road, Lightpill, Stroud, Gloucestershire, GL5 3QF, UK.
Tel: +44 (0)1453 752626 Fax: +44 (0)1453 756750
Email: sales@prima-medical.com