INSTRUCTIONS FOR USE  Neutral electrode

815-040, 815-070, 815-110, 815-140, 816-042, 816-071, 816-072, 816-092,
816-112, 816-141, 816-161, 816-162, 817-040, 817-070, 817-110, 817-140,

Medical products directive
The products bear the CE marking according to directive 93 / 42 / ECC
and conform to IEC 60601-2-2 und ISO 10993.

1. Intended use

Disposable neutral electrodes are self-adhesive, ready-to-use disposable
products and are an accessory for HF surgery in monopole applications.
The electrodes complete the electrical circuit between the patient and the HF
generator on the passive side.

2. General safety instructions

The neutral electrodes may be used only by trained medical personnel. The surgeon and the medical technicians must be
trained in and familiar with the fundamentals, codes of practice, and risks of HF surgery.

- Follow the operating instructions for the HF generator being used.
- Follow the operating instructions on the package of the neutral electrode.
- Adhere to the date of expiration on the package of the neutral electrode.
- Use only neutral electrodes that are compatible with your HF generator.
  Check the compatibility list.
- Heed any power limitations of the neutral electrode when setting up the HF generator.
- Make sure that the neutral electrode is in perfect condition before application.
- Ensure that the neutral electrode cannot be short-circuited.
- The neutral electrodes are ready to use.
  Do not use any additional contact gel.
  The neutral electrodes are not a sterile product, and must not be sterilized.
- Any modification of the neutral electrode (such as cutting) voids any liability of the manufacturer.

3. Selecting the electrode

Use the neutral electrode in the following areas of application:

<table>
<thead>
<tr>
<th>Illustration</th>
<th>Area of application</th>
<th>REF, no cable</th>
<th>REF, with cable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Electrode for patients with a body weight of &gt; 15 kg (adults)</td>
<td>816-162, 816-161, 816-141, 815-140</td>
<td>818-162, 818-161, 818-141, 817-140</td>
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<td></td>
<td>Electrode for patients with a body weight of 5 – 15 kg (children)</td>
<td>816-071, 815-070</td>
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<tr>
<td></td>
<td>Electrode for patients with a body weight of &lt; 5 kg (newborns)</td>
<td>816-042, 815-040</td>
<td>818-042, 817-040</td>
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</tbody>
</table>

Split neutral electrodes
If your HF unit has a contact quality monitoring system (CQM, e.g., "EASY", "REM", NESSY"), always use split neutral
electrodes. When split neutral electrodes are used with a CQM system, the contact with the patient is monitored
automatically.

Non split neutral electrodes
For HF units with no CQM system, and when using single neutral electrodes, the contact with the patient is not monitored.
Check the neutral electrode regularly, and after moving the patient, to ensure that the entire surface makes contact.
If a neutral electrode is partially pulled off, it can cause damage to the skin.
4. Application notes

Suitable application site:

- Select the site for application of the neutral electrode so that the current paths between the active and neutral electrode are as short as possible and run lengthwise or diagonally to the body, as muscles have greater conductivity in the direction of the fibrilles.
- Apply the neutral electrode on the closest upper arm or upper leg, depending on the operating field, but no closer than 20 cm.
- The neutral electrode must be positioned on the top side of the body for a reclining patient, in order to prevent it from being undermined.
- The application site must be dry. Allow any cleaning products used to dry out completely.

Contraindication

- The neutral electrode must not be applied to damaged or injured skin.

Patient preparation:

- Remove metal jewelry.
- Remove heavy hair growth.
- Clean the application area if necessary, but do not use alcohol, as this dries out the skin and increases the contact impedance.
- In case of poor circulation, massage or brush the application site.

Electrode preparation:

- Check the neutral electrode for damage prior to use. If damaged, the neutral electrode must not be used anymore.
- Remove the protective film.

Application:

- Stick the neutral electrode on.
- When using an elongated type of neutral electrode, ensure that the longer edge makes full contact with the skin area in the operating field. In this way there is no increase in the current density at the short edge. Other types of neutral electrode, such as REF 816-092, 818-092, 816-072, 818-072, can be oriented in any direction thanks to their design.
- Avoid applying to massive subcutaneous fatty tissue.
- Ensure that the application site is free of scar tissue, bone spurs, and hairy sites.
- Ensure that there are no ECG electrodes or implants (e.g., bone pins, bone plates, endoprosthetics) are in the path of the current.
- Avoid sites where liquids can collect.
- Avoid positioning the neutral electrode under the buttocks or back of the patient.
- When operating in the thoracic region, do not run the current path transverse to the body, and ensure that the heart is never in the current path.

Contacts:

- Brush the neutral electrode securely onto the body of the patient.
- Make sure that the neutral electrode is not wrinkled and that the entire surface makes contact, in order to prevent air bubbles under the neutral electrode.
- Make sure that the protective edge adheres completely to the patient, with no wrinkles.
5. **Routing the cable**

- Do not wrap or wind the cable around an arm, a leg, or a metal object.
- Do not run the cable on or under the patient.
- Do not place any cable terminals under the patient.

6. **Removing the neutral electrode**

**Pulling off the electrode:**

- Always pull the electrode cable at the plug.
- Remove the neutral electrode carefully after use, starting from one corner.
- Pulling the neutral electrode off too quickly can cause skin irritation (redness.)

**Single use:**

- Neutral electrodes are intended solely for single use.
- Do not reapply an improperly applied neutral electrode.
- Because the capabilities of the neutral electrode may be compromised, re-use presents a hazard to the patient in the form of HF burns.

**Disposal:**

- Dispose of the neutral electrode after use.
- The medical product, packaging material, and accessories must be disposed of in accordance with country-specific regulations and laws.

7. **Storage**

- Do not open the package until immediately before use.
- Neutral electrodes can be kept for up to 7 days in the opened bag.
- Store neutral electrodes in the original packaging in a dry area.
- Avoid direct sunlight and proximity to heat sources.
- Permissible storage temperature range is 0 °C to 40 °C.