



**(240)900-005(10)0602**

**ENGLISH**

**INSTRUCTIONS FOR USE**  
Accessories for electrosurgical units  
Disposable neutral electrode

**812-80H** Disposable neutral electrode EMED SAFE, hydrogel, split, for adults and children, 176x122mm, 110cm<sup>2</sup>  
**812-83H** Disposable neutral electrode EMED SAFE, hydrogel, split, for infants, 181x76mm, 37 cm<sup>2</sup>  
**812-85H** Disposable neutral electrode EMED SAFE, hydrogel, split, for adults and children, 176x122mm, 110cm<sup>2</sup> with 3m US cable  
**812-88H** Disposable neutral electrode EMED SAFE, hydrogel, split, for infants, 181x76mm, 37cm<sup>2</sup> with 3m US cable

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**Used symbols:**

	Manufacturer
	The device conforms to the Directive 93/42/EEC, certified by Notified Body no. 2274
	Consult instruction for use
	Refer to the instruction for use
	Protect from moisture
	Protect from sunlight
	LOT
	Catalogue number
	Warning of risk arising from a situation endangering the safety of the patient or user or interfering with the performance of the device
	Use to
	Safe temperature range (min. and max. values)
	Number of items in the packaging
	Do not re-use
	Do not use if package is damaged
	Electrode suited for adults (weight > 15kg)
	Electrode suited for children (weight 5kg to 15kg)
	Electrode suited for newborns (weight <5kg)

	Caution
	Use up to 7 days after opening the package
	Medical device
	Neutral electrode for adults and children without cable
	Neutral electrode for adults and children with integral cable
	Neutral electrode for newborns without cable
	Neutral electrode for newborns with integral cable
	Does not contain latex
	No PVC contained
	For qualified users only
	Unique device identifier

The electrosurgical accessories from EMED comply with the essential requirements defined by Council Directive 93/42/EEC amended by Directive 2007/47/EC .

**WARNING**  
Before starting the use of the neutral electrodes read the content of these Instructions for Use and keep them for the whole period of their use in a place accessible to the medical personnel and service staff. The present instructions for use do not substitute for those for the electrosurgical unit. Always follow the instructions for use for the electrosurgical unit provided by its producer and the guidance given in it, in particular the contraindications for the performance of electrosurgical procedures. This also applies to the instructions for the accessories used, including electrosurgical neutral electrodes to be used during monopolar application with the electrosurgical unit. Specifications, safety instructions and warnings contained in the respective instructions for use must always be observed and followed.

**1. Intended use**  
The disposable neutral electrodes are used for closing the current circuit between the electrosurgical unit and the patient in monopolar procedures.

**1.1 Indications**  
Neutral electrodes have no specifically defined purpose, with consideration given to clinical indications.

**1.2 Contraindications**  
Electrosurgery is not recommended for pregnant women and persons with: implantable electronic devices (e.g. cardiac pacemakers, nerve stimulators, cardioverters or hearing implants), metal implants, arterial hypertension, diabetes and blood coagulation disorders.

These factors pose a risk of adverse events.

The contraindications include:  
- contraindications in accordance with the current state of knowledge,  
- contraindications related to the patient's general condition,  
- any other situations where the level of the risk posed by hazards to the patient's health or life would outweigh the benefits of the use of the device.

The decision to use electrosurgery is the responsibility of the person performing the surgical procedure, while assessing the possible hazards.

Provide the patient with any information concerning the risks, adverse events or side effects related to the use of the medical device.

**1.3 Target patient group**  
Disposable neutral electrodes have no specifically defined purpose, with consideration given to the patients' clinical conditions or gender.

They are available in two sizes to better match the size of the patient: a size suitable for an adult or child and one intended for a newborn (weighing less than 5 kg).

**1.4 Intended users**  
Disposable neutral electrodes may only be used by a qualified healthcare professional with formal education in the relevant field of medicine and knowledge in the field of electrosurgery. They are not intended for use by lay persons.

**1.5 Use environment**  
The device may only be used in rooms intended for medical purposes.

**2. Clinical benefits**  
The use of the electrosurgery using disposable neutral electrodes brings clinical benefits which have been confirmed in the literature, including, among others:

- use of monopolar technique during the procedure - the neutral electrode is used to close the circuit between the patient and the electrosurgical unit in monopolar technique,
- reducing the risk of burns - disposable split gel electrodes adhere to the patient's skin (by sticking) and therefore reduce the risk of burns. They are covered with medical hydrogel, which facilitates an even heat effect by distributing the current across the electrode surface. The use of CQM (Contact Quality Monitoring) safety systems in electrosurgical units allows for monitoring of the contact between the neutral electrode and the patient's skin surface.

**3. Adverse events**  
The most common risk associated with surgical procedures is the incorrect application of disposable neutral electrodes, resulting in patient burns. Risks associated with the use of disposable neutral electrodes are mainly due to carelessness and mistakes made by staff preparing the patient for surgery and monitoring their condition during the procedure. Full responsibility for correct electrode application rests on the surgical team. Particular attention should be paid, therefore, to the correct fitting of the neutral electrode so that burns do not occur at the area of application during surgery. The disposable neutral electrode should be monitored throughout the procedure. Special care should be taken in surgical procedures where the patient is a person with contraindications. In order to minimise the risks involved in the use of electrosurgery, it is essential to follow the safety rules described in detail in the Instructions for Use.

**WARNING**  
When procedures are carried out there is a risk of interference with or damage to implantable electronic devices (e.g. cardiac pacemakers, nerve stimulators, cardioverters or hearing implants). In these cases, the use of the monopolar technique is not recommended. If it is necessary to use monopolar modes, the neutral electrode should be placed as far as possible from the implanted electronic device. The active electrode should also not be used close to the implanted electronic device. It is recommended that the current should be applied briefly at short intervals. Before applying electrosurgery, consult the manufacturer, the authorized representative of the manufacturer of the implanted electronic device and the attending physician. After the procedure, check thoroughly the correct operation of the implanted device.  
It is not permitted to use electrosurgical procedures on patients with implanted electronic devices in outpatient clinic conditions.

**WARNING**  
**Endogenous burns**  
High-frequency leakage currents can cause burns in the patient's tissues far from the electrode application sites, e.g. close to metal implants or if these sites are in contact with conductive elements, generating high current intensity. These burns can also be caused by direct contact between the conducting cables and the patient's skin.

**WARNING**  
In rare cases, due to the patient's skin type (e.g. excessively dry skin), it is not possible to use a neutral electrode. The CQM system will then not function properly and it will not be possible to activate the electrosurgical device. In this situation, conventional surgical techniques should be used.

**4. Characteristics of the products and their mode of action**

The neutral electrode is a non-sterile, disposable, ready-to-use product, not intended for sterilisation. Each new electrode may only be applied once and must not be reprocessed.

**WARNING**  
An improperly applied neutral electrode must not be reused (a new electrode must be used). Re-using an electrode may impair its functionality which may cause a risk to the patient (risk of high frequency burns).

The sales unit for disposable neutral electrodes without cable is a box of 50 units, which contains unit packs - hermetically sealed bags containing 5 electrodes each. The sales unit for disposable neutral electrodes with integral cable is a box containing 8 units individually packed in hermetically sealed bags of electrodes. The sales package contains instructions for use of the product.

**WARNING**  
Do not use neutral electrodes whose packaging has been damaged before its intended open.

In monopolar mode, a high-frequency current is applied to the tissue using an active electrode (e.g. knife, ball). It then flows through the patient's body to the neutral electrode. The neutral electrode has a many times larger surface area than the active electrode. Due to this solution, the high-density current accumulates on the small surface of the active electrode, which causes a temperature rise and evaporation of water from the tissues directly surrounding the active electrode. The contact of the large surface of the neutral electrode with the patient's body causes the current flowing to the electrode to be dispersed on its surface, thus reducing its density.

The lower current density at the site of correct application of the neutral electrode reduces the creation of an undesirable heat effect and allows safe discharge of the current.

When using a disposable neutral electrode with an electrosurgical unit generating high-frequency current, always remember the two fundamental rules:  
- the current flows along all the available paths;  
- the HF leakage current flows between two adjacent conductors even if they are not in contact with each other.

**5. Technical data**  
The disposable neutral electrodes are intended for use with EMED electrosurgical units equipped with the CQM neutral electrode control system (NEM).

The neutral electrodes REF 812-80H and REF 812-83H must be connected to the neutral electrode socket of the high-frequency unit using EMED neutral electrode cable REF: 294-030, 294-050, 380-030, 380-050.

Neutral electrodes with integrated cable REF 812-85H and 812-88H can be connected directly to the electrosurgical unit and do not require additional connection cables.

The type "BF"/"CF" applied part of the electrosurgical unit is extended with the accessory connected to it.

**WARNING**  
Disposable neutral electrodes must not be used in high current modes with heating factors exceeding 30 A<sup>2</sup>s in 60 sec.

**WARNING**  
Surgical procedures on infants weighing up to 5 kg require the use of an appropriately labelled neutral electrode (<5 kg). Ensure that the maximum power of the high-frequency device is limited to 150 W.

**WARNING**  
Do not use the REF 812-83H and REF 812-88H neutral electrode on patients weighing more than 5 kg, due to the small surface area of adhesion. Always use a neutral electrode with as large a conductive surface as possible, provided that it can be applied on the patient's skin without overlapping. The use of a neutral electrode with too small a surface area may cause burns.

**6. Maximum voltage**  
The maximum voltage for the disposable neutral electrode is **500 Vp**. Disposable neutral electrodes are designed to be connected of EMED electrosurgical units generating voltage up to 6000 Vp.

**WARNING**  
Avoid too high output settings. The settings should be selected according to the surgeon's experience by referring to the clinical recommendations for a given procedure and the medical practice pursued and should not be higher than necessary for the specific procedure. Both too low and too high settings of the electrosurgical unit may cause a malfunction of the device, damage to it and unintended burns. The maximum output voltage of the electrosurgical unit must not exceed the maximum permissible voltage of the connected active accessory (active electrode).

**6. Performance of procedures**  
**Preparing the neutral electrode for the operation**

**WARNING**  
Before starting the procedure, please refer to the instructions for use of the electrosurgical unit.

Immediately after purchasing a new product and before the operation, carefully examine the condition of the cable, the plugs and the surface with which the electrode will adhere to the patient's body, paying particular attention to any damage or irregularities present on their surface (cracks, breaks, damage to the gel layer).

**WARNING**  
Do not use the neutral electrode with visible defects on its surface or with damaged insulation. Do not use cables with visible bends or with damaged insulation. Neutral electrode connection cables with damaged/bent insulation or with damaged wires may cause burns to the user/patient or even start a fire.

**Checking the expiry date**  
Observe the date of use indicated on the product packaging.

**WARNING**  
Neutral electrodes with an expired expiry date must not be used. After opening the package, the use-by date is 7 days. Do not use the product if the opening date of the hermetic packaging has not been specified. The packaging of the device is not a sterile barrier system (its opening does not pose a risk of loss of sterility), but the device cannot be used safely if the hermetic packaging is damaged or unintentionally opened.

**Selection of the correct electrode application site**

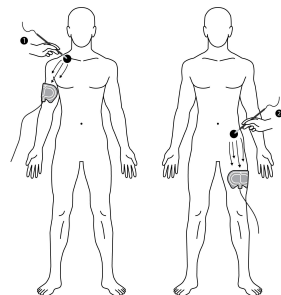
**WARNING**  
Choose such an application site that the current flow route does not go through the heart. It is forbidden to place the electrode in a manner causing the current flow along the whole body. Select such an application site that the current flow routes between the active and neutral electrodes are as short as possible and run along or diagonally across the body.

1. The patient should be isolated from any conductive elements.  
The operating table should be earthed.

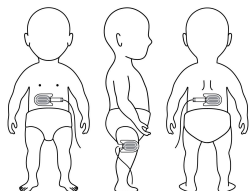
2. Cables should not be coiled or placed on the patient's skin as this may lead to burns. Untangle the cables and wires of the electrosurgical device before use. Do not secure them with metal objects ( clips).

- The patient should be placed on a dry, electrically insulated pad.
- Prevent contact between different parts of the patient's body. Dry gauze can be used as an insulator.
- Avoid applying the electrode between the patient's body and the operating table. Apply the electrode after the patient is positioned, on the side or the upper surface of the body, thus preventing fluids from penetrating under it.
- The electrode must not touch any metal objects, including metal parts of the operating table.

The correct positioning of the disposable neutral electrode on the patient's body for adults and children weighing more than 5 kg is shown in the figure below:



The correct positioning of the neutral electrode on the body of infants weighing less than 5 kg is shown in the figure below:



**Apply the neutral electrode:**  
- directly on patient's clean and degreased skin,  
- neutral electrode should be so applied as to ensure that it adheres to the patient's body with its entire surface,  
- close to the operative field, but not closer than at a distance of 20 cm,  
- in a well-vascularised area of the skin with a convex shape (the upper part of the thigh or arm).

**Do not apply the neutral electrode:**  
- on scars, lacerations, cuts, irritated or inflamed skin,  
- on the surface of the skin with implants underneath (e.g. pacemakers or other active implants). If the patient has a metal implant, it must not be on the path between the neutral electrode and the active electrode,  
- at places with a thick layer of subcutaneous fat tissue e.g. stomach, buttocks,  
- on the calves,  
- on tattoos and at places with skin lesions (e.g. on warts),  
- at places with a concave or strongly convex shape or at bony places ( e.g. elbow or knee),  
- on excessively hairy areas. If it necessary remove hair should be removed, taking special care not to scratch the patient's skin (the skin under the electrode must not be damaged - cuts, scratches).

**Preparation of the neutral electrode application site:**  
- remove hair from the selected application site,  
- clean the site, e.g. by removing any body lotions, and dry it. If it is cleaned with alcohol-based disinfectants wait for some time for the alcohol to evaporate,  
- in case of poor blood supply to the application site, apply local massage or brushing,  
- remove any jewellery from the patient.

The highest care must be exercised when applying a disposable neutral electrode. Particular attention must be paid, therefore, to the correct application of the neutral electrode so that burns do not occur at the application site during treatments.

**Neutral electrode application:**  
- choose the appropriate type of neutral electrode according to the patient's weight (as marked on the package),  
- open the package,  
- remove (peel off) the safety film protecting the adhesive surface of the electrode immediately before use,  
- do not wet the electrode or wrap it with anything,  
- place the electrode so that its longer edge faces the operative field,  
- do not put any conductive gels on it,  
- place the neutral electrode on the patient, pressing gently so that the whole surface of the electrode touches the patient's body (insufficient adhesion of the electrode to the skin may lead to burns),  
- make sure that the electrode is attached to the skin in a way that prevents it from displacing itself, without bends, wrinkles or air bubbles under the electrode,  
- make sure that no liquids get between the electrode and the patient's body,

- when disconnecting the neutral electrode, never pull on the cable.

In the course of a procedure, when the patient's position needs to be changed or the patient moves, in each case check if the electrode has not been displaced (peeled off) and if it adheres with all its surface to the patient's skin.

If the disposable neutral electrode is displaced, this significantly increases the risk of burns at the electrode application site. When the electrode application site needs to be changed, proceed as indicated above.

**WARNING**  
Make a note of the application site of the neutral electrode and the condition of the skin in contact with the electrode.

**Connecting the neutral electrode cable to the electrosurgical unit**  
Connect the electrode to the socket of the neutral electrode of the electrosurgical unit. In the case of reusable neutral electrodes without the ntegral cable, use the appropriate neutral electrode cable.

To connect the disposable neutral electrode cable to the corresponding neutral electrode,; open the cable clip lever by lifting it upwards, insert the tab of the disposable neutral electrode into the terminal slot up to the base of the electrode, close the cable clip lever by pressing it down as far as it will go (the lever will be flat against the surface of the cable socket). Make sure that the neutral electrode is correctly connected to the connection cable and that the plug of the neutral electrode cable is sufficiently firmly fixed in the electrosurgical unit's socket. The electrode cables should be connected in such a way as to avoid contact with the patient or other cables. After connecting the disposable neutral electrode to the electrosurgical unit, ensure that the electrode is correctly connected and properly adheres to the patient's skin - NEM control system (depending on the type of electrosurgical unit, the green neutral electrode icon appears or the green LED lights up).

**Monitoring correct electrode adhesion to the patient's skin by electrosurgical unit**

The CQM Neutral Electrode Application Monitoring System (NEM) used in electrosurgical units continuously controls the correct application of disposable, split neutral electrodes and the correct connection of the electrode to the unit. All information regarding the control system is contained in the Instructions for Use for the electrosurgical unit.

**Removing the electrode**  
Disconnect the electrode cable and then gently peel the neutral electrode from the patient's body, starting from one of the corners, observing the skin under the electrode at the same time. If the neutral electrode is peeled off too quickly, skin irritation (redness) may occur. Disconnect the cables from the electrosurgical unit by holding them by the plug. Never pull directly by the lead as this may damage it.

After the procedure, check the condition of the neutral electrode and the skin at the point in contact with the electrode to ensure that there is no injury/burn. It is recommended to make a note of the patient's skin condition.

**7. Warnings**  
**General warnings**

**WARNING**  
WARNING: Do not make any modifications to the product and do not use products which have undergone any modifications (e.g. trimming). EMED is not responsible for the use of products that have been modified in any way.

**WARNING**  
Always wear protective gloves during the use of neutral electrodes.

**WARNING**  
Monopolar procedures are not recommended for patients with metal components in the body, especially orthodontic braces. Jewellery should be removed from the patient's body before applying the neutral electrode.

**WARNING**  
Avoid long-lasting activations following each other at short time intervals. This may cause an increase in the temperature under the neutral electrode, enhancing the likelihood of damage to the patient's skin. In such a case, ensure sufficient skin cooling phases without current activation.

**WARNING**  
When the cutting and coagulation quality deteriorates for a given setting do not increase the power without prior:  
- checking of the placing of the neutral electrode,  
- checking of the correct connection of the cable plugs and accessory,  
- making sure that the function has been activated with the correct button in the handle or the footswitch (yellow - cutting, blue - coagulation),  
- checking if the insulation of the cables and electrodes is not damaged,  
- checking if the active electrode is clean. When it is not clean this can cause a deterioration of the operational quality of the electrosurgical unit.

**WARNING**  
The use of electrosurgery involves the generation of leakage currents during a procedure. These currents have low values; however, they can cause burns in the case of a small area of contact between the patent and e.g. the grounded operating table, the metal table equipment or other metal objects situated close to the operating field. In order to minimise the risk of burns caused by leakage current, comply with the rules for placing the neutral electrode and those for positioning and insulating the patient during surgical procedures.

#### **⚠ WARNING**

High-frequency cables (accessories and electrosurgical devices) should not be laid close to the cables of the monitoring equipment, run together, parallel to the camera cables or laid in a loop.

This may cause image interference with the monitoring equipment. Before starting the procedure, check that the operation of the camera does not interfere with the equipment to which the patient is connected. The test should be carried out in accordance with the instructions for use of the electrosurgical unit while observing the operation of the monitoring equipment. In addition, it is advisable to use monitoring equipment equipped with protection systems against high-frequency currents. Needle electrodes should not be used for monitoring devices due to the risk of current concentration at the site of their application, the thermal effect of which can cause burns.

#### **⚠ WARNING**

When performing electrosurgical procedures, minimise the risk of burns by:

- carefully applying the neutral electrode,
- preventing any liquid intrusion between the neutral electrode and the patient's body,
- preventing the patient from coming into any contact with metal and grounding elements. In particular, the patient should be effectively insulated from a grounded operating table. For this purpose, a plastic film should be placed between the operating table and the surgical drapes on which the patient is positioned,
- not touching the patient's skin during the activation of high-frequency current,
- not allowing the parts of the patient's body to come into contact with each other (for instance, the hand touching the thigh), where necessary, dry gauze should be used as insulation,
- applying the neutral electrode as close as possible to the procedure site, but not closer than 20 cm from the operating field,
- ensuring that urine is drained through a catheter,
- checking each time the cables connecting the neutral electrodes; in particular, the condition of their insulation.

#### **⚠ WARNING**

Non-flammable disinfectants should be used. If the use of flammable disinfectants is unavoidable, allow them to evaporate before treatment.

#### **⚠ WARNING**

Using EMED accessories with accessories, cables or medical devices made by other manufacturers may result in increased levels of electromagnetic emissions or reduced immunity to interference. Accessories should be safely combined with each other and with other devices according to their intended use, interface specifications and compatibility information provided by the manufacturer in the instructions for use. For any other use/combination of medical devices not in accordance with the recommendations, the manufacturer is not responsible.

#### **8. Processing**

The device is supplied in a non-sterile condition, is not intended for sterilisation, and is intended for single use. Electrodes must not be recycled or reused. EMED is not responsible for a product used more than once.

#### **9. Conditions of use, transport and storage**

Store and transport neutral electrodes in a clean dry place unexposed to the direct action of sunlight. Products must always be handled with the highest care during transport, storage and use.

The temperature for transport, storage and use must not be below 0°C or above 40°C.

Until their first use accessories should be stored in their original packaging. The expiry date is indicated on the product packaging. After opening the packaging, unused neutral electrodes should be stored in the original pouch and closed by wrapping the edge from where it was opened several times and then used within a maximum of 7 days. The products must reach room temperature before use.

#### **10. Repairs**

It is not allowed to repair defective neutral electrodes! Damaged electrodes may not be repaired and should be replaced by new ones. Any modification, self-repair or non-compliance with these instructions for use excludes the manufacturer's liability for the product.

#### **11. Disposal**

To minimise the risk of transmission of infectious agents immediately after use, placed the products in marked containers for medical and surgical waste, and it should be disposed in compliance with the applicable provisions of local law.

#### **12. Warranty**

The warranty for disposable neutral electrodes covers manufacturing defects and defects in material and is 12 months.

#### **13. Medical incidents**

Any serious incident relating to the device must be reported to the manufacturer and the competent authority of the Member State in which the user or patient reside.

Report medical incidents to the e-mail address: [incidents@emed.pl](mailto:incidents@emed.pl) or by phone. The e-mail addresses of the national safety supervision bodies can be found on the Government's websites.

A serious incident means any incident that directly or indirectly led, might have led or might lead to any of the following:

- (a) the death of a patient, user or other person,
- (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
- (c) a serious public health threat.

#### **14. Update of the instructions for use**

Keep the instructions throughout the working life of accessories.

After each update, the manufacturer publishes a new electronic version on the website.

The Instruction for Use are also available in electronic form after scanning the QR code situated below the code on the packaging.

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## 8. Ostrzeżenia

### Ogólne

#### ⚠ OSTRZEŻENIE

Nie wolno wprowadzać żadnych modyfikacji w wyrobie i używać wyrobów które zostały poddane jakiegokolwiek modyfikacji (np. przycinaniu).

Firma EMED nie ponosi odpowiedzialności za użycie modyfikowanych produktów.

#### ⚠ OSTRZEŻENIE

Podczas używania elektrod neutralnych należy używać rękawiczek ochronnych.

#### ⚠ OSTRZEŻENIE

Zabiegi monopolarne nie są zalecane u pacjentów z metalowymi elementami w ciele, zwłaszcza aparatami ortodontycznymi. Przed aplikacją elektrody neutralnej należy zdjąć biżuterię z ciała pacjenta.

#### ⚠ OSTRZEŻENIE

Należy unikać długotrwałych aktywacji następujących w krótkim czasie po sobie. Może to spowodować wzrost temperatury pod elektrodą neutralną, co zwiększa prawdopodobieństwo oparzenia pacjenta. Należy wtedy zapewnić wystarczające fazy chłodzenia skóry bez aktywacji prądu.

#### ⚠ OSTRZEŻENIE

Jeżeli jakość cięcia i koagulacji przy danej nastawie ulegnie pogorszeniu nie należy zwiększać mocy bez uprzedniego:

- sprawdzenia aplikacji elektrody neutralnej,
- sprawdzenia poprawnego podłączenia wtyków kabli oraz akcesoriów,
- upewnienia się czy funkcja była aktywowana odpowiednim przyciskiem uchwytu lub włącznika nożnego (żółty – cięcie, niebieski – koagulacja),
- sprawdzenia czy izolacja kabli i elektrod nie jest uszkodzona,
- sprawdzenia czy elektroda czynna jest czysta. Jej zanieczyszczenie może powodować pogorszenie jakości pracy aparatu elektrochirurgicznego.

#### ⚠ OSTRZEŻENIE

Stosowanie elektrochirurgii wiąże się z powstawaniem w trakcie zabiegu prądów upływowych. Prądy te mają niskie wartości, jednak mogą powodować oparzenia w przypadku małej powierzchni styku pacjenta np. z uziemionym stołem operacyjnym, metalowym wyposażeniem stołu lub innymi metalowymi przedmiotami, znajdującymi się w pobliżu pola operacyjnego. Aby zminimalizować ryzyko oparzeń spowodowanych prądem upływowym, należy przestrzegać zasad dotyczących umieszczenia elektrody neutralnej oraz pozycjonowania i izolowania pacjenta podczas zabiegów operacyjnych.

#### ⚠ OSTRZEŻENIE

Kabli wysokiej częstotliwości (akcesoriów i aparatów elektrochirurgicznych) nie należy układać w pobliżu kabli urządzeń monitorujących, prowadzić wspólnie, równoległe do kabli kamery ani układać w pętlę. Może to wywołać zakłócenia obrazu urządzeń monitorujących. Przed przystąpieniem do zabiegu należy sprawdzić, czy praca aparatu nie zakłóca pracy urządzeń, do których podłączony jest pacjent. Test należy przeprowadzić zgodnie z instrukcją użytkowania aparatu elektrochirurgicznego jednocześnie obserwując pracę urządzeń monitorujących. Ponadto zaleca się stosowanie urządzeń monitorujących, wyposażonych w układy zabezpieczające przed prądami wysokiej częstotliwości. Nie należy używać igłowych elektrod do urządzeń monitorujących ze względu na ryzyko koncentracji prądu w miejscu ich zastosowania, wystąpienia efektu termicznego, co może prowadzić do oparzeń.

#### ⚠ OSTRZEŻENIE

Wykonując zabiegi elektrochirurgiczne należy minimalizować ryzyko oparzeń przez:

- staranną aplikację elektrody neutralnej,
- niedopuszczenie do przedostania się jakichkolwiek płynów między elektrodę neutralną, a ciało pacjenta,
- zabezpieczenie pacjenta przed kontaktem z elementami metalowymi i uziemiającymi. W szczególności pacjent musi być skutecznie izolowany od uziemionego stołu operacyjnego. W tym celu zaleca się stosowanie folii z tworzywa sztucznego umieszczonej pomiędzy stołem operacyjnym, a obłożeniem na którym umieszczony jest pacjent,
- unikanie dotykania skóry pacjenta podczas aktywacji prądu wysokiej częstotliwości,
- poszczególne części ciała pacjenta nie mogą się ze sobą stykać (np. ręka do uda) (w razie potrzeby należy użyć, np. suchej gazy jako izolatora),
- elektrodę neutralną należy aplikować w miarę możliwości blisko miejsca zabiegu, ale nie bliżej niż 20 cm od pola operacyjnego,
- należy zapewnić odprowadzanie moczu poprzez cewnik,
- każdorazowe zwrócenie uwagi na stan kabli przyłączeniowych elektrod neutralnych, a w szczególności na stan ich izolacji.

#### ⚠ OSTRZEŻENIE

Należy używać niepalnych środków dezynfekcyjnych. Jeżeli użycie łatwopalnych środków dezynfekcyjnych jest nieuniknione, należy umożliwić ich odparowanie przed zabiegiem.

#### ⚠ OSTRZEŻENIE

Używanie akcesoriów EMED z akcesoriami, kablami lub urządzeniami medycznymi innych producentów może skutkować zwiększeniem poziomu emisji elektromagnetycznej lub zmniejszeniem odporności na zakłócenia.

Akcesoria należy bezpiecznie łączyć ze sobą oraz z innymi urządzeniami, zgodnie z ich przewidzianym zastosowaniem, specyfikacją interfejsu oraz informacjami dotyczącymi kompatybilności podanymi przez producenta w instrukcji używania.

Za każde inne używanie/łącznie wyrobów medycznych, niezgodne z zaleceniami, producent nie ponosi odpowiedzialności.

### 9. Przetwarzanie

Wyrób jest dostarczany w stanie niesterylnym, nie jest przeznaczony do sterylizacji, przeznaczony do jednokrotnego użytku. Elektrod neutralnych jednorazowych nie wolno przetwarzać ani stosować ponownie.

Firma EMED nie ponosi odpowiedzialności za produkt użyty więcej niż jednokrotnie.

### 10. Warunki eksploatacji, transportu i przechowywania

Elektrody neutralne jednorazowe należy przechowywać i transportować w czystym i suchym miejscu, nienarozonym na bezpośrednie działanie promieni słonecznych. Z produktami należy zawsze postępować z największą ostrożnością w czasie transportu, przechowywania i używania.

Temperatura transportu, przechowywania i używania nie może być niższa niż 0°C i wyższa niż 40°C.

Produkty aż do pierwszego użycia powinny być przechowywane w swoich oryginalnych opakowaniach. Termin przydatności do użycia podany jest na opakowaniu produktu. Po otwarciu opakowania nieużywane elektrody neutralne należy przechowywać w oryginalnej torebce i zamknąć ją przez kilkakrotne zawinięcie brzegu, od którego została otwarta a następnie zużyć w terminie maksymalnie do 7 dni.

Przed użyciem wyroby muszą osiągnąć temperaturę pokojową.

### 11. Naprawy

Pod żadnym pozorem nie należy dokonywać samodzielnych napraw elektrody neutralnej!

Uszkodzonych wyrobów nie można naprawiać, należy wymienić je na nowe. Każda modyfikacja, samodzielna naprawa lub nieprzestrzeganie niniejszej instrukcji używania wyłącza odpowiedzialność producenta za produkt.

### 12. Utylizacja

W celu zminimalizowania ryzyka przeniesienia czynników zakaźnych produkty przeznaczone do utylizacji, niezwłocznie po zakończeniu używania, należy umieścić w oznaczonych pojemnikach na odpady medyczne i utylizować zgodnie z obowiązującymi lokalnie przepisami prawa.

### 13. Gwarancja

Gwarancja elektrod neutralnych jednorazowych obejmuje wady fabryczne oraz wady materiału lecz wyłącznie w terminie przydatności do użycia (podanym na opakowaniu) i pod warunkiem należytego ich przechowywania.

### 14. Incydenty medyczne

Każdy poważny incydent związany z wyrobem należy zgłosić producentowi i właściwemu organowi państwa członkowskiego, w którym użytkownik lub pacjent mają swoje miejsce zamieszkania. Incydenty medyczne należy zgłaszać na adres e-mail: incidents@emed.pl lub telefonicznie. Adresów mailowych krajowych organów nadzorujących bezpieczeństwa należy szukać na rządowych stronach internetowych.

Poważny incydent oznacza incydent, który bezpośrednio lub pośrednio doprowadził, mógł doprowadzić lub może doprowadzić do któregokolwiek z niżej wymienionych zdarzeń:

a) zgon pacjenta, użytkownika lub innej osoby,
b) czasowe lub trwale poważne pogorszenie stanu zdrowia pacjenta, użytkownika lub innej osoby,
c) poważne zagrożenie zdrowia publicznego.

### 15. Aktualizacje instrukcji użycia

Należy zachować instrukcję przez cały czas użytkowania.

Po każdej aktualizacji producent publikuje nową wersję elektroniczną instrukcji na stronie www. Aktualne instrukcje używania dostępne są w formie elektronicznej po zeskanowaniu kodu QR znajdującego się poniżej lub kodu na opakowaniu.

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