

EN ELECTROSURGICAL PENCIL; REUSABLE

Utdannelse
- Utdannet læge, reservelæge, sygeplejerske eller specialsygeplejerske
Viden
- Forstår elektroteknologi og elektrotekniske teknikker
- Har læst og forstår de inkluderede brugsanvisninger eller mærkningerne på udstyret
Erfaring
- Nogen undervisning i teknikker eller undervisning med vejledning/supervision
Tilfælde svæktesker
- Nedtast læsessen eller korrigeret syn op til 20/20

VARNING: Do not use in the presence of flammable materials. Fire could result.

WARNING: Improper electrode installation may result in injury to the patient or operating room personnel by arcing at the electrode pencil connection.

WARNING: To avoid burn or shock injury, turn off the desiccator at the mains power.

WARNING: To avoid burn or shock injury, do not activate pencil while wiping electrode tip during use.

WARNING: Keep active accessories away from the patient when not in use. Accessories and electrodes should be placed in a clean, dry, nonconductive and highly visible area when not in use.

WARNING: Inspect prior to use. The device should be replaced if any physical damage such as nicks, cracks or cuts is noted on the handpiece or cable.

CAUTION: Product sold non-sterile. The use of a sterile sheath or sterilization prior to use is recommended.

CAUTION: Use the lowest possible setting to achieve the desired effect.

DIRECTIONS FOR USE:

- Place electrode into the handpiece. Ensure that the electrode is fully inserted.
- Connect the handpiece to the monopolar output receptacle of the electrological generator.
- To activate, depress the appropriate button for the desired effect. Yellow for Cut and Blue for Coag. Make sure the generator responds accordingly.
- After use, remove electrode and resterilize the pencil following the recommended procedure as follows.

CLEANING INSTRUCTIONS:

- Remove all gross matter (blood, tissue) by wiping down the pencil using a gauze pad or soft cloth dampened in warm tap water until all visible debris is removed.
- Wipe the pencil using a gauze pad or soft cloth dampened in an enzymatic detergent mixture diluted according to the manufacturer’s instructions. The pencil may also be gently scrubbed with a soft cleaning brush.
- IMPORTANT:** Abrasive material should not be used in the area of the barcode when cleaning the device.

- Remove cleaning agents from pencil by wiping with a tap water dampened cloth.
- Dry pencil thoroughly.

STERILIZATION INSTRUCTIONS:

Number of uses when sterilized by steam autoclave: 100
1. Steam autoclave at 121 °C (250 °F; gravity) for 20 minutes using an autoclavable pouch or wrapped cloth method. Consult the AAMI recommended practice for steam sterilization using the wrapped cloth method. Allow product to cool at least 30 minutes before use.

- Flash autoclave method is not recommended, as it may damage the pencil.

Medical Purpose/ Indication
The Device is necessary to be compatible with any standard RF generator that accepts a standard 3 pin monopolar connector and serves as the pathway to deliver RF energy via an assortment of RF electrodes to coagulate different kinds of tissues.

Operating Principle

The device is used in conjunction with an electrological generator and replaceable electrodes for the delivery of radiofrequency (RF) current. The device is to be used with a variety of monopolar electrodes for the coagulation and desiccation of tissue.

Patient Population

No restrictions

Site of Use and Site Conditions
Site of use – Soft Tissue
Site conditions – Aseptic

Intended User Profile

This device is intended to be used by trained physicians or individuals familiar with electrology.

Intended Conditions for Use

Education
• Trained physician, physicians assistant, nurse or nurse practitioner
Knowledge
• Understands electrology and electrological techniques
• Has read and understands supplied Instructions for Use or Device Labeling
Experience
• Some training on techniques or training under surveillance/supervision

Permissible impairments
• Mild reading vision impairment or corrected vision to 20/20

Intended Conditions for Use

• Doctor office, Surgery center or Hospital, intended for professional use only
• L1, clear and unobstructed view at point of use
• Ambient Temperature 10° C to 40° C

Frequency of use

- The ESPR2 is reusable and designed to withstand a maximum of 100 gravity autoclave sterilization cycles
- Disposal
 - Biohazard – Dispose of Pencil according to facility procedures

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CLEANING INSTRUCTIONS:

- Remove all gross matter (blood, væv) ved at tørre penncilen af med en gazepanen eller en blød klud, der er fugtet med varmt vand fra hanen, indtil alle synlige urenheder er fjernet.
- Tør penncilen af med en gazepanen eller en blød klud, der er fugtet med et enzymrengøringsmiddel i en opløsning, der svarer til producentens anvisning. Alternativt kan man skrubbet penncilen forsigtigt med en blød børste.
- VIGTIGT! Undgå at bruge silbende materialer i streptocodemrådet, ved rengøring af enheden.
- Fjern rengøringsmidlet fra penncilen ved at aftræke med en klud, der er fugtet med vand fra hanen.
- Aftr penncilen grundigt.

STERILIZATION INSTRUCTIONS:

Antal gange anordningen må bruges, når den steriliseres i dampautoklave: 100
1. Steriliser i dampautoklave ved 121 °C (250 °F; gravitation) i 20 minutter i en autoklavpose eller pakket ind i et klæde. Der henvises til AAMI's anbefalede praksis for dampsterilisation med indpakning i klæde. Lad produktet afkøle i mindst 30 minutter før brug.

Flashautoklaveringsmetoden anbefales ikke, da den kan beskadige penncilen.

Medicinsk formål/indikation
Enheden er et tilbehør, som er kompatibel med enhver standard RF-generator, der kan bruges med et standard monopolar stik med 3 splitter som bane til levere RF-energi via et udvalg af RF-elektroder til at koagulere forskellige typer væv.

Opereringsprincip
Anordningen anvendes sammen med en elektrokirurgisk generator og elektroder, der kan udskiftes, til levering af radiofreenstrøm (RF). Anordningen skal bruges sammen med forskellige monopolare elektroder til koagulation og udtræng af væv.

Patientpopulation
Ingen begrænsninger
Brugsted og stedbetingelser
Brugsted – bløddæle
Stedbetegnelse – aseptisk

Intenderet brugerprofil
Dette instrument er beregnet til at blive anvendt af uddannede læger eller personer, der er fortrolige med elektrokirurgi.

Påkrævede brugsbetingelser
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- TÆRKEÅB:** Hænkavaa materialejae ei saa käyttää viivakoodin kohdalla laiteita puhdistus tiläiksi.
- Poista kynästä puhdistusaineen jäämät pyyhkimällä sitä vesijohtoveteen kostutetulla liinalla.**
- Kuivaa kynä huolellisesti.**

STERILOINTIOHJEET:

- Höyryautoklaavissa 121 °C:ssa (250 °F; painovoima) 20 minuuttia käyttäen auto-klavattavaa pussia tai liinäkäärimenetelmää. Katso AAMI-suositukset höyrysterilointi-astian liinäkääröillä. Äänä tuottaa jäähtyä ainakin 30 minuuttia ennen käyttöä.
- Flash-autoklaavimenetelmää ei suositella, sillä se voi vahingoittaa kynää.

LÄÄKETEOTTEILAIN KÄYTTÖOHJEIDUKINDAKITO

Käyttö on yhteensopiva kaikkien sellisten vakioridatotaajausgeneraattorien kanssa, joiden kanssa voidaan käyttää kolmen nastan yksinäpäästä vakokäyttöllä, ja jissa käytetään reitintä radioaajausenergian toimittamiseen radiotaajuselektroden kautta erilaisten kudosten koaguloimaa varten.

Toimintapariatse

Laiteita käytetään yhdessä sähkökirurgisen generaattoriin ja vaihdettavien elektrodien kanssa radiotaajausvirran toimittamista varten. Laiteita käytetään erilaisten monopolaaristen elektrodien kanssa kudoksen koaguloimaa ja kuivattamista varten.

Potilaspopulatio

Ei rajoituksia

Käyttöpaikka ja paikan tila

- Käyttöpaikka – Pehmytkudos
- Paikan tila – Aseptinen
- Käyttövälineet

Yksityiskohtaiset kouluttajien lääkäreiden tai sähkökirurgiaan perehtyneiden henkilöiden käytettävissä.

Tarkoitettu käyttöolosuhteet

Koulutus
• Koulutettu lääkäri, lääkäriin apulainen, sairaanhoitaja tai sairaanhoitajaoppilas
Tiedot
• Hallitsee sähkökirurgian ja sähkökirurgiset tekniikat
• On perehtynyt laiteen mukana toimitettuihin käyttöohjeisiin tai laitteen merkintöihin
Kokemus
• Käyttökoulutus tai koulutus valtuutetoaljohtajana
Salitit väjävaiastus
• Luevia lukemia:näkövivaavaisuus tai näkö korjattuina tason 20/20

Tarkoitettu käyttöolosuhteet

- Anostaan ammattikäytön tarkoitettu lääkäriin vastaanotto, kirurgikeskus tai sairaala
- Väistää, sekä ja esteiden näkömy käyttöpaikasta
- Ympäristö lämpötilä 10–40 °C

Käyttöohjeys

- ESPR2 on uudelleenkäytettävää ja tarkoitettu kestämään enintään 100 painovoima-autoklaavin sterilisaatiokäyttöä.

Hävittäminen

- Biovaarallinen – Hävitä kynä sairaalan käytännön mukaisesti.

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