

# RaVoR™

## Bipolar Electrodes

### single-use



Rx only

# RaVoR™



#### EXPLANATION OF SYMBOLS:

- See instructions for use
- Protect from humidity
- Protect from sunlight
- Single patient use – do not reuse
- Batch code
- Article number
- Sterilized with ethylene oxide. Sterility guaranteed unless package opened or damaged.
- Temperature limitation
- Manufacturer
- Date of manufacture
- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
- European conformity symbol
- Date of expiry
- Do not use if package is damaged
- Single sterile barrier system
- Product is not made with natural rubber latex.
- Medical Device

RaVoR™ Bipolar Electrodes,  
single-use

REF: 70 44 62  
70 44 95

For US market only!

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#### Product / User / Disposal:

**Caution:** Electrosurgery accessories may only be used and disposed of by qualified medical personnel.

Notwithstanding these instructions, reading the instructions for use provided with the electrosurgery device and other accessories being used is mandatory.

#### Sterile product:

**Caution:** DO NOT recondition the instrument.

The thermolabile plastics used have **not** been validated regarding potentially suitable cleaning and sterilization processes.

Dispose of the instrument according to internal hospital guidelines for sharp, biologically contaminated items.

#### Indication for use:

Sutter RaVoR™ Bipolar Electrodes are to be connected to the bipolar output of the Sutter CURIS® RF Generator. Sutter RaVoR™ Bipolar Electrodes are indicated for ablation and coagulation of soft tissue in otorhinolaryngology (ENT) surgery.

The RaVoR™ Bipolar Electrode for the soft palate is indicated for submucosal tissue shrinkage and tissue coagulation in the uvula/soft palate for the treatment of snoring.

The RaVoR™ Bipolar Electrode for the turbinates is indicated for submucosal tissue shrinkage for reduction of hypertrophic nasal turbinates in patients with nasal turbinate airway obstruction.

#### Service life:

For single use only.

#### Before using:

**Warning:** INSPECT sterile packaging, instruments and cables for damage prior to each use. This may be done visually under magnification. Insulation failures may result in burns or other injuries to the patient or operator.

**Warning:** DO NOT use the instrument in the following cases:

- Discernible damage to the sterile packaging or electrode
- The package has gotten damp or was opened
- The sterility indicator does not have the required color
- The expiration date has been exceeded
- Always have a sterile bipolar electrode on hand as a replacement

**Warning:** DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.

#### During use:

The electrodes are coded for use with the CURIS® RF generator. After connecting the cable plug to the generator, the following program indicator has to light up briefly before the program setting is accepted:

For REF 704462: IC 01 EN

For REF 704495: IC 01 EN

The electrodes can only be operated in the RaVoR and Precise mode of the CURIS® RF generator.

**Warning:** Due to concerns about the carcinogenic and infectious potential of electrosurgical byproducts (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in electrosurgical procedures.

**Warning:** DO NOT USE in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N<sub>2</sub>O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.

**Warning:** DO NOT place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.

**Warning:** When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

**Warning:** The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.

**Warning:** DO NOT activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment.

**Warning:** Unintentional activation or movement of the activated electrode outside the field of vision can lead to unidentified tissue damage.

**Caution:** Max. voltage 600 Vp

**Warning:** Connect adaptors and accessories (Sutter Bipolar Electrodes) to the electrosurgical unit (CURIS® RF generator) only when the energy is off or in stand-by mode. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.

**Caution:** Keep the active electrodes clean. Build-up of eschar may reduce the instrument's effectiveness. Do not activate the instrument while cleaning. Injury to operating room personnel may result.

#### Storage / Transportation:

**Caution:** Observe the sterility expiry date.

Store in a cool, dry place. Protect from sunlight. Store at 10°C (50 °F) to 30°C (86 °F), relative humidity 30-80 %, non-condensing.

Sutter Medizintechnik GmbH explicitly warns against modifying the instrument. Any change or deviation from the instructions provided here waives the liability of Sutter Medizintechnik GmbH. Changes reserved.