INSTRUCTION FOR USE

ELECTROSURGICAL HANDLES

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Read Instruction

Non sterile

Medical device higher Class I and Number of the named place TÜV SÜD Production Service GmbH, Munich, Germany

LOT-Number

Cataloguenumber

Keep dry

Keep away from sunlight

RxOnly

Prescription - in the United States, this product may only be given by a doctor or on a prescription

Artikelnummern

34-9526	Electrode Holder double button slim, 3m
34-9526.50	Electrode Holder double button slim, 5,0m

1 Scope

The monopolar electrosurgical handles may be used only up to a maximum frequency of ≤ 1.5 MHz.

It is not permissible to use bipolar electrosurgical handles in conjunction with generators of the ArthoCare Company.

Maximum rated voltage of accessory:

identification	Umax
monopolar hf-handles	4,3 kVp
bipolar hf-handles	1,0 kVp

See also label or catalog.

In any combination with another electrosurgical accessory, the maximum rated voltage of the combination corresponds to the lowest rated voltage of the accessories used.

2 Authorized use

Only skilled medical personnel and personnel trained in this product are permitted to use the electrosurgical handles. The electrosurgical handles must be connected with the appropriate cable (monopolar/ bipolar) to the output (monopolar/ bipolar) provided for the purpose on the electrosurgical generator. They are intended for open or endoscopic surgery and are used as contact and switching elements. They are activated by means of a foot-operated switch or via the manual switch on the handle. It is recommended that a smoke evacuation system be used.

3 Safety notice

WARNING!

See these Instructions for Use, the label or the current product catalog for the maximum rated voltage of the electrosurgical handles.
If anything is unclear, contact the manufacturer. Before initial use, new electrosurgical handles must be cleaned and also sterilized according to a validated procedure (DIN EN ISO 17665) (In this regard see Section 4 "Cleaning and sterilization"). A function test must be performed before each use (see Section 5 "Function test"). If must be ensured that the electrosurgical handle is correctly connected to the generator. In addition, it is necessary to check whether the electrode is inserted firmly in the electrosurgical handle. This must be done carefully, in order to avoid damage to the electrosurgical handle and/or injuries to the patient or surgical personnel. The electrosurgical handle may be damaged if excessive force is applied. It is not permissible to activate the electrosurgi-cal-electrode as long as it is in contact with metal objects and/or optics. Throughout the complete procedure, care must be taken that no flammable substances are present in the immediate vicinity, since otherwise a danger of explosion exists.
The high-frequency current used in electrosurgery may interfere with cardiac pacemakers and implanted heart defibrillators, and so affected patients must consult a cardiologist prior to the operation.

4 Cleaning and sterilization

In view of the design, the materials used and the intended use, a maximum limit cannot be defined for the number of cleaning and sterilization cycles that may be possible.

Preparation for cleaning:
Remove the electrosurgical handles from their packaging. Place them in a container/ device provided for cleaning/ sterilization. It is not necessary to dismantle the monopolar electrosurgical handles.
For the bipolar electrosurgical handles with stopcock, the stopcock must be dismantled into its individual parts before cleaning.

Dismantling the stopcock:

The nut on the back of the stopcock must be loosened with an open-ended wrench (6 mm). In the next step, the stopcock plug must be removed. Now all components must be thoroughly cleaned. After cleaning and sterilization, the stopcock plug must be lubricated with a thin coating of grease (medically approved grease for stop-cocks). Thereupon the stopcock plug may be reinserted. The nut must now be tightened with the open-ended wrench.

Manual cleaning:

The electrosurgical handles must be disinfected immediately after each use. The electrosurgical handles should be thoroughly cleaned with a soft brush or synthetic fleece pad then rinsed, since otherwise particles or dried secre-tions may adhere to them. This could make subsequent cleaning and sterilization difficult or impossible. It must be ensured that areas with difficult access are thoroughly cleaned then rinsed several times. Highly alkaline cleaning agents with pH levels above 10 and below 13 have no detrimental influence on the useful life.

Automated cleaning:

Only washing machines/ disinfectors with efficiency tested according to DIN EN ISO 15883 may be used. For cleaning, use only commercially available cleaners, which are suitable for cleaning of plastics parts. Thermal disinfection must be performed for at least 5 minutes at a minimum of 90°C [194°F] to a maximum to 95°C [203°F]. The manufacturer's instructions about the dosage of cleaning agent and selection of program must be followed. If chemical disinfection has been applied, a final rinse with distilled or demineralized water must be performed. The electrosurgical handles must be mounted securely and protected against mechanical damage during machine cleaning/ disinfection.

Sterilization:

The electrosurgical handles are designed exclusively for steam sterilization in autoclaves. It must be ensured that the stopcocks are open throughout the complete process. The electrosurgical handles must be sterilized at a mini-mum of 134°C [273°F] and a maximum of 138°C [280°F] in saturated steam during a holding time of at least 5 minutes to at most 20 minutes, then dried in vacuum for at least 10 minutes. Sterilization must be performed in accordance with DIN EN ISO 17665 (Sterilization of Medical Devices in Moist Heat). It is not permissible to sterilize the electrosurgical-handles with hot air, EO gas, gamma radiation or plasma.
NOTE: Before use, the electrosurgical-handles must be cooled to room temperature.

Limitation of reconditioning:
The useful life of the product will depend on wear, damage and frequency of reconditioning.

5 Functional test

Before each use, the insulation of the electrosurgical handles must be inspected for pressure points or damage. Electrosurgical-handles with switching function must also be tested for correct functioning. It is not permissible to use electrosurgical handles exhibiting damage, pressure points or defective switching function.

6 Repair and modification

It is not permissible to repair defective electrosurgical handles. They must be replaced by new electrosurgical handles. Unauthorized modifications and repairs are strictly prohibited and will entail invalidation of the manufacturer's warranty.

7 Packaging, storage, transportation, handling

The electrosurgical handles must be stored in a clean and dry environment. They should be individually stored in a protective container with individual compartments or heat-sealed in film. The electrosurgical handles must always be handled with the utmost care during transportation, cleaning,

upkeep, sterilization and storage. This applies in particular for sensitive areas. It is the operator's responsibility to ensure that the sterile condition is preserved after the sterilization process.

8 Returns

Returns will be accepted only if they are marked as "hygienically safe" or "decontaminated" and have been securely packaged for shipping.

9 Disposal

The electrosurgical handles, the packaging material and the accessories must be disposed of in accordance with the regulations and laws specific to the country in which they are used.

10 About these Instruction of Use

Throughout the period of use of the electrosurgical handles, the Instructions for Use must be kept freely accessible for every user.