# Instructions for Use

# Electrosurgical Handles

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## ENGLISH

## 1 Scope

**Monopolare electrosurgical handles Art.-No.:** 92043 to 92049, 92096 to 92098, 92151, 92240 to 92300, 92443, 92447, 92540 to 92552, 92642 to 92649, 92736 bis 92739, 92740 to 92754, 92843, 92847

**Monopolare handles with smoke evacuation Art.-No.:** 92650 bis 92652, 92660 bis 92662

**Caps for monopolar electrosurgical handles with smoke evacuation Art.-No.:** 92670, 92671, 92672

Monopolar electrosurgical handles only are allowed to be operated with the following maximum rated voltage:

| Articles | Max. rated voltage |
|---|---|
| 92540 to 92552, 92736 to 92739, 92740 to 92754, | ≤ 1,5 MHz |
| 92043 to 92049, 92096 to 92098 92240 to 92300, 92443 to 92447 92642 to 92649, 92843, 92847 92650 to 92652, 92660 to 92662 | ≤ 4,0 MHz |

Maximum rated voltage of accessory:

| Identification | $U_{max}$ |
|---|---|
| All monopolar hg-handles | 4,3 kVp |

See also label or catalogue. In any combination with another electrosurgical accessory, the maximum rated voltage of the combination corresponds to the lowest rated voltage of the accessories used.

**Accessory:**

Sterile evacuation tube for Single Use for monopolar HF-handles incl. smoke evacuation, Art. No.. 92674s.

## 2 Intended use

Only skilled medical personnel is permitted to use the electrosurgical handles. The electrosurgical handles must be connected with the appropriate cable to the output provided for the purpose on the electrosurgical generator. Refer to the Instructions for use provided by the manufacturer of the electrosurgical generator and to the defined performance limits (Umax and max. rated voltage in the table under paragraph 1. Scope). For the handles with smoke evacuation it is necessary to plug on the sterile smoke evacuation tube art. no. 92674s at the proximal end of the handle. Please also consult the instructions for use of the smoke evacuation tube! Additionally clip on a cap (art. no. 92670 or 92671) to the distal end of the handles before use. The cap 92670 can be shortened by the user if necessary. Therefore choose one of the given recesses and cut along the recess with a scalpel. The Cap 92671 must not be cut since it has an invariable length. When you are assembling the parts please take care that both the cap at the distal end of the handle and the smoke evacuation tube at the proximal end are plugged on firmly. The caps may only be used in combination with Reger electrosurgical handles with smoke evacuation (Art. No. 92650 to 92652, 92660 to 92662). They are exchange parts for the mentioned handles. The electrosurgical handles 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 to use a smoke evacuation system.

## 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. Additionally the determined maximally allowed frequency of the high frequency current listed in section 1 has to be considered. Prior to each application, HF-electrosurgical handles have to be cleaned, disinfected and sterilized (DIN EN ISO 17665) according to a validated procedure, (refer also to paragraph 4 „cleaning and sterilization“). Prior to each application, a visual check and functional test hast o be done (see paragraph 5 „Visual and function test”). It 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. For handles with smoke evacuation also check whether the cap and the tube have been plugged on firmly. The electrosurgical handle may be damaged if excessive force is applied.It is not permissible to activate the electrosurgical-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, disinfection and sterilization

Reger Medizintechnik GmbH recommends the validated treatment processes described in the following. Equivalent deviant processes are possible. It is the sole responsibility ot the user to safeguard the suitability of the actual applied procedure by suitable means, f.e. validation, routine examination, verification of material compatibility, etc.

In view of the design, the materials used and the intended usse of the product, a maximum limit cannot be defined for the number of cleaning, disinfection or sterilization cycles that may be possible. During proper use of the electrosurgical handles, the products are subject to natural wear and tear depencing on type and duration of their application. Therefore a sight check and functional test has to be done prior to each application.

NOTE: The recommended accessory: smoke evacuation tube art. no. 92674s is delivered as a sterile product and is for single use only. It is not allowed to reprocess the tube!

**Preparation for cleaning:**

Where applicable, remove electrode from the handle. If it is about handles with removable cable, remove the cable. For the handles with smoke evacuation 92650, 92651, 92652, 92660, 92661 und 92662 it is necessary to take off the cap 92670 or 92671 before cleaning the handle. The caps must be cleaned, disinfected and sterilized separately. The smoke evacuation tube also has to be taken off and has to be disposed. The tube must not be reprocessed!

**Manual pre-cleaning:**

The electrosurgical handles and if applicable the cap must be disinfected immediately after each use. For pre-cleaning, pluese use water and where necessary aldehyde-free, non-fixing disinfectants. The electrosurgical handles should be thoroughly cleaned with a soft brush or synthetic fleece pad then rinsed, since otherwise particles or dried secretions 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 lifetime of the electrosurgical handles. This pre-cleaning procedure has to be applied prior to further cleaning processes with cleaning and disinfecting machines.

**Automated cleaning and disinfection:**

Only apply cleaning and disinfecting machines that are efficiency tested according to DIN EN ISO 15883. Please refer to the information of the manufacturer of the cleaning or disinfecting agent, and only use agents that are suitable to be applied for medical devices made from metal and steel and have a pH-value between 5,5 and 12,3. It is recommended tu use neodisher ® mediclean forte (Dr. Weigert GmbH & Co. KG). Do not use neutralization agents. Select the program for thermal disinfection. Regarding the program course, follow the instructions of use of the manufacturer of the agents. Do not clean electrosurgical handles together with sharp-edged or pointed objects.

Put the HF-handles in a suitable rinsing device and take care that when cleaning and disinfecting handles with integrated cables, the cable is not folded or squeezed.

Start the program course of the following features:

– Thermal disinfection: 5 to 10 minutes at 90°C to 93 °C (tolerance according to DIN EN ISO 15883-1 or -2), A0 ≥ 3000.

– Final rinsing with deminarilized water.

– Drying of product

At end of program course, remove the handles and verify if there are any staining residues. If staining/bonded residues are present, repeat the automated cleaning and disinfecting process as long as no visible residues are present. Dry any cavities and insufficiently dried areas with sterile compressed air < 2 bar. After the handles are taken out (after additional re-drying on a clean place), immediately pack them in a single-use sterilization package (single or double package) made of paper/foil or put them in a sterilization container (according to DIN EN ISO 11607 and DIN EN 868).

**Sterilisation:**

It is only allowed to sterilize instruments that have been cleaned and disinfected beforehand. Hf-handles are designed exclusively for steam sterilization in autoclaves (fractionated fore-vacuum procedure with sufficient product drying). ). Hf-handles have to be sterilized at a minimum of 132°C and maximum of 138°C in staurated steam during a holding time of at least 3 minutes to at most 20 minutes, then dried in a vacuum and sterilized for at least 10 minutes. Sterilizator according to valid national Norms and Guidelines (f.e. DIN EN 13060 or DIN EN 285). The sterilization process has been validated according to DIN EN ISO 17665. Please follow the recommendations and instructions of the sterilizator manufacturer regarding loading, handling and drying times. 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. It is the sole responsibility of the user to safeguard and maintain the sterile condition of the HF-handles after the sterilization process. In case the aforementioned described and recommended chemicals and machines for manual pre-cleaning and/or automated cleaning and disinfection are not available, it is the responsibility of the user to validate their procedure. Also, if another sterilization procedure is chosen, the procedure deviant from the procedure described in paragraph 4has tob e validated by the user accordingly.

**Limitation of reconditioning:** The lifetime of the product will depend on wear, damage and frequency of reconditioning. **The smoke evacuation tube 92674s must not be reprocessed.**

## 5 Visual and function test ⚠

Before each use, the the electrosurgical handles and if applicable the caps 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 or caps. 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 and the caps 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 and caps 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 "not contaminated" and have been securely packaged for shipping.

## 9 Disposal

The electrosurgical handles, if applicable the caps, 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 this Instructions for Use

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