

SKLAR LAPAROSCOPIC ELECTROSURGERY INSTRUMENTS INSTRUCTIONS FOR USE

DEVICE(S): The following instructions are for all Sklar Laparoscopic Electrodes. Read instructions prior to use. Improper operation and care or use for purposes other than that intended can lead to premature wearing out of the surgical instruments.

GENERAL INSTRUCTIONS

Handling	Products should only be used by clinically instructed and qualified personnel.
Inspection	When used as intended and depending on the intensity of use, electrosurgical products by nature are subject to wear. This kind of wear is caused by technical factors and cannot be avoided. Therefore thoroughly examine all instruments, cable, plugs and the electrode handle for visual irregularities on the surface prior to every use. Do not use cables with brittle or defective insulation. Test for functionality prior to each application.
Use	HF cables connect electrode handles, electrodes and instruments for monopolar or bipolar coagulation to HF units. Therefore carry out a thorough visual examination and a function test prior to each application of these products. In case a new product has externally visible defects or does not operate according to the instructions, contact the manufacturer. Never use damaged products.

Monopolar Mode

- Ensure that the skin is free from hair and grease.
- Affix the neutral electrode (return pad) to the patient. Recommended placement on upper arm or on thigh. If a reusable neutral electrode (return pad) is used, do not apply conductive gel.
- The current paths inside the patient's body should be short and must proceed diagonally. Current paths must never run in transverse direction through the body or across the thorax.
- Insulate patients against all electrically conductive parts. Ground the operating table. Place the patient on a dry electrically insulating layer. Prevent skin areas from touching each other by placing dry gauze in between. Connect the neutral electrode, the foot switch and the "active" HF cable to the HF unit. Then connect HF cable to the instrument or to the electrode handle (including the active electrode for coagulation) and switch on the HF unit. An electrode with the proper shaft diameter must be firmly attached to the handle tip.

Activation by the yellow (finger) switch means "cutting current."

Activation by the blue (finger) switch means "coagulating current."

- Always refer to the instruction manual for the HF unit and to its general information about electrosurgical procedures.
- All monopolar products can be operated up to 8500 Vp-p (monopolar forceps up to 5500 V p-p).

WARNING: In order to avoid interference with camera systems, do not guide HF cables in line with camera cables. Never place HF cables directly on the patient's skin. Never lay HF cables in loops.

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Power Output Always select the lowest possible output of the HF unit for any procedure. If the coagulating capacity of the electrode is below normal, do not increase the output of the HF unit without a thorough preliminary check. Inspect for correct fit of the neutral electrode (in case of monopolar mode), correct attachment of all HF cables and plugs, correct activation of current by the finger or foot switches, undamaged insulation of the HF cables and instrument, and check if the distal end of the electrode is clean and undamaged. Before operating, check if the signal transmission of the monitors works without interference (ie. without noise); this check is done by pressing the yellow button and the blue one.

Always unplug the HF cable by holding onto the connector. Never pull the cable itself as this may lead to defects. Cables with defect/brittle insulation or with a broken electrical wire may lead to burns of the user/patient or even cause fire. Avoid injuries by never placing active HF instruments and HF handles upon the patient in case of involuntary HF or “Auto Start” activation.

Caution Immediately after activation, electrode tips may be hot and can cause burns.

- Endogenous burns are those caused by high current density in the patient’s tissue. Inadvertent position of the patient in contact with electrically conductive parts or direct contact between skin areas and HF cables may lead to electrical capacitance, which in turn may cause burning.
- Exogenous burns are those caused by the heat of ignited fluids or gases. They may be caused by explosions. Avoid ignition of skin cleaning agents and disinfectants, narcotic gases, etc.

Cardiac Pacemakers may be damaged by electrosurgical current. Never use electrosurgical current on patients fitted with pacemakers. Consult a cardiologist for intervention.

PROCESSING INSTRUCTIONS

Warning Electrodes must not be twisted as this may cause damage of the material and the electrode might break.

Care & Cleaning **Do not clean HF cables, adapters or electrode handles in an ultrasound bath. Do not sterilize HF cables, adapters or electrode handles and electrodes in hot air sterilizers.** Wipe HF cables with an alcoholic surface disinfectant immediately after use. The HF cable or the handle may also be immersed in a combined cleaning and disinfecting solution. In this case, the service life may be reduced due to oxidation of the contacts and crystallization in the plugs. Observe the instructions of the chemical manufacturer and make sure that the agents used are compatible. Then rinse cable, connectors, pencil or electrode thoroughly with sterilized water. Inspect instruments and accessories for functionality and damage that may have occurred after each cleaning.

Safety Always deactivate the “Auto Start” mode (only in bipolar applications) or disconnect the instrument from the generator prior to cleaning the active electrode.

Storage Store products in their original packaging until initial use. Products should be stored in a clean, dry environment. Protect products from direct sunlight.

Temperature: 20°C/68°F - 50°C/122°F
 Relative Humidity: 0-75% (non-condensing)
 Atmospheric Pressure: 500-1600 mbar

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Repair Service Defective HF cables or electrode handles may not be repaired. Always replace a defective part with a new one. Return products directly to Sklar for service.

MONOPOLAR PRODUCT LINE

P/N	Description	Size	Type
31-2235	Insulated Electrode with Suction	5 MM	Spatula
31-2237	Insulated Electrode with Suction	5 MM	L-Hook
31-2241	Insulated Electrode with Suction	5 MM	Knife
31-2243	Insulated Electrode with Suction	5 MM	J-Hook
31-2244	Insulated Electrode with Suction	5 MM	Blunt
31-2227	Insulated Suction Control Valves	5 MM	With Single Trumpet Valve
31-2233	Insulated Suction Control Valves	5 MM	With Double Trumpet Valve
31-2229	Insulated Suction Control Valves	5 MM	With Double Trumpet Valve & Handle

Each coagulating electrode is able to connect to the suction control valve of choice.
Insulated electrodes and control valves sold separately.

P/N	Description	Size	Type
31-2435	Insulated Electrode without Suction	5 MM	Spatula
31-2437	Insulated Electrode without Suction	5 MM	L-Hook
31-2443	Insulated Electrode without Suction	5 MM	J-Hook
31-2445	Insulated Electrode without Suction	5 MM	Button
31-2447	Insulated Electrode without Suction	5 MM	Cone
31-4325	Insulated Electrode without Suction	3 MM	Spatula, Miniature
31-4326	Insulated Electrode without Suction	3 MM	L-Hook, Miniature
31-4327	Insulated Electrode without Suction	3 MM	J-Hook, Miniature
31-2242	Electrosurgical Cable	4MM	Monopolar, Compatible with Martin, Berchtold, Erb T-Series, 9'
31-2253	Electrosurgical Cable	8MM	Monopolar, Compatible with ValleyLab, Bovie, Conmed, 10'

Each electrode has a permanently fitted adaptor for connecting to the electrosurgical cable.
Insulated electrodes and cables sold separately.

Note: It is the responsibility of the operator to ensure that the reprocessing, as actually performed using equipment, materials and personnel in the reprocessing facility, achieves the desired result. Any deviation by the user from the instructions provided, must be properly evaluated for effectiveness and potential adverse consequence.