Instructions for Use for Bipolar Forceps

Intended Use
Bipolar forceps are used for grasping, dissection and coagulation of tissues. They have to be connected, by means of an appropriate bipolar cable, to the bipolar output of a high-frequency generator and may only be used with bipolar coagulation current.

Instruments for electrosurgery should only be used by persons who have been specially trained for the use of such instruments. These instructions do not substitute the instructions for electrosurgical and obsolete instruments must be properly disposed of in accordance to regulations.

Contraindications
Incidents which have been reported in connection with the use of bipolar systems:
- Unintended activation with resulting tissue injury on the wrong spot and/or damage to the equipment.
- Fire in connection with surgical drapes and other inflammable materials.
- Alternating current paths leading to burns on spots where the patient or user comes into contact with components without insulation.
- Explosions caused by sparks in the proximity of inflammable gases.
- Perforation of organs. Sudden severe bleedings.
- Bipolar forceps have proved inefficient for tubular sterilization or coagulation in the context of sterilization and should therefore not be used for this purpose.

Use and Safety Instructions
The non-observance of the present use and safety instructions may lead to injuries, malfunctions or other unexpected incidents.
- Before initial use and any other use, all instruments have to be completely cleaned, disinfected, sterilized and their function checked.
- It is very important to check each surgical instrument for visible damage and wear, such as cracks, breaks or insulation defects before each use. In particular areas, such as blades, tips, notches, locking and blocking devices as well as all mobile parts, insulations and ceramic elements have to be checked carefully.
- Never use damage instruments.
- Never use the instruments in the presence of flammable or explosive substances.
- The instrument may not be laid down on the patient.
- Frequently clean the tips from blood and debris.
- Coagulation should only be performed if the contact surfaces are visible and ensure a good contact to the tissue selected for coagulation. Do not touch any other metallic instruments, trocar sleeves, optics or the likes during use.

Prior to Use
Before connecting forceps and cables to an electrosurgical unit, make sure that the unit has been switched off or is in standby mode. Disregarding these instructions may lead to burns and electrical shock.

During use
Always use the lowest power setting available to achieve the desired surgical effect.

After use
Disconnect cable from forceps. Do not allow blood and debris to dry on forceps. Use a soft cloth or brush to remove blood and debris. Do not use aggressive/abrasive cleaners.
Rinse thoroughly with clean tap water before cleaning.
We generally recommend machine cleaning and thermal disinfection.

Machine Cleaning
Place the instruments in a basket on the insert module or on the inserts of the MIS module and start the cleaning process.
1. Pre-rinse for one (1) minute with cold water. Discharge.
2. Pre-rinse for three (3) minutes with cold water. Discharge.
3. Wash for five (5) minutes at 55°C with a 0.5% alkaline or at 45°C with an enzymatic cleaning agent. Discharge.
4. Neutralize for three (3) minutes with warm tap water (>40°C) and a neutralizing agent. Discharge.
5. Rinse for two (2) minutes with warm tap water (>40°C). Discharge.

Disinfection: Machine operated thermal disinfection has to be carried out in consideration of the regulation requirements with regard to the A0 value (ISO 15883).

Drying: Dry the outside of the instruments by carrying out a drying cycle of the cleaning/disinfection machine. If necessary, manual drying may additionally be carried out using a lint free cloth. Dry cavities by blowing with sterile compressed air.

Manual Cleaning
Ultrasonic Pre-cleaning
1. The instrument must be inserted in an ultrasonic bath with 0.5% enzymatic cleaning detergent. Ultrasound must be applied for 15 minutes at 40°C.
2. Remove the instrument and rinse completely with cold water to remove the cleaning detergent.

Cleaning: Prepare a cleaning bath according to the manufacturer's instructions.
1. Rinse products with cold tap water (<40°C) until all visible accumulations of dirt have been removed. Remove stuck dirt by using a soft brush.
2. Place products in the prepared cleaning bath so that they are completely submersed. Observe soak time according to the manufacturer's instructions.
3. Clean the instrument in the bath manually using a soft brush. Brush all surfaces several times.
4. The following steps only applies to channels and the insides of tubes: Push the brush into and out of the tubes at least six times. Rinse the tubes with distilled/desalinated water. Repeat the procedure.
5. Rinse the products thoroughly with distilled/desalinated water to remove the cleaning agents without residue.

Disinfection: Prepare a disinfectant bath according to the instructions of the disinfectant manufacturer. Place the instruments in the disinfectant bath and observe the specified soak time. Rinse the products thoroughly with fully demineralized water to remove the disinfectant without residue.

Drying: Manual drying is carried out using a lint free cloth and, in particular, for drying cavities and channels, sterile compressed air.

Non-stick Bipolar Forceps
A certain discoloring of the tips of non-stick instruments is normal and harmless. This does not lead to any malfunction.

Bipolar Forceps with Irrigation
The wire insert included with the product should always be inserted in the irrigation channel – except during utilization and cleaning, in order to prevent any clogging. The irrigation channel has to be rinsed very thoroughly during cleaning. The passage has to be checked after cleaning.

Sterilization
- 3 pre-vacuum phases with a pressure of at least 60 mbar.
- Heating up to a sterilization temperature of min. 132°C and max. 137°C
- Shortest exposure time: 3 minutes.
- Drying time: at least 10 minutes.

Storage
Sterilized instruments have to be stored in a dry, clean and dust free area at moderate temperatures from 5°C to 40°C.

Repairs
Never attempt to perform repairs yourself. Service and repair work may only be performed by persons qualified and trained accordingly.
*** Note: Defect products must be sterilized before being returned for repair.

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Safety Guidelines and Recommendations to Reduce Surgical Fires and Related Patient Injury:
FDA Safety Communication excerpt

FDA Date Issued:
May 29, 2018

Audience:

- **All health care professionals** involved in surgical procedures, including surgeons, surgical technicians, anesthesiologists, anesthesiologist assistants, certified registered nurse anesthetists (CRNA), physician assistants, nurses, etc.
- **Health care facility staff** responsible for patient safety and risk management.

Purpose:

The FDA is reminding health care professionals and health care facility staff of factors that increase the risk of surgical fires on or near a patient. The FDA is also recommending practices to reduce these fires from occurring, including the safe use of medical devices and products commonly used during surgical procedures.

Summary of Problem and Scope:

Although surgical fires are preventable, the FDA continues to receive reports about these events. Surgical fires can result in patient burns and other serious injuries, disfigurement, and death. Deaths are less common and are typically associated with fires occurring in a patient's airway.

Surgical fires can occur at any time when all three elements of the fire triangle are present:

1. **Oxidizer** (e.g., oxygen, nitrous oxide)
2. **Ignition source** (e.g., electrosurgical units (ESUs), electrocautery devices, lasers, and fiber-optic illumination systems)
3. **Fuel source** (e.g., surgical drapes, alcohol-based skin preparation agents, the patient's tissue, hair, or skin)

Most surgical fires occur in oxygen-enriched environments, when the concentration of oxygen exceeds 30 percent. When supplemental oxygen is delivered to a patient in an operating room, an oxygen-enriched environment can be created. An open oxygen delivery system, such as nasal cannula or mask, presents a greater risk of fire than a closed delivery system, such as a laryngeal mask or endotracheal tube. In an oxygen-enriched environment, materials that may not normally burn in room air can ignite and burn.

Recommendations to Reduce Surgical Fires:

Health care professionals and staff who perform surgical procedures should be trained in practices to reduce surgical fires. Training should include factors that increase the risk of surgical fires, how to manage fires that do occur, periodic fire drills, how to use carbon dioxide (CO2) fire extinguishers near or on patients, and evacuation procedures.

Specific recommendations to reduce surgical fires include:

- **A fire risk assessment at the beginning of each surgical procedure.**
  - Be aware the highest risk procedures involve an ignition source, delivery of supplemental oxygen, and use of an ignition source near the oxygen (e.g., head, neck, or upper chest surgery).
- **Encourage communication among surgical team members.**
  - Ensure communication exists between the anesthesia professional delivering medical gases, the surgeon controlling the ignition source, and the operating room staff applying skin preparation agents and drapes.
- **Safe use and administration of oxidizers.**
  - Evaluate if supplemental oxygen is needed for your patient.
    - Any increase in oxygen concentration in the surgical field increases the chance of fire.
    - At concentrations of approximately 30 percent, a spark or heat can ignite a fuel source.
  - If supplemental oxygen is necessary, particularly for surgery in the head, neck, or upper chest area:
    - Titrate to the minimum concentration of oxygen needed to maintain adequate oxygen saturation for your patient.
  - When appropriate and possible, use a closed oxygen delivery system.
    - If using an open delivery system, take additional precautions to exclude oxygen and flammable/combustible gases from the operative field, such as draping techniques that avoid accumulation of oxygen in the surgical field.
- **Safe use of any devices that may serve as an ignition source.**
  - Consider alternatives to using an ignition source for surgery of the head, neck, and upper chest if high concentrations of supplemental oxygen (greater than 30 percent) are being delivered.
    - If an ignition source must be used, be aware that it is safer to do so after allowing time for the oxygen concentration in the room to decrease. It may take several minutes for a reduction of oxygen concentration in the area even after stopping the gas or lowering its concentration.

- Inspect all instruments for evidence of insulation failure (device, wires, and connections) prior to use. Do not use if any defects are found.
- In addition to serving as an ignition source, monopolar energy use can directly result in unintended patient burns from capacitive coupling and intra-operative insulation failure. If a monopolar electrosurgical unit (ESU) is used:
  - Do not activate when near or in contact with other instruments. Use a return electrode monitoring system.
- Tips of cautery instruments should be kept clean and free of char and tissue.
- When not in use, place ignition sources, such as ESUs, electrocautery devices, fiber-optic illumination light sources and lasers in a designated area away from the patient (e.g., in a holster or a safety cover) and **not** directly on the patient or surgical drapes.
- Recognize that other items that generate heat, including drills and burrs, argon beam coagulators, and fiber-optic illuminators, can also serve as potential ignition sources.

- **Safe use of surgical suite items that may serve as a fuel source.**
  - Allow adequate drying time and prevent alcohol-based antiseptics from pooling during skin preparation and assess for pooling or other moisture to ensure dry conditions prior to draping.
  - Use the appropriate size applicator for the surgical site. For example, do not use large (e.g., 26mL) applicators for head and neck cases.
  - Be aware of other surgical suite items that may serve as a fuel source, including:
    - Products that may trap oxygen, such as surgical drapes, towels, sponges, and gauze – even those which claim to be "flame-resistant."
    - Products made of plastics including some endotracheal tubes, laryngeal masks, and suction catheters.
    - Patient-related sources such as hair and gastrointestinal gases.
- **Plan and practice how to manage a surgical fire.**
  - Stop the main source of ignition. Turn off the flow of flammable gas and unplug any electrical devices that may be involved.
  - Extinguish the fire – use fire blankets, water or saline, and a CO2 extinguisher if the fire persists.
  - Remove all drapes and burning materials and assess for evidence of smoldering materials.
  - For airway fires, disconnect the patient from the breathing circuit, and remove the tracheal tube.
    - Move the patient to a safe environment. Reestablish the airway to resume respiratory care.
  - Review the fire scene and remove all possible sources of flammable materials.

FDA Activities:

The FDA is working with The Joint Commission (TJC) and other organizations to inform health care professionals and health care facility staff about risks of surgical fires and provide recommendations to reduce them. The FDA also reviews product labeling for drugs and devices that are components of the fire triangle to ensure the appropriate warnings about the risk of fire are included.

Reporting Problems to the FDA:

Prompt reporting of adverse events will help the FDA identify and better understand the risks and adverse events associated with surgical fires. If you experience a surgical fire, we encourage you to file a voluntary report through Medwatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport/default.htm). Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationsandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm) should follow the reporting procedures established by their facilities.