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REUSABLE PLASTIC SURGERY INSTRUMENTS

Manufacturer: Lipokey . LLC

Method: Instructions for Use



- Devices shall be used in accordance with these instructions for use. Read all sections of this insert prior to use. Improper use of this device may cause serious injury. In addition, improper care and maintenance of the device may render the device non-sterile prior to patient use and cause a serious injury to the patient or health care provider.
- Inappropriate use of instruments may result in patient injury, damaged or broken instruments.
- Proper cleaning, handling, sterilization and standard routine maintenance (such as sharpening, lubrication if applicable) will ensure that the instruments perform as intended and will extend their useful life.
- Delicate Plastic Surgery Instruments require special handling to prevent damaging the tips. Use caution during cleaning and sterilization.
- Do not expose instruments to phenols or iodophors.
- Do not use dry heat sterilization for aluminum or plastic made, black coated or ebonized instruments.
- Do not apply excessive stress or strain at joints; misuse will result in misalignment or cracks at the box locks or jaws.
- Wear appropriate protective gloves, eyewear and clothing when handling biologically contaminated instruments.
- Instruments manufactured from different metals or with special coating, should be processed separately to avoid electrolytic action between the different metals.
- Before use, inspect the instruments for possible damage, wear or non-functioning parts. Carefully inspect the critical, inaccessible areas, joints and all movable parts.
- Damaged or defective instruments should not be used or processed.

Product Intended Use

The **Lipokey.LLC**. Plastic Surgery Instruments are designed to perform specific functions such as cutting, grasping, clamping, dissecting, probing, retracting, draining, aspirating, suturing, or ligating. Surgical & Plastic Surgery Instruments may also be used to facilitate the insertion of surgical implants.

Contraindications

No contraindications relating to the product are currently known. Use of the product is contraindicated if, in the opinion of the responsible physician, the patient's health is endangered through its use, e.g., due to the patient's general condition or if the method as such is contraindicated.



- Aluminium based products are damaged by alkaline (pH>7) detergents and solutions.
- Infection hazard for patients and/or users due to reuse without proper cleaning. If contaminated.
- Risk of injury, illness or death due to contamination.
- Do not use detergents or disinfectants containing the following substances:
- Strong Alkalines (>pH9)
- Strong Acids (<pH4)
- Phenols or iodophors
- Hydrogen peroxide (H₂O₂)
- Interhalogenic agents/ halogenic hydrocarbons/ iodophors
- Strong oxidizing agents / peroxides
- Organic solvents
- Water quality may influence the result of the cleaning and disinfection of the products. Therefore use only deionized water or purified water/high purified water for all the steps that require water. Corrosion of products may be caused by high contents of chloride or other minerals in tap water. If stains and corrosion occur and other reasons can be excluded, it may be necessary to test the quality of the tap water in your area. Most water quality problems can be avoided with the use of deionized water.
- Never attempt to make repairs yourself. Any repairs made by the users may void the warranty.
- The use of a product for a task other than that for which it is intended, as well as improper, ineffective and insufficient maintenance can greatly reduce the life of a product and will invalidate the product's warranty.

- Consult National Infection Control / Prevention Protocols for specific guidance regarding processing of medical devices.

Limitation on re-processing:

Frequent re-treating has little effect on the product. The end of the product lifetime is usually determined by wear and damage from use. They are then to be disposed of according to hospital procedure. Do not use any damaged products.

Point of Use

Remove surface contamination with a disposable cloth / paper towel. It is recommended to reprocess the products as soon as possible after they have been used.

Directly after use, they can be disinfected by hand in order to reduce the risk of infection for the user. Follow the instructions of the manufacturer of the disinfection solution.

Containment & Transportation

- Contain contaminated products in an approved sealed container during transport from the point of use to the decontamination area.
- Reprocess products as soon as is reasonably practical following use.

Preparation for cleaning

No special requirements.

Cleaning: Automated

- Use an ultrasound device such as Branson B-300 ultrasonic device or Miele G 7736 CD, or any equivalent suitable device for medical use.
- Place instruments in the wire basket.
- Rinse for 1 min. with cold water (<40°C).
- Discharging
- Rinse for 3 min. with cold water (<40°C).
- Discharging

- Ultrasonically clean for 5 min. at 55°C with a 0.5% alkaline (like Micro-90® or Neodisher® FA by Dr. Weigert) or at 45°C with an enzymatic cleaning agent such as Enzol® (Johnson & Johnson) one ounce of product per gallon of water or two ounces of product per gallon of water for cleaning devices with dried-on matter. Make sure that the instruments are completely submerged.
- Discharging
- Neutralize for 3 min. with warm water (>40°C) and 2 min. intermediate rinsing with warm water (>40°C).
- Discharging

Note:

- An overdose of the cleaning/disinfection solution is to be avoided.
- Special instructions of the manufacturer of the automated cleaning machine have to be followed.
- Inspect instruments for good cleaning result and repeat procedure if necessary. The best effects are achieved by cleaning and rinsing the instruments immediately after each application.

The following items should also be observed:

- The wire basket of the ultrasound device must be sufficiently large and deep to guarantee that the instruments are completely immersed.
- Instruments must be completely covered by the cleaning solution.
- Only use wire basins, which don't negatively affect the cleaning result.
- Don't overload wire basins.
- Avoid "acoustic shadows".
- Fill all channels and hollow spaces with cleaning solutions, without air bubbles.
- Remove instruments from the ultrasound device.
- Blow through all channels with air to remove any remaining liquid.
- Change the cleaning solution in the ultrasound bath at least once a day, and more often when contamination is visible.

Cleaning: Manual

Prepare the cleaning bath with detergent like Enzol Enzym (Johnson & Johnson) using one ounce of product per gallon of water or two ounces of product per gallon of water for cleaning devices with dried-on matter or prepare according to the manufacturer's instructions.

- Rinse the products with cold tap water (<40°C) until all visible soil has been removed. If needed a soft bristle brush should be used to remove stuck dirt/soil.

- Placed products in the prepared cleaning bath so that they are completely submersed. Observe residence time 2-3 minutes or according to the manufacturer's instructions.
- Clean the instrument in the bath manually using a soft brush. Brush all surfaces/channels and insides of instruments several times.
- Rinse the instrument under running tap water to remove the detergent.
- Inspect the instruments for good cleaning result and repeat procedure if necessary.
- Instrument is now ready for high-level disinfection or sterilization.

Disinfection

Prepare disinfectant solution with solution like Cidex® OPA (Johnson & Johnson) using one ounce of product per gallon of water or two ounces of product per gallon of water with dried-on matter or prepare according to the manufacturer's instructions.

- Completely submerge instruments in the disinfectant solution.
- Soak for a minimum of 12 minutes at 20°C or higher to destroy all pathogenic microorganism.
- There should be no contact between the instruments.
- Remove the instruments from the disinfecting solution with fresh disposable gloves.
- Thoroughly rinse the instruments by immersing it completely in water. Use deionized water.
- Keep the instrument totally immersed for a minimum of one minute in duration.
- Manually flush all lumens with large volumes of rinse water.
- Remove instrument and discard the rinse water. Always use fresh volumes of water for each rinse.
- Repeat the rinse procedure two additional time with a large volumes of fresh water to remove the Cidex® OPA solution residues. Residues may cause serious side effects. Three separate, large volume water immersion rinses are required.

IMPORTANT NOTE: Before using a Cidex® Solution for high level disinfection, a Cidex® test strip should be used to ensure that the solution concentration is minimally effective. Consult with the Cidex® user instructions, as well as the original equipment manufacturer's instructions for the Cidex® test strips, for guidance prior to use..

Drying

Products must be thoroughly dried and all residual moisture must be removed before they are stored. Use a soft, absorbent towel/cloth to dry external surfaces. Compressed air may be used to aid the drying process.

Maintenance

Product can be cleaned following the guidelines in the 'Cleaning' and 'Disinfection' above. Periodically check the condition of the Product, making sure there is no sign of corrosion. Discard the damaged products.

Inspection & Functional Testing

- Prior to use, visually check the product for bent, broken, cracked, worn, or missing component(s).
- Edges and surface should be free of nicks.
- Do not use the product if it is damaged, blocked or defective.

Packaging

A standard packaging material should be used. Ensure that the packaging is large enough to contain the product. When used as intended, these products do not need an outer wrap or additional protection.

Always use protective caps for packaging / storage of clean products, where needed.

Sterilization

Plastic Surgery Instruments must be processed in the completely open position to allow sterilant contact of all surfaces.

Recommended sterilization method: Steam sterilization with saturated steam with a fractionizing vacuum (EN ISO 17665)

Recommended temperature: 121 °C

Recommended pressure: 1 bar

Duration: ≥ 15 min

Drying time: ≥ 30 min

After sterilization, check the packaging of the sterilized instruments for damage. Check the sterilization indicators.

Note: Sterilization can only be maintained if the instruments remain packaged or wrapped, impermeable to microorganisms, following a validated sterilization. 

Storage

Plastic Surgery Instruments have to be stored under below listed conditions

- Stored in dry area.
- Between -20°C and +49°C and 10% and 95% relative humidity.

Protected from direct sunlight, moisture and excessive airflow.

Additional Information

When sterilizing multiple instruments in one autoclave cycle ensure that the sterilizer's maximum load is not exceeded.

Symbols

Symbols may be used on some package labeling for easy identification.



Manufacturer

(Company responsible for a device marketed under its own name regardless of whether "manufactured for" or "manufactured by" the company.)



Manufacturing Date



Catalog number



Lot number



Expiration Date



Non-Sterile



Latex Free



Temperature limitation



Do not use if package is damaged



Keep dry



Caution see warnings or precautions



Federal (USA) law restricts this device to sale by or on the order of physician or practitioner



Consult instructions for use

This instructions provided above have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to

ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Dated: April 01, 2017