

OCULO-PLASTIK LASER SECURE LINE

Oculo-Plastik LaserSecure® Line

CAUTION: Consult accompanying documents.

LaserSecure® Instrumentation

READ ALL INSTRUCTIONS BEFORE USING THIS PRODUCT.



OCULO-PLASTIK^{INC}

LaserSecure® line



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Instructions for Use

USE ONLY WITH PURE LASERS OR PURE IPL SYSTEMS. DO NOT USE WITH SYSTEMS THAT ARE INTEGRATED WITH ELECTRIC CURRENT.

After every case application and before sterilization, always verify visually and manually the condition of both surfaces and edges of the device.

WARNING

- Do not use with any systems that are integrated with RF (radio-frequency). Due to the electrical current from the RF, metal will conduct and retain heat causing burns to the surface of the skin.
- Do not use any device that is scratched or damaged. Any scratch on the non-reflective surface of the device renders it reflective and dangerous and may cause burns to the surface of the skin of the OR personnel.
- Do not use any device that has been dropped accidentally without thorough examination of its condition.
- Avoid direct light beam impact onto the metal pieces. Direct light beam impact will heat the metal and might reflect on the surroundings, including personnel.
- Lasers and other light sources should always be aimed away from the ocular globe and away from the metal device.

Our LaserSecure® shields and instruments are made of high quality stainless steel with a non-reflective finish. Even though these devices are low maintenance, they must be handled with extreme care in order to maintain their quality and safety performances. To ensure protection of the patient and the OR personnel a yearly refurbishing is suggested, although the condition of the shield or instrument will give a better indication.

Cleaning Procedure for the Devices

Devices must be inspected and cleaned before initial sterilization, and subsequently between each patient use. Use procedures that have been previously established and validated for your facility or use the following recommendations.

In considering methods for sterilization procedures, it is important to differentiate between sterilization and disinfection. Disinfection only reduces the number of viable microorganisms. Sterilization kills all viable microorganisms.

1. Before sterilizing, devices should be rinsed under warm running water to remove all debris.
2. Devices should be washed in a solution of water and neutral pH pre-soak detergent. DO NOT USE: CHLORIDE, STAIN REMOVERS, CHLORINE BLEACH, ENZYME CLEANING AGENTS, CLEANING AGENTS THAT CONTAIN ALKALIES OR CLEANING AGENTS NOT RECOMMENDED FOR SOFT METAL.

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3. A non-metallic brush should be used to remove stubborn debris. Do not use abrasive pads.
4. Devices should be cleaned in the open position, by hand, ultrasonic cleaner or automatic washer sterilizer.
5. Rinse extensively with distilled water after manual cleaning and ultrasonic cleaning. For automatic washer sterilizer follow manufacturer's recommendations.
6. Sterilize according to manufacturer's instructions.

Sterilization Recommendations

Stainless steel instruments can be sterilized repeatedly by ethylene oxide or autoclave.

Do not sterilize stainless steel devices in bleach, as bleach will corrode them.

This product is sold non-sterile.

Cold sterilization is not recommended.

Lubricate all instruments that have any "metal to metal" action. To sterilize devices, place them in a peel-pouch, on the sterilizer rack, in a single layer. Use either method:

Gravity Displacement Minimum Requirements:

- 250°F (121°C) for 30 minutes at 15 psi (103 kPa) or
- 270°F (132°C) for 15 minutes at 30 psi (207 kPa) or
- 273°F (134°C) for 15 minutes at 32 psi (221 kPa)

Pre-Vacuum Minimum Requirements:

- 270°F (132-134°C) for 4 minutes at 30 psi (207 kPa)

Follow your specific sterilizer equipment manufacturer's recommendations, or use cycles that have been previously established and validated for your facility.

- If you cannot remove stains from your shields or instruments we may be able to restore the surface qualities by refurbishing the instruments for a minimal cost.
- Please note that in severe cases of pitting or corrosion, refurbishing may not be possible.
- We will evaluate your shields or instruments at no cost and inform you of our suggestions and/or cost evaluation.
- Please do not return any shields or instruments without a return authorization number. Shipping and handling is the responsibility of the sender.

Call or fax for an RA number and for further details.