HAYDEN MEDICAL INC

COX®

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(en) COX® STAINLESS STEEL OCULAR LASER SHIELD

## INSTRUCTIONS FOR USE

READ ALL INSTRUCTIONS BEFORE USING THIS PRODUCT

CAUTION, consult accompanying documents.


This Product is sold Non Sterile.


Does not contain Natural Rubber (Latex)

## INTENDED USE

Cox® II ocular laser shields are inte
to protect the eyes during IPL and l
ser procedures close to the eyes
and on the face. They are inserted
under the eyelids, on the ocular

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globes for the length of the procedure. They should not be left in place more than 60 minutes. The posterior polished surface and well-polished edges are intended to avoid corneal abrasions. The anterior surface is non-reflective treated to avoid reflection of the laser beam or IPL light source.

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

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

For the comfort and safety of the patient during insertion of the ocular shields an ophthalmic topical anaesthetic and ointment (non petroleum based for laser) is recommended.

Users must choose a shield size appropriate to the globe. During periorbital surgery the shields should cover the entire globe.

## 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 ocular globe.
- Do not use any device that is scratched or damaged.
- For all ocular shields, any scratch on the posterior surface or edges; or any pressure on the cornea during

insertion or removal may increase the risk of CORNEAL ABRASION, etc.

- Do not use forceps to remove ocular shields, as they will be 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 O.R. personnel.
- Do not use any device that has been dropped accidentally without thorough examination of its condition.
- Invasive Stainless Steel Ocular shields should not be left in place more than 60 minutes.
- Cox® Stainless Steel Ocular shields should not be used externally over the lid.
- Avoid direct light beam impact onto the metal eye shields. Direct light beam impact will heat the metal and may cause burns to the cornea.
- During extensive periorbital treatment, especially with a high-energy laser, use extreme caution as ocular laser shields may absorb energy, retain heat, and may cause adherence to eyelids and globe. 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 protec-

tion of the patient and the O.R. personnel a yearly refurbishing is suggested, although the condition of the shield or instrument will give a better indication.

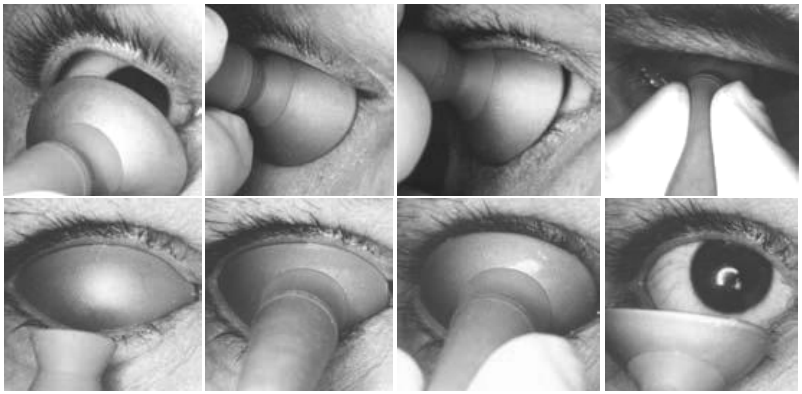
## INSERTION AND REMOVAL INSTRUCTIONS.

See our video section on our web site.

For the comfort and safety of the patient during insertion of the ocular shields an ophthalmic topical anaesthetic and lubricant is recommended.

The shields must be lubricated on the inside surface and around the edges before insertion. This makes it easier to insert. The ophthalmic topical anesthetic and gel lubricant may be purchased at your local pharmacy.

A simple method of insertion is to first place shield in lower fornix (inside lower lid) then pull the upper lid up over the shield and place shield under upper lid. To make the suction cup grip on the shield, users should practice before, while the shield and cup are in their hands. Always test first if the suction cup is functional.



For the removal of the shields, make sure there are no lashes under the suction cup, as the cup will not grip the shield. While placing the suction cup, simply lift one lid at a time and assure lashes are not in the way. Also while doing this, avoid pushing too hard on the shield and consequently on the globe. It is best to firmly compress the suction cup with 2 fingers and apply gentle pressure on the shield, so as not to press the globe more than is required.

When attempting to remove shields. If, after placing the suction cup, one pulls straight, the shield pulls the globe and that can be painful to the patient. It is recommended to remove the vacuum present between the globe and the shield. To remove the vacuum, one must gently tilt the suction cup and shield outward so as to let the air enter behind the shield, by the medial area. Once the vacuum is removed, the shield is free from the globe, but is still under the lids. To remove the free shield, the simplest way is to tilt the shield (always holding the suction cup) downward. The upper lid will leave the shield and reposition itself on the globe. Then the shield can be pulled away altogether.

## 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.
3. A non-metallic brush should be used to remove stubborn debris. Do not use abrasive pads.
4. Devices should be cleaned, 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 (SHIELD AND SUCTION CUP)

Stainless steel instruments can be sterilized repeatedly by steam autoclave.

The suction cups are also autoclavable but not for as many cycles. Extra suction cups may be purchased separately by the dozen.

Do not sterilize stainless steel devices or suction cups in bleach, as bleach will corrode/damage them.

Cold sterilization is not recommended for shields or suction cups. Ocular burns may occur due to inadequate rinsing or leaching out of sterilizing solution.

Steam sterilize following a validated cycle according to your institution's standards OR the following recommended parameters.

Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the following recommended parameters.

| Cycle Type | Temperature | Exposure Time | Dry Time |
|---|---|---|---|
| UK Prevacuum | 134°C (273°F) | 3 minutes | 30 minutes |
| Prevacuum | 132°C (270°F) | 4 minutes | 30 minutes |

- 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.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