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AUTOCLAVABLE PLASTIC OCULAR SHIELDS

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

The plastic ocular shields are used to protect the eyes when working with a scalpel, electro-cutter or other energy sources requiring protective plastic shields as the metal would be conductive (ex: RF system). The ocular shields are inserted under the eyelids over the globe, and remain in place for the

duration of the intervention. They should not be left in place more than 60 minutes.

PLASTIC OCULAR SHIELDS ARE NOT INTENDED FOR USE WITH LASER OR IPL SYSTEMS.

Our quality plastic ocular shields have all their surfaces and edges well polished to avoid corneal abrasions. They are made of high heat resistant plastic that can be autoclaved. The model has been designed from impressions made on ocular globes with a vault over the cornea. The elongated or pointed area must be positioned medially. The bilateral shields can be used on both eyes for lid treatments, simply by reversing them. Each shield without handle is supplied with a suction cup.

The unilateral shields with handle are non-reversible. They fit only over one eye. They are larger superiorly to cover more of the globe. They have a notch at the medio-superior aspect to avoid pressing the pulley. Shields with a handle are offered as a pair. The handle makes it easier to insert and remove the shield, but may be in the way depending on the treatment near the lids. The handle is near the limbus, close to the inferior lid. The position of the handle is ideal to avoid rotation or displacement of the shield. It allows easy closure of the upper lid without pushing on the handle and minimizes the possibility of pressing the cornea.

WARNING

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 any device that is scratched or damaged.
- Do not use any device that has been dropped accidentally without thorough examination of its condition.

- Devices must be inspected and cleaned before initial sterilization, and subsequently between each patient use.
- Do not use forceps to remove ocular shields. The plastic will be damaged.
- Invasive Plastic Ocular shields should not be left in place more than 60 minutes.
- Plastic shields are not for laser applications.

PLASTIC OCULAR SHIELDS

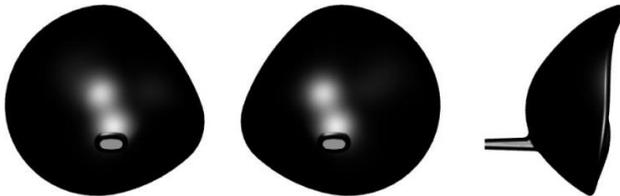
Bilateral
(with suction cup)



Bilateral
(with handle)

Medial

Unilateral (with handle)



Medial

Bilateral means they can be used on either eye.

CAUTION

The unilateral ocular shields must be inserted accordingly (left or right). If inserted in the wrong eye, the shields may not cover the globe adequately as intended. Inserting the shield in the wrong

eye may also pressure the globe, stretch the lids and cause discomfort to the patient.

Choice of size.

Although we offer 4 sizes, doctors usually choose the 3 most likely to be used given their clientele. In Asia, they usually choose the 3 smallest (the small being the most popular) while elsewhere the 3 largest are usually chosen (the medium being the most popular).

For lid surgery, the doctors choose mostly the medium and the large. Some like the largest to maximize protection while others prefer the medium.

For pure RF lid skin tightening, in order to maximize protection of the globe, the largest size possible to insert should be used. Since not all patients are identical, a selection of sizes is helpful. The final decision is up to the doctor, according to the patient to be treated.

Sizes (length x width)

(mm)	Bilateral	Bilateral (with handle)	Unilateral
Extra-small	23.5 x 21.5	23 x 21	23.5 x 23
Small	26 x 23.5	25.5 x 23	25.5 x 25
Medium	27.5 x 24.5	27 x 24	27.5 x 26.5
Large	28.5 x 25.5	28 x 25	28.5 x 27.5

Choice of color.

By far the most popular is the black; to block all light and patient vision. Transparent-yellow is when the patient is claustrophobic and mostly for general anesthesia, to enable the anesthesiologist to verify pupil dilation.

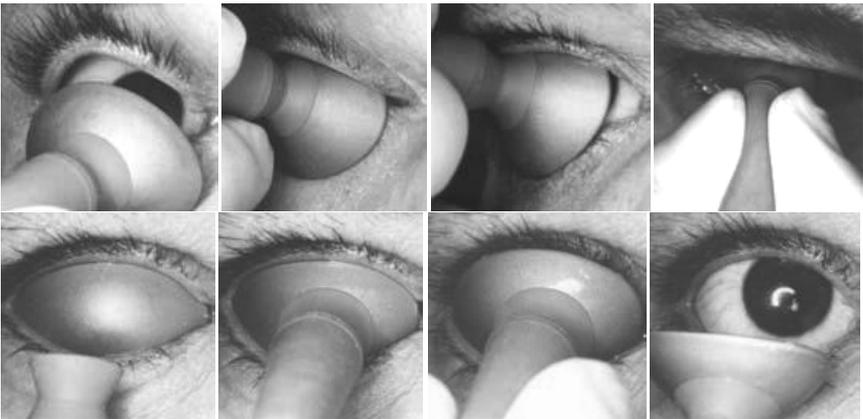
Insertion and removal instructions.

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.

ON DAMAGED SHIELDS AND VERIFICATION BEFORE USE.

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

Check surfaces of device for scratches or nicks, discard if necessary.

Touch the round edges with your fingers and make sure they are smooth and free of scratches. After many cycles of steam autoclave the shields will damage. This is the reason we recommend that the shields be inspected and verified every time before insertion. When the shields are damaged, there will be noticeable bumps and cracks on the surfaces and edges. These molecular changes in the plastic are caused by continuous autoclaving and are very visible during inspection.

CLEANING PROCEDURE FOR THE DEVICES

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.

- Do not use a brush or any abrasive pads or cleaning agents as they may damage devices.
 - Do not use alcohol as it may damage the devices.
1. Before sterilizing, devices should be rinsed under warm running water to remove all debris.
 2. Wipe devices with moist sponge or gauze pad to eliminate any debris.
 3. 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, OR CLEANING AGENTS THAT CONTAIN ALKALIES.
 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)

The shields and suction cups are autoclavable. The shields MAY be steam autoclaved for up to 50 cycles. The suction cups are also autoclavable but not for as many cycles. Extra suction cups may be purchased separately by the dozen.

We do not recommend soaking the shields in any sterilizing solution. If the shields are not rinsed properly this may cause corneal burns related to the solution.

Cold sterilization is not recommended for shields or suction cups. It will damage plastic and suction cup. 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



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