Expect Service Radiation Products Design Inc

INSTRUCTIONS

RPD INFORMATION

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RPD PRODUCT INFORMATION

Item Number	Tungsten Eye Shield with Aluminum Caps
936-583	11.6mm Inside Diameter x 2mm Thick
936-585	13.3mm Inside Diameter x 2mm Thick
936-587	15.0mm Inside Diameter x 2mm Thick
936-589	16.7mm Inside Diameter x 2mm Thick
936-591	18.4mm Inside Diameter x 2mm Thick
936-596	11.0mm Inside Diameter x 3mm Thick
936-598	12.7mm Inside Diameter x 3mm Thick
936-601	14.4mm Inside Diameter x 3mm Thick
936-623	16.1mm Inside Diameter x 3mm Thick
936-627	17.8mm Inside Diameter x 3mm Thick

DISCLAIMER

THESE PRODUCTS ARE NOT STERILE AND ARE TO BE USED BY AUTHORIZED PERSONNEL ONLY.

RADIATION PRODUCTS DESIGN INC assumes no liability for consequential damages of any kind for this material when used interchangeably with products of other manufacturers/suppliers or for any direct or indirect results and consequences of its use or misuse by the customer. Federal law (USA) restricts the sale of this device for use only by (or at the order of) a physician.

INTRODUCTION

Tungsten eye shields have less transmission than other eye shields

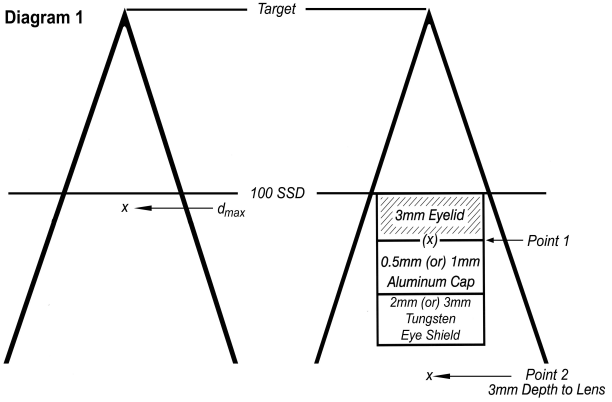
The Tungsten Eye Shield can use either the 0.5 mm or 1 mm thick anodized aluminum cap (both are included with each tungsten eye shield) to reduce the electron backscatter to the eyelid. The eye shield can be used without the aluminum cap when placed superficially.

Recommendations Based on Transmission Values:

The 2 mm tungsten eye shield should be used for 6 MeV, and the 3 mm tungsten eye shield should be used for 9 MeV. **These tungsten eye shields are not recommended for use above 9 MeV.**

Specifications:
Tungsten Density: 17 g/cm^3
Aluminum Density: 2.718 g/cm^3

The user will have to determine an acceptable amount of backscatter to decide whether to use the 0.5 mm or 1 mm aluminum cap. See diagram 1 and table 1.



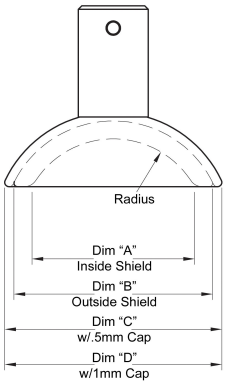
The doses are normalized to d_{max} without the eye shield (Diagram 1) using a 10 x 10 cone. When 1.00 Gy is delivered to d_{max} using 6 MeV with the shield, you get 1.08 Gy to the undersurface of the eyelid (Point 1) and 3.4% transmission to the lens (Point 2) (See table 1).

Table 1

TRANSMISSION USING XV-2 FILM*		DOSE IN Gy When 1.00 Gy is Delivered to d_{max} AT 3mm DEPTH*** USING TLD'S**			
6 MeV	9 MeV	6 MeV	9 MeV		
		0.72	0.77	Surface, No Shield	
		0.79	0.81	No Shield, Dose at Interface	Point 1
3.4%	5.6%	1.08	1.11	2mm Tungsten	Point 1
3.0%	4.8%	1.03	1.06	2mm Tungsten + 0.5mm Aluminum	Point 1
3.0%	4.4%	0.95	1.02	2mm Tungsten + 1.0mm Aluminum	Point 1
2.5%	3.3%	1.12	1.13	3mm Tungsten	Point 1
2.4%	2.9%	1.02	1.05	3mm Tungsten + 0.5mm Aluminum	Point 1
2.5%	2.8%	0.97	1.06	3mm Tungsten + 1.0mm Aluminum	Point 1

Unreferenced data on this product is preliminary findings of Radiation Products Design, Inc. and is not to be used as a technical reference.
*XV-2 Film placed under/below tungsten eye shield at 3 mm depth (anterior surface of lens).
**TLD Micro cubes placed under simulated eye lid using tungsten eye shields.

DIMENSIONS



Item #	Size	Thickness	Radius	Dim A	Dim B	Dim C	Dim D
936-583	XS	2	6.5	11.6	15.7	17.3	18.3
936-585	S	2	7.5	13.3	17.4	18.7	20.0
936-587	M	2	8.5	15.0	19.1	20.6	21.7
936-589	L	2	9.5	16.7	20.8	22.7	23.2
936-591	XL	2	10.5	18.4	22.5	23.9	25.1
936-596	XS	3	6.5	11.0	17.4	18.9	19.9
936-598	S	3	7.5	12.7	19.1	20.8	21.7
936-601	M	3	8.5	14.4	20.8	22.7	23.5
936-623	L	3	9.5	16.1	22.5	23.9	25.1
936-627	XL	3	10.5	17.8	24.2	25.9	27.1

All Dimensions In Millimeters

SPECIAL PRECAUTIONS

Immediately remove the eye shield if the patient has any of the following problems:

- Unusual eye secretions
- Eye pain such as: stinging, burning, itching, excessive watering, etc.

These problems are usually caused by soap residue left on the eye shield.

Note: **DO NOT** soak tungsten eye shields in Betadine Solution, as this will cause corrosion.

DO NOT assemble damp/wet eye shield parts because an electrolysis effect will take place between two dissimilar metals causing parts to pit.

DO NOT store in liquid - store dry and disassembled.

DO NOT use or store in saline (sodium chloride) solution.

DO NOT use or soak in any sodium, sodium nitrite, or sodium chloride products.

INSPECTION

Before each use and prior to sterilizing, examine eye shields and caps for burrs or rough edges, which could have occurred through normal use. Tungsten normally oxidizes over time, causing a discoloration of the eye shield. This does not affect performance of the eye shield. However, discoloration can be removed with Scotch-Brite Cleaning Pads, Item 878-160.

CLEANING

- All eye shields must be thoroughly cleaned before being disinfected or sterilized.
- The presence of organic matter can protect bacteria from the action of the disinfectant or sterilant, or react with the agent and make it ineffective.
- Cleaning can be done with 1) water alone, 2) with soap or detergent and water or 3) water and soap or detergent and disinfectant.

- Cleaning with a disinfectant reduces the risk of contamination to the cleaning staff, but does not eliminate them completely.

Be sure to rinse thoroughly with water to remove all soap or detergent and/or disinfectant residue from eye shield. **DO NOT** assemble damp/wet eye shield parts because an electrolysis effect will take place between two dissimilar metals causing parts to pit.

DISINFECT

Cidex OPA	Separate parts prior to disinfection. Wash with water and soap or detergent and disinfectant. Soak in Cidex OPA for 12 minutes. Than rinse in three different batches of sterile water to remove all traces of Cidex OPA. **Note:** This product does not require ACTIVATION. **DO NOT** assemble damp/wet eye shield parts because an electrolysis effect will take place between two dissimilar metals causing parts to pit.

STERILIZATION METHODS

Autoclave (Steam) Cleared for Gravity and Pre/Post-Vacuum Cycles	Separate all parts prior to sterilization. Autoclave wrapped parts for 5 minutes at 270°F (132.3°C). **DO NOT** assemble damp/wet eye shield parts because an electrolysis effect will take place between two dissimilar metals causing pitting of the eye shield and the aluminum cap.
	Separate all parts prior to sterilization. Sterrad® uses Hydrogen Peroxide solution. This type of sterilization will cause discoloration of some materials. The blue aluminum caps will discolor and tungsten will darken. This will not affect the density of the aluminum caps or the tungsten. Tungsten discoloration can be removed with Scotch-Brite Cleaning Pads, Item 878-160. **DO NOT** assemble damp/wet eye shield parts because an electrolysis effect will take place between two dissimilar metals causing pitting of the eye shield and the aluminum cap.

Sterrad®	Approved Cycles
100S	Cleared for Short and Long cycles
NX™	Cleared for Standard and Advanced cycles
100NX	Cleared for Standard cycle

Steris® **Not recommended**

System 1® Separate all parts prior to sterilization. **DO NOT** assemble when wet or damp. This sterilization process uses Peracetic Acid solution and will cause oxidation of some metals including aluminum, brass, nickel or silver. **Aluminum caps may oxidize if this method of sterilization is used.**

INSTRUCTIONS

1. The physicist must do calculations to determine which aluminum cap to use (0.5 mm or 1.0 mm).
2. Clean the eye shield with soap and water. Be sure to rinse thoroughly to remove all soap residues from the eye shield.
3. Inspect eye shield and cap carefully for scratches.
4. Disinfect and sterilize according to the instructions.
5. Optional: May insert a non-prescription contact lens to prevent possible scratches to the cornea and iris.
6. Hold eyelids open and insert the eye shield directly on the eye or over a non-prescription soft contact lens. Note: Ask patient if they are experiencing any burning sensation in the eye. If so, remove the eye shield immediately and rinse thoroughly to remove all soap residues.
7. The hole through the knob on the eye shield can be used with suture string to secure the eye shield to the patient's forehead using tape. Tape can also be used to hold the eyelid closed over the top of the eye shield.
8. After use, separate parts, wash per cleaning instructions, then rinse thoroughly to remove all soap or detergent and/or disinfectant residue from eye shield.
9. Store eye shields dry with parts disassembled.
10. The eye shields must be sterilized between patients.

Wax is not necessary to coat the eye shields. A soft contact lens can be used to protect the eye.

ELECTRON OR SUPERFICIAL SHIELDING

Purpose

To protect the lens and cornea of the eye when treating the eyelid with electrons. The tungsten eye shield with aluminum cap also limits the amount of backscatter to the overlying eyelid when using electron beam therapy.

Applications

Protection of the Eye

- Optional: May insert a non-prescription contact lens to prevent possible scratches to the cornea and iris.
- Place tungsten eye shield with aluminum cap directly on the eye or over a soft contact lens.
- Use aluminum cap (.5mm or 1mm-included with eye shield) for reduction of backscatter. Aluminum cap thickness used for treatment is to be determined by radiation physicist.
- The hole through the knob on the eye shield can be used with suture string to secure the eye shield to the patient's forehead using tape. Tape can also be used to hold the eyelid closed over the top of the eye shield.

External Shield of Eye or Superficial Shield

- Tungsten eye shields may be placed over the eyelid for external shielding during facial treatments.
- The aluminum cap is not used during this type of treatment.

WARRANTY

1 year from date of purchase.

REFERENCE

Evaluation of Eye Shields made of Tungsten and Aluminum in High-Energy Electron Beam - Randi D. Weaver B.S. Fairview - University Med. Ctr. PO Box 494, 420 Delaware St. SE, Mpls., MN 55455 Int. J. Radiation Oncology Biol. Phys, Vol. 41 Nal, pp 233-237-1998.

CT EYE SHIELDS

Item #	Description
935-5831	Simulates a 936-583 with 0.5 mm Al Cap
935-5832	Simulates a 936-583 with 1.0 mm Al Cap
935-5851	Simulates a 936-585 with 0.5 mm Al Cap
935-5852	Simulates a 936-585 with 1.0 mm Al Cap
935-5871	Simulates a 936-587 with 0.5 mm Al Cap
935-5872	Simulates a 936-587 with 1.0 mm Al Cap
935-5891	Simulates a 936-589 with 0.5 mm Al Cap
935-5892	Simulates a 936-589 with 1.0 mm Al Cap
935-5911	Simulates a 936-591 with 0.5 mm Al Cap
935-5912	Simulates a 936-591 with 1.0 mm Al Cap
935-5961	Simulates a 936-596 with 0.5 mm Al Cap
935-5962	Simulates a 936-596 with 1.0 mm Al Cap
935-5981	Simulates a 936-598 with 0.5 mm Al Cap
935-5982	Simulates a 936-598 with 1.0 mm Al Cap
935-6011	Simulates a 936-601 with 0.5 mm Al Cap
935-6012	Simulates a 936-601 with 1.0 mm Al Cap
935-6231	Simulates a 936-623 with 0.5 mm Al Cap
935-6232	Simulates a 936-623 with 1.0 mm Al Cap
935-6271	Simulates a 936-627 with 0.5 mm Al Cap
935-6272	Simulates a 936-627 with 1.0 mm Al Cap

ACCESSORIES

Item #	Description
466-401	Cidex OPA, 1 gal
466-403	Cidex OPA Solution Test Strips, 60 strips/ bottle
937-700	Soft Contact Lenses, 6/Pkg
937-706	Contact Lens Cases, 3/Pkg
937-711	Opti-Free Pure Moist Contact Lens Solution, 4 oz
878-160	Scotch-Brite Cleaning Pads, 10/Pkg

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