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Sterile Damato Ruthenium Plaque Templates Instructions for Use

Single-Use Device | Keep away from direct sunblight and keep dry | STERILE EO Sterilized in Ethylene Oxide | Instructions for use | Do not use if pack is damaged | CE 1639 Meets CE Mark Requirements

Use by date | LOT Lot number | REF Catalogue number | Fragile Handle with care | Caution, consult instructions for use | Manufactured by | Do not re-sterilize

Product Code	Product Description	Eckert & Ziegler BEBIG Ru-106 Eye Applicator Ru-106 Eye Applicator. For use with:	
A7075CCX	Damato Ruthenium Plaque Template CCX	Ru6.A03	CCX
A7077	Damato Ruthenium Plaque Template Small	Ru6.A04	CCA
A7075CCD	Damato Ruthenium Plaque Template CCD	Ru6.A05	CCD
A7078	Damato Ruthenium Plaque Template Medium	Ru6.A06	CCB
A7075CGD	Damato Ruthenium Plaque Template CGD	Ru6.A07	CGD
A7079	Damato Ruthenium Plaque Template Large	Ru6.A08	CCC
A7075COB	Damato Ruthenium Plaque Template COB	Ru6.A09	COB
A7075COC	Damato Ruthenium Plaque Template COC	Ru6.A12	COC
A7075CIA	Damato Ruthenium Plaque Template CIA	Ru6.A13	CIA


A7075CCX


A7077


A7075CCD


A7078


A7075CGD


A7079


A7075COB


A7075COC


A7075CIA

IMPORTANT: ***Only a suitably trained and qualified surgeon should carry out this procedure under normal operating room conditions.***

WARNING: ***If the sterile pouch is pierced or damaged in any way, the product must be discarded using hospital approved procedures.***

Intended Use:

The Damato Ruthenium Plaque Templates have been designed with directional grooves to assist with transillumination of the tumour boundaries. The table above shows the Ruthenium Plaques the Templates are compatible with. The Template is to be placed over a tumour that is inside the eye to help determine optimal positioning of an eye brachytherapy plaque.

The Surgeon will have determined the best course of treatment for the patient will be brachytherapy and will base their decision to treat using the ruthenium plaques, and by default the templates upon their experience and training and the individual patient's condition. The Surgeon will determine the Template size to be used.

Indications:
Choroidal and ciliary body melanomas and retinoblastomas. (Choroidal melanomas not exceeding 5mm).

Contraindications:
1. Optic disc involvement by tumour unless a notched plaque is used.
2. Diffuse melanoma
3. Extensive ciliary body melanoma
4. Extensive extraocular spread

Intra-Operative Complications:
1. Inadequate localization of tumour
2. Retinal damage when suturing plaque [or template] to eye.
3. Imprecise re-positioning of extraocular muscle

Post-Operative Complications:
1. Local tumour recurrence if the plaque was not well positioned in relation to the tumour or if the dose of radiation was not high enough to treat the entire tumour thickness.
2. Optic nerve damage from the radiation, with severe loss of central and peripheral vision
3. Macular damage from the radiation itself or caused by fluid leaking from the irradiated tumour.
4. With large tumours, the "toxic tumour syndrome" can develop, with severe retinal detachment, iris new blood vessels (i.e., "iris neovascularization") and high pressure in the eye caused by new blood vessels blocking the trabecular meshwork, which drains fluid from the eye (i.e., "neovascular glaucoma")
5. Cataract if excessive radiation is delivered to the lens.
6. Retinal detachment if a retinal tear occurs when suturing the plaque to the eye.
7. Double vision if the muscles are not re-positioned correctly.

Adverse Effects:
There have been no adverse effects found from the use of the Plaque Templates.
Please report any adverse events, complications, or other side effects to the Quality Department at Altomed.

Disposal.
After use it is recommended to dispose of these devices following hospital approved procedures for contaminated waste.
The devices are supplied as sterile and single use. Due to the material properties and their delicacy and the difficulty in processing, it is not recommended to reuse or reprocess. Reusing these devices and failure to properly clean and sterilise may result in cross contamination issues and/or infection.

PMMA - Biocompatibility.
Polymethylmethacrylate has a long successful history of use in ophthalmic surgical procedures and is often used in orbital implants. These devices do not contain latex or phthalates.