

Damato Ruthenium Plaque Templates and Damato Illuminator



STERILE EO



MR Conditional

EC REP

Authorised Representative in the European Community
Advena Ltd, Tower Business Centre, 2nd Flr,
Tower Street, Swatar, BKR 4013, Malta

Intended Use	The Templates have been designed with directional grooves to assist with transillumination of the tumour boundaries. The Template is to be placed over a tumour that is inside the eye to help determine optimal positioning of an eye brachytherapy plaque. Damato Illuminators are used to help define an ocular tumour boundary by providing a direct light source through either a: - Damato Ruthenium Plaque Template, or- Being attached to a Damato Depressor which aids in providing a direct light source over an Altomed tantalum marker.
Indication(s)	Choroidal and ciliary body melanomas and retinoblastomas. (Melanomas not exceeding 5mm).
Sterility	The Sterile templates and illuminators are all single use. Re-using or re-processing these devices will increase risks to the patient, including cross contamination, infection, and physical harm.
Intended Patient Group(s)	The devices are indicated for use on adult patients only. Patients with Choroidal and ciliary body melanomas and retinoblastomas. (Choroidal melanomas not exceeding 5mm).
Intended User(s) & Facilities	Professional use only, Consultant Ophthalmic Surgeon or other suitably trained personnel.
Clinical Benefits & Performance Characteristics	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.
Storage, Handling, Preparation & Use Considerations	Store at room temperature and humidity away from direct sunlight and water.
Contraindications	<ol style="list-style-type: none"> Optic disc involvement by tumour unless a notched plaque is used. Diffuse melanoma Extensive ciliary body melanoma Extensive extraocular spread.
Warnings & Precautions	Only a suitably trained and qualified surgeon should carry out this procedure under normal operating room conditions. If the sterile pouch is pierced or damaged in any way, the product must be discarded using hospital approved procedures. Ensure all connectors are fully inserted and secure. Check light output before use.
Residual Risks & Undesirable Side-Effects	<p>Intra-Operative Complications:</p> <ol style="list-style-type: none"> Inadequate localization of tumour Retinal damage when suturing plaque [or template] to eye. Imprecise re-positioning of extraocular muscle <p>Post-Operative Complications:</p>



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	<p>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.</p> <p>2. Optic nerve damage from the radiation, with severe loss of central and peripheral vision</p> <p>3. Macular damage from the radiation itself or caused by fluid leaking from the irradiated tumour.</p> <p>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”)</p> <p>5. Cataract if excessive radiation is delivered to the lens.</p> <p>6. Retinal detachment if a retinal tear occurs when suturing the plaque to the eye.</p> <p>7. Double vision if the muscles are not re-positioned correctly.</p> <p>There have been no adverse effects found from the use of the Plaque Templates.</p>
Performance Claims	<p>The templates, used in conjunction with the illuminators, are designed to allow for plaque placement with a high degree of accuracy. No specific claims are made regarding the precision of this placement.</p>
Disposal Considerations	<p>It is recommended to dispose of these devices following hospital approved procedures for contaminated waste.</p>
In the event of an incident or defective device	<p>If any serious incident has occurred in relation to the device, the user and/or patient should be report it to the manufacturer at the contact details below, and the competent authority of the Member State in which the user and/or patient is established (refer to https://ec.europa.eu/health/md_sector/contact_en)</p>

