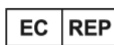


## Damato Ruthenium Plaque Templates and Damato Illuminator



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

<b>Intended Use</b>	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.
<b>Indication(s)</b>	Choroidal and ciliary body melanomas and retinoblastomas. (Melanomas not exceeding 5mm).
<b>Sterility</b>	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.
<b>Intended Patient Group(s)</b>	The devices are indicated for use on adult patients only. Patients with Choroidal and ciliary body melanomas and retinoblastomas. (Choroidal melanomas not exceeding 5mm).
<b>Intended User(s) &amp; Facilities</b>	Professional use only, Consultant Ophthalmic Surgeon or other suitably trained personnel.
<b>Clinical Benefits &amp; Performance Characteristics</b>	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.
<b>Storage, Handling, Preparation &amp; Use Considerations</b>	Store at room temperature and humidity away from direct sunlight and water.
<b>Contraindications</b>	<ol style="list-style-type: none"> <li>1. Optic disc involvement by tumour unless a notched plaque is used.</li> <li>2. Diffuse melanoma</li> <li>3. Extensive ciliary body melanoma</li> <li>4. Extensive extraocular spread.</li> </ol>
<b>Warnings &amp; Precautions</b>	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.
<b>Residual Risks &amp; Undesirable Side-Effects</b>	<p>Intra-Operative Complications:</p> <ol style="list-style-type: none"> <li>1. Inadequate localization of tumour</li> <li>2. Retinal damage when suturing plaque [or template] to eye.</li> <li>3. Imprecise re-positioning of extraocular muscle</li> </ol> <p>Post-Operative Complications:</p>

