2 Witney Way,
Boldon Business Park,
Boldon, Tyne and Wear.
NE35 9PE.
Comments, queries or orders please contact Altomed on:
Tel: (0) 191 519 0111
Fax: (0) 191 519 0283

Size	Bebig Ref. Ruthenium Plaque
Small (15mm)	Ru6.A04
Medium (20mm)	Ru6.A06
Large (25mm)	Ru6.A08

A7077: 15mm Template | A7078: 20mm Template | A7079: 25mm Template

A7077, A7078 and A7079 – Sterile Damato Plaque Templates

Symbols Used to BS EN ISO 15223-1 and ASTM F 2503:

Single-use Device | Keep away from direct sunlight and keep dry | Sterilized in Ethylene Oxide | Instructions for use | Do not use if pack damaged | Meets EU CE mark requirements

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

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

Intended Use
The Damato Ruthenium Plaque Templates have been designed with directional grooves to assist with transillumination of the tumour boundaries. The following table shows the Ruthenium Plaques the Templates are compatible with.

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 melanoma with a thickness not exceeding 5mm

Contraindications
1. Optic disc involvement by tumour, unless a notched plaque is removed
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

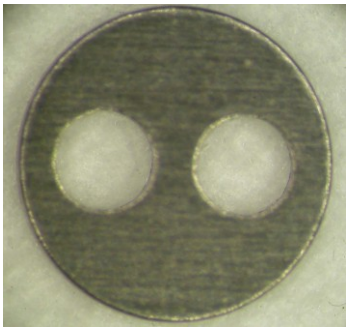
Post-Operative Complications
1. Local tumour recurrence if the plaque was not well positioned in relation to the tumour or if the dose of radiation was not high enough to treat the entire tumour thickness
2. Optic nerve damage from the radiation, with severe loss of central and peripheral vision
3. Macular 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.

Also Available: A7198S Sterile Tantalum Markers (Pack of 4) and A7198DS Pack of 10: Sterile Damato Tantalum Marker Depressors



Above, the A7198S Altomed Tantalum Marker under magnification

Damato Depressor: *Designed and developed with Professor Damato, Consultant Ophthalmologist, Ocular Oncology Service Royal Liverpool University Hospital.*

The Damato Depressor is clipped onto the end of an Altomed Right-Angled Transilluminator (A9520A or A9520AC) holding the latter in place over the Altomed Tantalum Marker, which has been sutured to the sclera. When indirect ophthalmoscopy is performed, the light shining through holes in the marker helps to localise the marker in relation to the tumour margin. *This procedure is repeated with each of the four markers used. X-rays of the eye subsequently localise the markers so that a computerised 3-D model of the eye can be generated for planning proton beam radiotherapy.*