Tantalum Markers

ALT I032 Issue 10/0522

EC REP

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

Intended Use	Tantalum markers are sutured to the sclera and act as radio-opaque markers to help define the location and extent of an intraocular tumour.
Indication(s)	Painful eye or visual identification of tumour during eye checks. Any ophthalmic procedure requiring a location marker.
Sterility	The Sterile tantalum markers are all single use. Re-using or re-processing these devices will increase risks to the patient, which includes cross contamination, infection, and physical harm.
Intended Patient Group(s)	Patients with an intraocular tumour. The most common lesions are choroidal melanomas, choroidal haemangiomas, iris melanomas, and conjunctival melanomas. Other tumour sites have been shown to be treated successfully at The Clatterbridge Cancer Centre's proton beams. Tumours of the ciliary body and the conjunctiva.
Intended User(s) & Facilities	Professional use only, Consultant Ophthalmic Surgeon or other suitably trained personnel.
Clinical Benefits & Performance Characteristics	Made from commercially pure tantalum, which is biocompatible for surgical implantation. Do not contain latex or phthalates. The only claims that Altomed make are that they are able to be used as a radiopaque marker.
Storage, Handling, Preparation & Use Considerations	Store at room temperature and humidity away from direct sunlight and water. Can be used with a Tantalum Marker Depressor and their Illuminator, suture, and an X-Ray machine. The Tantalum Markers do not contact the X-Ray machine directly, the only direct contact is with the suture material, the steel needle, and the Tantalum Marker Depressor.
Contraindications	Patients with existing implants, (e.g., scleral buckles, oils, valves etc) should be carefully reviewed as these implants may distort the shape of the eye affecting the proton beam placement.
Warnings & Precautions	Tie the suture tight enough to prevent movement, but not too tight that it causes tearing of the sclera. Placing the needle too deep into the sclera may cause a tear in the retina, which may result in retinal detachment. Scleral perforation over the tumour may also result in extraocular tumour extension. Anteriorly located markers may ulcerate the overlying conjunctiva. This risk can be minimised by suturing the markers posteriorly if possible so that they are not in contact with conjunctiva. If anterior markers are essential, they should be located outside the radiation field to prevent ulcerating the overlying conjunctiva and possible induced radiation in the markers. Patients with anterior markers should be observed and the markers removed if the conjunctiva threatens to ulcerate. If it is necessary to detach a muscle to insert the markers, take care to re-attach the muscle as close as possible to its original position to avoid diplopia. It helps to measure the knot-to-limbus distance before dis-insertion and to ensure that this is the same when the muscle is re-attached. Any diplopia usually resolves in a few days, especially if it occurs only in some directions of gaze.

Manufactured by:

Altomed Ltd, 2 Witney Way, Boldon Business Park, Tyne & Wear, NE35 9PE, UK
Tel: +44 (0) 191 519 0111, Fax: +44 (0) 191 519 0283, E--mail: admin@altomed.com

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	A needle pass may penetrate the tumour and provide an avenue for tumour cells to spread beyond the highly localized treatment area of the proton beam. Tantalum markers can cause artefacts which may obscure part of the eye, when used with CT scans. Do not place the markers in the path of the proton beam, this may cause dose shadows that could lower the proton beam dose or cause induced radiation from the markers. Do not place the markers so they cause a shadow on the tumour, they should be placed laterally or distally with respect to the tumour and at least 3mm from the tumour boundary. Ensure any swelling has gone down before the administration of any radiotherapy, normally between 2 and 4 weeks after the insertion of the markers, this is to eliminate any error resulting from maldistribution of the beam due to post-surgical swelling. Care should be taken with patients who have already been treated with implants as some software applications presume the globe is a perfect sphere. Irradiated tantalum creates nuclides, as such the markers should not be placed in the proton beam path. The nuclide dose delivered however will be substantially less than any already received by the X-Rays or Proton Beam.
Residual Risks & Undesirable Side-Effects	Complications are rare and can occur with markers from any manufacturer, not only Altomed. These complications are usually the result of the surgical procedure and not the markers themselves. The tantalum markers are non-magnetic so that their presence does not preclude magnetic resonance imaging. There is a small risk that the suture material may cause inflammation, in which case the markers should be removed. In the unlikely event the markers come loose they may cause minor cuts or scratches before expulsion.
Additional Safety Information	Non-clinical testing demonstrated that the Tantalum Marker (REF: A7198S) up to a set of four are MR conditional. A patient with up to four implants can be scanned safely in an MR system under the following conditions: •Static magnetic field of 1.5-Tesla and 3-Tesla, only. •Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m) (extrapolated). •Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode Under the scan conditions defined, the Tantalum Marker (REF: A7198S) is expected to produce a maximum temperature rise of 1.5°C after 15-minutes of continuous scanning (i.e., per pulse sequence). Artefact Information In non-clinical testing, the image artefact caused by the tantalum marker (REF: A7198S) extends approximately 3-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.
Disposal Considerations	Any markers that are removed should be disposed of in accordance with hospital-approved procedures for contaminated/clinical waste.

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In the event of an incident or defective device	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)

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