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CE 0120

A7198 Non-Sterile Tantalum Markers and A7198S Sterile Tantalum Markers.

EU Edition.

Caution: This device is only to be used by a suitably trained and qualified surgeon under normal operating room conditions. Contact Altomed for further details.

Unique Device Identifiers (UDI):
A7198 – Non-Sterile Bag of 50: 05055505118823
A7082 – Sterile Set of 4: 05055505140992

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

Single-use Device | Keep away from direct sunlight and keep dry | STERILE EO Sterilized in Ethylene Oxide | Instructions for use | Do not use if pack damaged | CE 0120 Meets EU CE mark requirements

Use by date | LOT Lot number | REF Catalogue number | Fragile handle with care | Caution, consult instructions for use | Manufactured by | MR MR Conditional MRI safe under the specified conditions | NON STERILE Non-Sterile

Please report any adverse events, complications or other side effects to the Quality Department at Altomed.

Intended Use and Purpose

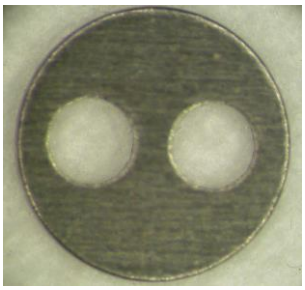
The tantalum markers are sutured to the sclera and act as radio-opaque markers to help define the location and extent of an intraocular tumour.

Device Description

The markers are 2.5 mm in diameter and consist of commercially pure tantalum discs with two suture holes, normally supplied sterile for single-use. It may be possible to arrange for a special "emergency" order of non-sterile markers if these are need urgently.

Contra-Indications

The surgeon should determine the risk of possible adverse reactions against the risk of not performing
the procedure. 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 (see*).



Above, Tantalum Marker under magnification and below showing Tantalum Markers sutured to the sclera

Adverse Reactions

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.

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 tantalum 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 tantalum 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.

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, e.g. scleral buckles, retinal implants, gases, oils etc. as the shape of the eye may have been affected and 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.

Disposal.

Any markers that are removed should be disposed of in accordance with hospital-approved procedures for contaminated/clinical waste.

Single-Use

The tantalum markers are all single-use. Re-using or re-processing these devices will increase risks to the patient, which include cross contamination, infection and physical harm.

Guidelines for Implantation

The devices should be implanted in accordance with the surgeon's standard procedures and training; however, a typical procedure is described below:

- Devices labelled as sterile. Inspect the packaging and the Tantalum Markers for any signs of damage, reject if necessary.
- Perform a conjunctival peritomy, using scissors.
- If necessary, detach one or two rectus muscles to improve access to the sclera overlying the tumour.
- Perform trans-pupillary or trans-ocular transillumination to define the tumour margins, a ***Damato Illuminator*** and ***Damato Depressor*** (both available from Altomed) can be used for this.
- Mark the tumour margins (anterior, posterior, superior, inferior) with a pen that is CE marked for this purpose, leave at least 3mm from the boundary of the tumour to the edge of the Tantalum Marker.
- Ensure the Tantalum Markers will not be positioned in the path of the proton beam or anterior to the tumour field.
- Using Mersilene 6-O. sutures, attach the Tantalum Markers to the sclera.
- Use Ophthalmic Calipers to carefully measure and record the distances from each marker to the tumour margin, to the limbus and to each other marker.
- Reattach any dis-inserted muscles and close the conjunctiva in the usual fashion.
- Inject local anaesthetic under the conjunctiva with a blunt-tipped needle.
- Apply a protective eye-pad for a few hours.
- After the operation, apply antibiotic drops 4 times a day for a week.

Processing of A7198 Non-Sterile Markers only.

For devices supplied only as Non-Sterile. Devices supplied as sterile should not be reprocessed. Altomed have validated the cycle below. Healthcare facilities should validate the sterilization process that they deploy routinely. Decontaminate in accordance with HTM 2030 rules and sterilize in accordance with HTM 2010 rules or Department of Health Guidelines.

Preparation	Inspect devices for signs of damage, reject if necessary. Place markers individually onto the arm of an Altomed Tantalum Marker Processing Stand and process in an ultrasonic bath as below.
Washer:	Ultrasonic bath CE marked for cleaning medical devices
Detergent:	Ruhof Endozyme AW Plus
Mix Ratio:	6 millilitres Endozyme to 1 litre deionized water
Wash Time:	A minimum exposure of solution to all surfaces of 6 minutes
Temperature:	20°C to 35°C - Not to exceed 40°C
Rinse solution:	Deionised water
Rinse:	Rinse thoroughly
Drying:	Air dry in laminar flow or hand dry using sterile absorbent lint free material
Drying Time:	Until visibly dry. Ensure the tantalum markers are dry before packing.
Pack:	Seal in a CE marked medical peel pouch for maintaining a sterile barrier (see ISO 11607 Parts 1 and 2 and EN 868)
Sterilizer:	CE marked Steam Autoclave
Temperature:	134-137°C
Holding time:	3 to 3 ½ minutes

Tantalum Markers - Biocompatibility.

The Altomed tantalum markers are made from commercially pure tantalum, which is biocompatible for surgical implantation. The tantalum markers do not contain latex or phthalates.

MRI Compatibility - MR Conditional

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

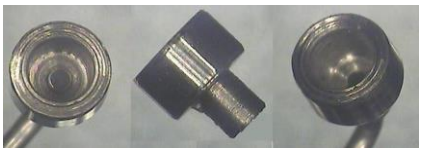
Under the scan conditions defined, the Tantalum Marker (REF: A7198S) is expected to produce a maximum temperature rise of 1.5°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

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.

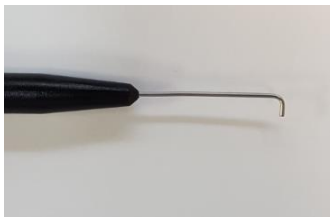
Accessories Available: Designed and developed with Professor Bertil Damato, Consultant Ophthalmologist.

A7198DS Pack of 10: Sterile Damato Tantalum Marker Depressors



The Damato Depressor is attached onto the end of a Damato Illuminator (A9520A or A9520AC). The depressor is placed over the tantalum marker, which has been sutured to the sclera. When indirect ophthalmoscopy is performed, light shining through is visible and helps localise the marker in relation to the tumour margin. This procedure is repeated with each of the four markers.

A9520A or A9520AC 90° Damato Illuminator.



The A9520A or A9520AC 90° Damato Transilluminator provides intraocular illumination over the A7198S tantalum marker or through perforations in ruthenium plaque templates. These devices are supplied sterile in cartons containing 10 packs of 1 transilluminator.