Intended Use	Orbital Implants are solid blocks of medical grade silicone intended for implantation use for more than 30 days. Used in evisceration or enucleation procedures to replace lost orbital volume and maintain shape of the eye socket, preserving the orbit and helping maintain cosmetic symmetry. The implant can be wrapped in a suitable material such as autogenous temporalis fascia, irradiated preserved fascia, preserved sclera, vicryl mesh etc, or implanted unwrapped and the muscles sutured anteriorly. If wrapped this provides a suitable anterior fixation site for the extra ocular muscles, which can help maintain implant movements and provide a base for the prosthesis. It allows fitting of a thinner artificial eye prosthesis in comparison to anophthalmic socket, which can then provide improved long-term cosmetic results.
Indication(s)	Enucleation: Intraocular malignancy or high suspicion for intraocular malignancy (most commonly uveal melanoma and retinoblastoma), blind painful eye, trauma, Sympathetic ophthalmia, microphthalmos, panophthalmitis. Evisceration: Endophthalmitis, ocular trauma, blind painful eye, microphthalmos.
Sterility	Single use devices, supplied sterile (Ethylene Oxide). They should not be re-sterilized, re-processed, or reused as the device may degrade or cause physical harm or infection.
Intended Patient Group(s)	Patients having an old implant removed or an eye enucleated or eviscerated, typical causes include eye trauma, eye cancer, painful blind eye and other congenital disorders (e.g., microphthalmia). Also used to treat patients with the symptoms of PESS.
Intended User(s) & Facilities	Professional use only, Consultant Ophthalmic Surgeon or other suitably trained personnel under facility approved and recommended conditions.
Clinical Benefits & Performance Characteristics	Used to fill the cavity formed once an eye has been enucleated or eviscerated. The conjunctiva is pulled down in front of the device and sutured closed, the implant is sealed within. The devices are biocompatible, able to be suitably decontaminated and to function over a long period of time as a scaffold to support orbital tissue.
Storage, Handling, Preparation & Use Considerations	Store at room temperature and humidity away from direct sunlight and water. It is expected the surgeon will have been trained in the procedures for enucleation and evisceration. Recommendations prior to surgery: Ensure the correct eye is selected for enucleation by marking pre-operatively, double checking with the operating room team and patient documentation. Prepare the patient appropriately, drape in a sterile manner and attach a speculum and ensure eye lashes are out of the operative field. Enucleation: Inject a local anaesthetic subconjunctivally to demarcate the available conjunctiva and Tenon's capsule and aid in haemostasis. The patient may visit an ocularist about 6 to 8 weeks after the operation to get a prosthesis fitted. Evisceration: During pre-operative evaluation check to make sure there is no intraocular malignancy in the operative eye. This procedure can be performed under general anaesthesia, or in some cases, local anaesthesia ideally with monitored intravenous sedation. Apply a pressure patch for 2- 5 days following surgery. The patient may visit an ocularist about 6 to 8 weeks after the operation to get a prosthesis fitted.

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
CE 1639

	Note: If the patient has a scleral buckle or glaucoma drainage device it should be removed. If the eye contains silicone oil, the limbus can be incised, and the silicone oil irrigated from the eye prior to peritomy.
Contraindications	Enucleation: Consideration should be given to risk of potential spread of infection with CSF space exposed, and the increased risk of haemorrhage. Evisceration: Where an intra-orbital neoplasm is suspected, where trauma may prevent the complete removal of uveal tissue or where a complete histological exam is required.
Warnings	Do not use in patients with known sensitivity to silicone.
Precautions	▪ Do not give the best motility to a prosthesis. If this is required, an alternative material to silicone is suggested. ▪ Should be implanted in accordance with the surgeon's standard procedures and training. ▪ It is important that the correct size is selected taking into account orbital tissue contraction and the risk of dehiscence; too small a sphere will not provide enough volume and too large may increase the risk of extrusion. ▪ Do not use if the implant or pouch has been damaged.
Residual Risks & Undesirable Side-Effects	There are complications with the use of orbital implants, but these are not limited to those supplied by Altomed. As with any operation the patient will undergo a period of discomfort and as such the patient should be suitably monitored after the operation. • Implant extrusion or exposure anteriorly. • Implant migration, typically inferotemporal if insufficient tissue support retained. Increased risk if coexistent. undiagnosed orbital floor fracture. • Implant infection. • Implant malposition, particularly a risk for secondary socket reconstruction where every effort should be made to place the implant above the inferior rectus. • Rejection of the implant in particular in children. • Socket fornix contraction. • Increased post-operative recovery time leading to increased time before definitive prosthesis fitting. • Post enucleation socket syndrome due to incorrectly small implant sizing. • Conjunctival inclusion cyst formation. • Lower lid malposition. • Upper lid ptosis and superior sulcus deformity. • Chronic orbital oedema. • Chronic orbital pain. • Coverage of deeper orbital tissue causing potential masking of future tumour recurrence. • Rarely tissue necrosis. If an implant is rejected or extruded, there are remedial procedures which may provide a good result. These may include removing the implant altogether, replacing it with a dermis fat graft or with an implant of alternative material. Ptosis caused by implant migration can be surgically repaired. Epithelial breakdown can also be treated with ointment. The device is made from implantable grade silicone, so biocompatibility risks have been minimised. Patient

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
CE 1639

	allergy or sensitivity to certain materials may result in tissue irritation. Patients should be notified of the possible complications.
Additional Safety Information	The Surgeon should monitor the patient at regular intervals as deemed necessary. It is important that a conformer or temporary prosthesis is used after enucleation or evisceration to prevent contracture of the socket. A temporary tarsorrhaphy will ensure the conformer is retained whilst the post-operative oedema settles and can usually be removed after a week or two post-operative. Adequate analgesia is essential, and post-operative antibiotics may be indicated. The surgeon should then examine the patient with the definitive prosthesis in place, this examination should note the: • Centration of the implant. • Size and depth of the Fornices. • Socket motility with and without the prosthesis in place. • Position of the upper and lower lids. • Levator function. • Symmetry of the upper lid skin folds and Sulci. Any corrective eyelid surgery is usually deferred for several months, and any secondary socket reconstruction is usually not done for 6-12 months. Silicone spheres may not be X-Ray or CT Scan detectable. They have not been formally tested in an MRI machine; however, there are no inorganic fillers in the silicone. There may be some fuzziness around the image degradation around the implant.
Disposal Considerations	Dispose of if the use by date has passed. Follow hospital approved procedures where provided. If there is no policy provided by your facility, dispose of as clinical waste
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)

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
CE 1639