Silicone Orbital Implant Information Sheet

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CE 0120

EU Edition.

Caution: This device is only to be used by a suitably trained and qualified surgeon under facility approved and recommended conditions.

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

Form ALT I012
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Please report any adverse events, complications or other side effects to the Quality Department at Altomed.

CAUTION

- This device is only to be used by a suitably trained or qualified healthcare professional.
- These devices do not give the best motility to a prosthesis. If this is required an alternative material to silicone is suggested.
- The device should be implanted in accordance with the surgeon's standard procedures and training.
- It is important that the correct size of sphere 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.
- ***Check device and packaging before use for any signs of damage; e.g. wet pouch, torn pouch etc. Do not use if the implant or pouch has been damaged.***

Intended Use and Purpose

The purpose of an implant:

- It is used in evisceration or enucleation procedures to replace lost orbital volume and maintain the shape of the eye socket, thus 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.

Device Description

The Altomed Orbital Implants are solid blocks of a medical grade silicone intended for implantation use for more than 30 days.

Indications:

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.

Contra-Indications:

Enucleation: Consideration should be given to the 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.

Complications:

There are complications with the use of orbital implants, but these are not limited to those supplied by Altomed. These in the main appear to be due to surgical complications, medications used, unsuitable surgical techniques or the type of wrapping material if any, and not necessarily to the product design or the raw materials used. It is important to select the correct size of implant; incorrect sizing may result in volume deficiencies or poor motility of the prosthesis. As with any operation the patient will undergo a period of discomfort and as such the patient should be suitably monitored after the operation. Examples of complications or issues with the use of the implants are:

- 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 allergy or sensitivity to certain materials may result in tissue irritation. Do not use in patients with known sensitivity to silicone. Patients should be notified of the possible complications.

Implant Procedure:

Enucleation: It is expected the surgeon will have been trained in the procedures for enucleation, however, below is a suggested procedure. 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. Inject a local anaesthetic subconjunctivally to demarcate the available conjunctiva and Tenon's capsule and aid in haemostasis. Perform a limbal conjunctival peritomy with Wescott scissors for 360 degrees. Carry out a blunt dissection in the sub-Tenon's plane in each of the oblique quadrants. Identify each rectus muscle and isolate with a muscle hook. Secure the muscles with a suture and bulldog clips if wrapping the implant and cut at the insertion to the globe. Isolate and transect the superior and inferior oblique muscles. Ensure the globe rotates

freely, then identify the optic nerve and cut with an enucleation snare or a pair of enucleation scissors. Attempt to cut a long segment of the optic nerve especially where histologic examination of the optic nerve is essential. Apply direct pressure in the intraconal space or cauterise the optic nerve if required to achieve haemostasis. Insert the correct size silicone implant into the intraconal space (an Altomed A7176 Carter Globe Introducer may be used), unless it has been deemed necessary to implant at later date due to issues such as severe infection. A sizing spheres can be used for this or, the diameter of implant needed = axial length -2 mm, this has been shown to provide adequate replacement of lost volume and minimize superior sulcus deformity and enophthalmos. Place the implant directly into the deep orbital tissues wrap in autogenous temporalis fascia, irradiated preserved fascia, preserved sclera, vicryl mesh etc as deemed necessary, avoiding any drag of anterior layers (an Altomed A7176 Carter Globe Introducer may be used). If the implant is wrapped the muscles can be sutured to the wrap or sewn directly to each other over the top of the implant. Close the tenons capsule then the conjunctiva carefully in layers with minimal tissue trauma and apply an antibiotic cream. Place a suitably sized conformer over the closed conjunctiva, and if necessary perform a temporary tarsorrhaphy keep the conformer in position then apply a pressure patch over the socket for 2-5 days post-operative. The patient may visit an ocularist about 6 to 8 weeks after the operation to get a prosthesis fitted.

Evisceration: It is expected the surgeon will have been trained in the procedures for evisceration, however below is a suggested procedure. During pre-operative evaluation check to make sure there is no intraocular malignancy in the operative eye. Ensure the correct eye is selected for evisceration 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. This procedure can be performed under general anaesthesia, or in some cases, local anaesthesia ideally with monitored intravenous sedation. Administer a retrobulbar anaesthetic with epinephrine to help with haemostasis and post-operative pain. Inject a local anaesthetic subconjunctivally to demarcate the available conjunctiva and Tenon's capsule and aid in haemostasis. Perform a 360-degree conjunctival peritomy at the limbus, then using a pair of Wescott scissors and undermine the anterior conjunctiva and Tenon's capsule. Make a full-thickness incision at the limbus with a keratome then extend with scissors to excise the cornea in a circumferential manner at the limbus. Next remove all the intraocular contents (including uveal tract, crystalline lens, vitreous body, and retina). This can be done with an evisceration spoon, spatula, or other instruments. Send these for histopathologic identification and examination. Use a cautery and direct pressure to achieve haemostasis of the nerve and vortex veins. If deemed necessary, denature and remove all remaining uveal material and micro-organisms from the scleral shell by using absolute of 70% alcohol, this may create additional irritation and oedema. Do not allow the alcohol to contact the conjunctiva, keep it within the sclera. The surgeon may prefer to initiate a posterior sclerotomy or similar scleral relaxing incisions to allow for a larger implant to be placed in the cavity. If necessary soak the implant in antibiotic solution prior to implant placement. Change surgical instruments and gloves prior to implant placement and closure to help reduce the risk of contamination and prolonged infection. Determine the best silicone orbital implant size using a sizing sphere to restore orbital volume while ensuring enough tissue for anterior closure without tension. Place directly into the scleral shell or wrap in autogenous temporalis fascia, irradiated preserved fascia, preserved sclera, vicryl mesh etc as deemed necessary, (an Altomed A7176 Carter Globe Introducer may be used). Alternatively open the posterior sclera, release the optic nerve and place the silicone orbital implant behind the scleral shell. Close a double-layer of sclera over the implant. This will allow you to place a large orbital implant which decreases superior sulcus hollowing and anophthalmic ptosis, giving in a better cosmetic result. In a layered approach, carefully close the anterior sclera, Tenon's capsule, and conjunctiva then position a suitably sized conformer. If necessary perform a temporary tarsorrhaphy keep the conformer in position. 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. 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.

Post-Operative Care:

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.

MRI and Scanners

Silicone spheres may not be X-Ray or CT Scan detectable. The Silicone Orbital Implants 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.

Processing and Storage:

The Silicone Orbital Implants are single use devices and are supplied sterile and ready to use. They should not be re-sterilized or re-processed or reused as the device may degrade or cause physical harm or infection to the patient. Store at room temperature and humidity away from direct sunlight and water. Dispose of if the use by date has passed.

Disposal

Follow hospital approved procedures where provided. If there is no policy provided by your facility, dispose of as clinical waste.

Single-Use

The Silicone Orbital Implants are all single-use. Re-using or re-processing these devices will increase risks to the patient and may include degradation of the device while implanted due to incorrect processing, cross contamination, infection and physical harm.

Unique Device Identifiers:

The full device identifier can be found on the packaging of the implants, it is not possible to mark the devices themselves due to the nature of the silicone and the increased risk involved.

REF:	Description:	GTIN:	REF:	Description:	GTIN:
A7100	Silicone Sphere 10mm Orbital Implant Sterile	05055505118335	A7107	Silicone Sphere 17mm Orbital Implant Sterile	05055505118472
A7102	Silicone Sphere 12mm Orbital Implant Sterile	05055505118359	A7108	Silicone Sphere 18mm Orbital Implant Sterile	05055505118496
A7103	Silicone Sphere 13mm Orbital Implant Sterile	05055505118373	A7109	Silicone Sphere 19mm Orbital Implant Sterile	05055505118526
A7104	Silicone Sphere 14mm Orbital Implant Sterile	05055505118397	A7110	Silicone Sphere 20mm Orbital Implant Sterile	05055505118540
A7105	Silicone Sphere 15mm Orbital Implant Sterile	05055505118427	A7111	Silicone Sphere 21mm Orbital Implant Sterile	05055505118571
A7106	Silicone Sphere 16mm Orbital Implant Sterile	05055505118441	A7112	Silicone Sphere 22mm Orbital Implant Sterile	05055505118595