osmed self-inflating tissue expanders are made of a specially developed hydrogel that uses the osmotic principle to gain volume. These implants are indicated in treatment of clinical anophthalmia, congenital microphthalmia and post enucleation socket syndrome. After implantation osmed hydrogel implants start to absorb body fluid and grow consistently to a predefined form and size. The increased volume of the implant – between 7 to 12 fold, depending on the product type – leads to an increase of soft tissue.
Tissue Expander Hemisphere

**Indications**
- Expansion of the conjunctival sac in clinical anophthalmia.
- Enlargement of the surface of the mucous membrane.
- Creation of a fold as abutment/support for artificial eye prosthesis.

**Contraindications**
- Local infection in the area of the conjunctival sac.
- Extreme cicatrization of the conjunctival sac after presurgery (relative contraindication – at minor cicatrization surgery possible; at pronounced/entire cicatrisation not recommend).

**Operative criteria**
Treatment before the age of one year has proved effective, preferably at the age of 4 months. An earlier beginning of treatment might involve a higher risk of cicatrization of the conjunctival sac and seems not to be medically necessary according to the current state of knowledge.

**Anesthesia**
Due to the age of the patient, general anesthesia is necessary.

**Implantation**
1. Disinfection of the skin.
2. Disinfection of the conjunctiva.
3. Insertion of a lid lock, or an assistant keeps palpebral fissure open with appropriate wound hooks (e.g. Desmarres retractor).
4. Preparation of positioning thread (e.g. Prolene 6/0) for fixation of the hemisphere/socket expander in the centre of the conjunctival sac.
5. The thread is run into the provided drill holes of the hemisphere/socket expander so that the convexity of the expander points forward.
6. Insertion of the socket expander into the conjunctival sac.
7. Final tying of the positioning thread.
8. A temporary tarsorrhaphy suture (e.g. 4x0 Greenfill or Prolene) in the centre of the lid.
9. Tarsorrhaphy suture remains until explantation of expander, to avoid risk of the expander due to manipulation of the expander by the patient.
10. While expander is implanted, a prophylactic local antibiotic via broad-spectrum eye drops is recommended.

**Explantation**
1. Disinfection of the skin.
2. Opening and removal of tarsorrhaphy suture.
3. Cut of the positioning thread of the expander.
4. Removal of socket expander.
5. Insertion of an artificial eye prosthesis or preferably implantation of an osmed Tissue Expander Sphere into the orbital soft tissue in combination with a preliminary artificial eye prosthesis.
<table>
<thead>
<tr>
<th>Order No.</th>
<th>Item</th>
<th>Volume Before swelling</th>
<th>Diameter Before swelling</th>
<th>Volume After swelling</th>
<th>Diameter After swelling</th>
<th>Swelling time*</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSM352-6040</td>
<td>Hemisphere 0.4 ml</td>
<td>0.06 ml</td>
<td>6 mm</td>
<td>0.4 ml</td>
<td>11.2 mm</td>
<td>1 day</td>
</tr>
<tr>
<td>OSM352-6090</td>
<td>Hemisphere 0.9 ml</td>
<td>0.13 ml</td>
<td>8 mm</td>
<td>0.9 ml</td>
<td>14 mm</td>
<td>1 day</td>
</tr>
<tr>
<td>OSM352-6090/P</td>
<td>Hemisphere 0.9 ml</td>
<td>0.13 ml</td>
<td>8 mm</td>
<td>0.9 ml</td>
<td>14 mm</td>
<td>1 day</td>
</tr>
<tr>
<td>OSM352-6150</td>
<td>Hemisphere 1.5 ml</td>
<td>0.20 ml</td>
<td>9 mm</td>
<td>1.5 ml</td>
<td>18 mm</td>
<td>1 day</td>
</tr>
<tr>
<td>OSM352-6200</td>
<td>Hemisphere 2.0 ml</td>
<td>0.28 ml</td>
<td>10 mm</td>
<td>2.0 ml</td>
<td>20 mm</td>
<td>2 days</td>
</tr>
</tbody>
</table>

*in vitro in 0.9% NaCl-Sol.

**In-vitro swelling curve**

*in vitro in 0.9% NaCl-Sol.
Tissue Expander Sphere

Indications

- Expansion of the orbit in clinical anophthalmia.
- Compensation of volume deficiency in the orbit.
- Creation of an abutment/support for an artificial eye prosthesis.
- Enlargement of the palpebral fissure due to forward pressure from the artificial eye prosthesis.

Contraindications

- Local infection of area of the conjunctival sac
- Extreme cicatrization of the conjunctival sac after presurgery (relative contraindication)

Operative criteria

Treatment before the age of one year has proved effective, preferably at the age of 4 months, at first with a conjunctival sac expander. After removal of conjunctival sac expander, an artificial eye prosthesis can be inserted and an orbita expander can be implanted during the same anesthesia.

Anesthesia

Due to the age of the patient, general anesthesia is necessary.

Implantation

1. Disinfection of the skin.
2. Disinfection of the conjunctiva.
3. Opening of the conjunctival central dorsal, preferably horizontally along the palpebral fissure, max. 10 mm necessary.
4. Predominantly blunt preparation of a sufficiently large implantation pocket.
5. Insertion of the expander deep into the tissue.
6. 2-layer closure: the tenon tissue with vicryl 4x0 EKN, the conjunctiva with vicryl 6x0.
7. Insertion of an artificial eye prosthesis.
8. Finally, a medial temporary tarsorrhaphy suture (e.g. 4x0 Greenfill or Prolene).

Expander augmentation (-exchange)

1. Disinfection of the skin.
2. Removal of the artificial eye prosthesis.
3. Disinfection of the conjunctival sac.
4. Opening of the conjunctival sac central dorsal, preferably horizontally along the palpebral fissure, max. 10 mm necessary.
5. Opening of the connective tissue capsule around the expander.
6. Exposure of the swollen expander, fragmentation and removal in pieces in order to limit the access to the size of the new expander.
7. Opening of the expander capsule on the level of its equator circular.
8. Insertion of the expander deep into the tissue.
9. 2-layer closure: the tenon tissue with vicryl 4x0 EKN, and the conjunctival sac with vicryl 6x0.
10. Insertion of an artificial eye prosthesis.
11. Finally, a medial temporary tarsorrhaphy suture (e.g. 4x0 Greenfill or Prolene).
### Dimensions

#### Before swelling

<table>
<thead>
<tr>
<th>Order No.</th>
<th>Item</th>
<th>Volume</th>
<th>Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSM352-7100</td>
<td>Sphere 1 ml</td>
<td>0.12 ml</td>
<td>6 mm</td>
</tr>
<tr>
<td>OSM352-7200</td>
<td>Sphere 2 ml</td>
<td>0.30 ml</td>
<td>8 mm</td>
</tr>
<tr>
<td>OSM352-7300</td>
<td>Sphere 3 ml</td>
<td>0.30 ml</td>
<td>8 mm</td>
</tr>
<tr>
<td>OSM352-7400</td>
<td>Sphere 4 ml</td>
<td>0.43 ml</td>
<td>9 mm</td>
</tr>
<tr>
<td>OSM352-7500</td>
<td>Sphere 5 ml</td>
<td>0.43 ml</td>
<td>9 mm</td>
</tr>
</tbody>
</table>

#### After swelling*

<table>
<thead>
<tr>
<th>Order No.</th>
<th>Item</th>
<th>Volume</th>
<th>Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSM352-7100</td>
<td>Sphere 1 ml</td>
<td>1 ml</td>
<td>12.4 mm</td>
</tr>
<tr>
<td>OSM352-7200</td>
<td>Sphere 2 ml</td>
<td>2 ml</td>
<td>15.5 mm</td>
</tr>
<tr>
<td>OSM352-7300</td>
<td>Sphere 3 ml</td>
<td>3 ml</td>
<td>18.0 mm</td>
</tr>
<tr>
<td>OSM352-7400</td>
<td>Sphere 4 ml</td>
<td>4 ml</td>
<td>19.7 mm</td>
</tr>
<tr>
<td>OSM352-7500</td>
<td>Sphere 5 ml</td>
<td>5 ml</td>
<td>21.8 mm</td>
</tr>
</tbody>
</table>

#### Swelling time*

- OSM352-7100: 1 day
- OSM352-7200: 2 days
- OSM352-7300: 3 days
- OSM352-7400: 4 days
- OSM352-7500: 4 days

*in vitro in 0.9% NaCl-Sol.

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### In-vitro swelling curve*

*in vitro in 0.9% NaCl-Sol.

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*Source: osmed gmbh*
Indications

• Expansion and compensation of volume deficiency of the orbita at congenital microphthalmia.
• Treatment of Post Enucleation Socket Syndrome (PESS).

Contraindications

• Full or partial vision in one eye.
• Missing counter bearing for expander (Pin expander is not suitable for volume filling of a shrunken dermis-fat transplant).

Operative criteria

Congenital blind microphthalmia:
Treatment before the age of one year has proved effective, preferably at the age of 4 months. Depending on the further tendency of the growth of the microphthalmia and the development of cranial growth, the implantation of further expanders might be necessary.

PESS:
In case of volume deficiency despite an orbita implant and an optimal adaption of the artificial eye prosthesis, which cannot be solved by augmentation of the artificial eye prosthesis, a volume filling via Pin expanders can be applied.

Anesthesia

General anesthesia for children. Local anesthesia is usually possible for adults.

Implantation

1. Disinfection of the skin.
2. Disinfection of the conjunctiva.
3. Determination of volume deficit: A retrobulbar injection cannula is inserted in the usual manner into the temporal lower orbita quadrant in retrobulbar/intraconal direction and via this access local anesthetic is injected. As much volume is injected until there is symmetry in comparison to the opposite side. If necessary intra-operative a Hertel exophthalmometry can be carried out for a comparison of the vertex of the artificial eye prosthesis and corneal vertex of the healthy partner eye.
4. After determination of the volume deficit, the necessary quantity of Pin expanders can be calculated. Calculation basis is that the final volume (in-vitro swelling) of an expander is 0.24 ml, i.e. 4 Pin expanders compensate a volume deficit of 1 ml.
5. At the spot where the retrobulbar cannula was placed, the implantation trocar is now inserted. The injection depth can be measured by the use of the scale of the trocar.
6. The implantation should be positioned preferably retrobulbar/intraconal, or respectively, behind an existing orbita implant to minimize the risk of extrusion of the expanders.
7. Once convinced of the correct position, the surgeon inserts each Pin expander separately via the trocar.
8. When the desired quantity of Pin expanders is implanted, the trocar is removed.
9. If an implantation at different areas is desired, it might be necessary to go transcutan again.
10. The implantation area is closed with skin suture.
11. A local antibiotic after-treatment is usually not necessary.
### In-vitro swelling curve*

*in vitro in 0.9% NaCl-Sol.

<table>
<thead>
<tr>
<th>Order No.</th>
<th>Item</th>
<th>Volume Before</th>
<th>Lenght Before</th>
<th>Diameter Before</th>
<th>Volume After</th>
<th>Lenght After</th>
<th>Diameter After</th>
<th>Swelling time*</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSM352-5024</td>
<td>Pin 0.24 ml</td>
<td>0.025 ml</td>
<td>8 mm</td>
<td>2 mm</td>
<td>0.24 ml</td>
<td>15 mm</td>
<td>4 mm</td>
<td>1 day</td>
</tr>
<tr>
<td>(5 pieces)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSM352-5024-10</td>
<td>Pin 0.24 ml</td>
<td>0.025 ml</td>
<td>8 mm</td>
<td>2 mm</td>
<td>0.24 ml</td>
<td>15 mm</td>
<td>4 mm</td>
<td>1 day</td>
</tr>
<tr>
<td>(10 pieces)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSM000-1001</td>
<td>Trocar</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*in vitro in 0.9% NaCl-Sol.
Safe Material

• Stable, dry devices, made of a crosslinked hydrogel: Co-polymers based on methyl methacrylate and N-vinyl-pyrrolidone.
• High biocompatibility: no toxical influence, no gentoxical effects, no immune reactions or material caused infections.
• Basically same hydrogel material also used in soft contact lenses.
• Controlled production: All manufacturing is done under GMP conditions in clean room.
• Pureness and safety of material: Vertical integration of manufacturing from polymerisation to final product ensure a reliable quality.

Safety

• High biocompatibility
• Low complication rate
• Low risk of infection
• Controlled swelling
• No search for valve
• No missed valve deflation

Variety

• Different shapes – pin, sphere and hemisphere
• Temporary and permanent use

Comfort

• Small incision
• Minimal trauma
• No periodic filling » Benefit in cost, time and less pain
• Short surgical time