osmed hydrogel expander Plastic Surgery - Product insert data sheet

Description

The Tissue Expander - Cylinder/Cupola Dental is made of hydrogel, which is a co-polymer of primarily methylmethacrylate and N-vinylpyrrolidone. The hydrogel is contained within a perforated silicone shell to reduce swelling speed.

Through physical absorption of body fluid, an increase of device volume up to approximately 9-12 times (see table) of the original volume is achieved. The final volume will occur after approximately 1 hour to 26 weeks depending on the size. Data about volume and time are product specific as for each single product there is a specifically defined enlargement and swelling time (s. table). Information in the table for final volume will not be exceeded, the duration is a minimum value which can be longer depending on location of implantation, but will never fall below that value.

Indications

Tissue expansion for:

- Preparation for closure of defects after resection of big tumors (e.g. nevi, basalioma, etc.).
- Scar correction, if a primary direct closure is not possible.
- Preloading of local flaps e.g. at the forehead.
- Direct closure of the donor defect of the radialis forearm flap
- Alopecia
- Delayed breast reconstruction.
- Congenital breast deformities, e.g. Poland´s syndrome, anisomastia, tubular breast deformities (Round).
- Immediate breast reconstruction after skin sparing mastectomy, if sufficient skin and healthy muscle is available and post-operative radiation can be excluded with certainty (Round).
- Increase of volume after enucleation, especially for secondary treatment, if formally no implant has been inserted. (Alternative to dermis-fat transplant)
- Increase of volume after defects e.g. in the face.
- After traumatic or iatrogenic loss of testicles (Ellipsoid)
- At sex change woman to man (Ellipsoid)
- Syndactyly
- Preparation for closure of cleft palate

Contraindications

The use of this prosthesis is contraindicated in patients who have any of the following conditions:

- Systemic disorders such as uncontrolled Diabetes mellitus
- Intravenous medication of bisphosphonates
- Heavy smoking
- Local infection in the area to be expanded.
- Thin, atrophied tissue in the area to be expanded.
- Damaged tissue caused by radiation therapy.

Patient education and informed consent

The surgical procedures associated with the use of tissue expanders are not without potential complications and risks. The use of this product is an elective procedure. The patient should be counseled prior to surgery regarding the benefits and possible risks associated with tissue reconstruction using tissue expanders and alternative procedures.

It is the responsibility of the individual surgeon to decide the best method by which to counsel a patient prior to surgery. **osmed** relies upon the surgeon to advise the patient of all potential complications and risks associated with the use of tissue expanders.

Instructions for use

The implantation of tissue expanders involves a variety of surgical techniques; therefore, the surgeon is best advised to use the method which his/her own practice and discretion dictate to be best for the patient.

Tissue expansion with Rectangle, Cylinder und Round (except breast reconstruction):

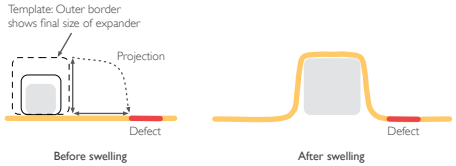
Operative criteria

Expander implantation has to be performed about 4-15 weeks before the resection or the intended tumor or scar.

Mark the position of the expander at a suitable location. The use of a template is recommended. The template indicates the recommended size of the pocket, and the final size of the expander after swelling.

To avoid interference with wound healing due to the tension of the expander as it swells, the skin incision should be placed relatively distant from implantation site.

Location of the expander:



General rule for distance:

Edge of the swollen expander + projection of the swollen expander = Outer border of the template + projection (also shown on the template)

Size of the pocket:

Size of bag = size of silicone shell = middle line of the template

Exception: by placing the expander under the Galea:
Size of the pocket = Size of the expander after swelling = Outer border of the template.

Preoperativ an i.v. antibiotic-treatment is recommended (e.g.Cephuroxim).

Anesthesia

General anesthesia or local anesthesia with sedation, depending on the patient's preference.

Implantation

- Disinfection of the skin. If local anesthesia is performed, a circular infiltration of the preparation area is recommended.
- Incision should be distant from the implantation site, if possible vertical to edge of the tumor/scar.
- Next, the skin is separated from the fascia partly bluntly and partly with cautery until a pocket is created, which is as big as the shell (please use template: middle ring). If possible a small subcutaneous tunnel from insertion to the pocket is built to avoid a movement of the expander in direction to the suture.
- Exception: by placing under the galea the pocket should have the size of the swelled expander (outer ring of the template). Wrinkling of the shell might occur.
- Irrigation of the pocket should be done with Ringer´s solution and subtle hemostasis should be done using cautery.
- Before the insertion of the expander the wound edge has to be painted with iodine solution.

- The surgeon should change his/her gloves. Only shortly before the insertion the expander is taken out of the sterile packaging, then inserted into the prepared pocket.
- Sharp instruments should not be used to insert the osmosis expander in order to avoid the damaging the silicone shell.
- A firm subcutaneous closure with single 4x0 or 3x0 vicryl sutures, stitched between subcutis and fascia. Possibly an external compression or tape bandage is applied - for fixation of the expander at the right position for the first 3-4 days, to avoid dislocation. A drainage tube generally is not required.

Explantation

- After opening of the old suture, the expander rises out of its pocket. The removal is supported by subtile pressure to the expander. Big expanders can easily be cut into two or more pieces in order to facilitate its removal through a small incision.
- The pocket should be carefully inspected in order to remove any small gel or silicone pieces that may have separated during manipulation and removal of the expander. Then, the pocket is irrigated copiously with 0.9% saline or Ringer's solution.
- Estimating of the created surplus tissue is done by pulling with small hooks. Marking of the resection area of the tumor or scar is done. After removal of the resection area, a layer wise wound closure is performed.

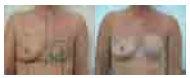
Tissue expansion for breast reconstruction with Round

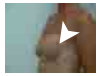
Operative criteria

The pectoralis major muscle and the overlying soft tissue mantle must be intact and undamaged. Expander implantation has to be performed 4-6 months before insertion of a breast implant to assure adequate tissue gain.

The use of a template is recommended to accurately mark the position. The template indicates the initial expander size, the recommended size of the pocket, and the final size of the expander after swelling.

Location of the expander:





Position the incision outside the expansion zone and put a small tunnel to the pocket. Regard the edges of the planned pocket.

Preoperativ an i.v. antibiotic-treatment is recommended (e.g.Cephuroxim).

Size of the pocket:

Size of bag = size of silicone shell = middle line of the template

Anesthesia

General anesthesia or local anesthesia with sedation, depending on the patient's preference.

Implantation

- The patient should be positioned on the table in the supine position with the hands fixated to the table at the level of the hips, which flexes the elbows and results in slight upper arm abduction.
- Desinfection of the skin. If local anesthesia is performed, a circular infiltration of the preparation area is recommended.
- In the case of an immediate reconstruction usually after mastectomy, the expander will be introduced into the submuscular pocket through the mastectomy incision.
- In the case of a delayed reconstruction, a 5-6 cm long incision is made in the lateral most aspect of
- the old mastectomy scar, in order to avoid placement of the expander directly under a fresh wound. This will reduce the danger of wound dehiscence as the expander swells.
- In cases of congenital deformity, the expander is placed through either a peri-areolar or an inframammary incision creating a subglandular pocket. The cut is only little longer than size of the expander.
- Cut through the subcutaneous tissue to the pectoralis fascia. At the level of the 5th to 6th rib, the pectoralis muscle is spread in direction of the fiber and dissected free. A caudal submuscular expander pocket approximately 3 times the size of the expander is created slightly higher than the level of the intended inframammary fold under direct vision using a combination of mono- and bipolar cautery. Blunt preparation of the submuscular expander pocket is not recommended, as subtle hemostasis is extremely important. The caudal insertion of the pectoralis muscle must be released, however the medial origin at the sternal border should remain intact. If the soft tissue mantle is laterally very thin, the serratus fascia has to be preserved.
- Irrigation of the pocket should be done with Ringer´s solution and subtle hemostasis should be done using cautery.
- Before the insertion of the expander, the wound edge has to be painted with iodine solution.
- The surgeon should change his/her gloves. Only shortly before the insertion the expander is taken out of the sterile packaging, then inserted into the prepared pocket.
- Sharp instruments should not be used to insert the osmosis expander to avoid the damaging the
- silicone shell. The expander should be placed into the pocket in so that the silicone shell does not built wrinkles.
- The base of the expander should be placed at the caudal part of the submuscular pocket at the level of the intended inframammary fold.
- A 3-layer wound closure is performed. A drainage tube is recommended.
- Three large 20 cm long strips of adhesive dressing are placed on the skin cranially, laterally, and medially around the expander to prevent expander dislocation during the early expansion phase. Additionally, a Stuttgart belt is worn for 2 weeks postoperatively to prevent cranial migration of the expander. For 24 hours a compression in favourably.

Explantation

- After 4 to 6 months, the osmotic expander is replaced by a cohesive silicone gel implant.
- Use of the old scar in the laterally most aspect. The expander, which has a solid gel consistency, is easily cut into 3 to 4 large pieces in order to facilitate its removal through the small lateral incision (soft squeezing).
- The submuscular pocket should be carefully inspected in order to remove any small gel and silicone shell pieces that may have separated during manipulation and removal of the expander, and then the pocket is irrigated copiously with 0.9% saline or Ringer's lactate solution. A partial capsulotomy may be performed to optimize the final implant position in relation to the inframammary fold. A capsulectomy may be necessary when significant capsule fibrosis has occurred.
- Before insertion of implant another change of cloves.

- A 3-layer wound closure is performed. A drainage tube is recommended.

Tissue expansion with Pin:

Anaesthesia

General anesthesia for children. For adults usually a local anesthesia is possible.

Implantation

Mark the position of the expander at a designated location. At use of several expanders foresee sufficient distance. Pin will double approx. in diameter and length compared to dry state.

A trocar with cannula with inner diameter of 2 mm shall be used as application device. First trocar is used to prepare subcutaneous pocket which corresponds to size of swollen expanders. When trocar is placed as designated, needle of trocar is removed. Expander is put into cannula of trocar and pushed with the needle. If needle of trocar reaches until the edge, expander safely went through the cannula into tissue/ pocket. Now trocar can be removed or via the same access next expander can be placed. When implantation is completed access location is closed one- or two-layered with absorbable suture, i.e. 7x0.

Explantation (optional)

After opening at end of respective Pin, expander will come out of pocket. Removal is supported by light pressure onto the expander.

Then, the pocket is irrigated copiously with 0.9% saline or Ringer's solution to remove any small gel pieces. Multi-layered wound closure.

Tissue expansion with Ellipsoid:

Anaesthesia

General anesthesia for children. For adults usually a local anesthesia is possible.

Implantation

- With local anesthesia, after desinfection of skin, a circular infiltration of the skin shall be done with 1% lidocaine solution. Adrenaline can be added to the local anesthesia at a dilution of 1:200,000 as vasoconstrictor.
- The incision for implantation is made outside of the tissue to be expanded, either in the area of the sacrum or at sex change into the labia majora.
- Then the subcutaneous fatty tissue is separated from the fascia, partly blunt and partly with cauter until a pocket of the size of the expander is achieved.
- The pocket shall be rinsed with Ringer's solution and a accurate haemostasis with cauter shall be applied.
- Before expander can be inserted desinfection solution has to be applied to edge of wound. A retractor dipped in desinfection solution is used.
- Subsequent surgeon shall change gloves. Expander is inserted into prepared pocket. A cuff is used to avoid skin contact.
- To avoid damages at expander sharp instruments must not be used to insert osmosis expander. As needed expander is fixated at holes of expander with absorbable suture at surrounding structure.
- Wound closure with 3-layer suture as well as corium suture with absorbable suture (3/0) for adaptation of deep layered subcutaneous tissue with the fascia at area between healthy tissue to be expanded and the edge of tumor or scar. Closure of skin with prolene 3/0. For subcutaneous suture shall be applied deeply with absorbable suture 4/0, intracutaneous suture with continuous suture 4/0. Adhesive bandage. A drainage is not necessary.
- Adhesive bandage can be applied circular around the expander to avoid a dislocation of expander during the first swelling phase.

Explantation (optional)

- After cut at the previous suture expander comes out of pocket. Removal is supported by light pressure on the expander. To facilitate a smaller cut bigger expander can be cut into two or more pieces without problems.
- Pocket has to be rinsed inspected carefully to remove all small pieces of gel which could have been separated at handling or removal of expander. Then, the pocket is irrigated copiously with 0.9% saline or Ringer's lactate solution.
- In case of use of a penis prothesis, prothesis can be inserted into gained volume.
- Wound closure with several layers. For subcutaneous a vicryl suture 3/0 or 4/0 is used and for wound closure a prolene suture 3/0 or 4/0. A drainage is not necessary.

Recording procedure for tissue expanders

Each expander is supplied with three patient record labels showing the catalog number and lot number for that unit. One of these labels should be attached to the patient's chart. The date of surgery should be indicated on the label.

How supplied

The osmed tissue Expander are supplied individually in a sterile and non-pyrogenic double-wrap packaging system. The double-wrap system facilitates the preferred method of sterile product transfer from the circulating area to the sterile field. Sterility cannot be guaranteed if the double-wrap packaging system has been damaged. The Tissue Expanders - Rectangle has been sterilized by gamma irradiation. Resterilization of the device is not allowed.

This product is for single use only. Sterility, safety and efficacy cannot be assured for damaged devices. Once the packaging is damaged a sterile product can not be guaranteed and the device cannot be used for implantation.

Storage, handling and packaging disposal information

Store product at ambient environmental conditions. Follow local governing ordinances and recycling plans regarding disposal or recycling of the device packaging materials.

Shelf life

Undamaged packages can be used until the expiration date that is printed on the outside of the package. After this date, the device cannot be used for implantation.

Precautions

- It is the responsibility of the surgeon to advise prospective patients or their representatives, prior to surgery, of the possible complications associated with the use of this product.
- Pre-existing infection should be treated and resolved before implantation of the expander.
- Lint, dust, talc, surgical glove powder, drape and sponge lint, fingerprints, skin oils and other surface contaminants deposited on an implant by improper handling may cause foreign body reactions. Strict adherence to clean, aseptic techniques should be maintained to prevent contamination of the expander and possible complications. Surgical instruments and gloves should be rinsed clean of any impurities before handling the expander.
- The silicone elastomer shell may be easily cut by a scalpel or ruptured by excessive stress, manipulation with blunt instruments or penetration by a needle. All expanders should be carefully inspected for structural integrity prior to and during implantation.
- Any subsequent surgical procedures in the area of the expander should be undertaken with extreme caution as damage to the expander could occur. In the event that an expander is damaged, it must be removed.
- This expander should not be implanted following any modifications to its original design. An expander which has been damaged, or on which repairs or modifications have been attempted, should not be implanted. A standby expander should be available at the time of surgery**.**
- Do not contact the device with disposable, capacitor-type cautery instruments as damage to the shell of the expander may result.

Warnings

It is the responsibility of the surgeon, and **osmed** relies on the surgeon, to advise the patient of all potential risks and complications associated with the proposed surgical procedure and device, including providing a comparison of the risks and complications of alternative procedures.

At the time of incision closure, care should be taken not to damage the expander with surgical instruments.

- This is a single use product and should not be reused.
- All products with a silicone shell (Round, Rectangle, Cylinder) are for temporary use only. The device should be removed upon completion of expansion and achievement of the desired result.
- All products without silicone shell (Pin, Ellipsoid) are mainly for permanent use.
- If radiation therapy is necessary, radiation should not start earlier than 8 weeks after the implantation of the Tissue Expander as damage to the expander and/or pain may result.
- Do not insert or attempt to repair a damaged or altered expander.
- The action of drugs (examples: antibiotics and steroids) in contact with the device has not been tested by the manufacturer and their use cannot be recommended. Each physician who chooses to use chemotherapeutic drugs with this expander must assure compatibility of the drug with the expander.
- Do not introduce or make injections of drugs or other substances into the expander. Injections through the expander shell will compromise the product's integrity.
- osmed relies on the surgeon to select the optimum incision and pocket size for the chosen expander design and projected volume. (Please use template).
- Preoperative evaluation of the expander design and expander size should include allowances for adequate tissue coverage. Pressure, force, tension and other stresses to which the expander site will be susceptible must be considered.
- Sepsis, hemorrhage or thrombosis may result from the placement of any foreign object in the body.

- Any subsequent surgical procedures in the area of placement should be taken with extreme caution as damage to the device could occur. In the event the device is damaged, it must be removed.
- Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, it is recommended that the device not be used until the bleeding is controlled.
- If a physician treats a hematoma or serous fluid accumulation by aspiration, or a biopsy or lumpectomy is performed, care must be taken to avoid damaging the expander.
- The incidence of extrusion of the expander has been shown to increase when the expander has been placed in injured areas: scarred, heavily irradiated or burned tissue, crushed bone areas or where severe surgical reduction of the area has previously been performed.
- Excessive fibrous capsular formation or contracture may occur around any expander placed in contact with soft tissues. The incidence and severity of this occurrence may increase if postoperative local hematoma or infection occurs.
- The physician should use personal discretion when deciding to use these expanders in patients who exhibit psychological instability.

Adverse reactions

Any patient undergoing a surgical procedure is subject to possible unforeseen operative and postoperative complications. Potential reactions and complications associated with the use of the expanders should be discussed with and understood by the patient prior to surgery**.** It is the responsibility of the surgeon, and **osmed** relies on the surgeon, to provide the patient with this information and to weigh the risk/benefit potential for each patient.

Adverse reactions which may result from the use of this product include the risks associated with the medication and methods used in the surgical procedure as well as the patient's degree of tolerance to any foreign object placed in the body. The complications may include, but are not limited to, the following:

Capsule formation and contracture

- Postoperative formation of a fibrous tissue capsule around an implanted device is a normal physiologic response to the implantation of a foreign object. Capsule formation occurs in all patients in varying degrees. Capsules range from thin to heavily thickened.
- Contracture of the fibrous capsule may occur, independent of its thickness. Discomfort, pain, excessive tissue firmness, misshapen expanded tissue, increased palpability and wrinkling of the shell and/or displacement of the expander may occur and may require surgical intervention. In some patients, tissue firmness may recur subsequent to corrective surgical procedures.

Infection

- Infection, manifested by swelling, tenderness, pain and fever, may appear in the immediate postoperative period or at any time after insertion of the device. In the absence of classic symptoms, subacute or chronic infections may be difficult to diagnose. If infection does not subside promptly with the appropriate treatment, removal of the device is indicated. Infections may result in Toxic Shock Syndrome (TSS). Symptoms of TSS include, but are not limited to sudden fever, vomiting, diarrhea, fainting, dizziness and/ or a sunburn like rash.

Extrusion of expander/Interruption of wound healing

- Skin necrosis and/or sloughing may result from undue tension of the skin overlying the expander, trauma to the skin flap during surgical procedures or inadequate tissue thickness inhibiting circulation. Subsequent exposure and/or extrusion of the expander may occur.
- Displacement, twisting, fracture or extrusion may occur from improper expander sizing and/or placement, e.g., when the expander is too large or the pocket too small or when there has been inadequate preoperative assessment of stresses causing movement to the expander.
- The incidence of extrusion of the expander has been shown to increase when the expander has been placed in injured areas: scarred, heavily irradiated or burned tissue or crushed bone areas; where severe surgical reduction of the area has been performed; and where steroids are used in the surgical pocket.

Hematoma

- Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, it is recommended that the device not be implanted until bleeding is controlled.
- Gross postoperative hematoma, manifested by enlargement, tenderness and discoloration of tissue may, if untreated, lead to extrusion of the device.

Fluid accumulation

- Excessive postoperative fluid accumulation and transient reaccumulation of fluid around the expander as a result of trauma and after vigorous exercise have been reported.

Dissatisfaction with cosmetic results

- Incorrect expander size, inappropriate scar location or appearance and misplacement or migration of expanders may interfere with a satisfactory cosmetic result. These complications are generally associated with the surgical procedure and technique.

Possible reactions to the hydrogel

Until now there are no known reactions caused by hydrogel.

Possible reactions to silicone

The issue of the possible relationship between silicone (and other implantable materials) and various diseases has been the subject of significant scientific debate. Concerns include immunological and neurological disorders, carcinogenicity and connective tissue disorders.

The report sponsored by the IOM, "Safety of Silicone Breast Implants", released in July 1999 states that women with silicone breast implants are no more likely than the rest of the population to develop cancer, immunologic diseases, or neurological problems.

Other

- Thrombosed veins, resembling large cords, have temporarily developed in the area of the device and have resolved without surgical or medical therapy.
- Pain from an improperly sized and/or placed implant, such as from compression of nerves or interference with muscle movement, may occur.
- Hypertrophic scarring has been reported.
- In single cases it can happen, that the expander grows slower and does not reach its final volume showed in the specifications. As remedy saline water could be injected.

Note: There might be some minute differences in the various translations of the Product Insert Data Sheets due to inherent differences in the languages.

Product evaluation

osmed requires that any complications and/or explantation (prior to the final expansion being achieved) resulting from the use of this device be brought to the immediate attention of osmed gmbh Ehrenbergstraße 11; 98693 Ilmenau, Deutschland.

Returned goods authorization

Authorization for return of merchandise should be obtained from osmed gmbh, Ehrenbergstrasse 98693 Ilmenau., Germany Phone: +49 3677/668 631. Merchandise must have all manufacturer's seals intact to be eligible for credit or replacement. Returned products may be subject to a restocking charge.

Product information disclosure

osmed expressly disclaims all warranties, whether written or oral, statutory, express or implied, by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability, fitness, or design. osmed shall not be liable for any direct, incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this product. No representation or other affirmation of fact, including but not limited to statements regarding suitability for use, or performance of the product shall be or be deemed to be a warranty by osmed for any purpose. osmed neither assumes nor authorizes any other or additional liability or responsibility in connection with this product.

Product order information

For product information or to order directly, contact, the local dealer, which you can find under www.osmed.biz/contact or osmed gmbh, Ehrenbergstraße 98693 Ilmenau. Phone: +49 3677/668 631

References

Literature references are available upon request from our webside www.osmed.biz/information or

osmed gmbh
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98693 Ilmenau
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Manufacturer

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Germany

Product specification

Rectangle		Before swelling**			After swelling*			
Order No.	Item	Volume	Projection	Length x width	Volume	Projection	Length x width	Swelling time*
352-2030	Rectangle 30 ml	3 ml	12 mm	22 x 12 mm	30 ml	31 mm	44 x 31 mm	50 days
352-2060	Rectangle 60 ml	5 ml	13 mm	25 x 13 mm	60 ml	36 mm	60 x 36 mm	80 days
352-2075	Rectangle 75 ml	6 ml	12 mm	32 x 16 mm	75 ml	35 mm	74 x 41 mm	90 days
352-2130	Rectangle 130 ml	13 ml	15 mm	40 x 20 mm	130 ml	45 mm	85 x 50 mm	100 days
352-2200	Rectangle 200 ml	20 ml	18 mm	45 x 24 mm	200 ml	52 mm	95 x 60 mm	100 days
352-2300	Rectangle 300 ml	30 ml	21 mm	54 x 28 mm	300 ml	58 mm	115 x 65 mm	100 days
352-2450	Rectangle 450 ml	50 ml	24 mm	60 x 32 mm	450 ml	60 mm	130 x 75 mm	100 days

* in vitro in 0.9% NaCl-Sol.
** without silicone shell

Round		Before swelling**			After swelling*			
Order No.	Item	Volume	Projection	⌀	Volume	Projection	⌀	Swelling time*
352-1200	Round 200 ml	20 ml	18 mm	37 mm	200 ml	52 mm	80 mm	90 days
352-1330	Round 330 ml	30 ml	21 mm	42 mm	330 ml	49 mm	101 mm	110 days
352-1450	Round 450 ml	43 ml	24 mm	51 mm	450 ml	60 mm	110 mm	120 days
352-1550	Round 550 ml	60 ml	26 mm	51 mm	550 ml	71 mm	115 mm	170 days
352-1650	Round 650 ml	70 ml	28 mm	55 mm	650 ml	75 mm	120 mm	180 days

* in vitro in 0.9% NaCl-Sol.
** without silicone shell

Cylinder		Before swelling**			After swelling*			
Order No.	Item	Volume	Length	⌀	Volume	Length	⌀	Swelling time*
352-3024	Cylinder 0.24 ml	0.045 ml	7.5 mm	3 mm	0.24 ml	12 mm	6 mm	10 days
352-3070	Cylinder 0.7 ml	0.15 ml	12 mm	4 mm	0.7 ml	20 mm	7 mm	20 days
352-3130	Cylinder 1.3 ml	0.25 ml	13 mm	5 mm	1.3 ml	22 mm	9 mm	30 days
352-3210	Cylinder 2.1 ml	0.42 ml	15 mm	6 mm	2.1 ml	24 mm	10.5 mm	60 days

* in vitro in 0.9% NaCl-Sol.
** without silicone shell

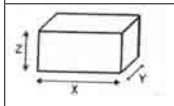
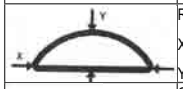
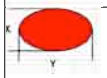
Ellipsoid		Before swelling			After swelling*			
Order No.	Item	Volume	Length	⌀	Volume	Length	⌀	Swelling time*
352-4010	Ellipsoid 10 ml	1.1 ml	15 mm	11 mm	10 ml	31 mm	23 mm	6 days
352-4014	Ellipsoid 14 ml	1.6 ml	17 mm	12 mm	14 ml	38 mm	26 mm	8 Tage
352-4019	Ellipsoid 19 ml	1.9 ml	18 mm	13 mm	19 ml	41 mm	30 mm	10 Tage
352-4024	Ellipsoid 24 ml	2.5 ml	20 mm	14 mm	24 ml	47 mm	31 mm	11 Tage

* in vitro in 0.9% NaCl-Sol.

Pin		Before swelling			After swelling*			
Order No.	Item	Volume	Length	⌀	Volume	Length	⌀	Swelling time*
352-5024-2	Pin 0.24ml (2 pieces)	0.025 ml	8 mm	2 mm	0.24 ml	15 mm	4 mm	1 day
352-5024-5	Pin 0.24ml (5 pieces)	0.025 ml	8 mm	2 mm	0.24 ml	15 mm	4 mm	1 day
352-5024-10	Pin 0.24ml (10 pieces)	0.025 ml	8 mm	2 mm	0.24 ml	15 mm	4 mm	1 day
000-1001	Trocar							

* in vitro in 0.9% NaCl-Sol.

Comment to labeling

QTY 1	Quantity: One Item
Initial volume	Initial volume of the expander
Final volume	Final volume of the expander
	Rectangle X Length (Initial and final) Y Width (Initial and final) Z Projection (Initial and final)
	Round X Diameter (Initial and final) Y Projection (Initial and final)
	Cylinder Y Length (Initial and final) X Diameter (Initial and final)
	Ellipsoid Y Length (Initial and final) X Diameter (Initial and final)
	Pin Y Length (Initial and final) X Diameter (Initial and final)
Date of Implant	Date of the implant surgery
20XY-AB	Expiry date
REF XYZ	Order-No.
LOT **XYZ**	Batch no.
	Manufacturer
	Single use
	Follow PIDS
CE 0297	CE- Mark + Number notified body
STERILE R	Radiation Sterilization

CE 0297