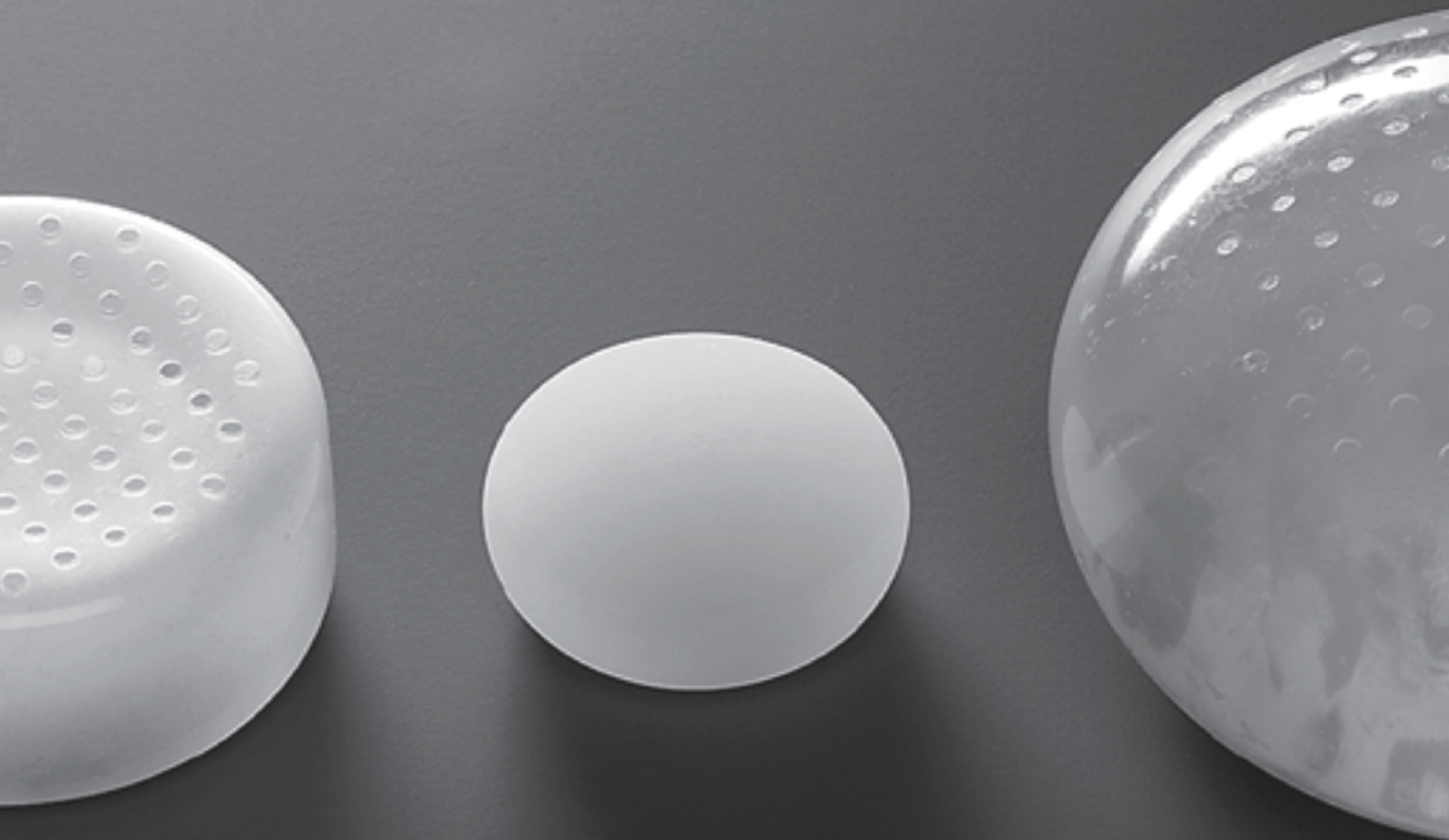
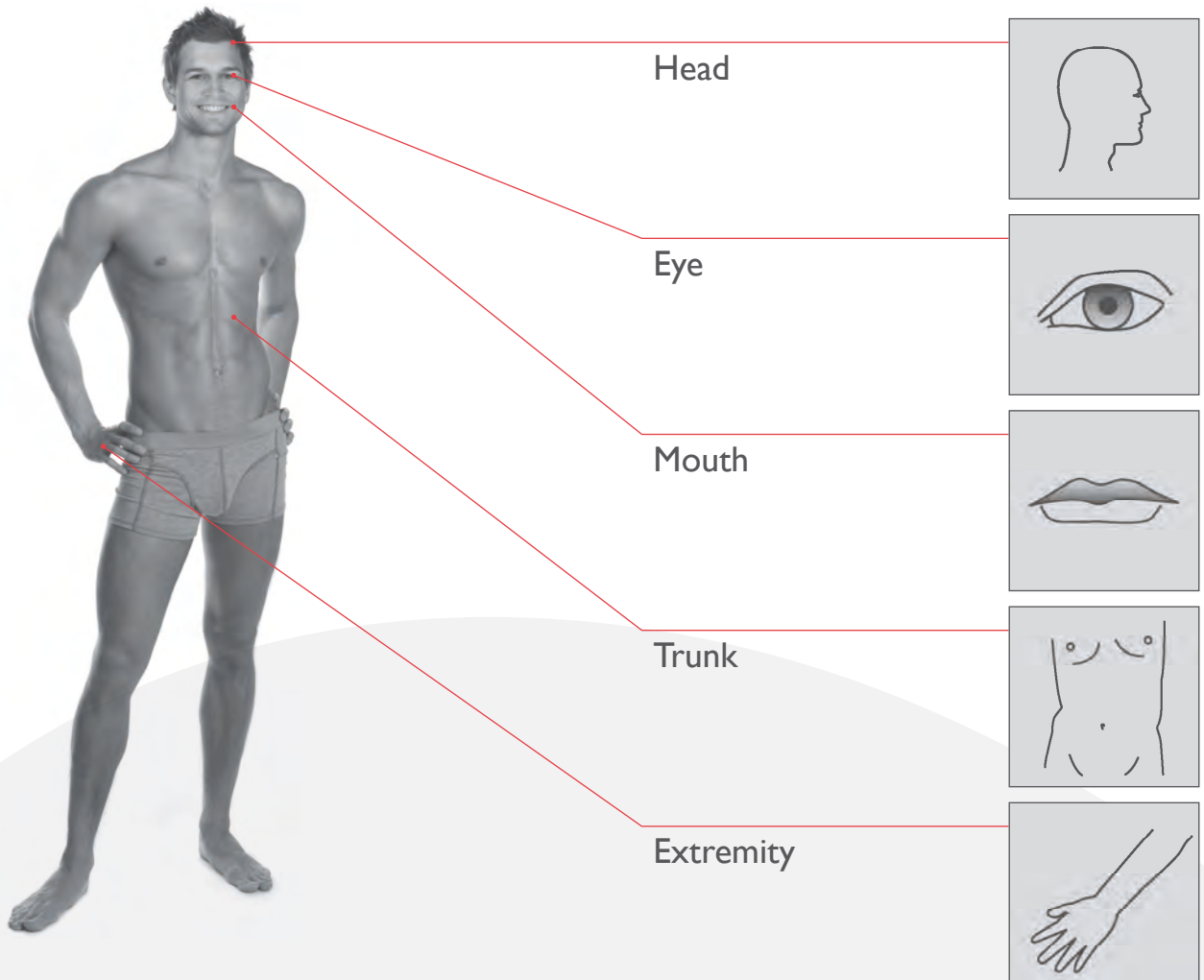


hydrogel competence

self-inflating tissue expander



One concept for various indications



| Indications for use

- ↳ Alopecia
- ↳ Anophthalmia
- ↳ Breast deformities e. g. Poland's syndrome, tubular breast
- ↳ Breast reconstruction
- ↳ Burns
- ↳ Cleft palate
- ↳ Clump foot
- ↳ Direct closure of the radialis forearm flap
- ↳ Naevus
- ↳ Reconstruction of small deformities e. g. Kallmann syndrome
- ↳ Scars
- ↳ Skin cancer
- ↳ Skin defects
- ↳ Syndactyly
- ↳ Testicle replacement
- ↳ Tissue expansion prior to augmentation of resorbed edentulous ridges
- ↳ Tissue filler



Alopecia

Rectangle 300 ml

Prof. Dr. Grantzow, Pädiatrisch-Plastische Chirurgie,
Ludwig-Maximilian Universität München, Germany



Ideopathic fat atrophy after tooth extraction

30 years ago - 30 Pins permanent

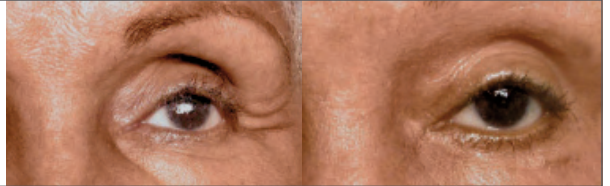
Dr. Hofheinz, Klinik am Rhein,
Düsseldorf, Germany



Anophthalmia left, prothesis support

10 Pins 0.24 ml, permanent

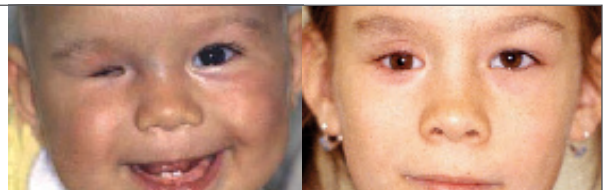
M.D. Goldberg,
Jules Stein Eye Institute, Los Angeles, USA



Right Congenital Anophthalmia

Socket and orbita expander, in 5 steps over 9 yrs.

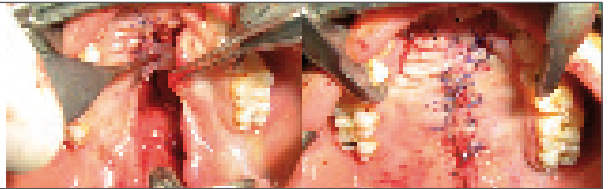
PD Dr. Schittkowski/Prof. Dr. Guthoff, Augen-
und Poliklinik, Universität Rostock, Germany



Cleft palate

2 Cylinder 2.1 ml

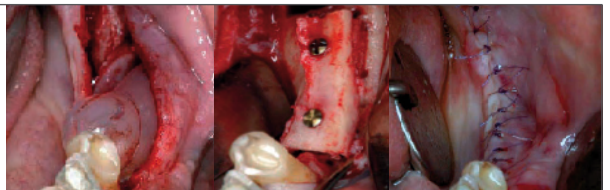
Dr. Nehal Patel, Swiss Cleft Centre,
BSES MG Hospital, Mumbai, India



Resorbed edentulous ridge

Cylinder Dental 2.1 ml

Dr. Kaner, Parodontologie,
Charité University Berlin, Germany



Breast reconstruction after mastectomy

2 Round 330 ml

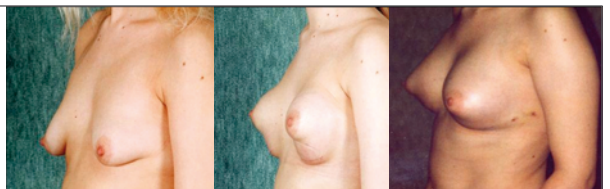
Dr. Hofheinz, Florence Nightingale, Hospital
Düsseldorf, Germany



Tubular Breast

Round 330 ml

Dr. Hofheinz, Florence Nightingale, Hospital
Düsseldorf, Germany



Scar on lower back

2 Rectangle 300 ml

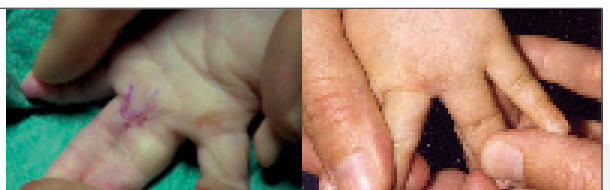
Dr. Mody, Plastic Surgery,
Hinduja National Hospital, Mumbai, India



Syndactyly

2 Cylinder 2.1 ml

Prof. Dr. Grantzow, Pädiatrisch-Plastische Chirurgie,
Ludwig-Maximilian Universität München, Germany



How it works

| Self-inflation by osmotic principle

osmed self-inflating tissue expanders are made of a specially developed hydrogel that uses the osmotic principle to gain volume.

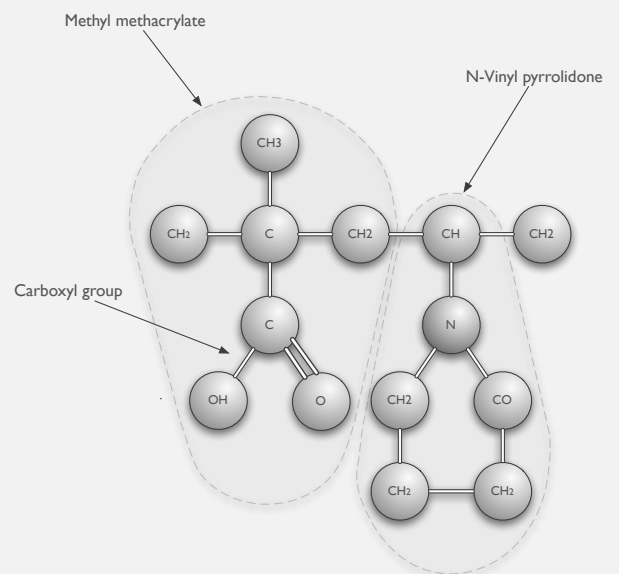
Preoperatively osmed hydrogel implants are in their pre-expanded state, and therefore are a small, hard and easy to handle device. After implantation osmed hydrogel implants start to absorb body fluid and grow consistently to a predefined form and size. The increased volume of the implant – dependent on the product type grows between 3 to 12 fold – leads to an increase of soft tissue. Some of the implants use a perforated silicone shell to reduce the swelling speed and effect a roughly linear growth. osmed offers a new concept with in surgical technique including the use of special instruments and template where required.



Rectangle hydrogel expander – unswollen, without silicone shell, swollen

| Safe Material

- Stable, dry devices, made of a crosslinked hydrogel: Co-polymers based on Methyl methacrylate and N-Vinyl pyrrolidone
- High biocompatibility: no toxic influence, no genotoxic effects, no immune reactions or material caused infections
- Basically same hydrogel material also used in soft contact lenses
- The outer silicone shell is well known and well proven in breast implants
- 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



Advantages

| Safety

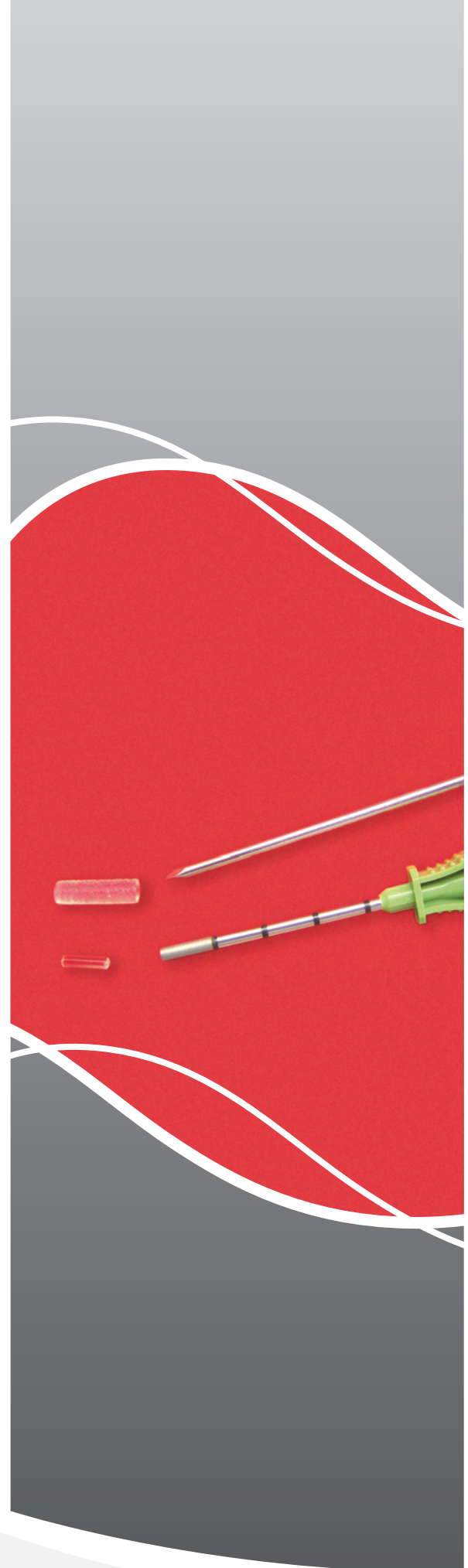
- ⌋ High biocompatibility
- ⌋ Low complication rate
- ⌋ Low risk of infection
- ⌋ Controlled swelling
- ⌋ No search for valve
- ⌋ No missed valve deflation

| Variety

- ⌋ Great variety of sizes – especially small devices: final volumes from 0.24 ml to 650 ml
- ⌋ Different shapes – rectangle, round, pin, cylinder, sphere and hemisphere
- ⌋ With and without silicone shell
- ⌋ Temporary and permanent use
- ⌋ A perfect solution for each indication


| Comfort

- ⌋ Small incision
- ⌋ Minimal trauma
- ⌋ No periodic filling » Benefit in cost, time and less pain
- ⌋ Short surgical time
- ⌋ No pressure peaks
- ⌋ Local anaesthesia possible
- ⌋ New indications especially for children



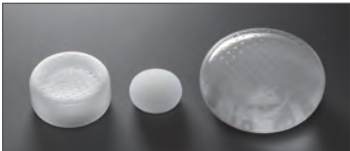
Product overview Plastic Surgery

Tissue Expander 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	96 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.

Tissue Expander Round

			Before Swelling			After Swelling*			
Order No.	Item	Volume	Projection	Diameter	Volume	Projection	Diameter	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.

Tissue Expander Cylinder

			Before Swelling			After Swelling*			
Order No.	Item	Volume	Length	Diameter	Volume	Length	Diameter	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.

| Tissue Expander Ellipsoid

Order No. Item		Before Swelling			After Swelling*			Swelling time*
		Volume	Length	Diameter	Volume	Length	Diameter	
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 days
352-4019	Ellipsoid 19 ml	1.9 ml	18 mm	13 mm	19 ml	41 mm	30 mm	10 days
352-4024	Ellipsoid 24 ml	2.5 ml	20 mm	14 mm	24 ml	47 mm	31 mm	11 days

* in vitro in 0.9% NaCl-Sol.


| Tissue Expander Pin

Order No. Item		Before Swelling			After Swelling*			Swelling time*
		Volume	Length	Diameter	Volume	Length	Diameter	
352-5024	Pin 0.24 ml	0.025 ml	8 mm	2 mm	0.24 ml	15 mm	4 mm	1 day
352-5024-2	Pin 0.24 ml (2 pieces)	0.025 ml	8 mm	2 mm	0.24 ml	15 mm	4 mm	1 day
352-5024-5	Pin 0.24 ml (5 pieces)	0.025 ml	8 mm	2 mm	0.24 ml	15 mm	4 mm	1 day
352-5024-10	Pin 0.24 ml (10 pieces)	0.025 ml	8 mm	2 mm	0.24 ml	15 mm	4 mm	1 day
AH - 01	Trocar							

* in vitro in 0.9% NaCl-Sol.


Product overview Ophthalmology

| Tissue Expander Hemisphere

		Before Swelling			After Swelling*			
Order No.	Item	Volume	Diameter		Volume	Diameter		Swelling time*
352-6040	Hemisphere 0.4ml	0.06 ml	6 mm		0.4 ml	11.2 mm		1 day
352-6090	Hemisphere 0.9ml	0.13 ml	8 mm		0.9 ml	14 mm		1 day
352-6090/P	Hemisphere 0.9ml (drill hole parallel)	0.13 ml	8 mm		0.9 ml	14 mm		1 day
352-6150	Hemisphere 1.5ml	0.20 ml	9 mm		1.5 ml	18 mm		1 day
352-6200	Hemisphere 2.0 ml	0.28 ml	10 mm		2.0 ml	20 mm		2 days


* in vitro in 0.9% NaCl-Sol.

| Tissue Expander Sphere

		Before Swelling			After Swelling*			
Order No.	Item	Volume	Diameter		Volume	Diameter		Swelling time*
352-7100	Sphere 1 ml	0.12 ml	6 mm		1 ml	12.4 mm		1 day
352-7200	Sphere 2 ml	0.30 ml	8 mm		2 ml	15.5 mm		2 days
352-7300	Sphere 3 ml	0.30 ml	8 mm		3 ml	18.0 mm		3 days
352-7400	Sphere 4 ml	0.43 ml	9 mm		4 ml	19.7 mm		4 days
352-7500	Sphere 5 ml	0.43 ml	9 mm		5 ml	21.8 mm		4 days

* in vitro in 0.9% NaCl-Sol.


| Tissue Expander Pin

		Before Swelling			After Swelling*			
Order No.	Item	Volume	Length	Diameter	Volume	Length	Diameter	Swelling time*
352-5024	Pin 0.24 ml	0.025 ml	8 mm	2 mm	0.24 ml	15 mm	4 mm	1 day
352-5024-2	Pin 0.24 ml (2 pieces)	0.025 ml	8 mm	2 mm	0.24 ml	15 mm	4 mm	1 day
352-5024-5	Pin 0.24 ml (5 pieces)	0.025 ml	8 mm	2 mm	0.24 ml	15 mm	4 mm	1 day
352-5024-10	Pin 0.24 ml (10 pieces)	0.025 ml	8 mm	2 mm	0.24 ml	15 mm	4 mm	1 day
AH - 01	Trocar							

* in vitro in 0.9% NaCl-Sol.

Product overview Dental


Cupola Dental

		Before Swelling*			After Swelling**			Swelling time**
		Volume	Projection	Diameter	Volume	Projection	Diameter	
Order-No.	Item	0.05 ml	3 mm	6 mm	0.35 ml	5,6 mm	9 mm	40 Days

* without silicone shell

** in vitro in 0.9% NaCl-Sol.

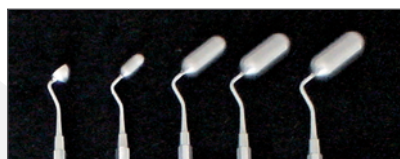
Cylinder Dental

		Before Swelling*			After Swelling**			Swelling time**
		Volume	Length	Diameter	Volume	Length	Diameter	
Order-No.	Item	0.045 ml	7.5 mm	3 mm	0.24 ml	12 mm	6 mm	20 Days
400-1070	Cylinder Dental 0.7 ml	0.15 ml	12 mm	4 mm	0.7 ml	20 mm	7 mm	40 Days
400-1130	Cylinder Dental 1.3 ml	0.25 ml	13 mm	5 mm	1.3 ml	22 mm	9 mm	50 Days
400-1210	Cylinder Dental 2.1 ml	0.42 ml	15 mm	6 mm	2.1 ml	24 mm	10.5 mm	90 Days

* without silicone shell

** in vitro in 0.9% NaCl-Sol.

Template



Order-No.	Item
001-0001	Set of templates Cylinder Dental and Cupola Dental
001-2035	Template for Cupola Dental 0.35 ml
001-1024	Template for Cylinder Dental 0.24 ml
001-1070	Template for Cylinder Dental 0.7 ml
001-1130	Template for Cylinder Dental 1.3 ml
001-1210	Template for Cylinder Dental 2.1 ml

Questions and Answers

| Is there a risk of uncontrolled oversized swelling?

No, osmed tissue expanders grow 10 to 12 times fold from its original dried implantation size like declared in the brochure. The special manufacturing procedure gives a memory effect to the material which effects, that shape and size, that has been produced before in the factory, will be achieved accurately in the human body.

| Why is the osmed tissue expander placed in a silicone shell?

In some products the osmed tissue expander comes in a silicone shell with an exact number and size of holes to assure gradual and consistent swelling of the device.

| How well is the osmed tissue expander tolerated in respect to pain?

The osmed expander's constant gradual expansion greatly minimizes the patient's discomfort. Conventional expanders require periodic large volume fillings (needle stitches), which create pressure peaks and are therefore associated with a larger degree of discomfort.

| Compare potential infection rates of conventional expanders with osmed tissue expanders.

Since the fill process for the osmed tissue expander is automated and periodic filling is avoided, the risk for exterior infection is greatly reduced.

| Is it possible to stop swelling after implantation?

An overfilling is precluded as the expander swells continuously in very small steps without pressure peaks. If the application is according to the indication a perforation is an exception. Stopping of the swelling is only possible by premature explantation.

| Is a „leakage“ possible?

It is not, because the absorbed liquid is chemically fixed. In addition the content is autologous fluid beside the hydrogel. In case the expander is damaged by outside impact there is no influence on the subsequent inflation and the same final size will be achieved as with an undamaged expander. The pieces remain in the capsule and can not migrate. At later explantation remove pieces and rinse capsule properly.

| What are the differences of different swelling factors?

General rule:

small swelling factor = small swelling speed and relatively hard material after finished swelling

high swelling factor = high swelling speed and relatively soft material after finished swelling.

A certain product always has the same swelling factor; which is adapted to the corresponding indication and size of the expander.

| How long shall the expander stay in situ?

That depends on the expander type. Rule: the bigger the expander, the longer is the time in situ. The brochure indicates the swelling time in vitro. The swelling time in vivo generally takes longer. To achieve a permanent gain of tissue, you should add 1 to 2 weeks depending on the location of implantation.

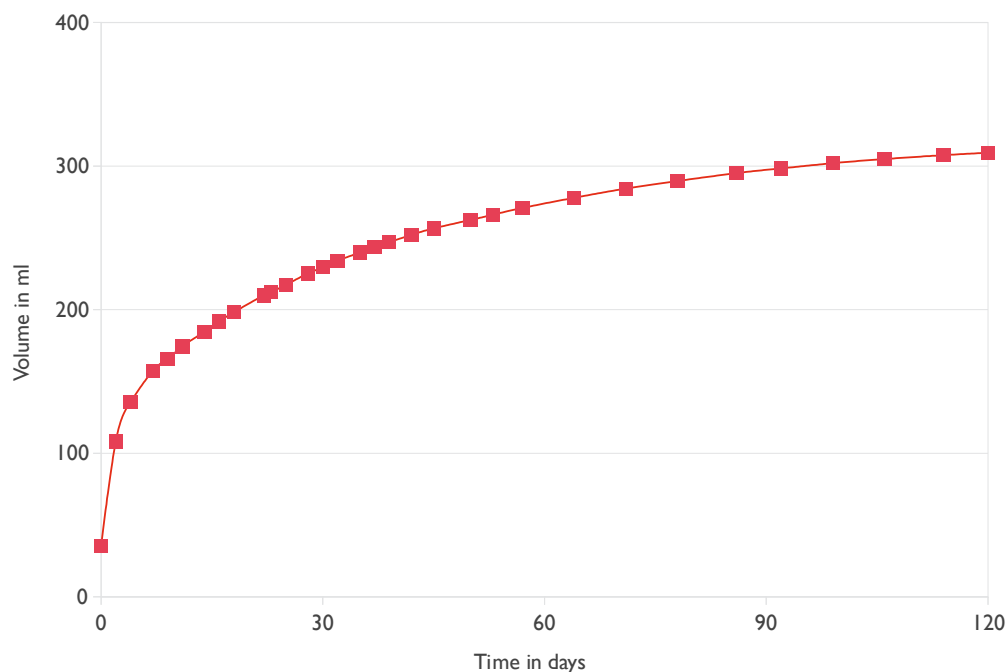
| What does the swelling curve show?

The swelling curve shows the swelling characteristics of the expander in vitro, as only such measuring is reproducible. In vivo the swelling curve runs more flat and is nearly straight.

| Where do I find updated product information?

Visit www.osmed.biz: At „Information“ there is „Literature“ for osmed related publications and „Downloads“ for detailed information about products and indications.

Example of a swelling curve of Rectangle 300 ml:



| Contact

osmed gmbh
Ehrenbergstraße 11
D-98693 Ilmenau
Fon: +49 3677/668 631
Fax: +49 3677/668 639
info@osmed.biz
www.osmed.biz



Management / International affairs:

Michael Kircheisen
Fon: +49 7633/101 456
Fax: +49 7633/101 434
michael.kircheisen@osmed.biz

CE 0297
02/2012

