

- ① EasyFit Gel™ — softer cohesive gel for smooth fit to rib cage
- ② Shapar Gel™ — firmer cohesive gel for tissue push-up effect
- ③ Prevention of delamination of gel or shell, high gel integrity
- ④ Nipple position
- ⑤ Maximum implant projection at 25%
- ⑥ Firmer gel at the bottom eliminates gel roll
- ⑦ Easy nipple positioning due to levelled dome-shaped projection

Diagon\Gel® 4Two

2 gels, 2 projections, 2 surfaces, 2 profiles



4Two AR



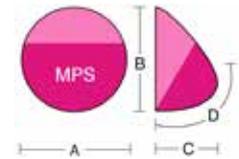
4Two AO

Implants made by POLYTECH – QUALITY made in Germany



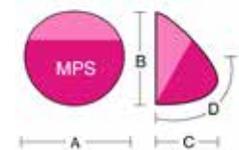
4TwoAR Microthane® CE 0483 anatomical | round

4Two AR Microthane®									
Base (mm)		HP High Projection			XP Extra-High Projection				
		Order n°	Projection (mm)		Volume (ml)	Order n°	Projection (mm)		Volume (ml)
A	B		C	D		C	D		
104	104	31631-195 ¹	40	79	195	31632-240 ¹	48	85	240
108	108	31631-225*	42	82	225	31632-270*	50	89	270
112	112	31631-255	44	85	255	31632-305	52	92	305
116	116	31631-285*	46	89	285	31632-335*	54	96	335
120	120	31631-315	48	92	315	31632-365	56	99	365
124	124	31631-345*	50	96	345	31632-390*	58	103	390
128	128	31631-400	52	99	400	31632-465 ¹	60	106	465
132	132	31631-440* ¹	54	103	440	31632-500* ¹	62	110	500
136	136	31631-480 ¹	56	106	480				

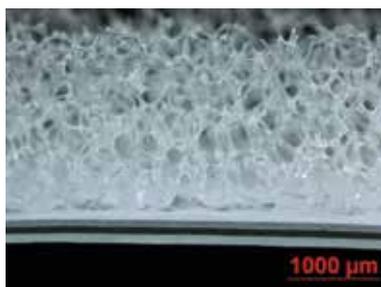


4TwoAO Microthane® CE 0483 anatomical | oval

4Two AO Microthane®									
Base (mm)		HP High Projection			XP Extra-High Projection				
		Order n°	Projection (mm)		Volume (ml)	Order n°	Projection (mm)		Volume (ml)
A	B		C	D		C	D		
104	94	31641-180 ¹	40	79	180	31642-215	48	86	215
108	98	31641-205*	42	83	205	31642-245*	50	90	245
112	102	31641-235	44	86	235	31642-285	52	93	285
116	106	31641-260*	46	90	260	31642-305*	54	97	305
120	110	31641-290	48	93	290	31642-335	56	100	335
124	114	31641-320*	50	97	320	31642-380*	58	104	380
128	118	31641-360	52	100	360	31642-415	60	107	415



Sizes highlighted in color and marked (1) will be produced on demand; supply ≈ 6 weeks after order. Silicone gel-filled, smooth sizers (sterile, re-sterilisable) are available for products marked with an asterisk (*).

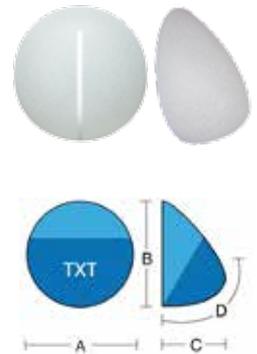


Microthane® is an implant shell cover of medical-grade micropolyurethane foam. This type of shell cover has a mean surface roughness of 1500μm. Due to the ingrowth of capsular tissue into the Microthane® surface numerous small capsules are created. These microcapsules significantly reduce the risk for capsular contracture. An extensive long-term study shows that after 8 years the capsular contracture rate with Microthane® implants compared to textured implants is 15% lower; it is even 30% lower compared to smooth implants. *

* Capsular contracture rates of implants with polyurethane cover: 0-3 %, i.e. 30% lower than with smooth-shell implants (Handel, 1991, 2006; Gasperoni, 1992; Pennisi, 1990; Shapiro, 1989; Baudelot, 1989; Artz, 1988; Hermann, 1984; Eyssen, 1984; Schatten, 1984; Hester et al., 2001; Vázquez, 2007)

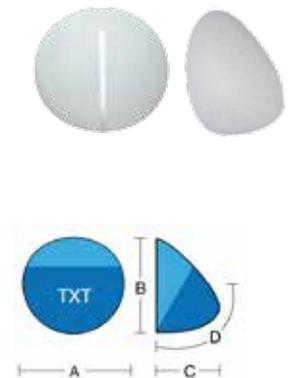
4TwoAR POLYtxt® CE 0483 anatomical | round

4Two AR POLYtxt®									
Base (mm)		HP High Projection			XP Extra-High Projection				
A	B	Order n°	Projection (mm)		Volume (ml)	Order n°	Projection (mm)		Volume (ml)
			C	D			C	D	
104	104	21631-195 ¹	40	79	195	21632-240 ¹	48	85	240
108	108	21631-225*	42	82	225	21632-270* ¹	50	89	270
112	112	21631-255	44	85	255	21632-305	52	92	305
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124	124	21631-345*	50	96	345	21632-390*	58	103	390
128	128	21631-400	52	99	400	21632-465 ¹	60	106	465
132	132	21631-440*	54	103	440	21632-500* ¹	62	110	500
136	136	21631-480 ¹	56	106	480				

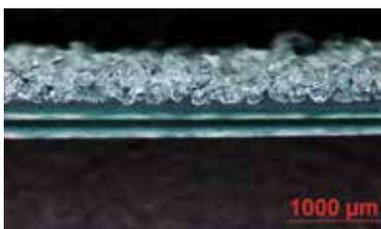


4TwoAO POLYtxt® CE 0483 anatomical | oval

4Two AO POLYtxt®									
Base (mm)		HP High Projection			XP Extra-High Projection				
A	B	Order n°	Projection (mm)		Volume (ml)	Order n°	Projection (mm)		Volume (ml)
			C	D			C	D	
104	94	21641-180 ¹	40	79	180	21642-215 ¹	48	86	215
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POLYtxt®, the POLYTECH macro-texture, has a rough open cell structure, on average of 200–300μm in height and 100–400μm in diameter to allow tissue adherence. This surface is known for its reliability and has been proven to contribute to a reduction of capsular contracture rates. For the textured surface, the rates are 8 to 15%, which is around 15% lower than with smooth implants^{2, **}

** Capsular contracture rates of implants with macro-textured shell: 8–15 % (Iwuagwu + Frame, 1997), i.e. 15% lower than with smooth-shell implants (Handel, 2006)

Diagon\Gel® 4Two

Product Description



The silicone-gel-filled Diagon\Gel® 4Two implant series is styled for simplicity. The morpho-structural design ensures that the deliberately reduced range of sizes provides a large variety of projections, thus facilitating the proper choice.

The Diagon\Gel® 4Two implants have an anatomical profile and a round or an oval base, the latter due to a reduction in implant height. The implants are available in two surfaces, either POLYtxt®

or Microthane®, and in two projections.

The Diagon\Gel® 4Two implants are filled with two gels: the softer EasyFit Gel™ at the back ensures a perfect fit of the implant to the rib cage, and the firmer Shapar Gel™ at the front provides for a push-up style tissue support.

Due to the spherical nature of the projection, the implant accommodates for optimal nipple positioning without pointing. The near 90-degree angle at the tapered edges of the implant does not allow dead space, thus reducing the occurrence of seroma, implant rotation and dislocation.

Information on Material

The POLYTECH Health & Aesthetics Diagon\Gel® 4Two implants are filled with two highly cross-linked, cohesive, form-stable clear gels: the softer EasyFit Gel™ at the back and the firmer Shapar Gel™ at the front. The softer gel at the back of the implant ensures that the implant molds smoothly to the rib cage and provides for a natural movement of the breast. The firmer gel at the front and the dome-shaped projection facilitate nipple positioning and support the residual breast tissue in push-up style. Additionally, the Shapar Gel™ offers a parenchyma-like, naturally slow response in motion and consistency as well as extra shape stability even in cases of low tissue coverage.

The chemically and mechanically resistant, elastic shell of the implants consists of several layers of a silicone elastomer, including a diffusion barrier layer. Due to the soft gel in the posterior implant section, the edges of the shell are almost imperceptible. Innovative chemistry prevents delamination between the gels and from the shell.

The surface of the implant shell is either POLYtxt® textured or Microthane®-coated (micropolyurethane foam). Both surfaces are known for their reliability and have been proven to contribute to a reduction of capsular contracture rates. (see literature mentioned on previous pages)

Production of the implants is based on a quality management according to ISO 9001 and ISO 13485. All materials used are of implantable medical quality.

Indications

- Breast reconstruction after mastectomy or ablatio mammae
- Contour augmentation and correction
- Adjustment of asymmetries, aplasia or hypoplasia
- Combined breast and thoracic deformities
- Ptosis or atrophy
- Implant exchange

Important Information

The implants are delivered individually packed and sterile.

Attention: Please note the detailed instructions for use included with each product.

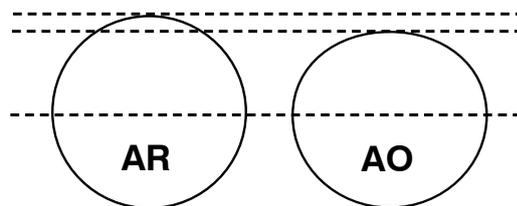
Additional Features

Facilitated nipple positioning due to a levelled dome-shaped projection



Perfectly round:

Compared to the implant base of the 4Two AR, the 4Two AO implant base is shorter. The innovative feature of the 4Two AO design in comparison to other short implants is that the 4Two AO implant is only shortened in the upper half, the lower half forms a perfect semi-circle.



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