POLYURETHANE
MAMMARY IMPLANTS

Maximal reduction
of capsular contracture

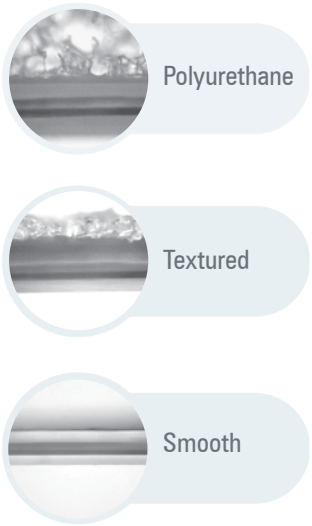
SILIMED

SILIMED, a company present in more than fifty countries of the five continents, has the largest line of products in the market, manufactured according to the highest standard of quality. They are all made with FDA-registered, medical-grade silicone.

Our manufacturing process is in strict compliance with the Good Manufacturing Practices determined by ANVISA and FDA, and our Quality Management System is certified according to the ISO 9001:2000, ISO 13485:2003 and ISO 13485:2003 standards (including the requirements from Canada) and our products bear the CE mark.

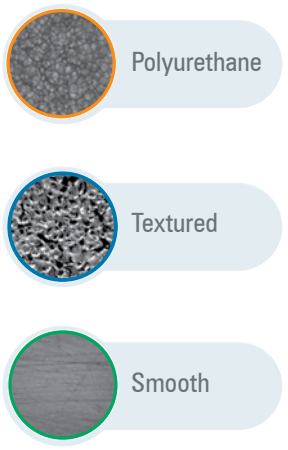
Every implant has its serial number, brand and size engraved, which makes its identification possible at any time. The individual serial number allows our company to have control not only of the products sold, but also of all the material and techniques used during the manufacturing process. This characteristic reflects the seriousness and professionalism present in our company's activities.

Shells / Barrier



The Low Bleed barrier assures lower permeability of the shell and, consequently, less gel transudation.

Surfaces



Foam Vulcanized to the Shell
less incidence of capsular contracture

Rough Surface
forming a structure of open cells

Classical Solution
for more than 30 years

Gel - BIODESIGN®

Silimed gel, with its high-cohesiveness and low-bleed properties, has been used for many years to meet the specific needs of each part of the human body. Featuring a high degree of cohesiveness, it can vary in physical characteristics according to the area where it is to be used and the specific indications for each patient, and is supplied in various degrees of hardness. It can reproduce faithfully the soft tissues to give the implant a better fit and provide a softer touch. Now, this gel has a name BIODESIGN, which expresses its main objective: to mold the body, improving its appearance and preserving its natural look.

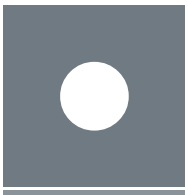
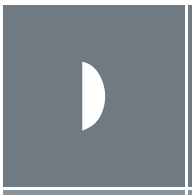
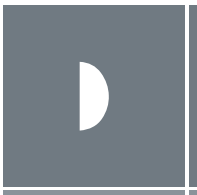
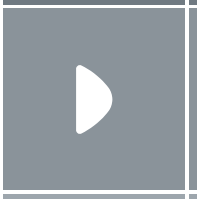
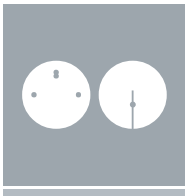
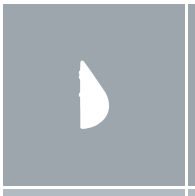
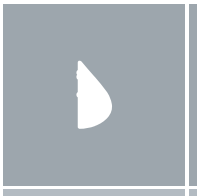
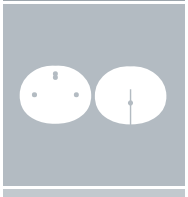
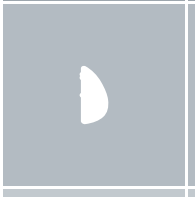
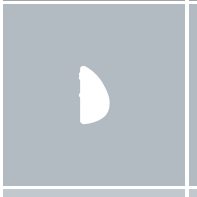
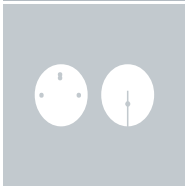
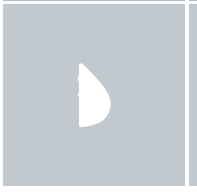
Biodesign's high cohesiveness contributes towards the gel transudating less. This property is responsible for keeping the molecules connected by not letting the gel "run" if the implant bursts. It denotes elongation and memory, and should not be confused with hardness.

Hardness / Consistency

Each type of implant produced by Silimed is filled with a high performance Biodesign silicone gel, which consistency has been chosen in order to achieve the best aesthetic and functional result. Hardness refers to the material's ability to resist penetration, allowing the manufacturing of implants that present a better adequacy of the gel' s hardness/consistency to each region of the body. It should be emphasized that high performance and hardness are different concepts: a high performance Biodesign gel does not need to be hard. Biodesign's hardness/consistence is measured by an instrument that measures the penetration of the gel, called Penetrometer. For each hardness/consistency grade a number is assigned, which corresponds to the penetration level of each gel type (see table below).

Degree of Penetration	Type of Implant
2,5	Textured Mammary and Polyurethane
7,3	Smooth Mammary
7,0	Calf, Gluteal, Pectoral and Testicular Implants

POLYURETHANE MAMMARY IMPLANTS

PRODUCT DESCRIPTION		BASE	PROJECTION			
			LOW	MODERATE	HIGH	EXTRA HIGH
MAXIMUM	Base: round Profile: spherical Pole: medial			*		*
ADVANCE	Base: round Profile: conical Pole: medial					
NATURAL	Base: round Profile: tear-drop Pole: medial					
NUANCE	Base: oval Profile: anatomical Pole: inferior					*
ENHANCE	Base: oval Profile: anatomical Pole: superior		*			*

SILIMED has the largest line of mammary implants, presented in different base shapes, profiles, projections and sizes. All the SILIMED mammary implants are made of a low-bleed envelope, filled with high-performance Biodesign gel. It is the only product in the market with memory and elasticity to provide stable shapes with minimum deformation. The surfaces available are: Smooth surface, Textured surface and Polyurethane-foam coated surface.

The appropriate choice of the type of implant is an important factor in the use of our products. We rely on the ability of our customers to make the correct choice. However, we recommend that the surgeon, when deciding on the sizes to be ordered, make use of the dimensions in the pre-operative consultation. For fine adjustment in the post-operative phase, we recommend the use of the sizer to confirm the correctness of the final choice.

Supplied sterile.

*** Under development**

MAXIMUM

Base: round
Profile: spherical
Pole: medial

LOW PROJECTION

MAXIMUM
PITANGUY / REBELLO

REF	VOL	cm	
	cm³	A	B
30615-040	40	7,1	1,9
30615-060	60	7,6	2,2
30615-080	80	8,3	2,5
30615-100	100	9,0	2,6
30615-120	120	9,4	2,7
30615-140	140	10,2	2,7
30615-160	160	10,6	2,8
30615-190	190	11,6	2,9
30615-220	220	12,2	3,0
30615-250	250	12,5	3,2
30615-280	280	13,3	3,3
30615-310	310	14,1	3,1
30615-350	350	14,7	3,1
30615-370	370	14,6	3,2
30615-400	400	15,0	3,5
30615-450	450	15,8	3,6
30615-500	500	16,2	3,7
30615-550	550	16,6	3,9
30615-600	600	17,1	4,2

HIGH PROJECTION

MAXIMUM
PITANGUY / REBELLO

REF	VOL	cm	
	cm³	A	B
30626-095	95	7,9	3,2
30626-115	115	8,3	3,4
30626-135	135	8,9	3,5
30626-155	155	9,1	3,9
30626-175	175	9,5	4,1
30626-195	195	9,8	4,2
30626-215	215	10,1	4,3
30626-235	235	10,6	4,3
30626-255	255	11,2	4,3
30626-285	285	11,5	4,4
30626-305	305	12,0	4,5
30626-325	325	12,0	4,7
30626-355	355	12,1	4,9
30626-385	385	12,6	5,0
30626-435	435	13,3	5,0
30626-485	485	13,8	5,1
30626-525	525	13,9	5,5
30626-575	575	14,3	5,7
30626-625	625	14,7	5,8
30626-695	695	15,2	6,0

ADVANCE

Base: round
Profile: conical
Pole: medial

LOW PROJECTION

ADVANCE
PITANGUY / REBELLO

REF	VOL	cm	
	cm³	A	B
30535-105LO	105	8,8	3,5
30535-135LO	135	9,3	3,8
30535-160LO	160	9,8	4,1
30535-190LO	190	10,3	4,4
30535-225LO	225	10,8	4,7
30535-260LO	260	11,3	5,0
30535-295LO	295	11,8	5,3
30535-350LO	350	12,3	5,6

MODERATE PROJECTION

ADVANCE
PITANGUY / REBELLO

REF	VOL	cm	
	cm³	A	B
30535-125MD	125	8,8	4,0
30535-150MD	150	9,3	4,3
30535-175MD	175	9,8	4,6
30535-210MD	210	10,3	4,9
30535-245MD	245	10,8	5,2
30535-300MD	300	11,3	5,5
30535-325MD	325	11,8	5,8
30535-375MD	375	12,3	6,1

HIGH PROJECTION

ADVANCE
PITANGUY / REBELLO

REF	VOL	cm	
	cm³	A	B
30535-140HI	140	8,8	4,5
30535-165HI	165	9,3	4,8
30535-185HI	185	9,8	5,1
30535-235HI	235	10,3	5,4
30535-275HI	275	10,8	5,7
30535-315HI	315	11,3	6,0
30535-355HI	355	11,8	6,3
30535-400HI	400	12,3	6,6

EXTRA HIGH PROJECTION

ADVANCE
PITANGUY / REBELLO

REF	VOL	cm	
	cm³	A	B
30535-150XH	150	8,8	5,0
30535-180XH	180	9,3	5,3
30535-215XH	215	9,8	5,6
30535-265XH	265	10,3	5,9
30535-300XH	300	10,8	6,2
30535-345XH	345	11,3	6,5
30535-380XH	380	11,8	6,8
30535-435XH	435	12,3	7,1

NATURAL

Base: round
Profile: tear drop
Pole: medial

LOW PROJECTION

NATURAL
PITANGUY / REBELLO

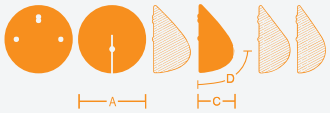
REF	VOL		
	cm³	cm	
		A	B
30635-105L	105	8,3	3,3
30635-120L	120	8,8	3,4
30635-135L	135	8,9	3,7
30635-150L	150	9,2	3,8
30635-165L	165	9,7	4,0
30635-185L	185	10,1	4,0
30635-205L	205	10,8	4,0
30635-225L	225	11,1	4,1
30635-245L	245	11,6	4,2
30635-265L	265	12,0	4,2
30635-285L	285	12,2	4,3
30635-305L	305	12,4	4,4
30635-325L	325	12,7	4,4
30635-345L	345	12,8	4,6
30635-375L	375	13,3	4,6
30635-405L	405	13,6	4,8
30635-435L	435	13,8	4,9
30635-465L	465	14,4	5,0
30635-495L	495	14,5	5,0
30635-535L	535	14,8	5,2
30635-575L	575	15,2	5,2
30635-615L	615	15,6	5,3
30635-655L	655	16,2	5,2
30635-685L	685	16,5	5,3

MODERATE PROJECTION

NATURAL
PITANGUY / REBELLO

REF	VOL		
	cm³	cm	
		A	B
30636-095L	95	8,0	3,2
30636-115L	115	8,4	3,3
30636-135L	135	8,9	3,7
30636-155L	155	9,2	3,9
30636-175L	175	9,5	4,1
30636-195L	195	9,7	4,3
30636-215L	215	10,1	4,4
30636-235L	235	10,4	4,8
30636-255L	255	10,5	4,9
30636-285L	285	11,0	4,9
30636-315L	315	11,3	5,2
30636-345L	345	11,5	5,7
30636-385L	385	11,9	5,7
30636-435L	435	12,4	5,7
30636-475L	475	12,6	6,3
30636-515L	515	12,9	6,6
30636-565L	565	13,2	6,7
30636-605L	605	13,4	6,9
30636-645L	645	14,0	7,0
30636-685L	685	14,1	7,2

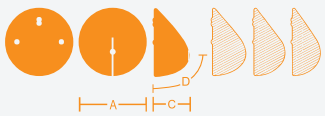
HIGH PROJECTION



NATURAL
PITANGUY / REBELLO

REF	VOL			
	cm³	cm		
		A	B	C
30637-185HI	185	96	4,9	6,7
30637-200HI	200	9,9	5,0	6,7
30637-215HI	215	10,2	5,1	6,8
30637-230HI	230	10,5	5,2	6,9
30637-250HI	250	10,8	5,3	7,1
30637-270HI	270	11,1	5,4	7,3
30637-315HI	315	11,7	5,6	7,6
30637-360HI	360	12,3	5,8	7,9
30637-410HI	410	12,9	6,0	8,2
30637-465HI	465	13,5	6,2	00
30637-525HI	525	14,1	6,4	00
30637-590HI	590	14,7	6,6	00

EXTRA HIGH PROJECTION



NATURAL
PITANGUY / REBELLO

REF	VOL			
	cm³	cm		
		A	B	C
30637-210XH	210	9,6	5,7	7,3
30637-230XH	230	9,9	5,8	7,4
30637-245XH	245	10,2	5,9	7,5
30637-270XH	270	10,5	6,0	7,7
30637-290XH	290	10,8	6,1	7,9
30637-315XH	315	11,1	6,2	8,1
30637-360XH	360	11,7	6,4	8,3
30637-410XH	410	12,3	6,6	8,6
30637-470XH	470	12,9	6,8	9,0
30637-530XH	530	13,5	7,0	00
30637-590XH	590	14,1	7,2	00

NUANCE

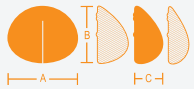
Base: oval
Profile: anatomical
Pole: inferior

LOW PROJECTION

NUANCE
PITANGUY / REBELLO

REF	VOL			
	cm³	cm		
		A	B	C
30644-170L	170	11,5	10,0	3,1
30644-220L	220	12,5	10,9	3,2
30644-270L	270	13,4	11,5	3,5
30644-320L	320	14,4	12,3	3,6
30644-410L	410	15,3	13,2	3,9
30644-500L	500	16,4	14,1	4,2

MODERATE PROJECTION



NUANCE
PITANGUY / REBELLO

REF	VOL			
	cm³	cm		
		A	B	C
30645-120L	120	9,0	8,2	3,6
30645-150L	150	9,5	8,7	3,8
30645-180L	180	10,1	9,1	4,1
30645-210L	210	11,1	10,0	4,2
30645-250L	250	12,0	10,5	4,3
30645-290L	290	12,4	11,4	4,5
30645-330L	330	12,9	11,6	4,7
30645-370L	370	13,3	11,8	4,9
30645-400L	400	13,6	12,1	5,1
30645-450L	450	14,0	12,6	5,3
30645-500L	500	14,5	13,0	5,5
30645-550L	550	15,1	13,5	5,5

HIGH PROJECTION

NUANCE
PITANGUY / REBELLO

REF	VOL			
	cm³	cm		
		A	B	C
30646-180L	180	9,9	8,4	4,5
30646-240L	240	10,6	9,5	4,7
30646-300L	300	11,4	10,4	5,2
30646-370L	370	12,4	11,1	5,5
30646-480L	480	13,5	12,1	5,8
30646-550L	550	14,5	12,9	5,9

ENHANCE

Base: oval
Profile: anatomical
Pole: superior

MODERATE PROJECTION

ENHANCE
PITANGUY / REBELLO

REF	VOL			
	cm³	cm		
		A	B	C
30676-115L	115	8,2	9,2	3,4
30676-135L	135	8,7	9,7	3,5
30676-155L	155	9,1	10,1	3,7
30676-175L	175	9,6	10,6	3,8
30676-195L	195	10,0	11,0	3,9
30676-225L	225	10,3	11,4	4,1
30676-245L	245	10,6	11,8	4,2
30676-265L	265	11,0	12,2	4,2
30676-285L	285	11,5	12,6	4,2
30676-305L	305	11,8	13,0	4,2
30676-325L	325	12,1	13,2	4,3
30676-365L	365	12,5	13,7	4,4
30676-390L	390	13,2	14,3	4,4
30676-430L	430	13,5	14,7	4,4
30676-480L	480	14,2	15,4	4,5
30676-530L	530	14,6	15,7	4,6
30676-570L	570	14,9	16,2	4,7
30676-640L	640	15,3	16,5	5,0

HIGH PROJECTION

ENHANCE
PITANGUY / REBELLO

REF	VOL			
	cm³	cm		
		A	B	C
30677-195L	195	9,7	10,5	4,3
30677-230L	230	10,1	11,0	4,6
30677-265L	265	10,7	11,5	4,7
30677-310L	310	11,0	12,0	4,9
30677-345L	345	11,4	12,5	5,1
30677-380L	380	11,9	12,9	5,3
30677-425L	425	12,3	13,6	5,6
30677-490L	490	12,9	14,1	5,6
30677-535L	535	13,2	14,8	5,9
30677-615L	615	13,9	15,3	6,3
30677-655L	655	14,1	15,7	6,4

MicroPolyurethane-foam Surface (MPS)

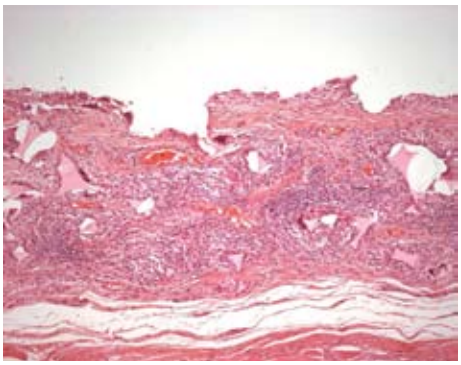


fig.1

The polyurethane foam provokes a foreign body reaction that is characterized by a predominant mobilization of macrophages and multinucleated giant cells, resulting in slow development of the spongy structured fibrosis due to microencapsulation of polyurethane particles.

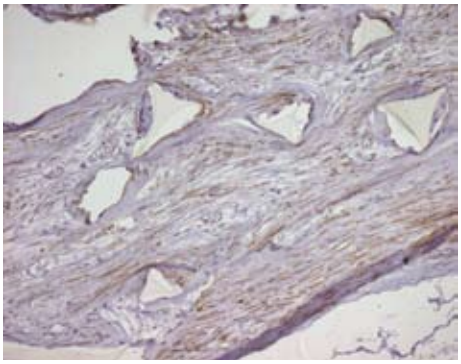


fig.2

The irregular surface of the polyurethane foam disfavors the formation of a linear fibrotic capsule, favoring multiplane formation of myofibroblasts. The formation of microcapsules around the irregularities of the polyurethane structure makes the contracture force multi-oriented instead of having a single direction. Presenting multiple vectors, these forces tend to annul each other thus reducing capsular contracture.

One of the principle considerations for any elective operations, e.g. breast reconstruction or augmentation is to minimize the number of complications. The most common complication of breast implant surgery is capsular contracture. MicroPolyurethane-foam Surfaced (MPS) implants have been developed to minimize the capsular contracture rate. In extensive clinical studies over the past twenty years reviewing high numbers of patients, the capsular contracture rate (Barker classification III-IV) has been determined. The capsular contracture rate for MPS implants in virgin tissue is 0-9 % compared to 9-50 % for other implants. In most of the large studies the capsular contracture rate for MPS implants is as low as 0-3 % [1)]. An extensive long-term study carried out in the United States, using Kaplan-Meier survival analysis, confirms the significant reduction of the risk for capsular contracture with MPS implants compared to textured implants is 15 % lower. It is even 30 % lower compared to smooth implants [2)].

The low capsular contracture rate is attributed to the ingrowth and microcapsulation of the fibroblasts in the polyurethane foam matrix (fig. 2) Due to the active healing process, a linear capsular contracture (fig. 1) and the resulting disfigurement of the implant are drastically reduced. Around MPS implants there is not one large capsule like around smooth and textured implants. In contrary, due to microencapsulation of the Polyurethane foam, numerous microcapsules around the foam are created, whereby contractile forces are neutralised.

The tissue fixation and the highly gross-linked silicone gel provide a natural feeling to the breast. Implant dislocation and rotation are not detected. The low capsular contracture rate also allows the prepectoral implantation and allows a pleasing aesthetic result for the augmentation and reconstruction of the breast.

SUMMARY

Patients with MPS implants enjoy a greater protection against capsular contracture for up to ten years after implantation and have in the mean longer duration until reoperation. Implant dislocatin and rotation are not described due to tissue fixation.

Due to the advantages of MicroPolyurethane-foam Surfaced implants in total, for the patient the total complication rate is drastically reduced.

Literature:

1) Handel, 1991; Penisi, 1990; Shapiro, 1989, Hester et all, 2001; Baudelot, 1989; Gasperoni, 1992; Hermann, 1984; Eyssen, 1984; Schatten, 1984; Artz, 1988;
2) Handel, 2006

Before using the product, the physician must read the Instructions for Use contained in the packaging.

SILIMED - SILICONE E INSTRUMENTAL MÉDICO-CIRÚRGICO E HOSPITALAR LTDA
Rua Figueiredo Rocha, nº 374 - CEP 21240-660 - Rio de Janeiro / RJ - Brasil
Tel (5521) 3687-7000
www.silimed.com.br
Responsável Técnico: Louise Azevedo Alves - CRF 3417
AUTORIZ. / MS 101021-8

EC REP **MPC INTERNATIONAL S.A.**
26, Boulevard Royal
L - 2449 Luxembourg