

PERTHESE™ Breast Implants

Cohesive silicone gel-filled breast implants



PERTHESE™

Breast Implants

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> Safety

- The PERTHESE™ Breast Implant is a sterile gel-filled implant made of a trilaminar silicone envelope.

The silicone envelope consists of an internal and external layer made with a high mechanical resistance medical grade silicone elastomer and an intermediate barrier layer to significantly reduce gel bleed.

The elongation at break of the shell is greater than 450%.

- The PERTHESE™ Breast Implant is manufactured and packaged under ISO 13485 quality standard applicable to medical devices. Quality controls are performed at all stages of the production.
- Each implant has engraved on the patch the manufacturer's identification, the serial number and the volume (in cc).
- The PERTHESE™ Breast Implant is supplied sterile within a rigid double blister package in order to ensure security and convenience. The prosthesis is sterilised by ethylene oxide under a validated sterilisation cycle.

> Tolerance

- The micro-textured envelope provides a soft envelope while allowing a non-aggressive disorganisation of the collagen structure.

The micro-texture carries several characteristics:

- Reproducible texture, identical from one implant to the other.
- Non-alterable physical features of the envelope.

> Warranty

All PERTHESE™ Silicone Gel-filled Breast Implants are covered by PERTHESE™ Quality Assurance Program warranty or PatientCare Promise limited warranty*

PERTHESE™ Breast Implants

PERTHESE™ Micro-Textured Breast Implants



TX
Low profile



MX
Moderate
profile



MP
Moderate
plus profile



540
High profile



550
Ultra-high
profile

PERTHESE™ Smooth Breast Implants



700 T
Low profile



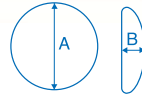
510 T
High profile

* In case of eligibility, depending on the date of surgery, the implant will fall under one of the above warranties.

PERTHESE™ Micro-textured Breast Implants

PERTHESE™ Breast Implants TX

> Low profile

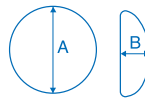


Reference	Volume (cc)	Base cm "A"	Projection cm "B"
TX 100	100	9,1	2,2
TX 125	125	9,7	2,4
TX 150	150	10,2	2,6
TX 170	170	10,8	2,7
TX 185	185	11,1	2,8
TX 200	200	11,4	2,9
TX 220	220	11,8	2,9
TX 240	240	12,2	3,0
TX 260	260	12,3	3,1
TX 280	280	12,5	3,2
TX 300	300	12,8	3,2
TX 325	325	13,1	3,3
TX 350	350	13,5	3,4



PERTHESE™ Breast Implants MX

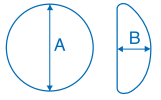
> Moderate profile



Reference	Volume (cc)	Base cm "A"	Projection cm "B"
MX 100	100	8,7	2,8
MX 125	125	9,2	3,0
MX 150	150	9,9	3,2
MX 175	175	10,4	3,3
MX 200	200	11,0	3,4
MX 225	225	11,5	3,5
MX 250	250	12,0	3,6
MX 275	275	12,2	3,7
MX 300	300	12,5	3,8
MX 325	325	12,8	4,0
MX 350	350	13,0	4,2
MX 375	375	13,2	4,4
MX 400	400	13,5	4,5
MX 450	450	13,9	4,6
MX 500	500	14,2	5,0
MX 550	550	14,5	5,2
MX 600	600	14,9	5,4
MX 650	650	15,2	5,5
MX 700	700	15,6	5,6
MX 800	800	16,1	6,0

PERTHESE™ Breast Implants MP

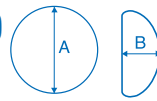
> Moderate plus profile



Reference	Volume (cc)	Base cm "A"	Projection cm "B"
MP 115	115	8,7	3,1
MP 135	135	9,2	3,2
MP 165	165	9,9	3,4
MP 190	190	10,5	3,6
MP 225	225	11,0	3,9
MP 260	260	11,6	4,1
MP 305	305	12,1	4,4
MP 320	320	12,3	4,5
MP 345	345	12,5	4,6
MP 380	380	12,7	4,9
MP 410	410	13,0	5,0
MP 440	440	13,2	5,3
MP 475	475	13,5	5,4
MP 510	510	13,8	5,5
MP 580	580	14,3	5,6
MP 635	635	14,4	5,9
MP 685	685	14,9	6,1
MP 735	735	15,2	6,3
MP 800	800	15,7	6,4
MP 910	910	16,2	6,8

PERTHESE™ Breast Implants 540

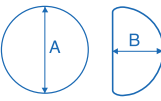
> High profile



Reference	Volume (cc)	Base cm "A"	Projection cm "B"
540-075	75	8,1	2,3
540-100	100	8,2	3,0
540-125	125	8,8	3,2
540-150	150	9,2	3,4
540-175	175	9,9	3,6
540-200	200	10,1	3,8
540-230	230	10,4	4,0
540-260	260	11,0	4,3
540-280	280	11,1	4,4
540-300	300	11,2	4,5
540-325	325	11,7	4,6
540-350	350	11,9	4,8
540-380	380	12,0	4,9
540-400	400	12,1	4,9
540-440	440	12,7	5,3
540-500	500	13,2	5,4
540-550	550	13,25	5,9
540-600	600	13,8	6,0
540-650	650	14,2	6,1
540-850	850	15,5	6,7

PERTHESE™ Breast Implants 550

> Ultra-high profile



Reference	Volume (cc)	Base cm "A"	Projection cm "B"
550-095	95	7,5	3,5
550-125	125	8,2	3,8
550-150	150	8,8	3,9
550-160	160	9,0	4,0
550-175	175	9,2	4,1
550-195	195	9,5	4,2
550-215	215	9,7	4,3
550-235	235	10,1	4,5
550-265	265	10,4	4,7
550-285	285	10,8	4,7
550-315	315	11,1	4,9
550-330	330	11,2	5,1
550-345	345	11,3	5,2
550-390	390	11,7	5,4
550-410	410	12,0	5,4
550-425	425	12,1	5,5
550-445	445	12,2	5,7
550-485	485	12,6	6,0
550-530	530	12,9	6,0
550-580	580	13,4	6,1
550-630	630	13,6	6,3
550-705	705	14,1	6,7

Note: Individual implant dimensions may vary slightly in products of this type.
Not all units will conform exactly to the dimensions noted above

Low profile

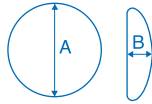
Moderate profile • Moderate plus profile

High profile • Ultra-high profile

PERTHESE™ Smooth Breast Implants

PERTHESE™ Breast Implants 700T

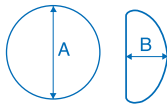
> Low profile



Reference	Volume (cc)	Base cm "A"	Projection cm "B"
700 T-120	120	9,7	2,4
700 T-140	140	10,3	2,4
700 T-160	160	10,8	2,5
700 T-180	180	11,2	2,6
700 T-200	200	11,2	2,8
700 T-220	220	11,9	2,8
700 T-240	240	12,1	2,9
700 T-260	260	12,2	3,1
700 T-280	280	12,6	3,2
700 T-300	300	12,8	3,2
700 T-325	325	13,1	3,3
700 T-350	350	13,5	3,3

PERTHESE™ Breast Implants 510T

> High profile



Reference	Volume (cc)	Base cm "A"	Projection cm "B"
510 T-080	80	8,1	2,5
510 T-100	100	9,1	2,7
510 T-120	120	9,3	2,9
510 T-140	140	9,6	3,3
510 T-160	160	9,6	3,4
510 T-180	180	10,0	3,6
510 T-200	200	10,2	3,7
510 T-220	220	10,7	3,9
510 T-240	240	10,7	4,2
510 T-270	270	11,0	4,3
510 T-300	300	11,4	4,4
510 T-340	340	11,7	4,6
510 T-380	380	11,9	4,8
510 T-400	400	12,2	5,0
510 T-450	450	12,6	5,3
510 T-500	500	13,3	5,5

Note: Individual implant dimensions may vary slightly in products of this type.
Not all units will conform exactly to the dimensions noted above

> Indications

- Contour reconstruction and size augmentation following a subcutaneous mastectomy for benign disease, e.g., chronic cystic mastitis, or for reconstruction and augmentation for correction of defects following radical mastectomy procedures.
- Unilateral or bilateral mammary augmentation or reconstruction to surgically correct various congenital or acquired anomalies such as amastia, aplasia, hypomastia, hypoplasia or following a reduction mammoplasty or for cosmetic purposes. Criteria for patient selection are the sole responsibility of the surgeon.

> Precaution for use

Precautions for use should be considered by the surgeon prior to the use of a PERTHESE™ Breast Implant:

- No breast cancer in progress at the time of implantation, even if a breast reconstruction can be considered in the case of a controlled metastatic syndrome, the prerequisite being that the benefits to the patient must be weighed up against the consequences of the surgical procedure and its non-interference with the required carcinologic treatments.
- If the patient exhibits a lack of skin it is the sole responsibility of the surgeon to decide on the use of an expansion technique or a tissue graft.
- Unwillingness on the part of the patient to accept the possibility of multiple surgeries for revision, which could be related to a lack of understanding, inappropriate motivation, or a history of repeated failures following cosmetic augmentations or subcutaneous mastectomy.
- From a general point of view, the health condition of the patient should be considered in view of the type of surgical procedure and the required anaesthesia.
- The patient should be informed of the existence of alternatives to breast implants surgery and/or to the availability of non silicone gel filled breast implants.

Each patient must be evaluated by the surgeon to balance the risk/benefit to the patient.

> Contraindications

PERTHESE™ Implants should not be implanted in a patient who has:

- a general or localised infection of the mammary sphere,
- an ongoing pregnancy,
- a history of autoimmune disease.

> Warranty

PEROUSE PLASTIE warrants that reasonable care in selection of materials and methods of manufacture was exercised in the fabrication of this product. PEROUSE PLASTIE shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this product. The foregoing warranties, as conditioned and limited, are in lieu of and exclude all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise.

PEROUSE PLASTIE neither assumes nor authorises any other person to assume for it any other or additional liability or responsibility in connection with this product.

PEROUSE PLASTIE intends that these products should be used only by physicians having appropriate training in plastic, reconstructive and aesthetic surgery techniques.

PERTHESE™ Implant is a trademark of PEROUSE PLASTIE.

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