MSA

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Quality and Experience · *since 1971*

Made in Germany

Titanised mesh implants for reconstructive breast surgery

› **TiLOOP® Bra Pocket**
› **TiLOOP® Bra**

www.pfmmedical.com

This document is intended for Healthcare Professionals only. This product (mesh implant) is not available for purchase by the general public. Always read the label and follow the Directions for Use (IFU/DFU).

General advantages

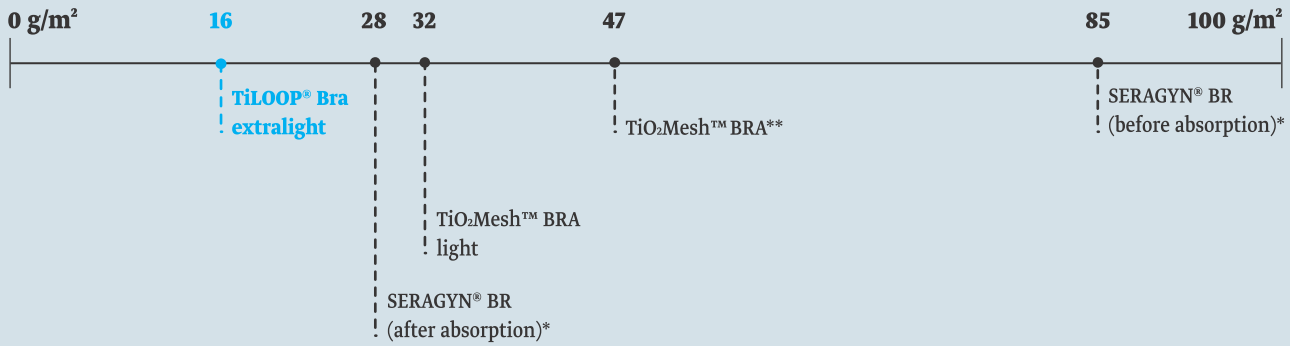
Complete portfolio

The TiLOOP® Bra product range covers indications for reconstructive breast surgery with tissue-reinforcing material.

TiLOOP® Bra Pocket ▸ For prepectoral placement
TiLOOP® Bra ▸ For subpectoral/universal placement

Exceptionally light, exceptionally soft

With TiLOOP® Bra extralight (16 g/m²) you introduce the least foreign material into the breast. This lightness enables optimal tissue adaptation, which is particularly important for use in the sensitive breast area.



* Brochure SERAGYN BR, item no. 851172, July 2019
** Brochure TiO₂Mesh™ BRA, MDD101.07/2021-09

Weight comparison of synthetic meshes approved for breast surgery in Europe

Quality proven in numerous studies

Our titanised meshes in breast surgery have been investigated in a large number of studies. TiLOOP® Bra has been used in breast surgery since 2008, and TiLOOP® Bra Pocket since 2017. A selection:

- **Reconstructions:** 250
  Description: TiLOOP® Bra in implant-based immediate prepectoral reconstruction, prospective
  Result: Higher quality of life, very high level of long-term patient satisfaction, very good aesthetic results and a low complication rate with TiLOOP® Bra
  Author: Casella et al., 2018[4]

- **Reconstructions:** 22
  Description: TiLOOP® Bra Pocket in implant-based immediate prepectoral reconstruction, prospective
  Result: Simple and efficient use of the TiLOOP® Bra Pocket with a short implantation procedure, and consequently short exposure to sources of contamination
  Author: Casella et al., 2019[5]

- **Reconstructions:** 216
  Description: TiLOOP® Bra vs ADM in implant-based immediate reconstruction, prospective
  Result: Lower complication rate, lower seroma rate and infection rate with TiLOOP® Bra
  Author: Quah et al., 2019[6]

- **Reconstructions:** 362
  Description: TiLOOP® Bra in implant-based subpectoral breast reconstruction, prospective
  Result: High quality of life for patients with TiLOOP® Bra (12 months post-op)
  Author: Thill et al., 2020[3]

- **Reconstructions:** 328
  Description: Histological investigation into tissue integration of TiLOOP® Bra after prepectoral breast reconstruction
  Result: The histological investigations show complete integration of TiLOOP® Bra into the tissue as well as physiological healing, a low complication rate, a low capsular contracture rate and high patient satisfaction
  Author: Gentile et al., 2021[2]

You can find an overview of publications on our titanised meshes to download here.

You can find more information about our studies here: www.pfmmedical.com/studies

General details

- Titanised type 1a polypropylene mesh
- Weight: 16 g/m²
- Pore size: 1.0 mm
- Monofilament fabric
- Non-absorbable
- Atraumatic, laser-cut edges
- EO-sterilised (ethylene oxide), pyrogen-free

Knowledge

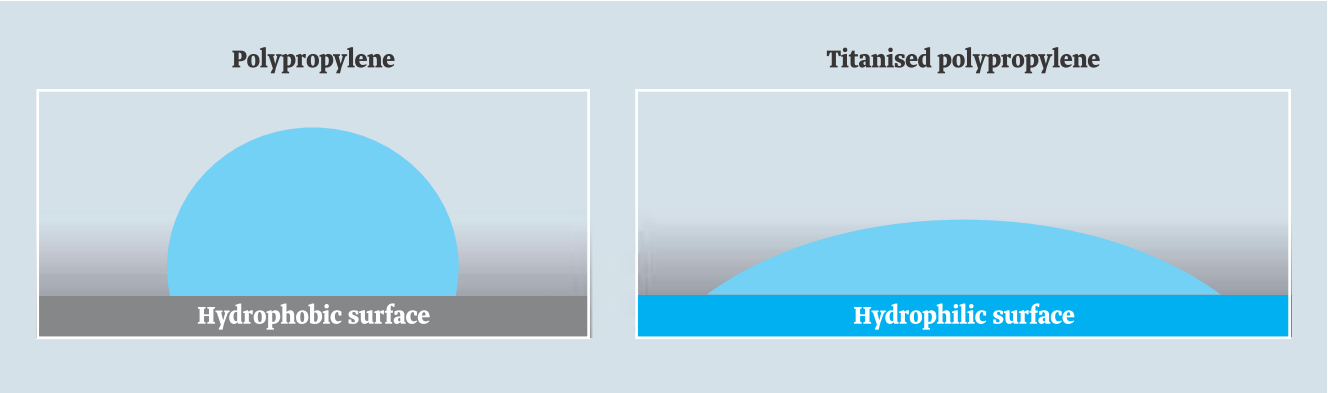
The right decision for or against the use of a tissue-reinforcing material (synthetic mesh or acellular dermal matrix (ADM)) is decisive for the long-term quality of a successful breast operation.

TiLOOP® Bra mesh implants* are type 1a polypropylene meshes (macroporous, lightweight and monofilament) with a titanised, hydrophilic surface. This offers many advantages compared to simple polypropylene:

- Lower risk of inflammation[1]
- Less scar formation[7]
- Less mesh shrinkage[1]

Titanisation of the mesh implants

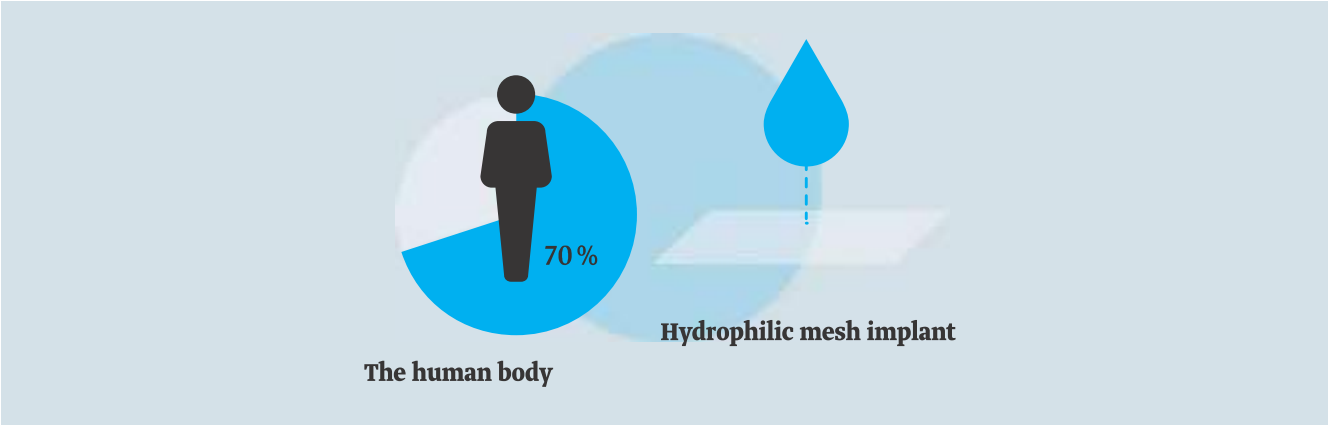
In 2002, pfmmedical succeeded in developing a globally unique process in which titanium is transferred to a flexible and elastic base material, specifically polypropylene mesh. TiLOOP® Bra und TiLOOP® Bra Pocket mesh implants are type 1a polypropylene meshes (macroporous, lightweight and monofilament) with a hydrophilic surface created by titanisation. A hydrophilic mesh implant integrates better into the surrounding tissue than a hydrophobic mesh.



Behaviour of a water drop on a hydrophobic and a hydrophilic surface

Biocompatibility

The human body is made up of approximately 70% water, so the titanised, and therefore hydrophilic, surface of our mesh implants gives better tolerance.[1, 8]

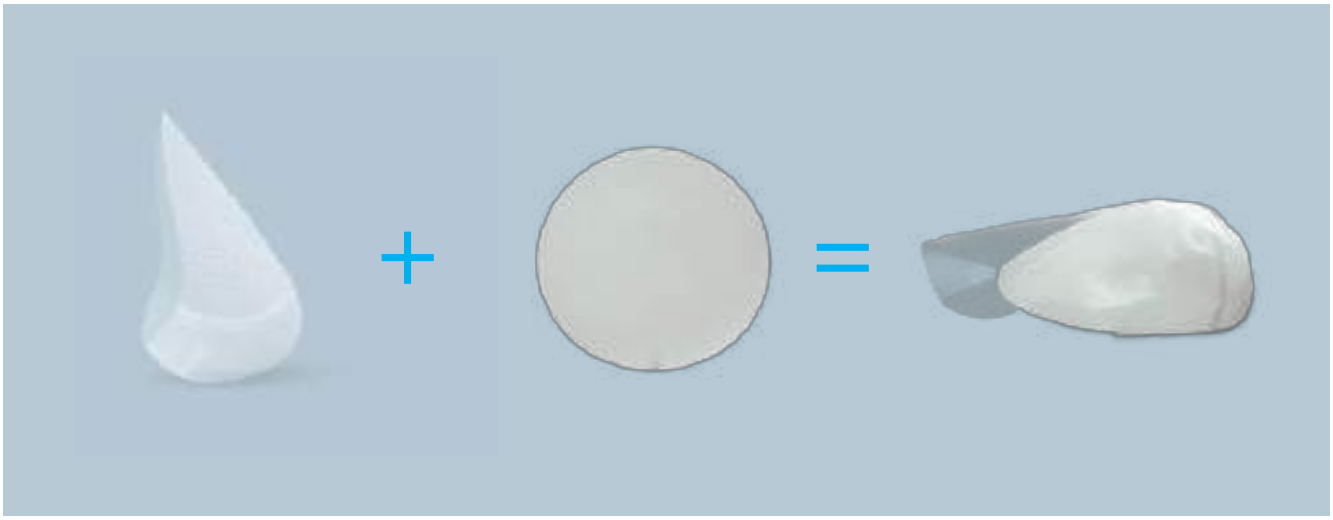


*TiLOOP® Bra mesh implants are not a tissue substitute

You can find more information about our titanisation here.

TiLOOP® Bra Pocket (ARTG ID: 503628)

View



Advantages

Muscle-preserving prepectoral

Prepectoral placement of the implant has the advantage that the muscle does not have to be detached from the chest wall, which in turn means less postoperative pain. The result is a rapid recovery after surgery and preservation of muscle function. Your patients can resume their daily lives sooner.

Very good aesthetic outcomes

Prepectoral placement enables the breast implant to assume the physiological position of the subcutaneous breast tissue. This means excellent aesthetics and a natural ptosis are achieved.[9, 10, 11]

High quality of life

Prepectoral reconstruction and the advantages that come with it lead to very good quality of life for your patients.[4, 10, 11]

Shorter surgery

TiLOOP® Bra Pocket is a ready-to-use implant pocket. There is no need for lengthy adjustment, e.g. intraoperative sutures or necessary hydration. Prepectoral reconstruction can be performed more quickly than subpectoral reconstruction because no preparation of the pectoralis major muscle is required.[5]This also shortens the duration of anaesthesia.

Protected implant

TiLOOP® Bra Pocket is an implant pocket that fixes the freely selectable breast implant on the muscle and can thereby prevent dislocation or twisting. Studies have demonstrated a very low capsular contracture rate plus high capsule quality.[7, 9]

Implant pocket with optimised flexibility

The flexibility properties of TiLOOP® Bra Pocket have been developed to meet the physiological demands of shoulder movements and ptosis.

Free choice of implant

TiLOOP® Bra Pocket can be used regardless of the implant shape and surface.

Range of uses

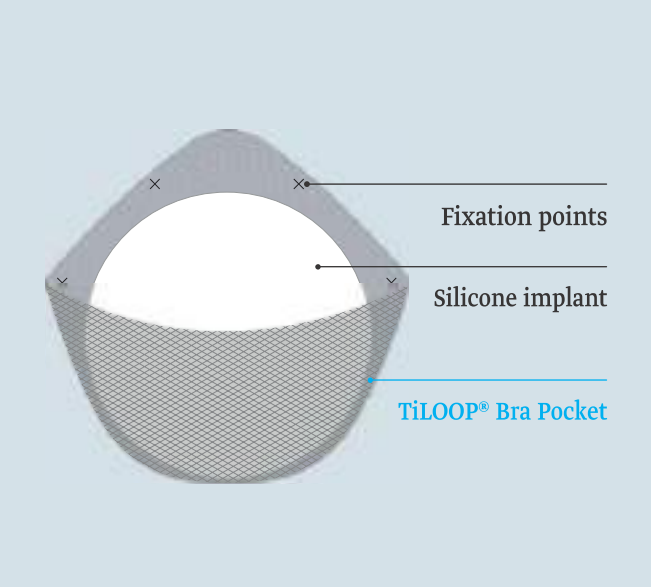
TiLOOP® Bra Pocket can be used in reconstructive breast surgery where the prepectoral placement of tissue-supporting, reinforcing and bridging materials is indicated.

- **Reconstructive breast surgery:** implant-based reconstruction (including with expander), e.g. skin-sparing or nipple-sparing mastectomy

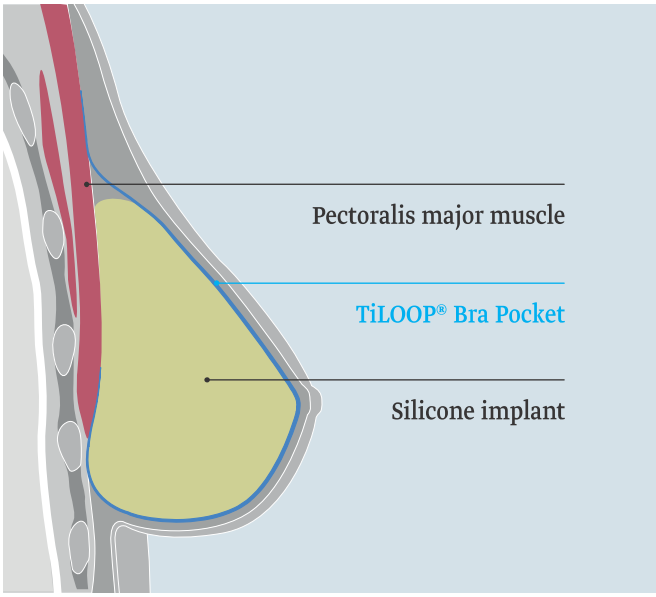
Application

Recommended implantation procedure

TiLOOP® Bra Pocket is fixed on the fascia of the pectoralis major muscle or directly on the muscle itself. The front surface of the implant facing the skin is completely covered with mesh material. Cranially, medially and laterally, TiLOOP® Bra Pocket is fixed prepectorally so as to prevent dislocation of the mesh and implant.



Recommended fixation points
View of the back of the mesh (resting against the thoracic wall)



Prepectoral position of the TiLOOP® Bra Pocket (ARTG ID: 503628)

Order data

TiLOOP® Bra Pocket (ARTG ID: 503628) ▸ Guide for selecting the mesh size

REF	Size	Width of implant	Implant projection height	Volume of implant	Weight	Qty
6001383	small	< 11.0 cm	< 4.5 cm	< 270 ml	16 g/m²	1
6001385	medium	< 13.0 cm	< 5.5 cm	< 420 ml	16 g/m²	1
6001387	large	< 15.0 cm	< 6.0 cm	< 550 ml	16 g/m²	1

TiLOOP® Bra (ARTG ID: 503627)

View

Range of uses

TiLOOP® Bra is used to support, strengthen and bridge the body's own tissue structures during aesthetic reconstructive breast surgery.

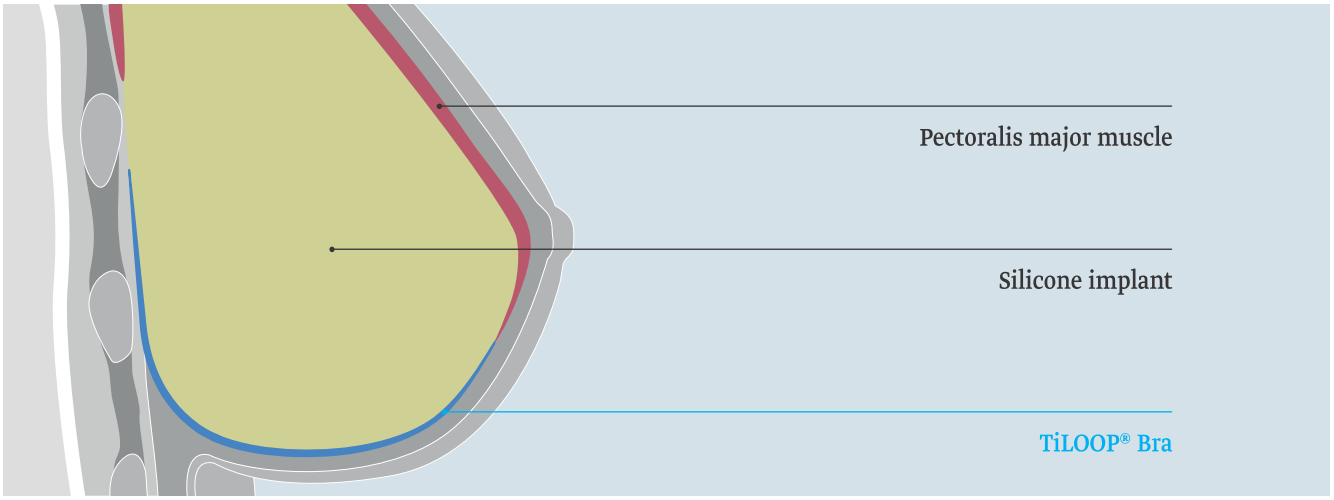
- Primary breast reconstruction, e.g. after skin-sparing or nipple-sparing mastectomy
- Secondary breast reconstruction

Versatile

TiLOOP® Bra can be used for primary or secondary breast reconstruction. The use of an expander is also possible.

Application

In implant-based subpectoral breast reconstruction with permanent implant or expander, TiLOOP® Bra is used as an extension of the pectoralis major muscle. TiLOOP® Bra covers the caudal pole of the breast implant and fixes it at the same time. The pectoralis major muscle is protected from cranial movement.

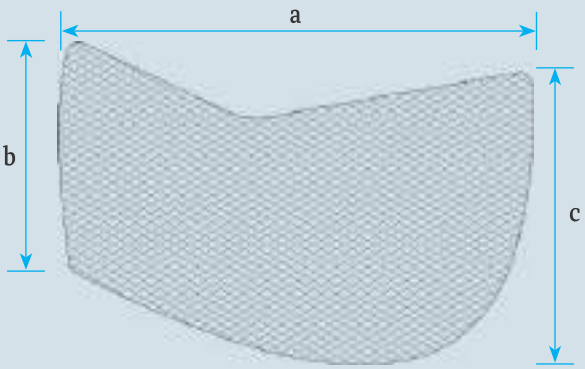


Subpectoral position of TiLOOP® Bra (ARTG ID: 503627)

Dimensions

TiLOOP® Bra (ARTG ID: 503627)

small 19.6 cm / **medium** 21.5 cm / **large** 23.6 cm



small 9.5 cm
medium 11.5 cm
large 13.5 cm

small 12.0 cm
medium 14.0 cm
large 16.0 cm

Order data

TiLOOP® Bra

REF	Size	Weight	Qty
6000636	small	16 g/m²	1
6000637	medium	16 g/m²	1
6000638	large	16 g/m²	1

Literature

1. Scheidbach et al., In vivo studies comparing the biocompatibility of various polypropylene meshes and their handling properties during endoscopic total extraperitoneal (TEP) patchplasty: an experimental study in pigs. Surg Endosc, 2004, 18(2): 211-220
2. Gentile et al., Titanium-coated polypropylene mesh as innovative bioactive material in conservatives mastectomies and pre-pectoral breast reconstruction. Bioact Mater, 2021, 6(12): 4640-4653
3. Thill et al., Patient reported outcome and cosmetic evaluation following implant based breast-reconstruction with a titanized polypropylene mesh (TiLOOP® Bra): A prospective clinical study in 269 patients. Eur J Surg Oncol, 2020;46(8): 1484–1490
4. Casella et al., Nipple-sparing bilateral prophylactic mastectomy and immediate reconstruction with TiLoop® Bra mesh in BRCA1/2 mutation carriers: A prospective study of long-term and patient reported outcomes using BREAST-Q. Breast, 2018, 39: 8-13
5. Casella et al., Evaluation of prepectoral implant placement and complete coverage with TiLoop Bra Mesh for breast reconstruction: a prospective study on long term and patient reported BREAST-Q outcomes. Plast Reconstr Surg, 2019, 143(1): 1e-9e
6. Quah et al., Veritas in Immediate Implant-based Breast Reconstruction Is Associated with Higher Complications Compared with TiLOOP. Plastic and Reconstructive Surgery - Global Open, 2019, 7(12): e2533
7. Scheidbach et al., Influence of Titanium Coating on the Biocompatibility of a Heavyweight Polypropylene Mesh. Eur Surg Res, 2004, 36: 313-317
8. Horstmann et al., Impact of polypropylene amount on functional outcome and quality of life after inguinal hernia repair by the TAPP procedure using pure, mixed, and titanium-coated meshes. World J Surg, 2006, 30(9): 1742-1749
9. Casella et al., TiLOOP® Bra mesh used for immediate breast reconstruction: comparison of retropectoral and subcutaneous implant placement in a prospective single-institution series. Eur J Plast Surg, 2014, 37(11): 599-604
10. Bernini et al., Subcutaneous Direct-to-Implant Breast Reconstruction: Surgical, Functional, and Aesthetic Results after Long-Term Follow-Up. Plast Reconstr Surg Glob Open, 2016, 3(12): e574
11. Casella et al., Subcutaneous Tissue Expander Placement with Synthetic Titanium-Coated Mesh in Breast Reconstruction: Long-term Results. Plast Reconstr Surg Glob Open, 2016, 3(12): e577

Links

Workshops
www.pfmmedical.com/meshworkshops

Videos
www.pfmmedical.com/meshvideos

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ARTG ID: 503627 (TiLOOP Bra)

ARTG ID: 503628 (TiLOOP Bra Pocket)

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