




Nipple-Areola Complex Reconstruction Implant

Enhancing the standard of care for a
Total Breast Reconstruction™

| A Confident Choice for Life™

A close-up, profile photograph of a woman with long, straight blonde hair. She is looking upwards and to the left with a gentle, confident expression. The lighting is soft, highlighting the contours of her face and shoulder. The background is a neutral, textured brown.



GC Aesthetics®

A Confident Choice for Life™

GC Aesthetics® is committed on being a reliable partner in Breast Reconstruction for patients and surgeons, **raising and enhancing the current standard of care by integrating and developing solutions** that are designed to support the best outcome for women undergoing immediate and delayed breast reconstruction surgery.

The importance of the positive psychosocial benefits of breast reconstruction in breast cancer treatment has been recognized now, more than ever¹. Many women who undergo breast reconstruction report feeling “whole” again and highly recommend it to other women facing a similar decision².

At GCA® we believe a **Total Breast Reconstruction™** is not only a choice, but **a pathway for women to a full recovery after a mastectomy**. We are committed to deliver safe options that establish a newer, higher, **and more beneficial standard of care** for women who seek to recover their breast and nipple shape, look, and feel.

GC Aesthetics® your partner in Breast and Nipple Reconstruction, with a complete, reliable and safe portfolio.



Nipple-Areola Complex

An essential part of breast reconstruction

Following the mastectomy procedure, breast reconstruction procedures are often performed.¹ Nipple-Areola Complex (NAC) reconstruction and tattooing represent the final two stages of breast reconstruction.³

The NAC reconstruction procedure is often overlooked, and it is currently considered an unmet need.⁴ However, **it should be considered an integral part of the breast reconstructive surgery.** It gives women an important psychological contribution to the breast reconstruction procedure and leads a greater well-being overall sense of self by increasing sexual behaviour and high satisfaction after being reconstructed⁵.

Various studies have demonstrated a correlation between **patient satisfaction** with breast reconstruction and the presence of a nipple and areola, helping combat the psychological consequences of a breast cancer diagnosis.^{5,6}



Presenting

FixNip™ NRI

A one-of-a-kind nipple implant for women who have undergone breast reconstruction

Until now, surgical techniques for nipple and areola reconstruction lose a degree of projection over time.⁴ Mainly, because soft tissues tend to shrink when no tension is applied. Due to this phenomenon, the reconstructed nipple shrinks and loses projection over time when done with local skin flaps, composite grafts and nipple sharing, or a combination of these techniques. Besides, complications include not only the loss of projection, but nipple flattening, necrosis, and low patient satisfaction.⁴

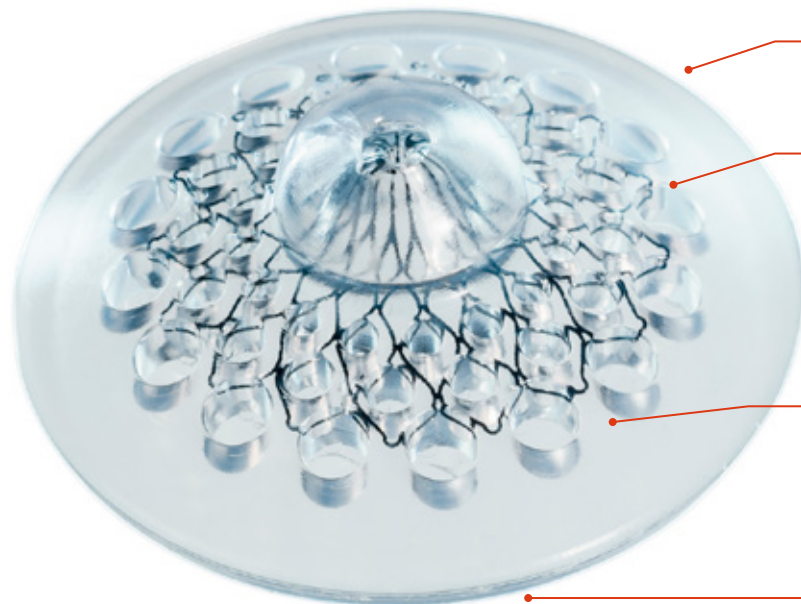
A variety of techniques are currently used but none has yet to provide an aesthetic solution for a long period.⁴

FixNip™ NRI is a safe, permanent aesthetic alternative to support soft tissue where weakness exists, offering long-lasting projection⁴ and NAC reconstruction at the final surgical step of breast reconstruction.



Designed for long-lasting projection of the Nipple-Areola Complex⁸

FixNip™ NRI is the **innovative** biocompatible⁷ smooth silicone implant especially designed for a **long-lasting projection⁸ of the Nipple-Areola Complex.**



Smooth, biocompatible silicone⁷

Floral shaped nitinol frame⁸

The nitinol frame allows a minimal incision, as it is key to recover the original shape of the implant when it is folded and inserted and also provides softness in response to pressure⁷.

Perforated silicone shell⁸

The perforated silicone capping allows a rapid integration and fixation to adjacent tissue, avoiding rotation or displacement⁸.

A stable platform for the nipple structure⁸



Design and structure for a softer feel
and natural appearance.

Flexibility, Softness and Projection

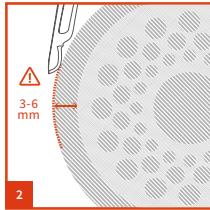
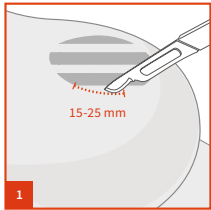
Where you need it most

The nitinol and biocompatible⁷ silicone are the optimal combination for increased performance.

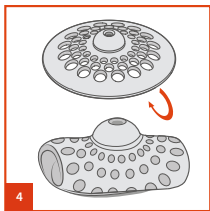
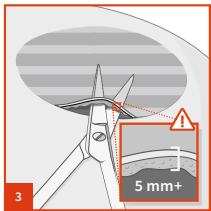
- The nitinol scaffold mechanical structure is flexible, allowing a minimal incision.⁸
- The floral design and mechanical structure help mimic the softness and flexibility of the original tissue.⁸
- It acts a nipple projection stabilizer maintaining the projection part in a stable position post implantation.⁸
- The nipple stabilization effect allows a shorter surgical procedure since no additional flaps at the base are needed to support it.⁸
- The silicone shell serves as an additional pressure absorber maintaining a soft touch, yet firmness of the reconstructed nipple when skin tension increases.⁸
- The biocompatible perforated smooth shell allows tissue ingrowth that can avoid rotation and displacement.⁸

How does it work?

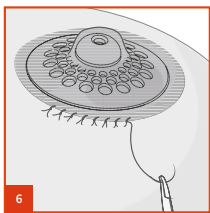
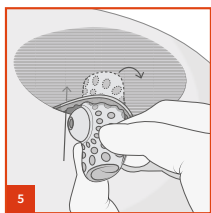
Implantation Steps¹⁰



An incision is made in the skin.



A subcutaneous precise pocket is created, and the implant is inserted.



The FixNip™ NRI is placed in the sub-cutaneous fat layer and the incision is sutured closed.



Minimally invasive⁹

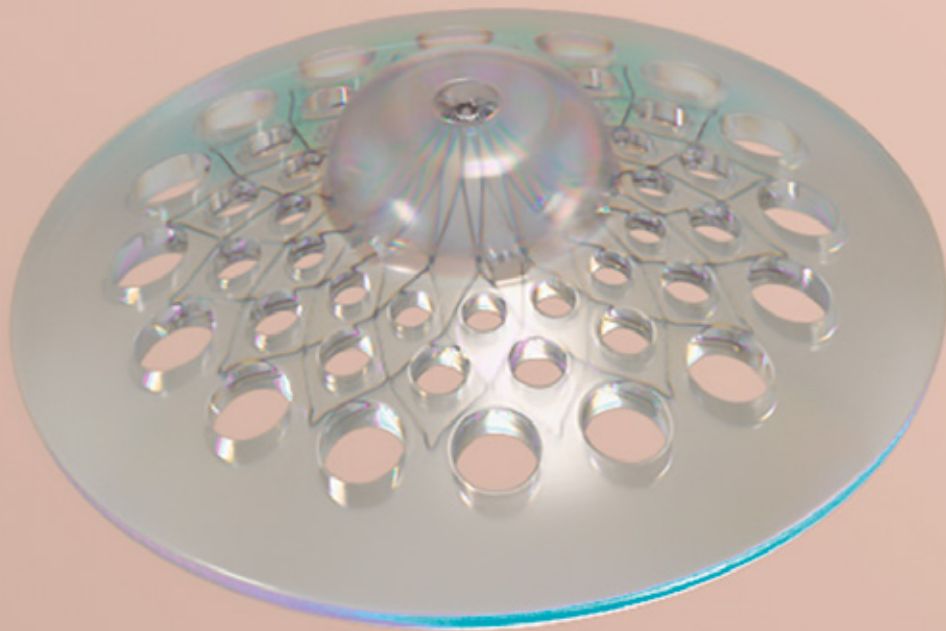
Surgical subcutaneous procedure with local anaesthesia^{9,10}

An office based procedure^{8,9}

Performed on average in 15 minutes or less⁹

Easy to use⁹

And immediate high-patient satisfaction^{8,9}



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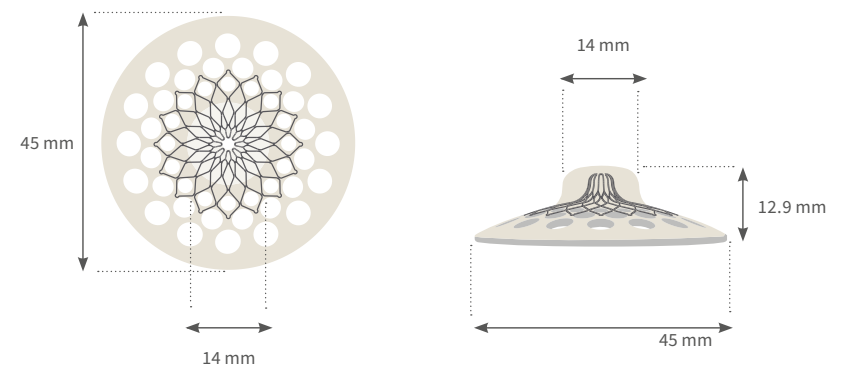
ISO 13485:2016 certified
(mdc medical device certification GmbH)

ixnip

The FixNip™ NRI is implanted by a trained physician to support soft tissue where weakness exists during nipple reconstruction procedure. It is provided sterile, intended for a single use and cannot be re-sterilized.

Important considerations

- Nipple and areola complex reconstruction should only be undertaken after achieving a stable breast mound, and once chemotherapy and radiation treatments are completed.¹⁰
- Breast reconstruction should be well healed before placing FixNip™ NRI. At least 6 months should have passed.¹⁰
- For patients who had been irradiated in the same breast/chest region, consider waiting to implant the device for at least 1 year following their final treatment.¹⁰
- Tissue at the implant site should be adequately thick (at least 1.0 cm), soft and pliable before implanting the device.¹⁰





The final surgical step For Total Breast Reconstruction™

Nipple-Areola Complex Reconstruction Implant

1. Minimally invasive, an office-based procedure.⁹
2. Subcutaneous pocket, under local anaesthesia.⁹
3. Easy to use.⁹
4. Performed on average in 15 minutes or less.⁹
5. MRI compatible.^{8,10}
6. Excellent safety profile: 0% device related adverse events.⁹
7. Less patient anxiety and less overall risk.¹¹
8. Minimum downtime, supports return to normal activities after intervention.⁹
9. High and immediate patient satisfaction.¹¹
10. Tested successfully in different patient profiles: patients with breast implants, expanders, flaps (PAP, DIEP, latissimus dorsi...), lipofilling and a combination of those, and in both non-irradiated and irradiated patients.⁹

Give your patients the gift of Total Breast Reconstruction™ by GC Aesthetics®

Covered by the GCA Comfort Plus™ Warranty.



For more information visit :
gcaesthetics.com/comfort-plus-warranty



FixNip™ NRI is Manufactured by FixNip LTD, Medical Device Company based in Israel, the FixNip™ NRI is CE Approved and licensed for sale and distribution to GC Aesthetics® in selected regions.





GC Aesthetics® A Confident Choice for Life™

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