



# FixNip™ NRI

## Clinical Studies

---



A Confident Choice for Life™





# GC Aesthetics®

## Total Breast Care™ Company

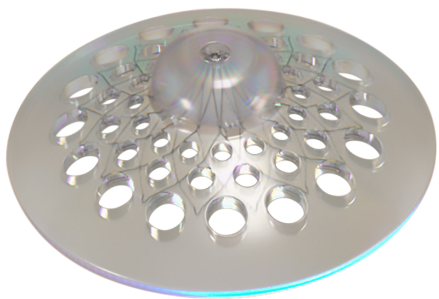
GC Aesthetics® is an established global medical device company focused on Aesthetic, Revision and Reconstruction procedures.

Much more than a European manufacturer of high-quality implants, we are proud to support our surgeons and patients by integrating and developing solutions that are designed to support the best outcome for women’s breast enhancement journey.

+40	+70	MDR	10Y	17Y	100%
Years of expertise in Aesthetic and Reconstructive surgery <sup>1</sup>	Countries world-wide with GCA® Products <sup>2</sup>	First breast implant on the market under the latest regulations (Luna XT™) <sup>3</sup>	Prospective and multicentric long-term proven safety data <sup>4</sup>	Extended long-term high patient satisfaction data <sup>5</sup>	Designed and manufactured in Europe <sup>1</sup>

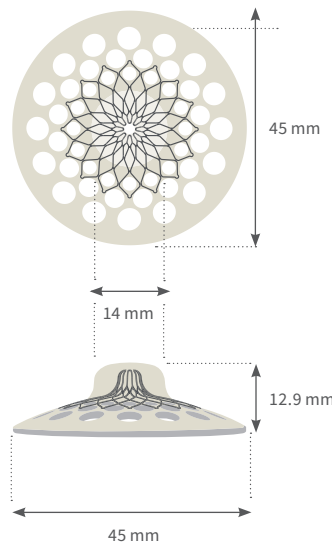
## About FixNip™ NRI

FixNip™ NRI is the innovative biocompatible<sup>6</sup> smooth silicone implant specially designed for a long-lasting projection<sup>7</sup> of the Nipple-Areola Complex (NAC).



### Main features:

- Minimally invasive, an office-based procedure<sup>8</sup>.
- Subcutaneous pocket<sup>8</sup>.
- Easy to use. Performed on average in 15 minutes or less<sup>8</sup>.
- MRI compatible<sup>6,9</sup>.
- Has low complication rates and noted device related adverse events<sup>8</sup>.
- Patients are relieved to see their breast fully reconstructed<sup>10</sup>.
- Minimum healing time: Procedure can be performed under local anaesthesia supporting return to normal activities<sup>8</sup>.
- High patient satisfaction levels in terms of aspect and Feel/Touch<sup>10</sup>.
- Tested successfully in different patient profiles: patients with breast implants, expanders, flaps, lipofilling and a combination of those, and in both techniques non-irradiated and irradiated patients<sup>10</sup>.







*“As a team, we are proud to be part of a project that plays an important role in enhancing the well-being of women. The FixNip™ NRI is an advanced solution which enable the surgeon to support women in reclaiming their sense of femininity and self-esteem. The combination of technical skill and compassion is at the heart of this work, ensuring that each woman’s journey toward recovery is as positive and empowering as possible.”*

**Cosmo Maurizio Ressa**  
**Daniela Anna Cutrignelli**  
**Andrea Armenio**  
**Valerio De Santis**

Department of Plastic Surgery, Cancer Research Institute  
 “Giovanni Paolo II”, Bari, Italy.

# Nipple–Areola Complex Reconstruction Using FixNip™ NRI Implant after Mastectomy: An Innovative Technique

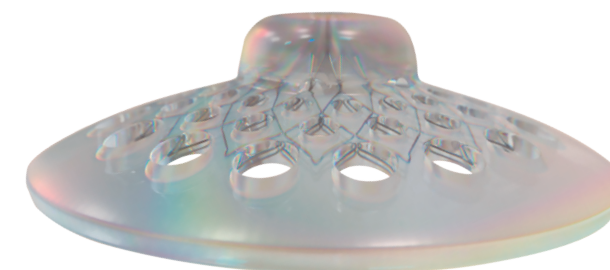
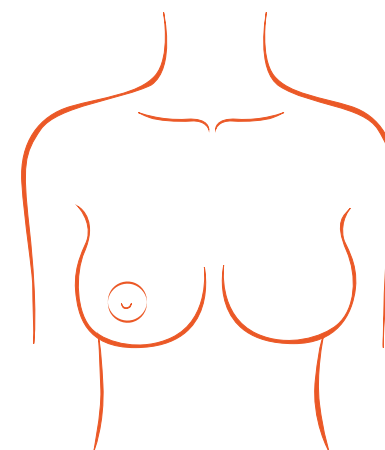
High patient satisfaction and satisfactory aesthetic outcomes

## Introduction

Nipple–areolar complex reconstruction is the final stage of breast reconstruction, and it improves quality of life in patients with post-mastectomy breast cancer.

Breast cancer treatment includes a total or partial mastectomy followed by breast reconstruction. The latter represents a series of clinical, surgical and psychological processes that involve patients in every aspect of the emotional and health sphere.

An innovative NAC prosthesis called FixNip™ NRI has been developed for aesthetic improvement of the female nipple with softer feel and natural appearance. It is an implantable solid hypodermic implant intended to be placed under the skin.




Iacovelli S, De Palma G, De Santis V, Cutrignelli DA, Armenio A, Bove S, Comes MC, Fanizzi A, Vitale E, Massafra R, Ressa CM. Nipple-Areola Complex Reconstruction Using FixNip NRI Implant after Mastectomy: An Innovative Technique. Aesthetic Plast Surg. 2024 Oct 4. doi: 10.1007/s00266-024-04418-y. Epub ahead of print. Erratum in: Aesthetic Plast Surg. 2024 Oct 30. doi: 10.1007/s00266-024-04492-2. PMID: 39367231.


# Publication Objective

This study presents a case of a breast cancer patient who underwent breast reconstruction and subsequent nipple-areolar complex reconstruction using an innovative biocompatible smooth silicone implant, FixNip™ NRI, to evaluate the aesthetic outcomes, particularly the long-lasting restoration of the nipple-areola complex and patient satisfaction.


## Main goals:




**Patient Satisfaction**




**Aesthetics outcomes**



**Evolution of the nipple morphology**



**Long lasting Restoration**



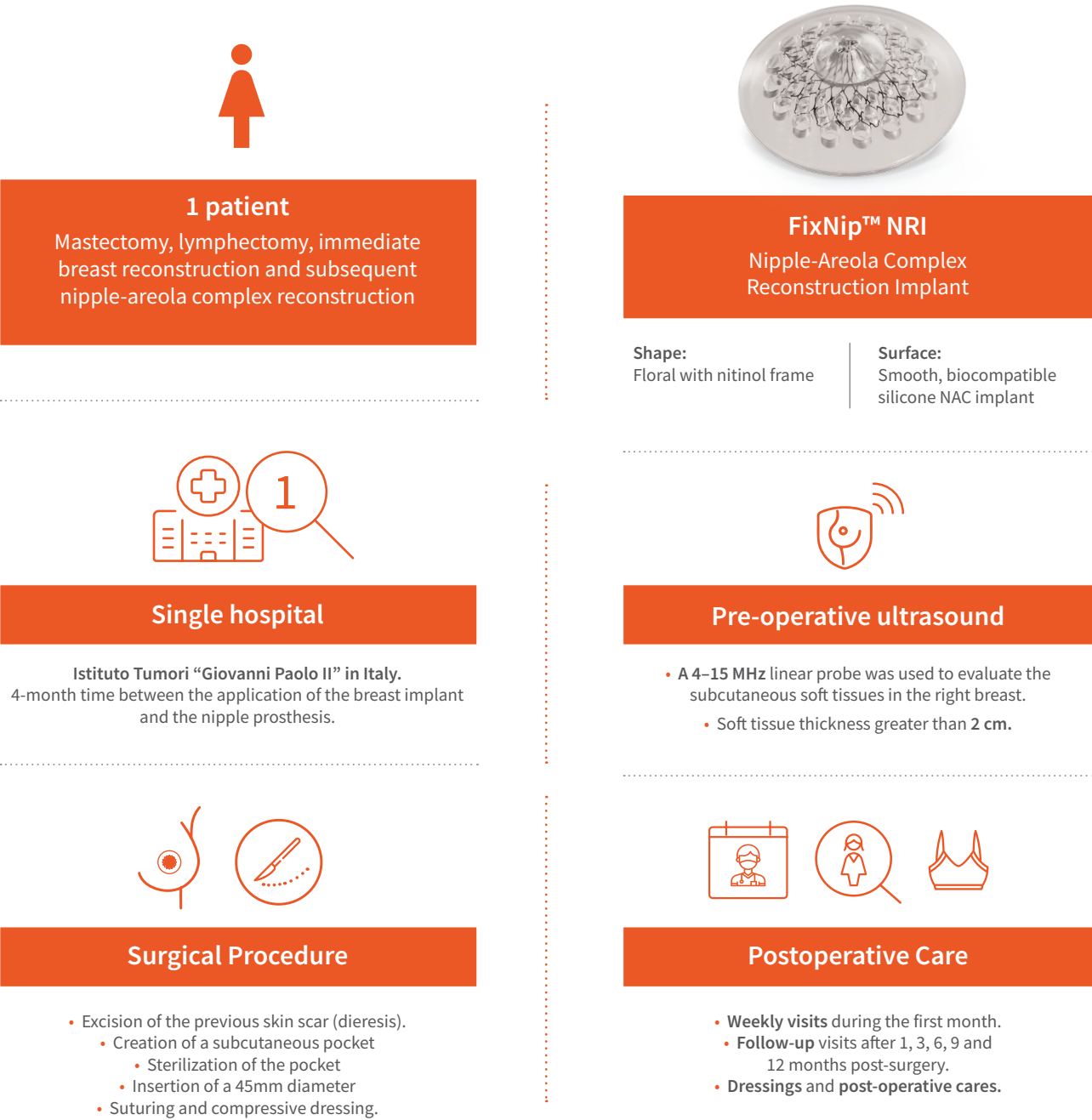
**Complication assessment:**  
Fibrous capsule, Infections  
other complications

## Key findings of the study:

- Highly predictable outcome.
- Average 17 years follow-up. Extended long-term data available for breast implants.
- Follow-up: First 30 days after NAC prosthesis application.
- First 15 days: White skin with slight elevation and poorly defined nipple.
- After 15 days: Reddening of the skin, hyper-projection of the nipple, better definition of morphology, and skin thickening.
- Patient report: No short- or long-term complications.
- No pain or inflammation: Except for slightly reddened skin in the central NAC area until 6 months post-surgery.
- 6 months post-surgery: Implant remains in place with fibrous capsule formation and fibrous bridges between the anterior and posterior surfaces of the device.
- Postoperative care: Patient received antibiotic prophylaxis with amoxicillin and clavulanic acid.

# Study Methodology

- A retrospective study was undertaken of a 59-year-old woman diagnosed with right breast carcinoma, who underwent mastectomy, lymphectomy, and immediate reconstruction with a breast expander in May 2019.
- In June 2022, the expander was replaced with a 390 cc prosthesis, following a gradual expansion process over about a year.
- In October 2022, a FixNip™ NRI implant was used for NAC reconstruction. The procedure was performed successfully without complications.



# Results

FixNip™ NRI's is a definitive aesthetic alternative to support soft tissue where it is weak, offering durable projection and allowing reconstruction of the areola–nipple complex during the final surgical phase of breast reconstruction.



**No complications**

No pain, inflamtion or long-term issues, only redness in the NAC center



**Permanent results  
After single  
implantation**



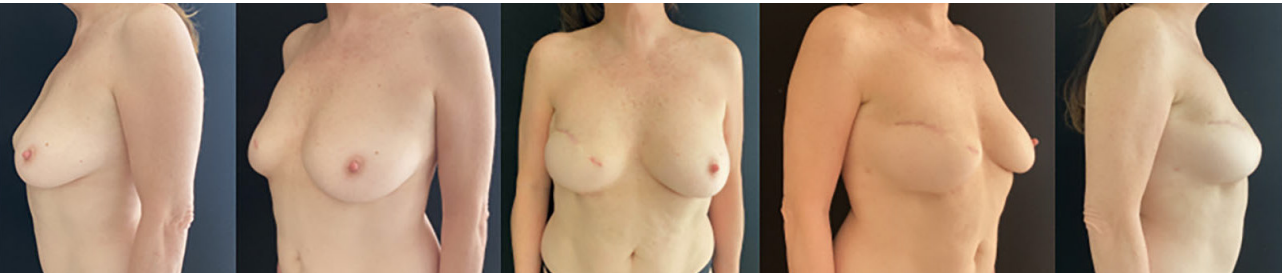
**Aesthetic  
Solution**



**High patient satisfaction  
and long lasting  
projection**

## Before and after pictures

Photographs at 12 months postoperative FixNip™ NRI prosthesis implantation. Full bilateral breast view.



Before



After

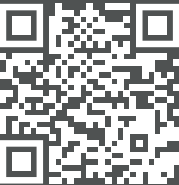
# Conclusions

The FixNip™ NRI implant provides a stable, long-lasting solution for nipple-areola complex (NAC) reconstruction, with improved nipple projection and definition over time. Postoperative follow-ups showed no major complications, only mild redness at the NAC center. The implant's permanent results and durability make it a superior option compared to autologous reconstructions. Overall, FixNip™ NRI offers a reliable, aesthetic solution for long-term NAC restoration.

## Nipple–Areola Complex Reconstruction Using FixNip™ NRI Implant after Mastectomy: An Innovative Technique

High patient satisfaction and satisfactory aesthetic outcomes

Lead by Dr. Maurizio Ressa. Plastic and Reconstructive Surgery. Bari. Italy.



Scan to read  
the original study



# GC Aesthetics®

## A Confident Choice for Life™

GC Aesthetics®, registered in Ireland with number 466501. Registered office: Suite 601, Q House, Furze Road, Sandyford Industrial Estate, Dublin 18, Ireland.  
© 2025 GC Aesthetics®. A50-429.

For more information about our products please visit: [gcaesthetics.com](https://gcaesthetics.com)  
or email: [info@gcaesthetics.com](mailto:info@gcaesthetics.com)

GC Aesthetics® is a registered trademark of Global Consolidated Aesthetics.



---

### References:

1. GC Aesthetics®, Data on file. 2024
2. Data on file, GC Aesthetics®, Countries Sales Report, 2025
3. BSI, EU Technical Documentation Assessment Certificate, MDR 746961 R000. 2022-09-24
4. Duteille F, Perrot P, Bacheley MH, Bell E, Stewart S. Ten-Year Safety Data for Eurosilicone's Round and Anatomical Silicone Gel Breast Implants. Aesthet Surg J Open Forum. 2019;1(2):ojz012. Published 2019 Apr 27.
5. Kooiman L, Torensma B, Stevens H, van der Lei B. Single Center and Surgeon's Long-Term (15-19 Years) Patient Satisfaction and Revision Rate of Round Textured Eurosilicone Breast Implants. Aesthet Surg J. 2022;42(5):NP282-NP292.
6. FixNip LTD. Internal data, 2021. Biocompatible test.
7. FixNip LTD. Internal data, 2022.
8. GC Aesthetics®, Internal Data. Product Trial, 2022.
9. FixNip™ NRI. Instructions for use. 2022.
10. GC Aesthetics® Patient Video Testimonials, April 2022. Internal Data.

FixNip™ NRI is manufactured by FixNip Ltd.

