



FixNip™ NRI

Clinical Studies



A Confident Choice for Life™



GC Aesthetics®

Total Breast Care™ Company

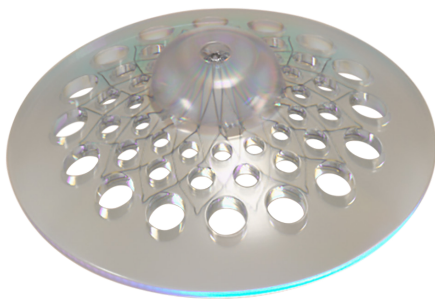
GC Aesthetics® is an established global medical device company focused on Aesthetic, Revision and Reconstruction procedures.

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 ¹	Countries world-wide with GCA® Products ²	First breast implant on the market under the latest regulations (Luna XT™) ³	Prospective and multicentric long-term proven safety data ⁴	Extended long-term high patient satisfaction data ⁵	Designed and manufactured in Europe ¹

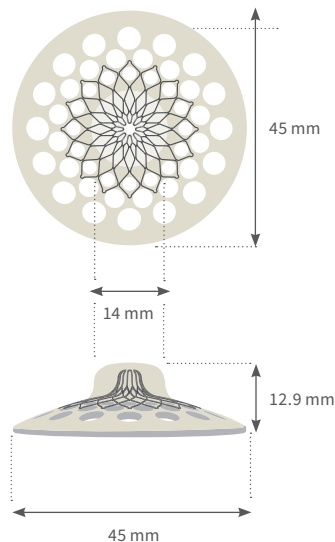
About FixNip™ NRI

FixNip™ NRI is the innovative biocompatible⁶ smooth silicone implant specially designed for a long-lasting projection⁷ of the Nipple-Areola Complex (NAC).



Main features:

- Minimally invasive, an office-based procedure⁸.
- Subcutaneous pocket⁸.
- Easy to use. Performed on average in 15 minutes or less⁸.
- MRI compatible^{6,9}.
- Has low complication rates and noted device related adverse events⁸.
- Patients are relieved to see their breast fully reconstructed¹⁰.
- Minimum healing time: Procedure can be performed under local anaesthesia supporting return to normal activities⁸.
- High patient satisfaction levels in terms of aspect and Feel/Touch¹⁰.
- 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 patients¹⁰.





“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

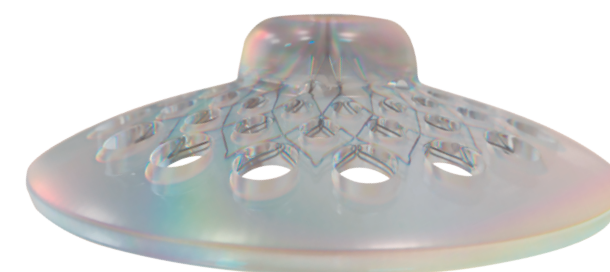
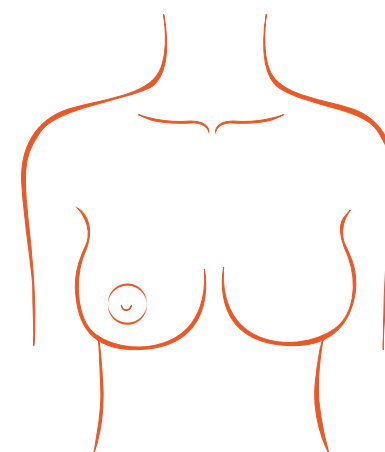
High patient satisfaction and satisfactory aesthetic outcomes

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

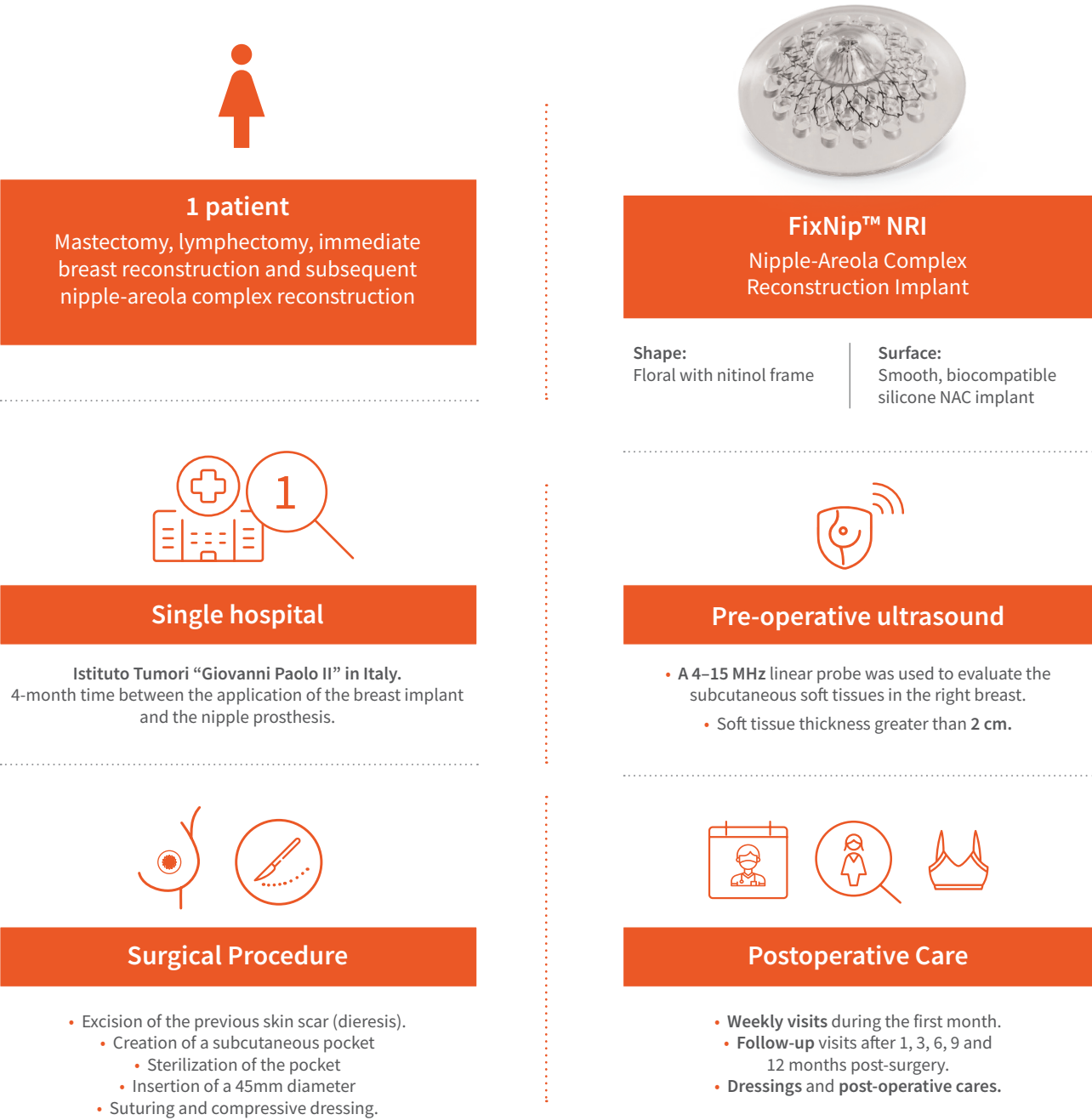
Complication assessment:
Fibrous capsule, Infections
other complications

Key findings of the study:

- Highly predictable outcome.
- 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**



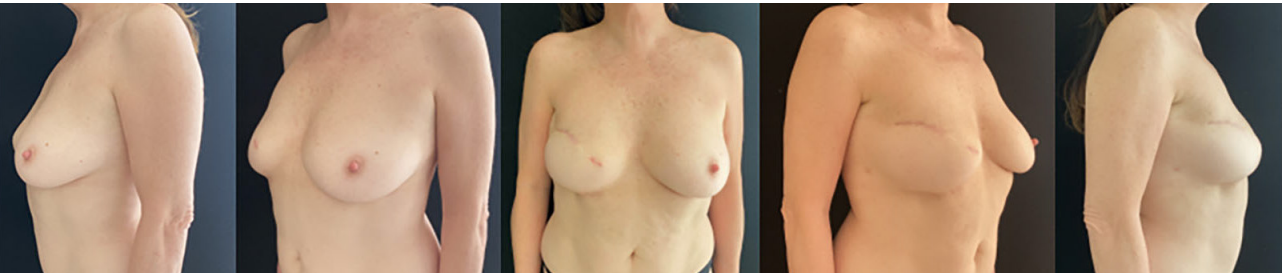
**Aesthetic
Solution**



**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

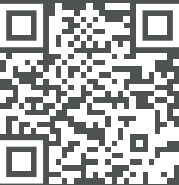
Conclusions

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.



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the original study



*“FixNip™ NRI: bringing happiness to life
with a simple surgical procedure”*

Professor Michele Riccio

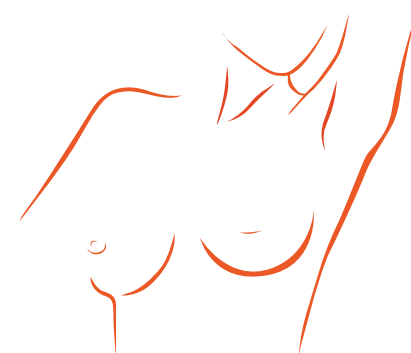
Direttore Dipartimento delle Chirurgie Specialistiche.
Direttore UOC Chirurgia Ricostruttiva e Chirurgia della Mano.
Azienda Ospedaliero Universitaria delle Marche.
Presidente SICM - Società Italiana di Chirurgia della Mano.

Innovations in Nipple-areolar Complex Reconstruction: Evaluation of a New Prosthesis

A Promising Reconstructive Option: Safety, Satisfaction,
and Accessibility in Breast Reconstruction

Introduction

The reconstruction of the nipple-areola complex (NAC) is essential for completing breast restoration and achieving patient satisfaction. However, surgical reconstruction or tattooing may not always be viable or preferred for all patients. There is no universal method ideal for every patient or clinical situation, and many techniques fail to maintain projection over time. Over the years, various techniques, including the C-V flap, have been perfected to improve and support projection in patients with bilateral implant-based reconstructions.



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.



- Smooth, biocompatible silicone¹⁶
- Floral shaped nitinol frame¹⁹
- Perforated silicone shell¹⁹
- A stable platform for the nipple structure¹⁹

Riccio M, Aquinati A, Fordellone M, Carboni N, Marchesini A, De Francesco F. Innovations in Nipple-areolar Complex Reconstruction: Evaluation of a New Prosthesis. *Plast Reconstr Surg Glob Open*. 2025 Jan 10;13(1):e6410. doi: 10.1097/GOX.0000000000006410. PMID: 39802274; PMCID: PMC11723670.

Publication Objective

This study pretends to evaluate the use of prosthetic devices for nipple-areola complex (NAC) reconstruction following breast reconstruction surgery. The study aims to assess the safety, ease of implantation, and patient satisfaction with these prosthetic devices, as an alternative to traditional surgical methods or tattooing, which may not be preferable or feasible for some patients. By using a survey to collect data on a 1-year follow-up, the study seeks to determine how the prosthetics impact appearance, body self-image, and self-regard, and whether they provide a safe, noninvasive, and affordable reconstructive option for patients seeking to restore the NAC post-reconstruction.

Main goals:



Patient Satisfaction



Psychosocial well-being



Sexual well-being



Safety



Complication assessment

Study Methodology

- The study involved the implantation of a NAC prosthetic device in 40 patients undergoing breast reconstruction.
- The procedure was performed in an outpatient setting.
- The prosthetic device was implanted into the subcutaneous layer after irrigating the surgical pocket and inserting the implant.
- A protective dressing was applied after surgery, which was changed after one week.
- Patients underwent ultrasound evaluations to measure skin thickness before and after surgery.
- A satisfaction questionnaire (BREAST-Q) was used to assess:
 - Aesthetic satisfaction.
 - Device tolerance.
 - Any adverse reactions.
 - Statistical analysis compared pre- and post-operative results.

Study Methodology



40 patients

Underwent immediate or delayed breast reconstruction following mastectomy with NAC excision, including those with bilateral NAC excision.



Single hospital

Azienda Ospedaliera Universitaria delle Marche in Italy.
1 year patient follow-up



Surgical Procedure

- 2 cm incision made along mastectomy scar.
- Subcutaneous pocket created and irrigated with modified Adams solution.
- FixNip prosthesis placed, and incision sutured.
- Protective dressing applied (Vaseline gauze, foam, occlusive film).
- Procedure done in outpatient clinic.
- Sutures removed 15 days post-op during office visit.



FixNip™ NRI


Nipple-Areola Complex Reconstruction Implant

Shape:

Floral with nitinol frame


Surface:

Smooth, biocompatible silicone NAC implant



Pre-operative ultrasound

- At 3, 6, and 12 months post-surgery, and before aesthetic tattooing.
- Skin thickness assessed in each ultrasound.
- Examinations conducted by the same experienced observer.



Breast-Q

Before and after surgery

(6 and 12 months)

Results

FixNip™ NRI promotes favourable outcomes that indicate a significant rate of safety and patient satisfaction. This product is straightforward, noninvasive, affordable medical device that deserves consideration as a reconstructive option for all patients seeking breast reconstruction, promoting full body integrity.



90%
patients

High satisfaction rates | body image, self-regard



4%
patients

Low satisfaction rates | Adverse skin reactions, infections or erosion

Before and after pictures



Bilateral FixNip™ NRI implant

1-year follow-up

1-year follow-up after tattooing.

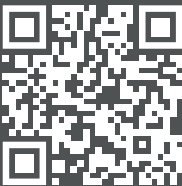
Conclusions

NAC reconstruction is key to postmastectomy recovery, boosting quality of life and self-esteem. FixNip™ NRI offers a customizable, minimally invasive option with high satisfaction. This innovative technique improves outcomes and reduce complications. Collaboration between patients and surgeons is essential for successful, personalized results, restoring both physical appearance and emotional well-being.

Innovations in Nipple-areolar Complex Reconstruction: Evaluation of a New Prosthesis

A Promising Reconstructive Option: Safety, Satisfaction, and Accessibility in Breast Reconstruction

Lead by Professor. Michele Riccio. Plastic, Aesthetics and Reconstructive Surgery. Ancona. Italy.



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FixNip™ NRI is manufactured by FixNip Ltd.

