Patient Information Leaflet FixNip NRI Nipple Reconstruction Implant

Dear Patient,

You receive this Patient Information Leaflet from your surgeon, as you have expressed an interest in nipple reconstruction.

As with any surgical procedure, potential complications may occur in association with nipple reconstruction procedures with implants, as a result of individual health conditions, medication, surgical technique, and postoperative care. General risks, such as those related to anesthesia, medication and infection, are general, and are present with any surgical procedure.

There are alternatives for nipple reconstruction that do not include the use of implants. Your surgeon should inform you fully and comprehensively about the available procedures prior to your decision.

You should receive educational material, take time to think about this information, discuss it with your surgeon and ask questions, to make sure you have fully understood all the risks and benefits of each procedure. If you are not convinced, do not feel pressured to undergo any procedure.

At FixNip Ltd. we believe in providing comprehensive safety-related information to patients, your decision should be personal and informed. Please read this form carefully.

When making your final decision, consider both risks and benefits of breast surgery involving implants and the specific risk-benefit profile of implants. Your express and unconditioned decision in favor of nipple reconstruction with FixNip NRI implants must be recorded in the appropriate Informed Consent forms, provided to you by the surgery team in advance.

If you opt for nipple reconstruction with FixNip NRI implants, after the procedure you will receive from your surgeon an Implant Card, with the identification of your implants and our contact information, in case of enquiries or to report an issue. Please always keep this document safely with you.

After nipple reconstruction surgery, it is important that you follow your surgeon’s recommendations, and that you undergo regular check-ups. If you experience swelling, aesthetic changes, pain, or other concerns, contact your surgeon immediately.

We wish you all the best in this journey, whatever direction you choose.

The FixNip Ltd. Team

Device Overview

Device Name: FixNip NRI

Intended Use: FixNip NRI is intended for nipple reconstruction in patients who have undergone mastectomy with removal of the nipple or nipple-areolar complex (NAC).

The implant should only be placed by a trained physician familiar with nipple reconstruction procedures.

Who is the Intended Patient Population?

FixNip NRI is intended for patients who have undergone mastectomy with removal of the nipple or nipple-areolar complex (NAC) and are seeking nipple reconstruction.

Your surgeon will assess your medical history, the condition of the tissue at the intended implantation site, and other relevant factors to determine whether the FixNip NRI implant is appropriate for you.

About the Device

The FixNip NRI, the Nipple Reconstruction Implant, is an implantable subcutaneous, silicone implant designed for nipple reconstruction. The implant contains a "floral-shaped" nitinol frame (a metal made of nickel and titanium) that is embedded within medical-grade silicone (Figure 1).

FixNip NRI is intended to be implanted in the subcutaneous tissue (the layer of tissue just beneath the skin).

FixNip NRI is provided sterile and is intended for single use only.



Figure 1: FixNip NRI – Nipple Reconstruction Implant

What is our implant made of?

The FixNip NRI Implant is made of:

- **Nitinol** - a metal made from nickel and titanium that is commonly used in medical devices,
- **Medical-grade silicone** – a type of silicone that is widely used in medical implants designed to remain in the body.

Important information about implant materials

FixNip NRI contains nitinol, an alloy of nickel and titanium, and medical-grade silicone.

The implant may also contain trace amounts of residual chromium materials, which may cause an allergic reaction in sensitive individuals.

Inform your surgeon if you have any known allergies or sensitivities to implant materials.

Regulatory Information

The device is CE-marked for the European market and is licensed by Health Canada for its approved intended use.

The applicable regulatory status and approved indications may vary by country.

Contraindications

You should **not receive the FixNip NRI implant** if any of the following apply to you:

- You have known sensitivity or allergy to nickel or titanium.
- You are currently pregnant or breastfeeding.
- The tissue thickness of the treated breast in the nipple area is less than 1.0 cm (10 mm).
- You have an active infection anywhere in your body

Inform your surgeon about your medical history, known allergies, current medications, and any medical conditions that may affect wound healing.

Your surgeon will determine whether the FixNip NRI implant is appropriate for you.

Note: FixNip NRI is contraindicated in patients who are pregnant or breastfeeding. No studies have been conducted to evaluate the performance of the implant in patients who are pregnant, may become pregnant, or are breastfeeding. Breastfeeding may not be feasible following FixNip NRI implantation.

Warnings and Precautions

- **Allergies and sensitivities:** Inform your surgeon about any known allergies or sensitivities, particularly to nickel, titanium, chromium, silicone, or other implant materials.
- **Tissue condition and thickness:** Adequate tissue thickness of at least 1.0 cm (10 mm) must be present at the intended implantation site. The tissue should be healthy, well-vascularized, soft, and pliable.

  Your surgeon will assess the tissue thickness and condition before implantation.
- **Previous radiation therapy:** If you have received radiation therapy to the same breast or chest region, your surgeon should consider waiting at least one year after completion of your final radiation treatment before implanting the device.

  Radiation therapy may affect tissue healing.
- **Medical conditions affecting wound healing:** Patients with a compromised immune system, including those with autoimmune diseases, diabetes, or those undergoing chemotherapy or radiation therapy, may experience impaired wound healing.

  Inform your surgeon about any relevant medical conditions or ongoing treatments.
- **Smoking:** Smoking may interfere with tissue healing and increase the risk of postoperative complications. Discuss smoking cessation with your surgeon before undergoing the procedure.
- **Existing breast implants or supportive materials:** The safety and performance of FixNip NRI when used in combination with different breast implant types or supportive materials, such as surgical mesh, have not been thoroughly evaluated due to limited clinical evidence.

  Inform your surgeon if you have existing breast implants or other implanted materials.

- **Tattooing:** You should wait at least six months after FixNip NRI implantation before undergoing tattooing of the reconstructed nipple. The timing of tattoo placement, the quality of tattooing instruments, and the tattooing technique may affect nipple projection.
- **Mammography:** Mammography should not be performed within two months following FixNip NRI implantation.

  Inform your healthcare provider that you have a FixNip NRI implant before undergoing breast imaging.
- **Pregnancy and breastfeeding:** FixNip NRI is contraindicated during pregnancy and breastfeeding. If you become pregnant after implantation or plan to breastfeed, consult your healthcare provider.

Possible Risks and Complications

Complications

As with any surgical procedure, nipple reconstruction with FixNip NRI may be associated with complications.

Potential complications may be related to the surgical procedure, the implant, or individual patient factors.

The following complications may occur during or after nipple reconstruction. This list is not exhaustive, and the occurrence and severity of complications may vary between patients.

Discuss the potential risks and benefits of the procedure with your surgeon before making your decision.

Potential Complications

Possible complications associated with the procedure or device may include:

- **Allergic Reaction to implant materials:** You may have an allergic response to materials used in the implant, which may cause itching, swelling, or redness. Please inform your healthcare provider of any known allergies.
- **Inflammation:** Redness, warmth, and swelling around the implant area may occur as part of the healing process. This may be temporary but should be monitored by your provider.
- **Implant Migration or displacement:** The implant may shift from its original position, which could affect its appearance and may require correction.
- **Implant Extrusion or Exposure:** The implant may push through the skin or become visible. This may require implant removal or other corrective procedures.
- **Seroma (fluid accumulation):** Fluid may collect around the implant, causing swelling. This may resolve on its own or may need to be drained by a healthcare provider.
- **Hematoma (blood collection):** A collection of blood near the implant, leading to swelling or pain. It may require medical attention.
- **Numbness:** You may experience a temporary or permanent loss of sensation around the implant area.
- **Paresthesia (tingling or prickling sensations):** Tingling or prickling sensations may occur due to minor nerve irritation. This may improve with time but can be persistent in some cases.
- **Infection:** Infection at the implant site can cause swelling, redness, and fever, which may require antibiotics or possibly implant removal.
- **Tissue Ischemia:** Reduced blood flow to the tissues around the implant can lead to pain or slow healing. Your healthcare provider will monitor your recovery to address this.
- **Localized Necrosis (tissue damage or tissue death):** Tissue around the implant may lose blood supply and die. This may require removal of affected tissue and extended healing time.

- **Epidermolysis (skin fragility or breakdown):** Fragile skin around the implant can sometimes become damaged. Special care may be needed for proper healing.
- **Skin Discoloration:** Changes in skin color around the implant may be temporary but could be permanent in some cases.
- **Induration (hardening of tissue):** Hardening or thickening of the skin or tissue around the implant may occur, which can feel uncomfortable
- **Palpation** (feeling) of exposed metal framework of the implant
- **Bleeding:** Bleeding can occur near the implant post-surgery, leading to swelling and discomfort.
- **Pressure-related skin injury or sores:** Prolonged pressure on the skin around the implant may cause sores, especially if the tissue is thin or fragile.
- **Skin Rupture or breakdown:** The skin over the implant may tear or break, requiring immediate medical care.
- **Capsular Contracture:** Scar tissue may form around the implant, causing it to feel firm, appear misshapen, or cause discomfort.
- **Implant Inversion (Flip Over):** The implant may turn or flip within the tissue, affecting its shape or appearance and potentially requiring adjustment.
- **Implant Folding:** The implant may crease or fold, which can impact its appearance and feel.
- **Discomfort/Unnatural Feeling:** Some patients may feel the implant more than others, which can feel unnatural. This sensation may decrease over time.
- **Pain:** Some pain around the implant area may occur after surgery or due to complications such as inflammation or infection.
- **Insufficient or Excessive nipple projection:** The size or shape of the reconstructed nipple may not be as expected. Further adjustments may be required.

If you experience any of these symptoms or have concerns about your recovery, please contact your surgeon.

MRI Safety Information - MR Conditional

The FixNip NRI implant is MR Conditional. This means that you may undergo an MRI examination, but only under specific conditions.

Before undergoing an MRI examination:

Inform your doctor and MRI staff that you have a FixNip NRI implant.

Present your Implant Card and the MRI safety information below to the MRI staff before your examination.

The MRI staff must review the specified conditions to determine whether the examination can be performed safely. Failure to follow these conditions may result in injury.

MRI Safety Conditions

Information to be presented to MRI personnel

1.5 Tesla and 3 Tesla MRI

Parameter	MRI Safety Condition
Static magnetic field	1.5 or 3 Tesla only
Maximum spatial gradient magnetic field	4,000 Gauss/cm (40 T/m) or less

Maximum whole-body averaged SAR	Less than 2 W/kg
Operating mode	Normal Operating Mode
Scanning duration	15 minutes per pulse sequence

The presence of other implants or the patient's health condition may require a reduction in the applicable MRI limits.

Under the conditions specified above, the FixNip NRI is expected to produce a maximum temperature rise of 1.5°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the implant extended approximately 5 mm from the device when imaged using a gradient echo pulse sequence and a 3-Tesla MRI system.

7 Tesla MRI – Important Limitations

The following conditions are specified for 7-Tesla MRI:

Parameter	MRI Safety Condition
Static magnetic field	7 Tesla only
Maximum spatial gradient magnetic field	5,000 Gauss/cm (50 T/m)

MRI testing at 7 Tesla was limited to the assessment of magnetic field interactions and image artifacts.

The evaluated MRI system had transmit/receive RF head and knee coils, but no transmit/receive RF body coil. The FixNip NRI is not implanted in the anatomical regions of the head or knee.

MRI-related heating has not been evaluated for the relevant body-coil application.

Therefore, the MRI team must consider these limitations before performing a 7-Tesla MRI examination. The listed magnetic field conditions alone do not establish the safety of scanning the implanted breast at 7 Tesla.

Important reminder for patients

Always inform healthcare professionals that you have a FixNip NRI implant before undergoing an MRI examination.

Keep your Implant Card and ensure that the MRI team has access to this Patient Information Leaflet before your examination.

What to Expect

- **Pre-Procedure Consultation:** Your surgeon will discuss your medical history and explain the procedure.
- **Placement Procedure:** The implant is inserted to achieve nipple shape and projection.
- **Post-Procedure Care:** Follow all care instructions, including any temporary restrictions on activity.

Note: The FixNip NRI is designed to support reconstructed nipple structure; however, individual results may vary.

Post-Implant Care and Follow-Up

Follow your surgeon's instructions regarding wound care and activity restrictions.

During the initial healing period, avoid direct pressure, excessive friction, or trauma to the reconstructed nipple, as directed by your surgeon.

Your surgeon may recommend temporarily avoiding sleeping on your stomach, wearing tight or compressive garments over the surgical site, strenuous upper-body activity, heavy lifting, or contact sports.

The duration of these restrictions will depend on your healing progress and your surgeon's recommendations.

Attend scheduled follow-up appointments to allow your surgeon to assess wound healing and the condition of the reconstructed nipple.

If you experience persistent pain, redness, swelling, drainage, fever, changes in the implant's appearance, or any other concerning symptoms, contact your surgeon promptly.

Your Implant Card

Following implantation, you will receive an Implant Card containing information that identifies your FixNip NRI implant.

The card provides important information about your implant, including its identification details and manufacturer information.

Keep your Implant Card in a safe and accessible location and present it to healthcare professionals whenever you receive medical treatment or undergo medical imaging.

The information on your Implant Card may be needed to identify your implant if you experience a device-related problem or require further medical treatment.

If your Implant Card is lost or damaged, contact your surgeon or healthcare provider to obtain the relevant implant identification information.

Frequently Asked Questions

Q: Will the implant interfere with future medical imaging?

A: The FixNip NRI is MR Conditional and may interfere with breast imaging modalities (such as ultrasound and MRI) and could obscure detection of breast cancer recurrence or breast implant rupture. Always inform healthcare providers that you have a FixNip NRI implant before undergoing imaging.

Q: How long is the expected lifespan of the implant?

A: The FixNip NRI is designed for long-term implantation. However, individual outcomes may vary.

Q: Can I engage in normal activities after recovery?

A: Once fully healed, you should be able to resume normal activities. Follow your healthcare provider’s guidance.

Manufacturer Information

Manufacturer:

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Reporting Adverse Events

If you experience pain, swelling, redness, changes in the appearance of the reconstructed nipple, or any other symptoms that may be related to your FixNip NRI implant, contact your surgeon or healthcare provider promptly.

If you experience a serious medical problem or require urgent medical attention, seek immediate medical care.

You may also report suspected device-related problems to the manufacturer using the contact information provided in this leaflet or on your Implant Card.

For patients in the European Union:

Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the competent authority of the EU Member State in which you reside.

For patients in Canada:

Suspected medical device-related problems may also be reported to Health Canada through its medical device problem-reporting system.