

TABLE OF CONTENTS

LIST OF ABBREVIATIONS.....	2
1. Device identification and general information	2
2. Intended use of the device.....	2
2.1. Intended purpose.....	2
2.2. Indications for use and target population.....	3
2.3. Contraindications and limitations	3
3. Device description	3
3.1. General device description.....	3
3.2. Previous generations and variants.....	4
3.3. Description of any accessories which are intended to be used in combination with the device	4
3.4. Description of any other devices and products which are intended to be used in combination with the device	4
4. Risks and Warnings.....	4
4.1. Residual risks and undesirable effects	5
4.2. Warning and precautions	5
4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN).....	6
5. Summary of Clinical Evaluation and Post Market Follow-up	6
5.1. Summary of clinical data related to equivalent device	6
5.2. Summary of clinical data from conducted investigations of the device before the CE-marking.	6
5.3. Summary of clinical data from other sources	6
5.3.1. Device-specific published literature	6
5.3.2 PMS data: Vigilance and CAPA information	7
5.3.3 Post-market clinical follow-up.....	7
5.4. Overall summary of clinical performance and safety.....	8
5.5. Ongoing or planned post-market clinical follow-up.....	8
6. Possible diagnostic or therapeutic alternatives	9
7. Suggested profile and training for users	9
8. Reference to any harmonized standards and CS applied.....	10
Summary of safety and clinical performance for patients.....	10
1. Description of the device.....	10
2. Expected benefits	10
3. Possible risks and side effects	10
4. Summary of the safety and clinical performances of the device	11

LIST OF ABBREVIATIONS

CER	Clinical Evaluation Report
IFU	Instruction For Use
MD	Medical device
MDCG	Medical Device Coordination Group Document
MDD	Medical Device Directive
MDR	Medical Device Regulation
NB	Notified body
NSN	Number of Necessary Subjects
PMCF	Post Market Clinical Follow-up
PMS	Post-Market Surveillance
PSUR	Periodic Safety Update Report
SOA	State of the Art

1. DEVICE IDENTIFICATION AND GENERAL INFORMATION

Device	
Device name	Ungual Prosthesis
EMDN Code and description	P090499: HAND PROSTHESES - OTHER
Device class	Class IIb
BASIC UDI-DI	3663357UNGUEAL9F
Year when the first certificate (CE) was issued	1998
Legal manufacturer	
Name	FRANCEMED
Adress	34 Avenue du Dr Durand, 94110 Arcueil, France
SRN	FR-MF-000008936
Authorized representative	
Name	NA
Adress	NA
SRN	NA
Notified body	
Name	SGS Belgium NV
Adress	Noorderlaan 87, 2030 Antwerpen – Belgium
Notified body identification number	CE1639

2. INTENDED USE OF THE DEVICE

2.1. Intended purpose

The D2105 Ungual Prosthesis is intended for the treatment of ungual dystrophies of the fingernails and toenails of traumatic, infectious or congenital origin.

The device is intended to temporarily replace the natural nail plate and facilitate its regrowth. It may be used in emergency situations when an avulsed nail cannot be repositioned, in scheduled procedures to avoid harvesting a healthy nail, or in reconstructive surgery.

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The prosthesis is positioned over the nail bed, in the anatomical position normally occupied by the natural nail plate. It temporarily covers and protects the underlying nail bed during healing and natural nail regrowth.

The D2105 Ungual Prosthesis is a single-use, sterile, temporary implantable device.

2.2. Indications for use and target population

The D2105 Ungual Prosthesis is indicated when temporary replacement of the natural fingernail or toenail plate is required in the treatment of ungual conditions of traumatic, infectious or congenital origin.

Clinical situations in which temporary nail replacement may be required include:

- Traumatic loss or avulsion of the nail plate, when the natural nail is absent, severely damaged or unsuitable for repositioning
- Ungual dystrophy of traumatic, infectious or congenital origin requiring temporary nail replacement;
- Scheduled surgical procedures in which temporary nail replacement is required to avoid harvesting a healthy nail
- Reconstructive nail surgery where temporary coverage and protection of the nail bed are required during healing and regrowth.

The device may be used on both fingernails and toenails.

Target patient population

The D2105 Ungual prosthesis is intended for pediatric and adult patients, both male and female, requiring temporary replacement of a fingernail or toenail in accordance with the indications described above.

No specific age or sex restriction applies. Patient eligibility is determined by the surgeon based on clinical indication, applicable contraindications and the individual patient's clinical condition.

2.3. Contraindications and limitations

The D2105 Ungual prosthesis is contraindicated in the following situations

- Sensitivity to materials,
- All infections which may compromise the implant's function.

3. DEVICE DESCRIPTION

3.1. General device description

The D2105 Ungual Prosthesis is a temporary implantable device intended for the treatment of ungual dystrophies of the fingernails and toenails of traumatic, infectious or congenital origin. It is intended to temporarily replace the nail and facilitate its regrowth. It may be used in emergency situations when the avulsed nail cannot be repositioned, in scheduled procedures to avoid harvesting a healthy nail, or in reconstructive surgery.

The device is manufactured from high-density polyethylene according to ISO 5834-2 and is available in three sizes corresponding to references 21.001.01, 21.001.02 and 21.001.04.

The prosthesis is curved to adapt to the shape of the nail. Its concave surface is longitudinally striated to reproduce the natural inner surface of the nail plate. Fenestrations allow passage of fixation sutures used to maintain the prosthesis in position over the nail bed.



Figure 1: Ungual prosthesis - Top view



Figure 2: Ungual prosthesis - Bottom view

According to Rule 8 of the annex VIII of the regulation (EU) 2017/745 of the European parliament and of the council of 5 April 2017, these devices are in class IIb.

They are delivered sterile by gamma radiation.

3.2. Previous generations and variants

The D2105 Ungual Prosthesis has been CE marked and marketed since 1998. Based on the available historical documentation, no major change affecting the intended purpose, material, mode of action or fundamental design concept of the device has been identified since its initial commercialization.

The following design changes and variants have been introduced during the lifecycle of the device:

- **2005 – Modification of surface grooves:** Grooves originally present on the upper and lower surfaces of the prosthesis were removed from the upper surface and retained on the lower surface.
- **2012 – Addition of an intermediate size:** The product range was expanded through the introduction of an intermediate prosthesis size following feedback from surgeons. The currently available references therefore correspond to different sizes of the same device design.
- **2018 – Addition of fixation holes:** Two additional holes were incorporated into each prosthesis following surgeon feedback. The modification was subject to the applicable design-control, verification and validation processes.

These modifications did not change the intended purpose, material, mode of action or fundamental design concept of the D2105 Ungual Prosthesis and are therefore not considered to constitute separate generations of the device.

The D2105 Ungual Prosthesis remains a polyethylene ungual prosthesis intended to temporarily replace the nail and facilitate nail regrowth. The different references currently available represent size variants of the same device.3.3. Description of any accessories which are intended to be used in combination with the device

No accessories that are not themselves medical devices are intended by FRANCEMED to be used in combination with the D2105 Ungual Prosthesis.

3.4. Description of any other devices and products which are intended to be used in combination with the device

No specific other devices or products are intended by FRANCEMED to be used in combination with the D2105 Ungual Prosthesis.

Standard surgical instruments and fixation products may be used during implantation and are not specific to the D2105 Ungual Prosthesis.

4. RISKS AND WARNINGS

4.1. Residual risks and undesirable effects

The identified residual risks and possible undesirable effects associated with implantation and use of the D2105 Ungual Prosthesis include:

- early or late infection;
- haematoma;
- allergic or inflammatory reaction;
- pain or discomfort;
- tissue injury or onycholysis;
- migration, displacement or incorrect positioning of the prosthesis;
- deformation, fracture or rupture of the prosthesis; and
- premature removal of the prosthesis or additional surgical intervention due to a complication.

These risks are controlled through device design and material selection, manufacturing and process controls, validated cleaning, packaging and sterilisation processes, and information provided in the instructions for use. Appropriate device selection, positioning and fixation, maintenance of aseptic conditions and compliance with postoperative precautions further contribute to risk reduction. The Risk Management Report confirms that the identified individual residual risks have been reduced to an acceptable level following implementation of the applicable risk-control measures.

Quantitative information on clinically relevant residual risks and undesirable effects is summarized below. Device-specific quantitative data are derived primarily from Post-Market Clinical Follow-up (PMCF) and Post Market Surveillance conducted between 2022 and 2025.

Residual risk / undesirable effect	Ungual prosthesis quantitative data
Infection	0% infections reported in PMCF No infection-related complaints or vigilance events identified through PMS
Overall postoperative complications	0% device-related postoperative complications reported in PMCF No PMS signal indicating a device-related complication trend
Migration / displacement	0% device migrations or displacements reported in PMC. No related complaints or vigilance events identified through PMS.
Unplanned device-related reintervention	0% unplanned device-related reinterventions reported in PMCF
Pain / discomfort	Postoperative pain was reported in the PMCF dataset and generally decreased during follow-up. Pain during stitch removal was reported in the 2023 data.
Tissue injury / onycholysis	No event reported in the PMCF data
Allergic / inflammatory reaction	No event reported in the PMCF data
Hematoma	No event reported in the PMCF data
Deformation / fracture / rupture	No event reported in the PMCF data

4.2. Warning and precautions

The patient should be informed of the postoperative precautions applicable following implantation of the ungual prosthesis.

Particular attention should be paid to:

- any pain or unusual discomfort at the treated finger or toe;
- signs of local or surrounding infection;
- displacement, damage or other apparent change in the position or condition of the prosthesis.

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Any suspected infection should be assessed and treated appropriately.

The level of activity permitted during the postoperative period should be determined by the surgeon according to the patient's clinical condition and the treated anatomical site. Excessive activity or mechanical stress involving the treated finger or toe should be avoided where it may interfere with healing or the intended function of the prosthesis.

4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN)

No Field Safety Corrective Actions (FSCAs) or Field Safety Notices (FSNs) related to the D2105 Ungual Prosthesis have been identified during the evaluated post-market period. No other relevant safety issues requiring corrective action have been identified through post-market surveillance.

5. SUMMARY OF CLINICAL EVALUATION AND POST MARKET FOLLOW-UP

5.1. Summary of clinical data related to equivalent device

No equivalent device is claimed for the D2105 Ungual Prosthesis for the purpose of the clinical evaluation.

Similar or benchmark devices identified during the state-of-the-art assessment are used only to characterize current clinical practice, alternative technologies and relevant clinical safety and performance benchmarks. Their clinical data are not considered clinical evidence for D2105 on the basis of equivalence.

5.2. Summary of clinical data from conducted investigations of the device before the CE-marking

No pre-market clinical investigation conducted by FRANCMED specifically on the D2105 Ungual Prosthesis has been identified.

The Ungual Prosthesis is a legacy device that has been CE marked and marketed since 1998. The clinical evaluation is based on device-specific scientific literature together with clinical information generated through PMS and PMCF activities. Based on the available clinical evidence, continued clinical evidence generation is performed through PMS and PMCF.

5.3. Summary of clinical data from other sources

The clinical evaluation of the Ungual Prosthesis is based on device-specific published literature, post-market surveillance (PMS) data and device-specific post-market clinical follow-up (PMCF) data. The available clinical evidence is assessed against clinical safety and performance criteria established from the current state of the art.

5.3.1. Device-specific published literature

One publication specifically addressing the D2105 Ungual Prosthesis was identified: Guero S. (2014), *Benefits of an Ungual Prosthesis in Traumatology and Reconstructive Surgery of the Nail*.

The publication describes the use of the ungual prosthesis when the natural nail is absent or cannot be repositioned, including in traumatic nail avulsion and reconstructive nail surgery. The prosthesis is generally maintained for approximately two months, with natural nail regrowth reported over approximately 2–4 months. No immediate infectious complications were reported with the described treatment protocol.

The publication also reports experience from 153 digital reconstructions, with satisfactory aesthetic results in 80% of cases according to patients and 65% according to the operator, and a mean gain in nail regrowth of 4 mm (range: 2–11 mm). As not all procedures involved the D2105 Ungual Prosthesis, these results cannot be considered exclusively device-specific.

The publication provides supportive clinical evidence for the D2105 Ungual Prosthesis. Its evidentiary value is limited by the absence of a prospective controlled design, incomplete device-specific population and endpoint data, and a declared potential conflict of interest.

5.3.2 PMS data: Vigilance and CAPA information

PMS data are periodically reviewed to monitor the continued safety and performance of the D2105 Ungual Prosthesis under actual conditions of use.

During the 2022–2025 reporting period, no serious incidents, reportable incidents, field safety corrective actions (FSCAs), CAPAs or complaints related to D2105 were identified. No reported or observed use errors, abnormal use or off-label use were identified.

Trend analysis did not identify any statistical signal, previously unidentified risk or increase in the frequency or severity of known risks. Review of user feedback, scientific literature and public vigilance databases, including FDA MAUDE and ANSM, did not identify any new or increased safety risk associated with D2105.

5.3.3 Post-market clinical follow-up

Device-specific PMCF data were collected between 2022 and 2025 through questionnaires completed by healthcare professionals following use of the D2105 Ungual Prosthesis under actual conditions of use.

The main clinical findings are summarised below:

Clinical outcome	PMCF result
Ease of implantation	Reported as easy or very easy in all evaluated cases
Device-related postoperative complications	No device-related postoperative complications reported
Infection	No postoperative infections reported
Aesthetic outcome	Satisfactory aesthetic outcomes reported in all evaluated cases
Unplanned device-related reintervention	No unplanned device-related reinterventions reported
Migration or displacement	No clinically significant migration or displacement reported

Postoperative pain was observed, with reported pain generally decreasing during follow-up. Two difficulties during implant removal were reported in 2023: pain during stitch removal and implant adhesion. One fixation difficulty was reported in 2024 and was attributed to the type of suture rather than to the implant itself. No such difficulties were reported in the 2025 dataset.

The PMCF data provide supportive device-specific clinical information obtained under actual conditions of use. The interpretation of these data is subject to limitations, including the limited sample size, observational and non-comparative design, absence of a control group, and reliance primarily on clinician-reported data.

No new or increased device-related safety signal was identified from the available PMCF data.

5.4. Overall summary of clinical performance and safety

The clinical performance and safety of the D2105 Ungual Prosthesis were evaluated using the available device-specific published literature, post-market surveillance (PMS) data and post-market clinical follow-up (PMCF) data.

The intended clinical benefits of the D2105 Ungual Prosthesis are the temporary replacement of the natural nail, protection of the nail bed during healing, support of natural nail regrowth and achievement of a satisfactory aesthetic outcome.

The available clinical evidence supports these intended clinical benefits. Device-specific published literature reports natural nail regrowth over approximately 2–4 months following use of the prosthesis. Satisfactory aesthetic outcomes were reported in all cases evaluated through PMCF between 2022 and 2025.

Quantitative device-specific PMCF data on nail-regrowth time remain limited, as this outcome was not specifically collected as a quantitative endpoint in the available PMCF questionnaires. Available device-specific published literature nevertheless supports nail regrowth within the expected clinical timeframe. Continued PMCF is intended to further strengthen the device-specific clinical evidence for this outcome.

With respect to clinical safety, no device-related postoperative complications, postoperative infections, unplanned device-related reinterventions or clinically significant migration or displacement were reported in the available PMCF data collected between 2022 and 2025. Postoperative pain was reported but generally decreased during follow-up. PMS data for the evaluated period did not identify any new or increased device-related safety signal.

The identified undesirable effects and residual risks have been evaluated in conjunction with the available clinical evidence and applicable risk-control measures. No new or increased clinical risk has been identified that would adversely affect the established safety or benefit-risk profile of the device. Taking into account the documented clinical benefits, available clinical performance and safety data, identified undesirable effects and residual risks, the overall benefit-risk profile of the D2105 Ungual Prosthesis is considered acceptable for its intended purpose.

5.5. Ongoing or planned post-market clinical follow-up

PMCF activities will continue in accordance with the current PMCF Plan. Ongoing device-specific PMCF includes the collection of clinical data through questionnaires completed by healthcare professionals following use of the Ungual Prosthesis under actual conditions of use.

The PMCF activities are intended to confirm the continued safety and clinical performance of the device, identify any previously unknown or emerging risks or undesirable effects, and further strengthen the available device-specific clinical evidence. Particular attention will be given to increasing the amount of available clinical data and obtaining further quantitative information on nail-regrowth outcomes, for which device-specific quantitative data are currently limited.

PMCF is complemented by ongoing PMS activities, including review of complaints and vigilance information, user feedback and relevant scientific literature.

No new or emerging risks, unexpected device failures or increase in the frequency or severity of known risks have been identified from the available PMS and PMCF data. Any new safety or performance information identified through ongoing PMS or PMCF will be evaluated and, where applicable, incorporated into the clinical evaluation and risk-management process and used to determine whether additional corrective or preventive measures are required.

6. POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

Management of nail-bed injuries or ungual defects depends on the condition of the natural nail plate, the extent of the nail-bed injury and the clinical situation.

The main currently available treatment options include:

- **Repositioning of the natural nail plate**, when the avulsed nail remains available and suitable for reuse. The nail may be cleaned and repositioned over the nail bed to protect the underlying tissues and maintain the nail fold during healing.
- **Temporary artificial nail substitutes or splints**, when the natural nail cannot be reused. Published literature describes the use of materials such as silicone sheets, foil, polypropylene and other temporary substitutes intended to cover and protect the nail bed during healing.
- **Purpose-designed nail splints**, developed specifically for temporary nail-bed protection and fixation. These devices may offer predefined shape, curvature, rigidity and fixation features.
- **Reconstructive procedures** for more extensive nail-bed or matrix defects where simply temporary nail replacement is insufficient. These may include nail-bed reconstruction, nail-bed grafting or flap reconstruction.

For more complex defects, more extensive reconstructive techniques, including vascularized nail-tissue transfer, may be considered in selected cases.

The current state of the art therefore includes both reuse of the patient's natural nail where possible and temporary artificial or purpose-designed nail substitutes where the natural nail is unavailable or unsuitable. The choice of treatment depends on the extent and type of injury, the condition of the nail bed and surrounding tissues, and the individual clinical situation.

A commercially available purpose-designed nail splint with a similar clinical function has been identified: the INRO Surgical Nail, intended for temporary nail-bed splinting following nail trauma or reconstructive surgery. It is considered a similar device for characterization of the state of the art. No equivalence between the INRO Surgical Nail and the D2105 Ungual prosthesis is claimed.

7. SUGGESTED PROFILE AND TRAINING FOR USERS

The Ungual Prosthesis is intended for use by qualified healthcare professionals in an appropriate clinical or surgical environment.

- **Surgeons:** Implantation, positioning, fixation and removal of the ungual prosthesis are intended to be performed by a qualified surgeon with appropriate knowledge and experience in the surgical management of nail injuries, nail-bed procedures and/or reconstructive nail surgery. No device-specific training provided by FRANCEMED is required. The device shall be used in accordance with the Instructions for Use and the applicable surgical technique.
- **Operating-room nurses and other assisting healthcare professionals:** Qualified operating-room nurses or other appropriately trained healthcare professionals may assist the surgeon during preparation and implantation of the device in accordance with their professional qualifications and responsibilities. They are not intended to independently perform implantation of the Ungual Prosthesis.
- **Personnel responsible for storage:** The device shall be stored by healthcare personnel in accordance with the storage conditions specified by the manufacturer and provided in the Instructions for Use.
- **Personnel responsible for disposal:** Following removal, the single-use device shall be handled and disposed of by the responsible healthcare personnel in accordance with the healthcare facility's procedures and applicable local requirements.

The instructions for Use are available electronically on the manufacturer's website. A paper copy may be provided upon request in accordance with the applicable requirements for electronic instructions for use.

8. REFERENCE TO ANY HARMONIZED STANDARDS AND CS APPLIED

HARMONIZED STANDARDS		Compliance with the standard
NF EN ISO 13485 (04/2016)	Medical devices - Quality management systems - Requirements for regulatory purposes	Full compliance as seen in the company's certificates:
NF EN ISO 13485/A11 (09/2021)	Medical devices - Quality management systems - Requirements for regulatory purposes	Full compliance as seen in the company's certificates:
NF EN ISO 14971 (12/2019)	Medical devices - Application of risk management to medical devices	Full compliance as can be seen in risk management file.
NF EN ISO 14971/A11 (12/2021)	Medical devices - Application of risk management to medical devices	Full compliance as can be seen in Risk management file.
ISO/TR 24971 (06/2020)	Medical devices - Guidance on the application of ISO 14971	Full compliance
NF EN ISO 15223-1 (09/2021)	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: general requirements	Full compliance as seen on the labels
NF EN ISO 15223-1/A1 (03/2025)	Amendment of NF EN ISO 15223-1	Full compliance as seen on the labels
NF EN ISO 20417 (04/2026)	Medical devices - Information to be provided by the manufacturer	Full compliance as seen on the labels
NF EN ISO 14630 (12/2024)	Non-active surgical implants - General requirements	Full compliance

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR PATIENTS

1. Description of the device

The D2105 Ungual Prosthesis is a sterile, single-use device designed to temporarily replace a natural fingernail or toenail when the natural nail is damaged, lost or cannot be put back in place.

The prosthesis is placed over the nail bed by a surgeon. It temporarily covers and protects the nail bed while the area heals and the natural nail grows back.

The device is available in three sizes so that an appropriate size can be selected according to the treated nail.

The D2105 Ungual Prosthesis has been CE marked and marketed since 1998 and is based on an established technology.

2. Expected benefits

The main expected benefits of the Ungual Prosthesis are to:

- temporarily replace the missing or damaged natural nail;
- cover and protect the nail bed during healing;
- allow natural nail regrowth;
- provide a satisfactory appearance during the healing process.

The final appearance and regrowth of the nail can vary between patients and depend on factors such as the original injury or condition of the nail and nail bed.

3. Possible risks and side effects

Possible complications associated with the D2105 Ungual Prosthesis include:

- infection;
- collection of blood under or around the treated area (haematoma);
- allergic or inflammatory reaction;
- pain or discomfort;

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- movement or incorrect positioning of the prosthesis;
- deformation, fracture or rupture of the prosthesis;
- early removal of the prosthesis or the need for an additional surgical procedure because of a complication.

These possible complications are also described in the Instructions for Use.

4. Summary of the safety and clinical performances of the device

The safety and clinical performance of the D2105 Ungual Prosthesis have been evaluated using scientific literature concerning the device, information collected after the device has been placed on the market and post-market clinical follow-up (PMCF). The clinical evaluation does not rely on evidence from another device claimed to be equivalent to the D2105.

During the 2022–2025 reporting period, no serious incidents or complaints related to the D2105 Ungual Prosthesis were reported to the manufacturer, and post-market surveillance did not identify any new or increased safety risk.

Clinical follow-up information was available for patients treated between 2022 and 2025. In these patients, implantation was reported as easy or very easy and tolerance of the prosthesis was good or very good. No device-related postoperative complications or infections were reported. Aesthetic results were satisfactory or very satisfactory, and pain reported after surgery generally decreased during follow-up.

Some difficulties were reported, including pain during stitch removal, implant adhesion and one difficulty with fixation related to the type of suture used. These findings were reviewed as part of the manufacturer's ongoing safety monitoring.

Based on the available clinical information, the expected benefits of the D2105 Ungual Prosthesis are considered to outweigh the identified risks when the device is used as intended.

Clinical follow-up and post-market surveillance will continue to confirm the safety and performance of the device, collect further information on clinical outcomes, including nail regrowth, and identify any new or changing risks.