Study Title: A Prospective Clinical Evaluation of the Bridging Technique Using AILEENE Vol. 2 Dermal Filler for the Treatment of Nasolabial Folds

IRAS Short Title: Bridging Technique Validation for Nasolabial Folds – JN-BRIDGE1

IRAS Project ID: 360828

REC Reference: 25/NW/0251

NHS REC Form Reference: 25/PR/1094

Sponsor Reference: JNL-BridgingNL-2025

Protocol Number: JN-BRIDGE-2025-01

Sponsor: JNL Aesthetics Limited, 10 Marsh Street, Warrington, WA1 3QA, UK

Chief Investigator: Prof. Joseph Mitchell Novoa Libermann (GMC #7200191 | MBBS | QCCP-qualified in Dermal Fillers & Neurotoxins)

NCT Number: (to be assigned upon PRS registration)

Document Title: Informed Consent Form

Version / Date: Version 1.0, 27 August 2025 – REC approved

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Patient Informed Consent Form (ICF)

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Chief Investigator:
Dr Joseph Novoa Libermann

Sponsor:
JNL Aesthetics Limited

Version: 1.0
Date: 27/08/2025

Participant ID Number: _____

Introduction

You are invited to take part in a clinical research study. Before you decide, it is important that you understand why the research is being done and what it will involve. Please take time to read this information carefully. You may also wish to discuss it with family, friends, or another healthcare professional before making your decision.

If you agree to participate, please **initial each box** below and sign at the end of the form.

About the Treatment (Bridging Technique)

The Bridging Technique is an injection method developed by Dr Joseph Novoa Libermann. It is used to soften the lines that run from the side of the nose to the corner of the mouth (nasolabial folds).

The product used in this study is **AILEENE Vol. 2**, a **hyaluronic acid based dermal filler**. Hyaluronic acid occurs naturally in the body and is widely used in aesthetic medicine to restore volume and improve skin structure.

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Protocol Version: 1.0 Date: 27 August 2025

During the procedure:

- A **numbing cream (topical local anaesthetic)** will be applied to the skin to reduce discomfort.
- A **fine needle** is then used to make a small **entry point** in the skin.
- Through this entry point, a **blunt tipped cannula** is inserted. The cannula is designed to glide gently through tissue, reducing the risk of damaging blood vessels or surrounding structures.
- Small amounts of AILEENE Vol. 2 are placed in **thin threads** that run underneath the fold, creating tiny "**bridges**" of support for the skin.

This technique is designed to:

- use a **minimal amount of product**,
- provide a **natural looking improvement**, and
- **reduce the risk** of bruising and other complications compared with some alternative injection methods.

Although this method has been used successfully in clinical practice for several years, the purpose of this study is to **formally evaluate its safety and effectiveness** in a structured way so that other practitioners may adopt it with confidence.

Risks and Possible Side Effects

As with all cosmetic injectable procedures, hyaluronic acid dermal fillers carry risks. Most side effects are mild and temporary, but **serious complications are possible**.

Common, usually temporary effects
• Pain, discomfort, or stinging at the injection site
• Redness, swelling, itching, warmth, or tenderness
• Bruising or minor bleeding
• Small lumps, bumps, or irregularities under the skin
• Temporary asymmetry or unevenness

Less common effects
• Prolonged swelling or redness
• Infection at the injection site
• Skin discolouration or changes in skin texture
• Granuloma formation (firm nodules)
• Allergic reaction to the product or to lidocaine (the numbing ingredient)
• Migration of filler from the original site

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Rare but serious risks
• **Vascular occlusion** (filler entering a blood vessel), which may cause blanching, severe pain, tissue damage or **necrosis**
• **Visual disturbance**, or in extremely rare cases **blindness or stroke**, if filler enters a vessel supplying the eye or brain
• **Scarring** at the injection site

Other considerations
• Results vary between individuals.
• There is a possibility of **dissatisfaction with the cosmetic outcome** (e.g., less visible effect than expected, unevenness, or not meeting personal expectations).
• Additional treatment or corrective procedures may be required in some cases.

If you experience any unexpected effects or concerns after treatment, contact the study doctor immediately. **All adverse events will be documented in your study records. All serious adverse events will also be reported to the Research Ethics Committee and the sponsor in line with Good Clinical Practice (GCP).**

Study Costs

- There is **no cost to you** for the treatment, follow up visits, photographs, questionnaires, or any study related care.
- The dermal filler (AILEENE Vol. 2) and all study procedures are provided **free of charge**.
- If you require **external communication support services** (e.g., interpreter/translation, braille, or large print materials), these services are **not covered by the sponsor** and, as this is an elective cosmetic study, would be at **your own expense** if required.

Data Protection and Confidentiality

Your personal data will be handled in confidence and in accordance with data protection law. Study data will be **pseudonymised/anonymised** for analysis and any publications will **not identify you**. Authorised individuals from the research team, the sponsor (JNL Aesthetics Ltd.), or regulatory authorities may review your study records where relevant to your participation.

Photographs of your face will be taken at baseline and follow up visits for assessment. These images will be coded to protect your identity. Anonymised images may be used in reports, publications, or educational materials; you will **not be personally identifiable**.

You may **withdraw** from the study at any time without giving a reason. Data already collected up to the point of withdrawal may still be used to ensure study integrity and safety reporting.

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Consent Statements (please initial each box)

Please initial	Statement
☐	I have read and understood the Participant Information Sheet (Version [x], dated [date]). I have had time to consider the information, ask questions, and these have been answered satisfactorily.
☐	I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason and without my medical care or legal rights being affected.
☐	I understand that the treatment involves injection of **AILEENE Vol. 2, a hyaluronic acid based dermal filler**, using the Bridging Technique to treat nasolabial folds.
☐	I understand that the filler is MHRA registered and CE marked for use in the UK/EU and is provided free of charge for this study.
☐	I understand the possible risks and side effects, including but not limited to pain, swelling, redness, tenderness, itching, bruising, bleeding, lumps or irregularities, infection, skin discolouration, granuloma formation, allergic reaction, migration, **vascular occlusion**, **tissue necrosis**, **scarring**, **visual disturbance**, **blindness**, **stroke**, and **dissatisfaction with the cosmetic outcome**.
☐	I understand that **all adverse events will be documented**, and that **any serious adverse events will be reported** to the Research Ethics Committee and the sponsor in line with GCP.
☐	I understand that photographs of my face will be taken at baseline and follow up visits for assessment. These images will be anonymised for analysis, publication, and education, and I will not be personally identifiable.
☐	I understand that authorised individuals from the research team, sponsor, or regulators may review my records where relevant to my participation.
☐	I understand that there is **no cost to me** for the treatment, follow ups, or study related care. If I require external communication support services (e.g., interpreter, translation, braille, large print), these are **not covered by the sponsor** and would be at **my own expense**.
☐	I understand there is no guaranteed personal benefit, and that the knowledge gained may benefit others in the future.
☐	I agree to take part in this study.

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Participant

Name (print): _____
Signature: _____
Date: ____ / ____ / _____

DOB: ____ / ____ / _____ (Age Between 30 – 65) ☐

Person Taking Consent

Name (print): _____
Position: _____
Signature: _____
Date: ____ / ____ / _____

Chief Investigator (or Delegate)

I confirm the participant had adequate opportunity to discuss the study, ask questions, and gave informed consent freely.

Name (print): _____
Signature: _____
Date: ____ / ____ / _____

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