Lipoderma™ Consent Form

Purpose of Procedure

Lipoderma™ is a human adipose tissue allograft intended for the repair, reconstruction, replacement, or supplementation of adipose tissue losses in the face or body. Your provider recommends Lipoderma to help restore natural contours and improve overall aesthetic appearance. Lipoderma supports the body's natural tissue repair process and is gradually replaced by the body's own tissue over time, which may contribute to longer-lasting results.

I understand that Lipoderma is regulated for clinical use in the United States by the Food and Drug Administration (FDA) as a Human Cell, Tissue, and Cellular and Tissue-Based Product (HCT/P) under Title 21 of the Code of Federal Regulations, Part 1271, Section 361 of the Public Health Service Act.

Procedure Description

After a local anesthetic is administered, Lipoderma will be placed beneath the skin into targeted soft-tissue areas to restore volume and improve contours. Procedural techniques, volume of the product used, and specific treatment sites are determined by the provider based on clinical judgment.

I understand that multiple procedures may be required to achieve the desired result and that outcomes can vary significantly based on several factors, including but not limited to age, sex, weight, medications, general health, and lifestyle.

I understand that results vary by individual, and no outcome can be guaranteed.

Risks & Potential Complications

No procedure is without risk. I understand that there are inherent and potential risks, including risks that may not be anticipated or listed here. Possible risks and side effects may include, but are not limited to:

- Swelling, redness, or bruising
- Pain or tenderness
- Allergic reaction
- Infection
- Irregular texture or asymmetry
- Necrosis due to blood vessel occlusion

I understand that unexpected complications may occur and that additional treatment may be necessary.

Medical Considerations

I agree to inform my provider if any of the following apply:

- Pregnancy or breastfeeding
- Use of blood-thinning medication
- Active local or systemic infection

I agree to provide accurate and complete medical information and to update my provider if my health status changes.

Voluntary Consent

I understand that this is an elective procedure, and I voluntarily consent to the use of Lipoderma for volume restoration. The procedure has been explained to me, and all questions have been answered to my satisfaction.

I understand that the procedure is solely between myself and the healthcare provider performing the procedure, and I agree to direct all post-procedure questions or concerns to that provider. I acknowledge that no guarantees have been made regarding the results of the procedure.

I understand that it is my responsibility to notify my healthcare provider of any changes in my medical condition.

I consent to photography or video documentation for (check all at apply):

□ Medical record
□ Education / training
□ Marketing

I hereby consent to receive Lipoderma.

Printed Name of Patient: _____

Patient Signature: _____ Date: _____