

# Patient Information and Consent Form

## Injection of diluted local anesthetic (Mepivacaine, “Meaverin”) into subcutaneous fat tissue for the treatment of pain in lipedema

Patient name / Date of birth Center name

### Dear Patient,

You have lipedema with painful symptoms. You are consistently using compression, which provides some relief. We would like to offer you a treatment in which diluted local anesthetic (Mepivacaine / Meaverin) is injected directly into the subcutaneous fat tissue.

### 1. Purpose of the treatment

- Relief of pain in the affected tissue.
- The method is based on a long-established procedure: during liposuction, diluted local anesthetic is routinely introduced into the fat tissue.
- Local anesthetic injections are also successfully used for other nerve-related pain (e.g., herpes zoster, scar pain, phantom pain).
- Initial studies in lipedema (see literature below) show that even local anesthetic alone, without liposuction, can lead to significant pain reduction lasting for several months.

### 2. Procedure

- Under sterile conditions and ultrasound guidance, the subcutaneous fat tissue is punctured with a fine cannula.
- Diluted Mepivacaine (Meaverin) is then injected slowly and over a wide area into the affected regions.
- The anesthetic is highly diluted to allow safe dosing over large lipedema areas.
- For large areas, treatment must be divided (e.g., one leg per day) to stay within safe dosage limits.
- Afterward, your compression garment is reapplied.
- Treatment is performed on an outpatient basis.

- The numbing effect begins within minutes but lasts only a few hours. Pain reduction, however, begins immediately, builds over days, peaks after about one week, and may persist for months.
- After the treatment:
  - Do not drive a car on the day of treatment (mandatory restriction in many countries after local anesthesia of the legs).
  - Walking is encouraged to help distribute the fluid.

### 3. Safety and possible side effects

- Mepivacaine (Meaverin) is a long-established local anesthetic.
- At the recommended dosage, no side effects are expected.
- Known but rare side effects include:
  - Local reactions at the injection site (redness, bruising, temporary numbness)
  - Very rarely, allergic reactions
  - In cases of overdose: cardiac arrhythmias, seizures, breathing problems (not expected under correct administration)
- We deliberately do not add adrenaline, as is done in liposuction, to avoid unnecessary risks, since some patients do not tolerate it well.

### 4. Aftercare

- Continue wearing your compression garment as usual.
- Bandages or small plasters will be placed over injection sites; some fluid leakage may occur for a few hours.

## 5. Documentation / Register

- All treatments are recorded in an anonymized registry (standard quality control in medicine).
- You may object to this recording.

### Optional participation in pain documentation:

If you agree, you can record your pain levels (morning, noon, evening):

- Daily for one week before treatment
  - Daily for one week after treatment
  - Once after three months
- You will receive a link to the “Survey Monkey” website, a GDPR-compliant platform accessible only to the registry leadership (Arrien Ltd, Wunstorf, Germany, created for research and training in phlebology by Erika Mendoza, PhD developer of the method). This allows better scientific evaluation of the treatment in lipedema.

## 6. Alternatives

- Standard therapy (compression, manual lymphatic drainage in case of additional edema, exercise therapy, pain medication)
- Surgical liposuction
- No treatment

## 7. Register and Data Protection

- All interventions are entered into a medical register for quality assurance. This is fully anonymized – no personal data (like name, date of birth or address) are stored. Only medical details are documented (diagnosis, treatment, treatment date, pain score results). Personal identification is not possible.
- **Right to object:** If you do not wish your data to be entered, please inform us. Your decision has no impact on your treatment.
- **Optional additional documentation:** If you agree to online pain questionnaires

before/after treatment, data will be pseudonymized (linked only to a code number). Only your treating practice holds the code key, under strict confidentiality.

- **Patient rights:** You may withdraw your consent to data processing at any time. You may request access to your stored data or their deletion, as legally possible.

## 8. Consent to treatment

Treatment will only be performed with your explicit consent. If you are uncertain, only a small area may be treated initially. Please discuss this with your physician.

### Comments:

- Treatment may not be covered by insurance. The cost per session is \_\_\_\_\_, with an estimated total of \_\_\_\_ sessions required.
- Complete pain relief cannot be guaranteed; in rare cases, pain reduction may not occur. The duration of effect is not precisely known, but early experience suggests several months. In related uses (e.g., scar pain), effects can last years.

### Pain score assessment:

- Participation is voluntary.
- You may withdraw consent at any time without giving reasons.

I have read and understood the information. I have had the opportunity to ask questions, and all questions have been answered.

- I consent to the treatment.
- I have received a copy of this information sheet.
- I additionally consent to the pain score survey, which I may discontinue at any time without reason.

Place, Date: \_\_\_\_\_

Patient signature: \_\_\_\_\_

Physician signature: \_\_\_\_\_