

## **Informed Consent Form**

I am interested to undergo anti-cellulite treatment with the Slimspec, manufactured by Medispec Ltd. This device creates acoustic mechanical waves which are activated on the Cellulite area. The Slimspec increases Collagen and Elastin synthesis in the walls supporting the fat cells that protrude to the skin surface in Cellulite. In addition, this treatment reduces the concentration of toxins in the surroundings of the fat cells.

Prior to treatment I will undergo physical examination that will document Cellulite level as follows:

1. A piece of skin in the thigh, pelvis or buttocks area will be held between the thumb and the index finger. If the skin of this area will assume wavy, dimpled or "orange peel" appearance – this is Cellulite. Usually the Cellulite area has a paler shade and it's cooler in comparison to other skin areas of the body. The Cellulite area skin is softer under pressure of massage. People with Cellulite might feel as though the Cellulite area is "heavier".
2. During the physical examination the severity of Cellulite in my body will be evaluated and classified to one of the following levels:

Level 0 – No visible dimples on the skin surface.

Level 1 – There is visible result at "pinch test".

Level 2 – The skin seems as orange peel even without "pinch test".

Level 3 - Orange peel skin appearance, multiple and visible lumps under the skin.

Level 4 – Mattress-like skin appearance.

**Expected Duration (Treatment & Follow-Up):** I'm about to undergo a series of 12 treatment sessions of 20 minutes each two treatment areas). Treatment will be conducted in six sequential weeks – twice a week. Treatment evaluation will be conducted prior to each treatment, at the completion of a treatment series (12 sessions), 1 month post treatment and 3 months post treatment.

Treatment evaluation will include:

1. Full **physical evaluation** of the Cellulite area. All findings will be documented.
2. The area dedicated to treatment will be **photographed** prior to the initiation of each treatment, at the completion of a treatment series, 1 month following treatment completion, and 3 months following treatment completion.
3. **The circumference** of the treated area will be measured prior to initiation of the treatment series, prior to each session, at the completion of treatment series as well as one month and three months following treatment series completion.
4. **Patient Excel:** I will be requested to fill a questionnaire prior to treatment series initiation, as well as immediately following treatment aeries completion and 1 and 3 months following treatment series completion.
5. **Expected Benefit:** Based on similar treatments conducted in people with a similar problem to mine , I expect to have a certain temporary improvement expressed by decreased circumference in the area treated for Cellulite in comparison to pre-treatment measurements, decrease in Cellulite grading as detailed above, visible improvement in photographs taken after treatment series completion in comparison to photos taken prior to treatment initiation, as well as improved satisfaction expressed in a questionnaire I'll be filling.
6. **Adverse Events:** There are no known adverse reactions to this treatment. Nevertheless, should they occur they are expected to be mild such as a local temporary "blue mark" lasting for several days. Should any adverse events occur, I'll report them to the caregiver.
7. **Potential Risks:** I'm aware of the fact that acoustic radial wave treatment for a variety of applications such as orthopedic pathologies is accepted for years. Low energy acoustic radial wave treatment is easy to conduct, non-invasive, with no apparent adverse events and has short treatment series duration.
8. **Potential Inconvenience:** Based on past experience, my caregiver does not expect any inconvenience during treatment except for a feeling of light blows in the treated area.

**Relevant information** including substitute treatment techniques, and their comparison to the currently suggested treatment, from the efficacy and safety perspective, as well as the modes of treatment of potential adverse events:

1. I'm aware of the fact that the beneficial effect of with acoustic radial waves treatment with the Slimspec™ is temporary, therefore should be repeated for maintenance treatment once in a few months.
2. I'm aware of the fact that the available substitute treatments are:

*Massage Therapy:* Massage therapy can decrease tissue edema. Massage devices were developed, creating local pressure that might improve body contours and skin texture.



Locally Acting Cosmetics: Creams, gels, etc, which contain active ingredients such as: Xanthines, PPAR Agonists, Retinoids, Caffeine, Hydroxycitrate and similar materials that can improve Cellulite condition.

*Oral Treatment:* This treatment also includes material detailed in paragraph 3.2.2.

*Mesotherapy:* Injection of Cellulite dissolving medications.

*Cellulite Disintegration:* Cellulite may be disintegrated by heating or mechanical force.

I hereby declare that that I have given my informed consent to the above treatment of my own free will, and I'm entitled to stop treatment at any stage, and consult anyone I wish. In addition I received a copy of this informed consent form as well as an additional information document (if available). By signing this informed consent form I consent that the treatment initiator will have direct approach to my file. This will be conducted while keeping my personal information confidential according to the rules and regulations of confidentiality.

In case of need I can approach \_\_\_\_\_ at phone number \_\_\_\_\_.

Patient's Name and ID	Patient's Signature

**Practitioner's Declaration:**

I have received this clients consent after explaining her all of the above and confirming that all my explanations have been well understood.

Practitioner's Name	Practitioner's Signature