



# Informed Consent

## Contraindications

Please do not perform the treatment if you have the following contraindications:

### C1

Cold-associated disorders (cryoglobulinemia, paroxysmal cold hemoglobinuria, Raynaud's disease, etc.)

### C2

Pregnancy and lactation

## Warnings

In certain cases, treatment may be authorized under medical supervision. However, Cocoon Medical is not responsible for it. Be careful before performing the procedure under the following conditions, the effects of these conditions have not been studied. The doctor must authorize the treatment if the patient has the following conditions:

### W1

Dermatological medical treatments in the treatment area (chemical peeling, dermabrasion, etc.)

### W2

Altered vascular circulation in the treatment area (varicose veins, phlebitis, thrombophlebitis)

### W3

Periodontal diseases (treatment in facial area)

### W4

Skin sensitivity disorders or neuropathies

### W5

Blood disorders, use of anticoagulants and antiplatelet agents

### W6

Recent surgeries, scar tissue in or adjacent to the treatment area and history of hernias in the treatment area

### W7

Wounds or active dermatological lesions in the treatment area (dermatitis, psoriasis, sensitive skin, burns, etc.)

### W8

Implanted devices (pacemakers or defibrillators)

### W9

Chronically degenerative diseases that are poorly controlled (hypertension, diabetes, heart failure, kidney failure, liver failure, etc.)

### W10

Infectious diseases (local or systemic)

### W11

Autoimmune diseases (systemic lupus erythematosus, scleroderma, Sjögren's syndrome, etc.)

### W12

Immunosuppression conditions (AIDS) and use of immunosuppressive drugs

### W13

Malignant pathologies, precancerous lesions or neoplasms and immunotherapy treatments

### W14

History of hyperplasia or hypertrophy

### W15

Corticosteroid Treatments

### W16

Psychiatric disorders (nutritional, somatic, etc.)

### W17

Allergic reaction to membrane or gel compounds

## Side effects

A bibliographic review was conducted using various metasearch engines (Pubmed, Cochrane, etc.). Articles from a maximum period of 10 years since publication and with an A or B level of evidence were included. A total of 129 articles were analysed.

The different frequencies of the occurrences of side effects were classified in accordance with the Inter-

national Organisation CIOMS (Council for International Organizations of Medical Sciences) and the EMA (European Medicines Agency) as:

- Very frequent
- Frequent
- Infrequent
- Unusual
- Very unusual

### During the session and immediately afterwards:

#### SE1

Temporary skin sensitivity disorders as a result of the cold: numbness, tugging sensation (very frequent)

#### SE2

Reddening and inflammation (very frequent)

#### SE3

Muscular spasms (frequent)

#### SE4

Vasovagal symptoms: dizziness, nausea (frequent)

#### SE5

Discomfort (frequent)

#### SE6

Allergic reaction to the compounds in the membrane or gel (infrequent)

#### SE7

Thermal injuries (very unusual)

### After the session (24 hours post treatment)

#### SE8

Discomfort (very frequent)

#### SE9

Temporary skin sensitivity disorders: paraesthesia or dysaesthesia (very frequent)

#### SE10

Bruisin (very frequent)

#### SE11

Reddening and inflammation (very frequent)

#### SE12

Hyperpigmentation and hypopigmentation (frequent)

#### SE13

Atrophies (hypotrophy or hypertrophy), panniculitis, paradoxical adipose hyperplasia, fibrosis, nodules, etc. (infrequent)

#### SE14

In the submental region: motor neuron disorders and a reduction in salivary secretion (very unusual)

\*Most of these conditions are temporary and resolved over the course of a few days or weeks. In case of feeling any different or more severe symptoms please contact a specialist doctor.

## Side effects

In section ES6, the frequency of occurrence of thermal injuries has been calculated based on clinical data from the manufacturer and medical reports from users.

In section ES12, different side effects have been included that produce a visible increase in the volume of the treated zone. This grouping includes changes in cell quantity and structure, inflammatory processes or formation of fatty cysts. Nonetheless, each of these side effects should be diagnosed individually based on its histological characteristics: The occurrence of these side effects is observed two to five months post-treatment, and a surgical intervention may be required to resolve them.

In section ES13, there is insufficient bibliography indicating the frequency of occurrence of submental disorders. This has been calculated based on the opinion of experts and on non-systematic reviews and physiopathological schedules.

The occurrence of hernias has been reported as a side effect; however, as there are few reported cases, the manufacturer is unable to determine a frequency of occurrence.

## cooltech define informed consent

I \_\_\_\_\_, with date of birth \_\_\_\_\_  
and ID: \_\_\_\_\_

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### Declare:

That through this document, I authorise the Medical Professional and their authorised personnel \_\_\_\_\_  
\_\_\_\_\_ to perform the cryoadipolysis treatment with the cooltech define, a non-invasive technique that removes localised fat through the direct action of controlled cold applied to the treatment area with a suction applicator.

### I understand that:

In general terms, the purpose of the treatment is to enhance my physical appearance and redefine the contour of my body.

The advantage of cryoadipolysis over surgical procedures is that it is a non-invasive treatment that only demands the time taken to perform the treatment and does not require a period of inactivity for the purpose of recovery. The potential benefits provided by this treatment are a reduction in the circumference of the treatment area and a reduction in the thickness of the skin fold.

Cryoadipolysis is indicated in patients with normoweight or overweight. More than one treatment session on the same area is occasionally required to achieve the desired contouring. Waiting at least 6 weeks before repeating the treatment on the same area is advised, although the process of adipose tissue reduction can take up to 3 months.

The treatment is elective and results cannot be guaranteed, nor can guarantees be given about obtaining results. It may take approximately 3 months following the procedure before the final results are visible.

Medicine is not an exact science and each patient will respond differently. This is not a solution for weight loss and does not replace traditional methods such as liposuction.

To optimize the results, it will be necessary to follow a low fat diet and perform physical activity for at least 3 months post treatment. Pain, reddening, skin inflammation, tingling sensations, itchiness, discomfort and haematomas on sensitive skin are common or very common side effects, all of which are associated with the treatment. Most of these conditions are temporary and will subside over the course of a few days or weeks. In the event that any symptoms that are different or more intense than expected are experienced, contact a specialist medical professional.

### I confirm that:

I have been informed in detail, in language that I understand, of the effects and the nature of the procedures that will be carried out, including the potential risks, the alternative surgical and non-surgical procedures, and the discomfort and side effects that I may experience ("Side Effects" section) even during a normal post-treatment period. I have also been informed of the contraindications of the cryoadipolysis treatment ("Contraindications" section) and all the questions that I personally and freely composed regarding cooltech cryoadipolysis have been answered satisfactorily. The importance of using the **Cool Gel Pad** cryoprotective membrane during my treatment has been explained to me, as has the importance of the packaging of the **Cool Gel Pad** membrane being opened in my presence, since this item is only used once per area and treatment.

## Finally, I Declare And Certify:

That I have not omitted or altered any information which could be understood as a contraindication for cryoadipolysis treatment (“Contraindications” section) when declaring my medical and surgical history and background, and I have expressly informed the medical professional of whether I have taken any medication in the 24 hours prior to the performance of the treatment, rendering the centre, the medical professional and the manufacturing company exempt from any responsibility with regard to potential side effects that may be caused to the patient due to a lack of transparency during the signing of this document.

## Consent:

I accept that I cannot be given guarantees or absolute assurances with respect to the results of the treatment and I state that my questions in this regard have been answered satisfactorily. I assume the risk that, following a properly performed treatment, I may not be satisfied by my personal and subjective perception of the achieved aesthetic result, and that this is something that the medical professional is unable to predict or avoid.

I recognise that the proposed treatment does not use up all the available resources and further therapeutic measures may be required. I accept that certain personal circumstances (sicknesses, habits and treatments that I have not withheld which are present in my medical record) may increase the occurrence of the indicated complications. I accept that, as a result of the treatment, I could experience detrimental aesthetic results rather than improvement. I also agree to adhere to the aftercare instructions that have been prescribed and, in particular, to take all the precautions of which I have been notified.

I expressly consent to being contacted via the methods I have provided, in order to receive proposals for future treatments that may be of my interest to me, in relation to my dermatological characteristics and medical history. I expressly consent to being photographed and/or filmed before, during and after the treatment, as the resulting images represent a graphic means of diagnosis and a record for my medical history.

I have been able to resolve all my doubts regarding the above and I have satisfactorily understood this document which I now sign:

Patient signature  
Name and surname  
Date

Physician/ authorized person signature  
Name and surname  
Date