

## PARTIE IV : ACCOMPANYING FORMS



You can find this document in MY ACCOUNT on our website: [www.deleo-medical.com](http://www.deleo-medical.com)

## 1 INFORMED CONSENT FORM FOR CRISTAL

The principle of CRISTAL cryolipolysis is to practice a sustained suction of tissues while diffusing a controlled cooling on the surface of the skin. This technique leads to a reduction of fat mass in the targeted area. This is not a weight loss solution and it does not replace traditional methods such as liposuction. An overweight patient should expect less improvement than one with smaller fat deposits. Clinical studies have shown that CRISTAL cryolipolysis naturally destroys fat cells. However, as with most techniques, the results vary from one individual to another.

### OBSERVED EFFECTS

- The phenomenon of suction can cause feelings of deep tugging and pinching. You may experience intense tingling, pain or cramps at the beginning of the treatment. These sensations usually stop as the treated area becomes numb.
- The treated area may have a rigid appearance (observed and felt) as a result of the treatment. A temporary whitening of the skin can be observed. It is possible to feel nausea and vertigo, your body reacting to the treatment. These reactions are normal and usually go away in minutes.
- Bruises, swelling, and tenderness may appear on the treated area as well as redness of the skin that may persist for several hours after the treatment. Subcutaneous induration, lumps with pain and / or discomfort as well as hyperpigmentation with dark coloration of the skin may appear at the site or at the edge of the treatment area.
- You may experience a loss of sensation in the treated area for several weeks after the treatment. Other observable changes - including severe itching, tingling, numbness, tenderness, pain in the treated area, severe cramps and painful muscle contractions - are the main adverse effects observed after a cryolipolysis treatment.
- The effects differ among patients and a late onset of the previously mentioned effects has been observed (1 to 2 weeks after treatment). Contact us immediately if any side effects not listed appear or if symptoms persist.
- Burns may also be observed in some patients as well as brown skin coloration, stiffness and hypoesthesia or deformity of the treated area. Surgery may be required to correct this deformity. Late-onset pain can also occur.
- Vasovagal episodes during or immediately after treatment may be observed in some patients.
- Paradoxical hyperplasia (PAH) may occur 2 to 9 months after treatment. PAH is an increase in the volume of fatty tissue treated. In this case, contact us immediately.
- Contact us immediately if any side effects mentioned or not mentioned appear, or if symptoms persist.
- You can see results as early as 4 to 6 weeks after cryolipolysis treatment and the more results after three months. Your body continue to naturally eliminate damaged fat cells for up to four months after the treatment
- It is possible to perform several sessions until the desired result is achieved.

I have been informed of these side effects and that some other unknown ones may appear.

Name:

Signature :

Date :

## DO YOU HAVE ONE OR MORE OF THE FOLLOWING CONDITIONS?

Please circle the answer.

### Formal contraindications:

If one of the answers surrounded is «YES» you will not be able to be treated with cryolipolysis.

Cryoglobulinemia	Yes / No
Cold paroxysmal hemoglobinuria	Yes / No
Cold agglutinin disease	Yes / No
Known sensitivity to cold such as cold urticaria	Yes / No
Hernia at or near the treatment site	Yes / No
Hemochromatosis	Yes / No
Pregnancy and breastfeeding	Yes / No
Known sensitivity to cold such as Raynaud's disease, frostbite	Yes / No
Altered peripheral circulation in the area to be treated	Yes / No
Neuropathic disorders or neurological impairment, nerve pain (post-herpetic neuralgia or diabetic neuralgia)	Yes / No
Skin conditions (eczema, dermatitis, rashes, open or infected wound)	Yes / No
Bleeding disorders or simultaneous use of anticoagulants	Yes / No
Recent surgery or scar tissue in the area to be treated	Yes / No
Active implantable device such as pacemaker or defibrillator	Yes / No
Evolutionary cancer	Yes / No
Scleroderma	Yes / No
HIV infection, hepatitis C	Yes / No
Liver insufficiency, liver disease	Yes / No
Myocardial infarction and/or stroke < 6 months	Yes / No

### Precautions of use:

Chronic pain or chronic conditions requiring treatment	Yes / No
Infectious and fever, anxiety	Yes / No
Known sensitivity or allergy to propylene glycol, fructose or glycerin	Yes / No

I have read the formal contraindications and precautions for the use of cryolipolysis.

I have read the above information and I agree to be treated with cryolipolysis CRISTAL by the Doctor ..... and their assistant.

Name:

Signature:

Date:

## 2 INFORMED CONSENT FOR DIAMOND TREATMENT

The principle of the DIAMOND treatment is to combine a mechanical stimulation of the knead/roll technique with the High Intensity Focused Diode (HIFD) technology.

The 940nm diode radiation is absorbed by the target tissue and converted into thermal energy to heat the fat cells. This enables the release of the stored triglycerides, a reduction in adipocytes and a reduction of the fat tissue. The IR thermal energy also acts on the dermis and triggers a chain of physiological responses (neocollagenesis, elastin production) that will induce a skin tightening.

The suction stimulates the fibroblasts through mechanical stress and stretches the septas. This technique promotes neocollagenesis and the release of septas, thus leading to cellulite reduction. It also stimulates lymphatic drainage, which in turn stimulates the lymphatic circulation and drains the toxins and cellular residues.

As with the majority of techniques, results vary between individuals.

### OBSERVED EFFECTS

- The increase in temperature induced by the heating phase may cause a heat sensation on the treated area.
- Bruises may appear on the treated area, as well as skin redness that may persist a few hours or days after the treatment.
- In extreme cases, vasovagal responses may be observed in some patients as well as burns, a brown coloration of the skin as well as stiffness and hypoesthesia of the treated area.
- The results are usually visible after 6 sessions with the DIAMOND treatment.

I have been informed of these side effects and that some other unknown ones may appear.

Name :

Date :

Signature :

### DO YOU HAVE ONE OR MORE OF THE FOLLOWING CONDITIONS?

Please circle the answer.

Chronic pathologies requiring treatment	Yes / No
Photosensitivity	Yes / No
Permanent implants at the treated area	Yes / No
(metal prothesis, pacemaker or electronic implants)	Yes / No
Damaged skin, skin diseases such as eczema, dermatitis or skin rashes on the area to be treated	Yes / No
Open or infected wounds	Yes / No
Keloid or recent scars on the area to be treated	Yes / No
Tattoos	Yes / No
Recent surgery on the area to be treated	Yes / No
Pregnant or lactating women	Yes / No
Blood circulation problems at the treated area	Yes / No
Infectious state	Yes / No
Neuropathic disorders or neuropathic diabetes	Yes / No
Bleeding disorders	Yes / No
Allergy to one or several ingredients in the massage oil	Yes / No

I have been informed of the risks and existing side effects.

I have read the above information and I agree to be treated with the DIAMOND Handpiece device by the Doctor .....and his/her assistant.

Name:

Signature:

Date:

### 3 PATIENT INFORMATION SHEET FOR CRISTAL

This treatment is for patients with localized excess fat.

This procedure allows the crystallization of fat cells that self-destruct under the action of cold. The crystallized fat will then be eliminated naturally and permanently over the weeks following the session, to make way for harmonious curves.

This innovative technique, which guarantees efficiency and safety, is non-invasive and requires no anesthesia. After 12 weeks, the result is optimal and definitive.

Medical cryolipolysis treats localized excess fat, so it is ideal for patients with recalcitrant bulges but without a generalized excess weight.

This technique cannot replace a diet in the case of a general fat overload but may be associated with it.

#### THE BEST AREAS

In order to achieve an optimal result, it is important to properly target the area to be treated. Thanks to its versatility, the CRISTAL cryolipolysis can treat many areas in women and men:

- Chin / Neck
- Arms
- Bra fold / Back fold
- Pseudogynecomastia
- Abdomen
- Love handles (flanks)
- Saddle bags
- Inner/Outer thighs
- Knees
- Ankles

Other areas can also be treated in both men and women.

#### THE CRISTAL SESSION

The CRISTAL medical cryolipolysis session is divided into five stages:

1/ After setting your goals and treatment plan, the doctor takes measurements of the areas to be treated as well as photos.

2/ The doctor sits you comfortably on the treatment table and first applies a cryoprotective wipe to the area to be treated.

3/ The applicator is then positioned on the greasy fold, then the cooling and suction are launched. The bulge will lodge in the applicator cavity to cool evenly.

4/ At the beginning of the session, it is possible to feel a feeling of traction and pinching of the skin when placing the applicator. Then after a few minutes of cooling, the area is numbed by the cold and the sensations of tightness disappear. A session lasts from 30 to 60 minutes during which you can relax, listen to music or read.

5/ Once the session is over and the applicators are removed, the doctor or her/his assistant will massage the treated area for about ten minutes to warm up the area. This massage stimulates lymphatic drainage and thus promotes the elimination of fat cells.

#### THE POST ACT PHASE

The cryolipolysis CRISTAL treatment is safe, non-invasive and very painless. So, you can resume your daily activities as soon as the session is over. Side effects are mild such as redness, small bruising or swelling, and numbness.

These effects naturally disappear within hours or days.

The results are not immediately visible because the fat cells are phased out by the lymphatic system. From 8 weeks, you will be able to observe the results, but you will continue to eliminate up to 3 months after the session.

### **POST-TREATMENT ADVICES**

- Hydrate well (1.5 L of water per day) and combine a natural drain with your drinks to facilitate the removal of fat cells by the lymphatic system. This step is essential for good results.
- Have a good lifestyle, especially from a nutritional point of view, to prevent fat clumps from reforming.
- Exercise daily to tone and shape your body (30 minutes of exercise per day).
- Avoid alcohol consumption during the lymphatic drainage process.
- It is advisable to practice draining massages of the type palpate-rolling, with the use of anticellulite creams, to maximize the results of your session at least during the first week after treatment.

### **HOW MANY SESSIONS ARE NEEDED TO ACHIEVE AN EFFECTIVE AND PERMANENT RESULT?**

Results vary from patient to patient. In general, there is a loss of from 20 to 40% of the fat bulge volume for an area in one sitting, which is usually sufficient for small lipodystrophies.

However, adjacent areas will sometimes be treated for a harmonious result. If the fat zone is large, the treatment may be repeated after the first session. Fat cells are permanently destroyed and eliminated from your body, so the result is lasting. It is up to you to take care of your new figure, thanks to a balanced diet and regular physical activity.

### **WHAT ARE THE LIMITS OF THE CRISTAL MEDICAL CRYOLIPOLYSIS?**

CRISTAL medical cryolipolysis is a truly effective technique provided certain indications are followed. Because of its mode of action, it can only address the treatment of localized bulges. This method is by no means a regime substitute. The effectiveness of the CRISTAL cryolipolysis technique is more limited than that of a real liposuction. Liposuction remains a surgical technique with its inherent pros and cons. However, without being surgical, the medical cryolipolysis CRISTAL has the best efficiency/comfort ratio for the patient.

### **IS THERE ANY CLINICAL STUDIES THAT PROVE THE INNOCUITY OF THE METHOD?**

Several clinical studies have proven the safety and efficacy of the CRISTAL cryolipolysis technique. Following the study of Dr. M. NAOURI the results obtained are as follows: the average circumference loss was 3.2 -1.7cm. The maximum circumference differential was 6 cm and patient satisfaction was estimated at 3/4 (significant satisfaction).

83% of the patients treated wanted to do a second session in the same or adjacent area, in order to optimize their result.

### **WHY CHOOSE THE CRYOLIPOLYSIS CRISTAL TREATMENT?**

CRISTAL is the latest generation of medical cryolipolysis on the market. Do you want to harmonize your figure in a natural way through a gentle and safe method? CRISTAL medical cryolipolysis is the perfect solution! CRISTAL cryolipolysis is a medical device. It meets European standards for medical products 93/42/EEC. By choosing the CRISTAL cryolipolysis technique, you choose performance, safety, while focusing on French technology and know-how.

### **CONCLUSION :**

CRISTAL medical cryolipolysis is an innovative and effective method based on numerous scientific studies. It is nevertheless a technique reserved for localized fat clumps, apart from any significant overweight justifying a diet that crystal cryolipolysis could not replace.

Cristal medical cryolipolysis is a medical procedure, performed under the supervision of a doctor.

Name :

Signature :

Date :

## 4 PATIENT INFORMATION SHEET FOR DIAMOND TREATMENT

The DIAMOND treatment treats cellulite and is therefore perfect for patients with an “orange peel” problem. This procedure enables a reduction of cellulite as well as skin tightening and enhancement of skin texture. This innovative technique guarantees effectiveness and safety, is non-invasive and requires no anaesthesia. The result is optimal and permanent after a few sessions.

### THE DIAMOND TREATMENT

The DIAMOND treatment procedure is done in 5 stages:

1/ Once your objectives and treatment plan have been defined, the doctor marks the area to be treated and takes photos.

2/ Once you are comfortably installed on the bed, the doctor applies DIAMOND oil onto the area to be treated to ensure the handpiece slides properly on your skin. You are also given protection goggles or shells for your eyes.

3/ The doctor places the handpiece onto your skin and starts the treatment.

4/ The doctor starts with the “heating phase”. At first, he makes small circular movements on the area to be treated with LED radiation to generate heat.

5/ The doctor then moves onto the “dynamic phase”. The handpiece pulls on the skin using suction, while maintaining a high temperature.

At the start of the session you may feel a painless pulling and heating sensation. A session usually lasts between 20 and 30 minutes.

6/ Once the session is over and the handpiece is taken off, the doctor or his assistant massages the treated area to enable the oil residues to be absorbed by your skin. This massage stimulates the lymphatic drainage process and promotes the elimination of fat cells. Once the session is over, you can resume your normal activities. You might notice redness and feel a heat sensation on the treated area. These effects will fade within a few hours following the session.

### THE POST-TREATMENT PHASE

The results are not immediately visible, since the fat cells are gradually eliminated by the lymphatic system. The DIAMOND treatment is safe, non-invasive and not painful. You can resume your normal activities immediately after the session. Slight side effects include redness and small bruising. These side effects disappear naturally in the hours or days following the treatment.

#### How many sessions are needed to obtain effective and permanent results?

The results vary between patients according to the volume of the cellulite and size of the treated area. 6 to 10 sessions (2 sessions a week) are needed to obtain satisfying results according to your indication.

### 4 POST-TREATMENT TIPS

- Drink a lot of water following the session (1.5 litre of water per day).
- Use anticellulite creams or oils on the treated zone.
- Lead a healthy lifestyle and exercise daily.
- It is recommended to do knead/roll draining massages with anticellulite creams to optimise results.



## 5 ADVERSE REACTION REPORT CARD

CHE-73A Signalement d'évènement indésirable / form event report form CRISTAL v1.0-020920

Identification du dispositif médical <i>Identification of the medical device</i>				
Date de traitement / <i>Treatment date</i>	_ _ _ / _ _ _ / _ _ _ _ _ _ _			
Information du Patient / <i>Patient information</i>	Genre / <i>Gender</i> :	Age:	Epaisseur du pli cutané / <i>Fat skin fold thickness</i> :	IMC / <i>BMI (kg/cm²)</i> :
	<input type="checkbox"/> F <input type="checkbox"/> M	_ _ _	_ _ _ , _ _ _  cm	<input type="checkbox"/> 18 - 24.9 <input type="checkbox"/> 25 - 29.9 <input type="checkbox"/> ≥ 30
	Phototype / <i>Phototype</i> :	<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> VI		
Numéro de série / <i>Serial number</i>	_____			
Type d'applicateur utilisé et numéro de série associé / <i>Type of applicator used and serial number associated</i>	<input type="checkbox"/> Ruby n° _____ <input type="checkbox"/> Sapphire n° _____ <input type="checkbox"/> Emerald n° _____ <input type="checkbox"/> A1 n° _____ <input type="checkbox"/> A2 n° _____ <input type="checkbox"/> A3 n° _____		<input type="checkbox"/> Amethyst n° _____ <input type="checkbox"/> Agate n° _____ <input type="checkbox"/> Diamond n° _____	
Paramètres utilisés / <i>Parameters used</i>	Temperature/ <i>Temperature</i> : -  _ _ _  °C			Lingette utilisée/ <i>Gel pad used</i> :
	Aspiration / <i>Vacuum</i> : Niveau d'aspiration précis / <i>precise vacuum</i> :  _ _ _ _  mbar <input type="checkbox"/> Niveau / <i>level</i> 1 <input type="checkbox"/> Niveau / <i>level</i> 2 <input type="checkbox"/> Niveau / <i>level</i> 3 <input type="checkbox"/> Niveau / <i>level</i> 4  Durée de traitement / <i>treatment time</i> :  _ _ _  min  Niveau de puissance / <i>Power level (DIAMOND option)</i> : <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10			Numéro de lot/ <i>Batch number</i> : _____  Date de péremption/ <i>Expiration date</i> :  _ _ _ _ / _ _ _ / _ _ _

Date d'apparition de l'EI / Date of AE onset:	_ _ _ / _ _ _ / _ _ _ _ _
Description de l'évènement indésirable (type et grade) / Description of adverse event (type and grade)	
Signes cliniques (caractéristique de l'EI) / Clinical symptoms (characteristics of the AE)	
Zone traitée, affectée / Treated, affected areas	
Ressenti du patient pendant et après la séance / Patient experience during and after the session	
Prise en charge du patient (soins dispensés, médicaments administrés, etc.) / Patient management (care provided, medication administered, etc.)	
Suivi du patient (médicament(s) prescrit(s), protocole de soin à effectuer, etc.) / Patient follow-up (medication prescription, care protocol to be performed)	
Conséquences de l'EI sur la vie quotidienne du patient (arrêt de travail, hospitalisation, etc.) / Consequences of the AE on the patient's daily life?	

Signature et tampon :

55

## 6 AUTHORIZATION TO USE IMAGE

PATIENT	DOCTOR
Name: _____	Name: _____
First name: _____	First name: _____
Date of birth: _____	Signature/Stamp: _____

The doctor has taken one or more photographs on which the model appears.

These images were taken from the date of \_\_\_\_\_ to \_\_\_\_\_

### PURPOSE OF THE PHOTOGRAPHS

The photographs will aim to verify the real and visible results of the CRISTAL and/or DIAMOND medical cryolipolysis treatment.

### SHOOTING CONDITIONS

The photograph should not:

- show the face of the model
- undermine the model
- allow any recognizable element of the model appear (ex: tattoo)

The photograph will have to:

- be taken of the treated area
- be taken with a neutral background.

### DIFFUSION MODES

The model (which attests not to be bound by a third party with an exclusive contract of his/her image) authorizes the doctor to use the photographs for the uses mentioned below. In the event of disagreement with any of the uses, the model should circle the concerned use. He/she is informed that by not refusing authorization, his/ her photograph can be used on all the supports indicated below:

- Clinical studies
- Internal presentations
- External presentations
- Publications
- Exhibitions
- Advertising

### DURATION OF AUTHORIZATION

This authorization is granted for an indefinite period after signature.

### PHYSICIAN'S COMMITMENT

The doctor is expressly forbidden from exploiting photographs likely to infringe on the private life or the reputation of the model, or any other detrimental exploitation.

The doctor will keep a proof of each issue available upon request and encourage his partners to do the same by personally doing everything possible to achieve this goal.

Date:

Signature of the model:

## 7 CRISTAL QUOTATION TEMPLATE FOR PATIENT

To be given to the patient following the pre-treatment consultation

### CRISTAL CRYOLIPOLYSIS

This procedure allows the crystallization of fat cells that self-destruct under the action of the cold. The crystallized fat will then be eliminated naturally and permanently over the weeks following the session, leading to harmonious curves.

This innovative technique, which guarantees effectiveness and safety, is non-invasive and requires no anesthesia. Once the session is over, you can easily return to your activities!

Versatile, CRISTAL can treat many areas of the body for both men and women:

- Chin / neck
- Arms
- Bra fold / Back fold
- Pectoral area
- Abdomen
- Love handles
- Saddlebags
- Inner / outer thighs
- Knees
- Ankles

After 12 weeks, the result is optimal and definitive: you can enjoy your new silhouette. CRISTAL is the reference in medical cryolipolysis, do not wait to find out!

### DIAMOND TREATMENT AGAINST CELLULITE

The “orange skin” effect is caused by the stored adipocytes that apply pressure and deform the connective tissue under the skin – also called “septa”. This causes significant changes in the skin's appearance.

The DIAMOND applicator combines various technologies that offer an effective cellulite and skin tightening solution. The radiation from 940nm will target the adipocytes and promote collagen production, while the modular suction mechanically massages the area and stretches the septa, thus stimulating the lymphatic drainage process.

### PATIENT INFORMATION

Name:

First name:

Address:

Postal code:

City:

E-mail:

Phone number:

Gender: MALE / FEMALE

Age: \_\_\_\_\_ year-old

Weight: \_\_\_\_\_ kg

Size: \_\_\_\_\_ cm

**Did you follow a diet in the last 12 months ? YES / NO**

If YES, which one?

You can find this document in MY ACCOUNT on our website: [www.deleo-medical.com](http://www.deleo-medical.com)

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Did you undergo any surgery? YES / NO

If YES, which one(s)?

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Are you allergic to certain substances? YES / NO

If YES, which one (s)?

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### TREATMENT INFORMATION (TO BE FILLED IN BY THE DOCTOR)

What are the areas to be treated?

CRYOLIPOLYSE CRISTAL
Chin / Neck
Arms
Bra fold / back fold
Pectoral area
Abdomen
Love handles
Saddlebags
Inner / outer thighs
Knees
Ankles

Number of recommended cryolipolysis sessions: \_\_\_\_\_.

## 8 CRISTAL TREATMENT PLAN

Name: \_\_\_\_\_ First name: \_\_\_\_\_.

Gender: Female / Male

Weight (kg): \_\_\_\_\_ Height (cm): \_\_\_\_\_

Did you follow a diet in the last 12 months? Yes / No

If yes, which one?

Did you undergo any surgery? Yes / No

If yes, which one?

### PRE-TREATMENT CHECK-LIST:

Check that the patient has no contraindications. Have the patient sign the CRISTAL cryolipolysis sheet.

Have the patient sign the informed consent form. Have the patient sign the right to image form

Ask the patient to dress appropriately for photos and for treatment

Sessions scheduled

### WHAT ARE THE AREAS TO BE TREATED?











CRYOLIPOLYSE CRISTAL	DIAMOND
Chin / Neck	Arms
Arms	Abdomen
Bra fold / back fold	Love handles
Pectoral area	Saddlebags
Abdomen	Tummy
Love handles	Calves
Saddlebags	
Inner / outer thighs	
Knees	
Ankles	

### Validated treatment plan:

Number of cryolipolysis sessions: \_\_\_\_\_

Number of Diamond sessions: \_\_\_\_\_

## TREATMENT FOLLOW-UP

<b>TRAITEMENT N°</b>	Date:				
Treated areas	Chin / Neck Arms Bra fold / back fold Pectoral area Abdomen		Love handles Saddlebags Inner / outer thighs Knees Ankles		
Applicator(s) used	AMETHYST RUBY SAPPHIRE EMERALD		AGATE AMBER JADE		
Measurements (cm)	Area 1:		Area 3:		
	Area 2:		Area 4:		
Picture before treatment	Reference picture:				
Sensations during treatment	No pain 	Bearable pain 	Slightly painful 	Painful 	Unbearably painful 
Comments					
<b>Visite de suivi</b>	Date:				
Measurements (cm)	Area 1:		Area 3:		
	Area 2:		Area 4:		
Picture after treatment	Reference picture:				
Patient's satisfaction	Very satisfied 	Satisfied 	Not very Satisfied 	Disappointed 	Very disappointed 
Comments					