CRISTAL® CRYOLIPOLYSIS CONSENT

Do you currently have or have had any of the following?

Yes / No Cryoglobulinemia (a condition in which an abnormal level of proteins thicken the blood in cold temperatures), or paroxysmal cold hemoglobinuria or cold agglutinin disease (blood disorders in which cold temperatures lead to red blood cell death).
Yes / No Known sensitivity to cold such as cold urticaria (hives triggered by cold), Raynaud's disease (disorder in which cold leads to reduced blood flow in the fingers, which appear white, red, or blue), pernio or Chilblains (itchy and/or tender red or purple bumps that occur as a reaction to cold).
Yes / No Poor blood flow in the area to be treated
Yes / No Neuropathic (nerve) disorders such as post-herpetic neuralgia or diabetic neuropathy
Yes / No Impaired skin sensation
Yes / No Open or infected wounds
Yes / No Bleeding disorders or use of blood thinners
Yes / No Recent surgery or scar tissue in the area to be treated
Yes / No A hernia or history of hernia in the area to be treated or adjacent to treatment site
Yes / No Skin conditions such as eczema, dermatitis, or rashes
Yes / No Pregnancy or lactation (making breast milk or breast feeding)
Yes / No Any active implanted devices such as pacemakers and defibrillators
Yes / No Any major health problems such as liver disease
Yes / No Any known sensitivity to isopropyl alcohol (rubbing alcohol) or propylene glycol

The CRISTAL® Cryolipolysis® procedure is a non-invasive procedure that is intended to change the appearance of the treatment area by delivering controlled cooling at the surface of the skin to break down fat cells that are just beneath the skin. This procedure is not a treatment for obesity or a weight-loss solution. The CRISTAL® Cryolipolysis procedure does not replace traditional methods such as diet, exercise or liposuction.

Clinical studies of a treatment site have shown that the CRISTAL® Cryolipolysis procedure can break down fat cells to change the appearance of visibly localized bulges of fat that is just beneath the skin on the abdomen, thighs, flanks and submental area. The submental area is the area under the chin. Following the procedure, the treated fat cells are naturally processed by the body. Visible results can vary from person to person.

Initials……Date……

TEMPORARY SENSATION

- The suction pressure of a vacuum applicator may cause sensations of deep pulling, tugging and pinching. A surface applicator may cause sensations of pressure. You may experience intense cold, stinging, tingling, aching or cramping as the treatment begins. These sensations generally subside during treatment as the area becomes numb.
- Dizziness, light-headedness, nausea, flushing, sweating, or fainting may occur during/immediately after the treatment.
- The treated area may look or feel stiff after the procedure and transient blanching (temporary whitening of the skin) may occur. These are all normal reactions that typically resolve within a few minutes.
- Bruising, swelling, redness, cramping and pain can occur in the treated area and the treated area may appear red for one to two weeks after treatment.
- After submental area treatment, a feeling of fullness in the back of the throat may occur.
- You may feel a dulling of sensation in the treated area that can last for several weeks after the procedure. Prolonged swelling, itching, tingling, numbness, tenderness to the touch, pain in the treated area, cramping, aching, bruising and/or skin sensitivity also have been reported.

POTENTAL SIDE EFFECTS & RISKS

- Paradoxical Hyperplasia -- A small number of patients have experienced gradual development of a firmer enlargement, of varying size and shape, of the treatment area, known as "paradoxical hyperplasia", in the months following the treatment. If such paradoxical hyperplasia occurs, it will be distinguishable from temporary swelling and will probably not resolve on its own. The enlargement/lump can be removed by means of a surgical procedure such as liposuction.
- Treatment area demarcation -- A small number of patients have experienced excessive fat removal in the treatment area, resulting in an unwanted indentation. The indentation may be improved through corrective procedures.
- In rare cases, patients have reported the CRISTAL® Cryolipolysis treatment area to have darker skin color, hardness, discrete nodules, frostbite (local injury due to cold), hernia or worsening of existing hernia. Surgical intervention may be required to correct hernia formation.
- Patient experiences may vary. Some patients may experience a delayed onset of the previously mentioned symptoms. Contact your physician immediately if any unusual side effects occur or if symptoms worsen over time.
- I understand that these and other unknown side effects may also occur.

RESULTS

- You may start to see changes in as early as three weeks after your CRISTAL® Cryolipolysis procedure and will experience the most dramatic results after one to three months. Your body will continue to naturally process the injured fat cells from your body for approximately four months after your procedure.
- Results vary from person to person. You may decide that additional treatments are necessary to achieve your desired outcome. Although highly unlikely, it is possible that you will not experience any noticeable result from the procedure.

Initials……Date……

NON-FDA CLEARED AREAS

Other areas that can be treated through CRISTAL® Cryolipolysis but are NOT FDA-CLEARED include the back of the arms, the front of the armpit, above the knee, back of the leg, gynecomastia, and other various areas with localized bulges of fat. I acknowledge that if I chose one of the above areas, I understand that it is not an FDA-Cleared CRISTAL® Cryolipolysis procedure.

CRISTAL® CRYOLIPOLYSIS + INDIBA® Skin tightening

At the end of the CRISTAL® Cryolipolysis treatment, the INDIBA® Skin tightening device might be used to massage the treated tissue. The INDIBA® Skin tightening uses high energy sound waves to increase metabolic activity. As a result, the skin tightens, collagen production increases, and blood circulation increases aiding in the removal of fat cells by the lymphatic system. On occasion there are patients that do not respond to treatments so the outcome cannot be guaranteed. The INDIBA® Skin tightening therapy is a non-invasive procedure with limited risks and side effects. Some patients reported minor redness and bruising from the treatment that normally resolves within a few days. The INDIBA® Skin tightening has been cleared by the FDA for the temporary reduction in the appearance of cellulite. The use of the INDIBA® Skin tightening post CRISTAL® Cryolipolysis treatment is currently considered off-label.

DISCLAIMER: I understand the nature of the procedure to be performed, the contraindications, side effects, risk, and complications. I have been given the opportunity to ask any questions regarding the procedure, and these questions have been answered to my satisfaction. I understand the pre and post care instructions. By not following the pre and post care instructions, I understand side effects and complications may occur. I understand the practice of medicine and the subsequent use of CRISTAL® Cryolipolysis is not an exact science. Although good results are expected, there is no guarantee on the results that may be obtained. I hereby give my unrestricted informed consent for the procedure and subsequent treatments. I hereby release the doctor, the NP/PA, and the facility from liability associated with this procedure. I am aware this is a cosmetic procedure and I am fully responsible to pay for the entire amount charged. I understand no refunds for any treatment may be rendered, regardless of the results. I understand it is my responsibility to inform the office staff of any changes to my medical history including those that are contraindications to this treatment.

Printed Patient's Name: _____

Patient's Signature: _____ Date: _____

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