**SYSTEM SOFWAVE**TM

**SUPERBTM Technology - Synchronous Ultrasound Parallel Beam**

**Patient Consent Form**

I understand that there are many types of treatments for fine lines and wrinkles and that each has its own benefits, risks, and potential side effects. The treatment with the Sofwave System requires a non-invasive, dermatological procedure performed by a healthcare provider who is trained to use this product.

By completing this patient consent form, I am consenting to the treatment with the Sofwave System and acknowledging that I have read and understood the following points and all information contained in this form, and made an informed and careful decision to receive the treatment with the Sofwave System.

* The Sofwave System is used to treat wrinkles, fine lines, cellulite[[1]](#footnote-1), acne scars1 and upper arms1 appearance on the skin.
* The procedure is non-invasive and uses ultrasound beams.
* The Sofwave system delivers ultrasound energy to the skin. The heat from the ultrasound stimulates new collagen and elastin to form.
* I understand that there may be some discomfort during the treatment when the ultrasound beam is being delivered.
* My healthcare provider may choose to apply a topical anesthetic and/or administer nitrous oxide and/or nerve blocks and/or intramuscular Toradol to me before the procedure to minimize the pain.
* Following treatment, there may be some redness and/or swelling on the treated area that may last for few hours; there should be no pain when the procedure is completed while post-procedure discomfort or tenderness is possible.
* My experience in receiving the treatment and the results of my treatment may be different from others.
* The Treatment may be done using the Lift or Precise handpieces (applicators). The Lift applicator contains 7 Ultrasound transducers, and the Precise applicator contains 3 Ultrasound transducers. The transducers in both applicators are identical. The healthcare provider will decide which one to use according to the treatment areas (can use one or both of the two applicators).
* While receiving treatment with the Sofwave System can provide potential benefits for me, there are also potential risks/complications associated with the treatment. These risks include, but may not be limited to, the following:
* Burn
* Significant pain
* Tenderness
* Changes in skin pigmentation
* Persistent redness and/or swelling
* Ulceration/Erosion
* Bruising

Do you have any of the following?

**Contraindications**

* Pacemakers and electronic device implants in treatment area(s) Yes/ No
* Open wounds or lesions on the treatment area(s) Yes/ No
* Severe or cystic acne on the treatment area(s) Yes/ No

**Precautions**

* Pregnant or planning to become pregnant, having given birth less than three

months ago, and/or breast feeding. Yes/ No

* Presence of any active systemic or local infections. Yes/ No
* Presence of active local skin disease that may alter wound healing. Yes/ No
* History of chronic drug or alcohol abuse. Yes/ No
* Significant scarring in the area to be treated. Yes/ No
* Presence of a metal stent or implant in the facial area. Yes/ No
* The Sofwave system has not been evaluated for use over various materials. Yes/ No
* Treatment is not recommended for use directly over areas with a dermal filler. Yes/ No
* Taking Isotretinoin or other retinoid within the past 6 months; taking psychiatric drugs,

anti-platelet or anti-coagulant within the past 2 weeks. Yes/ No

* History of melasma. Yes/ No
* History of recent local skin infection in the intended treatment area (such as HSV-1, Yes/ No

Varicella Zoster, dermatitis, acne, etc.).

As per the physician’s discretion, any physical or mental condition which might make it unsafe for the patient.

For additional information about the Sofwave System, I can call 1-855-sofwave or log on to: <https://sofwave.com>

After learning about the Sofwave System, I choose to use the Sofwave System.

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(Patient name) (Patient signature) (Date)

Witnessed by:

The patient above has signed this consent in my presence after I counseled him/her and answered his/her questions.

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(Name of Healthcare Provider) (Healthcare Provider Signature) (Date)

**Photograph Consent:**

By checking the box below, you give you permission to use photographs and digital images of your treated areas, which were taken before and after the Sofwave treatments for the purpose of professional publications, training, or education. These materials might include printed or electronic publications, websites, or other electronic communications/presentations.

By checking the box below, you declare that you have no history of any kind of epilepsy (seizure disorder) and that you will inform the study doctor in if you suffer from eye sensitivity to camera flashes (in which case, you will be provided with eye shields).

Statement:

I may cancel or withdraw my photography consent at any time during or after my treatment. I must do so in writing and submit that withdrawal of consent to the doctor or clinic team or to Sofwave representative. I agree to have photographs taken as part of this procedure as described in this paragraph.

□ Yes

□ No

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Cleared indication in USA only [↑](#footnote-ref-1)