PATIENT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

Non FDA Approved Indication: SoftWave OrthoGold Shockwave Therapy (SWT) to reduce the symptoms of Alzheimer's by the improvement of blood supply to the brain.

STUDY DOCTOR:

STUDY SITE:

SPONSOR:

Background:

What you should know about this compassionate use:

- You are being asked to allow the use of the SotfWave OrthoGold device for a non FDA approved indication. The device is FDA cleared for acute and chronic wounds, connective tissue activation, pain relief and to increase the temporary blood supply in tissue excluding the brain as this has not been studied.
- The SoftWave OrthoGold device is not approved by the Food and Drug Administration (FDA) for your condition and therefore this use is investigational.
- This consent form explains how the SoftWave OrthoGold device will be used.
- Please read it carefully and take as much time as you need. Ask your doctor to explain any words or information in this informed consent that you do not understand.
- Should any new information arise while you are in your treatment plan, you will be informed.

Discussion of the SoftWave Therapy:

The OrthoGold device generates shockwaves through an applicator/probe filled with water, connected to an acoustic wave generating device. The SoftWave OrthoGold is FDA 510(k) cleared for acute and chronic wounds, as well as connective tissue activation, inflammation, temporary pain relief and improved blood supply. There is no FDA clearance for Alzheimer's or any similar indication although our clearance includes temporarily increasing blood supply to tissues excluding the brain.

The SoftWave OrthoGold device and applicator resembles an ultrasound device in size, appearance, and function. During therapy, the handheld applicator is place firmly against the skin of the targeted areas. The targeted areas are the base of the skull directed towards the brain stem moving 3 inches left to right; and, the center of the forehead in the direction of the cerebrum moving back and forth 3 inches in each direction from the center line. A maximum of 1000 pulses per session will be applied to each location (2000 maximum pulses per session). A maximum energy level of .12 mj/mm^2 will be selected and applied. It has been published

(Holfeld et.al.) that this energy level and this number of shockwaves cannot cause injury in human tissue. A maximum of 4 pulses per second shall be applied. Two to four pulses per second are acceptable. A maximum number of 12 treatments will be applied over a maximum of 10 weeks, preferably 2 treatments per week over the first 6 weeks. Missed treatments can be made up weekly over weeks 7 – 12.

All technologists or doctors will be trained and certified by SoftWave Tissue Regeneration Technology prior to the first treatment and SoftWave personnel will attend the first treatment day of each treatment provider.

The treatment areas will be prepared for SoftWave application by first applying ultrasound gel or silicone oil to the therapeutic area. This gel or oil will help conduct the acoustic waves. The SoftWave applicator will then be placed in contact with the gel and the treatment will be initiated. The probe shall be located to avoid hair, or to minimize the hair at the treatment site. The treatment should not be painful. If you sense pain, please immediately inform the technician and the energy can be lowered or the treatment discontinued. The treatment is performed in a doctor's office under the supervision of a doctor. The therapy may be performed by a technologist trained and certified by SoftWave Tissue Regeneration Technology under the supervision of the patient's doctor. The duration of the procedure usually lasts between 10 to 20 minutes.

RISKS:

Risks include:

- Theoretically, shockwaves produce mechanical energy that if targeted to an existing aneurysm could cause a rupture. However, in over 10,000 treatments with SWT for Alzheimer's in Europe with a substantially higher energy device, there has never been a reported case of this occurring. While there is no evidence that unfocused SWT could cause an aneurysm, theoretically SoftWave may cause an existing vascular lesion or aneurysm to erupt or break, potentially resulting in death.

  This risk is addressed by patients undergoing a MRI prior to treatment, or reviewing a recent MRI to preclude the existence of an aneurysm. If an aneurysm is found during your MRI, the area surrounding the aneurysm will not be targeted with SWT. Further, if you have a high risk of aneurysm or a family history of the same you should not be treated with SWT without considering the additional risks. If this is the case, please consult your doctor to discuss the risks.

- SoftWave can cause pain or discomfort when targeting inflamed tissue, especially in an acute injury. SoftWave treatment for Alzheimer's should not be painful since there is not typically inflamed, painful tissue in the brain associated with Alzheimer's. If the treatment results in any substantial pain, the treatment will be discontinued immediately. Immediately inform the doctor or technician if there is discomfort during or after the treatment session. The energy level can be lowered or the treatment can be discontinued.

- It is possible, however very unlikely, that you may develop some localized petechial bruising (tiny bruising spots which are pinpoint to pinhead size in the skin) at the treatment site after the SoftWave treatment. You may also have some numbness or tingling. The skin bruising or the numbness and tingling usually goes away within a few days of the therapy. Report anything unusual or any bruising, or numbness, or pain, or tingling to your doctor immediately by or at the next session.

- One of the mechanisms of action associated with SoftWave is improved vascularity and blood supply at the therapy site. An improvement in blood supply could aid the growth of cancer cells although animal studies have shown no increase in the growth of cancer cells. Since the introduction of shockwave therapy in 1987 in the United States for kidney stones, over 15 million patients have been successfully treated with shockwaves and there has never been a report of a cancerous growth attributed to shockwave therapy. To address any risk associated with cancer, any patient diagnosed with cancer of the brain or head, or at high risk of cancer of the head or brain, should not undergo this treatment.

- You should not undergo this therapy if you are pregnant or plan to become pregnant during the treatment period.

Potential Benefits:

Shockwave technology is being used by another shockwave device manufacturer, Storz, in Europe for the treatment of Alzheimer's. It was CE Marked (European Regulatory Approval) based upon the results of a randomized, controlled study performed at three European hospitals, which showed that shockwave therapy could stop the progression of Alzheimer's and even reverse the symptoms in some patients. The protocol consisted of 3 treatments per week for at least 6 weeks. That device is utilized at energy levels as high as .3 mj/mm^2. SoftWave protocol does not exceed .12 mj/mm^2. The SoftWave protocol calls for 2 weekly treatments for a maximum of 12 treatments over 10 weeks as compared to 3 treatments per week for 6 weeks for a maximum of 18 treatments with the other device. SoftWave strongly encourages you to read the published results of the Storz trial before initiating treatment with our device. A copy of the study publication will be made available to you upon your request.

You may directly benefit from SoftWave therapy; however, these results have not been measured over a long period of time and further clinical evaluations are needed, so direct benefits cannot be assured. Your symptoms may improve and then return to as they were before therapy, or even worsen.

ALTERNATIVES TO THIS THERAPY:

You do not have to allow this compassionate use. If you decide not to undergo treatment with the SoftWave OrthoGold device, your current treatment regimen with the study doctor will not be affected. While there is no cure for Alzheimer's there are other treatments available that may change disease progression and there are drug and non-drug options that may help treat symptoms. If you have any questions about alternative treatments, please consult your doctor.

COSTS OF THERAPY:

A maximum fee of $300 per treatment session will be charged to you by your doctor (total maximum fee of $3600 for a maximum of 12 sessions) to solely recover a portion of the costs associated with manufacture, research, development, probe replacement, and handling of the device. The cost of the treatment is not approved for reimbursement by your insurance company, Medicare, or Medicaid, or any type of insurance. The provider will not apply for reimbursement with any insurance company or governmental agency.

INCIDENTAL FINDINGS:

There is a possibility that while reviewing results of any tests performed associated with this treatment your doctor may see an abnormality that he or she did not expect to see. This is what is called an "incidental finding."

Your doctor will let you know if such an incidental finding is seen. Depending on the type of incidental finding, you may be contacted by phone. In the case of a potential serious emergency, your doctor will inform you right away.

- An incidental finding may cause you to feel anxious.
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this compassionate use. These costs would be your responsibility.

VOLUNTARY PARTICIPATION:

The decision to take part in this compassionate use is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the compassionate use at any time. If you choose not to take part in this compassionate use or if you leave the compassionate use before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this compassionate use that may relate to your decision to continue participation.

USE OF MEDICAL RECORDS:

As a participant of this compassionate use, you will be identified only by initials and an identification number. Your medical records may be used as a source of information regarding the investigational/compassionate use of this device. Your records will be available to the Study Doctor, their associates, Sterling Institutional Review Board (IRB), SotfWave Tissue

Regeneration Technologies, M Squared Associates (TRT's Regulatory Consultants), state and federal agencies such as the Food and Drug Administration (FDA), and others.

The Study Doctor and others associated with this study will utilize your study records for presentation on publications for scientific or education purposes. However, your identity will not be disclosed in these publications or presentation.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The Study Doctor must get your permission (authorization) to use or give out any health information that might identify you. By signing this form, you give your Study Doctor permission to use or give out the information listed below for the purposes indicated in this form.

In this study, the Study Sponsor will identify your study records by a study ID number and not by your name. Every precaution will be taken to protect your privacy and identity.

What information may be used and given to others?

If you choose to be in this study, the Study Doctor will collect personal information about you. This may include information about your health including:

- Past and present medical records
- Research records
- Records about phone calls related to the study, hospital visits, and doctor's office visits made during the study
- Study questionnaires
- Records about your surgical treatment

Who may use and give out information about you?

Information about your health may be used and given to the others by the Study Doctor and staff. They might see the research information during and after the study.

Who might get this information?

Your information may be given to the Sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the Sponsor, or are owned by the Sponsor.

Information about you and your health that might identify you may also be given to:

- The U.S. Food and Drug Administration (FDA) (Washington, D.C.)
- Department of Health and Human Services (DHHS) agencies (Washington, D.C.)

- Sterling Institutional Review Board (IRB) (Atlanta, GA)
- Government agencies in other countries
- Government agencies to which certain diseases (reportable diseases) must be reported

Why will this information be used and/or given to others?

Information about your health that might identify you may be given to others to carry out the research study. The Sponsor will analyze and evaluate the results of the study. In additional, people from the Sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the Sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of government agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed. MRI, X-rays, photograph, videos, or audio tape recordings of you may be used for educational and research purposes, including publishing in scientific journals, for presentation at medical meetings, and for other publications and presentations for educating other doctors and other personnel associated with the medical industry about the SoftWave OrthoGold device and this study, but again, your identity will be protected.

The information may be reviewed by Sterling Institutional Review Board (IRB). The IRB is a group of people who perform independent review of research as required by regulations.

What if I decide not to give permission to use and give out my health information?

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to take part in this research study.

May I review or copy the information obtained from me or created about me?

You have the right to see and make copies of your medical records. However, to ensure the reliability of the study, you will need to wait to see your study records until the study is completed. If you decide to access your records before the end of the study, you may no longer be able to be in the study.

May I withdraw or revoke (cancel) my permission?

Yes, but this permission will not stop automatically. This permission (also called an authorization) will have no end date. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the

Study Doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, new health information which identify you will not be gathered for study purposes after your Study Doctor received written notice from you. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be release to others without your permission.

QUESTIONS

If you have questions, concerns or complaints about the research study or you experience a research- related injury, please contact the Doctor listed above, or the study staff at (404) 402-6844. This phone number is available 24 hours a day.

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1(888) 636-1062 (toll free).

THE REMAINDER OF THIS PAGE IS LEFT BLANK

My signature below means that:

I have read the information in this consent form. I have been given an opportunity to discuss this clinical research study with my Study Doctor and to ask questions. All of my questions have been answered to my satisfaction.

I willingly agree to participate in this clinical research study.

I authorize the use and disclosure of my health information to the parties listed in authorization section of this consent for the purposes described above

By signing this consent form, I have not waived any of the legal rights that I otherwise would have as a patient in a research study. I also understand that I will be given a copy of this signed consent form, which has 9 pages, to take with me.

_____	_____	_____
Participant Name (print)	Signature	Date
_____	_____	_____
Name of Person Conducting Informed Consent Discussion	Signature	Date
_____	_____	_____
Study Doctor Name (If not consenter)	Signature	Date

Title of Person Conducting Informed Consent Discussion:

☐ Principal Doctor and Investigator
☐ Sub- Investigator
☐ Study Coordinator

_____	_____
Witness Signature*	Date and Time

*A witness is not required unless the participant is unable to read (such as blind or illiterate). If a witness is present, however, the witness must observe the entire Informed Consent process, including participate signature.