



acousana™
Live Life - Pain Free

Patient Consent For Acousana™ Therapy

This document is intended to serve as confirmation of informed consent for Acousana™ Therapy, also known as Extracorporeal Shock Wave Therapy (ESWT), as ordered by your medical practitioner (Practitioner).

A. PURPOSE ESWT therapy is a non-invasive technique that uses pulsatile waves to stimulate blood flow to the applied area. ESWT is a safe procedure and has been used for a variety of health conditions.

When a medical device is approved for use by the Food and Drug Administration (FDA), the device manufacturer produces a “label” to explain its use. Once a device is approved by the FDA, physicians may use it “**off-label**” for other purposes if they are well-informed about the device, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects.

The ESWT device used in this therapy is FDA 510K cleared for the activation of connective tissue and registered for pain reduction and improved blood supply.

B: BENEFITS

Scientific studies have shown that when applied to an area, ESWT increases blood flow and activates connective tissue while relieving pain and inflammation.

C. CONSENT FOR PROCEDURE

I have received either written or verbal information about my condition, the proposed treatment, alternatives, and related risks. I have received an explanation of any unfamiliar terms and have been offered the opportunity to ask questions. This form contains a brief summary of this information.

I understand I may refuse consent and I GIVE MY INFORMED AND VOLUNTARY CONSENT to the proposed procedures and the other matters shown below. I also consent to the performance of any additional procedures determined in the course of a procedure to be in my best interests and where delay might impair my health.

1. I authorize Practitioner to treat my condition, including performing further diagnosis, and the therapy procedures described below.
2. I understand the purpose of the therapy procedure(s) to be: apply Extracorporeal Shock Wave

Therapy with an FDA cleared medical device to those areas that the Practitioner believes will be most effective in treating my condition.

3. Although ESWT has been performed on thousands of patients and the risks are very low, we must list them. I understand the most common risks associated with the proposed procedure(s) to be: swelling, reddening of skin, soreness. Less common risks to the proposed procedure(s) to be: hematoma (bruising), petechiae (minor broken blood vessels).

4. I also understand that there may be other RISKS OR COMPLICATIONS, OR SERIOUS INJURY from both known and unknown causes. I am aware that the practice of medicine and surgery is not an exact science and I acknowledge that no guarantees have been made to me concerning the risks of the procedure. I furthermore release The Source Chiropractic and all staff of any liability knowing the risk of using this equipment having been fitted with a pacemaker. Acousana has made known the risk of ESWT with said device.

5. By initiating a course ESWT, Practitioner is using his or her best judgment in recommendations for you and there is no guarantee of an outcome.

6. I understand that if I did not wish to accept the risks associated with this therapy then I would choose to not sign this consent.

D. PATIENT CERTIFICATION By signing below, I state that I am 18 years of age or older, or otherwise authorized to consent. I have read or have had explained to me the contents of this form. I understand the information on this form and give my consent to what is described above and to what has been explained to me.

SIGNATURE OF PATIENT

DATE



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Patient Information:

Date: _____

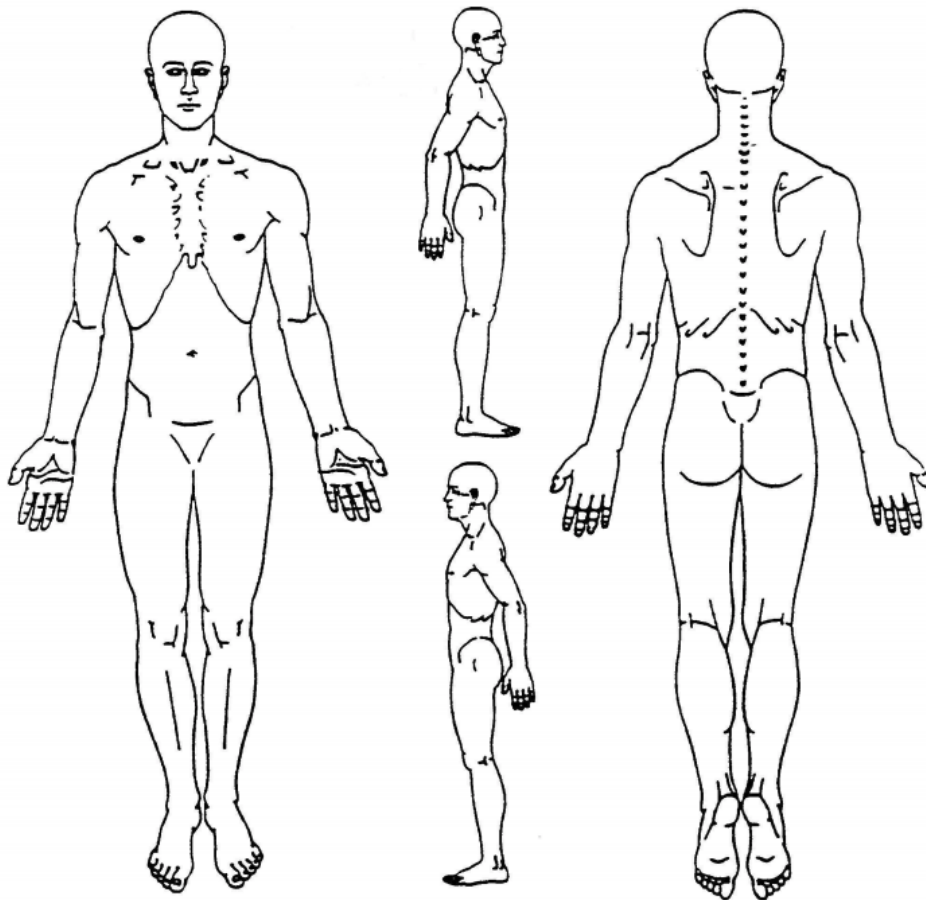
First Name: _____ Last Name: _____ Age: _____

Phone: _____ Email: _____

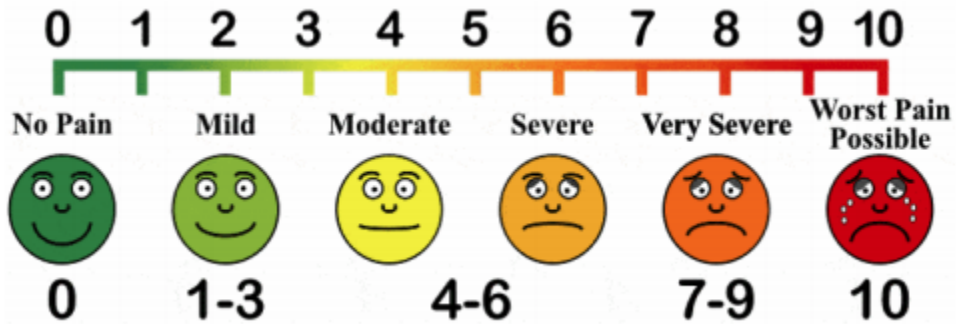
How Did You Hear About Us? _____

What Brings You In Today? _____

Place X's on the chart where you are feeling pain. If the pain is starting in one location and ending in another, draw a line showing how the pain travels.



Pain History:



Choose a number from the pain scale and describe the pain (i.e. aching, sharp, shooting, etc.) during the following activities:

Sitting

0 1 2 3 4 5 6 7 8 9 10
Aching Sharp Shooting Dull Numb Other: _____

Standing

0 1 2 3 4 5 6 7 8 9 10
Aching Sharp Shooting Dull Numb Other: _____

Walking

0 1 2 3 4 5 6 7 8 9 10
Aching Sharp Shooting Dull Numb Other: _____

Daily Activities

0 1 2 3 4 5 6 7 8 9 10
Aching Sharp Shooting Dull Numb Other: _____

Sleeping

0 1 2 3 4 5 6 7 8 9 10
Aching Sharp Shooting Dull Numb Other: _____

Is This Pain From an Injury? **Yes / No**

If yes, give a brief description of the injury and diagnosis: _____

Has this pain been diagnosed by a doctor? **Yes / No**

If yes, please list the type of doctor and diagnosis given: _____

Have you tried any other treatments or remedies? **Yes / No**

If yes, give a brief description of the treatment or remedy: _____

Do you have an active hemorrhage? **YES / NO**

Do you have a Pacemaker or Implantable Defibrillators? **YES / NO**

Are you currently pregnant? **YES / NO**

Have you been diagnosed with cancer? **YES / NO**

Do you have a coagulation disorder? **YES / NO**

Have you been diagnosed with hemorrhagic diathesis? **YES / NO**

Have you been diagnosed with a serious infectious disease? **YES / NO**