Demographic Information

Name: First _____ MI _____ Last_____ Suffix _____

Address: Street _____ City_____ State____ Zip _____

DOB: (MM/DD/YYYY) _____ SSN _____

Home Phone Number _____ Cell Phone Number_____

Email Address _____

Did someone refer you to us for this treatment? Yes No Who _____

Basic Medical Information

Drug Allergies_____

Height _____ Weight _____

Do you smoke? Yes No

Do You use oral chewing tobacco? Yes No

How long have you had this problem? _____ Years Months

Have you been treated with oral medications for this problem? Yes No

Are you currently using this medication to help with your erections?

Yes No

Do you have any hormonal, Neurologic or psychologic problems? Yes No

Do you have any of the following problems?

High blood Pressure Yes No

Cholesterol or triglyceride problems Yes No

Coronary heart disease Yes No

Diabetes Yes No

EXCLUSION CRITERIA

These exclusion criteria were used in almost every clinical trial of this technology. For the trials they were absolute (If you had any of these you would NOT be treated), At this time, they are relative exclusions and men these problems are being treated worldwide. These must be discussed with your physician.

Have you had prostate cancer surgery or any other extensive pelvic surgery? Yes No

Have you had ANY cancer in the past year? Yes No

Do you have any unstable medical, psychological, spinal cord injury problems, or penile anatomic problems? Yes No

Do you have any clinically significant chronic hematologic disease? Yes No

Do you take Anti-Androgen Medications Yes No

Have you had any radiation therapy treatments to the pelvic region? Yes No

Do you take any blood thinners? Yes No

Do you have any other significant medical history I should be informed of ?

Erectile Function Questions:

It is very important that you attempt to ansewer the following questions very accurately. Please do not try to overestimate or underestimate your condition. Circle your ansewers on the chart below.

The International Index of Erectile Function (IIEF-5) Questionnaire

The International Index of Erectile Function (IIEF-5) Questionnaire

Over the past 6 months:					
1. How do you rate your **confidence** that you could get and keep an erection?	Very low 1	Low 2	Moderate 3	High 4	Very high 5
2. When you had erections with sexual stimulation, **how often** were your erections hard enough for penetration?	Almost never/never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always/always 5
3. During sexual intercourse, **how often** were you able to maintain your erection after you had penetrated (entered) your partner?	Almost never/never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time)4	Almost always/always 5
4. During sexual intercourse, **how difficult** was it to maintain your erection to completion of intercourse?	Extremely difficult 1	Very difficult 2	Difficult 3	Slightly difficult 4	Not difficult 5
5. When you attempted sexual intercourse, **how often** was it satisfactory for you?	Almost never/never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always/always 5

Erection hardness score: My Score from the Choices below is _____

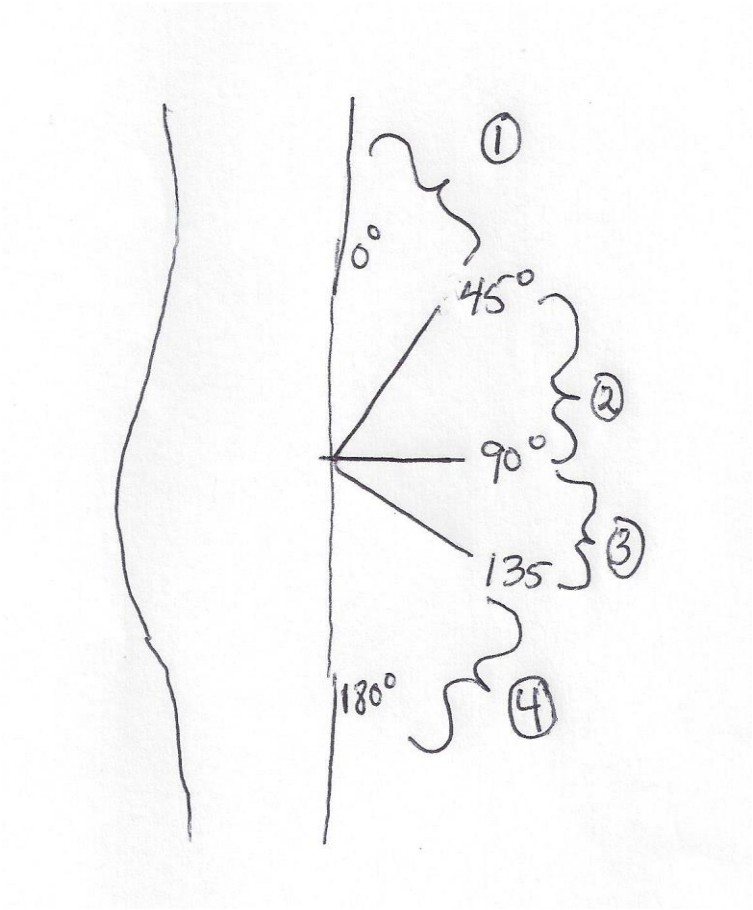
Score 0 - Penis does not enlarge.

Score 1 -Penis is larger, but not hard.

Score 2 -Penis is hard, but not hard enough for penetration.

Score 3 -Penis is hard enough for penetration, but not completely hard.

Score 4 –Penis is completely hard and fully rigid.



From the Diagram above please pick the score (circled number) that best illustrates the angle of your usual erection.

My Score is _____

How often do you awaken in the morning with an erection?

1. Never 2. Sometimes 3. About half the time 4. Often 5. Almost every day

My score is _____

WHAT NOW?

Now that I answered all these very personal questions what does this mean to me and what can I expect?

Your answers to these questions will be recorded into an electronic medical record and scored. You will complete a brief physical exam and you will than review all these findings with your doctor.

If you elect to go forward with treatment:

- You will be asked to sign the release of liability and disclaimer form.
- You will be asked to pay for the first 4 treatment sessions and your appointments will be scheduled. Your treatments will NOT be started until your doctor's office has been informed of receipt and processing of payment.

How likely is this treatment going to be successful and is it painful?

Do you remember the IIEF-5 Questionnaire you just filled out? Those questions are scored as follows:

IIEF-5 scoring:

The IIEF-5 score is the sum of the ordinal responses to the 5 items.

22-25: No erectile dysfunction

17-21: Mild erectile dysfunction

12-16: Mild to moderate erectile dysfunction

8-11: Moderate erectile dysfunction

5-7: Severe erectile dysfunction

Statistically speaking scores of 5-8 must improve by 7 points or more, scores of 9-14 must improve by 5 points or more and scores of 15-21 need only to improve by 2 points or more to be considered a statistical success. But who cares about statistics, **you** want to know if **you** will be happy with the treatment and **you** will consider it a success. Based on available medical literature and personal discussions with physicians providing this treatment it appears as if approximately 80% of patients were statistically improved. In Addition approximately 77% of these men said they were satisfied or very satisfied with their treatment results and just over 80% of these men said they would recommend the treatment to others. This treatment has been VERY successful worldwide. Indeed even 50% men with very severe erectile dysfunction who do not respond to medications have reported converting to men who do respond to medications! **NO** man reported any pain with this treatment.

How much does it cost?

The treatment sessions are scheduled as a block of 4 treatments at 2 treatments per week with the possibility of two additional treatments. The total number of shockwaves delivered determines the cost of the procedure. The Motil algorithm will be used to determine the optimal number of shockwaves per treatment you should receive. 4 treatments of 4,000 shockwaves per treatment would equate to 16,000 total shockwaves for the 4 treatment block. The cost of this 4 treatment block would be $1,600. If you were to receive 6,000 shockwaves per treatment the cost for the 4 treatment block would be $2,400. Any payment must be remitted to Patient Direct Healthcare, LLC. When Patient Direct Healthcare LLC confirms the appropriate payment to Dr. Mosca your treatments can begin. If you elect 2 Additional treatments you will once again have to make payments to Patient Direct Healthcare LLC before those 2 treatments can begin.

Charge Estimate for LiSWT (Energy Wave Therapy) treatments delivered by Dr. Mosca

By using the Motil Algorithm it is estimated that I would do best with _____ shockwaves per treatment session for 4 treatment sessions.

My charge would be $_____.

I agree to pay to Patient Direct Healthcare LLC $_____.

PATIENT SIGNATURE _____ **DATE**_____ **TIME** _____

_ PRINTED NAME _____

AUTHORIZATION AND CONSENT FOR OFF LABEL MEDICAL TREATMENT

PLEASE READ THE FOLLOWING INFORMATION CAREFULLY. IF YOU HAVE ANY QUESTIONS REGARDING THE INFORMATION, ASK FOR FURTHER EXPLANATION.

I,_____, hereby request treatment for erectile dysfunction utilizing energy wave therapy which I understand, although no specific result is guaranteed, is expected to improve erectile dysfunction.

The treatment will be provided by, Your Doctor, the "administering physician", at His/Her office or other agreed to location. I understand that other appropriate personnel may be involved in the treatment.

I understand that the device to be utilized in providing the treatment has been listed with the United States Food and Drug Administration ("FDA") with an intended use as a therapeutic massager and that utilization of the device for treatment of erectile dysfunction may be considered an "off-label" use.

I acknowledge that the administering physician has explained to me, given me an opportunity to ask and satisfactorily answered questions regarding the: device use; the manner of treatment, its purpose and nature, and its reasonably foreseeable risks; and alternatives treatments for erectile dysfunction.

I understand that the reasonably foreseeable risks of the treatment include reddened skin, soreness at the treatment site and failure to improve erectile dysfunction. Additionally, I acknowledge that the administering physician has explained to me, and I understand, that that there may be risks which are unexpected or not reasonably known and that the long-term effects of the treatment are not known.

I understand the reasonable alternatives to the treatment (which include penile injections, urethral suppositories, vacuum erection devices, pharmaceutical treatment, and/or implantable penile prosthesis), possible consequences of remaining untreated, and the risks and possible complications of each alternative.

I understand that the practice of medicine is not an exact science, that it may involve medical judgments based on the facts known to the physician at the time, and that it is not reasonable to expect the physician to be able to anticipate or explain all possible risks and complications. I understand that an undesirable result does not necessarily indicate an error in judgment, and that no guarantee as to the results has been made to, or relied upon by, me.

I understand that I have the right to refuse to receive the treatment.

I understand that a portion of the Energy Wave treatment fee will be paid to Patient Direct Healthcare, LLC and/or affiliates to compensate them for management services, equipment rental and/or technician services provided by them.

I understand that I will be asked to complete post treatment questionnaire. While this is NOT required by me doing so may help Dr. Mosca's treatment of other patients in the future.

In full agreement with and understanding of all of the above statements, I request the administering physician to provide energy wave therapy erectile dysfunction treatment to me utilizing a device that may be considered off-label when utilized for treatment of erectile dysfunction

ADMINISTERING PHYSICIAN'S DECLARATION

I have explained to the patient/patient's representative the energy wave therapy erectile dysfunction treatment with a device that may be considered off-label when utilized for treatment of erectile dysfunction and the risks, benefits, recuperation and alternatives (including the likely consequences if no treatment is pursued). I have answered all of the patient's questions and to the best of my knowledge, I believe the patient has been adequately informed.

PHYSICIAN SIGNATURE _____ **DATE** _____ **TIME** _____

PRINTED NAME _____

PATIENT'S CONSENT AND RELEASE

I HEREBY CONSENT TO ENERGY WAVE TREATMENT FOR ERECTILE DYSFUNCTION WITH A DEVICE THAT MAY BE CONSIDERED OFF-LABEL WHEN UTILIZED FOR TREATMENT OF ERECTILE DYSFUNCTION AND ACCEPT ALL THE RISKS INHERENT IN IT. I HAVE READ AND FULLY UNDERSTAND THIS CONSENT FORM. I UNDERSTAND I SHOULD NOT SIGN

THIS FORM IF ALL ITEMS, INCLUDING MY QUESTIONS, HAVE NOT BEEN EXPLAINED OR ANSWERED TO MY SATISFACTION, OR IF I DO NOT UNDERSTAND ANY OF THE TERMS OR WORDS CONTAINED IN THIS CONSENT FORM. I UNDERSTAND THAT I CAN WITHDRAW THIS CONSENT AT ANY TIME BEFORE THE BEGINNING OF THE TREATMENT. **IF YOU UNDERSTAND AND AGREE WITH THE INFORMATION IN EACH PARAGRAPH ABOVE, PLEASE PLACE YOUR SIGNATURE BELOW.**

DO NOT SIGN UNLESS YOU HAVE READ AND THOROUGHLY UNDERSTAND THIS FORM.

PATIENT SIGNATURE _____ DATE_____ TIME _____

_ PRINTED NAME _____

WITNESS TO PATIENT SIGNATURE _____DATE _____ TIME _____

PRINTED NAME _____