Piedmont Stone Center, PLLC

MOBILE LITHOTRIPSY

(Patient Name) _____

(Date of Birth) _____

HEALTHCARE CONSENT FOR EXTRACORPOREAL SHOCKWAVE LITHOTRIPSY (ESL)

(1) DESCRIPTION OF PROCEDURE. My physician has explained to me that I have been diagnosed as having urinary stones. My physician has recommended that I undergo Extracorporeal Shockwave Lithotripsy (ESL), which I understand to be a means of pulverizing urinary stones without surgery so that the stones may pass spontaneously in my urine. I understand that ESL may require either anesthesia or sedation while shockwaves are passed through my body. I understand that intravenous fluids will be given to me during the procedure by placing a needle into one of my blood veins, and a urinary catheter may be placed in my bladder prior to ESL and may remain in my bladder during and immediately following the ESL treatment. I understand that antibiotics, pain medications and other medications may be given as required.

I understand that I will be closely monitored throughout the procedure and that the lithotripsy suite is equipped to provide for emergencies.

(2) RISKS/POSSIBLE COMPLICATIONS. I have been advised regarding the possible risks and consequences associated with this procedure, including (but not limited to) the following:

(a) ESL commonly results in bruising to the skin and kidney region as a result of the shockwave. Research has not totally eliminated the possibility of long-term kidney damage, development of high blood pressure and damage to the bowel or lung (as they lie close to the kidney). Blood in the urine is common; however, urinary bleeding serious enough to require transfusion or surgical repair or removal of the kidney is rare. There is a rare chance of hematoma formation in the kidney and injuries to the spleen, liver, or pancreas.

(b) I understand that I may sustain ureteral colic (painful spasm of the ureter) as the stone fragments pass from the kidney to the bladder, or urinary obstruction, which may require surgery for relief.

(c) I understand that, as a result of the treatment, I may sustain a urinary tract infection or any infection of the blood system or tissue.

(d) I understand that the use of IV sedation and/or anesthesia (general or epidural) carries risks, which include but are not limited to, infection, irregular heartbeat, irregular blood pressure, heart attack and stroke, which rarely could lead to death. If I experience a cardiopulmonary event, emergency measures will be initiated, EMS will be notified, and I will be transferred to the local hospital even if I have an Advance Directive for a Do Not Resuscitate Directive.

(e) I understand that there is no objective evidence to date to support a theory that shockwaves damage unfertilized eggs and/or ovaries. However, the manufacturer of this lithotripsy equipment states that treating a urinary stone, located in the lower end of the tube that goes from the kidney to the urinary bladder, could possibly result in damage to these female organs.

(3) ALTERNATIVES TO PROCEDURE. I understand that, in addition to doing nothing, there are alternatives to the recommended procedure including surgical removal of the stones. I have been advised of the possible risks and consequences of these alternatives as they compare to ESL.

(4) NEED FOR ADDITIONAL PROCEDURES. It has also been explained to me that sometimes in conjunction with the ESL, it is necessary to perform additional procedures such as a catheter placement for localizing the stone or draining the kidney.

(5) NO GUARANTEES GIVEN. I acknowledge that no guarantees have been made concerning this procedure. I have been advised that if I desire a further or more detailed explanation concerning my diagnosis, recommended and alternative procedures, or possible risks and consequences, it will be given me by my physician. However, I am satisfied with the explanation given me and authorize my physician and such assistants as may be selected by him to perform the recommended procedure outlined above. For the purpose of advancing medical education, I consent to the admittance of observers, residents, medical students, or other allied health personnel in the patient care/treatment area.

(6) ADMINISTRATION OF DRUGS. I authorize the staff of Piedmont Stone Center, PLLC (PSC) and/or hospital staff to administer such drugs and to perform such pathological studies as may be necessary or advisable.

(7) PHYSICIAN FINANCIAL DISCLOSURE. I have been informed that my physician may have an ownership interest in PSC which owns the lithotripsy unit. I further understand that alternative lithotripsy units are available at my request.

(8) PERSONS AUTHORIZED TO SIGN FOR PATIENT. If this form is executed by another on the patient's behalf, the person signing certifies that he is authorized to consent on the patient's behalf, and, where the context requires, all references herein to "I", "me" or "my" refer to the patient rather than the one who signs for the patient.

(9) BLOOD PATHOGENS. In the event of an accidental exposure of my blood or bodily fluids to a physician, contractor, or employee of PSC, I consent to testing for HIV and Hepatitis.

I consent to ESL on the ( ) Right side ( ) Left side

Witness	Patient or Person Authorized to Consent for Patient	Date	Time
_____	_____	_____	_____

The above information has been explained to the patient or the patient's representative.

Physician: _____ **Date:** _____ **Time:** _____