1) Metropolitan Lithotriptor Associates, PC operates a as a Medical Treatment Center that is utilized for the management of renal stone disease.

2) A History and Physical must be completed within 30 days prior to the procedure, updated the day of the procedure and be present in the patient’s chart.

3) All patients will be provided the opportunity to review a patient educational video. A patient informational brochure is also provided at the sites. Summaries translated into Spanish and Chinese are available.

4) Policies of the sites comply with OSHA regulations.

5) **Pre-testing guidelines** are as follows for all patients being treated with lithotripsy at the sites:

   a) **Hemogram** (CBC without differential) within 30 days prior to SWL. This should include a platelet count. A repeat CBC is needed prior to a repeat treatment within 30 days if clinically indicated.

   b) **Urine analysis** within 30 days prior to treatment

   c) **Blood or urine test for Pregnancy**: within one week prior to SWL on all women of childbearing age unless previous history rules out possibility of pregnancy (i.e. hysterectomy, 1 year post menopausal etc.)

   d) **Blood, Chemistry Study** within 30 days prior to SWL including Na, K, BUN, Creat, Glucose.

   e) **EKG** within six months on male patient’s over 40 and female patient’s over 50, however, if cardiovascular problems are present, an EKG is required regardless of patient’s age;

   f) **Chest X-ray** not required as routine pre testing. To be ordered by the physicians or anesthesiologist as needed. It is stated in our Referring Physician Pre-op Guidelines that a chest x-ray is recommended for patients over 65 or any patient with medical problems.

6) Additional test guidelines will include the following:

   a) **C/S report of urine** when suspected infection is present.

      i) **Bleeding Profile** (PT, PTT) requested for patients having been on anticoagulants within 10 days prior to SWL and for patients who have blood dyscrasias or suspected bleeding tendencies as indicated on the pre-treatment Health Questionnaire.
To facilitate stone visualization, it is recommended that patients have a light lunch the day prior to their SWL procedure. Patients are instructed to drink one 8oz bottle of citrate of magnesia the afternoon prior to their procedure. Clear liquids only are advised after the ingestion of citrate of magnesia until 12 midnight. Prescription medications should be taken at their assigned times with a sip of water.

A recent IVP, Renal Sonogram, CT Scan report and/or KUB must be present prior to starting the SWL procedure.

A KUB/hardcopy iris image will be completed on every patient immediately prior to SWL treatment. A review of the film by the physician or Medical Director will be made prior to the start of the case.

When any increased risk factors are present in a patient receiving SWL, the Nurse/Anesthesiologist will contact a Medical Director to discuss the case. The Medical Director and or anesthesiologist will then discuss case with the primary Physician. Special arrangements (e.g. Pacemaker controller, AICD, platelet transfusion) will be made as needed.

In order to reduce the risk of perirenal hematoma and parenchymal hemorrhage, it is recommended that the Medical Director of the day be notified when a patient’s pre-SWL diastolic blood pressure is 100 mm or above. If the patient’s diastolic blood pressure remains above 100 mm after IV sedation has been given, the patient will be referred for additional blood pressure studies before rescheduling renal SWL treatment. Ureteral stones well below the kidney may be treated despite elevated BP at the anesthesiologists’ and physician’s discretion.

With exceptionally large (wide girth) or small patients, and patients with a severe skeletal deformity, horseshoe or ectopic kidney, the Medical Director should be contacted prior to the scheduling of the SWL procedure to discuss the position of the patient. Additional information such as height, weight, stone size and location will be helpful to determine machine applicability.

The Physician of Record and/or Medical Director shall be the only person controlling the shock wave application. If the Physician leaves the control area for any reason the shockwave treatment will be stopped and will resume upon his/her return. The number of shocks, KV/power setting, fluoro time, and number of IRIS images and plain films will be recorded on a procedure data sheet.

A KUB may be ordered post-SWL to document fragmentation. If this film is taken by the treating physician, it must be returned within 30 days.

A procedure report of the SWL procedure will be completed immediately post-SWL by the Physician. A copy of the report can be given or mailed to the Physician for his records if requested. Payment to the Physician will be made subject to completion of this procedure report.

Patients will be discharged according to the anesthesia discharge criteria as outlined in the anesthesia guideline section. If there are significant complications, as determined by the PACU nurse, Medical Director or Anesthesiologist, the patient’s Physician will be notified to arrange appropriate follow-up care.
17) Current literature has documented occasional cases of silent hydronephrosis due to stone fragment obstruction (Steinstrasse) post-SWL. It is recommended that the physician follow up post-SWL cases with sonography or CT if clinically indicated (based on patient’s condition or appearance of standard post-SWL kub). Post-swl studies are especially recommended when treating patients with a solitary kidney. All patients will be given a urine strainer to recover stone fragments post-SWL. Stone analysis and metabolic work-up are recommended to guide stone recurrence prophylaxis.

18) Patients will be given post-SWL instructions prior to discharge.

19) It is the policy of Allied/MLA that patients must be discharged in the care of a responsible adult who is also present at the time of discharge to receive all post-operative instructions. Allied/MLA recommends that a responsible adult remain with the patient as a 24 hour companion following discharge. In the event that the patient can not arrange for a discharge escort, Allied/MLA can provide a list of agencies which provide escort and home care services.

20) Radiation exposure should be kept to a minimum. Radiation badges must be worn by clinical staff members, the anesthesiologist, the Medical Director and the treating physician (if requested). A monthly report is reviewed by a Medical Director in his capacity as Director of Radiological services.

21) General cautions and advisories:
   
a. It is recommended that when treating lower ureteral stones in women of childbearing age, they be informed that, thus far, no adverse side effects have been noted post-SWL. Experimental and clinical studies to date have shown no birth defects, infertility, ovarian pathology or increased miscarriage rate. Since the effects of SWL in women of childbearing age can not be absolutely determined, an advisory will be included in the “Risks, Benefits, Alternatives of Lithotripsy” document distributed to patients along with the lithotripsy consent. It is recommended that the Physician discuss this with their patient in advance of the procedure.

b. Although there have been no significant detrimental effects of SWL on growth of kidneys, acetabula, or femurs in infant rabbits, caution is recommended in the treatment of pediatric patients. Close assistance of the Medical Director and Technologist is advised for all pediatric treatments.

c. In general, it is the policy of MLA to avoid concurrent treatment of both kidneys. A delay of at least 2 weeks is advised before treating the contralateral kidney. In a survey of US Lithotripsy centers conducted in 2003, 75% do not treat concurrently at all, 25% will treat concurrently with restrictions (stenting, special consent, etc). A Medical Director should be consulted where appropriate.

d. **Retreatment policy**: If only partial fragmentation of a RENAL calculus is obtained after one SWL session, or if multiple calculi in the same kidney require treatment, a second session may be scheduled after a delay of 2 weeks. The timing of retreatment of URETERAL calculi should be determined by the treating Physician.
e. Treatment of a renal and contralateral *ureteral* stone may be considered subject to approval by the Medical Director.

f. When nephrostomy tubes are placed pre-SWL, it is recommended that the urine flow from the nephrostomy tube be inspected and a report placed on file that the urine is grossly clear of blood or purulent urine prior to proceeding with the SWL procedure. (The patient must be afebrile, have a c/s report, and be on appropriate antibiotic coverage). If the urine is not purulent or bloody, the fluid interface for fragmentation can be enhanced by temporarily clamping the NT during the procedure. It must be unclamped immediately post-SWL if there is any evidence of obstruction.

g. **Double-j stents:** Placement of double-j stents may be beneficial in selected out-patients to aid in the prevention of colic, sepsis and obstruction from Steinstrasse.

   i) In general, stones greater that 2 cm should be pre-treated with stents. Exceptions may be lower pole stones for which slow clearance may be anticipated.

   ii) As a guideline patients with a solitary kidney or ureteral obstruction should be stented prior to treating renal or ureteral calculi.

   iii) Current literature favors treatment of non- or minimally obstructing ureteral stones *in situ*, without stenting or stone transposition.

   iv) It is the judgment of the Medical Directors that, when needed, stents be inserted *in advance* of lithotripsy, preferably several days earlier.

      1. Complications from stent insertion (perforation, malposition, migration, obstruction) should make themselves evident independent of the confounding effect of simultaneous SWL.

      2. In general, litho tables make poor cysto tables, thus necessitating stent insertion under less than ideal circumstances (fluoro visualization, etc).

      3. The risks of a separate anesthesia are minimal for the majority of patients and are probably comparable to the risks of proceeding with treatment in the face of an obstructing malpositioned stent.

      4. Excessive hematuria, when it occurs post SWL, can be an indication of significant renal injury. This clinical sign is less reliable in the presence of hematuria from traumatic instrumentation.

      5. Most litho centers do not perform routine stenting at the time of SWL, although occasional cases may require retrograde catheter insertion to assist visualization.

      6. Stenting on the litho table represents inefficient use of the machine by reducing the number of SWL cases per day and unpredictably delaying subsequent cases.
7. SWL is not considered an emergency procedure. Patients should be stented for pain control prior to scheduling. Patients with severe pain lithotripsy.

h. Parenteral antibiotics are recommended in the presence of stents, struvite stones, or if there has been recent instrumentation. If a UTI is suspected, it should be pre-treated with at least several days of oral antibiotics.

i. Diabetic patients s/p joint replacement less than 2 years should be pre-treated with antibiotics.

j. Staghorn calculi treated with SWL must have well planned multiple staged procedures or have been previously debulked by percutaneous surgery. Treatment of the renal pelvis and the upper calices should precede treatment of the lower calyx.

k. When treating multiple renal calculi, focus from lower to upper stones and smallest to largest stones due to falling fragments.

l. **Pacemakers** are no longer a contraindication, but sensing models should be reprogrammed to non-sensing mode prior to treatment. A company technician representative should be present at the time of treatment to assure proper programming. Full medical clearance must be on the chart along with information concerning the type, serial number and indication for pacemaker placement. EKG tracing will be mandatory post SWL.

22. **Procedure Guidelines:**

a) **Number of shocks:** At Metropolitan Lithotriptor Associates the recommended number of shocks for routine cases of small to moderate stones is 2400, in accordance with the initial FDA trials of the Medstone machine. However, larger stone burdens may be treated with up to 3600 shocks at the Physician’s discretion, provided that there are no medical contraindications (hypertension, recent infection, steroids, diabetes, bleeding disorder). Ureteral stones can all be treated with 3600 shocks, as needed.

   The Dornier Delta shock maximum is 2500 in the kidney or ureter above the level of iliac crest with a maximum power level of 4. Three thousand (3000) shocks at power level 6 can be used in the ureter if stone lies below the level of the iliac crest. Although a power level of 6 is approved by the manufacturer for treatment in the kidney, this level results in a greater incidence of peri-renal hematoma, splenic rupture, etc. and is not routinely recommended. In general, treatment should be performed with the minimum number of shocks to achieve adequate fragmentation.

   For Solitary Kidneys, the current Medical Advisory Board recommendation is: 2400 shocks on the Medstone, Dornier and Storz machines.

   The Storz-SLX shock maximum is 2500 in the kidney and 3000 in the ureter.

b) **EKG Gating:** Metropolitan Lithotriptor Associates was one of the first centers to pioneer non-gated lithotripsy. Over 10,000 patients have been treated to date with this modification. In this manner, shocks can be delivered at a rate of 120 per minute, regardless of the patient’s native heart rate. The following cautions apply:
i) Patients with underlying rhythm disorders should NOT be so treated.

ii) Patients with pacemakers should not be treated without a pacemaker company representative present.

iii) When initiating treatment, careful observation of the patient’s native EKG must be made. Lidocaine prophylaxis may be instituted at the anesthesiologist’s discretion. Treatment without gating can be continued if there is only minor ectopy. Long runs of PVC’s or evidence of V-tach mandate immediate cessation of treatment and conversion to standard gating.

iv) Care must be used in interpreting the EKG tracing to avoid confusion with “artifact” created by the spark-gap discharge.

v) Clinical studies reported in the last quarter 2003 suggest that on certain machines, a modest improvement in stone free rate can be achieved with slower (~60) treatment rates. This has not been validated in larger studies and on all machines, however selection of treatment rate is at the Physician’s discretion.

c) Energy Level

i) In general, on the Medstone machines, all treatment should be performed at 24 KV, maximum power. This has proven safe in nearly 10,000 treatments at our sites. Exceptions include: extremely thin patients, small stones which may migrate from targeted position, pediatric patients all of whom require treatment at reduced voltage (18KV).

ii) For Dornier Delta a maximum power level of 4 is used for the kidney and the ureter above the level at the iliac crest. A maximum power level of 6 may be used in the ureter if stone is below the level of the iliac crest.

iii) For the Storz-SLX a maximum power level of 7 is used for the kidney. A maximum power level of 9 may be used in the ureter.

   Exceptions include:

   a) Extremely thin patients whom would start at a power level of 1 and may progress as above.
   b) Children should start at a minimum power level of 1 and not exceed a maximum power level of 4.

d) Relative contraindications to SWL:

   i) Patient with uncorrected bleeding disorder
   ii) Severely obstructed kidney without stent or PCN.
   iii) Non-function of the stone-containing kidney.
   iv) When x-ray exposure is contra-indicated (e.g. pregnancy)
   v) Ipsilateral renal malignancy
vi) Non-visualization of the stone, unless facilitated by contrast agent (IV or retrograde) in the case of Uric Acid stones.

vii) Patient with urosepsis

viii) Patient who is considered an unacceptable risk by the anesthesiologist

ix) Uncontrolled hypertension
The following laboratory tests must be done within 30 days prior to procedure:

1. For a healthy patient under age 40:
   - CBC w/Platelet Count
   - Basic Metabolic Profile (BMP)
   - *Pregnancy test for women in childbearing age
   - **PT/PTT
   - **Thyroid Function Tests (TFT’s) for patients on Thyroid Replacement Therapy

2. For male patients over 40 and for female patients over 50
   
   ...Add EKG
   - UA and C&S

3. For patients over 65, or any patient with medical problems:
   - CBC w/Platelet Count
   - **PT/PTT
   - **Liver Function Tests (LFT’s) for patients with liver disease. If LFT’s are abnormal, repeat within 2 days of procedure or medical clearance to confirm they are stable.
   - Complete Metabolic Profile (CMP)
   - EKG and Chest x-ray
   - Urine Analysis *Not required for Orthotripsy cases
   - Urine Culture when suspected infection is present.*Not required for Orthotripsy cases.
   - Medical Clearance

   **Required for patients having been on anticoagulants and patients who have blood dyscrasias or suspected bleeding tendencies as indicated on the pre-treatment health questionnaire.

4. When practical, a telephone history will be taken by the RN within 24 hours of booking the procedure. In the event that the patient has significant medical problems, the history will be reviewed with medical director, physician and/or anesthesiologist as appropriate.

**Shock Wave Lithotripsy patients**: For reimbursement documentation, and to maintain optimum quality of care, a recent IVP, Renal Sonogram, CT Scan report and /or KUB is required with the above laboratory tests.

A letter of *Medical Clearance* from your patient’s medical doctor should be included with the laboratory tests if there are any chronic non-urologic conditions (Hypertension, Diabetes, etc) which would affect the type or use of anesthesia.

**See Pre-Laboratory Testing and Medical Clearance.**

Revised 1/14/0
## SUMMARY OF PREOPERATIVE TEST RECOMMENDATION

<table>
<thead>
<tr>
<th>AGE</th>
<th>MEN</th>
<th>WOMEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 MONTHS-39 YEARS</td>
<td>NONE</td>
<td>CBC PREGNANCY TEST</td>
</tr>
<tr>
<td>40-50 YEARS</td>
<td>EKG</td>
<td>CBC PREGNANCY TEST</td>
</tr>
<tr>
<td>50-64 YEARS TEST?</td>
<td>CBC/EKG</td>
<td>CBC/EKG/PREGNANCY</td>
</tr>
<tr>
<td>65-74 YEARS</td>
<td>CBC/EKG/BUN/</td>
<td>CBC/EKG/BUN/GLUCOSE</td>
</tr>
</tbody>
</table>
| 75YEARS & ↑    | CBC/EKG/BUN/   | CBC/EKG/BUN/GLUCOSE/CHEST X-RAY (WITHIN 1 YEAR) |}

The above tests are for those patients that have no medical history. Please refer to the pre-anesthesia Evaluation form for any additional test required.