



MedStar Georgetown University Hospital

3800 Reservoir Rd., NW
Suite 403B, PHC
Washington, DC 20007-2113
202-444-4922 PHONE
877-625-1478 FAX
georgetownurology.org

John H. Lynch, Chairman
Gaurav Bandi, MD
Keith J. Kowalczyk, MD
Kevin G. McGeagh, MD
John J. Pahira, MD

Department of Urology

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To Whom It May Concern:

I have been asked to share my experience with the Medispec Shock Wave Lithotripter which I have been using since 1997 in the Center of Kidney Stone Disease at Georgetown University Hospital. As Director of the Kidney Stone Center and Lithotripsy Unit, I have had an opportunity to work with multiple shock wave lithotripsy machines since 1986. We treated over 9,000 patients during a nine year period with the unmodified Dornier HM3 and over 2,500 patients with the Dornier MFL 5000 from 1995 to 2000. We also tested the Siemens Lithostar Plus and Shock Head C during an FDA clinical trial at Georgetown University Medical Center.

In August 1997, we acquired the Medispec ESWL Unit as an additional shock wave lithotripsy unit to supplement the MFL 5000. We had such excellent results with the Medispec that in September 2000, we sold the MFL 5000 for parts and continued doing all ESWL procedures on the Medispec Unit. We were excited about the Medispec for many reasons. First, it is a small, compact and light weight unit which can easily be moved in and out of the operating room when not in use. It does not require a dedicated room, nor does it require any special room preparation. This was a significant cost savings over other lithotripter options that needed special plumbing and electrical requirements. The system is modular and the three components are easily moved by one nurse or x-ray technician to reconfigure the room for other use. The GE, OEC C-Arm that is available with the Medispec Unit provides the highest quality images, which makes stone localization very easy. Also, the C-arm is not permanently attached to the lithotripter. It can be used with the excellent treatment table for many other endourologic procedures such as cystoscopy with stent placement, ureteroscopy and percutaneous stone removal. We have found it to be a truly multi-functional system.

Once we started treating patients we found that there was a very short learning curve for both our faculty and staff. The Medispec has one of the largest second focal zones of any lithotripter on the market, and at 13 x 60 mm, the second focal zone (F2) can consistently strike the targeted stone. It can deliver up to 910 bar of pressure, which I have found makes it effective at breaking both renal and ureteral stones that have been referred to our unit after failing to fragment on other units. Our patients have ranged in age from 6 years to 86 years and in weight from 50 lbs to 420lbs. We have treated patients with spina bifida and other difficult body habitus or complex renal anatomy (horseshoe, pelvic kidneys and multiple patients with morbid obesity). In all cases, we have noted the ease with which patients can be positioned, stone localized and coupled on the Medispec Unit.

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Re: Medispec Experience

After treating my first 141 patients, we reviewed our initial treatment results. Fifty six of the patients had a single stone and 85 patients had multiple stones. We had 97 patients for whom we had evaluable data at the time of our review. Forty nine percent of all patients had their primary targeted stone(s) in the lower pole . Overall, 85 of the 97 patients (88 %) had a successful treatment and were either stone free or had clinically insignificant residual fragments (< or equal to 4 mm). For patients that had single stones, 11% required a repeat treatment to achieve a successful outcome. No significant adverse effects were recorded in the study group. These early treatment results have held consistent as we have now treated more than 3,000 patients on the Medispec Unit. Our Unit has been used by some 22 clinical urologists. They have now more than 20 years of clinical experience with the Medispec Unit and find it easy to localize the stone and position their patients. During a questionnaire to evaluate their satisfaction with the Medispec Lithotripter, all physicians reported a very high degree of satisfaction with the effectiveness, safety and ease of use.

In 2012 we upgraded to the next generation, the Medispec E 3000. Our overall experience with both the Medispec E 2000 and E 3000 has been very favorable in terms of our clinical results. Also, we have had no significant downtime secondary to mechanical or technical problems during our 20 years of experience with the Medispec. When we have had questions, we have found the support from the company to be prompt, courteous and accurate.

In summary, we feel we have chosen the best lithotripter for our institution. If I can provide you with any additional information, please do not hesitate to contact me.

Sincerely,



John Pahira, MD
Professor of Urology
Georgetown University