

**Technology and Equipment
Committee Meeting**

**Lithotripsy
Material**

April 29, 2009

Lithotripsy

Introduction

Lithotripsy is defined as the pulverization of urinary stones by means of a lithotripter. Extracorporeal lithotripsy is lithotripsy that occurs outside the body. Extracorporeal shock wave lithotripsy (ESWL) is the non-invasive procedure with which this section will concern itself.

A lithotripter is a device that uses shock waves to pulverize urinary stones, which can then be expelled in the urine. An emitter is placed in contact with the patient's abdomen and the shock waves are focused on the stone, which is shattered by the force.

A lithotripter's service area is the lithotripter planning area in which the lithotripter is located. The lithotripter planning area is the entire state.

Lithotripter Utilization

Lithotripter utilization can be reasonably estimated by the incidence of urinary stone disease. Urinary stone disease, or urolithiasis, is a disease in which urinary tract stones or calculi are formed. The annual incidence of urinary stone disease is approximately 16 per 10,000 population¹; ~~which translates into 15,036 urinary stone disease cases per year in North Carolina based on the estimated population of the state as of July 1, 2009.~~ Not all cases of urinary stone disease would be appropriately treated by lithotripsy. ~~; thus, the cases that could be treated by this technology would be less than the 15,036 cases that occur annually.~~ It has been estimated that 85 to 90 percent of kidney stone patients, when surgery is indicated, can be treated successfully by ESWL treatment. ~~The above estimate translates to 13,532 cases based on 90 percent that could be treated by ESWL; thus, approximately 13,532 patients have the potential to be treated by lithotripsy per year.~~ The annual treatment capacity of a lithotripter has been estimated at between 1,000 and 1,500 cases.

North Carolina Utilization

The number of lithotripsy procedures reported in North Carolina for the period of 2007-08 was 11,420 procedures. There were 14 lithotripsy units operated by eight providers. Procedures were provided by a fixed unit at one hospital, and by 13 mobile units operated by seven providers. There was one need determination for a lithotripter in Mecklenburg County in the North Carolina 2007 State Medical Facilities Plan and the Certificate of Need (CON) was awarded to The Stone Institute. ~~Including the non-operational CON approved lithotripter, there is a total of 14 lithotripsy units.~~ Given the 14 lithotripsy units, the average number of procedures per lithotripter for the 2007-08 year is 816.

Access

Due to the mobility of lithotripter services, and the subsequent number of sites from which the service is provided, it may be concluded that geographic access is available to the maximum economically feasible extent.

North Carolina's Need Determination Methodology

North Carolina uses a methodology based on the incidence of urinary stone disease. The need is linked to the above estimate of 15,036 urinary stone disease cases and is based on the assumption that 90 percent could be treated by ESWL; thus, approximately 13,532 patients in the state have the potential to be treated by lithotripsy per year.

~~Not all cases of urinary stone disease would be appropriately treated by lithotripsy; thus, the cases that could be treated by this technology would be less than the 15,036 cases that occur annually. It has been estimated that 85 to 90 percent of kidney stone patients, when surgery is indicated, can be treated successfully by ESWL treatment. The above estimate translates to 13,532 cases based on 90 percent that could be treated by ESWL; thus, 13,532 patients have the potential to be treated by lithotripsy per year.~~

~~With an annual treatment capacity of a lithotripter being estimated at between 1,000 and 1,500 cases, the maximum number of lithotripters needed in the state would be 14, based on the estimated 13,532 cases and 1,000 procedures per lithotripter.~~

The standard methodology used for determining need for lithotripters is calculated as follows:

- Step 1. Divide the July 1, 2010 estimated population of the state, available from the North Carolina Office of State Budget and Management, by 10,000 and multiply the result by 16, which is the incidence of urinary stone disease per 10,000 population.
- Step 2. Multiply the result from Step 1 by 90 percent to get the number of patients in the state who have the potential to be treated by lithotripsy in one year.
- Step 3. Divide the result of Step 2 by 1,000, which is the low range of the annual treatment capacity of a lithotripter, and round to the nearest whole number.
- Step 4. Sum the number of existing lithotripters in the State, lithotripters not yet operational but for which a CON has been awarded, and lithotripter need determinations published in previous SMFPs for which a CON has yet to be awarded.
- Step 5. Subtract the result of Step 4 from the result of Step 3 to calculate the number of additional lithotripters needed in the state.

North Carolina's Need

With an annual treatment capacity of a lithotripter being estimated at between 1,000 and 1,500 cases, the maximum number of lithotripters needed in the state would be 14, based on 13,532 estimated cases and 1,000 procedures per lithotripter. There are 14 lithotripters (~~including the CON approved lithotripter~~) in the state, and the methodology indicates a maximum need of 14 lithotripters in the state. As a result, it is determined that there is no need for additional lithotripters anywhere in the state.

Lithotripsy Services in North Carolina

The eight providers that offer lithotripsy services in North Carolina are listed on the following pages.

¹ Pahiri, J.J. & Razack, A.A. (2001) "Chapter 9: Nephrolithiasis". In Clinical Manual of Urology, by Philip M. Hanno, Alan J. Wein, S. Bruce Malkowicz. McGraw-Hill Professional Publisher.

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2008 data as reported on the 2009 Lithotripsy Registration and Inventory Form for Mobile Equipment)

Provider: Carolina Lithotripsy, LTD, 2014 Litho Place, Fayetteville, NC 28304-

Machines 2 Purchased or Replaced: 12/15/2001

Areas Generally Served: Eastern NC

<i>Facility and Location</i>	<i>Procedures</i>
Beaufort County Hospital, Washington, NC	49
Carteret General Hospital, Morehead City, NC	45
Carteret Surgery Center, Morehead City, NC	9
Columbus County Hospital, Whiteville, NC	118
Craven Regional Medical Center, New Bern, NC	63
Dosher Memorial Hospital, Southport, NC	49
Duke Raleigh Hospital, Raleigh, NC	198
Halifax Memorial Hospital, Roanoke Rapids, NC	42
Highsmith Rainey, Fayetteville, NC	198
Johnston Memorial Hospital, Smithfield, NC	95
Lenoir Memorial Hospital, Kinston, NC	53
Moore Regional Hospital, , NC	151
New Hanover Regional Medical Center, Wilmington, NC	238
Onslow Memorial Hospital, Jacksonville, NC	17
Pitt County Memorial Hospital, Greenville, NC	86
Rex Healthcare, Raleigh, NC	136
Richmond Memorial Hospital, Rockingham, NC	27
Southeastern Regional, Lumberton, NC	75
WakeMed, Raleigh, NC	54
Wayne Memorial Hospital, Goldsboro, NC	17
Wilson Memorial Hospital, Wilson, NC	72
<i>Total Procedures:</i>	1,792
<i>Average Number of Procedures per Lithotripter:</i>	896

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2008 data as reported on the 2009 Lithotripsy Registration and Inventory Form for Mobile Equipment)

Provider: Carolinas Mobile Lithotripsy Service, 810 Fairgrove Church Road, Hickory, NC 28602-

Machines 1 Purchased or Replaced: 12/1/2001

Areas Generally Served: Western and Central NC

<i>Facility and Location</i>	<i>Procedures</i>
Catawba Valley Medical Center, Hickory, NC	146
Frye Regional Medical Center, Hickory, NC	109
Grace Blue Ridge Health Care, Morganton, NC	35
Harris Regional Medical Center, Sylva, NC	124
Haywood Regional Medical Center, Clyde, NC	105
Murphy Medical Center, Murphy, NC	65
Scotland Memorial Hospital, Laurinburg, NC	141
The McDowell Hospital, Marion, NC	11
The Rutherford Hospital, Rutherford, NC	81
Valdese Blue Ridge Health Care, Morganton, NC	47
<i>Total Procedures:</i>	864
<i>Average Number of Procedures per Lithotripter:</i>	864

Provider: Fayetteville Lithotripters Limited Partnership, 9825 Spectrum Drive, Bldg 3, Austin, TX 78717-

Machines 1 Purchased or Replaced: 9/1/2002

Areas Generally Served: Western NC and South Carolina

<i>Facility and Location</i>	<i>Procedures</i>
Duke University Ambulatory Surgery Center, Durham, NC	15
Heritage Hospital, Tarboro, NC	7
Margaret Pardee Hospital, Hendersonville, NC	77
Park Ridge Hospital, Fletcher, NC	37
Transylvania Community Hospital, Brevard, NC	13
Abbeville Area Medical Center, Abbeville, SC	13
Laurens County Healthcare, Clinton, SC	4
Oconee Memorial Hospital, Sececa, SC	31
Self Regional Healthcare, Greenwood, SC	39
St. Francis Hospital, Greenville, SC	221
<i>Total Procedures:</i>	457
<i>Average Number of Procedures per Lithotripter:</i>	457

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2008 data as reported on the 2009 Lithotripsy Registration and Inventory Form for Mobile Equipment)

Provider: Fayetteville Lithotripters Limited Partnership- Virginia I, 9825 Spectrum Drive, Bldg 3, Austin, TX 78717-

Machines 1 Purchased or Replaced: 2/1/2003

Areas Generally Served: Eastern NC and Virginia

<i>Facility and Location</i>	<i>Procedures</i>
Albemarle Hospital, Elizabeth City, NC	18
Chowan Hospital, Edenton, NC	57
Roanoke-Chowan Hospital, Ahoskie, NC	16
Community Memorial Healthcare, South Hill, VA	26
Harborview Medical Center, Suffolk, VA	62
Louise Obici Memorial Hospital, Suffolk, VA	57
Mary Immaculate Hospital, Suffolk, VA	107
Mary Washington Hospital, Fredericksburg, VA	260
Rappahannock General Hospital, Fredricksburg, VA	260
Riverside Regional Medical Center, Kilmarnock, VA	41
Riverside Tappahannock Hospital, Tappahannock, VA	17
Riverside Walter Reed Hospital, Jappahorack, VA	44
Southside Community Hospital, Newport News, VA	81
Southside Regional Medical Center, Petersburg, VA	89
<i>Total Procedures:</i>	1,135
<i>Average Number of Procedures per Lithotripter:</i>	1,135

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2008 data as reported on the 2009 Lithotripsy Registration and Inventory Form for Mobile Equipment)

Provider: Piedmont Stone Center, PLLC, 1907 South Hawthorne Road, Winston-Salem, NC 27103-
 Machines 4 Purchased or Replaced: 3/26/2002

Areas Generally Served: Western and Central NC and Virginia

<i>Facility and Location</i>	<i>Procedures</i>
Alamance Regional Medical Center, Burlington, NC	228
Annie Penn Memorial Hospital, Reidsville, NC	30
Caldwell Memorial Hospital, Lenoir, NC	49
Davis Regional Medical Center, Statesville, NC	26
High Point Regional Health System, High Point, NC	462
Iredell Memorial Hospital, Statesville, NC	130
Lexington Memorial Hospital, Lexington, NC	171
Maria Parham Hospital, Henderson, NC	111
Morehead Memorial Hospital, Eden, NC	215
Northern Hospital of Surry County, Mount Airy, NC	67
Piedmont Stone Center, PLLC, Winston-Salem, NC	738
Randolph Hospital, Asheboro, NC	123
Rowan Regional Medical Center, Salisbury, NC	179
Wake Forest Baptist Medical Center, Winston-Salem, NC	20
Watauga Medical Center, Boone, NC	192
Wesley Long Hospital, Greensboro, NC	425
Wilkes Regional Medical Center, North Wilkesboro, NC	93
Lynchburg General Hospital, Lynchburg, VA	191
Martha Jefferson Hospital, Charlottesville, VA	171
Piedmont Day Surgery Center, Danville, VA	51
Twin County Regional Hospital, Galax, VA	61
Urology Associates of New River Valley, Christiansburg, VA	108
Wythe County Community General, Wytheville, VA	29
<i>Total Procedures:</i>	3,870
<i>Average Number of Procedures per Lithotripter:</i>	968

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2008 data as reported on the 2009 Lithotripsy Registration and Inventory Form for Mobile Equipment)

Provider: Stone Institute of the Carolinas, LLC, 705 Griffith St., Suite 205, PO Box 4509, Davidson, NC 28036-

Machines 2 Purchased or Replaced: 1/1/2001

Areas Generally Served: Western and Central NC

<i>Facility and Location</i>	<i>Procedures</i>
Carolinas Medical Center, Charlotte, NC	355
Cleveland Regional Medical Center, Shelby, NC	137
CMC-Northeast Medical Center, Concord, NC	252
CMC-Pineville, Charlotte, NC	0
CMC-University, Charlotte, NC	176
Gaston Memorial Hospital, Gastonia, NC	181
Lake Norman Regional Medical Center, Mooresville, NC	120
Lincoln Medical Center, Licolnton, NC	60
Presbyterian Orthopaedic Hospital, Charlotte, NC	353
Stanly Memorial Hospital, Albemarie, NC	45
Union Regional Medical Center, Monroe, NC	130
Piedmont Medical Center, Rock Hill, SC	254
Springs Memorial Hospital, Lancaster, SC	12
<i>Total Procedures:</i>	2,075
<i>Average Number of Procedures per Lithotripter:</i>	1,038

Provider: Triangle Lithotrispy Corp., 7003 Chadwick Dr #321, Brentwood, TN 37027-

Machines 1 Purchased or Replaced: 10/1/2002

Areas Generally Served: East Central NC

<i>Facility and Location</i>	<i>Procedures</i>
Central Carolina Medical Center, Sanford, NC	100
Durham Ambulatory Surgical Center, Durham, NC	143
Durham Regional Hospital, Durham, NC	136
Franklin Regional, Louisberg, NC	28
Nash Day, Rocky Mount, NC	115
Rex Hospital, Raleigh, NC	366
Wake Med, Raleigh, NC	244
Wayne Memorial, Goldsboro, NC	95
<i>Total Procedures:</i>	1,227
<i>Average Number of Procedures per Lithotripter:</i>	1,227

Total Procedures for State: **11,420**

Average Number of Procedures per Lithotripter: **816**