



## Prostiva® RF Therapy Set up *Guidelines*

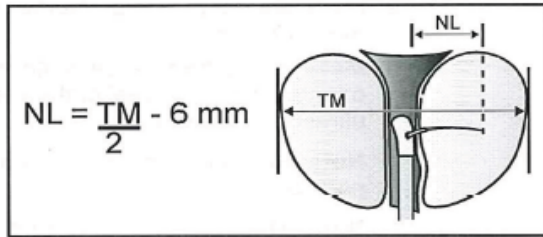
**ALL MEDICAL DECISIONS ARE MADE AT THE DISCRETION OF THE TREATING PHYSICIAN.**

*This is not intended to constitute medical advice by Urologix, nor is it intended to be an endorsement of any product or preferred treatment regimen. Rather, it is a list that physicians have used in treating patients before, during, and post-procedure. A physician must exercise his/her best judgment in fashioning a treatment regimen and in choosing medications while also considering patient co-morbidities, other prescription or OTC medication being taken, and the patient's sensitivity to other procedures including cystoscopy or catheterization. Indications, contraindications, warnings, precautions, adverse events and instructions for use can be found in the product labeling "System User Guide" and/or "Instructions for Use" supplied with each medication, generator or the hand piece kit.*

*Nothing is intended to replace or cancel any of the required procedural steps listed in the Prostiva "System User Guide" or "Instructions for Use" (IFU) including but not limited to measurement of the prostatic urethral length and transverse width.*

	Time		
<b>Supplies Needed</b>		<ul style="list-style-type: none"> <li>• Prostiva RF Therapy Generator</li> <li>• Clean and sterilized Telescope</li> <li>• Sterile Hand piece</li> <li>• Xylocaine hydrochloride liquid and gel anesthetic or similar agent</li> <li>• Betadine swabs or similar</li> <li>• Water soluble lubricant gel such as KY Jelly</li> <li>• Penile Clamp</li> </ul>	<ul style="list-style-type: none"> <li>• 500ml sterile irrigation solution with irrigation tubing and stopcock</li> <li>• Aspiration tubing and vacuum source</li> <li>• Catheters and leg bag for Post Procedure</li> <li>• Surgical attire</li> <li>• Patient drape</li> <li>• Light source and light cord</li> <li>• Optional video camera and display</li> <li>• Supplies for optional prostate block</li> </ul>
<b>PRE Procedure</b>	<b>45-60 Minutes Before</b>	<ul style="list-style-type: none"> <li>• Oral sedative</li> <li>• Oral analgesic</li> </ul>	
	<b>20 Minutes Before</b>	<ul style="list-style-type: none"> <li>• Attach Return Electrode to the patient.</li> <li>• Empty bladder.</li> <li>• Instill analgesic into bladder.</li> <li>• Instill urethral analgesic, then clamp penis.</li> <li>• Some physicians find using a prostate block enhances patient comfort.</li> <li>• Drape patient.</li> </ul>	
<b>Procedure Prep</b>		<ul style="list-style-type: none"> <li>• Ensure correct prostate size measurements are complete.</li> <li>• Set needle length.</li> <li>• Ensure Prostiva telescope and hand piece are sterile.</li> <li>• Connect components – telescope, light source, hand piece, tubing system as shown in System User Guide page 76.</li> <li>• Attach the sterile H2O irrigation source to the Prostiva Irrigation Kit luer lock. Flush to test and remove all air bubbles.</li> <li>• Test needle deployment. Needles are tested by deploying and retracting.</li> <li>• Attach hand piece and return electrode to generator.</li> <li>• Turn on Prostiva Generator.</li> <li>• Hand piece is instilled and procedure begins.</li> </ul>	
<b>Post Procedure</b>		<ul style="list-style-type: none"> <li>• Place Foley Catheter for voiding trial.</li> </ul>	

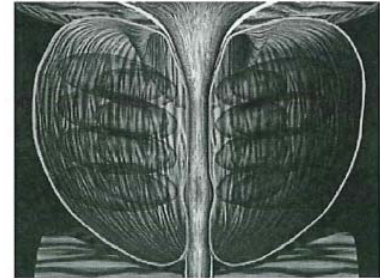
Needle length is typically calculated by taking one half of the transverse diameter of the prostate and subtracting 6 millimeters as shown in the following equation:



Transverse Measurement Range (mm)	Needle Length (mm)
36	12
36-40	12, 14
40-44	14, 16
44-48	16, 18
48-52	18, 20
52-56	20, 22
56-80	22

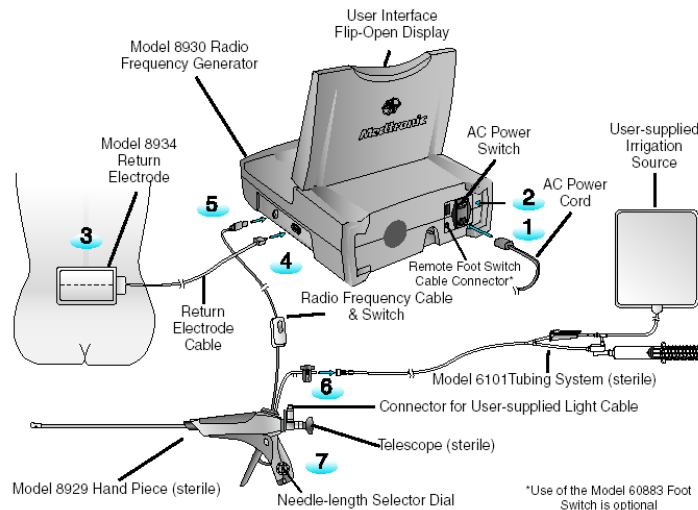
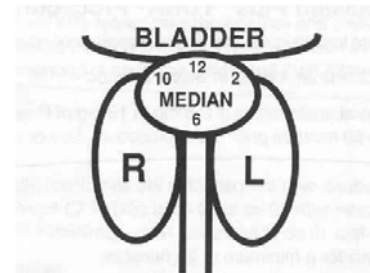
### Determining the number of treatment planes:

Bladder Neck to Verumontanum Length	Number of Treatment Planes	Treatment Planes
<3 cm	2-3	proximal and distal
3-4 cm	3-4	proximal mid-point and distal
4-5 cm	4-5	proximal mid-point and distal



### Determination of Median Lobe treatment locations:

Median Lobe Dimensions (cm)	Treatment Regions	Treatment Locations
<3 cm wide	1	10, 12, 2 o'clock
3 cm wide	2 or more	10, 12, 2 o'clock
3 cm long	1	12 o'clock
>3 cm	2	6, 12 o'clock



Refer to pages 75 & 76 in the System User Guide for detailed descriptions.

**Indications:** Prostiva RF Therapy is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20cc and 50cc.

**Adverse Events:** Side effects may include obstruction, bleeding, pain/discomfort, urgency, frequency and urinary tract infection.

**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician. For a listing of indications, contraindications, precautions and warnings, please refer to the System User Guide. Prostiva is a registered trademark of Medtronic. Urologix is the exclusive licensed distributor for Prostiva RF Therapy products.