

CONSENT FOR MICROWAVE THERMOTHERAPY TREATMENT FOR THE TREATMENT OF BENIGN PROSTATIC HYPERPLASIA CAUSING BLOCKAGE OF THE URINARY CHANNEL

I, _____, hereby authorize DRNAMES.HED, along with medical assistants under his/her control, to perform the American Medical Systems Microwave Thermotherapy for the treatment of Benign Prostatic Hyperplasia. This treatment will be performed on _____, 200 . I understand that during the treatment a catheter-like tube will be inserted into my urethra using anesthetic jelly. There will also be a small probe inserted into my rectum. These probes will be connected to the microwave generator. This treatment has been used investigationaly since 1988 and received FDA approved in 2001.

The benefit of this treatment is relief of my bladder outflow obstruction. I understand the possibility of risks associated with transurethral microwave thermotherapy. Some of the risks include blood in my urine, small amounts of blood in the sperm, temporary inability to urinate, urinary infection, frequent urination, urgency, discomfort in the bladder, prostate or rectum, and a burning sensation during urination. My physician has also explained that not all patients benefit equally, and some may not appreciate any benefit at all. Additional possible side effects that were **not** noticed in the clinical study included loss of sexual functioning, sterility, exposure to excessive microwave energy, and heat damage to tissue. Specific but very rare risks reported by similar technologies include injury to the rectum or urethra requiring subsequent surgical procedures.

My physician has explained alternative methods for the treatment of benign prostatic hyperplasia. Alternatives include watchful waiting, drug therapy, surgical procedures such as transurethral resection of the prostate, open prostatectomy, and other heat therapies such as laser treatments or TUNA. My physician has discussed these alternatives with me and feels that microwave thermotherapy is the best treatment for my particular condition. The doctor has answered all my questions regarding this treatment and I agree to proceed with the American Medical Systems Microwave Thermotherapy treatment.

My signature below indicates that I have read and understood this consent form.

Signed _____ Witness _____

Date _____ Time _____

MICROWAVE THERMOTHERAPY TREATMENT, including the possible risks, complications, alternative treatments (including non- treatment) and anticipated results, was explained by me to the patient before the patient consented.

Physician's Signature _____ Date _____

PATIENT INSTRUCTIONS FOR Transurethral Microwave Thermotherapy Treatment

Your appointment is scheduled on (date) _____ at _____ o'clock

Please follow the directions below. If you have any questions or if for any reason you will be unable to make your appointment, please call 206.292.6488 and ask for Liz Roberts.

AT HOME BEFORE THE TREATMENT

1. **Please make arrangements for transportation to and from the treatment. Someone will need to drive you to the doctor. The treatment medications, although very mild, could interfere with your driving.**
2. Reduce the amount of alcoholic and caffeinated beverages and tobacco products 48 hours prior to the treatment.
3. At home, **on the day prior to treatment, take the antibiotic**, one pill
You will have been given either [Levaquin = levofloxacin] or [Cipro XR = ciprofloxacin] or [Septra = Bactrim = trimethoprim/sulfamethoxazole]
4. On the day of treatment:, be sure to eat something.
5. You may bring books, magazines or your favorite music to pass the time.
6. Wear comfortable or loose fitting clothing the day of the treatment. A catheter will be placed in your bladder and most likely stay there for the next few days (even longer if you already required a catheter before treatment.) Your doctor will instruct you on how and when the catheter will be removed.
7. **You may take all your daily medications unless otherwise indicated by your physician.**
Your physician will have instructed you specifically about blood thinners such as aspirin, Plavix or coumadin/warfarin.

In particular, it is important to continue taking any of the following medications:
Flomax/tamsulosin, Uraxtral/alfuzosin, Hytrin/terazosin, Cardura/doxazosin.

If you are already on any of the following medications, you should continue taking them up to and including the day of treatment, but will need to stop them thereafter before the catheter is removed: Detrol LA/ Detrol/Ditropan XL/Ditropan XL/oxybutynin/Levsin/hycosamine.
These medications are usually stopped three days before removing the catheter to ensure they do not interfere with your ability to urinate completely.

8. **On the day of the treatment, prior to departure:**

8A.) Take one antispasmodic. Your physician will have given you [Detrol LA, 4mg] or [Ditropan XL, 10mg]

8B.) Take another antibiotic pill. Your physician will have given you [Levaquin] or [Cipro] or [Septra]

Take the anti-inflammatory. Your physician will have given you either [Celebrex, 400mg, or two 200mg capsules] or [Bextra 20mg] or [Mobic 15mg]

8C.) Administer one Fleets enema well before leaving the house, but as close as possible to 2 hours prior to treatment.

9. **Upon Arrival to the office:**

You will be asked to sign the informed consent:

Thereafter, you will be asked to take part of the sedative.

[Usually Ativan=Lorazepam, Two 0.5 mg tablets] In the office at least 1 hour prior to treatment

Although you may not be able to appreciate the effects, the sedative makes the procedure much easier.

Sometime thereafter, you may be asked to take more sedative [Usually Ativan=lorazepam, two 0.5 mg tablets] shortly before beginning the procedure.

Sometimes we will administer Levsin/hycosamine (sublingual) to suppress bladder spasms during the procedure.

AT THE DOCTOR'S OFFICE:

You will go to an exam room and be asked to get undressed from the waist down. You will then cover yourself with a drape and get up on a cushioned exam table. The entire American Medical Systems® treatment takes about 60 minutes. You will be able to urinate during the treatment because the treatment catheter allows urine to drain. After the catheter and rectal sensor are placed, the system begins to work. The system slowly raises the temperature in the prostate. It commonly takes 20 minutes to reach a therapeutic temperature. When the system reaches treatment temperature, it holds that temperature for 40 minutes.

You may feel some minor sensations during the treatment. Some patients feel warmth in the groin area and the urge to urinate. Many patients read, listen to music, or sleep during the American Medical Systems treatment.

The most common cause of discomfort is bladder spasms. If necessary, your doctor will give you an oral medication that will help you avoid bladder spasms.

The American Medical Systems® DOT system will automatically shut off after the treatment is complete. Your doctor will remove the treatment catheter and rectal sensor. A temporary urine drainage catheter will then be placed. You will usually wear this catheter for 2 to 5 days.

AFTER THE TREATMENT:

You will be able to leave the office soon after the treatment, though you may be drowsy. Someone will need to drive you home.

At home, you should drink at least eight 8 oz. glasses of water every day (total= 64 oz. per day). Make sure that you take all medications prescribed by your Doctor. Avoid strenuous activities for the rest of the day. You may resume normal activities, including returning to work, as early as the next day.

Post-Treatment Instructions for Transurethral Microwave Thermotherapy

Your bladder will be emptied with the help of a catheter for the next few days. A catheter has been placed through your urethra to your bladder. You do not have to do anything to urinate; the catheter will automatically drain urine from your bladder. If you are drinking plenty of fluids and see no urine draining into the bag, and you are uncomfortable, please call our office. A little leakage around the catheter is normal.

Please refrain from taking baths while the catheter is in place. Showers are fine. It is very important that the drainage bag is always lower than your abdomen. Before going to bed at night please empty your leg bag. Switch the leg bag daily from one leg to the other.

You may observe some bloody discharge from your penis. You may find that your lower abdomen is sore and that sitting is uncomfortable. All of these are normal reactions to the treatment.

Please try to take it easy for the next few days. Until your catheter is removed, you should refrain from any strenuous activity. Be sure to continue to eat balanced meals and drink plenty of water.

Please call the office immediately if you experience any of the following:

- " Temperature greater than 101.5 F
- " Evidence that the catheter is not draining urine or constant leakage around the catheter.
- " Excessive bleeding
- "
- A Excessive discomfort
- " Any chills or shaking

You may notice no change in your enlarged prostate symptoms immediately after the treatment. However, your body is actively working itself to heal. In the weeks after the treatment, the tissue treated with American Medical Systems will gradually be reabsorbed by your body and your symptoms will be reduced. Most men will start to see improvement in their symptoms within 6-12 weeks, although this varies with each person.

Prescriptions Given:

1. Antibiotic _____ to be taken for _____ days.

2. Antispasmodic _____ to be taken for _____ days.
3. Anti-inflammatory _____ to be taken for _____ days
4. Alpha Blocker _____ continue until told not to
5. Drink At least 8 ounces of water every 8 hours while the catheter is in place.

Your catheter will be removed on _____.

Please follow up with your doctor about _____ days following the treatment.

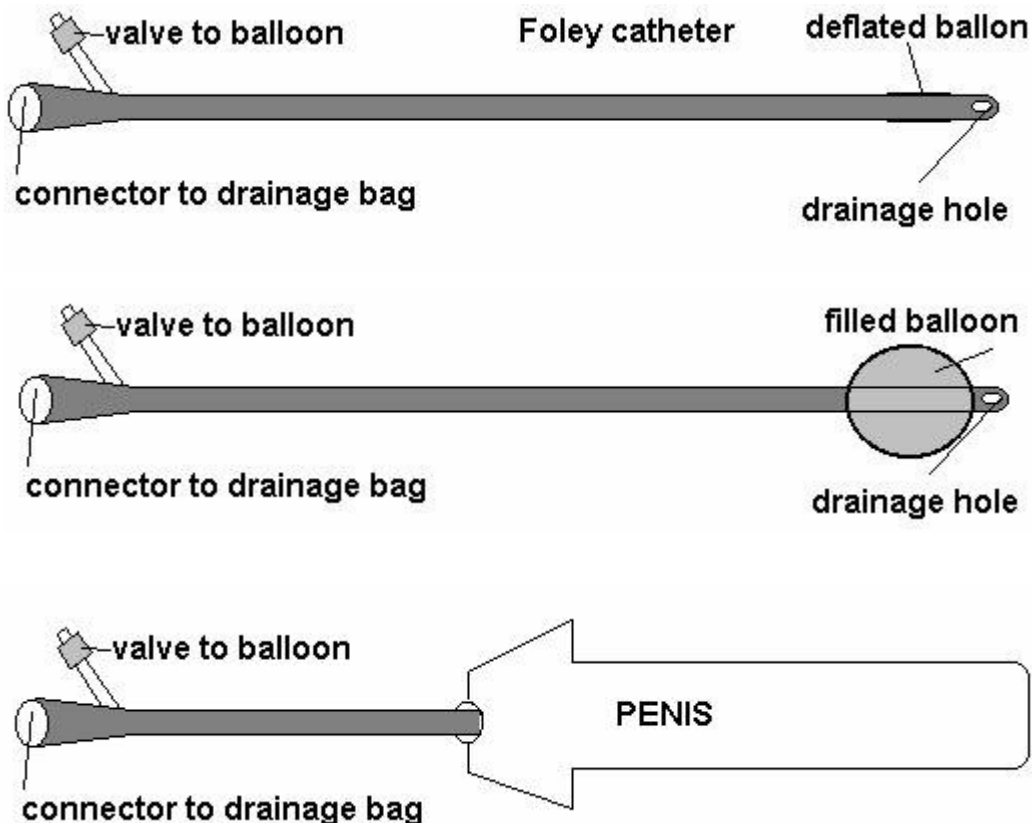
URINARY CATHETER REMOVAL AFTER TUMT

You have been discharged from the office after your procedure with a urinary catheter. These tubes (usually called "Foley", named after the inventor) are used to drain the urinary bladder of urine normally stored in the bladder. We expect the prostate gland to swell a bit for the first few days after the procedure. This swelling is likely to close the urinary channel enough that voiding might be difficult or impossible.

We will suggest that the catheter be removed by yourself at home a few days after the procedure. The thought of doing something 'medical' may be frightening to some. However, removing the catheter is quite easy and with no serious risks. Normally this is done **early in the morning during a weekday**. The reason for this is that if you are unable to urinate after removal of the catheter, we will still be in the office to assist you.

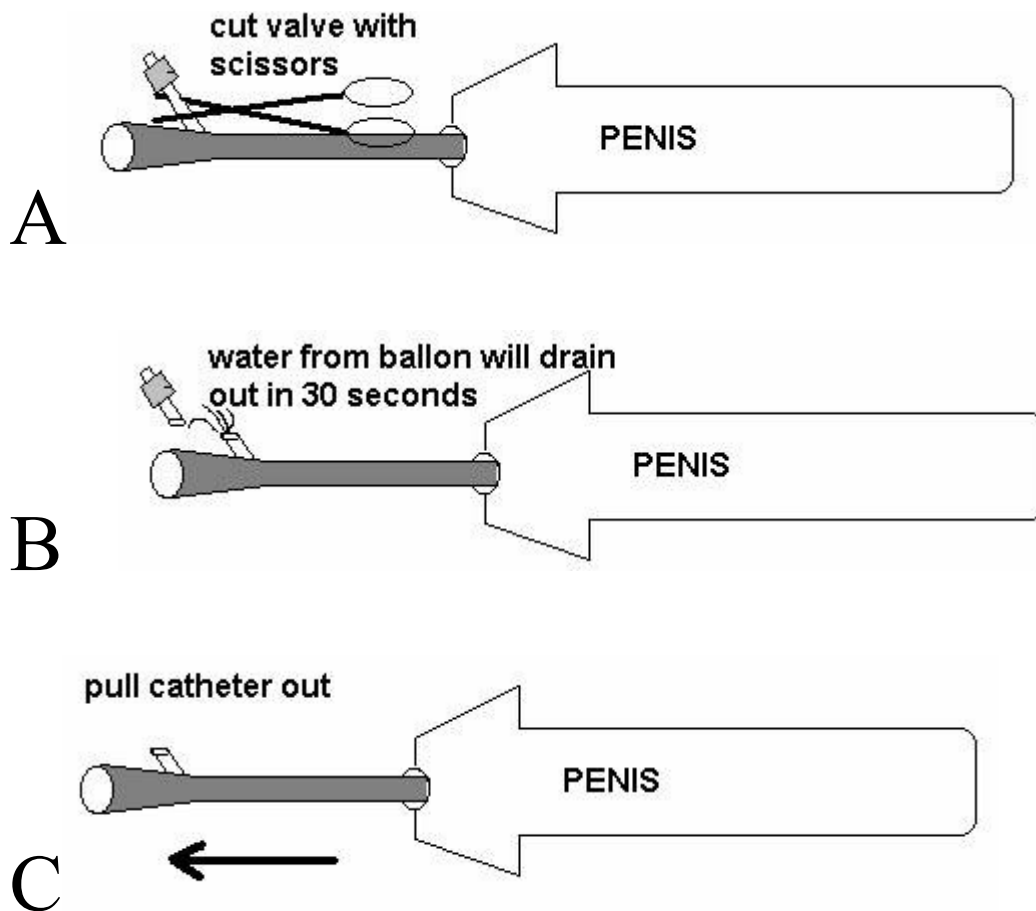
To remove the catheter you must understand the construction of the catheter

Design: The catheter is a hollow tube with a hole on each end. A side arm can be seen on the catheter and this allows a small balloon to be filled in the bladder so that the catheter does not fall out.



Removing the catheter:

From the diagram at the beginning of this pamphlet you can see the catheter stays in place in the bladder because of a balloon at the end that is inflated with water once the catheter end is placed into the bladder. Therefore, removing the water from the balloon flattens the catheter and allows you to pull the catheter out. Removing the water from the balloon requires that you cut the valve stem completely across with a scissors (figure A). The balloon will slowly drain one to two teaspoons of water within 30 seconds (figure B). The catheter can then be easily pulled out with a gentle tugging movement (figure C). If removed, you may want to monitor the times and amount of urine that you pass for the next 24 hours unless you have an appointment for the day the catheter comes out.. Expect a slight burning sensation with urination for the first day or so. If you are unable to urinate, or have the sensation that you are not emptying your bladder, please call. You may then throw the catheter into the garbage.



NOTE: DO NOT REMOVE THE CATHETER UNLESS SPECIFICALLY REQUESTED TO DO SO

If you cannot urinate for a prolonged period at any time after the catheter is removed, you will need to contact us. If we are in the office we may need to see you. If the office is closed, you may

need to be seen in the emergency room to have another catheter placed.