



CoreTherm[®] Thermotherapy

Patient Information Guide

CoreTherm[®]

BRINGING QUALITY TO LIFE

This documentary material has been produced by ProstaLund AB and is medically reviewed by:

Sonny Schelin MD, PhD, Specialistläkargruppen i Kalmar

Eva Broström RN, Skånes Universitetssjukhus, Malmö

Jennifer Braun RN, Capio St Görans Hospital, Stockholm

© 2013 ProstaLund

www.prostalund.com

Choosing to have the CoreTherm® Treatment

Just like the thousands of other men who have suffered from BPH, you have chosen to have this unique treatment solution for your enlarged prostate. The men who have undergone this treatment are very pleased with the results and have reported a dramatic improvement with their ability to urinate normally thus improving their quality of life.

It is normal to feel anxious before any medical treatment. This guide was written to describe what you can expect before, during and after your treatment. It will also provide you with a recommended protocol that your doctor may want you to follow before you arrive for treatment and after you go home.

It is important to understand that each patient is unique. The CoreTherm treatment is adapted and tailored to each person and prostate so, individual results may vary. The statements in this guide are based on typical outcomes from several clinical trials. If you have any questions or concerns, please consult with your doctor.



Things To Do At Home Before The Treatment

Before the day of treatment

- Ask your Urologist if you should take your regularly prescribed medications.
- It is important to inform your doctor if you are taking aspirin, aspirin-containing products or any non-prescribed supplements.
- Your doctor may prescribe medication that you will need to take before and after your treatment. Please fill these prescriptions at your pharmacy **before** the day of your treatment and bring all medications with you on the day of your treatment.

Treatment Day

- You should eat a light meal prior to coming to the doctor's office. **DO NOT** eat a heavy meal.
- You should have a Fleet enema the morning of the treatment if you have not had a bowel movement.
- Wear comfortable, loose fitting clothing. You will be going home with a urinary catheter and it will be easier for you to get dressed.
- Please arrive at the doctor's office one hour prior to the treatment. It will give you time to check in, prepare for your treatment and take the prescribed medication that will help you relax during the treatment.
- Someone **MUST** be available to drive you home. You will not be allowed to drive after your treatment.



Preparing For The Treatment

In a private room, you will be asked to lie on a treatment bed. Make sure that you are comfortable.

The treatment area will be washed with an antibacterial solution and an anesthesia gel will be applied to the tip of your penis and into the urethra. This anesthetic will help numb the area reducing your discomfort when the treatment catheter is inserted.

A soft, flexible drainage catheter will be gently inserted into your urethra to empty your bladder before the treatment begins.

A special temperature monitoring device will be inserted into your rectum and a soft band, which also measures temperatures, will be placed around the base of the penis.

The treatment catheter containing a special temperature monitoring device and the thermotherapy treatment device will be inserted into your urethra. While this may be slightly uncomfortable, it should not be painful.

These devices help your doctor and the treatment technician perform your procedure in a safe manner.



If you have had a reaction to dental or topical anesthesia before, please, inform your doctor about it.

What To Expect During The Treatment

Your doctor will decide how much of the prostate needs to be treated while the computer calculates and monitors the temperature of the prostate, the prostatic blood flow, and the tissue reduction.

The treatment takes between 10 to 20 minutes on average.

During the treatment, the doctor will be monitoring eight safety sensors that are measuring temperatures in the prostate, inside the rectum and around the penis to ensure that the treatment is safely and effectively done. A slight heat sensation normally occurs and near the end of the treatment, you may feel the intense urge to urinate even though your bladder is empty. This sensation should not be painful and will decrease. If you are experiencing pain, it is important to tell your doctor.

The treatment will automatically be stopped if any of the temperatures in the prostate, rectum or at the base of the penis reach unsafe levels. The doctor can adjust the heat or stop the treatment depending on your individual needs.

After the treatment, the catheter is taken out. The tissue around the prostate will normally swell in response to the treatment. Your doctor will place a soft catheter into your bladder to drain your urine until the swelling subsides. You may need to keep this catheter in for approximately one to three weeks.

Your doctor will determine when to remove the catheter as each person's recovery is unique. You will be instructed on how to care for catheter and empty the drainage bag.

What You Can Expect After The Treatment

You can usually go home shortly after the treatment. Plan to rest and take it easy for a few days. You should avoid heavy lifting and excessive or intense physical activity.

The urethra and prostate swell after the treatment and will need time to heal. You may feel some slight discomfort from the catheter and the swelling, particularly during the first 24 hours. After a few days, the irritation and discomfort should disappear.

Your doctor may prescribe medications to help with pain and to reduce the possibility of infection. You should take the medication as directed and finish all of your antibiotics.

Following the treatment, you may have frequent urges to urinate. This is normal and these urges will gradually go away.

Please pay particular attention to genital hygiene after treatment to prevent the risk of infection. Do not disconnect the catheter from the drainage bag unless directed by your doctor.

You may see a small amount of blood in your urine after the treatment. This is completely normal and harmless. It will go away as you begin to heal.

Your doctor will watch your progress as you continue to heal and get better over time.

 **Avoid heavy lifting and excessive or intense physical activity for a few days after the treatment.**

Your Return Visit

You will need to follow up with your doctor at the office to have your catheter removed. This appointment will be determined by your doctor depending on the treatment, how much swelling has gone down and how quickly your body heals.

Remember, you may not notice an immediate improvement when the catheter is removed. The full benefits will take place over the weeks and months that follow. Most men experience a significant improvement within one to three months. The improvement tends to be gradually noticeable each week during that time frame. So start looking forward to a better quality of life.

” Several studies have shown a marked and long-term improvement in BPH symptoms after CoreTherm Thermotherapy Treatment.

IMPORTANT INFORMATION

You should call your doctor/nurse if you experience any of the following:

- Unexplained high fever or chills as this may be a sign of infection
- Heavy or excessive bleeding
- A stoppage in the catheter
- Severe pain at any time

CoreTherm Thermotherapy is a safe and effective treatment with a low risk of side effects or complications.* However, like any treatment, there can be side effects and complications. Your doctor will explain the potential side effects, including how they compare to other treatment in more detail.

*The major side effects reported in the FDA controlled clinical study of CoreTherm were: urinary urgency, urinary retention, urinary tract infection, and hematuria (blood in the urine), generally short in duration.

FAQs

How Does CoreTherm® Work?

CoreTherm uses heat to remove additional tissue which blocks urinary flow in men with Benign Prostatic Hyperplasia (BPH). CoreTherm uses a unique, patented technology that allows medical personnel to continuously monitor the temperature in the prostate and customize treatment for each person's clinical needs.

Is The Treatment Painful?

The treatment is done in your doctor's office, using an anesthetic gel to numb the area to be treated. Your doctor may prescribe a medication to be taken orally before the treatment that will help you relax during the treatment. During the treatment, some patients feel discomfort from the heat and others may feel the need to urinate. After the treatment, you may feel a mild urgency to urinate for a few weeks. Your doctor may prescribe additional medication that will help you be more comfortable. The experience after the treatment will vary from person to person.

Are There Any Sexual Side effects?

The CoreTherm treatment should not affect your ability to have an erection or an orgasm. Semen quantity may be reduced or disappear for some men. If you are currently sexually active, then you can look forward to remaining so.

Is CoreTherm® Effective Long term?

Yes! Several studies have shown a substantial and long-term improvement of BPH symptoms after heat treatment. CoreTherm can give you and your loved ones those results you hope for.

Glossary

Antibiotic: A medicine used to treat or prevent infection.

Treatment Catheter: A soft, flexible tube into the bladder through the urethra which contains both the probe used for temperature monitoring in prostate, and means for thermotherapy.

BPH: Benign Prostatic Hyperplasia is a non-cancerous enlargement of the prostate that can cause pressure on the urethra, making it difficult to empty the bladder.

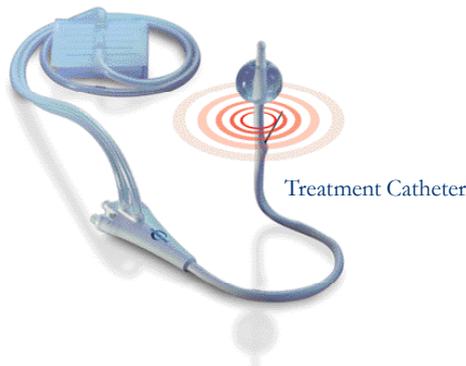
Catheter: A soft and pliable tube which carries urine from the bladder into a urine collection bag.

Local anesthesia: Drugs that are either injected or applied directly to skin or mucosa to produce numbness to a specific area.

Minimally invasive treatment: Treatment through a natural body opening, such as the urethra. Treatment not requiring hospital resources, general anesthesia or spinal anesthesia.

Urethra: The tube in the penis through which urine is passed from the bladder.

Urologist: Doctor who specializes in urinary tract health.



ProstaLund AB has been active since the early 1990s in the medical business.

ProstaLund develops and sells equipment for the treatment of benign prostate enlargement based on patented personalized CoreTherm Thermotherapy. More than 50 000 men have undergone treatment with CoreTherm.

The method is currently used in hospitals and doctors' offices in the U.S., Sweden and around the world.



CoreTherm®

BRINGING QUALITY TO LIFE

CoreTherm Medical Inc.

120 Commerce Blvd. Suite 5, Oldsmar, FL 34677

Corporate Headquarter ProstaLund AB

Scheelevägen 17, SE-223 63 Lund, Sweden
info@prostalund.com • www.prostalund.com

