



CoreTherm

EVIDENCE-BASED TREATMENT FOR BPH

Patient information

CoreTherm[®] thermal therapy for prostate gland enlargement



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INFORMATION ABOUT CORETHERM®

Each person with symptomatic enlargement of the prostate is unique. CoreTherm® makes it possible to adapt the treatment to suit You.

This brochure relates to thermal therapy with CoreTherm®, and describes what you can expect before, during and after a CoreTherm® treatment.

For further information, please read about CoreTherm® at www.coretherm.com or call ProstaLund's patient phone line at (+46) 046-12 09 04 (open weekdays 8:00 to 17:00).

You can also ask your doctor or contact nurse for more information and assistance.

Please write the phone number of your healthcare contact for CoreTherm® here:

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Towards the end of this brochure, you will find a glossary of terms to help you. Words included in the list are marked in *italics*.

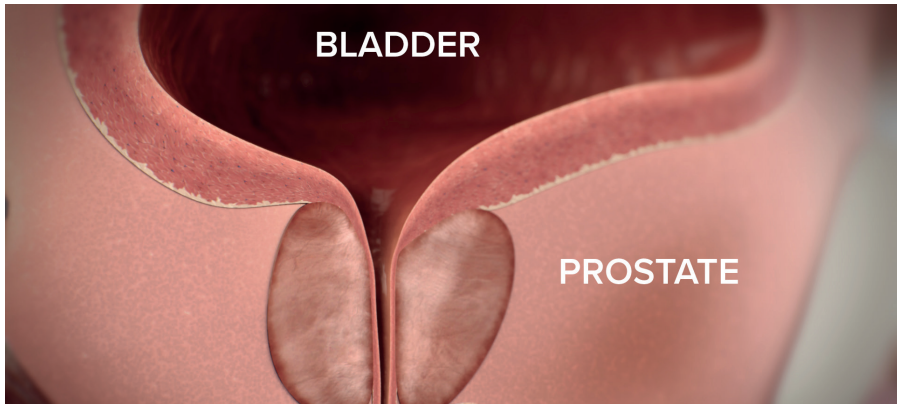
BPH - BENIGN PROSTATIC HYPERPLASIA

Prostate gland enlargement (BPH) can cause pronounced difficulties to urinate.

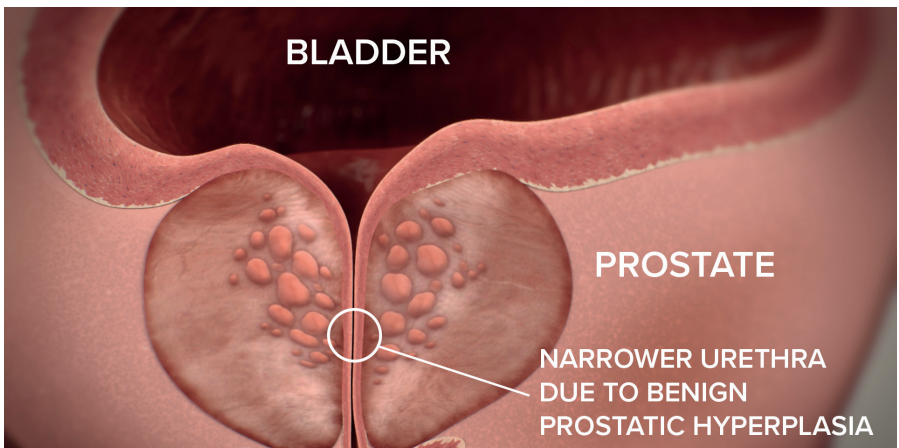
About half of all men over the age of 50 and up to 80% of men over the age of 80 suffer from urinary problems related to BPH.

BPH is not a form of cancer, but if left untreated it can lead to serious damage to the bladder and/or kidneys with permanent impairment.

NORMAL PROSTATE GLAND



BENIGN PROSTATE ENLARGEMENT



WHAT DOES CORETHERM® INVOLVE?

CoreTherm® involves thermal treatment of the prostate gland using microwaves. The method is a minimally invasive treatment designed for patients suffering from BPH.

The treatment, which is performed under local anaesthesia, takes less than 15 minutes. The entire visit takes about 1-2 hours from start to finish. This includes preparations, treatment and information.

The results are as good as surgical treatment requiring hospitalisation. In addition, CoreTherm® results in fewer serious complications than surgery.

PREPARATIONS AT HOME PRIOR TO TREATMENT

- Take your regular medicines the morning of the treatment day, unless told otherwise by your doctor.
 - Your doctor will prescribe the medicines you need to take before and after the treatment.
 - You are allowed to have breakfast on the day of treatment.
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Minimally invasive treatment
designed for patients
suffering from BPH

THE DAY OF TREATMENT

BEFORE COMING TO THE DOCTOR'S OFFICE

Eat a light meal before coming to the doctor's office. It's a good idea to have emptied the bowel before the visit. We recommend that you wear comfortable clothing.

PREPARATIONS AT THE DOCTOR'S OFFICE, INCLUDING LOCAL ANAESTHESIA

Your groin area will be washed with an antibacterial soap. Your *urethra* will be filled with local anaesthetic gel, which will be kept in place using a soft penis clamp. Local anaesthesia will be applied to the prostate gland using an anaesthetic catheter. You may feel a prick during the injection. Local anaesthetics will minimize / eliminate pain sensation, it also contains adrenaline which makes the treatment fast. The local anaesthetic catheter will also empty your bladder.

TREATMENT CATHETER AND TEMPERATURE MEASUREMENT

After the local anaesthesia has been administered, the *treatment catheter* is inserted into the urethra. A thermometer will be inserted into your rectum. An additional thermometer will be fastened around the base of your penis. These safety thermometers ensure your safety during treatment.



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If you have had a reaction to “dental anaesthesia” previously, it is important to inform the medical staff about this

TREATMENT WITH CORETHERM®

The CoreTherm® treatment takes less than 15 minutes. The temperatures in the prostate gland, the urethra, rectum and around the base of your penis are monitored in the treatment computer. The treatment effect is continuously calculated to control the treatment.

During the procedure, the doctor will be monitoring eight safety temperature sensors – three in the prostate, three in the rectum, one in the treatment catheter, and one under the urethra around the penis. All to ensure the procedure is safe and effective.

EXPERIENCE DURING CORETHERM® TREATMENT

A slight sensation of heat is normally felt during the treatment. Near the end of the procedure (usually 2–4 minutes before the treatment time is over), you may feel an urge to urinate. The urge may be intense but is a false alarm since your bladder was emptied before the treatment began. Any sensation of heat or urge to urinate will relieve as soon as the treatment ends.

The treatment will be stopped automatically if any temperature (prostate, rectum, urethra, penis base) reach the preset safety levels. The doctor or nurse will adjust the heat output and “customise” the treatment to your individual needs.

After the treatment, the treatment catheter and thermometers will be removed. A conventional *urinary catheter* or a *CoreFlow- Soft Stent* will then be inserted.

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The treatment takes
less than 15 minutes

CATHETER AFTER CORETHERM®

Thermal therapy causes tissue damage and swelling of the prostate gland. The swelling could persist for several weeks and will gradually decrease.

The swelling will initially make it more difficult to urinate. Therefore a catheter or a CoreFlow - Soft Stent will be inserted after the treatment to provide relief. This relief will be needed for 3 to 6 weeks, depending on factors such as prostate size, bladder function, and the need for a catheter prior to treatment.

Your doctor/nurse will decide what is best for You and provide you with catheter / *CoreFlow -Soft Stent* instructions.



THE PERIOD AFTER CORETHERM®

WHAT TO EXPECT AFTER CORETHERM®

You can normally go home immediately after the treatment. Plan to stay home from work and take it easy for a few days. Avoid heavy lifting and too intense physical activity. How the body reacts after a CoreTherm treatment varies a lot between individuals. It will take a few days for the urethra to get used to the urinary catheter. There may be some irritation with burning and an urge to urinate, but this normally disappears after a few days.

Your doctor will prescribe you medicines to reduce your discomfort after the treatment. *Antibiotics*, anti-inflammatory agents and medicine to suppress the urge to urinate are often prescribed. After treatment, keep your groin area clean with the help of lukewarm water from a hand-held shower.

Visible blood in the urine may be seen on and off for several weeks after the treatment. Pieces of tissue may come out even when the catheter has been removed. There may be secretion around the opening of the urethra. This is completely normal and harmless, and will disappear over time.

In all other respects, live your life as usual. But, avoid cycling and heavy lifting for 1–2 months after the treatment.

TO KEEP IN MIND AFTER CORETHERM®

In case of fever, chills, severe bleeding, blockage in your catheter / CoreFlow - Soft Stent, nausea, vomiting, or if you feel generally poor, you need to seek medical attention from a doctor/hospital immediately for assessment of your condition. However, these symptoms are uncommon.



Avoid heavy lifting
and intense physical activity
after the treatment.

RETURN VISIT

RETURN VISIT TO REMOVE THE CATHETER

When it is time to remove your catheter / CoreFlow - Soft Stent, you will receive an appointment at your urologist or your medical centre. Instructions will be given to you by the healthcare staff.

Catheter users are always at risk of developing a urinary tract infection. Urine cultures and even targeted antibiotic regimens are therefore common. Symptoms from the urinary tract will gradually decrease after the treatment and removal of the catheter / CoreFlow - Soft Stent.

POST-TREATMENT CHECKS

After about 3–4 months, you may be called in for a return visit to your urologist. The full effect of the treatment may not occurred yet. For patients with an overactive bladder in addition to the obstruction, it may take longer to reach the symptom-free stage.

The improvement will come gradually over the weeks and months that follow. Most patients experience a significant improvement, usually week by week, over the first three months. So, be prepared to look forward to a quality of life that gets better and better over time.



Several studies have shown a significant and long-term improvement of BPH symptoms after CoreTherm® thermal therapy.

FREQUENTLY ASKED QUESTIONS

HOW DOES CORETHERM® WORK?

CoreTherm® uses heat to remove the extra tissue that blocks urine flow in men with prostate gland enlargement. CoreTherm® uses a unique, patented technology that enables continuous monitoring of the temperature in the prostate and customisation of the treatment.

IS THE TREATMENT PAINFUL

The treatment is performed during a visit to the doctor's office. Prior to treatment, you will be prescribed medicines to prevent pain and the urge to urinate. The urethra will be numbed with local anaesthetic gel. Local anaesthesia will be injected in four positions in your prostate via a special catheter. The treatment is then substantially painless. However, during the treatment you may feel a moderate to severe urge to urinate and some feel a sensation of heat. Additional medicines to relieve any discomfort can be prescribed.

WILL MY SEXUAL FUNCTION BE AFFECTED?

The ability to have an erection is normally not affected. Reduced or dry orgasm may occur in 30–40% of men after treatment. If you do not have difficulties achieving an erection prior to treatment, then you should expect this to be true afterwards as well.

IS CORETHERM® A PROVEN METHOD?

CoreTherm® is an evidence-based treatment according to evaluation by European and American authorities and specialist organisations (SBU, FDA and AUA). CoreTherm® has been evaluated in a number of studies, and has been compared in studies with TURP (transurethral resection of the prostate) and open surgery (total removal of prostate through surgery).

IS CORETHERM® EFFECTIVE IN THE LONG TERM?

Several studies have shown a significant and long-term improvement of BPH symptoms after thermal therapy. CoreTherm® can give you and your loved ones the results you've been hoping for.

IMPORTANT INFORMATION

CoreTherm® is a safe and effective treatment that involves a very small risk of complications. But, as with all medical procedures, in rare cases it can lead to complications and side effects.

Contact your doctor/nurse if you experience any of the following:

- +** Inexplicably high fever or chills - it may be a sign of an infection.
- +** Heavy bleeding
- +** Blockage in your catheter / *CoreFlow® - Soft Stent*
- +** Severe pain - regardless of when and where it comes from

GLOSSARY

Antibiotics: Medicine used to treat or prevent infection

BPH: Benign prostatic hyperplasia (also known as prostate gland enlargement). BPH may lead to pressure on the urethra, making it difficult to empty the bladder.

CoreFlow® - Soft Stent: Can be used instead of urinary catheters and thereby reduce the risk of infections.

Local anaesthesia: Medicine that is injected or applied directly to the skin or mucosa to produce numbness in a specific area.

Minimally invasive: Treatment through a natural body opening, such as the urethra. Treatment that does not require hospital resources, general or spinal anaesthesia.

Treatment catheter: A soft, pliable tube that is inserted into the bladder through the urethra. During treatment it contains a microwave antenna and a thermometer measuring prostate temperatures.

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

Urinary catheter: A soft, pliable tube which carries urine from the bladder to a urine collection bag or a valve that you open to empty the bladder during a visit to the toilet.

Urologist: Doctor who specialises in the urinary tract and male genitalia.

RIGHTS FOR YOU AS A PATIENT (in Sweden)

PATIENT LAW (2014: 821) PRESCRIBES AMONG OTHER THINGS:

- You as a patient should receive information about the possibility of choosing treatment options and information about the care guarantee.
- When there are several treatment options that are in accordance with science and proven experience, you as a patient should be given the opportunity to choose the option that you prefer.
- As a patient, you should have the opportunity to choose a provider of publicly funded outpatient care, regardless of whether it is in your or another region.
- If the care guarantee is not fulfilled, you as a patient must receive care from another care provider at no extra cost.

CARE GUARANTEE

- As a patient, you should at most have to wait for **90 days**, after a referral has left, for a **first visit** to the specialized care.
- As a patient, you should not have to wait more than **90 days** for the **treatment or surgery** prescribed by your specialist doctor.

” Get information about the possibility of choosing treatment options

HOW TO SEEK CARE

Treatment with CoreTherm® is performed by nurses and / or urologists at various doctor's surgeries and hospitals around Sweden and in the Nordic countries.

In some cases, you as a patient need to get a referral from your health center to be treated. If a referral is requested, you can contact your health center for help with being referred to a treating hospital / doctor's surgery.

Feel free to contact us at ProstaLund AB to get more information about which hospital or doctor's surgery that are treating with CoreTherm®. Contact information can be found at the back of this brochure.



ProstaLund AB is a Swedish company with its head office in Lund. The company has been active since the early 1990s and operates in the medical technology field.

ProstaLund develops and sells equipment for the treatment of benign prostatic hyperplasia based on patented, personalised thermal therapy known as CoreTherm®.

More than 50,000 men have undergone treatment with CoreTherm®. The method is currently being used in hospitals and doctor's clinics in Sweden and around the world.

Read more at: www.coretherm.com



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