CoreTherm®
Patient Specific Thermal Therapy for BPH

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www.coretherm.com
Symptomatic Benign Prostatic Hyperplasia
Treat the Problem, Not the Symptoms!

As male life expectancy approaches 80 in the developing part of the world, more men live long enough to encounter symptomatic BPH.

Increasing prevalence and costs are two of the reasons that explain the demand for new, alternative and more cost effective treatments. CoreTherm® is an effective and cost saving treatment system for your office. It is based on technology that focuses on patients.

Don’t delay! Find out how you can start providing the highest standard of care to your BPH patients without TURP.

Contact us toll free at 866-917-1919 to schedule your appointment.
CoreTherm®
Patient Specific Thermal Therapy for BPH

The preferred alternative over symptom-relieving medications, other minimally invasive treatments and TURP

Several new minimally invasive treatments (MiT) have been launched in the last 15 years but not developed to replace or truly compete with TURP and open surgery. CoreTherm® patient specific thermal therapy treatment is the only thermotherapy that has developed continuously and consequently has reached widespread application.

CoreTherm® thermal therapy is a unique patented method that measures the actual core temperature in the prostate during treatment and has become a proven and popular alternative to surgery (TURP) and symptom-controlling medication.

CoreTherm® patient specific thermal therapy has gained wide acceptance around the world and is rapidly becoming the choice for benign prostatic hyperplasia (BPH) by physicians and patients.

"CoreTherm® is my preferred minimally invasive treatment for BPH. The results are TURP-like, no general anesthesia is needed, and my patients are satisfied."

Pat Hezmall, M.D.
Arlington, Texas

“When I consider using a minimally invasive treatment to achieve significant improvements in AUA symptom score, Qmax and QOL, I use CoreTherm® for its efficacy and safety."

Ruben Ramirez, M.D.
Monterey Park, California

“With CoreTherm®, I can offer quick and individualized treatments that only take about 10 to 30 minutes on average. This frees up my time to treat more patients. The treatment is less traumatic to my patients than TURP, saves them money and contributes to health economics."

Edward Gheiler, M.D.
Hialeah, Florida
CoreTherm®
Treatment is Tailored To Each Individual Patient and Prostate

Other minimally invasive options on the market just treat patients with standard treatment protocols.

Patients suffering from Benign Prostatic Hyperplasia (BPH) are not all the same. Prostates differ in size, blood flow and how they react to heat. With CoreTherm®, microwave power can be precisely controlled to customize tissue necrosis and treatment time. Most treatments can be completed in an average of 10 to 30 minutes. After the treatment the patient can go home.

"The most appealing feature of CoreTherm® is the predictable outcome. Due to the calculation of prostatic blood flow and the intraprostatic temperature measurement, I can customize the treatment to the needs of my patients."

Kalish R. Kedia, M.D.
Cleveland, Ohio

CoreTherm® is suitable for a wide variety of BPH patients including patients with urinary retention, non-catheterized patients and patients with large prostates.

"I have used the CoreTherm® system to treat patients with moderate to severe symptoms, including patients in retention. My experience is that this minimally invasive treatment option offers patients durable outcomes comparable to TURP, without the risks associated with surgery and without the need for hospitalization."

Jorgen Balslev Jorgensen, M.D.
Copenhagen, Denmark
CoreTherm®
Your superior choice for efficacy, safety and ease of use.

Quick and Simple Office-based Outpatient Procedure

Your patients deserve the convenience and efficiency of an individually-tailored safe and effective treatment that actually works. Unlike surgery or laser treatments, CoreTherm® is truly minimally invasive and an attractive option for patients with clinical BPH. No general anesthesia is required. Patients go home immediately following the procedure.

Safe and Efficient

The unique antenna used in CoreTherm® delivers a heat pattern with the highest temperatures focused at the bladder neck, and with the heat tapering off towards the apex. This allows the external sphincter to be spared from high heat.

Long Lasting TURP-Like Results

Clinical results show that CoreTherm® is the only TUMT device that creates TURP-like results. Our data comes from an FDA-controlled, prospective, randomized, multi-center study comparing CoreTherm® and TURP. The durability of the procedure is unparalleled when compared to other TUMT technologies based on 60 months follow up.

Data from 5 year clinical studies* shows you cannot find a more effective, minimally invasive treatment for BPH.

* Wogrell et al. Urology 64; 698-702. 2004;
FDA on Thermatrix: Summary of safety and effectiveness data
FDA on Prolieve: Summary of safety and effectiveness data
The Science Behind Coretherm®

History
One important observation from the early transurethral microwave thermotherapies was the large variation in treatment outcome; some patients responded quite well, whereas the majority did not. Also there was no way to predict outcome. All patients were treated the same way irrespective of prostate size, shape, tissue composition, vascularity and patient age.

The intraprostatic blood flow works like a heat sink by transporting heat away from the treatment area during thermotherapy. This is the explanation for the unpredictable outcome and frequent treatment failures described after low-energy transurethral microwave thermotherapy.

Two Biophysical Equations
Researchers at CoreTherm® by ProstaLund developed a software algorithm to calculate the amount of coagulated tissue from the measured intraprostatic temperatures. The idea was based on a novel approach to combine the Bioheat Equation, proposed by Pennes, for assessing the temperature distribution in the prostate, with the sensitivity of tissue described by Henriques. Two quantities can now be calculated in real time: the intraprostatic blood flow index and the amount of coagulated tissue.

Pennes' Bioheat Equation

\[ qc \ \frac{dT}{dt} = \lambda \Delta T - \omega h Q_h (T - T_s) + Q_\text{v} + Q_m \]

Henriques' Equation

\[ \Omega = A f e^{-Ea/RT} \ dt \]

Blood flow calculation based on "Pennes' BioHeat Equation."
Cell-Kill calculation based on "Henriques Damage Integral."

Customized Tissue Necrosis: We Treat the Bladder Neck
The ability to debulk obstructive tissue is crucial to achieving good results. Only CoreTherm® creates a symmetrical cylindrical and cone-shaped coagulation necrosis around the urethra with the widest diameter towards the bladder neck.

References:
Henriques FC. Arc Pathol. 1947; 43:489-502
Technology On Your Side

How It Works
CoreTherm® treatment employs a patented intraprostatic temperature probe that measures actual tissue temperatures at three locations within the prostate. Prostate volume is reduced by heating and coagulation action caused by microwaves emitted from the antenna. During the treatment session the intraprostatic temperature is monitored. Prostatic blood flow and cell kill are calculated.

During treatment, the temperatures in the prostate, the changes in the intraprostatic blood flow and the tissue destruction through calculated cell kill are monitored in real-time. The easy to use software system also measures other bodily temperatures for added safety, such as the rectal temperature and the temperature at the penile-scrotal angle as part of the extensive safety system. The device automatically turns off if these temperatures exceed the safety settings.

Getting Started
The CoreTherm® system comes with a control unit, a laptop computer with treatment software, a printer, an owner’s manual, a power cord, a calibration kit, and a treatment procedure kit. The treatment procedure kit includes 10 treatment catheters, two microwave antennas, two intraprostatic temperature probes, two rectal temperature probes and two safety penis probes.

Call now to discuss an evaluation of Coretherm® for your patients. Ask us about leasing or buying options or how we can assist you with mobile service providers in your area that offer CoreTherm®.

CoreTherm®
is the only thermal therapy treatment that offers:

- Quick and individualized treatment for each patient
- Intraprostatic temperature measurement
- Cell kill estimates for ablation control
- Calculation of prostate blood flow
CoreTherm® Patient Specific Thermal Therapy for BPH
SPECIFICATION SHEET

CoreTherm® Control Unit Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Specification Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Temp Range:</td>
<td>+50°F to +86°F (+10°C to +30°C)</td>
</tr>
<tr>
<td>Storage Temp Range:</td>
<td>+41°F to +104°F (+5°C to +40°C)</td>
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<tr>
<td>Humidity:</td>
<td>30% to 75%, non-condensing</td>
</tr>
<tr>
<td>Main Supply Voltages:</td>
<td>100 V to 120 V at 50 Hz or 60 Hz</td>
</tr>
<tr>
<td></td>
<td>220 V to 240 V at 50 Hz or 60 Hz</td>
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<tr>
<td>Fuses:</td>
<td>2 x 10 A, slow blow (100 V to 120 V)</td>
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<tr>
<td></td>
<td>2 x 6.3 A, slow blow (220 V to 240 V)</td>
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<tr>
<td>Power Consumption:</td>
<td>1.5 kVA</td>
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<tr>
<td>Power Output:</td>
<td>0 W to 80 W, continuous</td>
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<tr>
<td>Operating Frequency:</td>
<td>915 MHz</td>
</tr>
<tr>
<td>Dimensions:</td>
<td>H 949 mm, D 453 mm, W 605 mm, Width with pull drawer 735 mm</td>
</tr>
<tr>
<td>Weight:</td>
<td>180 lbs (82 kg)</td>
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CoreTherm® Catheter and Accessories

<table>
<thead>
<tr>
<th>Accessory</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transurethral Catheter:</td>
<td>Silicon, 22 F°, Sterile, Single-use</td>
</tr>
<tr>
<td>Microwave antenna:</td>
<td>Reusable</td>
</tr>
<tr>
<td>Intraprostatic Temperature Probe:</td>
<td>Reusable, 4 sensors</td>
</tr>
<tr>
<td>Rectal Temperature Probe:</td>
<td>Reusable, 3 sensors</td>
</tr>
<tr>
<td>Penis Safety Probe:</td>
<td>Reusable, 1 sensor</td>
</tr>
</tbody>
</table>

CoreTherm® Biomodels
Blood flow calculation based on “Pennes BioHeat Equation.”
Cell-Kill calculation based on “Henriques Damage Integral.”

CoreTherm® offers patient specific treatment. After all, each patient and prostate is unique.

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