Angelini Pharma

ThermaCare®
HEATWRAPS

# New ThermaCare® knee heat wraps

In Partnership With

Irish Society of Chartered Physiotherapists
The Voice of Physiotherapy in Ireland

ThermaCare® the pioneers of heat cell technology

## Key Facts & Clinical Data

**for all Healthcare Professionals (HCPs)**

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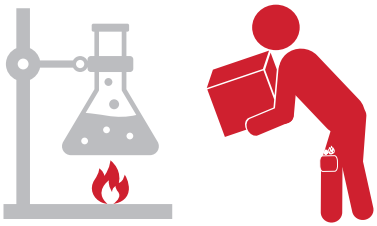
# Contents



# Part 1

## Mechanism of action of ThermaCare®



# 1. Mechanism of Heat Therapy.

The application of superficial heat is a non-pharmacological treatment approach that involves the application of a heat source to the body to raise the local tissue temperature

The application of low-level superficial heat generates many effects:

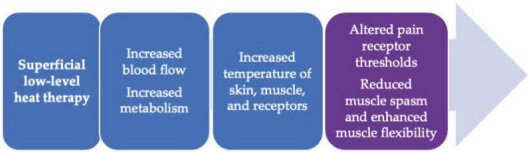
An increase in tissue temperature via the application of heat packs leads to increased metabolism and vasodilation and accelerates the healing processes. Heat-dependent vasodilation increases the blood flow at the site of injury, **facilitating healing through an enhanced supply of nutrients and oxygen, and via the removal of pain-inducing mediators produced as a by-product of tissue damage.** *(Freiwald et al., 2021)*

Continued application of heat increases nitric oxide production from endothelial cells. Nitric oxide, a vasodilator, activates cyclic GMP which increases potassium permeability, reduces Ca++ permeability, and blocks actomyosin ATPase intracellularly. **These activities result in relaxation of smooth muscle.** *(Clinical Evaluation Report v1.1, 2022)*

Applied heat decreases alpha motor activity from the spinal cord, **thereby relaxing muscles**. *(Clinical Evaluation Report v1.1, 2022)*

Continued application of heat activates temperature-sensitive nerve endings (thermoreceptors), which, in turn, **initiate signals that block the processing of pain signals (nociception) in the lumbar dorsal fascia and spinal cord**. *(Freiwald et al., 2021)*

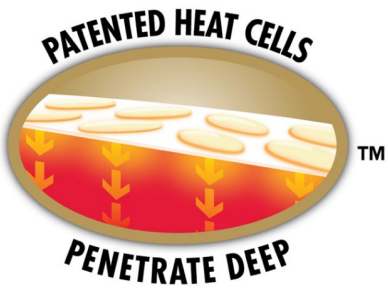
Connective tissues may also change in viscosity and density in response to heat, thereby **improving the range of movement and enhancing tissue extensibility**. (*Freiwald et al., 2021)*



## 2. Mechanism of action of ThermaCare® knee wrap.

ThermaCare® Knee wraps are single-use medical devices intended to provide 8 hours of constant heat for effective, targeted and prolonged relief of knee pain associated with: overexertion, strains and sprains, osteoarthritis, muscle tension, through the application of heat to the skin surface of the affected area, either directly or through clothing. (Clinical Evaluation Report v1.1, 2022)

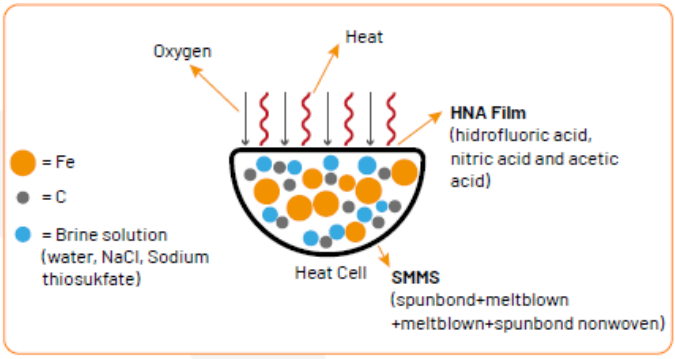
These large single use heat wraps contain 12 air activated heat cells. The cells are contained in a heat pack and surrounded by a laminate of soft non-woven fabric. The knee wrap is applied to the knee with an elastic bandage fastening system. Each heat wrap is packaged in a laminated material pouch. (Technical




The heat cells heat through a controlled, accelerated iron oxidation exothermic reaction as soon as the package is opened and in contact with oxygen.

**Fe + H20 +02 → Fe(0H)3 → Fe304/Fe203 + H20 -> HEAT**

The reaction rate and subsequent heat output (37 to 44 °C) is determined by the oxygen permeation rates of an apertured top sheet. The exothermic reaction ceases when all the free iron is oxidized or when oxygen is excluded by re-wrapping the product. Heat cell manufacturing uses a pre-mix of iron, carbon, and water, with a brine solution of sodium chloride, sodium thiosulfate, and water.


Oxygen
Heat
HNA Film
(hidrofluoric acid,
nitric acid and acetic
acid)
= Fe
= C
= Brine solution
(water, NaCl, Sodium
thiosukfate)
Heat Cell
SMMS
(spunbond+meltblown
+meltblown+spunbond nonwoven)


ThermaCare
HEATWRAPS / FASCE AUTORISCALDANTI / WARMTE KOMPRESSEN /
WÄRMEUMSCHLÄGE / PATCHS AUTO-CHAUFFANTS
FOR KNEE PAIN
PER IL DOLORE AL GINOCCHIO
TEGEN KNIEPIJN
BEI KNIESCHMERZEN
POUR LES DOULEURS AU GENOU
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2
HEATWRAPS
FASCE AUTORISCALDANTI
WARMTE KOMPRESSEN
WÄRMEUMSCHLÄGE
PATCHS AUTO-CHAUFFANTS
CE
1639

# Part 2

## Clinical data of ThermaCare® knee wraps

# 1. Knee Pain

Of all musculoskeletal pain, knee pain is among the most frequently occurring and it can be a source of significant disability, restricting the ability to work or perform activities of daily living. *(Holtedahl R. 2018, Calmbach WL et al., 2003; part I)*

Knee pain affects approximately 25% of adults. The prevalence of knee pain has increased almost 65% over the past 20 years, accounting for nearly 4 million primary care visits annually. *(Bunt et al. 2018)*

The recent data suggest that men younger than 65 years do suffer more often from knee pain than age matched women. This might be a result of sports related injuries and chronic articular changes. Women show an increasing prevalence with advancing age, which correlates with the expected development of chronic diseases of the joint. This leads to the reported higher consultation prevalence for knee pain in women older than 74 years compared to age matched men. *(Frese et al., 2013)*

# 2. Clinical Data of ThermaCare® knee – synopsis of clinical trials and references.

## A) Therapeutic benefits of continuous low-level heat wrap therapy (CLHT) for osteoarthritis (OA) of the knee.

McCarberg W et al. The Journal of Pain 2005;6 (Suppl 1):S53.

**Aim** - This was a randomized, multi-site, single blind, active and placebo-controlled, parallel design study aimed to evaluate the therapeutic effects of ThermaCare® Knee wraps in subjects with osteoarthritis (OA).

**Materials and methods** – Subjects (40-70 yrs.), with radiographic evidence of OA with moderate/greater pain, were randomized to:

**ThermaCare® (n=44; 40°C; 8 hrs.),** oral placebo **(n=21; 2 tablets q.i.d.**), acetaminophen (APAP) **(n=20; 500 mg 2 tabs, q.i.d.)**, ibuprofen **(n=21; 200 mg, 2 tabs. t.i.d.)** or unheated knee wrap (blinds) **(n=4). The treatment lasted for 3 days followed by 2-5 days of follow-up observation.**

Efficacy measurements: pain relief (0-5 scale), knee joint stiffness (NRS-101 scale), walking rate (50 ft distance) on a flat surface, repeated sit to stand time, range of motion assessment (Goniometer), and quality of life (WOMAC). **The primary study endpoint: Day 1-3 mean pain relief score.**

**Results** – **ThermaCare® was significantly effective in relieving symptoms associated with moderate to severe pain from knee OA**. improvements in subjective pain relief ($p<0.05$), objective range of motion improvement ($p<0.05$), and reduced disability ($p=0.05$) vs placebo were demonstrated. **ThermaCare® provided superior pain relief vs APAP** ($p<0.05$) and increased range of motion ($p<0.05$) vs ibuprofen.

## B) Effect of heat and cold on tendon flexibility and force to flex the human knee

*Petrofsky JS et al. Med Sci Monit 2013; 19: 661-667.*

**Aim** - This study was accomplished to quantify the effect of heat and cold on the force needed to flex the knee and laxness of the anterior and posterior cruciate ligaments.

**Materials and methods** - The present study examined 20 male and female subjects, ages 20–30, with no diagnosed tendon or other orthopedic injuries. The subjects were non-athletes and of normal body weight. **There were 4 experiments in the series**: the first was a room temperature series; the second was a series where cold was applied with an ice pack for 20 minutes; in the third, hydrocollator heat packs were applied for 20 minutes; and in the fourth, ThermaCare®® heat wraps were applied for 4 hours on the quadriceps and knee.

**Results** - The results showed that the **anterior and posterior cruciate ligament flexibility increased, and the force needed to move the knee decreased with heat by about 25% compared to cold application. The application of ThermaCare® heat wraps caused an increase in the laxness of the anterior and posterior cruciate ligaments.**

# Part 3

## Clinical data of ThermaCare® in "add on" therapy

## A) ThermaCare® low level heat wrap: faster healing and pain relief during rehabilitation for back, knee and neck injuries.

Petrofsky J et al. World Journal of Preventive Medicine 2015;3 (3):61-72.

**Aim** - In this investigation, Petrofsky and colleagues used continuous low level heat wraps as **an adjunct to physical therapy for back, knee and neck pain** (the most common reported injuries that are treated) to see if the use of continuous low level heat wraps (ThermaCare®) **would reduce pain and increase compliance and healing over 2 weeks of therapy.**

**Materials and methods** - Two hundred and forty-eight subjects participated. There were 3 control groups and 3 investigational groups. Two groups had diagnosed back pain, 2 with knee pain and 2 with neck pain. An initial evaluation and rehabilitation program was established which included a home exercise program. **The heat group was given ThermaCare® which was applied to the sore area 6 hours before the subjects performed their home exercise each day they were not in therapy. A knee wrap was used for the knee**, a neck wrap for the neck studies and a lower back wrap for the back. The control group only participated at the clinic and home therapies. **Subjects were followed for 2 weeks with 2 therapy sessions per week**. Progress was measured by analog visual pain scales, range of motion, strength measurements and mobility questionnaires.

**Results Knee Group** - The change in strength for flexion and extension before and after the 2 weeks of clinical and home therapy for the knee is shown in Figure 25.

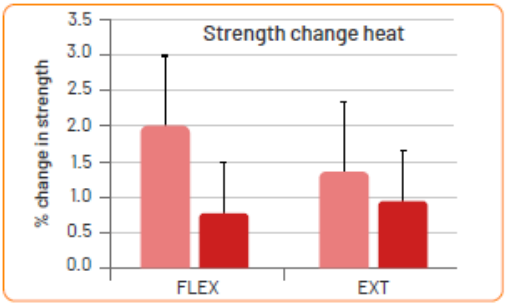


*Figure 25. The change in strength from the beginning to the end of the study for knee flexion and extension in the heat and control group.*

**The increase in strength in the heat group was more than double that of the control group over the 2 weeks and was significantly greater (p<0.01) for flexion but not significant for extension**. Figure 26 shows the change in range of motion of the heat and control groups over the 2-week periods, respectively. As shown in this figure, there was a significant increase in range of motion at the knee without pain in both groups of subjects. **However, the increase in range of motion was significantly greater in the heat group than that measured in the control group over the 2 weeks of therapy and home exercise (p<0.05).**

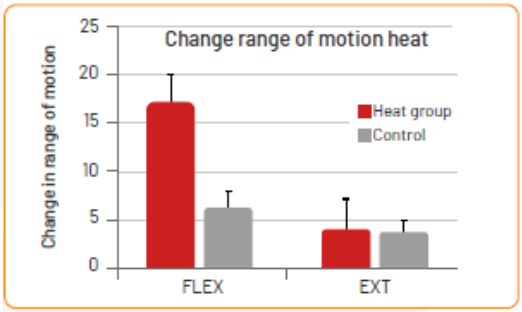


*Figure 26. The change in range of motion from the beginning to the end of the study for knee flexion and extension in the heat and control groups.*

The results of the disability score measurement are shown in Figure 27. Both groups had a significant decrease in disability (increase in the score) associated with the 2 weeks of therapy (p<0.01). However, the reduction in the disability score was greater (p<0.05) at 1 and 2 weeks in the heat at home group. While there was no significant difference in the score in the 2 groups pre-therapy (p>0.05), post-therapy (2 weeks) the heat group showed an improvement of 23 points, the increase in the control group was 11.28 points.

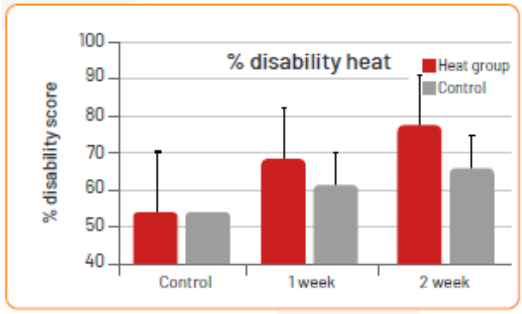


*Figure 27. Disability score in the heat and control groups.*

The pain scale as self-reported by the subjects is shown in Figure 28 and Figure 29 for the heat at home and control groups with knee pain, respectively. As can be seen in Figure 28, **for the heat group, pain was less each day for the 10 days of home measures (p<0.05)**. In addition, heat always caused a significant reduction in knee pain each day before home exercise therapy. Comparing the figures, **there was a greater reduction in pain over the 10 sessions before heat in the heat group (Figure 28) compared to the control (Figure 29) group**. The reduction in pain before heat was significantly greater after the 2nd day of heat in the heat group compared to the control group (p<0.01). **Each day heat was applied, there was a reduction in pain that was significant (p<0.01)**. The compliance for home exercise averaged 79.3+/-7.2% in the heat at home group and 61.2+/-7.2% for the control group. **The increased compliance in the heat at home group was significant (p<0.05).**

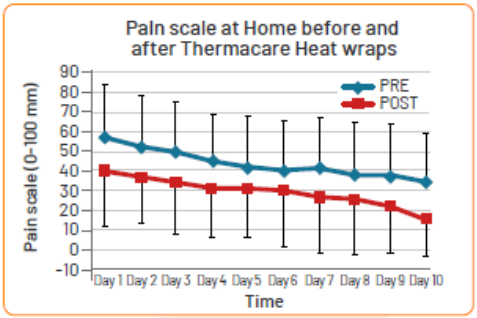


*Figure 28. The pain recorded before and after heat use at home before home exercise.*

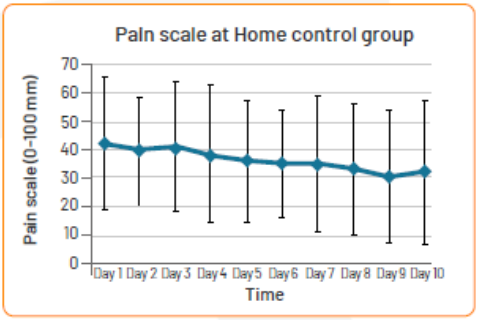


*Figure 29. The pain recorded before home exercise in the control group.*

**Conclusion** - continuous heat wraps are an important adjunct to rehabilitation outpatient therapy, reducing pain and increasing recovery.

## B) Use of low level of continuous heat as an adjunct to physical therapy improves knee pain recovery and the compliance for home exercise in patients with chronic knee pain: a randomized controlled trial

*Petrofsky JS et al. J Strength Cond Res 2016;30(11):3107-3115.*

**Aim** - This study examined if the use of continuous low-level heat (LLCH) wraps at home between physical therapy sessions at a clinic resulted in better therapy outcomes in patients with chronic knee pain.

**Materials and methods** - Fifty individuals with chronic nonspecific knee pain were randomly allocated to 2 groups: the LLCH group and the placebo group. All subjects **underwent 1 hour of conventional physical therapy** (which included thermotherapy, joint mobility, stretching, isometric exercise, and postural exercise) **twice per week for 2 weeks** at the outpatient clinic and they were asked to accomplish 1 hour of therapeutic exercise (including stretching and exercise) at home each day between sessions. **The LLCH group applied LLCH knee wraps for 6 hours at home before home exercise, while placebo group took a placebo ibuprofen before starting home exercis**e. Before, during, and after intervention, pain intensity, active range of motion of the knee (AROM), knee strength, and home exercise compliance were measured.

**Results** - Both groups had a significant decrease in disability (increase in the score) associated with the 2 weeks of therapy ($p<0.001$). However, **the reduction in the disability score was greater ($p = 0.01$) in the LLCH group**. There was no significant difference in the score in both groups pre-therapy ($p = 0.968$), **whereas post-intervention (2 weeks) the LLCH group showed a significant improvement of 23 points and the increase in the placebo group was 11.28 points ($p = 0.010$; Figure 30).**

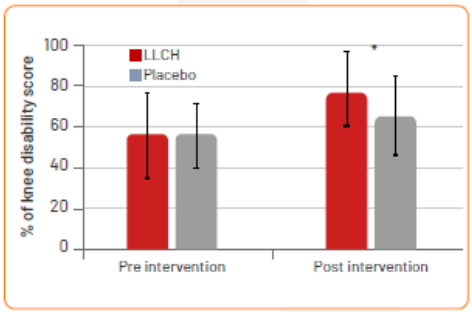


*Figure 30. Disability score in pre- and post-intervention in the LLCH and placebo groups.*

**Significant difference between the LLCH and placebo groups.*

As can be seen in Figure 31, for the **LLCH group, subjective pain was less each day for the 10 days of home measures (p≤0.05).**

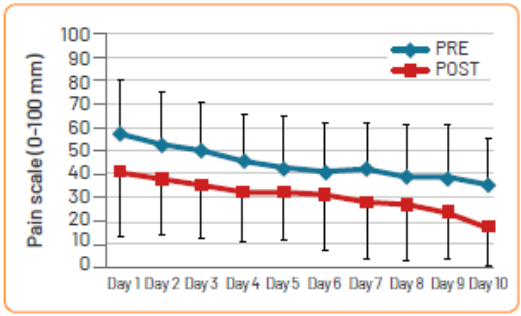


*Figure 31. Subject self-reported pain scale between before and after LLCH warp applied over time in the LLCH group.*

Both groups showed significant increase of strength (Figure 32) between pre- and post-intervention; **the increase in strength in the LLCH group was more than double (248.2%) that of the placebo group over the 2 weeks for flexion (p<0.001)** but not significant for extension (p =0.272). **Active range of motion in the knee joint without pain significantly increased in both groups pre and post-intervention (p<0.01). However, the increase in AROM in the knee joint was significantly greater in the LLCH group than that measured in the placebo group over the 2 weeks for flexion but not significant for the extension (p = 0.021 and p = 0.905, respectively**; Figure 33).

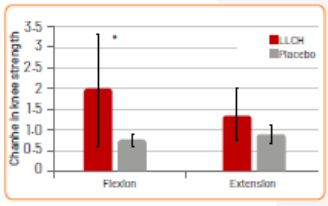


*Figure 32. The change in strength between pre- and postintervention for knee flexion and extension.*
**Significant difference between the LLCH and placebo groups.*

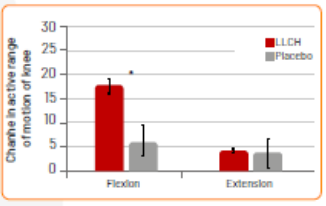


*Figure 33. The change in active range of motion between pre- and postintervention for knee flexion and extension.*
**Significant difference between the LLCH and placebo groups.*

**Conclusion - These results indicated that the use of LLCH as an adjunct to conventional physical therapy for chronic knee pain significantly improved pain attenuation and recovery of strength and movement in patients with chronic knee pain.**

For the coach or trainer, this study suggests a different approach. In addition to using whirlpool and other heat modalities after exercise, recovery from injuries and overexertion of muscles may be faster if 8-hour continuous low level heat wraps are used at home. This will reduce pain and increase healing and maintain flexibility in soft tissue to optimize return to activity.

ThermaCare HEATWRAPS

## Contact

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# ThermaCare® clinically proven heat wrap family

ThermaCare® knee


ThermaCare® heat wraps for lower back and hip.


ThermaCare® heat wraps for neck, shoulder and wrist.

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