



Treatment of Osteoarthritis

Non-drug, non-invasive treatment for osteoarthritis of the knee

Until recently physicians have had limited choices in treating osteoarthritis of the knee. A great many patients remain symptomatic despite the best available drug therapy. Others are not yet ready or willing to undergo surgery.

Now you can treat osteoarthritis of the knee without drugs or surgery. The BioniCare® Knee Device is a pulsed electrical stimulation device with a targeted indication:

An adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee, and for the overall improvement of the knee as assessed by the physician's global evaluation (clinical studies).

The Knee Device home-based treatments have many patient benefits:

- ❖ Targeted relief of pain and associated symptoms
- ❖ Durable relief of pain
- ❖ Substantial improvement over baseline NSAID therapy
- ❖ Excellent safety profile
- ❖ High patient acceptability
- ❖ Easy for patients to use

45% of patients tested demonstrated improvement in range of motion by ≥5 degrees of flexion as compared with 18% of control group.

Rigorous clinical studies show that the Knee Device helps relieve pain and associated symptoms of osteoarthritis of the knee¹. In the multicenter, prospective, parallel, double-blind, randomized, placebo-controlled clinical study, both physicians and patients rated the Knee Device superior to placebo at the end of four weeks. Based on physicians' global evaluations, time-compliant patients exhibited 130 percent more improvement with active treatment compared with NSAIDs and/or analgesics and inactive treatment.

The Knee Device's pulsed electrical stimulation bears no resemblance to transcutaneous electrical nerve stimulation (TENS). The wave form, frequency, amplitude and mechanism of action are totally different.

RS Medical is the exclusive distributor of the Knee Device to orthopedic, pain management and physical medicine and rehabilitation physicians. The Knee Device is a product of BioniCare Medical Technologies, Inc., which distributes the product to rheumatologists and other physicians.



Treatments can be taken throughout the day or through the night, allowing patients to receive the recommended daily treatment time of 8 ±2 hours.

¹ Zizic, T.M. et. al., J. Rheumatol 1995; 22:1757-1761



Knee Device Features

Benefits

| | |
|---|---|
| ❑ Knee Device treats osteoarthritis of the knee | ❑ The first and only non-drug, non-invasive system for adjunctive management of pain due to osteoarthritis of the knee |
| ❑ Targeted indication | ❑ An adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee, and for the overall improvement of the knee as assessed by the physician's global evaluation (clinical studies) |
| ❑ Pulsed electrical stimulation | ❑ Unique waveform specifically used for treatment of osteoarthritis of the knee |
| ❑ Targeted relief of pain and associated symptoms | ❑ Patients noted relief of pain and improvement of associated arthritis symptoms. Level of pain relief increased through the four-week double blind, placebo controlled study. |
| ❑ Improvement over baseline NSAID therapy | ❑ Patients demonstrated statistically significant improvement in self-assessed parameters as well as physician-assessment parameters while being maintained on NSAID and/or analgesic therapy |
| ❑ Fast onset of action | ❑ Many patients noted relief of pain within four weeks of therapy as an initial response |
| ❑ Excellent safety profile | ❑ The only side effect in some patients is a transient rash due to the electrode gel |
| ❑ Applicator | ❑ Comfortable garment-like applicator accurately positions electrode pads on the knee and thigh for optimum treatment |
| | ❑ Soft fabric wrap with Velcro® closures is easy for patients to use |
| | ❑ High patient acceptance |
| | ❑ Flexible and lightweight enough to be worn under clothing and during sleep |
| ❑ Signal Generator (stimulator) | ❑ Lightweight device weighs approximately 4 oz.; powered by 9-volt rechargeable battery |
| ❑ Smart Device | ❑ Informs user of conditions under which the stimulator should be turned off |
| | ❑ Identifies open lead condition |
| | ❑ Determines when user should return device for certain servicing, repair or replacement |
| | ❑ Records and stores patient usage information |
| ❑ LCD display | ❑ Informative for the user to read the following: <ul style="list-style-type: none">• Operational status of Channel 1 and Channel 2• Treatment output in increments of one tenth of a volt in the range of 0.0 to 12.0 volts• Usage timer shows treatment time in hours and minutes• Low battery status• Software version and serial number |
| ❑ Physical characteristics | |
| ❑ Frequency | ❑ 100+/- 5 Hz, fixed, digital |
| ❑ Waveform | ❑ Negative monophasic spike-shaped pulse |
| | ❑ Analog generated |
| ❑ Voltage Output Range | ❑ 0-12 volts peak – Channel 1/Channel 2, digital |
| ❑ Voltage Pulse Width | ❑ 1.8 ms @ 10% of peak |
| | ❑ 0.64 ms @ 50% of peak |
| ❑ Current Output Range | ❑ 0-24 mA peak @ 500 ohms resistive load |
| | ❑ 0.2 mA average @ 500 ohms resistive load |
| ❑ Maximum Output Charge | ❑ 20 µC into a load of 500 ohms |
| ❑ Power source | ❑ 9 volt battery, Ref. ANSI 1604 A or IEC 6LR61 |
| ❑ Weight | ❑ 4.8 ounces, 136 grams with battery |
| | ❑ 3.2 ounces, 90.8 grams without battery |
| ❑ Electrical Protection Rating | ❑ Type BF Equipment, Battery Operated |

WARNING: FEDERAL LAW RESTRICTS THE SALE OF THIS DEVICE ON THE ORDER OF A LICENSED DOCTOR OR PHYSICIAN, UNDER THE LAWS OF THE STATE WHERE LICENSED TO PRACTICE. **Indications:** The BionCare Knee Device (Stimulator System Model BIO-1000) is indicated for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by the physician's global evaluation (see clinical studies). **Contraindications:** Do not use the BionCare Knee Device for any contact element (electrode) placement that applies current to carotid sinus (neck) region. Do not use the BionCare Knee Device on patients who have a demand-type cardiac pacemaker. Do not use the BionCare Knee Device for any contact element (electrode) placement that causes current to flow transcranially (through the head). Do not use the BionCare Knee Device whenever pain syndromes are undiagnosed until etiology is established. **Warnings:** The safety of the BionCare Knee Device for use during pregnancy or birth has not been established. The BionCare Knee Device is not effective for pain of central origin (this includes headache). The BionCare Knee Device is a prescription device that should be used only under the continued supervision of a physician. The BionCare Knee Device has no curative value. The user must keep the BionCare Knee Device out of the reach of children. Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when the BionCare Knee Device is in use. **Precautions:** Isolated cases of skin irritation may occur at the site of contact element (electrode) placement following long-term application. Effectiveness is highly dependent upon patient selection by a person qualified in the management of arthritis. **Adverse Reactions:** Skin irritation or electrode burns are potential adverse reactions. Patients with skin irritation/reactions should be monitored.

BionCare Medical Technologies, Inc., is licensed to use the trademark BionCare®, which is a registered trademark of Murray Electronics Associates Limited Partnership. BIO-1000™ is a trademark and The NON-DRUG, NON-INVASIVE ADVANTAGE™ is a service mark of BionCare Medical Technologies, Inc. The BionCare® Knee Device employs the BionCare Model BIO-1000 System. Velcro is a registered trademark of Velcro Industries B.V.

Copyright © 2005 RS Medical BF01 D 01/09/06

RS Medical