AposTherapy®

THE POWER TO MOVE

PATIENT USER GUIDE

1 General Information

It is important that you read this information completely before using your AposTherapy® device. Prior to receiving the AposTherapy® device, you must have had a consultation with a trained practitioner who conducted a walking analysis and calibrated the device to suit your unique needs. It is important to attend all follow-up appointments to ensure that a trained practitioner can monitor your progress and re-calibrate the device as necessary to ensure you meet your treatment goals.

The discussion provided below in Section 4 describes results from a clinical study conducted independently using the AposTherapy® device. This information will help you understand that use of this device may help relieve joint pain and assist in retraining your muscles to adopt a corrected and less painful walking style in an effort to help relieve symptoms of knee OA pain.

2 Indications for Use

The AposTherapy® System is intended to be used by trained professionals for adjusting the amount of weight/force(s) that is being applied to a lower limb, encouraging proper load distribution of the leg and reducing knee pain from knee osteoarthritis, as well as improving function. The System allows a trained professional to adjust the amount of weight/force applied to the plantar surface of the foot for the proper calibration of the device.

3 Description of the AposTherapy® Device

The AposTherapy® System is a corrective shoe that was calibrated specifically for you. The device is intended to reduce knee OA pain and improve function by re-establishing normal symmetrical walking. A trained practitioner analyzed your walk and assessed your pain, function, stability, comfort and quality of life to calibrate the device specific to your needs. As you walk with the device, the shoes are designed to reduce pressure and strain on painful areas and ultimately retrain your muscles to adopt a correct walking pattern.

The device consists of pods (pertupods) attached to the heel and forefoot, the primary weight-bearing areas, of the shoe (shown in Figure 1 below).

The pertupods create a mild, comfortable instability to help your muscles adopt a correct walking pattern as you complete your normal daily routine. During follow up appointments, your progress will be monitored by a trained practitioner who will evaluate your walk, quality of life and any pain you experience while using the corrective shoe. The practitioner will use standard off-the-shelf gait analysis software to evaluate your gait for velocity, single limb support and step length to help in calibration of the device and monitor for changes over time. The device will be adjusted as necessary during your personalized therapy program to ensure that your treatment goals are achieved.

Figure 1
Pertupods and AposTherapy® Device

4 Risks and Benefits

A clinical trial studied the effectiveness of the AposTherapy® System in 220 patients suffering from knee osteoarthritis (OA). The study was designed to show a statistically significant difference in pain scores (measured using validated pain scales) between AposTherapy® device users and control subjects after 24 weeks.

Study patients were randomly assigned to either a control group or to the AposTherapy® device group. Device group participants received the AposTherapy® corrective shoe with the pertupods attached at the heel and forefoot. The control group received a device that had the same appearance as the AposTherapy® corrective shoe, but without the pertupods on the sole of the foot.

Subjects who received the AposTherapy® device and control subjects were very similar in age, gender and had similar levels of pain at the start of the study.

Study subjects who used the AposTherapy® device demonstrated a statistically significant decrease in pain compared with the control group after 24 weeks of treatment. Additionally, patients using the AposTherapy® device showed improvements in stiffness and physical function at 24 weeks. Ultimately, the results of the study demonstrate that the AposTherapy® System helps to improve function and reduces knee pain due to OA.

Although 3 serious adverse events occurred in patients who used the AposTherapy® device, none of these were treatment related and were likely due to chance. There were a total of 30 adverse events in 23 patients (20.7%) who used the AposTherapy® device. Most of these adverse events were mild.

5 Instructions for Using the AposTherapy® Device

Wear your AposTherapy® device during indoor daily activities at home or work including sitting (resting), standing and walking. Socks should be worn while using device. The recommended time to spend wearing the AposTherapy® device and the recommended time to spend walking or standing in the AposTherapy® device is provided in the Table 1 below:

Week #	Time Spent Wearing the AposTherapy® Device per day	Time Spent Walking or Standing in the AposTherapy® Device per day
1	30 minutes	6 minutes
2	40 minutes	8 minutes
3	50 minutes	10 minutes
4	60 minutes	12 minutes

Depending on your evaluation, the practitioner may recommend a different schedule for wear time. It is important to follow the schedule prescribed by your practitioner.

It is important to rest for short periods during indoor activities and not to walk continuously. When wearing the AposTherapy® device, you should only stand and/or walk 20% of the total wear time.

Special Instructions

During or after use of the device you may experience certain physical symptoms similar to those experienced when beginning any new type of physical activity, such as slight muscle soreness.

As your body gets accustomed to the treatment, these symptoms should get better. If the symptoms persist, contact your AposTherapy® trained healthcare practitioner. In case of emergency please call 911.

Do not attempt to increase the period of time with your biomechanical device if you are experiencing muscle cramps, any kind of pain or inconvenience. In the event of unusual pain during or after the treatment, discontinue use and contact the AposTherapy® practitioner.

6 Warnings and Precautions Warnings

Do not use the device before a specially trained AposTherapist has properly adjusted it. Use of the device should be according to the instructions of the AposTherapist.

Only use the device in your existing environment during your daily routine activities. Do not use the device during enhanced or irregular activities or outside your natural environment, unless specifically instructed otherwise by an AposTherapist.

Do not run or play sports that involve constant running and/or fast changes of direction (e.g. basketball or tennis) with the device.

Do not drive or operate heavy machinery while wearing the device.

Users with disabilities (e.g., neurological disorders, osteoporosis), which may cause falling, or users for whom falling may be extremely dangerous, must take precaution to ensure their safety when using the device (e.g., supervision, walking by a wall/banister).

Do not use the device if you suspect that it is faulty or has been damaged. Do not try to repair the device on your own and do not wear the damaged shoes.

Report any change in your medical condition that is related to the treatment (e.g., any change of your stability) to your AposTherapist.

Do not give, sell, rent or allow the use of your device to or by another person.

Precautions

Using the device on dangerous surfaces, such as wet or slippery surfaces (polished floors, ice, snow etc.), gravel, climbing up or down stairs (or escalators), near sharp objects, on carpets or rugs (which are not fitted wall to wall), or any other day to day environments that may be dangerous, may result in falling or injury.

Prior to each use of the device you may want to re-check and confirm that parts are properly attached to the sole of the shoe.

Should any problem occur as a result of the device, you are advised to discontinue use immediately and contact your AposTherapy® practitioner.

7 Contact Information

If you experience any medical problems or mechanical problems with the AposTherapy® device or have questions regarding the use of your AposTherapy® device, please contact your AposTherapy® provider.

If you have any serious adverse events with the AposTherapy® device, please contact AposTherapy® at the number provided below.

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