



PATIENT USER GUIDE



AposHealth[®]
(previously AposTherapy[™])

1

General Information

It is important that you read this information completely before using your AposHealth® device. Prior to receiving the AposHealth® device, you must have had a consultation with a trained clinician 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 clinician 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 AposHealth® 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.



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Indications for Use

The AposHealth® System is intended to be used by trained professionals for adjusting the distribution of weight/force 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 distribution of weight/force applied to the plantar surface of the foot for the proper calibration of the device.



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Description of the AposHealth® Device

The AposHealth® 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 clinician analysed 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 clinician who will evaluate your walk, quality of life and any pain you experience while using the corrective shoe. The clinician 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 personalised therapy programme to optimise your treatment results.



Figure 1
Pertupods and
AposHealth® Device

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Risks and Benefits

A clinical trial studied the effectiveness of the AposHealth[®] 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 AposHealth[®] device users and control subjects after 24 weeks.

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

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

Although 3 serious adverse events occurred in patients who used the AposHealth[®] 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 AposHealth[®] device. Most of these adverse events were mild.

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Instructions for Using the AposHealth® Device

Wear your AposHealth® 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 AposHealth® device and the recommended time to spend walking or standing in the AposHealth® device is provided in the Table 1 below:

Week #	Time Spent Wearing the AposHealth® Device per day	Time Spent Walking or Standing in the AposHealth® 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 clinician may recommend a different schedule for wear time. It is important to follow the schedule prescribed by your clinician.

It is important to rest for short periods during indoor activities and not to walk continuously. When wearing the AposHealth® 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 AposHealth® trained healthcare clinician. In case of emergency please call 999.

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 AposHealth® clinician.

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Warnings and Precautions

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 AposHealth® clinician.

7 Contact Information

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

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

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