THUASNE®

SpryStep® Agilik™ KAFO

Custom Microprocessor Powered KAFO

Early clinical results suggest that the Agilik™ can:

- improve knee extension and flexion
- improve step length
- improve walking endurance and speed

BionicPower
Stand Taller, Walk Stronger™

The SpryStep® Agilik™ KAFO

Thuasne® x Bionic Power's smart orthosis is no ordinary KAFO. It is a gait state driven, microprocessor-controlled, powered mobility device. It provides the wearer with both resistance and assistance to enhance muscle performance at all stages of gait. The **SpryStep® Agilik™ KAFO** lifts patients out of crouch, assisting with knee flexion and extension. Patients with flexed-knee gait or stiff knee gait from CP, spina bifida, post-stroke, and other conditions are all potential candidates for the smart orthosis.

This proprietary technology has been developed through a Cooperative Research and Development Agreement with the National Institutes of Health (NIH, Bethesda, USA). The robotic hinge can be easily integrated into a custom-made KAFO by a certified orthotist.

1. Thigh Shell
2. Battery/Data Plug
3. Actuator
4. LED Indicator/Pushbutton
5. Condyle Cover
6. Aluminum Upright
7. Foot Sensor Cable
8. Footbed Insert
9. Calf Shell
10. Cable Guide
11. Drive Arm
12. Battery
13. Power Button

ACTIVELY CHANGES POSTURE WITHOUT FORCING PRE
DETERMINED TRAJECTORY
NON-INVASIVE MOBILITY SOLUTION
CUSTOMIZABLE FOR EACH PATIENT'S CHANGING CONDITION AND THEIR GROWTH
SMART SYSTEM: REAL-TIME GAIT PHASE DETECTION DRIVES ASSISTANCE FOR FLEXION AND EXTENSION

Thuasne® trains a member of the patient's clinical team (normally either their orthotist or physical therapist) to tune the **SpryStep® Agilik™ KAFO** using our custom Agilik™ App, and we are available during business hours to help with any future tuning sessions. The App controls the delivery of assistance and resistance during specific phases of the wearer's gait, improving their mobility and quality of life. The app will record session data and allow monitoring of patient progress.

The test drive

Gait Biomechanics
- Increase step length
- Improve knee extension during stance and swing gait phases
- Improve knee flexion during swing phase

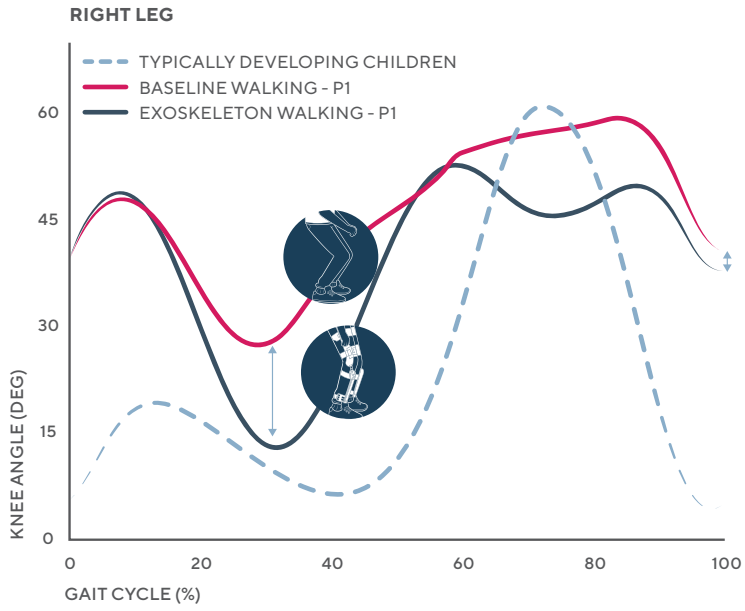
Ambulation Abilities
- Increase walking distance and speed
- Increase overall fitness
- Reduce energy costs
- Aid with balance and coordination
- Mitigate necessity of wheelchair use

Long-term Patient Implications
- May reduce fatigue and joint deterioration
- May reduce progression of muscle contractures
- May increase patient time in physical therapy

The model above is wearing the Test Drive, an adjustable test unit for patient assessments and demonstrations of the **SpryStep® Agilik™ KAFO**. Super lightweight, the Test Drive comes with multiple sizes of thigh cuffs and footplates to fit a range of 4'2" to 6'1" (127-185cm) tall. (Arrangements can be made for shorter or taller ranges.) If you plan to have numerous patients try out the Agilik™, this is the way to do it.

"Evaluating an Extension Assist Knee Ankle Foot Orthosis to Improve Gait in Children with Movement Disorder"

National Institutes of Health, Dr. Thomas Bulea



Preliminary results indicate:

- Crouch is improved in children with spastic diplegia (CP) and spina bifida.
- Interleaved assistance and resistance is well tolerated and shows immediate benefits in EMG*.
- Researchers are describing the Agilik™ as "robust, lightweight, power efficient and well tolerated."
- 100% of patients who have completed trial met primary endpoints (>10° of crouch improvement on one leg).

**EMG = Elektromyografi*

Clinical trials

Clinical trials utilizing the Agilik™ are ongoing at the NIH Clinical Center in Bethesda, USA and at IRCCS Medea in Lombardy, Italy. They are actively looking for volunteers to enroll. If you believe your patient may be a good candidate, please review the study description and eligibility information on our website or contact the institutions directly (info below).

NIH Clinical Center

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Is the SpryStep® Agilik™ KAFO right for my patient?

Indication for Use

The **SpryStep® Agilik™ KAFO** is intended for orthotic fittings of the lower limbs.
Complete indications available on the IFU.

Intended User Profile

The **SpryStep® Agilik™ KAFO** is intended for patients with lower extremity weakness resulting in gait pathology such as, but not limited to crouch gait from a diagnosis of cerebral palsy, muscular dystrophy, spina bifida, incomplete spinal cord injury or stroke hemiparesis. It is intended for patients aged 5 years and above, who can understand and follow simple directions based on a parental report and physician observations during recent history and physical examination, and able to walk at least 3m (10 feet) without stopping with or without a walking aid. It is the responsibility of the therapist/clinician to determine if the patient is physically and cognitively able to use and understand the product.

Contraindications

- Children below the age of 5 years, body weight below 20 Kg or body weight above 125 kg / 300 lbs
- Orthoprosthesis • Moderate to severe spasticity (as determined by the clinician)
- Flexion contracture of more than 20° in the knee and/or hip joint

Ordering the Agilik™ or SpryStep® Agilik™ KAFO

If you feel the **Agilik™ or SpryStep® Agilik™ KAFO** would be the correct device for your patient, please contact us for more information:

agilik@thuasne.com

Please note that the **Agilik™** can be ordered either on its own or in combination with the **SpryStep® KAFO.**

Availability of this product may vary from one country or region to another, depending on specific local regulatory approval or clearance requirements for sale in that country or region.
The medical device referenced in this document is a custom-made device manufactured in accordance with the applicable requirements of the European Regulation (EU) 2017/745 on medical devices. As a custom-made device, it is not subject to CE marking and is accompanied by an individual Declaration of Conformity for each KAFO produced.
For further details on regulatory compliance, please contact Thuasne®.
The full list of medical indications and contraindications is available in the instructions for use.
Please carefully read the instructions for use, as well as the indications and contraindications associated with the product.

WINGS
FOR YOUR HEALTH

EC REP For Agilik™:
Bionic Power Inc.
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BionicPower

Bionic Power is registered with Health Canada, the US FDA and the EU as a Class 1 Medical Device Manufacturer. The Agilik™ is registered as a Class 1 medical device in Canada, the US and the European Economic Area.

intertek

Thuasne LLC is the assembler of SpryStep® Agilik™ KAFO

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