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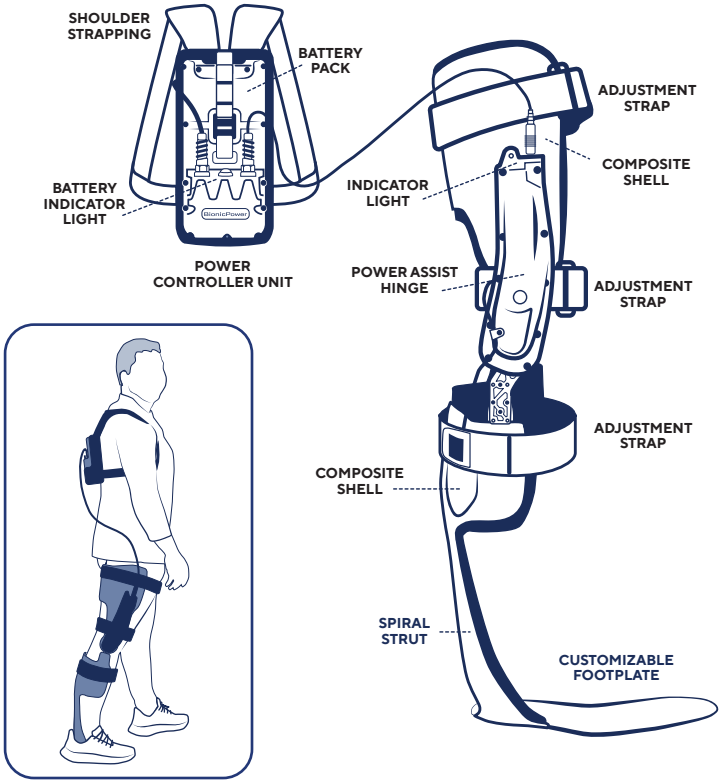
SpryStep® Agilik™ KAFO

CUSTOM FABRICATED Dynamic Knee-Ankle-Foot-Orthosis (KAFO)
with POWER ASSIST/RESIST Motion.

BRACE COMPONENTS



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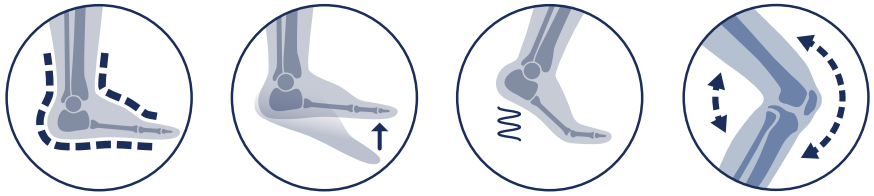
THUASNE

SpryStep® Agilik™ KAFO

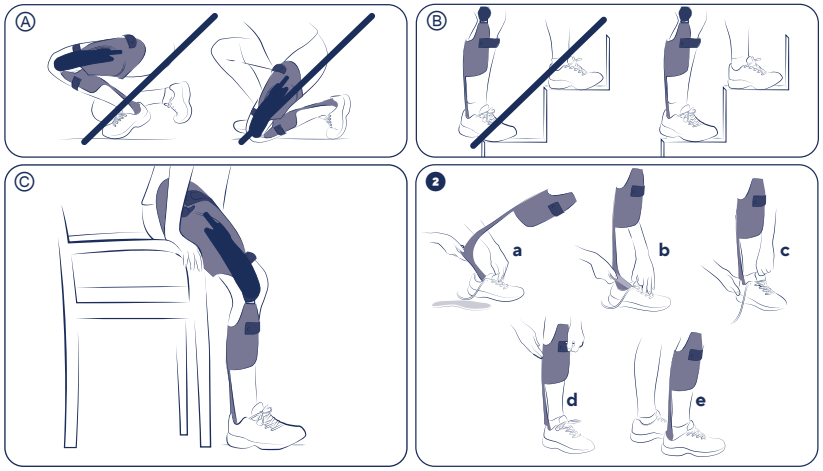
Instructions for use
DYNAMIC KNEE-ANKLE-FOOT-ORTHOSIS (KAFO) WITH POWER ASSIST/RESIST MOTION

Custom-made device.
Custom fabricated orthosis, made from a positive model of the patient's limb.



Stabilisation | Biomechanical Correction | Energy Return | Power Assist/Resist

MD



Description/Destination
The device is intended only for the treatment of the indications listed.
This device is a dynamic knee ankle-foot orthosis (KAFO) that supports and/or stabilizes the foot, ankle and knee while walking.
The instructions for operating the Agilik™ system are provided in a separate Instructions for Use document, which is supplied with the SpryStep® Agilik™ KAFO.

Composition
Rigid components: carbon fibre - glass fibre - high density polyethylene - ethylene propylene diene monomer - stainless steel.
Textile components: polyamide - elastane - polyurethane - ethylene vinyl acetate.

Properties/Mode of action
The device is composed of two parts (KAFO and Agilik™) already assembled.
The KAFO, made of composite materials and polyamide, is positioned under the foot and along the leg to provide stabilisation, biomechanical correction and energy return.
The Agilik™ is a powered orthosis system that can assist or resist motion independently in each gait phase.
It can be used as a pair (bilateral) or as a single joint orthosis (unilateral) on one or both legs, according to the configuration.
The device can apply up to 12 Nm across the knee joint in the direction of either flexion or extension.
The instructions for operating the Agilik™ system are provided in a separate Instructions for Use document, which is supplied with the SpryStep® Agilik™ KAFO.

Indications
The product 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, or incomplete spinal cord injury or post stroke hemiparesis.

Contraindications
Do not use the product if the diagnosis has not been confirmed.
Do not apply the product in direct contact with broken skin.
Do not use in the event of known allergy to any of the components.
Do not use for patients weighing < 20 kg / 44 lbs and > 135 kg / 300 lbs.
Open ulcers of the foot, ankle or lower leg.
Severe loss of sensation in the lower limb.
Running/jumping/high impact activities on lower limb.
Orthoprosthesis.
Moderate to severe foot deformities (including fixed ankle varus or valgus conditions).
Flexion contracture of more than 20° in the knee and/or hip joint.
Unability to initiate swing phase.
Children below the age of 5 years.
Moderate to severe spasticity of the foot and ankle (as determined by the clinician).

Precautions
Verify the product's integrity before every use.
Verify that the battery is providing power by ensuring the indicator light on the battery pack is green, the cable is connected to the Agilik™, and that the indicator light on the Agilik™ is orange Ⓓ.
Do not use the product if it is damaged.
The initial fitting and all following adjustment must be done by a healthcare professional.
Strictly comply with your healthcare professional's prescription and recommendations for use.
Check the condition of the affected limb and the state of the skin daily (with particular attention for patients with sensory deficit).
In the event of discomfort, significant hindrance, pain, variation in limb volume, abnormal sensations or change in color of the extremities, remove the device and consult a healthcare professional. For hygiene, security and performance reasons, do not re-use the product for another patient.
Do not use the device in case of application of certain products on the skin (creams, ointments, oils, gels, patches...).
Do not wear the product in a medical imaging machine.
Driving while the device is connected to the battery is not permitted.
The ability to drive a vehicle with the device must be assessed by a healthcare professional and according to local regulations.
The systematic use of a sock is recommended when wearing the device.
It is recommended to adequately tighten the device to achieve a good fit on the limb without restricting blood circulation.
Do not expose the product to extreme temperatures (below 5°C, above 30°C).
In the event of any modification in the product's performance, remove it and consult a healthcare professional.
Do not kneel or squat with the device. Ⓐ
Avoid excessive pressure on the forefoot area:
-Always place the entire foot on any step or uneven surface. Ⓑ
-Transition sitting/standing position (chair, toilet, car, ...): put the foot flat on the ground before moving to standing. Use any fixed support (armrests, support bar...) to limit the overload of the foot lifter. Ⓒ
In pediatric applications:
It is recommended that an adult supervises the application and use of the product by a child.
Regularly check the patient's growth (change in shoe size, floor-to-calf height...).
It is recommended to renew the device (bigger size) if the child's shoe size (foot length) evolves by more than 2 sizes.

Undesirable side-effects
This device can cause skin reactions (redness, itching, burns, blisters,etc.) or wounds of various degrees of severity.
Possible risk of venous thrombosis.
Any serious incidents related to the product should be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is resident.

Instructions for use/Application
The device must be worn in shoes with the following features:
-Stiff posterior heel cup sufficiently high to fully encapsulate the foot and the orthosis.
-Shoe closure system: self-fastening tabs or laces.
Trainers or athletic shoes are the best type of shoes to use with the device.
Preparation of the orthosis performed by the healthcare professional:
Make sure that the patient's footwear complies with the recommendations.
The healthcare professional must supervise the fitting of the product and the specific walking conditions of the patient when using the device for the first time.

Fitting the orthosis:
Have the patient sit on the edge of a chair, and have the patient bend his/her knee to a position of approximately 30-60° of flexion.
Take the inlay out of the shoe, if removable.
Place the device into the shoe ❷a.
Ensure the device's foot plate sits flat on the sole of the shoe and that the posterior heel cup of the shoe is not distorted.
Replace the removable inner sole on top of the device's footplate, unless it makes the shoe too tight ❷b.
If there is no removable inner sole then disregard this step.
Loosen the shoe laces and slide the foot inside the shoe ❷c.
You may use a shoe horn if required.
Check the fit:
Secure the strap(s) ❷d:
Feed the strap(s) through the corresponding buckle(s).
If a strap is too long, remove the self-fastening tab, trim the strap with scissors and reposition the self-fastening tab.
Tighten the strap(s).
Ensure laces or other tightening mechanisms are firmly fastened. ❷e
Ensure comfort of foot and leg, with no impingements, prior to use.
After securing the orthosis to the leg, refer to the Agilik™ Joint Instructions for Use to activate the joint prior to walking.
It may take several weeks to feel comfortable with the brace on your leg.
Depending on country of sale, additional accessories/spare parts could be available.
Fitting the spare parts (by a healthcare professional or by the patient):
The spare parts kit contains the following components: foam pad(s), strap(s), self-fastening tab(s).
Remove the textile parts and the self-fastening tab(s) (if damaged) sticked on the rigid part.
Clean the area where the self-fastening tabs were applied.
Replace the self-fastening tab by new one(s) and then position the new foam pad.
If needed, shorten the replacement strap(s): remove the self-fastening tab, trim the strap(s) and replace the tab.
Position the buckle of the strap on the rigid part and follow the fitting instructions.

Alterations that can be done to the brace during fitting:
- Femoral shell: if needed a portion of the thigh shell can be removed to improve patient comfort or ease of use.
- Do not remove material within 2 cm / 3/4" of the knee joint insert.
- Make sure the surface of the shell is sufficient to support the force pattern of the brace and contain soft tissue without discomfort.
- Tibial shell: some minimal trimming of the tibial shell can be done (max. 2 cm / 3/4").

Do not remove material within 2 cm / 3/4" of the knee joint insert & the strut insertion.

Footplate:
- Trimming of the footplate to facilitate shoe fitting.
- Adding posting intrinsically or extrinsically to fine tune the alignment or accommodate for plantarflexion contracture.

The following actions would waive the warranty:
- Trimming in or near (< 2 cm / 3/4") the strut.
- Over trimming of the femoral or tibial shell.
- Trimming the footplate below the patient foot length.
- Any attempt to heat-mold the composites materials.

Care/Maintenance
Cleaning
Product can be washed in accordance with the instructions shown on this leaflet and on the label. If the device comes into contact with water, dry the textile part and wipe the rigid part well with a dry cloth. If the device is exposed to seawater or chlorinated water, make sure to rinse it in clear water and dry it. Rigid components: wash the rigid part with a moist cloth.
Textile components: the soft part can be fully removed for washing.
Replace in the original location before next use. Machine washable at 30 °C (delicate cycle). Remove the self-fastening tabs before washing. Do not use detergents, fabric softeners or aggressive products (products containing chlorine). Do not dry clean. Do not tumble-dry. Do not iron. Squeeze out excess water. Dry flat, away from any direct heat source (radiator, sun, etc.). After prolonged use, if the fibers on your strap do not adhere as well to the self-fastening tab, cut the strap shorter so the self-fastening tab adheres to a section of the strap that has fresher fibers. If this is not possible, you should contact the medical provider who fit your brace.
Care
Maintenance performed by a healthcare professional must be scheduled every 6 months for the KAFO, and every 12 months for the Agilik™ component.
During this maintenance, particular attention must be given to the knee hinges wear pattern. If the healthcare professional notices any kind of early wear on the hinges, he must notify Thuasne and provide all required information (pictures etc.) to evaluate whether or not a repair is required.
Hinges: The hinges on the brace are pre-lubricated in the factory. If sand, dirt or water gets inside the hinges, they may require lubricating again. If you notice the hinges not gliding smoothly, a few drops of a synthetic lubricant can be applied. Wipe off any excess lubricant before wearing the brace to prevent stains on clothing.

Storage
Store at room temperature, preferably in the original packaging.

Disposal
Dispose of in accordance with local regulations.
Keep these instructions for use.

COMMERCIAL WARRANTY AGREEMENT AND WARRANTY LIMITATIONS
Thuasne offers a free, limited commercial warranty to the user, in the territory where the device was purchased, against defects in manufacturing and workmanship for a period of:
- six months for the textile components;
- two years for the rigid components;
- two years for the Agilik™ component.

The limited warranty is effective from the date of purchase of the product by the end-user.
The above may vary by market, consult your local representative for details.
The limited commercial warranty does not apply to any defects in manufacturing and workmanship in case of:
- misuse of the product or any damage occurred by a usage outside the normal and intended use of the product as mentioned in the instructions for use,
- damages occurred while user is squatting or kneeling,
- heavy loads on the toe plate,
- damage that occurs due to attempts to modify the product.

Any claim for this commercial warranty must be sent by the user or its legal representative (parents, guardian...) to the entity where the product was purchased, which will forward this claim to the corresponding Thuasne entity.
Any warranty claim will first be reviewed by Thuasne to determine if the conditions of the limited warranty are fulfilled and do not fall into one of the cases of exclusion of the commercial warranty.
To benefit from the warranty, the buyer must mandatorily provide:
- an original and dated proof of purchase of the product;
- an original and dated proof that the scheduled maintenance was performed every 6 months.

If the conditions of the limited warranty are fulfilled and the claim is made by the user or its legal representative (parents, guardian...) within the warranty delays indicated above, the buyer will get a new substitution product.
It is expressly agreed that this commercial warranty is in addition to the legal warranties binding the entity which sold the product to the user, in accordance with the applicable local legislation in the country of purchase of the product.