

# HERCULES



## PATIENT EVALUATIONS FOR A NOVEL DYNAMIC SWING-ASSIST KAFO WITH TENSION LOCK

Icarus' patented Hercules KAFO includes a unique tensioning system and swing-assist hinge, which is fully adjustable by the user. The system generates up to 40 lbs of force to stabilize and support the knee, providing stance assist at maximum tension levels. When engaged, the hinge assists the quads during flexion, significantly reducing forces within the knee. Users of the KO component report 61% pain relief and 43% improvement in function. Varus and valgus correction can be incorporated into the frame during the digital customization process if required, and a number of other customization features enable the clinician a range of options to restore the patient's gait. Clinicians involved in our pilot study have cited improved gait and improved activity in their patient populations due to the Hercules KAFO.

### Posterior + Anterior Models Available:

The anterior Hercules model is the easiest to don and doff, making it our go-to-design for most patients. Our posterior Hercules model is designed to prevent the tibia from translating forward as the patient is in gait. The AFO cups the calf to provide support to patients with fused ankle issues.

**Method:** Patients of varying clinical indications were recruited to wear the Icarus KAFO in order to observe the effectiveness of the swing-assist for lower limb instability. Each of the devices were custom fabricated and 3D-printed, utilizing Icarus' mobile 3D scan app. Anecdotal observations were collected from clinicians on the patient's gait, function, stability, and patient satisfaction as outlined below:



Patient 1 - **Diagnosis:** Monoparesis secondary to myloradiculopathy and neuropathy

Fit: Experienced KAFO user. Unilateral growth extension Icarus KAFO. Higher brim to accommodate surgical site. Overall fit was good; biggest challenge was identification of knee center, anatomic vs mechanical-- adjusting for Icarus rotation point while also fabricating struts into AFO with appropriate line of progression. Patient likes being able to manipulate the Sidewinder system through his pocket. Patient likes the hinges as compared to metal as it does not pinch the fingers when picking up the orthosis and it is much lighter.

Walking: After modifications to shoe lift, patient is able to have more uniform steps. Patient allows slight knee flexion and utilizes the extension assist to aid with daily ambulation including navigating a therapeutic obstacle course. Other interventions are aiding in strength gains in the extremity. Patient is able to easily pedal a bike with wearing the

orthosis as well as work on his golf swing and feels stable.

Patient 2 - **Diagnosis:** Spina Bifida

Fit: Experienced dual-stage KAFO user. Bilateral dual stage Icarus KAFO. Patient had previously used KAFO primarily for use in stander. Currently patient is using extension KAFO for beginning ambulation with support at therapy. Goal is for independent ambulation with assistive devices. Currently using max extension of joints as strength is built for independent patient balance. Family initially found the strapping challenging but are getting used to it over time; challenge of feeding straps through slots. The attachment block on the AFO to the inset on the KO fit great. In process of shifting the attachment blocks more superiorly to better align to current knee center.

Walking: Patient is working on standing weight bearing and basic ambulation during therapy. Patient was recovering from surgery that left them

seated for a prolonged period of time and needs to rebuild strength. Therapy likes the extension adjustability features.

**Patient 3 - Diagnosis:** Cerebral Palsy  
Fit: Patient is new to KAFO; previously used SMO's and AFO's but experiencing knee instability and angulation that impaired gait. Bilateral growth extension Icarus KAFO. Patient experienced a health decline from eval to fitting and stronger joints were needed to prevent knee flexion. At second fitting after new joints, patient's health had greatly improved and patient was able to ambulate with hands held using SMO's but showed decreased control at ankles, knee flexion and right knee valgus as well as flexion at hips.

Walking: Icarus KAFO evaluated against SMO's and older AFO's plus OTS knee brace. Icarus KAFO provided most overall upright body posture with greatly decreased right knee valgus. With Icarus KAFO with dorsi-assist joints, patient is developing heel strike and improved overall alignment during ambulation. Control of right knee is best with A/I KAFO. Biggest challenge had been catch of RT KAFO on LT KAFO at the medial knees but this is decreasing with patient strength gains and accommodation to orthoses. Ease of use may be improved if this patient's design had the quick release buckles. Family finds it challenging to use KAFO's relative to toileting as currently KAFO's are worn over clothing and disposable undergarments are needed. Family likes adjustability of KO joints to allow for ambulation, getting into van and then release for sitting.



**Patient 4 - Diagnosis:** Arthrogryposis  
Fit: Experienced dual stage KAFO user. Bilateral dual stage Icarus KAFO. Patient has valgus knee alignment and very small legs circumferentially. Overall fit went well. Had to replace large back pad with standard width pad. Perhaps due to small circumference, challenge to get the attachment blocks to easily align to inset on the KO. Feeding straps thru anterior slots was challenging but doable.

Walking: Patient had suffered a leg fracture between eval and fitting and was fit within days of being released to weight bearing. Goal for this patient is for max extension for use in stander and allowing flexion when appropriate, such as in a gait trainer, to allow patient to maintain ROM that is still possible. Adjustability is key through patient's day. Limited use at this time until shoes identified to work with KAFO's due to buildups on AFO section to accommodate contractures.

**Clinician 1 - Overall Feedback:**

- Selection of joint strength is great to accommodate degree of extension strength of patient
- Families and therapists appreciate the ability to instantly adjust knee joint strength/release.
- Quick disconnects seem to work well
- Feeding anterior straps through slots seem to be the hardest to maneuver
- The cuffs tend to be "deep" on the thigh and calf when the patient's are smaller
- The decrease in weight against a traditional system is significant especially when factored against strength.
- A lot more adjustability in less time compared to the traditional system
- Important to identify anatomic to mechanical knee center as well as to align struts during fabrication of the integrated growth extension AFO section.

**Clinician 2 - Overall Feedback:**

- Overall, the KAFOs fit great!
- Optimal height, alignment, and fit around the legs, the shape was great too!
- For now the patient is happy and working with PT on her walking.
- She has not walked in about 8 months but was able to take her first steps with these KAFOs!