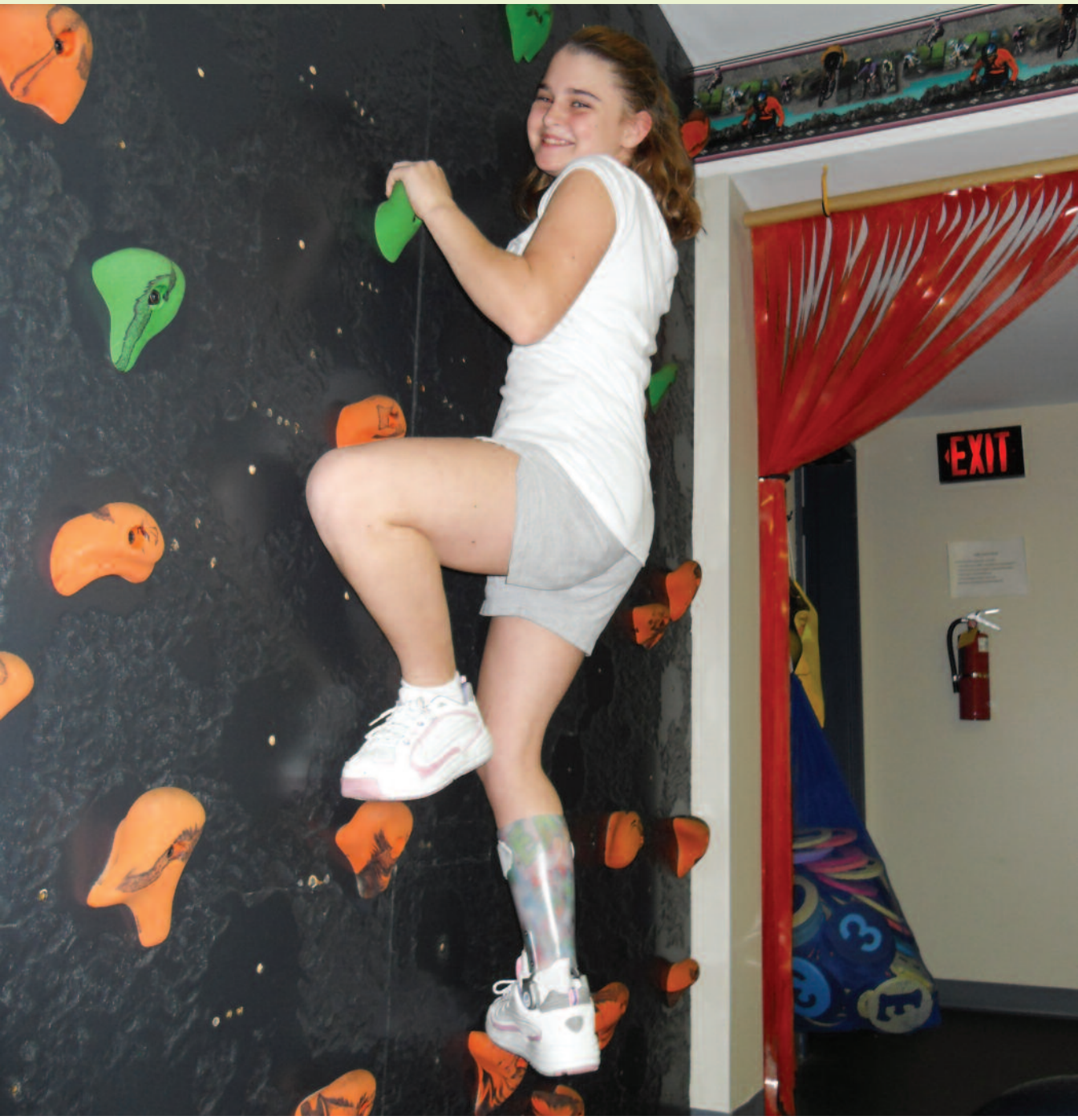
Managing Pediatric Gait Dysfunction



Functional Bracing with Adjustable Dynamic Response™ (ADR™)

only from...

Ultraflex®

Patient Inspired Solutions

Ultraflex Adjustable Dynamic Response™ (ADR™)

Optimize gait with a functional bracing solution with resistance or dampening effects that are adjustable while being worn

- Allows for normal range in the knee and/or ankle
- Selectively augments weak muscles
- Increases stability and dynamic balance
- Assists foot clearance in swing

Clinical Presentations:
- Crouch
- Equinus
- Variant of crouch and equinus

Age/Weight:
- Pediatric/adolescent 55 lb/25 kg (one side) – 110 lb/50 kg (two sides) — Ultraflex ADR™ UltraSafeGait™
- Adolescent/adult 110 lb/50 kg (one side) – 250 lb/115 kg (two sides) — Ultraflex ADR™ UltraSafeStep®

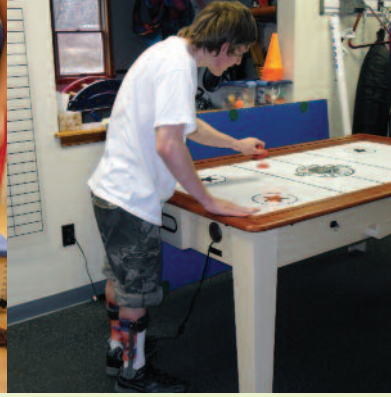
Treatment Specialties:
- Cerebral Palsy (hemiplegic, diplegic, quadriplegic, GMFCS Levels 1 – 4)
- Spina Bifida
- TBI
- Challenging neurological and developmental conditions
- Post-stroke
- Idiopathic toe walking syndrome
- Spinal cord pathology

Biomechanical Rationale

Ankle
- Allows for normal range in the ankle (0 – 40° dorsiflexion, 0 – 40° plantarflexion resistance or dampening effects), changing the resistance can be accomplished with simple set screw adjustments
- 0 – 140 in/lb of torque restraint for plantarflexion and for dorsiflexion (Ultraflex ADR™ UltraSafeGait™)
- 0 – 600 in/lb of torque restraint for plantarflexion and for dorsiflexion (Ultraflex ADR™ UltraSafeStep®)
- Selectively augments and provides support for the tibialis anterior and gastroc-soleus muscles and alters their response to ground reaction forces (GRF) as needed
- ADR™ restrains ROM, does not hold it or stop it unless desired, rigid stops can be created by compressing the stop channel(s)

Knee
- Allows for normal range in the knee (0 – 30° dampened flexion), adjustable dynamic stance control
- Knee component prevents knee buckling from sit-to-standing with ratchet support from 120° flexion to full extension
- The sit-to-stand slide lock/safety release is low profile and easy to engage and disengage for patients with adequate cognition and manual dexterity (no cable release needed)





What Do Patients Say About Their Ultraflex Adjustable Dynamic Response™ (ADR™) Brace?

"What I like most about my braces are that they help me walk; help me play with my friends at school."

"I have more endurance and I can walk further."

"It helps me keep up with my friends."

"The more steps I take, the better my walking becomes."

"It helps me do things by myself."

What Do Parents/Caregivers Say About Their Ultraflex Adjustable Dynamic Response™ (ADR™) Brace?

"Braces have improved his function by making him more stable."

"The combination of the nighttime bracing and the daytime bracing has improved his balance and stability."

"She has more mobility, never complains about wearing them because they help her move around."

Comprehensive Orthotic Management for the Growing Child with Spasticity and/or LOM

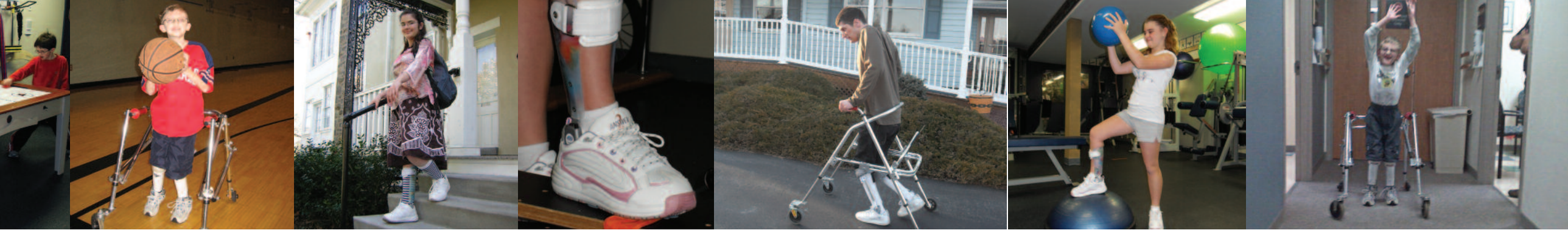
To address range and maintain muscle length during growth – consider Ultraflex therapeutic/stretching braces worn at night or during rest as part of the total bracing solution. The following general guidelines address range as part of the clinical assessment. Patients with insufficient range for Adjustable Dynamic Response™ functional bracing may be good candidates for Ultraflex therapeutic/stretching bracing with the goal being to achieve the required range for successful functional bracing.

An Ultraflex therapeutic/stretching KO joint component can also be used in combination with ADR™ AFO joint component in a single brace. A therapeutic KO and an ADR™ AFO (Total Day/Night Crouch Solution) connected by an Ultraflex UltraQuick Release™ can be successfully used to treat crouch – please see the following guidelines.

To learn more:

Call: 800-220-6670

Visit: www.ultraflexsystems.com



General Guidelines for Adjustable Dynamic Response™ (ADR™) UltraSafeGait™

Common Clinical Presentations*	Common Clinical Measurements			Common Clinical Goals	*Ultraflex* Solution/Rx	ADR™ Component Channel Adjustments				*Ultraflex* Solution/Rx
	R1 and R2	Strength	First (Heel) Second (Ankle) Third (Toe) Rocker	Manage Gait (ADR™) Improve Muscle Length (Therapeutic/Stretching)**	Functional/Day Bracing (UltraSafeGait™ ADR™)	Posterior Elastomer	Posterior Stop	Anterior Elastomer	Anterior Stop	Therapeutic/ Stretching Bracing night and/or at rest**
Early Childhood Equinus (Extension Gait Moment) **Soleus Spasticity with *flexible* rear, mid, and/or forefoot deformities**	**R1:** <10° dorsiflexion **R2:** within normal limits	Weak tibialis anterior and gastroc-soleus	**First:** mid or forefoot contact **Second:** no tibial progression **Third:** early heel rise	**Achieve Heel First Rocker, Tibial Advancement, Control Knee Hyperextension, Allow Third Rocker**	**Rx:** Ultraflex Custom Molded ADR™ AFO w/ Posterior Calf Shell and SMO	Near to fully compressed	Only if posterior elastomer compression alone does not control knee hyperextension	Little to no compression needed	Usually none needed	Consider **Rx:** Ultraflex AFO CM**
Late Childhood Equinus (Extension Gait Moment) **Soleus Spasticity with *rigid* foot deformities**	**R1:** <0° dorsiflexion **R2:** <15° dorsiflexion	Weak tibialis anterior and gastroc-soleus	**First:** mid or forefoot contact **Second:** no tibial progression **Third:** early heel rise	**Achieve Heel First Rocker, Tibial Advancement, Control Knee Hyperextension, Allow Third Rocker;** Lengthen Soleus**	**Rx:** Ultraflex Custom Molded ADR™ AFO w/Posterior Calf Shell *(consider SMO for comfort & heel post to bring floor to patient)*	Near to fully compressed	Only if posterior elastomer compression alone does not control knee hyperextension	Little to no compression needed	Usually none needed	**Recommended Rx:** Ultraflex AFO CM**
Earlier Childhood Crouch (Flexion Gait Moment) **Hamstring and Gastroc-Soleus Spasticity with *flexible* rear, mid, and/or forefoot deformities**	**R1:** popliteal >30° knee flexion; gastroc <5° dorsiflexion **R2:** within normal limits	Weak hip extensors, quadriceps, and gastroc-soleus	**First:** full, mid, or forefoot contact **Second:** too much hip flexion, knee flexion, and ankle dorsiflexion in mid-stance **Third:** no heel rise (crouch with constant heel contact)	**Improve Shock Absorption at Weight Acceptance and Dynamic Balance, Create Knee Extension Moment in Mid to Late Stance, Allow Third Rocker**	**Rx:** Ultraflex Custom Molded ADR™ AFO w/Anterior Proximal Shell and SMO *(recommended with rigid toe plate)*	Little to no compression needed	Only if required for swing clearance and initial contact with heel	Near to fully compressed	Only if anterior elastomer compression alone does not create sufficient knee extension moment in mid to late stance	Consider **Rx:** Ultraflex KAFO CM**
Late Childhood Crouch (Flexion Gait Moment) **Hamstring and Gastroc-Soleus Spasticity with *rigid* rear, mid, and/or forefoot deformities**	**R1:** dynamic limitation **R2:** popliteal >30° knee flexion; gastroc-soleus <5° dorsiflexion	Weak hip extensors, quadriceps, and gastroc-soleus	**First:** full, mid, or forefoot contact **Second:** too much hip flexion, knee flexion, and ankle plantarflexion in mid-stance **Third:** early heel rise (crouch with no heel contact)	**Improve Shock Absorption at Weight Acceptance and Dynamic Balance, Create Knee Extension Moment in Mid to Late Stance;** Lengthen Hamstring and Gastroc-Soleus**	**Rx:** Ultraflex Custom Molded ADR™ AFO w/Anterior Proximal Shell *(consider SMO for comfort and heel post to bring floor to patient)*	Little to no compression needed	Only if required for swing clearance and initial contact with heel	Near to fully compressed	Only if anterior elastomer compression alone does not create sufficient knee extension moment in mid to late stance	Add Therapeutic KO CM section with UQR™ to ADR™ AFO with Posterior Calf and pre-tibial shell — total day/night crouch solution (see below) **Recommended Rx:** Ultraflex CM KO ADR™ AFO with UltraQuickRelease™**
Severe Crouch (Flexion Gait Moment) **Hamstring and Gastroc-Soleus Spasticity** gross LE weakness and instability, prone to knee buckling	**R1:** dynamic limitation **R2:** popliteal — deficit no greater than 10° from normal limits	Weak hip extensors, quadriceps, and gastroc-soleus or lever arm extensor dysfunction	**First:** full, mid, or forefoot contact **Second:** too much hip flexion, knee flexion, and ankle dorsiflexion in mid-stance **Third:** early heel rise (crouch with no heel contact)	**Improve Standing Alignment, Stability, and Dynamic Balance, Fine-tune Rockers, Create Knee Extension Moment in Mid to Late Stance;** Lengthen Hamstring and Gastroc-Soleus**	**Rx:** Ultraflex Custom Molded ADR™ KAFO w/ sit-to-stand slide lock/safety release, (KO ADR™ with adjustable 0-30° flexion)	Little to no compression needed	Only if required for swing clearance and initial contact with heel	Near to fully compressed	Only if anterior elastomer compression alone does not create sufficient knee extension moment in mid to late stance	Consider **Rx:** Ultraflex KAFO CM**

* This chart is provided as an example only; the final bracing solution will be determined by the prescribing physician and the physician's rehab team. Although there are many variants to equinus and crouch, these guidelines address 1) Weakness plus dynamic spasticity; 2) Weakness, dynamic spasticity, and muscle shortening; and 3) Weakness alone.

** In addition to Ultraflex ADR™, Ultraflex offers LE and UE therapeutic/stretching bracing solutions.

Ultraflex Exclusive Component Technology*

Component	Description	Features
	**Adjustable Dynamic Response™(ADR™) Ankle Joint** Dually adjustable dynamic stance phase control for motion with stability	• Recommended for patients up to 110 lb (medial and lateral joints together) • Continuously adjustable: 0-40º Plantarflexion ROM 0-40º Dorsiflexion ROM • Adjustable Dynamic Response™ muscle augmentation: Plantarflexion up to 140 in/lb Dorsiflexion up to 140 in/lb
	**Adjustable Dynamic Response™ (ADR™) Knee Joint** Safe stance control without locking the knee	• Continuously adjustable, 0 - 30° flexion • Sit-to-stand ratchet support from 120° flexion to full extension • Sit-to-stand slide safety/lock release, low profile easy to engage/disengage • Elastomer durometer of 85D or 95D depending upon the desired stiffness of Adjustable Dynamic Response™

*Components come with a limited lifetime warranty.

Ultraflex recommends the Ultraflex Universal Joint for use as a companion joint to ADR™. It is a lightweight, low profile clevis design and can be used on ankles, elbows, and wrists.
Ultraflex toe pads are available for sale individually or with Ultraflex custom fabricated orthoses made in the Ultraflex lab and are recommended for use with ADR™.

ADR™ Component Adjustment Based on Patient Presentation

Setting the Channels

Ultraflex recommends adjusting the posterior and anterior elastomer channels to first obtain a smooth gait, after which the rigid stops may be adjusted if required

Posterior Elastomer Channel

Compress to augment tibialis anterior at initial contact
(Resist foot drop or slap/equinus and promote heel-ankle rockers in early stance)

Anterior Elastomer Channel

Compress to augment the gastroc-soleus from mid-stance to pre-swing
(Resist crouch gait, premature advancement of the tibia during stance, and rapid dorsiflexion/kneebuckling; promote smooth second and third rockers in late stance)

Plantarflexion and Dorsiflexion Stop Channels

Create a rigid stop for patients as desired (Variable stop, 0-40º as needed; please see inside chart, General Guidelines for UltraSafeGait™, for stop usage by gait pattern type)

Note: Nylock patches on adjustment screws help prevent screws from backing out once adjusted.

ADR™ Component Maintenance

Please review biomechanical performance of components every three to six months. Replace elastomers and lubricate channels, as needed, with replacement kit. Replacement kits are sold separately. For more information, please call 800-220-6670.

Total Day/Night Crouch Solution



- Therapeutic custom molded KO section for lengthening hamstring and gastroc-soleus
- Improve base of support, dynamic balance, and stability with ADR™ AFO section
- Easily disconnect KO from ADR™AFO with an Ultraflex UltraQuick Release™

Ultraflex ADR™ plus therapeutic options enable the clinical team to: (1) fine-tune first, second, and third rockers by easy adjustment at any time (ADR™), (2) change the dynamic angle of tibial inclination at any time (ADR™), (3) preserve and improve range of motion at rest (therapuetic).

Compliance

Ultraflex ADR™ UltraSafeGait™ orthosis can be worn throughout the day for ambulatory and non-ambulatory activities as tolerated but should be removed during sleep. Ambulatory activities may include running, jumping, squatting, bending, and kneeling. Patients may need to gradually work into wearing their orthosis and should follow the specific instructions given to them by their orthotist.

(Adjustments or modifications may be necessary to the orthosis. Patients/caregivers should report any discomfort, irritation, or rubbing caused by the orthosis to their orthotist.)

Delivering Patient Inspired Solutions

For Support	Call 800-220-6670, Monday - Friday, 7:00am - 6:00pm (ET)
Clinical	brace selection/design, measurement, casting, fitting, wear schedule guidelines
Reimbursement	pricing, L Code, and prior authorization recommendations
Fabrication	assistance with fabrication or for custom fabrication through Ultraflex – wide selection of custom interface designs and colors available
Ultraflex's Patient Assistance Program	uninsured or patients with financial need

Our FDA Class I braces are available only through a physician's prescription and are fitted and billed by certified orthotists. Ultraflex braces and components are covered by most insurance providers.

For education, please call: 800-220-6670
www.ultraflexsystems.com