Orthomerica PEDIATRIC PRODUCTS



STARband —

the most prescribed cranial remolding orthosis in the world

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Partnering with STARband®

STARband—the Gold Standard

More than 600,000 infants have been successfully treated with the STARband. The design is intended to allow for the successful completion of treatment for nearly all plagiocephaly and brachycephaly patients in a single orthosis. This presents a significant cost savings to the families and payers. Additionally, follow-up appointments are scheduled relative to the age of the infant and severity of the deformity, and this individualized schedule helps to decrease stress for the family.

STARband—One and Done!

Families must comply with the recommended 23-hour per day wearing schedule and participate in a structured followup program for ongoing adjustments and modifications to the STARband. If the clinical protocols are followed, there are rarely indications for a second band.

Clinical Partners—STARband Cranial Clinicians

Partnering with an experienced cranial clinician is key to the success of the cranial care program. STARband cranial clinicians have extensive experience and expertise in the management of infants with skull deformities. Recommendations for STARbands are made only for infants with moderate to severe deformities, and orthotic treatment programs include ongoing adjustments to effectively direct cranial growth into the correct dimensions.

Advanced Pediatric Scanning Technologies

The STARscanner[®] and SmartSoc[®] scanning systems are the leaders in scanning technologies for infants with cranial deformities, as they were specifically developed to meet the needs of this patient population. Cranial scanners for infants must be safe, accurate and function quickly to capture the required head shape data from these active little patients. The STARscanner and SmartSoc are the most accurate laser and hand-held scanners available for cranial applications.

Clinical Documentation and Reports

Both the STARscanner and SmartSoc scanning systems offer detailed anthropometric reports that establish baseline measurements during repositioning and therapeutic treatments. Additional scans are acquired as needed, and a comparative report shows both the qualitative and quantitative improvements obtained by the orthotic treatment program.

Commitment to Quality Cranial Care Programs

The STARband team involves a clinical network of exceptional clinicians dedicated to the care of infants with deformational plagiocephaly and post-operative craniosynostosis. Quality clinical outcomes depend upon the clinical skills of the STARband cranial clinician and use of the most effective orthotic designs.

STARband Locations

A list of STARband clinics can be found at <u>www.starbandkids.com</u>. Partnering with experienced STARband clinicians will enhance the referral process, improve communications within the medical team and family, streamline patient care procedures, and optimize clinical outcomes.





www.starbandkids.com 1 (800) 498-STAR



ORTHOMERICA'S STAR® FAMILY C

	STARband [®] Side-Opening Band	STARband Bi-Valve	STARlight [®] Side-Opening Band
General Information	Most widely prescribed headband design	Most used for scapho- cephalic head shapes	Clear material allows visual inspection
Used to Treat*	 Plagiocephaly Brachycephaly Scaphocephaly Post-operative craniosynostosis 	 Plagiocephaly Brachycephaly Scaphocephaly Post-operative craniosynostosis 	 Plagiocephaly Brachycephaly Scaphocephaly Post-operative craniosynostosis
Measurements	Custom fabricated from scan (or plaster cast)	Custom fabricated from scan (or plaster cast)	Custom fabricated from scan (or plaster cast)
Designer	Orthomerica	Orthomerica	Orthomerica
Materials	Plastic shell with foam liner	Plastic shells with foam liner	Clear plastic shell with foam pads
Style	Side and top openings	Overlap design	Side and top openings





Before Treatme

F CRANIAL REMOLDING ORTHOSES

STARlight Bi-Valve	STARlight PRO Living Hinge	Fractional State State Living Hinge	Image: Starband 3D [™] Bi-Valve
Clear material allows visual inspection	For post-endoscopic craniectomy	Low profile design with foam liner	3D printed design
 Plagiocephaly Brachycephaly Scaphocephaly Post-operative craniosynostosis 	 Post-operative craniosynostosis 	 Plagiocephaly Brachycephaly Scaphocephaly Post-operative craniosynostosis 	PlagiocephalyBrachycephalyScaphocephaly
Custom fabricated from scan (or plaster cast)	Custom fabricated from scan (or plaster cast)	Custom fabricated from scan (or plaster cast)	Custom fabricated from scan
Orthomerica	Drs. Jimenez & Barone	Orthomerica	Orthomerica
Clear plastic shells with foam pads	Clear plastic shell with foam pads	Plastic shell with foam liner	3D printed nylon shell with foam pads
Overlap design	One piece living hinge	One piece living hinge	Top opening with side closures

*Selection of cranial remolding orthosis design and treatment protocol is subject to clinical evaluation and physician prescription.





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After STARband Treatment



(877) 737-8444 | www.orthomerica.com



A New STAR[®] is Born. Introducing STARband[®] 3D[™]

LEARN MORE AT www.orthomerica.com/3D



The STAR[®] Family of Cranial Remolding Orthoses welcomes its newest member!



STARband® SIDE-OPENING BAND Most widely prescribed headband design



STARband BI-VALVE Most used for scaphocephalic head

shapes



STARlight® SIDE-OPENING BAND Clear material allows visual inspection



STARlight BI-VALVE Clear material allows visual inspection



STARlight PRO LIVING HINGE For post-endoscopic

craniectomy



STARband Plus[™]

LIVING HINGE

Low profile design with

foam liner



STARband 3D[™] BI-VALVE 3D printed design

Discover the latest innovation from Orthomerica—the STARband 3D! This is the newest addition to the STAR[®] Family of cranial remolding orthoses. This new STAR is a testament to our commitment to advancing cranial care programs and achieving exceptional clinical outcomes for infants in need of this treatment.

With over 25 years of experience as the global leader in cranial products, we understand that each infant requires a unique approach. Seven STAR Family designs are customized by cranial experts to address the individual needs of each infant and family.

At Orthomerica, we are committed to supporting the cranial care programs delivered by the largest international network of multidisciplinary

cranial experts. This support includes advanced clinical education and training, ongoing research and development, unsurpassed customer service, clinical consultations with our staff of expert cranial clinicians, and a variety of other outreach activities.

STARband clinical care programs are supported by more than 40 independent peer-reviewed publications. Our annual STAR Summit continues to be the premiere clinical conference focusing on infant skull deformities and cranial remolding programs. 25 years of clinical collaboration and design refinement has positioned the STARband as the most prescribed cranial remolding orthosis worldwide.

The STARband 3D is yet another example of our commitment to this special patient population. With 3D printing, we offer different levels of design flexibility, still maintain the structural integrity needed with reduced weight, and minimize waste with environmentally friendly materials.

Experience the difference with Orthomerica's STAR Family of cranial remolding orthoses and our newest innovation, the STARband 3D!

Interested in the STARband 3D? Want to hear what others are saying? Contact us for more information.





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STARband[®] & STARscanner[®] The gold standards since 2001.







Before STARband treatment

After STARband treatment

- Used by leading children's hospitals and cranial clinics worldwide
- · Facilitates high volume scanning of patients
- FDA cleared for safety and accuracy
- · Comprehensive printouts track progress
- · Two-second scan and clear craniofacial imaging
- Pre- and post-operative scans for craniosynostosis

PRODUCTS



Custom STAR[®] cranial

remolding orthoses



Custom fracture &

burn masks



Custom protective helmets

ORTHOMERICA star & band

(877) 737-8444 | www.orthomerica.com www.starbandkids.com



When nature needs a nudge.

Star Stand Complete System for the Orthotic Management of Plagiocephaly, Brachycephaly & Scaphocephaly. **Complete System for the Orthotic**



- 600,000 infants successfully treated with the STARband
- Largest selection of cranial remolding orthoses for treatment of deformational plagiocephaly & Postoperative Craniosynostosis
- Scan infant's head shape in 2 seconds or less eliminating the need for plaster casting
- Capture 3-D Data that can be viewed in multiple planes





Over 200 STARscanners[®] in use at prestigious institutions across the globe.

UNITED STATES

- Altru Rehab Center North Dakota
- Arnold Palmer Hospital for Children– Orlando, FL
- Carrie Tingley Hospital–New Mexico
- Children's Healthcare of Atlanta
- Children's Hospital & Medical Center-Omaha, NE
- Children's Hospital of Colorado–Denver, CO
- Children's Medical Center–Dallas, TX
- Hasbro Children's Hospital–Providence, RI
- Lutheran General Hospital–Chicago, IL
- Marshfield Clinic–Marshfield, WI
- Mary Free Bed Orthotics and Prosthetics Holland, MI
- Mary Free Bed Rehabilitation Hospital Grand Rapids, MI
- Massachusetts General Hospital
- Mayo Clinic–Rochester, MN
- MCG Health–Augusta, GA
- Miami Children's Hospital–Dan Marino Center
- Oakland Children's Hospital–Oakland, CA
- Park Nicollet–Minneapolis, MN
- Rehabilitation Medical Supply–South Dakota
- Seattle Children's Hospital
- Shriner's Hospital–Chicago, IL
- Tufts Medical Center–Boston, MA
- UCSF Medical Center–San Francisco, CA
- University of Missouri Hospital
- University of Rochester Medical Center
- University of Texas Health Science Center at Houston
- University of Texas Health Science Center at San Antonio
- Wolfson's Children's Hospital–Jacksonville, FL

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WORLDWIDE

- AHS–Tokyo, Japan
- Alberta Children's Hospital–Calgary, Alberta
- Bandagist Jan Nielsen A/S–Denmark
- BC Children's Hospital–Vancouver, BC
- Beagle Orthopedics-Blackburn, United Kingdom
- Clínica del Country–Bogota, Colombia
- Clínica Heads—São Paulo, Brazil
- Clinical Orthotic Consultants–Windsor, ON
- CUREMED Tabsh Medical Centers–Saudi Arabia
- Eemland Orthopedie Techniek B.V.-Amersfoort, Netherlands
- EFMO, Gabinete STARcenter–Madrid, Spain
- Hospital for Sick Children–Toronto, Canada
- Matsumoto P&O Manufacturing Co.– Aichi, Japan
- Mediclinic Welcare Hospital–Dubai, UAE
- Nishinomiya Kyoritsu Neuro Hospital— Hyōgo, Japan
- Orthokorea–Seoul, Korea
- Ortho Pro Associates–Cumbaya, **Quito Ecuador**
- Orthotic Solutions Ltd.–Edmonton, Alberta
- OTH De Hoogstraat–Utrecht, Holland
- Profile Plastic Surgery and Dentistry Seoul, Korea
- Pro Walk GmbH–Egelsbach, Germany
- RSL Steeper–Leeds, United Kingdom
- Taiwan Orthotics and Prosthetics Company– Taipei, Taiwan
- United Family Health Hospital–Beijing, China

Scores more—throughout local O&P facilities in the US and overseas.



orthomerica. 877-737-8444

STARscanner® Testimonial





Our institution offers both the endoscopic-assisted strip craniectomy and open treatments (such as fronto-orbital advancement) to patients with craniosynostosis. For the open operation, I control the postoperative head shape outcome;

however, in the endoscopic procedure the orthotist dictates the head shape outcome. A skillful orthotist and constant communication are required for success. The use of the STARscanner is vital in providing this visual communication for these infants, as many patients live far away. The STARscanner provides accurate measurements for the best possible fit of the orthotic helmet and allows for comparison scans which are crucial in tracking the patient's progress during treatment.

Kamlesh B. Patel MD
 Associate Professor
 Washington University in Saint Louis
 Plastic and Reconstructive Surgery



The information gained with the STARscanner provides a critical part by assisting in the diagnosis of the asymmetry and providing guidance in the evaluation of the treatment protocols, including both physical therapy and cranial orthosis.

It allows us to not only create and manage orthotic helmets when necessary, but also, to manage total patient care. It provides accurate, reproducible and understandable objective data for the family and the caregiver.

Frank A. Vicari, M.D., FACS, FAAP
 Pediatric-Plastic Surgery/Craniofacial Surgery
 Advocate Children's Hospital
 Chicago, IL



As a craniofacial surgeon who has treated hundreds of patients with head shape anomalies, including plagiocephaly and craniosynostosis, I can attest to the fact that use of the STARscanner is vital in providing treatment for these infants. The STARscanner

is fast and well-tolerated by the youngest pediatric population. It is non-invasive with no radiation exposure, it provides accurate measurements for the best possible fit of the orthotic helmet and allows for comparison scans which are crucial in tracking the patient's progress during treatment. Tracking changes in head shapes over time, as part of the evaluation, provides consistent criteria for determining when helmet treatment is indicated. In addition, the STARscanner provides more measurements to evaluate head shape than taking measurements by hand and is far more accurate. Without a doubt, the STARscanner is a revolutionary device in helping to provide the best available treatment for infants with craniofacial anomalies.

- G. E. Ghali, DDS, MD, FACS, FRCS(Ed)



ORTHOMERICA[®] www.orthomerica.com/starband



The clinically proven pocket-sized 3D image capturing system

NEW!

New and enhanced features with eBrace[®] Global and CurveCapture[™] O&P for Apple[®] iPhone[®] 11(s) & 12(s)

Key clinical benefits

- New features to organize scans by patient profile
- Enhanced device security
- Additional labels sort patient scans during the treatment program— Fabrication, Follow-up and End-of-treatment
- Administrator visibility over patient profiles in multiple user accounts

SmartCam[™] for fast, safe, and accurate video scans

- Apple iPhone 11(s) & 12(s) with iOS®
- User friendly-requires minimal training to use
- Accurate to 0.1%
- Generic model on the device display shows real-time SmartScan® progress
- Scanning halo turns green, indicating optimal stand-off distance
- Allows patient movement during a SmartScan
- Portable-easily taken to clinics and satellite offices

CurveCapture™ O&P App converts 2D video images to a 3D model

- Revolutionary technology analyzes 2D video images for optimal 3D conversion in the cloud
- HIPAA compliant

eBrace® Global web portal

- Allows users to review the 3D Model
- Platform for ordering STAR[®] Family of Cranial Remolding Orthoses and Prosthetics from Orthomerica

Product offerings

- STAR Family of Cranial Remolding Orthoses
- Custom protective helmets
- Prosthetics
- More modules to come!



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U.S. Patent: 14/062,994 & Patents Pending

A-Flex[™] Plus Protective Headgear





Orthomerica introduces the A-Flex Plus Protective Headgear, an adjustable alternative to other hard protective devices. The A-Flex Protective Headgear is fabricated from a flexible plastic that readily conforms to varying head shapes making it easy-to-fit upon demand. The protection is ideal for low impact forces that are distributed across the entire surface without cracking or penetrating. The headgear is equipped with chin straps that are recommended for active and noncompliant patients. The posterior strap "locks" the device below the occiput and mastoids and accommodates size variations. The lateral straps are used for easy donning and doffing. Lateral straps and side-slits are also optional. The A-Flex features ventilation holes to improve air circulation and cooling. It can be easily trimmed with a pair of heavy duty scisssors without the need for complex equipment and tools. It can be stocked in various sizes.

Clinical Indications

- Post-operative craniectomy or craniotomy
- Cranial vault reconstruction or other cranial surgery
- Skull anomalies
- Seizure disorders
- Self-injurious behaviors related to head banging, hair pulling, etc.
- Instability secondary to poor balance and/or disequilibrium reactions

Contraindications

- Individuals who are at high risk for facial injuries (Custom products including face guards and other forms of cranial protection are available from Orthomerica)
- Individuals requiring high impact protection

Size	Blue	White	Circumference
Pediatric SM	783.805	783.90S	44-47 cm
Pediatric MD	783.815	783.915	46-49 cm
Pediatric LG	783.825	783.925	48-51 cm
Pediatric XL	783.835	783.935	50-53 cm
Adult XS	783.845	783.94S	52-55 cm
Adult SM	783.855	783.955	54-57 cm
Adult MD	783.865	783.96S	57-60 cm
Adult LG	783.875	783.975	60-63 cm
Adult XL	783.885	783.98S	63-66 cm
Adult 2X	783.895	783.995	66-69 cm
Chin Strap Kit—B	lue		783.15
Chin Strap Kit—V	Vhite		783.13
Chin Strap Kit—T	ransfer Pattern		783.16
Replacement Side Strap Kit—Blue			783.17
Replacement Side Strap Kit—White			783.20
Donlacomont Cic	le Strap Kit—Custo	m	783.19



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SCOLIOSIS MANAGEMENT FROM ORTHOMERICA

Join practitioners from major children's hospitals who trust Orthomerica to fabricate custom spinal designs for their patients with scoliosis and kyphosis. Each orthosis is precisely fabricated to produce symmetry, correction, and control.

SCOLIOSIS CURVE TREATMENT APPROACHES

- Dynamic Scoliosis TLSOs
 - Focus on overall spinal balance in all three planes including Cobb angle correction
 - Pad options maximize adjustability and in-brace correction
 - Cast modifications and thoracic window encourage trunk shift
- Hybrid designs with and without thoracic extensions
- Neuromuscular scoliosis designs

KYPHOSIS MANAGEMENT

- Low profile hybrid systems with modular posterior thoracic extensions
- High profile thermoplastic TLSOs with thoracic extension pads

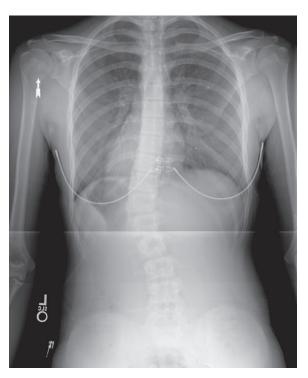
BENEFITS

- Impressions can be taken by measurements, cast or scan
- Quick, reliable turn-around time
- Finished and strapped
- Transfer patterns available on straps and/or plastic





Modification and fabrication of the orthosis is based on the patient's x-ray and practitioner's instructions.





Introducing the new...

$KC \ COMBO-$ Knee Control Orthosis

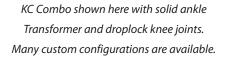
Practitioners managing patients with knee flexion instability in stance are often faced with the dilemma of whether the patient needs a knee ankle foot orthosis or just an AFO to correct the instability. Those with poor quadriceps may experience knee flexion in stance, especially if they lack strength and endurance. Locking up the knee all the time may interfere with the patient's ability to actively strengthen the muscles that will provide long term stability.

The KC Combo provides opportunities for developing knee control with the AFO alone, or with the attached knee component to provide more proximal alignment and stability.

Indications

- Knee flexion instability
- Patients who experience changing muscle strength in the lower limb
- Patients who are working towards eliminating the knee control portion of their lower limb orthosis
- Patients who need simultaneous stretching of the foot, knee and ankle to maintain range of motion
- Those patients who need a KAFO to stabilize the knee for standing and transfers
- Patients who wear an AFO for most activities, but require a KAFO for longer distances or prolonged standing
- Adults with central nervous system disorders including CVA, traumatic brain and spinal cord injuries







Features

- Ring pin fastener attaches or detaches the knee orthosis quickly without the use of tools
- Growth adjustment option for pediatric applications
- Available with practitioner's choice of knee joints/locks
- Compatible with a variety of AFO designs including most TC Flex AFOs
- Patient-selected transfer patterns
- Total contact design fabricated from the practitioner's impression of the limb



FuzionTM Family greater fit, function & freedomSM



KNOW BETTER ORTHOSES

KEY BENEFITS

- Proprietary heat adjustable plastic to enhance the orthotic management programs for challenging patient profiles
- New treatment options for patients experiencing the need to:
 - Address heightened sensitivities to touch, pressure, movement and temperature
 - Decrease excessive loading of ligaments, muscles, tendons and joints
 - Provide circumferential joint and segment stabilization

Fuzion resources available online at www.orthomerica.com/fuzion

- Address unresolved pressures
- Accommodate volume changes
- Optimize wearing opportunities for patients with limited acceptance of more traditional plastic designs
- Easy cleaning for daily, part-time and transitional wearing programs
- Available for both pediatric and adult patients





Group 1 - Hind Foot Control

De	escription	Orthomerica Model #	Cascade Model #
C - A	Sub-Mo Open Sub-Mo Open with MIB*	0510A	DAFO 5 DAFO 5 Softy
	Sub-Mo Wrap Sub-Mo Wrap with MIB*	0511A	N/A** N/A**
	Supra-Malleolar Supra-Malleolar with MIB*	0512A	DAFO 4 DAFO 4 softy



De	escription	Orthomerica Model #	Cascade Model #
B I	Leaf Spring		DAFO 3.5
	Leaf Spring with MIB*	0520A	DAFO 3.5 Softy
	Leaf Spring Combo	0521A	DAFO Two-Step
	Plantar Blocker		DAFO 3
	Plantar Blocker with MIB*	0522A	DAFO 3 Softy
-	Full Blocker Combo		DAFO Turbo
	Full Blocker Combo with MIB*	0523A	DAFO Turbo Softy
	Full Blocker Resting		DAFO 8
	Full Blocker Resting with MIB*	0524A	DAFO 8 Softy

T(flex.

De	escription	Orthomerica Model #	Cascade Model #
	Dorsi-Free Overlap		DAFO 2
	Dorsi-Free Overlap with MIB*	0530A	DAFO 2 Softy
	Dorsi-Free Stretch		DAFO 9
	Dorsi-Free Stretch with MIB*	0531A	N/A**
	Articulating Wrap		DAFO Tami 2
	Articulating Wrap with MIB*	0532A	N/A**
	Articulating Combo		DAFO Tami 2
	Articulating Combo with MIB*	0533A	N/A**



Descr	iption	Orthomerica Model #	Cascade Model #
	Full Blocker Reactor	0540A	DAFO 1 Floor Reactor
	Dorsi-Blocker Reactor	0541A	DAFO 1H
-	Transformer		N/A**
	Transformer with MIB [*]	0542A	N/A**
Available upon request	Floor Reaction Combo	N/A**	DAFO Floor Reaction

PEDIATRIC UFO[®]

The Pediatric UFO from Orthomerica is a comfortable, pre-fabricated orthosis for stretching and maintaining dorsiflexion range of motion. This unique lower-limb orthosis positions the foot and ankle in optimal alignment for placing stretch on the soleus while the patient is sleeping. When used in conjunction with a knee immobilizer, this orthosis can also stretch the two-joint gastrocnemius group.

Indications

- · Cerebral Palsy or other neuromuscular diseases
- · Idiopathic toe walking
- Severs disease
- Tightness at the foot and ankle
- Following Achilles tendon lengthening

Features

- · Copolymer plastic resists strain
- Replaceable CoolFoam[™] interface is comfortable and wicks moisture away from the limb
- Easy strapping system adjusts to increase or decrease the amount of dorsiflexion
- · Non-skid sole on the plantar surface allows limited ambulation in the orthosis
- 45 degree ankle strap holds calcaneus into the heel cup
- Straps can be added to increase forefoot and midfoot control
- Dorsiflexion wedge included to reduce toe grasp and increase dorsiflexion range over time

Infant/ Toddler Shoe Size

Size	Model #	US	UE	UK	Estimated Foot Plate Length	Brace Height
Small	3614	<0-7	16-23	0-6	51⁄4″	61⁄2″
Medium	3615	7-10	23-27	6-9	61⁄2″	8″
Large	3616	10-13>	27-31	9-13	71/2″	101⁄2″

For replacement liners, add .01 suffix, (e.g., 3614.01) Universal sizing fits right or left. For Purple Butterflies transfer pattern, add .02 suffix. For Tornado transfer pattern, add .03 suffix. Surcharge applies for all transfer patterns. White Co-Poly, Butterflies and Tornado transfers are stock items and available for same-day shipment. Other transfer options are subject to additional upcharge and require a two-day lead-time.



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Newport STEM

The Newport Jr Hip System with the new PJ—Virtual[®] Pediatric Joint enhances hip stability by supporting and positioning the hips in optimal alignment while allowing controlled range of motion. This pediatric hip orthosis can be used post-operatively to maintain the corrected surgical position, or can be provided to maximize function during activities of daily living. Improved alignment through the hip encourages appropriate acetabular and femoral modeling, and reduces the tendency for subluxation and dislocation.

INDICATIONS

- Post-operative stabilization of the pediatric hip
- Patients with subluxed hips who require better alignment to relieve pain
- Children needing improved sitting and standing balance

Design Features:

The new lightweight Virtual[®] Pediatric

[oint (P]) weighs only 5.4 oz.

- Universal pelvic module
- Bilateral thigh cuffs
- Washable Coolfoam[™] liners
- Comfortable lumbar pad
- Anatomical design captures and stabilizes the pelvis
- Available in five sizes

VIRTUAL[®] PEDIATRIC JOINT (PJ):

- The smallest and lightest hip joint available in the market
- Adjustable control of flexion, extension, abduction and adduction
- Curved proximal joint attachments provide clearance over the incision and trochanter
- Joints with straight bars available for sale as components

New Adjustable Abduction Bar

The new hip abduction bar self-adjusts to the angle of the thigh cuffs and attaches easily. Designed to provide maximum rigidity, similar to what is provided by a hip spica cast, the Newport Jr with abduction bar is the perfect post-operative orthotic choice.

- Dual sliding bar design: One bar is slotted for maximum adjustability, and the other has predrilled holes for stable fixation
- Thumb screw stabilizes the desired setting and can be released quickly to facilitate entry into cars, doorways, etc.
- Adjustable for up to 30 degrees of abduction on each side





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