PRODUCT OVERVIEW THE ADM MODULAR BRACE SYSTEM™

FOR CLUBFOOT PATIENTS AGED 0 TO 16 YEARS







C-Pro Direct has combined its knowledge and experience of clubfoot brace design with modern materials and manufacturing technology. Footwear manufacture has been revolutionised in recent years through technological improvements. Now the community of clubfoot patients, clinicians and carers can benefit from more comfortable, appealing and flexible bracing solutions. We believe the ADM Modular Bracing System[™] for clubfoot patients represents the most significant advancement in clubfoot bracing for many years.

The Denis Browne and Dobbs style Foot Abduction Braces are the wellestablished standard of care bracing and recommended for most patients with well corrected clubfeet in accordance with the Ponseti Method. But there are also a significant number of patients with more complex needs where other brace types, such as articulating bars, unilateral braces and custom AFOs are necessary. No single clubfoot brace type is right for every clubfoot patient. The bracing system prescribed for a patient may need to change or evolve over time. Moreover clubfoot treatment does not always finish by 5 years of age. Some patients require bracing to continue throughout their teenage years and into adulthood.

The **ADM Modular Bracing System™** for clubfoot patients is the result of a collaboration between C-Pro Direct and a leading large-scale footwear manufacturer. The ADM Modular Bracing System provides the most technologically advanced and flexible system of braces for the broadest range of treatment methods and patient age ranges available anywhere today.

The ADM Modular Bracing System provides the most technologically advanced and flexible system of braces for the broadest range of treatment methods and patient age ranges available anywhere today.

The ADM Modular Bracing System[™]

The ADM Modular Bracing System[™] for clubfoot patients provides, for the first time, a single coherent interchangeable system of braces for all clubfoot patients whatever their bracing requirements.

The system supports idiopathic, complex and syndromic clubfoot patients from 0 to 16 years of age and provides clinicians with the most comprehensive set of bracing options available anywhere. The core components of the ADM Modular Bracing System[™] are:

- The ADM Clubfoot Ankle Foot Orthosis
- The ADM External Rotation Bar
- The Abduction Dorsiflexion Mechanism (with night AFO or ambulatory footwear)
- ADM Ambulatory Footwear



The ADM Modular Bracing System[™] is an integrated system of bracing covering the broadest range of clubfoot patient requirements and ages.



The ADM[™] Ankle Foot Orthosis (ADM AFO)

The ADM AFO forms the core component of the night bracing system. For the first time modern footwear manufacturing technology has been applied to meet the challenging clinical requirements of bracing clubfoot patients. The result is the stunning ADM AFO; the most comfortable, close fitting, lightweight and appealing clubfoot foot orthosis available today. Every detail of the ADM AFO has been designed to promote tolerance of required bracing protocols and clinical effectiveness.



The ADM AFO is constructed from soft, ultra-lightweight and comfortable EVA foam around a rigid core. The AFO combines the best of established clubfoot sandal design principles with modern sports-shoe manufacturing processes and materials. The result is a very comfortable lightweight and appealing orthosis with all the features necessary for the prevention of clubfoot relapse.





The ADM AFO is the only sandal that can be used with both bilateral external rotation bars, and unilateral Abduction Dorsiflexion Mechanisms.

Later in 2021 the AFO will also support the range of Dobbs[™] articulating and conventional foot abduction bars.

A three way stretch tongue system made from flexible materials comfortably secures patients feet without compromising sub-talar or tibiotalar motions.

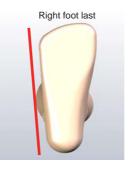


The ADM[™] Ankle Foot Orthosis is striking, comfortable and effective. It is the only orthosis that can be used with both bilateral External Rotation Bars, Dobbs Bars and unilateral Abduction Dorsiflexion Mechanisms

The ADM AFO foot liner has been modelled around real corrected left and right clubfeet to provide a more comfortable and secure fitting AFO than can be achieved with conventional symmetrical straight-lasted sandals. The liner and internal structure incorporate a straightened lateral border and no arch support to facilitate foot shape improvements for clubfoot patients.



Like modern footwear the ADM AFO is constructed using lamination technology to achieve the elusive combination of low-weight, high-strength and comfort. The internal structure includes a counter to achieve the physical and corrective properties required from a clubfoot orthosis.







The internal structural components and strap system are engineered to gently promote lateral border straightening.

Heel progression can be accurately measured using the rear sight hole and and depth aauae tool

The ADM[™] Ankle Foot Orthosis represents a fusion of clubfoot orthosis design expertise and modern large scale footwear manufacturing technology



The ADM[™] External Rotation Bar

The ADM External Rotation Bar provides a modern, lightweight, elegant and convenient to use implementation of the Denis Browne bar style Foot Abduction Brace for clubfoot patients.



Parents just need to use the bar configuration as prescribed for their child. Busy clinics will save time by not having to train parents in bar adjustment. Complications arising from incorrect brace adjustment will also be avoided.



Select 70 or 60 degree clips for bilateral clubfoot and 30 degree clips for the unaffected side in unilateral cases. Use 45 degree clips for atypical clubfoot and or where 70 or 60 degrees external rotation is not tolerated. Measure the patient's shoulder width and select the required bar from the kit provided. When the patient grows simply switch the bar for the next size up.



The ADM[™] External Rotation Bar is elegant, light and effective. For parents and carers it represents a simple, worry-free solution requiring no configuration or adjustment.



Extra Short (and ultra-lightweight) Bars are available in all clip configurations to suit the very smallest patients and where clinicians wish to set the feet less than shoulder width apart.



Select and Insert Clip

Twist and Click

Bar assembly takes just a few seconds. No screws or tools are required to assemble the bar. Just select the bar length you require. Insert the clips, twist and click. Disassembly requires the use of a Clip Removal Tool (tool supplied with each Bar kit).



Cost Limit Guarantee

With every pair of small or large bar clips purchased all the bar lengths required to serve the bracing journey of the patient are provided free of charge. A patient will need just one or two pairs of clips for the duration of the treatment. Clips have a lifetime guarantee.

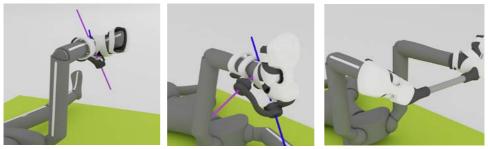
The ADM[™] External Rotation Bar has been designed to increase patient throughput at busy clinics. Just select the required components and deliver the prescribed bar configuration to the parents or carers

The Abduction Dorsiflexion Mechanism provides the only credible unilateral brace option for clubfoot patients and the only bracing option for many more complex patient conditions.



The Abduction Dorsiflexion Mechanism is a device with two rotating mechanisms that, when fitted to an ADM AFO, are anatomically aligned to the patient's Sub-Talar (STJ) and Tibio-Talar (TTJ) joints. The ADM mechanisms are powered by springs which abduct and dorsiflex the patient's foot.

The ADM spring powered mechanisms allow the patient to mobilise their sub-talar and tibio-talar joints normally, but when relaxed in sleep the ADM moves the foot into a position of abduction and dorsiflexion. During sleep the ADM maintains a corrected foot position and a long duration low-intensity stretch to the tendons and ligaments of the foot and lower leg.



Biomechanical analysis using advanced digital animation has demonstrated the ADM and Denis Browne bars achieve similar foot positions. The two devices work very differently, but ultimately achieve a similar outcome. C-Pro Direct does not advocate one type of device over another, but regards the availability of additional bracing options as a major benefit to the patient community. Our experience is that no single device represents the best option for every patient at every time.

For many patients with more complex needs the ADM[™] represents the only viable bracing option. Our experience is that no single device represents the best option for every patient at every time





Abduction Dorsiflexion Mechanisms attach to footwear via the ADM Side Clip System. ADMs may be attached to ADM Ankle Foot Orthosis as a night brace, but may also be attached to adapted ambulatory footwear or even custom AFOs.

ADMs are not generally used as the first bracing option for uncomplicated Clubfoot patients, but may be used this way out of preference. There are many examples of patients who have used the ADM exclusively as their only brace and have now successfully completed their clubfoot treatment.

ADMs are currently most frequently used when there are issues tolerating the Denis Browne style of brace or when more standard treatment is failing, and an alternative conservative option is being sought. Very often this can be when the patient is hypermobile, is relapsing, experiencing blisters and sores or has other complications. Older children who require ongoing bracing very often accept the ADM more readily than External Rotation Bars.

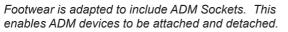
A significant advantage provided by the ADM Modular Bracing System is that a single ADM Ankle Foot Orthosis accommodates **both External Rotation Bars and ADMs**. This greatly facilitates investigating alternative brace options when required.

By sharing a common side clip system it is now possible to use ADMs and External Rotation Bars with a single Ankle Foot Orthosis.

The Abduction Dorsiflexion Mechanism (Ambulatory ADM™)

The Abduction Dorsiflexion Mechanism attached to adapted normal daytime footwear creates an ambulatory AFO that simultaneously abducts and dorsiflexes the foot during ambulation. For patients with residual dynamic supination, even after correction, or patients with complex ongoing needs the ambulatory ADM can be a highly effective treatment option.





Footwear can be adapted by C-Pro Direct or by other O&P workshops using ADM Footwear adaption kits. Footwear adaption kits also allow ADM Sockets to be incorporated into custom made AFOs when there are very specialised patient requirements.





The ADM[™] design has been changed to share a common side clip system. Now all ADMs can be used as both night-time and ambulatory devices.

As an ambulatory orthosis the ADM modifies the patient's gait. Stride length is increased, heel strike improved and inward rotation decreased. Patients using the Ambulatory ADM frequently report increased endurance and mobility and comfort compared with other orthoses.









1. Initial swing phase: The patient shows evidence of walking in varus without the ADM.

2. Mid swing phase: The ADM is correcting heel varus and heel strike is now in slight valgus.





3. Terminal swing phase: The ADM enables a more active heel strike, there is less internal rotation and greater dorsiflexion.





Centre of Pressure (COP): COP analysis illustrates how the ADM modifies the COP of a patient with a supinated gait to reduce pressure on the lateral border

Typical patient Centre of Pressure profile without ADM (Red line) and with ADM (Green line)

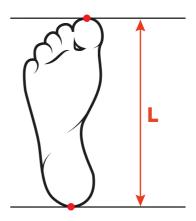
When used as an ambulatory bracing system the ADM[™] can immediately achieve significant gait improvements providing patients with greater mobility endurance and confidence.

Product Size and Configuration Guide

Ankle Foot Orthosis

Clubfoot Ankle Foot Orthosis' should fit closely to the patient's foot. The toe strap should cover the toes and the toes should not extend beyond the end of the AFO liner. The size guide below provides for some growing room. To select the required size measure the foot length as shown in the diagram. This can be achieved without special equipment by standing the patient on a sheet of paper and drawing the two parallel lines at the heel and toe. Then use a ruler to measure the length L in millimetres (mm). So for example a 120mm foot would normally require a size 4 AFO. This would allow for at least 7mm of growth.

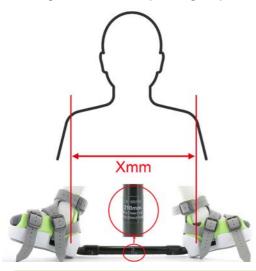
Foot Length L (mm)	Sandal Size		
67 to 70	0000		
71 to 75	000		
76 to 80	00		
81 to 87	0		
88 to 92	1		
93 to 102	2		
103 to 112	3		
113 to 122	4		
123 to 132	5		
133 to 142	6		
143 to 152	7		
153 to 162	8		
163 to 172	9		
173 to 182	10		
183 to 192	11		
193 to 202	12		



The sizing table above provides for growing room. It is important not to use AFOs that are too large for the child as the therapeutic function of either the External Rotation Bars or ADMs may be compromised

ADM Modular Bracing System[™] Bar Selection

External Rotation Bars are generally adjusted to set the heels of the AFO at shoulder width apart. However, it is recognised clinicians may prescribe shorter or longer bar widths depending on patient indications.



NOTES:

Select the length of bar that corresponds most closely to the patient's shoulder width (Xmm) or the distance between the heels of the orthosis required.

Bars are available in 20mm width increments from 130mm to 350mm.

Extra Short Bars are supplied with permanently attached clip ends. Therefore Clip angle requirements must be specified with each Extra Short Bar order e.g., 130mm Left 30 degrees Right 60 degrees.

Orderable Bar Type	Width Between Heels (mm)	Sandal Compatibility	
Extra Short Bar	130 to 150	0000 to 5	
Small Bar Kit 1	170 to 250 (5 bars)	0000 to 5	
Small Bar Kit 2	270 to 290 (2 bars)	0000 to 5	
Large Bar Kit 1	250 to 310 (4 bars)	6 to 12	
Large Bar Kit 2	330 to 350 (2 bars)	6 to 12	
Single Bars	All sizes (1 bar)	0000 to 12	

The Small and Large Bar Kit 1s (in bold text)will support most patient requirements throughout their treatment.

Zero Cost Bars

For every pair of small or large bar clips purchased all the bar lengths required to serve the bracing journey of the patient are provided free of charge. A patient will need just one or two pairs of clips for the duration of the treatment. Clips have a lifetime guarantee.

Bars kits are free of charge for each pair of clips purchased. Discounts on bar clips are available for packs supporting 10 or 25 patients.

ADM Modular Bracing System[™] Clips

ADM Modular Brace Bar Clips have a fixed angle. They come in two sizes, Left and Right and four abduction angles (70, 60, 45 and 30 degrees).

For example an order for a Left side unilateral clubfoot patient, size 2 AFO would require a Small Left 60 and a Small Right 30 clip.

Clip Range	External Rotation Typical Angle (deg) Application		
Small	70	Clubfoot	
Small	60	Clubfoot	
Small	45	Complex clubfoot	
Small	30	Non-Clubfoot	
Large	70	Clubfoot	
Large	60	Clubfoot	
Large	45	Complex clubfoot	
Large	30	Non-Clubfoot	

The Small Clip range is for AFOs size 0000 to 5. The Large Clip range is for AFOs size 6 to 12.

Lifetime Guarantee

Bar clips have a lifetime warranty. For a single child the maximum amount spent will be either 1 or 2 pairs of clips for the whole bracing journey.

This image is of a Left 60 degree and Right 60 degree bar configuration as would be typically used on a bilateral clubfoot patient





Busy clinics treating many patients may prefer to keep a stock of a range of clips and bar kits. Discounts are available for packs of 10 and 25 which significantly reduces the cost of treatment.

Abduction Dorsiflexion Mechanism[™]

ADMs are supplied in eight sizes from XXXS to L. An additional Extra Large (XL) size is also available on request for small adult feet over 202mm in length. ADM Size selection is based on foot length using the table below. When placing orders the required ADM spring configuration must also be specified. Most clubfoot patients with well corrected feet will achieve a good position and a degree of stretch that can be tolerated during sleep with **Standard STJ** (Sub-Talar Joint) and **Standard TTJ** (Tibio-Talar Joint) springs. However, Stronger and Softer options for these springs are also available. For help, advice and guidance on ADM sizing or spring selection please contact C-Pro Direct by email at **clinicalsupport@c-prodirect.com**.

L Foot Length Range (mm)	ADM Size	AFO Size	H2 Max Height (mm)	H1 Min Height (mm)
81 to 92	XXXS	0 to 1	115	65
93 to 102	XXS	2	136	76
103 to 122	XS	3 to 4	156	76
123 to 132	S	5	185	76
133 to 142	SM	6	188	84
143 to 162	М	7 to 8	210	90
163 to 182	ML	9 to 10	223	103
183 to 202	L	11 to 12	250	103
203 to 272	XL	n/a	270	115
203 to 272	XL	n/a	330	115



When fitted the top of the ADM must not extend close to the patient's Popliteal crease (P) as this will cause discomfort.

Please contact C-Pro Direct if XL sizes are required. Additional details may be required to ensure an optimal configuration. X-L ADMs are available in standard height (H2=270) and long (H2 = 330). They are also available for standard and wider calf circumferences.

C-Pro Direct is always on hand to provide advice on ADM[™] sizing and spring selection. More help is available at www.c-prodirect.com

c-prodirect



All enquiries contact us at adm@c-prodirect.com

TRY NOW

Contact us to try out the world's most advanced Clubfoot bracing system Distributor enquiries welcome



BOX CONTENTS: 1. ANKLE FOOT ORTHOSIS (1 PAIR) 2. TONGUE KITS 3. HEEL POSITION GAUGE 4. INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE

THE READ THE INSTRUCTIONS FOR USE

▲ 孝 NOT STERILE KEEP AWAY FROM DIRECT SUNLIGHT KEEP DRY

С-РИО DIRECT_UD_EDENNINGER_KENT_INNTED КИМОДОМ_ET_ED_ROD DIRECT_D_RAMO LIMITED КИМОДОМ_ETEED (CONTRACT, CONTRACT, C

www.c-prodirect.com 0044 (0) 1732 860 158 adm@c-prodirect.com

The ADM Modular Clubfoot Brace System[™] products are manufactured by C-Pro Direct Ltd, an ISO 13485 certified company and are labelled and packaged to comply with UK, European (MDR) and US regulations for Class 1 Medical Devices. All products are protected by a range of international patents and patent applications and all rights are reserved. ADM Modular Brace System[™], ADM[™] and ADM Ponseti[™] are Trademarks of C-Pro Direct Ltd.



C-Pro Direct Ltd. 7a Enterprise Way, Edenbridge, Kent UK. TN8 6HF