Instructions for Use

Ambulatory Abduction Dorsiflexion Mechanism (ADM)

1 Intended Use / Contraindications

The Ambulatory Abduction Dorsiflexion Mechanism (ADM) comprises an ADM device and ambulatory footwear that has been made or adapted to connect to an ADM. The Ambulatory ADM may be worn unilaterally or bilaterally by patients with a range of conditions affecting the main joints and motions of the ankle and foot - specifically the sub-talar and tibio-talar joints. Ambulatory ADMs are suitable for a range of conditions that result in an abnormal (typically supinated) gait. This includes Clubfoot and some neurological and muscular conditions. Ambulatory ADMs should be used as directed by a qualified clinician to achieve a specific purpose, such as maintenance of improved foot position or range of motion and gait improvement. Patients with poor ambulatory potential, such as triplegics and quadriplegics are not indicated for ambulatory ADMs.

2 Device Function and Purpose

Ambulatory ADMs alter the resting foot / ankle position and gait. Gait alterations typically include reversal of a tendency to supinate (ie., for the foot to turn inwards and downwards). Expected gait alterations include a lengthening of the stride, prevention of foot-drop, improved heel-strike and a reduction of inward rotation at the hip and knee. Patients with neurological conditions may also experience improved balance, endurance and confidence. Range of motion improvements may also be achieved with prolonged consistent use.

③ Package Contents

An Ambulatory ADM system comprises:

- One or two ADM devices with a side clip system for attachment to footwear.
- Pootwear, typically a pair of adapted shoes. Depending on the requirement, one or both items of footwear will be modified to incorporate an "ADM Socket" which enables attachment of an ADM device
- Two ADM Removal Tools to enable removal of the ADM device from the footwear.



4 Detachable ADM

The ADM may be attached and detached from the footwear. It is a matter of personal preference whether the footwear is donned before or after attaching the ADM. Some users may find it more convenient to leave the ADM permanently attached, others may prefer to detach the ADM from the footwear after removal.

Warning: Do not use footwear incorporating an ADM Socket without the ADM attached. This may result in permanent damage to the ADM Socket renderaing the device unusable.

5 Attaching ADM to Footwear

- Carefully insert the ADM device side clip into the ADM Socket. Note: The ADM mechanism is positioned laterally, ie. on the outside of the ankle (the photo below is of a left side device).
- Press firmly until two distinct "clicks" are heard and felt as each side of the ADM side clip engages with the footwear socket.





6 Detaching ADM from Footwear

- **6** Carefully insert the ADM removal tools into the holes on each side of the footwear until you can feel the tool engage with the ADM side clip.
- Gently push both removal tools and the ADM device should unclip from the footwear





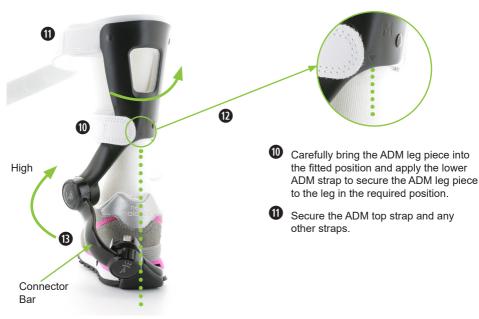
7 Fitting the ADM



Fit the footwear as normal with either the ADM detached or attached to the footwear. If the ADM is attached then the leg piece should be positioned to the side of the leg.

Make sure the footwear laces, straps or fixings firmly secure the footwear to the patient's foot. Use the extra lace hole if available to achieve the most secure fit.

9 If appropriate attach the ADM to the footwear as described at steps 4 and 5.



8 Confirm ADM is Correctly Positioned on Leg

With the patient's foot and ankle in a neutral position check the ADM device is correctly positioned on the leg. A neutral position means the foot is positioned relative to the leg such that there is zero dorsflexion or plantarflexion at the tibio-talar joint and zero inversion or eversion at the sub-talar joint.

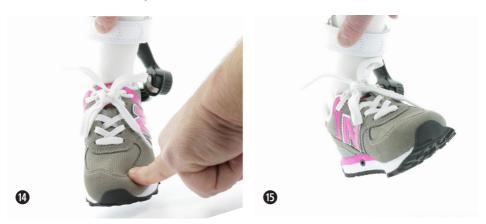
- $oldsymbol{arrho}$ The small arrow on the leg piece should be at the centreline of the leg.
- The ADM Connector Bar should be high and close to the limit of its allowable range of motion.

9 Verification of Function

On first fitting a clinician should observe the patient walking in the ADM and determine that the device is altering the gait or positioning the foot of the user as intended. If the device is not performing as intended it should not be used. Often changes in ADM spring strength configuration can make significant changes to how the device impacts on the user.

The simple test illustrated below can be undertaken to confirm the basic function of the ADM on the patient in a fitted condition.

- With the user relaxed stabilise the leg and press the foot into a position of plantarflexion and inversion.
- Release the foot and the ADM will move the foot about the patient's tibio-talar and sub-talar joints towards the limit of their range of motion.



Warnings and Precautions

- Use only in accordance with these instructions and as directed by your clinician. Patient's with flatfoot (collapsed foot arches) should use footwear providing arch-support to achieve a neutral subtalar position when standing. If required custom insoles should be used.
- Do not use if the patient is experiencing pain, blisters or sores through use of the device or if the
 patient's gait is less satisfactory than without the device. In these circumstances consult your
 clinician.
- Do not dis-assemble or tamper with the ADM mechanism. Do not use the ADM if any part is damaged, not functioning or does not correctly fit the patient.
- Clean using warm water and mild detergent, avoid avoid excessive wetting. Do not immerse
 products in water and do not put ADM or footwear in a washing machine. With the ADM detached
 from the footwear use the ADM Removal Tools and water to rinse mud or dirt from the ADM socket
 areas.
- User's may engage in mild active play whilst using the ADM, but use during contact sports or
 activities such as climbing risks damaging the device.
- Device is not sterile and supplied for use by the original end user only. The device may be
- returned to C-Pro Direct for safe disposal or disposed / recycled as other household items. Store between 2 degree
- and 22 degree Centigrade. Keep out of direct sunlight, clean and dry.
- Visit www.c-prodirect.com or contact C-Pro Direct for further support and guidance.
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