

INSTRUCTION FOR USE
Ponseti® Lite Foot Abduction Bracing (FAB) System
Ponseti® Lite Boots
Ponseti® Lite Bar

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Intended Use & Indications

The Ponseti® Lite FAB is intended for use with children whose clubfoot is being corrected with the Ponseti Method of treatment. The Ponseti® Lite Bar and Ponseti® Lite Boot comprise the Ponseti® Lite FAB System.

Ponseti® Lite FAB is for managing the advised width and orientation of the corrected clubfoot. The adjustable width bar system utilizes multiple clip locations to accommodate patients throughout the treatment plan and easily clips on and off the Ponseti® Lite Boots by means of “Quick Clip” system. Dorsiflexion and abduction are controlled with the geared quick clip in 10 and 15 degrees. This system provides greater ease of use.

The Ponseti® Lite Foot Abduction Brace (FAB) is intended for the use in the Ponseti Method of treatment for the correction of Congenital Talipes Equinovarus (CTEV) in infants and children less than or equal to eight years of age. The brace is intended to prevent relapse (equinus and varus deformity of the heel).

Clinical Benefits:

The MD Orthopaedics Ponseti Lite FAB System retains the position of the anatomically corrected clubfoot deformity until the health care provider indicate the device is no longer needed following successful manipulation and casting as described by Dr. Ignacio Ponseti (the Ponseti Method), with a relatively low risk of relapse/recurrence and/or surgical intervention.

Manufacturing Information

MD Orthopaedics, Inc.

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1-877-766-7384

The manufacturer is not liable for cases of material damage or personal injury caused by incorrect handling or non-compliance with instructions. In such cases, the warranty will be voided. Warranty of the Ponseti Lite FAB System is one year under normal use. Normal use is defined as a single user following intended use.

MD Orthopaedics does not provide medical treatment, advice or recommendations about the risks and benefits of medical treatment, including treatment that involves the use of MD Orthopaedics products. This information should be provided solely by the health care provider treating your child. If you have questions about your child’s treatment, it is important for you to discuss those questions with the appropriate health care provider.

Cleaning Instructions

Ponseti® Lite Bar

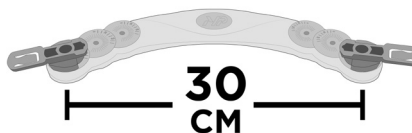
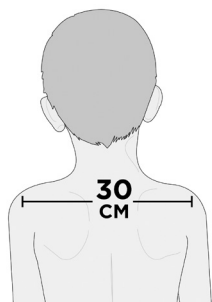
Cleaned by using a mild detergent and damp cloth. Do not submerge.

Ponseti® Boots

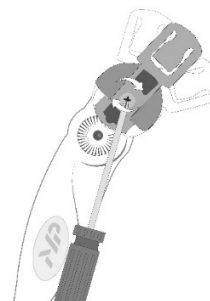
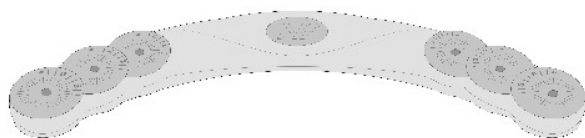
Hand or machine wash using cool water, and mild detergent. A gentle washer cycle may be used. Air dry, do not place in dryer. Do not use hot water when washing.

Preparation

The Ponseti Lite FAB System is shipped at room temperature and requires no special handling during transport or storage.



Step 1



Step 2



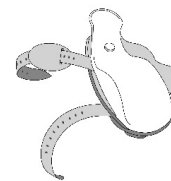
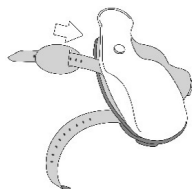
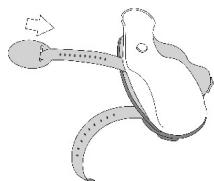
Step 3

Note: It is important to attend all scheduled provider appointments to ensure that shoulder measurements and bar width adjustments are completed properly.

For sizing information email info@mdorthopaedics.com

1. The width of the bar should match the shoulder width of the child to determine where quick clips need to be. The clips should be set that the width of the bar is equal to – or even slightly wider than the measurements of the child’s shoulders.
2. Insert screw into the Quick Clip at desired dorsiflexion advised by health care provider. Use a #2 Phillips head screw driver to screw quick clip securely to the bar.
3. Set bar aside to place boot on to the child’s foot.

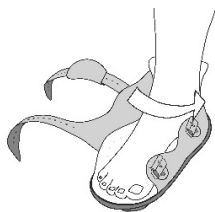
Boot Instructions



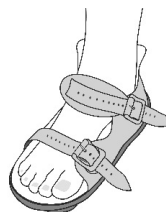
Step 1



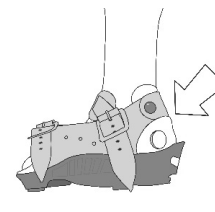
Step 2



Step 3



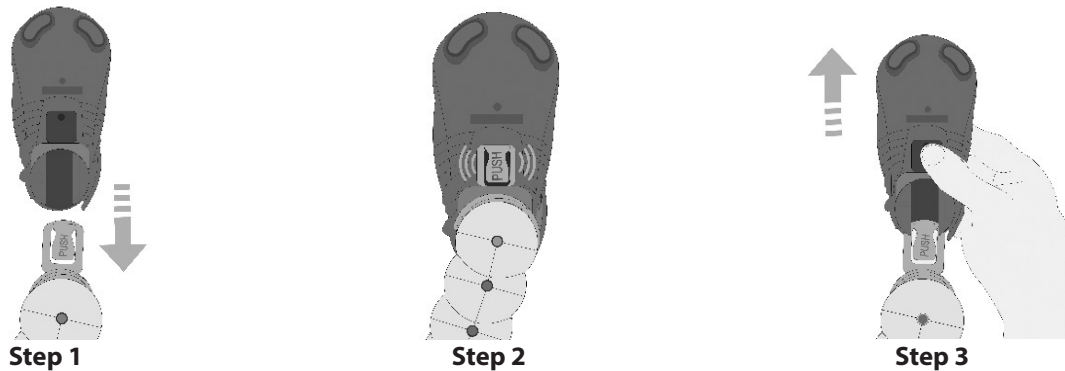
Step 4



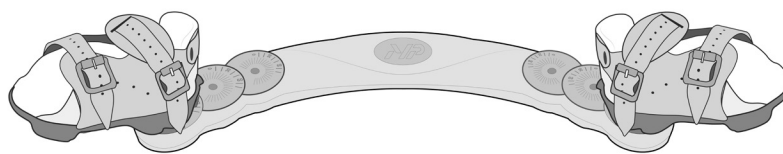
Step 5

1. Insert the top strap through the loose leather piece.
2. Insert the child's foot into the open boot, with the buckles on the inside (facing the other foot).
3. Secure the top strap and buckle it firmly in place.
4. Fasten the toe strap, making sure that the child's foot is flat and the toes are straight. Make sure it is just tight enough to keep the Boot in place.
5. Check the hole at the back of the Boot for proper placement of the heel.

Connecting Boot and Bar Instructions

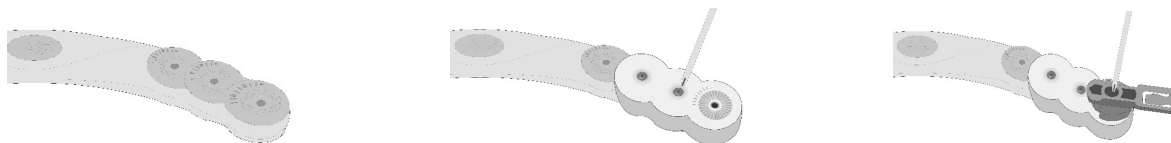


1. Insert the clip into the sole of the Boot.
2. Push until you hear a "click". Verify that the Quick Clips are engaged by pulling on the boot to make sure it does not disconnect from the bar.
3. To disconnect the Boot from the bar, push firmly on the "PUSH" while pulling back on the bar until it slides free.



Shown above is the Boots and Bar fully assembled.

Adding Extensions



1. Place the extension over the bar
2. 2 screws will need to be screwed in using a Philips screw driver. Make sure screws are tight.
3. Once extension is secure, place clip at desired position on the bar and screw the quick clip on to the extension.
4. Once Clip is secure to the bar follow Boot instructions.

Inherent Risks & Contraindications

Never use boots or bar that is damaged, broken or not functioning properly.
Modification is not recommended for the Ponseti Lite FAB System.

Safety Information Regarding Use

- o Follow the qualified health care provider instructions or treatment plan.
- o Consult your health care provider immediately if the child is experiencing pain, blisters, sores, or if the boot is visibly slipping on the child's foot.
- o Socks should be worn when wearing the boots.
 - Note:** The use of socks lowers the risk of the Boot slipping, pain, redness, blisters, and sores.
- o Children should not stand or walk in the boots and bar.

If a user and/or patient experiences any serious incident that has occurred in relation to the device, it should be reported to the MD Orthopaedics, Inc. and the competent authority in which the user and/or patient is established.
















Safe Disposal


The boots and bar can be disposed of in the regular trash. None of the components of the device are recyclable.


Reusing the Device


All parts were designed to be used by a single patient under normal use conditions and as prescribed by a health care provider. Normal use includes the daily application of the boots and bar up to 23 hours per day, or as recommended by a health care provider.


Symbol Legend

Symbol	Meaning	Symbol	Meaning
	Boots		Caution
	Authorized Representative in the European Community		Date of manufacture
	Manufacturer		Importer of record
	Single Patient, Multiple Use		Non-sterile
	Indicates Item is a Medical Device		Catalog number
	CE Mark (in compliance with Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on Medical Devices)		Batch code
	Information considered important, but not hazard-related		Electronic Instructions for Use
	Authorized Representative in Switzerland		

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