Pavlik Harness - Instructions for Use

REF PAV

The following should be read thoroughly before use:

Important Notes:
This document is designed to provide instructions on how this product/s is used. It is not a reference to clinical techniques, and does not replace local or national guidance or protocols.

Intended User:
For use by both suitably trained healthcare professionals in a healthcare establishment and 'Lay Users' in a home use environment.

Intended Purpose:
Provides stability to the hip.

Indications For Use:
- Subluxation and congenital hip luxation
- Hip dysplasia

Product Characteristics / Features:
- Soft lined fabric straps for comfort
- Hook and loop fastening for ease of adjustment and secure fit
- Booties to help keep the feet in place

How it's supplied:
It is supplied non-sterile, ready for single patient multiple use.

Devices Required For Use, And Interoperability Requirements:
None

Storage Conditions:
Store in a cool and dry environment.

Contraindications:
None

Care and Maintenance:
- The harness should be washed by hand with a gentle detergent and then drip dried - a tumble drier can be used but the harness should be dried on its own and on a "no heat" setting.
- Do not expose to alcohol, ointments or solvents.
- The device should be safety checked by the providing service and/or user every 6 months.

Precautions / Warnings / Residual Risks:
If allergic skin rashes occur, please consult your healthcare professional

Possible Adverse Reactions:
None

Single Patient Use Precaution:
This device is designed and sold for single patient use only. The effects of any unauthorised reuse can result in the following complications:
Risk of Cross contamination;
Risk of mechanical fatigue, and/or associated failure.

Serious Incident Reporting
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Disposal
Discard and dispose of as common waste according to national guidelines.

Directions For Use / Fitting Instructions:
1. Lie the child down on the V-portion of the harness.
2. Fasten the chest strap just below the armpits (leaving a little clearance).
3. Attach the shoulder straps to the front of the chest strap.
4. Place the child's feet into the booties, ensuring the heel is positioned at the back of the bootie.
5. Position the leg straps through their buckles and pull through to the desired position of flexion/adduction.

Please see Parent's Guide overleaf.

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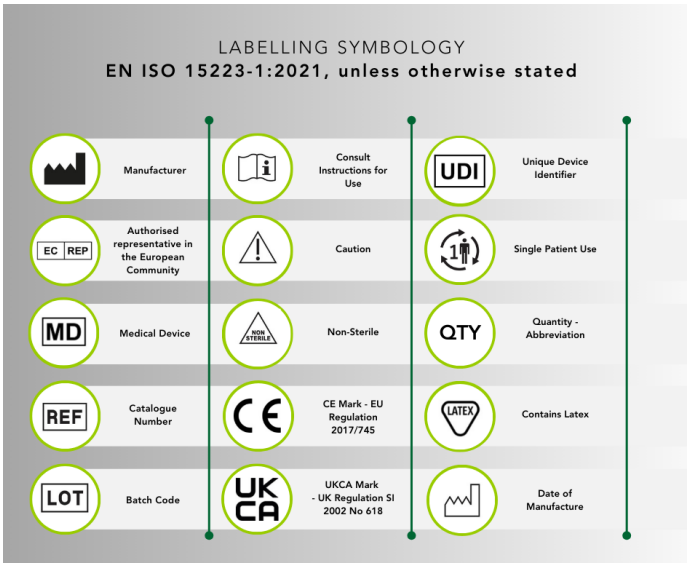
Guide for Parents:

- Your Orthotist or clinic will have fitted the harness and made the necessary adjustments to the shoulder and leg straps to hold the hips in the best position for proper hip development.
- Don't take the harness off or make any adjustments to the straps unless your Orthotist or clinic tells you to.
- Follow the wearing instructions given by your Orthotist or clinic (the harness may need to be worn all the time and next to the skin at first).
- Watch for signs of skin irritation - if this becomes a problem, go back to your Orthotist or clinic.
- If bathing out of the harness is not allowed, a daily sponge bath should be carried out instead. You may unbuckle the shoulder straps one at a time to change clothing and have a second person hold the hips in a flexed/abducted position.
- Once the hip has stabilised you may be told that the harness can be taken off for a time. Please follow the instructions provided by your Orthotist.
- Mark the position of all the straps so that the harness can be re-fitted in the same position after washing.
- Your baby will need to visit the Orthotist or clinic regularly for check-ups and adjustments to be made - REMEMBER to re-mark the straps with any new adjustments.

Sizes & REF / Codes

Size	Age	Chest Circumference		Code
		Inches	CM	
X Small	Early Baby	12 - 14	30 - 36	PAV-XS
Small	0 - 3 Months	14 - 16	36 - 41	PAV-S
Medium	3 - 6 Months	16 - 18	41 - 46	PAV-M
Large	6 - 9 Months	18 - 21	46 - 53	PAV-L
X Large	9+ Months	21 - 23	53 - 58	PAV-XL



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