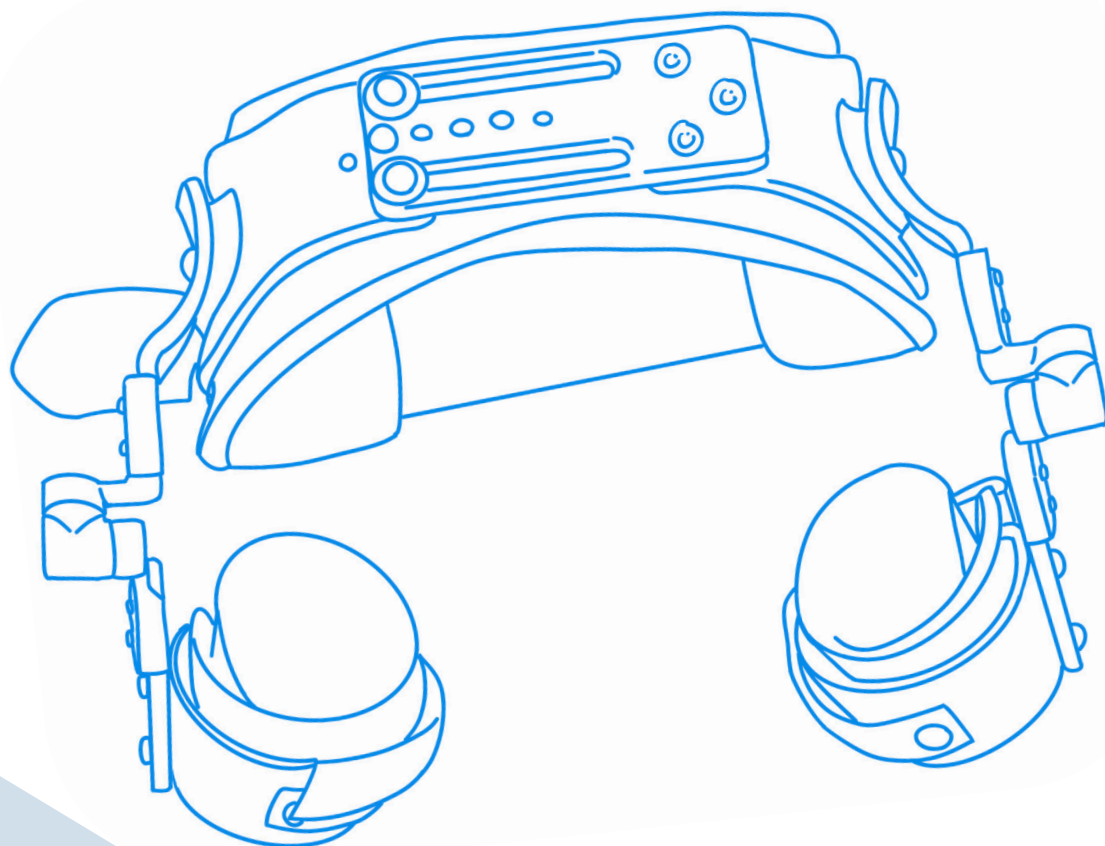




PediSMHipTM

Rigid Brace

User Manual

Intended Use

The PediHip™ Rigid Brace is intended for treatment of Developmental Dysplasia of the Hip (DDH) and post-operative stabilization in pediatric patients ages three years and younger, as instructed by a healthcare provider.

Device Summary

The **PediHip™ Rigid Brace** is a bilateral hip abduction brace that maintains DDH correction, and is available in **7 sizes (XXS – XXL)**. The brace is bilateral in nature and comes fully assembled. All braces come with a **Hex driver** and **Socks**.

The brace consists of the following interchangeable components which were designed to be used by a single patient under normal use conditions including the daily application of the brace as instructed by a Health Care Professional (HCP):

Hip hinges: allows for HCP adjustment of flexion/extension as well as abduction/adduction as needed. The hinge for flexion/extension and abduction/adduction has a significant range of flexibility from -90° to $+90^{\circ}$. A $1/8"$ hex driver is used to adjust flexion/extension and abduction/adduction.

Thigh cuffs: wrap around the anterior of the thigh and anchors the hip hinge. *Thigh cuffs are compatible with all PediHip™ braces and are interchangeable between sizes.*

Rigid pelvic section: comprised of rigid co-poly plastic and foam to maintain the hip position and provide a secure attachment for the hip hinges.

Posterior brace adjustment: located on the back of the brace and allows the HCP to change the width of the brace to the appropriate patient size.

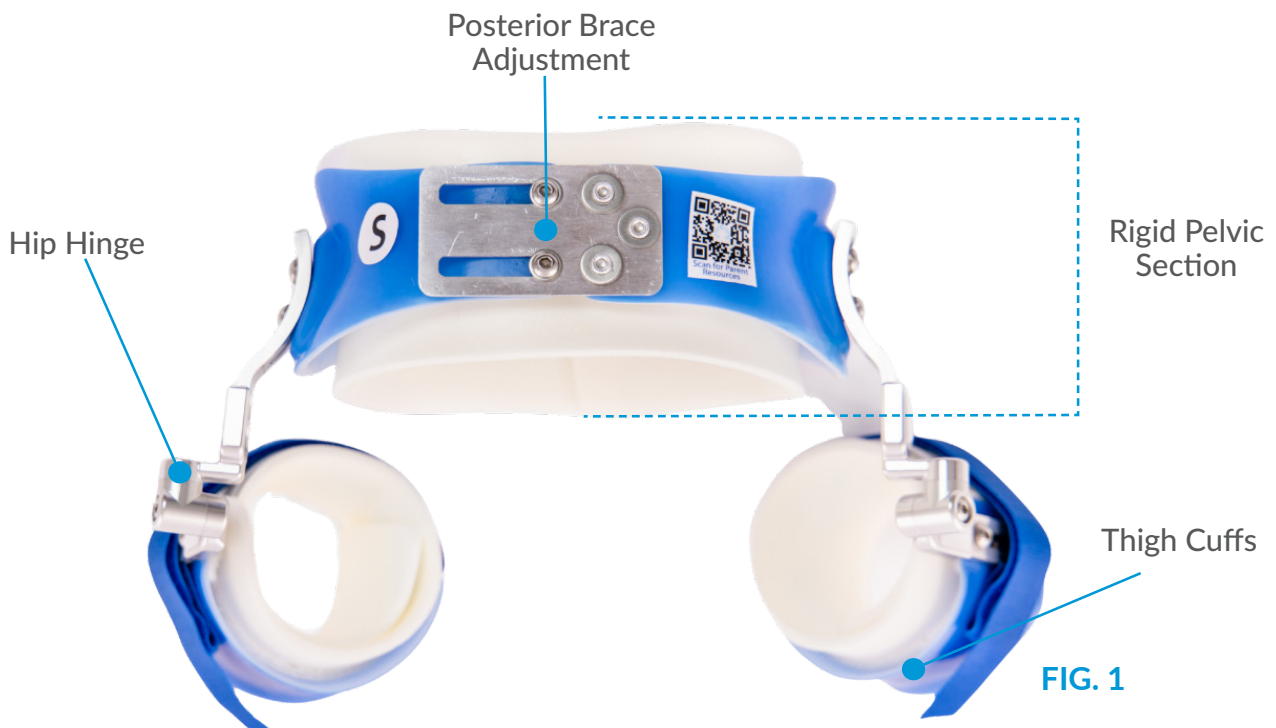


FIG. 1

Determining Proper Brace Size

Selecting the proper brace size is critical to the patient’s comfort and the outcome of their treatment. The following measurements should be taken (See fig 2):

- Pelvis Medial to Lateral
- Mid Thigh Circumference
- Upper Thigh to Knee Center

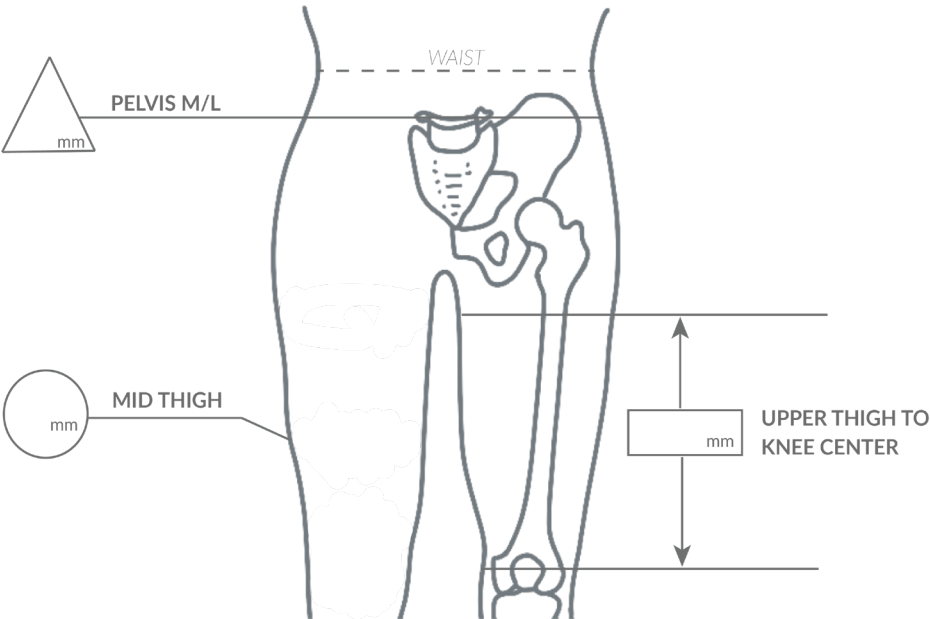


FIG. 2

Size	Pelvis Medial to Lateral Width (mm)	Mid Thigh Circumference (mm)	Upper Thigh to Knee Center (mm)
XXS	105-135	170-185	60-80
XS	130-160	205-235	70-90
S	155-185	235-270	75-100
M	178-212	270-300	90-120
L	203-238	300-330	105-140
XL	225-265	330-360	120-160
XXL	250-290	360-390	135-180

How to Adjust the Brace

Once the proper brace size is selected, the brace can be adjusted to ensure the correct fit. The posterior pelvic section is adjusted with a 1/8" hex driver. Based on the desired width, the posterior screws can be loosened, moved and then retightened to the new width.

The thigh cuff position can also be moved relative to the distal hinge bars so that it is in an ideal position on the patient's thigh. If this is adjusted, Loctite should be re-applied to the screws to prevent loosening. **Ensure all screws are TIGHTLY locked and use Loctite if necessary, taping over screws if necessary.**

Hip hinge can be adjusted for the desired amount of flexion/extension and abduction/adduction using the same hex driver. **Do not articulate hip hinge outside of a clinically acceptable range. The hinges must be locked in place.**

**Note* The hip hinge from the DF2® Brace could also be swapped onto this brace if the ability to unlock the hip hinge is desired.*



FIG. 3 Close up hip hinge



FIG. 4 Close up of posterior adjustment



FIG. 5 Thigh cuff adjustment

Applying the Brace

1. Prior to applying the brace, take any necessary measurements and determine brace size. Pelvic M/L and thigh circumference should be measured for every patient.
2. Make as many adjustments as possible prior to applying the brace, utilize posterior adjustment section to match brace to the patient's M/L width before applying (see fig 4). If any modifications are made to the brace, ensure there are no sharp edges.
3. Ensure all Velcro straps are undone.
4. Adjust hip hinges (see fig 3) to approx. amount of flexion and abduction before putting on the patient.
5. Apply stockinette/clothing to patient's thighs to provide a layer of protection between the child's skin and the brace. *Ensure there is a barrier between the patient's skin and the brace.*
6. Place patient in the brace, and their thighs into the thigh cuffs.
7. Adjust the Velcro around the thigh cuffs and patient's waist until they are snug.
8. Excess material on thigh cuffs can be trimmed as desired.
9. Make any final adjustments to hip hinges and lock in place.

Suggested Follow Up Protocol

Caregiver Information

It is important to clean the foam liner of the orthosis on a **daily basis**. The foam will not absorb moisture, but perspiration will collect on it.

Cleaning Instructions

Remind parents it is important to wipe down the foam liner of the brace **on a daily basis**. The foam will not absorb moisture, but perspiration will collect on it.

- ◆ Clean the brace with 70% rubbing alcohol, or warm soap and water.
- ◆ The brace should be allowed to air dry, do not use a hair dryer or other heat source.
- ◆ The brace needs to be dry before putting it on.

Tips for Clinics

- ◆ Check for any **loose screws** and tighten them as needed, Loctite may be required!
- ◆ Pick the patient up by under their arms or their bottom, and you may hold the child normally.
- ◆ Keep a **protective barrier in between the brace and the patient**– socks, clothes, etc.
- ◆ Infant/toddler leg warmers work well as a soft interface to help further protect the skin.
- ◆ **Diapers can be changed while the brace is still on the child's legs.** Undo the Velcro waist strap and change the diaper.
- ◆ Car seats should be secured as recommended by the car seat manufacturer.

Safe Disposal

The brace can be disposed of in regular trash. None of the components of the device are recyclable.



*Scan for Our Rigid
Brace Resource Library*



Important Statements

OrthoPediatics Specialty Bracing (OPSB) does not provide medical treatment, advice or recommendations about the risks and benefits of medical treatment, including treatment that involves the use of OPSB products. This information should be provided solely by the physician or other qualified health care provider treating the patient. The appropriate HCP should be discussing questions about treatment with the patient and family.

The manufacturer and distributor are not liable for cases of material damage or personal injury caused by incorrect handling or non-compliance with instructions. Normal use is defined as a single user following intended use.

Instructions for Use (IFU) manuals are available in English and other languages at <https://opsb.com> (Regulation (EU) 207/2012). To obtain a copy of the paper IFU, please call Customer Service at (877) 766-7384.

Contra-indications

Do not use if the PediHip™ Rigid Brace is damaged, broken or not functioning properly.

Warnings

Patients must follow the qualified HCP's instructions for the treatment plan.

Follow instructions to ensure straps are tightened properly, to reduce risk of irritation, blisters, and pressure ulcers.

If the patient is experiencing pain, irritation, blisters, swelling, pressure ulcers, or if the brace is not fitting properly this should be reported to the HCP immediately.

Protective barriers (i.e. clothing) should be worn when wearing the brace. Do not apply the brace directly to the skin.

All parts were designed to be used by a single patient under normal use conditions and as instructed by a clinical provider. Normal use includes the daily application of the PediHip™ Rigid Brace.

MRI Safety Information



The PediHip™ Rigid Brace is MR unsafe and should remain outside the MRI scanner room.

Part Numbers: Rigid Brace Assembly

PART NUMBER	PART DESCRIPTION	GTIN
NS-5001-2001	PediHip Rigid Brace, XXS	00840194496346
NS-5001-2002	PediHip Rigid Brace, XS	00840194464970
NS-5001-2003	PediHip Rigid Brace, S	00840194464987
NS-5001-2004	PediHip Rigid Brace, M	00840194496889
NS-5001-2005	PediHip Rigid Brace, L	00840194497145
NS-5001-2006	PediHip Rigid Brace, XL	00840194497152
NS-5001-2007	PediHip Rigid Brace, XXL	00840194497169

Part Numbers: Replacements

03-5001-2010	Pelvic Section Foam Pad, XXS	00840194497770
03-5001-2011	Pelvic Section Foam Pad, XS	00840194497787
03-5001-2012	Pelvic Section Foam Pad, S	00840194497794
03-5001-2013	Pelvic Section Foam Pad, M	00840194497800
03-5001-2014	Pelvic Section Foam Pad, L	00840194497817
03-5001-2015	Pelvic Section Foam Pad, XL	00840194497824
03-5001-2016	Pelvic Section Foam Pad, XXL	00840194497831

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PediHip™



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