



OrthoPediatrics Corp.
2850 Frontier Drive
Warsaw, IN 46582 USA
Tel: 574-268-6379



R_x ONLY



Above symbols are valid only if also printed on the device label.



**IFUs &
Symbol
Glossary**

www.orthopediatrics.com/ifu

ORTHOPEDIATRICS® PEDIHIP RIGID BRACE AND MODULAR ABDUCTION HARNESS**DESCRIPTION**

The PediHip Rigid Brace and Modular Abduction Harness are semi-rigid abduction orthoses. The Braces hold the hips in the correct abduction position. They can be used full-time, or for night-time wear only (as instructed by a healthcare provider).

MATERIALS

The PediHip Rigid Brace and Modular Abduction Harness are made from various types of metal and plastic materials. The materials include copolymer plastic, LDPE, foam, aluminum, stainless steel, brass, nylon, velcro, plastic, volara foam, FELT, orthopedic lining leather, PU Foam.

INDICATIONS FOR USE

The PediHip Rigid Brace and Modular Abduction Harness are semi-rigid abduction orthoses, which are 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.

CONTRA-INDICATIONS

Do not use the PediHip Rigid Brace and Modular Abduction Harness in the presence of any contraindication. Contraindications include, but are not limited to:

- Do not use a brace that is damaged, broken or not functioning properly.
- Material sensitivity documented or suspected.
- Inability to follow treatment protocol and care instructions.

WARNINGS

- Federal Law restricts the PediHip Rigid Brace or Modular Abduction Harness to sale by, or on the order of, a qualified physician or healthcare provider and is only to be used as prescribed.
- Follow the qualified health care provider and physician instructions or treatment plan.
- Follow instructions to ensure straps, screws, etc. are tightened properly, to reduce risk of irritation, blisters, and pressure ulcers.
- Consult your physician or clinical team immediately if the child is experiencing pain, irritation, blisters, swelling, pressure ulcers, or if the brace is not fitting properly.
- Do not use the brace without a stockinette underneath it. This will prevent skin breakdown and improve overall hygiene during patient's time in the brace.
- Do not remove subcomponents of the brace as they may present a choking hazard. Ensure proper assembly to prevent loose components around small children.
- The PediHip Rigid Brace or Modular Abduction Harness are a single-patient reusable device and shall not be used on multiple patients.
- Extra care should be used with the brace when used with any open wounds and/or infections.
- The PediHip Rigid Brace or Modular Abduction Harness should be used without additional components or accessories, unless instructed by clinical provider.

POSSIBLE ADVERSE EFFECTS

Consult your physician or healthcare provider immediately if the patient is experiencing any of the following:

- Skin irritation
- Pressure sores
- Pain, discomfort, or abnormal sensations due to the presence of the device

- Increased swelling
- Signs of infection
- Brace failure
- Femoral Nerve Palsy

These risks should be explained to the patient. The patient should contact a healthcare provider in relation to the operation of the device.

MRI SAFETY INFORMATION

The PediHip Rigid Brace and Modular Abduction Harness are MR unsafe and should remain outside the MRI scanner room.

CLEANING INSTRUCTIONS

1. Hook-and-loop straps of the brace may be undone to access the inside of the brace for cleaning purposes.
2. Stockinette changes will be directed by your physician or healthcare provider. If the stockinette becomes soiled, reach out to your healthcare provider for changing instructions.
3. The PediHip Rigid Brace and Modular Abduction Harness may be cleaned with a washcloth and warm water.
4. The PediHip Rigid Brace and Modular Abduction Harness may be disinfected with rubbing alcohol or mild antibacterial wipes.
5. Harsh cleaners, such as bleach, are not recommended as the brace is in close contact with the skin.
6. Do not put the PediHip Rigid Brace and Modular Abduction Harness into a mechanical dryer. Air dry only.
7. Do not submerge the PediHip Rigid Brace and Modular Abduction Harness in water or cleaning liquids.

REUSE LIFE

All parts are to be used by a single patient under normal use conditions and as prescribed by a physician or healthcare provider. Normal use includes full-time wearing of the PediHip Rigid Brace and Modular Abduction Harness as prescribed.

STERILIZATION INFORMATION

The PediHip Rigid Brace and Modular Abduction Harness cannot be sterilized via steam, gamma, ETO, or x-ray. The brace does not require sterilization before use.

STORAGE AND HANDLING

- The PediHip Rigid Brace and Modular Abduction Harness require no special handling during transport or storage.

IMPORTANT STATEMENT

- Please see the User Manuals for additional information. Electronic copies can be found at <https://www.orthopediatrics.com/>. To obtain a copy of the User Manuals, please call the Customer Service Group at OrthoPediatrix at 574-268-6379.
- PediHip Rigid Brace and Modular Abduction Harness should be checked for defects before use and to verify the appropriate sizing.
- The PediHip Rigid Brace and Modular Abduction Harness can be disposed of in accordance with applicable local, state, and federal regulations. None of the components of the device are recyclable.
- Only a qualified physician or healthcare professional may modify the PediHip Rigid Brace and Modular Abduction Harness.