

RHINO STOMPER Instructions For Use









Instructions For Use

RHINO STOMPER

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DESCRIPTION

The Rhino Stomper is a pediatric boot with a unique rocker bottom design which simulates normal gait. The Rhino Stomper is a medical device intended for use with pediatric patients receiving post operative or non-operative treatment for medical conditions that impact the foot, such as fractures, tendon injury, sprains, or shin splints and as instructed by a healthcare provider. A consistent examination scheduled with the clinical provider is needed to ensure proper fit, use, and instruction for caregivers and/or users. Compliance with instructions for use and clinical care treatment plan is important to achieve clinical and therapeutic outcomes.

INDICATIONS FOR USE

The Rhino Stomper is intended for use with pediatric patients receiving post operative or non-operative treatment for medical conditions that impact the foot, such as fractures, tendon injury, sprains, or shin splints and as instructed by a healthcare provider.

WARNINGS AND PRECAUTIONS

- Follow the qualified healthcare provider and physician instructions or treatment plan.
- Follow instructions to ensure straps are tightened properly, to reduce risk of irritation, blisters, and pressure
 ulcers.
- Consult your healthcare provider immediately if the child is experiencing pain, irritation, blisters, swelling, pressure ulcers, or if the brace is not fitting properly.
- Protective barriers (i.e. stocking) should be worn when wearing the Rhino Stomper.
- Do not apply the brace directly to the skin. Use protective barrier/clothes between stirrups and skin (e.g., long stretchy pants, lightweight pajamas, socks etc.).
- The Rhino Stomper should be used without additional components or accessories, unless instructed by the healthcare provider.
- Do not use a Rhino Stomper that is damaged, broken or not functioning properly.
- Modification is not recommended for the Rhino Stomper.

MRI SAFETY INFORMATION

The Rhino Stomper brace is MR unsafe and should remain outside the MRI scanner room.

CLEANING INSTRUCTIONS

Wash on delicate cycle or hand wash with mild detergent. Rinse thoroughly.

STORAGE AND HANDLING

- The Rhino Stomper requires no special handling during transport or storage.
- The Rhino Stomper is a nonsterile device.

APPLYING THE BRACE



- 1. Seat the heel of the cast in the back of the Rhino Stomper.
- 2. Attach the straps to the opposite side of the Rhino Stomper snuggly.

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REUSE LIFE

All parts were designed to be used by a single patient under normal use conditions and as instructed by a healthcare provider. Normal use includes the daily application of the Rhino Stomper as healthcare provider instructed.

SAFE DISPOSAL

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

IMPORTANT STATEMENT

- MD Orthopaedics, Inc. 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, Inc. products. This information should be provided solely by the physician or other qualified 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.
- 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) are available in English at https://opsb.com/ifu. To obtain a copy of the paper IFU, please call Customer Service at MD Orthopaedics, Inc. at (877) 766-7384.
- If a user and/or patient experiences any serious incident that has occurred in relation to the device, it should be reported to MD Orthopaedics, Inc. and the competent authority of the EU and EEA Member State in which the user and/or patient is established.

SYMBOL LEGEND

Symbol	Meaning	Symbol	Meaning
***	Manufacturer	$\overline{\mathbb{Z}}$	Date of manufacture
REF	Catalog number	LOT	Batch code
	Single Patient, Multiple Use	NON STERILE	Non-sterile
i	Consult Instructions for Use or Consult Electronic Instructions for Use	MR	MR Unsafe