

RGFB

INSTRUCTIONS

RADIAL GUTTER FRACTURE BRACE

antimicrobial treated*

AEM 5700 Antimicrobial EPA #: Reg. #64881-1



Distributed by: DJO, LLC
1430 Decision Street,
Vista, CA 92081
P 800.336.6569
F 800.936.6569
djoglobal.com

no. 10096 Rev D

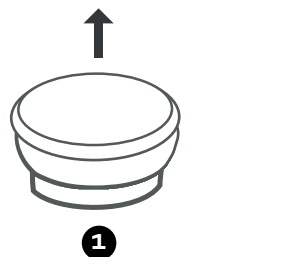
USA and International Patents Pending



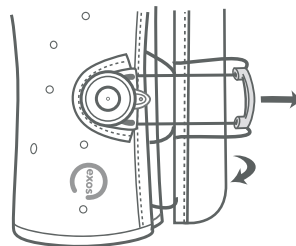
Exos™ Corporation
1122 Red Fox Road
Arden Hills, MN 55112



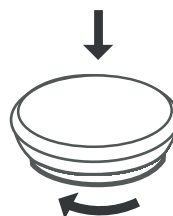
Medical Device & QA Services Ltd
Timperley, Cheshire.
WA15 7SN United Kingdom



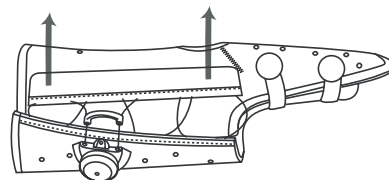
1



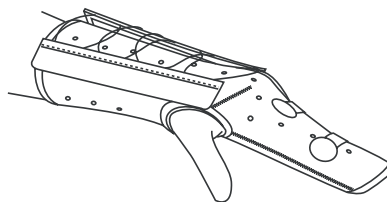
2



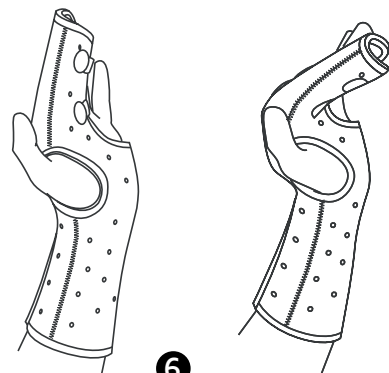
3



4



5



6

ENGLISH

Before using the device, please read the entire instruction manual. Correct application and care is vital to the proper functioning of the device.

INDICATIONS

The Radial Gutter Fracture Brace (RGFB) provides stabilization to the second and third metacarpals, second and third metacarpophalangeal joints, and the second and third digits, and the wrist joint.

CONTRAINDICATIONS

Patients with known allergies to foams, adhesives, or plastic products.

⚠️ WARNINGS and PRECAUTIONS

- ▶ Brace should be fitted by a qualified healthcare professional.
- ▶ Do not heat brace on the body.
- ▶ Check to make sure brace is not too hot prior to application.
- ▶ Brace should be appropriately sized to the patient to ensure proper support and function.
- ▶ Care should be taken with patients with delicate or compromised skin, especially the elderly, not to apply the brace too tightly, which MAY cause pressure and shear to the fragile tissue. PATIENTS SHOULD BE INSTRUCTED ON APPROPRIATE TENSIONING DURING ONGOING USE. An under sleeve or STOCKINETTE may be used for added protection.
- ▶ Do not heat Exos™ products to greater than 212°F (100°C).

OPERATING BOA® LACING SYSTEM

- To Loosen:**
- ▶ Lift Boa® Knob. (Figure 1)
 - ▶ Pull Tab. (Figure 2)
 - ▶ Pull hook-and-loop Full Release Ribbon – to open fully.
- To Close and Tighten:**
- ▶ Push Boa® Knob down. (Figure 3)
 - ▶ Turn Boa® Knob clockwise. (Figure 3)
 - ▶ Boa® Knob must be in the down locked position when wearing brace.

HEATING AND APPLICATION

- ▶ Detach hook-and-loop fastener Full Release Ribbon and pull open Boa® lace. (Figure 4)
- ▶ Unfold brace.
- ▶ Note: Larger braces are packaged with the finger sections folded lengthwise. Do not unfold fingers until the brace has been fully heated.
- ▶ Proper heating temperature is 200°F (93°C).
- ▶ Heat brace in Exos™ oven approximately 5 minutes or until brace is pliable. Brace should not be too hot to handle comfortably.
- ▶ Ensure that skin is completely dry before application.
- ▶ Fit brace on patient. (Figure 5)
- ▶ Secure hook-and-loop fastener release ribbon.
- ▶ Secure hook-and-loop fastener straps on fingers.
- ▶ Remove slack in lace by tightening Boa® Knob.
- ▶ Caution: Do not tighten brace fully until brace has returned to room temperature otherwise indentations in plastic may occur.
- ▶ Mold brace into desired position. (Figure 6)
- ▶ Once brace has hardened, the Boa® Knob may be tightened to desired tension.
- ▶ Warning: The brace should not be worn too tightly. This may produce excessive mechanical force or shear forces to the skin.

For fitting tips on each Exos™ device:
Visit the Exos™ Provider Center at:
<http://exosmedical.com/provider/RGFB> or
Scan the QR image with your smartphone



LIMITED PRODUCT WARRANTY

Exos™ covers defects in workmanship and materials up to 8 weeks from date this product is dispensed. Damage caused by normal wear and tear, abuse, or alterations is not covered.