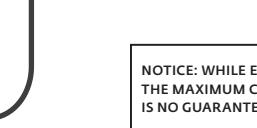
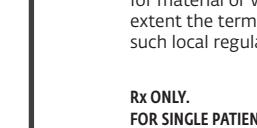
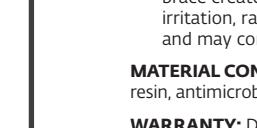
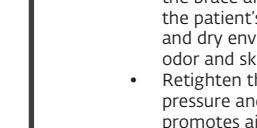
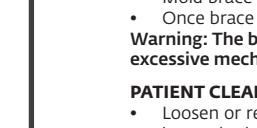
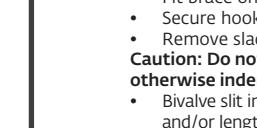
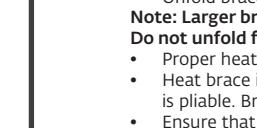
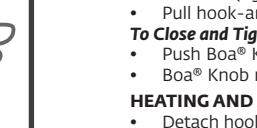
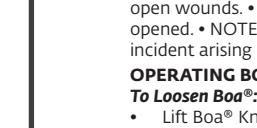
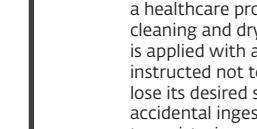
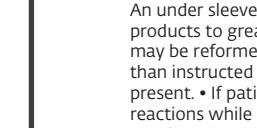
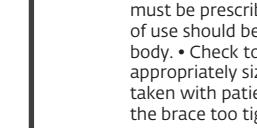
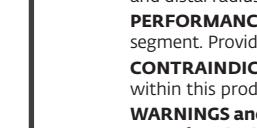
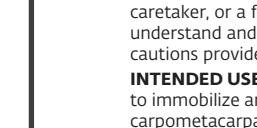


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ENGLISH

BEFORE USING THE DEVICE, PLEASE READ THE ENTIRE INSTRUCTION MANUAL.
CORRECT APPLICATION AND CARE IS VITAL TO THE PROPER FUNCTIONING OF THE DEVICE.

INTENDED USER PROFILE:

The intended user should be a licensed medical professional, the patient, the patient's caretaker, or a family member providing assistance. The user should be able to read, understand and be physically capable to perform all the directions, warnings and cautions provided for use.

INTENDED USE / INDICATIONS:

The Thumb Spica Fracture Brace (TSFB) is designed to immobilize and stabilize the first phalanx, first metacarpalphalangeal (MCP) joint, first metacarpophalangeal (MCP), the primary articulation carpometacarpal (CMC), the articulation of the thumb in flexion and extension; the pulgar in abduction, the distal radius and distal ulna.

PERFORMANCE CHARACTERISTICS:

Providing stabilization to the limb or body segment. Providing immobilization or controlled movement to the limb or body segment.

CONTRAINDICATIONS:

Do not use if you are allergic to any of the materials contained within this product.

WARNINGS and PRECAUTIONS: Instruction for wearing, opening, closing &

removing the brace should be provided by a healthcare professional. This product must be prescribed and fitted by a healthcare professional. The frequency and duration of use must be determined by your healthcare professional. • The brace should be appropriately sized to the patient for the intended use. • Wear 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 NOT BE INSTRUCTED ON APPROPRIATE TENSIONING DURING ONGOING USE.** An under sleeve or STOCKINNETTE should be used for added protection. • Do not heat Exos® products to greater than 100 °F (38 °C). • Do not use if the brace is too tight or too loose. • Do not modify this device without a healthcare professional present. • If patient experiences any pain, swelling, sensation changes or any unusual reactions while using this product, consult a healthcare professional immediately. • Patient should be instructed to check for breaks and cracks and informed to see a healthcare professional for a replacement. • Patient should be instructed on proper cleaning and drying instructions (see Patient Cleaning Instructions below). • If the brace becomes wet, it should be dried with a clean cloth and then re-applied. • Do not expose the brace to heat over 100°F (38°C) as this brace may soften and lose its desired shape. • Keep out of reach of children under five years of age to avoid accidental ingestion of the small parts. • Patient should be instructed not to expose to moisture, chemicals, or solvents, as they may affect durability. • Do not use over open wounds. • Do not use if it is damaged and/or the packaging has been opened. • NOTE: Contact manufacturer and competent authority in case of a serious incident arising due to usage of this device.

OPERATION BOA® LACING SYSTEM:

• Lift Boa® Knob. (Figure 1)
• Pull Tab. (Figure 2)
• Pull hook-and-loop Full Release Ribbon - to open fully.

To Close and Tighten Boa®:

• Push Boa® knob down. Turn Boa® Knob clockwise. (Figure 3)
• Boa® Knob must be in the locked position when wearing brace.

HEATING AND APPLICATION:

• Do not use and-loop fastener Full Release Ribbon and pull open Boa® lace. (Figure 4)

NOTES:

• Larger braces are packaged with the finger sections folded lengthwise. 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 100 °F (38 °C).

• Heat brace in Exos® recommended 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.

• Remove hook-and-loop Fastener Full Release Ribbon.

• Secure hook-and-loop Fastener Full Release Ribbon.

• Remove sleeve in lace by tighening Boa® Knob.

Caution: Do not tighten brace until heat has returned to room temperature otherwise indentation in plastic may occur.

• Bivalve slits in thumb may be adjusted while brace is warm to better fit the circumference and/or length of the thumb, then secure hook-and-loop fastener tabs. (Figure 6)

• Once brace has hardened, the Boa® Rest may be tightened to desired tension.

Warning: The brace should not be too tight, this may produce excessive mechanical force or shear forces to the skin. (Figure 7)

PATIENT CLEANING AND STORAGE INSTRUCTIONS:

• Loosen or remove the brace as instructed by healthcare professional. The brace may be washed or worn while swimming or bathing, only if the healthcare professional allows the patient to loosen or remove the brace.

If not, the patient cannot get the brace and skin wet.

• Hand wash only. Do Not iron. Do Not tumble dry.

• Do Not bleach. Do Not expose to temperatures superior a 55 °C.

• Hand wash inside and outside of brace and skin with antibacterial soap and water (86°F/30°C).

• Rinse thoroughly with water. **NOTE: If not rinsed thoroughly, residual soap may cause irritation, and could deteriorate material.**

• Use a hair dryer set on high volume and cool setting to thoroughly dry the interior of the brace and skin.

• It is imperative that the inside surface of the brace and the patient's skin are completely dry after swimming or bathing. A clean and dry environment inside the brace will help maintain healthy skin and reduce odor and skin issues.

• Retighten the brace. (Figure 10) Exos® braces are meant to be worn under light pressure and not tight to the skin. A little wiggle room inside an Exos® brace promotes air circulation and helps maintain healthy skin. An over-tightened brace creates shear or pressure on the skin during motion, and can result in irritation, rash, odor, or skin issues. Wearing the brace too loose will reduce support and may compromise healing.

MATERIAL CONTENTS: EVA foam, spandex, nylon, terpolymer, polyester, steel, nylon 6/6 resin, antimicrobial treatment, polycarbonate, thermoplastic elastomer, polyoxymethylene.

WARRANTY: DJO, LLC will repair or replace all or part of the unit and its accessories for material or workmanship defects for a period of 8 weeks from the date of sale. To the extent the terms of this warranty are inconsistent with local regulations, the provisions of such local regulations will apply.

SOLO POR PRESCRIPCION MEDICA.
PARA USO EN UN SOLO PACIENTE.

Rx ONLY.
FOR SINGLE PATIENT USE ONLY.

NOT MADE WITH NATURAL RUBBER LATEX.

ESPAÑOL

ANTES DE UTILIZAR EL DISPOSITIVO, LEA EL MANUALE DE INSTRUCCIONES EN SU TOTALIDAD. LA APLICACIÓN Y MANEJO CORRECTO SON DE FUNDAMENTAL IMPORTANCIA PARA UN FUNCIONAMIENTO CORRECTO.

PERFIL DE USUARIO PREVISTO:

El usuario previsto debe ser un profesional médico autorizado, el paciente, el cuidador del paciente o una familia que provee asistencia. El usuario debe poder leer, comprender y ser físicamente capaz de seguir todas las instrucciones, advertencias y precauciones proporcionadas en la información de uso.

