



FlexiSplint[®]

Light Cured Polymer Immobilizer

FOOT AND ANKLE SPLINT

INSTRUCTIONS FOR USE

Please read these instructions carefully before application.
Stickers should be used from the label to keep record of product identity.



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FlexiSplint®

Light Cured Polymer Immobilizer

PRODUCT DESCRIPTION

- FlexiSplint® Foot and Ankle Splint is a breathable, washable, pre-padded, light-cured polymer immobilizer for immobilization of the ankle and foot. It is a non-circumferential splint that leaves part of the limb circumference open, with both edges secured by hook-and-loop fastener to allow room for swelling and permit skin inspection and care.
- The device consists of a foam-lined silicone pocket containing a light-curable liquid resin. In its uncured state it is soft and pliable and can be moulded around the foot and ankle. When exposed to visible blue light from the RizyCure® Light Device it becomes rigid and immobilizes the foot and ankle. The device is supplied non-sterile. It may be removed and re-applied to the same patient as needed during a single course of treatment.

FOOT AND ANKLE SPLINT

- FlexiSplint® Foot and Ankle Splint comes in 3 different sizes: S, M and L.

INTENDED PURPOSE/ INTENDED USE

- FlexiSplint® Foot and Ankle Splint is a non-sterile, external immobilization device for the foot and ankle for use in patients with musculoskeletal injuries or requiring post-surgical support. It is primarily intended for acute and interim immobilization. In selected cases, such as minor or stable injuries and certain post-surgical cases, the treating healthcare professional may also use it for definitive immobilization. The splint provides non-circumferential, removable, semi-rigid support that allows for soft-tissue swelling, inspection and local care, particularly when circumferential casting is not yet appropriate or not required.
- FlexiSplint® Foot and Ankle Splint is applied and adapted by a healthcare professional and is intended for single-patient, multiple-use during one course of treatment. The patient then wears and uses the splint in daily life according to instructions provided for the patient.

INDICATIONS FOR USE

For use as directed by a qualified healthcare professional for immobilization of the foot and ankle in musculoskeletal injuries such as fractures, sprains, strains, joint injuries, and other soft-tissue injuries, when non-circumferential immobilization is clinically indicated, including:

- Acute post-traumatic cases as a bridge to definitive casting, bracing or surgery.
- Short-term post-operative protection and support.
- Stable or minor injuries requiring immobilization or step-down support when a removable splint is clinically appropriate.

CONTRAINDICATIONS

- Patients with known allergy or hypersensitivity to nitrile rubber.

INTENDED USERS

- **Professional user (healthcare professional):** Physicians and other trained and duly licensed healthcare professionals are responsible for selecting the appropriate size, applying, adjusting and curing the FlexiSplint® Foot and Ankle Splint, and for providing clinical follow-up.
- **End user (patient):** The patient wears the splint during daily life for the prescribed duration, ranging from days to weeks, and is responsible for basic care of the device and monitoring of symptoms, according to the instructions provided by the treating healthcare professional and this manual.

PART 1

INSTRUCTIONS FOR PROFESSIONAL USERS

APPLICATION PROCESS

A. STEPS BEFORE APPLICATION

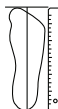
1 SIZE SELECTION

Measurement : Use paper tape measure provided inside the shrink wrap of the box to measure foot length.

Size Selection : Select the appropriate size using the size chart. When in doubt, use the large size according to your discretion.

2 SIZE CHART

Size	Maximum foot length	Shoe Size
S	22cm - 24.9cm	36- 40
M	25cm - 26.9cm	40- 42
L	27cm - 28.3cm	42- 45



3 UNBOXING AND INSPECTION

- **Open the box and take out all contents:** Box contents include the splint in a sealed opaque black sleeve and one IFU sheet. Paste labels on records as needed for documentation, billing etc.. Ensure opaque black sleeve is intact.
- **Open black sleeve and inspect:** Open the opaque black sleeve, taking care not to damage the product, bring out the product and thoroughly inspect it to rule out any areas of resin leakage, cracked foam or other mechanical defects or damage. If any pre-existing defect or damage, is found, don't use that product and contact supplier representative.

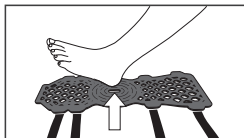
4 CHECK-IN WITH PATIENT

- Rule out history of skin allergies, particularly to nitrile rubber e.g Nitrile Gloves. Also rule out any open wounds, with whose care the splint may interfere. Document any existing conditions or ongoing medications that may affect skin sensitivity and sensation, use clinical judgment and counsel patient accordingly
- Inform patient about the splint care precautions that must be followed and elicit willingness and ability to comply
- Ask patient to inform you immediately in case of any tightness, pain or excessive heat felt during application

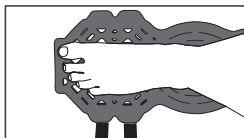
B. STEPS OF APPLICATION

Position the patient comfortably in a seated or lying down position, with the foot and leg at a comfortable working height for the operator.

WRAP



Splint placement: Place the heel area on splint with the rear heel tip aligning with the highlighted landmark on the pattern.

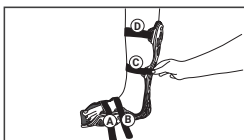


Splint placement (horizontal):

Ensure that the vertical midline of the foot and leg is aligned with the vertical midline of the splint.

Note: Splint placement should be guided by the highlighted landmark only, and not by the distal margin of toes. This helps ensure adequate lengths of both the foot and leg segments. Foot segment projecting beyond the toes is acceptable. It may be curved up vertically while curing, per clinical discretion.

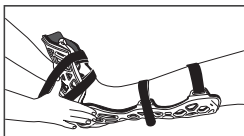
STRAP



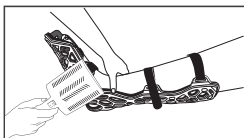
Strapping: Securely fasten the hook and loop fastener, ensuring a snug fit but NO distortion of the splint from excessive stretching. Move from the bottom up, and fasten the 4 straps in sequence: B, C, A, D, and cut off any excess strap length with scissors.

Final check: Ensure there are no areas hanging loose, nor any areas of excessive tightness or distortion due to excessive stretching.

CURE



Neutral position: Hold the leg, foot and the splint in the required position.



Curing: Once neutral position achieved, start curing around the ankle using RizyCure® Light Device. Once ankle area turns rigid, start curing both proximally and distally. Cure the rest of the splint for 5-10 mins until the splint gets rigid. Mold to patient's anatomy while curing.

CURING AND MOLDING TECHNIQUE

- **PPE:** External surface heats up during curing. Use appropriate caution and protection while applying and curing the splint. All present (patient, operator, assistant(s) and bystanders, if any) must wear **yellow goggles** (provided with RizyCure®) for eye protection.
- **Angle:** Keep the surface of the RizyCure® Light Device panel parallel to the surface of the splint to maintain a uniform light to splint distance.
- **Distance:** Carefully maintain a distance of 8-10 cm between the light device and the splint being cured. Reducing the distance can increase temperature. Increasing distance can impact curing.
- **Molding:** To precisely mold the splint around patient's anatomy as needed, press and hold the splint into the desired shape while exposing it to blue light, and hold it in place until rigid. If holding it in shape while exposing blocks light, first expose with light for 10 seconds (this triggers the curing reaction), then hold it in the desired shape for 1-2 minutes until rigid (this will ensure that curing occurs in the desired shape). **Note:** Applying molding pressure **before** blue light exposure can squish the area thin, creating a weak point. Applying it **after** an area has cured completely will not have any effect. Therefore, molding pressure must be applied when the concerned area is in the process of curing i.e. start when the area has become partially rigid, and maintain the pressure until it has cured completely.
- **Avoiding pressure points:** While curing ensure that no rigid edges impinge on the skin, especially on bony prominences such as the malleoli. Keep the edges parallel to the limb (not bent inward, which can cause pressure injury). The edges on the side of the foot should rise vertically upward, not curving inwards. Splint edges around the malleolar prominence should stay slightly above the skin, not pressing onto it. Same for all the splint edges. This technique also facilitates easy splint removal.

C. STEPS AFTER APPLICATION

- **Wait:** Retain the patient at your facility for up to 30 minutes after application and ensure that the splint fits properly, and there are no areas of excessive tightness or looseness before discharging the patient. A splint once cured cannot be remolded. If there are any issues with fitting, remove and re-apply. This avoids subsequent issues including emergency visits.
- **Explain:** Explain all splint care instructions in detail, with special emphasis on warning signs which should prompt the patient to seek immediate medical attention.

D. STEPS OF REMOVAL

- Unfasten the hook & loop fasteners, and remove the splint.
- Apply gentle opening pressure if needed.
- Break the struts of the splint using the cast/splint cutting tool if the parts are wrapped around the limb, making removal difficult.
- Dispose the used splint as per local biomedical waste norms.

ADVERSE EFFECTS

The use of splints may cause adverse effects such as slight itching, warmth under the splint, minor redness or imprint marks on the skin, mild swelling of the foot or toes, and stiffness or weakness in nearby joints. These are usually transient and improve with elevation, skin care and time, but the patient should inform their HCP if they are persistent, bothersome or worsening.

Warning signs – seek medical attention promptly (immediate removal may be needed)

- Progressive rash, itching, hives or blisters, especially under areas in contact with the splint (may indicate allergic contact dermatitis or other allergic reaction, including to nitrile rubber).
- Increasing or severe pain, marked swelling and tightness under the splint (may indicate excessive pressure or evolving compartment syndrome).
- Numbness, tingling, loss of sensation or inability to move the toes, or toes that become pale, bluish or cold, (may indicate nerve compression or reduced blood flow).
- Persistent redness, skin breakdown, blisters and ulceration (may indicate pressure injury).
- Foul or unusual odour, fluid discharge, persistent wetness (may indicate skin infection).

STORAGE CONDITIONS

Store in the original packaging in a cool, dry place, protected from direct sunlight. Do not use after the indicated "use-by" date. Avoid stacking or loading that may deform the packaging or the product.

OPERATING CONDITIONS

Recommended operating temperature range: 25 +/- 5 °C.

MR COMPATIBILITY

All the materials used in the FlexiSplint® are non-ferrous and MR compatible however it has not been formally tested for MR compatibility.

REPORTING OF ADVERSE EVENTS

In case of any event please notify 'care@orthoheal.com' along with device name, and lot/serial number, or the local regulatory authority.

WARNINGS AND PRECAUTIONS

WARNINGS

- Defective pieces with cracked foam and/or resin leakage must not be used since it can cause thermal injury while curing.
- Curing from a distance of less than 8-10 cm can expose patient skin to high temperatures. Curing from a larger distance can cause inadequate curing and subsequent splint breakage. To avoid these risks, the curing distance should be meticulously maintained between 8-10 cm.
- Patient skin must not come in contact with the external surface of the splint when it is being cured. Operators should use caution and appropriate protection.

CAUTIONS

- Appropriate fit should be achieved through proper size selection and molding. Splints that are too tight can cause pressure injury, (and rarely, compartment syndrome). Splints that are too loose can cause failure of immobilization.
- Patients should follow instructions provided in this manual for safe and effective use.
- Patients must not bear weight or walk on the FlexiSplint®.
- RiziCure® Light Device poses no skin hazard under normal use and is comparable to sunlight exposure. Indirect or reflected light exposure during normal use is safe for the eyes. However, to prevent eye discomfort and cumulative photochemical risk, operators and patients must not gaze directly at the light source without protective goggles - especially for several seconds or on a repeated basis. All individuals present near the light must wear protective goggles when the curing light is in operation.
- The skin of patients with light sensitivity - due to photosensitizing medications or medical conditions - may react to RiziCure® Light Device similarly to sunlight. Use clinical discretion and caution as needed.

SYMBOL GLOSSARY

	Medical Device
	Caution: Federal law restricts this device to sale by or on the order of a HCP
	Single patient multiple use.
	Do not use if package is damaged and consult instructions for use
	Non-sterile
	Consult instructions for use.
	Device is not made with natural rubber latex.
	Keep away from sunlight.
	Manufacturer
	Date of Manufacture
	Use-by Date
	Catalogue Number / Reference code
	Batch code / Lot Number
	Serial Number
	Unique device identifier
	Authorised representative in the European Union

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INSTRUCTIONS FOR PATIENT/ END USERS

Read and follow each point carefully for your safety and best results. Detailed information is available with your doctor. Follow your doctors advice at all times.

BEFORE APPLICATION

Inform your HCP about any health problems, especially diabetes and skin allergies (like nitrile rubber allergy, for instance to gloves). If needed, your doctor will take special precautions or suggest alternatives.

DURING APPLICATION

- **If splint feels too hot**

Some warmth is normal during blue light curing, but immediately alert the doctor if it feels too hot or painful.

- **If splint feels too tight**

Inform the HCP if the splint feels tight at any time - before, during, or after curing. Signs of excessive tightness include pain, pressure, coldness, numbness, and tingling sensation.

- **External surface**

External surface heats up while curing, it should not touch your skin.

- **Blue light**

Blue light is safe for your skin. Use goggles and don't look at the light source directly.

JUST AFTER APPLICATION

Your doctor may ask you to wait ~30 minutes after application to ensure the splint fits comfortably. Inform the doctor if there is any discomfort.

AFTER GOING HOME

Watch for warning signs and if any of these occur, contact your doctor immediately:

- Progressive rash, itching, hives or blisters, especially under areas in contact with the splint.

INSTRUCTIONS FOR PATIENT/ END USERS

- Increasing or severe pain, swelling and tightness.
- Numbness, tingling, loss of sensation or inability to move the toes, pale, bluish or cold toes.
- Persistent redness, skin breakdown, blisters and ulceration.
- Foul or unusual odour, fluid discharge, persistent wetness.

Rest is important: Do not use, strain, or exercise the limb unless the doctor specifically advises.

Avoid injury or Splint breakage:

- No sports or risky activities (e.g., running, slippery floors, construction areas, cricket).
- Avoid all situations where you might fall or hit the splint.
- FlexiSplint[®] Foot and Ankle Splint is NOT intended for weight bearing, do not bear weight or walk on it. Cast/splint shoes, if provided by the HCP, are intended to protect the Splint from wear and tear.

Swelling management: Keep the splinted leg elevated by placing it on a stool while sitting down and on a pillow stack/tether while lying down.

SPLINT CARE

Keep it clean:

- Bathe daily with soap and water (if permitted by HCP).
- Wash the splint regularly with soap and water .
- After each wash, drying with unheated air is recommended (e.g., with hairdryer).
- Rinse the splint with tap water if exposed to mud, sand, saltwater, or pool water.

Don't peel or remove parts:

- Outer and inner soft layers must remain intact.
- Don't remove extra foam pad(s); inform the doctor if they tear or get dislodged or lost.