



FlexiOH[®]

Light Cured Polymer Immobilizer

ULNAR GUTTER IMMOBILIZER

INSTRUCTIONS FOR USE

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

FlexiOH[®]

Light Cured Polymer Immobilizer

GENERAL DESCRIPTION

FlexiOH is the first of its kind - an orthopedic immobilizer, that is breathable and washable. The design of FlexiOH is rigid enough to hold the fractured part as well as ensures skin ventilation. FlexiOH comes in a flexible form which is wearable. Light treatment completes the curing process and makes the immobilizer rigid. Curing is done by Rizycure, which is a handheld high intensity portable visible blue light system. FlexiOH is made of silicone rubber, light curable resin and nitrile rubber foam. The device is for single use only and supplied non-sterile. The curing process is quick and takes around 5-10 minutes for curing depending on the size. Post treatment the FlexiOH can be removed easily without the use of any other cast cutter or spreader.

The device is tested for biocompatibility and radiolucency.

KEY FEATURES



Washable



Breathable



Easy Application



Comfortable



Safe



Latex Free

ULNAR GUTTER IMMOBILIZER

FlexiOH Ulnar Gutter Immobilizer comes in 4 different sizes: XS, S, M and L.

INTENDED USE

The FlexiOH – light cured polymer immobilizers are intended to be used for immobilization of the body parts having musculoskeletal injuries like fractures, sprains, ligament injuries as well as for pre-surgical and post-surgical immobilization.

INDICATION FOR USE

FlexiOH Ulnar Gutter Immobilizers are intended to be used for immobilization of meta-carpal fractures and phalanges of the third and fourth fingers. The immobilizers can be used on patients suffering from:

- Boxer's fracture.
- Non-displaced fourth or fifth metacarpal fractures.
- Non-displaced fourth or fifth proximal phalanx fracture.
- Non-displaced fourth or fifth middle phalanx fracture.

CONTRAINDICATIONS

The FlexiOH - light cured polymer immobilizers should not be used where the device comes in contact with breached skin.

PATIENT POPULATION

Patients suffering from upper limb bone fractures that require immobilization of metacarpals and phalanges of the third and fourth fingers.

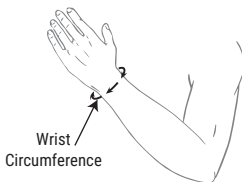
INTENDED USERS

A health care professional (HCP) such as an orthopedic surgeon, emergency room doctor, physician assistant, orthopedic technician or nurse practitioner.

SIZE CHART (IN CM)

	Wrist Circumference
XS	12.5-14.5
S	14-16
M	16-18
L	18-20

MEASUREMENT GUIDE



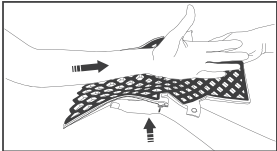
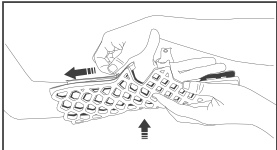
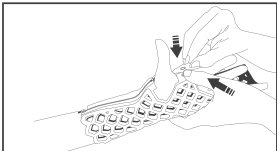
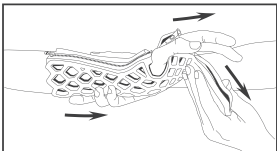
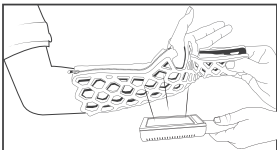
Notes :

* Above sizes fit better as per dimensions mentioned in the table.

* We advise healthcare professionals to choose the size as per patient's comfort.

APPLICATION PROCESS

Follow the steps to apply FlexiOH Ulnar Gutter Immobilizer :

- (a)  Place FlexiOH Ulnar Gutter immobilizer below the hand along with arm as shown in the picture.
- (b)  Adjust the immobilizer and make sure that it covers the 4th and 5th metacarpal and phalanges. Then start zipping along the arm line.
- (c)  Lock the press button to fix it around the palm. Make sure the adjustment should be comfortable to the patient.
- (d)  After that, adjust the immobilizer as per required position.
- (e)  Start curing around the finger area first using RiziCure. Then cure wrist and forearm area for about 5-10 minutes until it's rigid. Apply strap loop around fingers to secure the position.

NOTE : While curing maintain the distance between FlexiOH and RiziCure - less than 1 cm for rechargeable RiziCure and 10 cms for corded RiziCure.

REMOVAL PROCESS

- Step 1 : Cut the fabric liner of the zip using scissors.
- Step 2 : Break the rib of FlexiOH Immobilizer on the opposite side of zipper line using bone cutter pliers (Bone Cutting Forceps Straight Double Action).
- Step 3 : Apply gentle force to open the immobilizer from zip side to remove it.
- Step 4 : Dispose the used immobilizer as per local biomedical waste norms.

WARNINGS AND PRECAUTIONS

- For best fit, choose size before application of FlexiOH immobilizer from the size chart. Make sure that the patient feels comfortable before the curing process.
- Inspect FlexiOH for any manufacturing defect i.e. foam damage, leakage, etc. Do not use the product for treatment if found with such defect. Dispose such defective product only after curing as per local biomedical waste norms.
- In case, the box is damaged but the product is intact in the sealed sleeve bag, product can be used for the treatment.
- Ensure that the zipper is always aligned to the lateral side when in supine position.
- RzyCure light device is used to cure FlexiOH immobilizer. Usually, it takes 5-10 minutes for curing, it might take shorter or longer time duration depending on the size of the immobilizer.
- The curing process is quick, hence always ensure that the position of hand and fingers are properly aligned before you start the curing process.
- After curing keep the patient's hand and fingers static until 10 minutes to allow complete curing of the cast.
- Do not reuse, as it may lead to cross-contamination or infection.
- Do not use the device on patient allergic to the materials used in the device.

CAUTION : In any case of constant discomfort, skin rashes, increased pain, numbness or redness of the skin, patients should consult immediately to HCPs. FlexiOH should be removed immediately if required as per HCP's opinion.

ADVERSE EFFECTS:

- The known adverse events related to cast application are - Itching, Pain, Rash, Odor, Skin breakdown, Joint stiffness, Compartment syndrome, Muscle atrophy, Distal oedema, Development of swelling.
- **Skin Complication:** Erythema, Pressure sore, Dermatitis, Skin allergic reaction.

STORAGE CONDITIONS

Keep the device away from sunlight until final application and curing process.

MR COMPATIBILITY

All the materials used in the FlexiOH are non-ferrous and MR compatible.

REPORTING OF ADVERSE EVENTS

In case of any event please notify to 'contact@orthoheal.com' or to the competent authority of the respective EU member state.

INSTRUCTIONS FOR PATIENT

Do's

- Normal day-to-day activities which require less movement of the fractured part can be performed while wearing immobilizer.
- Bathing and swimming in shallow pool is allowed.
- Dry immobilizer with hair dryer if required.
- Clean immobilizer regularly to maintain skin hygiene.
- Keep injured limb in elevated position in order to reduce swelling.

Dont's

- Don't touch upper surface of immobilizer during light curing process. Higher temperature may cause burns.
- Don't lift any weighted object with the fractured limb without your doctors permission.
- Don't try to remove immobilizer without doctor's permission.
- Avoid any strenuous musculo-skeletal activities.
- Don't remove / peel off cushioning foam from immobilizer, it may expose the hard edge or surface to the skin.
- Don't put unnecessary pressure on the immobilizer.
- Don't go near fire, as FlexiOH may catch fire.

Contact health care professional (HCP) in case the immobilizer is too loose/ too tight/ broken / crack and increased swelling or redness of skin is observed.

SYMBOL GLOSSARY



Medical Device



Caution: Federal law restricts this device to sale by or on the order of a HCP



Do not re-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

Copy of the design or technology may infringe IP rights.



FDA
LISTED



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