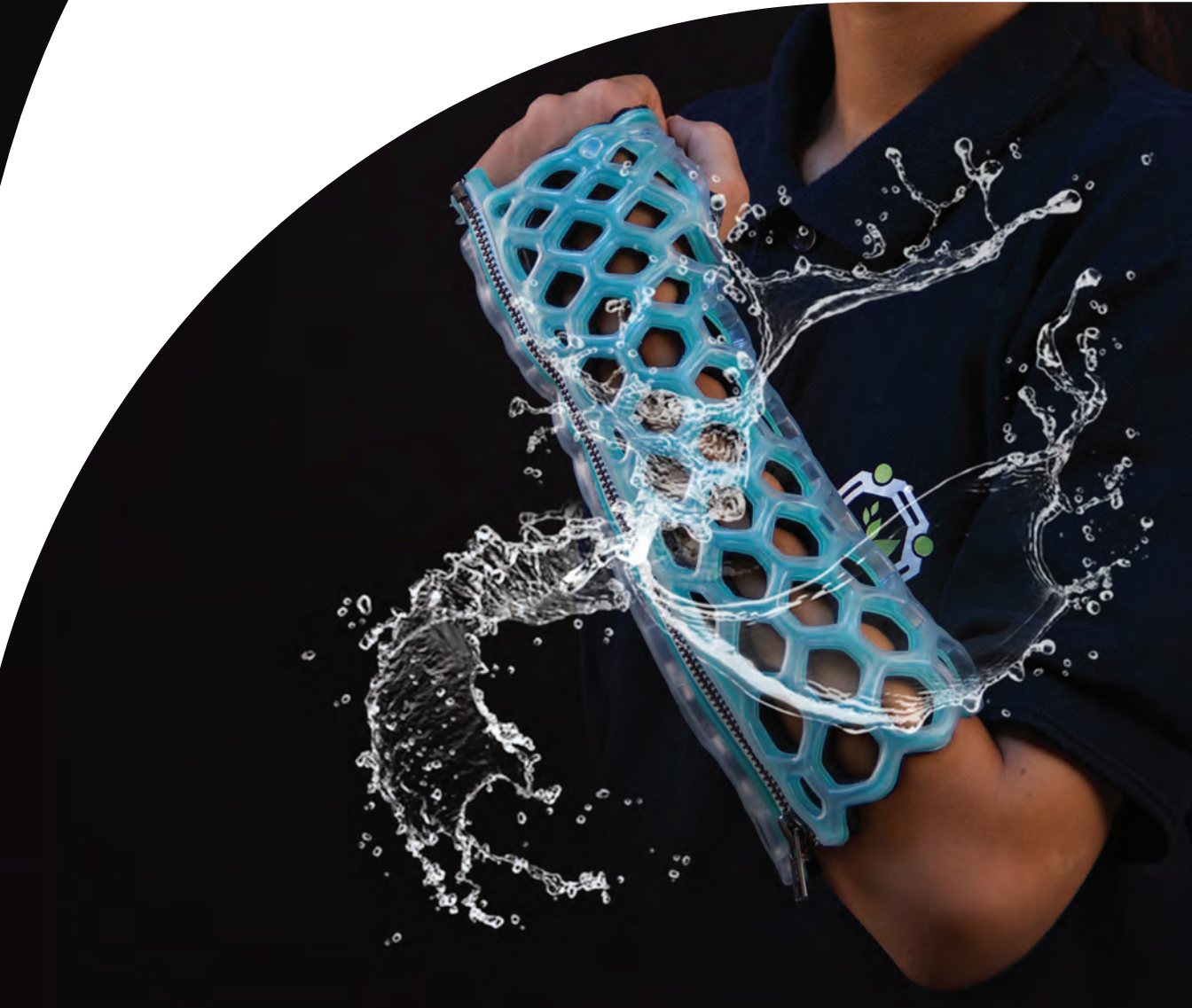




OrthoHeal

Healing comfortably



In compliance with



FlexiOH[®]

The **NextGeneration**

Orthopedic Immobilization Technology

About Technology

FlexiOH[®] is the first of its kind- an orthopedic immobilizer that has the rigidity to hold the fractured part as well as it ensures proper skin ventilation. FlexiOH[®] comes as an easy to fix wearable material on the injured part. After wearing, light treatment completes the curing process and makes the FlexiOH[®] immobilizer rigid. This process is quick and only takes 3-10 minutes, depending on the size of FlexiOH[®] immobilizer. After the course of therapy, FlexiOH[®] can be removed easily without the use of any other external cast cutter/spreader.

The design and material of FlexiOH[®] are engineered to provide superior comfort to the patient. A foam, which is in contact with the skin, is biocompatible (**ISO 10993-10 certified**) and provides cushioning against the hardened polymer. The FlexiOH[®] immobilizers are designed in such a way that the intermittent hollow spaces facilitate circulation of air and evaporation of sweat or water from the skin surface.

Radiolucency of FlexiOH[®] does not interfere with the radiological imaging and diagnosis.

Solution

FlexiOH[®] provides these robust solutions for major issues related to conventional casts :



Safer



Washable



Latex Free



Comfortable



Breathable



Lightweight



Quick Application

Awards and Recognition



BIRAC - SRISTI
GANDHIAN YOUNG TECHNOLOGICAL
INNOVATION AWARD (GTYP) 2015



DST-LOCKHEED MARTIN
India Innovation Growth Programme 2015



FlexiOH[®]

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Orthopedic Immobilization Technology

Absolute washable orthopedic Immobilizer for immobilization of wrist joint and closed fractures at radius-ulna.



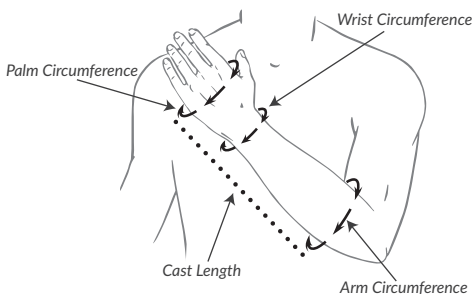
INTENDED USE

- Non-displaced / Stable / minimally displaced / Buckle fracture of distal radius fracture
- Carpal bone fracture other than Scaphoid / Trapezium
- As a removable splint during rehabilitation

SHORT ARM

FlexiOH[®] short arm immobilizer comes in 5 different sizes : XS, S, M L and XL. All of the immobilizers vary in terms of palm circumference, wrist circumference, and arm circumference. For the best fit of FlexiOH[®] short arm immobilizer, taking the measurement of patient's hand is necessary before application.

MEASUREMENT GUIDE



SIZE CHART (in cm)

| Size vs Measurement: | XS | S | M | L | XL |
|------------------------------|----|------|------|------|------|
| Palm Circumference: | 13 | 16.5 | 18.5 | 21 | 23.5 |
| Wrist Circumference: | 11 | 14 | 16 | 18.5 | 21.5 |
| Arm Circumference: | 18 | 21 | 25.5 | 28.5 | 32 |
| FlexiOH [®] Length: | 24 | 28 | 30.5 | 34 | 38 |

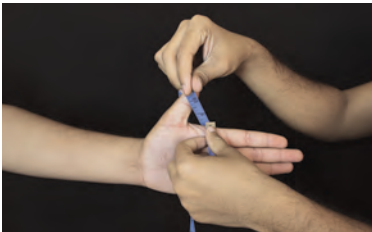
Notes :

- * Above sizes fit better as per dimensions mentioned in the table.
- * However FlexiOH[®] adapts to an oversize to a certain extent by stretchability.
- * We advise the healthcare professionals to choose size as per patient's comfort.

FlexiOH[®] short arm immobilizers are designed for distal radius/non-displaced/stable fractures or carpal bone fractures other than scaphoid fractures. This breathable, washable and light weight (~300 gms) immobilizer provides better comfort to the patients compared to conventional casts. For application of FlexiOH[®] short arm immobilizer, healthcare professional first need to apply it on the patient's hand with the zip and then cure it with the Rizycure[®] light device (recommended) or direct sunlight for around 3-10 minutes depending on the size of immobilizer. Once it is rigid, cut the puller of the zip with pliers so that patients can not remove the immobilizer by themselves.

APPLICATION PROCESS

FlexiOH[®] short arm immobilizer application process is as follows -



Choose the appropriate size from given chart



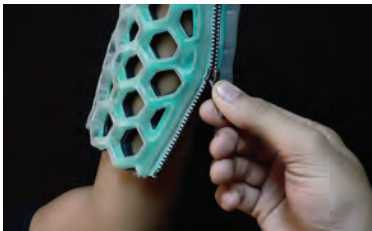
Apply cushioning to thumb to give extra comfort to pressure points



Place immobilizer over the fractured hand anchoring thumb



Lock the zip by placing insertion pin into retainer box



Pull the puller of the zip until the end



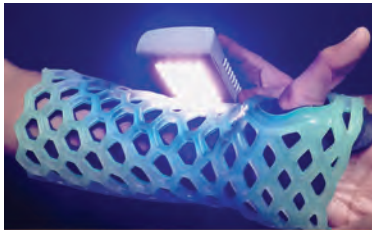
As it adapts to the shape of the hand, start reduction process



Take fully charged Rizycure[®] Light Device



Start curing around the thumb to give initial support to the broken bone



Expose 3-10 minutes thoroughly and check every corner until it's hardened

REMOVAL PROCESS



It's very simple, just unlock the zip



Apply little force and pull hand out from the immobilizer

FlexiOH[®] provide 46% open area of skin to breathe, wash and exposure to sunlight which are necessary to maintain healthy skin.

SHORT ARM



FlexiOH[®]

The NextGeneration
Orthopedic Immobilization Technology

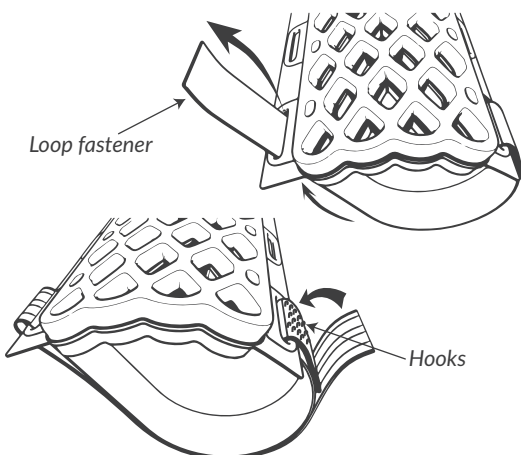
Absolute washable orthopedic Immobilizer for immobilization in the pre-operative, post-operative and rehabilitation period.

INTENDED USE

- Acute swelling of fractured / injured limb / joint
- Pre-operative stabilization
- Post-operative support after surgery
- Ligament sprain / soft tissue injury
- Support during rehabilitation

SPLINT/SLAB

FlexiOH[®] Splints / Slabs are available in different sizes : 3 in X 10 in, 3 in X 12 in, 3 in X 15 in, 4 in X 12 in, 4 in X 15 in, 4 in X 18 in, 5 in X 12 in, 5 in X 15 in and 5 in X 18 in. All of the Splints / Slabs vary in terms of length and width.



AVAILABLE SIZES

| | | |
|--------------|--------------|--------------|
| 3 in X 10 in | 4 in X 12 in | 5 in X 12 in |
| 3 in X 12 in | 4 in X 15 in | 5 in X 15 in |
| 3 in X 15 in | 4 in X 18 in | 5 in X 18 in |

FlexiOH[®] Splints / Slabs are designed for immobilization in the pre-operative, post-operative, acute swelling and rehabilitation period. FlexiOH[®] has a built-in soft hook and loop fastener that secures the splint over the limb which is very comfortable for skin contact. With unique FlexiOH[®] technology, this splint gives better patient comfort along with breathability and washability. For application of FlexiOH[®] Splint / Slab, doctors need to apply it on the patient's limb with the soft hook and loop fastener and then cure it with the RizyCure[®] light device (recommended) for 3-10 minutes depending on the size of splint/ slab. Once it is rigid, it will provide support during rehabilitation. With valcro, the splint can be removed / adjusted anytime for dressing and rehabilitation.

APPLICATION PROCESS

FlexiOH[®] Splint/Slab application process is as follows -

SPLINT/SLAB



Choose the appropriate size from given chart



Take the suitable size for the application



Apply the splint by passing the hand in between the loop and splint



Check the position of the loops is comfortable to the patient



Start tightening the first loop at the palm circumference



Tighten the last loop at the end



Tighten all in between loops to fit the splint perfectly before curing



Take Fully charged RizyCure[®] light device



Start exposing the splint / slab with RizyCure[®] light device



Re-tighten all the loops once the splint /slab is rigid



Cut the extra length of loops with scissors

FlexiOH[®] provide 30% open area of skin to breathe, wash and exposure to sunlight which are necessary to maintain healthy skin.

FlexiOH[®]

The NextGeneration
Orthopedic Immobilization Technology



Absolute washable weight-bearing orthopedic Immobilizer for lower extremity fractures and soft tissue injury.

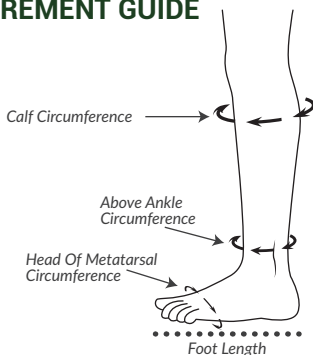
INTENDED USE

- Lower leg fractures around ankle
- Fractures of foot bone
- Severe ankle sprains and strains or fractures.
- Immobilize leg or foot muscles and tendons in place after surgery to allow healing.

SHORT LEG

FlexiOH[®] Short Leg Immobilizer comes in 5 different sizes : XXS, XS, S, M and L. All of the immobilizers vary in terms of calf circumference, above ankle circumference, head of metatarsal circumference and foot length. For the best fit of FlexiOH[®] Short leg immobilizer, taking the measurement of the patient's leg is necessary before application.

MEASUREMENT GUIDE



SIZE CHART (in cm)

| Size vs Measurement: | XXS | XS | S | M | L |
|-----------------------------------|-----|------|----|------|----|
| Calf Circumference: | 22 | 24 | 29 | 34.5 | 40 |
| Above Ankle Circumference: | 17 | 20 | 21 | 24.5 | 26 |
| Head of Metatarsal Circumference: | 18 | 19.5 | 23 | 25.5 | 27 |
| Foot Length: | 16 | 20 | 22 | 24 | 27 |

Notes :

- * Above sizes fit better as per dimensions mentioned in the table.
- * However FlexiOH[®] adapts to an oversize to a certain extend by stretchability.
- * We advise the healthcare professionals to choose size as per patient's comfort.

FlexiOH[®] Short leg immobilizers are designed as a weight bearing orthopedic casting technology for lower extremity fractures and soft tissue injury. It has a built-in zip system which makes the application process very easy and comfortable. With unique FlexiOH[®] Technology, this short leg immobilizer gives better patient comfort along with breathability and washability. For application of FlexiOH[®] short leg immobilizer, doctors need to apply it on the patient's leg with the zip and then cure it with the Rizycure[®] light device (recommended) or direct sunlight for 8-10 minutes depending on the size of immobilizer. Once it is rigid, it will take the shape of the patient's leg for support during immobilization.

APPLICATION PROCESS

FlexiOH[®] Short Leg immobilizer application process is as follows -



Choose the appropriate size from given chart



Take the suitable size for the application



Put Short leg immobilizer under the leg



First start zipping in center of metatarsal area of the foot



Start zipping second zip over the shin from ankle to knee end



Align the fracture part appropriately before curing



Take Fully charged Rizycure[®] light device



Start curing process near the ankle by holding from both side



Expose foot and area below first to fix the ankle joint area



Expose remaining area thoroughly until it gets rigid



Hold the leg in correct position and let immobilizer achieve rigidity

FlexiOH[®] provide 45% open area of skin to breathe, wash and exposure to sunlight which are necessary to maintain healthy skin.

SHORT LEG

FlexiOH[®]

The NextGeneration
Orthopedic Immobilization Technology

Absolute washable orthopedic Immobilizer for immobilization in above elbow, at the elbow knob and at the inside of elbow tip.

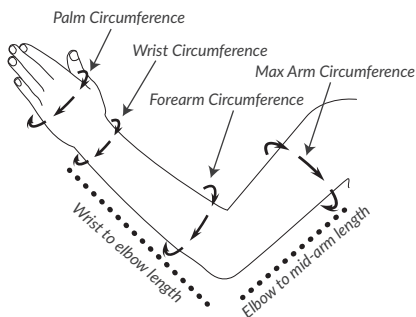
INTENDED USE

- Proximal of radius and ulna fractures (Monteggia fractures, Galeazzi fractures)
- Distal humerus fractures
- Elbow fractures (Supracondylar/Epicondyle fracture of humerus)
- Mid shaft fractures of radius ulna

FULL ARM

FlexiOH[®] Full Arm Immobilizer comes in 5 different sizes :XS, S, M, L and XL. All of the immobilizers vary in terms of palm, wrist, forearm circumference, maximum arm circumference, wrist to elbow length and elbow to upper arm length. For the best fit of FlexiOH[®] full arm immobilizer, taking the measurement of the patient's hand is necessary before application.

MEASUREMENT GUIDE



SIZE CHART (in cm)

| Size vs Measurement: | XS | S | M | L | XL |
|--------------------------|------|------|------|------|------|
| Palm Circumference: | 13 | 16.5 | 18.5 | 21 | 23.5 |
| Wrist Circumference: | 12 | 14 | 16 | 18.5 | 21.5 |
| Forearm Circumference: | 17.5 | 21 | 25.5 | 28.5 | 32 |
| Max. Arm Circumference: | 16.5 | 24.5 | 29 | 34 | 40 |
| Wrist to Elbow Length: | 19.5 | 24 | 25.5 | 30 | 32.5 |
| Elbow to Mid-arm Length: | 15.5 | 19 | 23 | 26 | 29.5 |

Notes :

- * Above sizes fit better as per dimensions mentioned in the table.
- * However FlexiOH[®] adapts to an oversize to a certain extent by stretchability.
- * We advise the healthcare professionals to choose size as per patient's comfort.

FlexiOH[®] Full arm immobilizers are designed for immobilization in above elbow (supracondylar), at the elbow knob and at the inside of elbow tip. The Full arm immobilizer is engineered with new features designed to provide secure and comfortable support. Patients can do daily activities while wearing this immobilizer. For application of FlexiOH[®] full arm immobilizer, doctors need to apply it on the patient's hand with the zip and then cure it with the Rizycure[®] light device (recommended) or direct sunlight for around 5-10 minutes depending on the size of immobilizer. Once it is rigid, it will take the shape of the patient's hand for support during the treatment.

APPLICATION PROCESS

FlexiOH[®] Full arm immobilizer application process is as follows -



Choose the appropriate size from given chart



Take the suitable size for the application



Put full arm immobilizer under the hand



First start zipping forearm zip over the forearm area



Start zipping second zip over the elbow to mid-arm area



Align the fracture part appropriately before curing



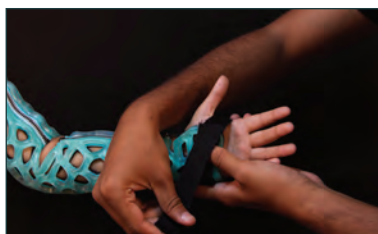
Take Fully charged Rizycure[®] light device



Start the curing process near the palm by holding from both sides



Expose all over the remaining area with Rizycure[®] light device



Once it's rigid, tie a strap loop around the palm over immobilizer



Hold the hand in correct position and let immobilizer achieve rigidity.

FlexiOH[®] provide 35% open area of skin to breathe, wash and exposure to sunlight which are necessary to maintain healthy skin.

FULL ARM



FlexiOH[®]

The **NextGeneration**
Orthopedic Immobilization Technology

*Absolute washable orthopedic Immobilizer
for immobilization of thumb*

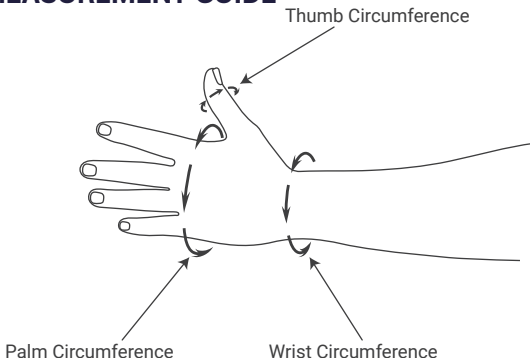
INTENDED USE

- Scaphoid fracture - seen or suspected
- De Quervain tenosynovitis / other ligamentous or soft tissue injuries to the thumb.
- Non-angulated, non-displaced, extra-articular fractures at the base of the first metacarpal.

THUMB SPICA

FlexiOH[®] Thumb Spica Immobilizer comes in 3 different sizes : S, M and L. All of the immobilizers vary in terms of palm circumference, wrist circumference, and thumb circumference. For the best fit of FlexiOH[®] Thumb Spica Immobilizer, taking the measurement of patient's hand is necessary before application.

MEASUREMENT GUIDE



SIZE CHART (in cm)

| Size vs Measurement: | S | M | L |
|----------------------|-----|-----|-----|
| Palm Circumference: | 16 | 18 | 23 |
| Wrist Circumference: | 15 | 16 | 21 |
| Thumb Circumference: | 5.5 | 6.5 | 8.5 |

Notes :

- * Above sizes fit better as per dimensions mentioned in the table.
- * However FlexiOH[®] adapts to an oversize to a certain extent by stretchability.
- * We advise the healthcare professionals to choose size as per patient's comfort.

FlexiOH[®] Thumb spica immobilizers are designed for immobilization of thumb. It has an inbuilt soft hook and loop fastener which is very comfortable for skin contact. It is used to provide support for thumb injuries (ligament instability, sprain or muscle strain), gamekeeper's thumb, de Quervain's syndrome or fractures of the scaphoid or first metacarpal. Doctors need to apply it on the patient's hand and then cure it with the Rizycure[®] light device (recommended) or direct sunlight for around 3-5 minutes depending on the size of immobilizer, until it gets rigid.

APPLICATION PROCESS

FlexiOH[®] Thumb spica immobilizer application process is as follows -



Choose the appropriate size from given chart



Take the suitable size for the application



Put Thumb spica immobilizer over the hand



Fix the first snap button over the palm area



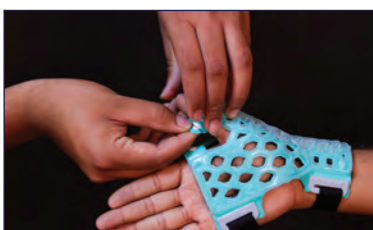
Tighten the first loop around the palm circumference



Tighten the other loop around the wrist circumference



Align the Thumb spica immobilizer along with first metacarpal line



Fix the other snap button around the thumb



Take Fully charged RizyCure[®] light device



Start curing around the thumb and then expose remaining area



Re-tighten all the loops once the Thumb spica immobilizer is rigid

FlexiOH[®] provide 30% open area of skin to breathe, wash and exposure to sunlight which are necessary to maintain healthy skin.

THUMB SPICA



The Portable Rechargeable Light Device

Rizycure® is the handheld light system which is high intensity portable blue light, developed by OrthoHeal. Rizycure® is visible blue light device, specially designed to cure FlexiOH® - an innovative orthopedic immobilizer. It is very easy to use and has been made for the doctors' convenience.

One full charged, Rizycure® Light System can cure 2-3 FlexiOH® immobilizer in a row without recharging. Once it indicates half battery, you need to charge it again for ~60 minutes for uniform intensity*.

Application of RizyCure® LED Light System

Use of RizyCure® Light System is to cure FlexiOH® immobilizer with high intensity uniform blue light, which gives deep and smooth curing. One needs to just expose the uncured region moving slowly for 5-10 seconds over every corners and regions and make sure that it has been cured properly and becomes rigid. While curing, RizyCure® should be very near to the FlexiOH® surface (ideally <1 cm away).

- Before using of RizyCure®, check the battery level indicator.
- Press ON/OFF button to operate the light.
- Use only provided charger with RizyCure® Light System.
- It is recommended that after curing 2-3 FlexiOH®, Charge again before using it.

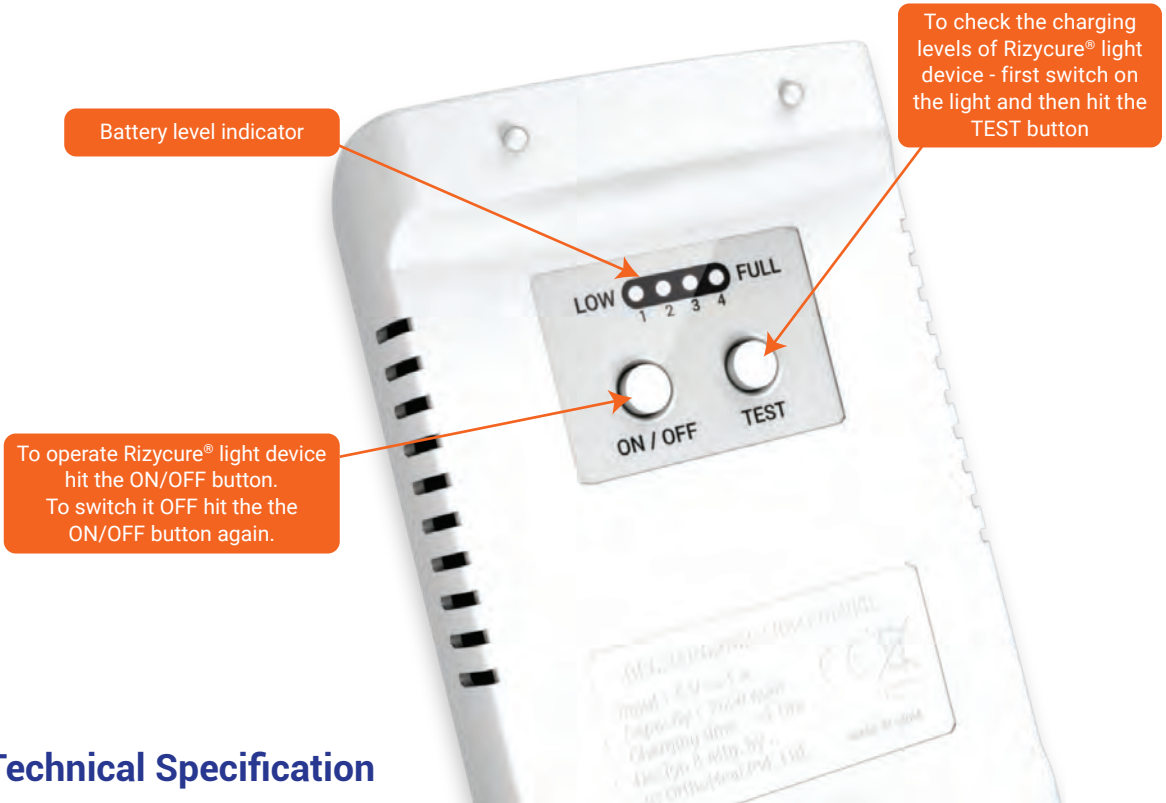
Precautions:

- If you determine that the RizyCure® becomes hot or you observe change in color or shape, switch it off immediately. The device must not be used again and needs to be replaced or contact 'OrthoHeal Customer Care' at 'info@orthoheal.com' for further guidance.
- Do not use RizyCure® while connected to the charger.
- Do not open the RizyCure® Light System or charger.
- Keep away from children / Do not let children to play with this.
- Use goggles while using RizyCure® to avoid eye fatigue.
- In case of low intensity or discharged battery FlexiOH® can not be cured to full strength in given time.

Safety Guideline

- Before switching "ON" light, put on yellow colour goggles provided with the Rizycure® Light system (These goggles provide eye comfort during curing process).
- Do not see the light directly with naked eyes as it may create slight discomfort and blurring of vision for few minutes.

* Tested with 2A-5V USB adapter provided with the Rizycure® light device.



Technical Specification

| | |
|-----------------------------------|--|
| Weight of light | 138 gm |
| Equipment class | Class I |
| Battery type | Li-ion 18650 3.7 V / 2000mAh |
| Battery charging time | Approx. 120 minutes / 2 Hrs. |
| Battery life | <300 cycle |
| Output Power | ~3 Watt |
| Light intensity | ~20-30 mW/cm ² |
| Light charger Input | 110V-240VAC, 50Hz |
| Light charger Output | DC 5V - 2Amp (max) |
| Protection from shock | Type B ⚡ |
| Operating and Storage temperature | 0 to 104°F (0° to 40°C) 10% to 85% relative humidity (non-condensing) 0.5 atm to 1.0 atm (500-1060-hPa) atmospheric pressure. |

This pack includes three protective goggles



in compliance with





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Healing comfortably

FlexiOH[®] COMMON INDICATIONS

| | Short arm immobilizer | Full arm immobilizer | Boxer's immobilizer | Thumb spica immobilizer | Short leg immobilizer | Splint / Slab |
|---|-----------------------|----------------------|---------------------|-------------------------|-----------------------|---------------|
| Distal radius (Non-displaced/ minimally displaced / stable) | ■ | | ■ | | | |
| Colles' fracture/Smith's fractures | ■ | | | | | |
| Hutchinson (chauffeur) | ■ | | | | | |
| Salter-Harris fractures | ■ | | | | | |
| Barton's fractures | ■ | | | | | |
| Monteggia fractures | ■ | ■ | | | | |
| Humerus fractures | | ■ | | | | |
| Mid-shaft of radius-ulna fractures | ■ | ■ | | | | |
| Elbow fractures | | ■ | | | | |
| Stable wrist fractures | ■ | | | | | |
| Pre/post operative surgery | | | | | | ■ |
| Ligament sprain/soft-tissue injury | | | | | | ■ |
| Torus fractures | ■ | | | | | |
| First CMC (carpometacarpal) fractures | | | | ■ | | |
| Scaphoid fractures | | | | ■ | | |
| De Quervain tenosynovitis | | | | ■ | | |
| Skier's /game keeper's thumb | | | | ■ | | |
| Carpal bone injuries | ■ | | ■ | | | |
| Phalangeal fractures | | | ■ | | | |
| Bennett's fractures | | | ■ | | | |
| Sprain or dislocation of thumb | | | ■ | ■ | | |
| Bumper/pott's fractures | | | | | ■ | |
| Cotton's fractures | | | | | ■ | |
| Pilon/ Aviator's fractures | | | | | ■ | |
| All Metatarsal fractures | | | | | ■ | |

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Government of India

Department of BioTechnology
Ministry of Science & Technology



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CENTER

ACKNOWLEDGEMENT

STANFORD
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SCHOOL



LOCKHEED MARTIN

ic² INSTITUTE
THE UNIVERSITY OF TEXAS AT AUSTIN



MEDIA PARTNERS



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