



Instructions for Use

Document No.	OH-IFU-01	Rev No. & Date	00 & 02/01/2019	Issue No & Date	01 & 02/01/2019
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FlexiOH™-Technology

Device Description

- FlexiOH™ is the first of its kind- an orthopedic cast that has the rigidity to hold the fractured part as well as ensuring proper skin ventilation. FlexiOH™ comes as an easy to fix wearable material on the fractured part. After wearing, light treatment completes the curing process and makes the FlexiOH™ cast rigid.
- It includes upper limb cast/Splint which is made of silicone rubber, light curable resin and nitrile rubber foam.

Intended Use

This device is intended for-

- Non-displaced
- Minimally displaced
- Buckle fracture other than Scaphoid / Trapezium
- As a removable splint

Contradictions

- Skin allergic reaction due to nitrile rubber
- To mentally unstable patient.
- Patients having severe open wound.
- Compartment Syndrome

Warnings

1. Cast/ slab might be hot and or may cause discomfort on touching external surface while curing process.
2. **Risk of Reuse:** FlexiOH™ is only for single use. Once it is cured and applied on the patient, after treatment it must be disposed properly. Reuse of this device on any patient might cause skin-irritation or skin related problems

Precautions

1. For Doctors

- The Product is intended for use by physicians trained and experienced in diagnostic.
- For best fit, choose size before the application of FlexiOH™ from the size chart. Make sure that the patient feels comfortable before curing process. If patient is feeling too tight or too loose, change to another size.
- FlexiOH™ immobilizes through Rizycure™ light device. Usually, it takes 3-5 minutes for curing medium size short arm FlexiOH™, it might take shorter or longer time duration depending on the size of FlexiOH™.





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2. For Patients

- Don't remove /peel cushioning foam from FlexiOH™, it may expose the hard edge of skin
- Don't put unnecessary pressure on the FlexiOH™
- In some circumstances FlexiOH™ rib may break or crack but that will not affect the treatment's outcome.
- Wash FlexiOH™ regularly for better skin hygiene.
- Do not try to damage FlexiOH™ without consultation of doctor or medical supervision.
- Contact your doctor in case of FlexiOH™ is too loose, too tight, broken, increased swelling or redness of the skin

Directions for Use

1. Choose the appropriate size.



2. Apply cushioning to thumb to give extra comfort to pressure points



3. Place cast over the fractured hand anchoring thumb



4. Lock the zip by placing insertion pin into retainer box



5. Pull the puller of the zip to the end



6. As cast adapts to the shape of hand, start reduction process





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7. Take fully charge RizyCure™ Light Device and Start curing around the thumb to give initial support to the broken bone



8. Expose 3-4 mins thoroughly and check every corner until it gets harden



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












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Labelling Symbols

The following is an explanation of symbols that may be used on your product packaging

	Read Instructions Before Use
	Keep Away from Sunlight
	Lot Number
	Date of Manufacture
	Use By
	Single Use
	Temperature Limitation
	Non-Sterile
	FDA listed
	'Medical Prescription'.
	Do not use if package is damaged
	Does Not Contain Natural Rubber Latex
	Manufacturer Address
	European Union Representative Address

