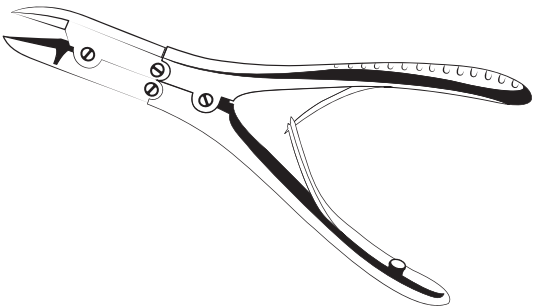


DOUBLE ACTION PLIERS

INSTRUCTIONS FOR USE

Please read these instructions carefully before application.

Double Action Pliers

GENERAL DESCRIPTION
Double Action Pliers is used for easy and safe removal of FlexiOH-Light Cured Polymer Immobilizer.

INTENDED USE / INDICATION
To be used solely for the removal process of FlexiOH light cured polymer immobilizers.

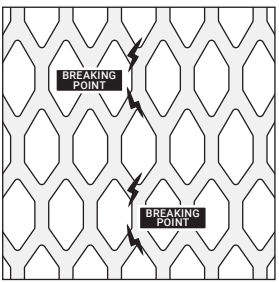
CONTRAINDICATIONS
None known.

PATIENT POPULATION
Patients undergoing fracture immobilization treatment using FlexiOH - Light Cured Polymer Immobilizer.

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

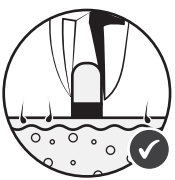
APPLICATION INSTRUCTION
Follow the steps to remove the FlexiOH Light Cured Polymer Immobilizer before /after the treatment:

1. Cut the fabric liner of the zip using scissors.
2. Select the breaking points as per image.
3. Break the rib of the FlexiOH immobilizer on the opposite side of the zipper line using double action pilers as shown in the image.
4. Apply gentle force to open the immobilizer from the zip side to remove it.



BREAKING POINT

Keep pliers away from skin



Correct Pliers postion

WARNINGS AND PRECAUTIONS

- Keep away from children / Do not allow children to play with Double Action Pliers.
- In case, the box is damaged but the product is intact in the box, the product can be used for the removal of immobilizer.
- Use goggles while Double Action Pliers removing the immobilizer to avoid eye injury.
- Double Action Pliers is for Professional use only.
- To be sold and used only for removal of FlexiOH immobilizer.

ADVERSE EFFECTS

None Known.

STORAGE CONDITIONS

Keep the device in a cool and dry place.

REPORTING OF ADVERSE EVENTS

In case of any event please notify to 'care@orthoheal.com' or to the respective country regulatory authority.

CLEANING GUIDELINE

It is recommended to clean the Double Action Pliers by 70% IPA wipes before every use.

SYMBOL GLOSSARY

MD	Medical Device
	Do not use if package is damaged and consult instructions for use
NON STERILE	Non-sterile
	Consult instructions for use.
	Manufacturer
	Date of Manufacture
REF	Catalog Number / Reference code
LOT	Batch code / Lot Number
UDI	Unique device identifier
EC REP	Authorised representative in the European Union

Copy of the design or technology may infringe IP rights.

bsi. ISO 13485 : 2016 Quality Management System

FDA LISTED CE

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