YOGESHWAR IMPLANTS (I) PVT. LTD.

LIFT-EXTRA ARTICULAR DISTAL HUMERUS

PLATE-3.5MM- RIGHT-LEFT

SURGICAL TECHNIQUE

Index

Index 2

1. **Description of Surgical Technique** 3
2. **Feature & Benefits** 4
3. **AO Principle** 5
4. **Indications** 6
5. **Intended Purpose** 7
6. **Contraindications** 8
7. **Surgical Steps** 9
8. **Implant Removal** 13
9. **Caution** 14
10. **Disposal of Implants** 15
11. **Packaging Material Disposal** 16
12. **MRI Information** 17
13. **Note** 18

1. Description of Surgical Technique

Name-Lift-extra articular distal humerus plate-3.5mm- right-left

The lift humerus tibia system, featuring locking compression technology, is indicated for intra- and extra-articular fractures and osteotomies of the distal humerus.

Available in SS316L & Titanium Gr. 5 materials.

2. Feature & Benefits

- **Plates Features:**

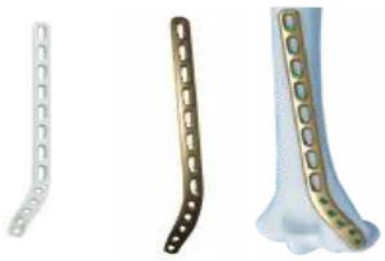
Anatomically precontoured

-Minimal irritation of ligaments and soft tissue from a flat plate and screw profile, rounded edges and polished surfaces.

- **Extra Articular distal humerus plates**

Depending on the indication, plates are selected with distal humerus placement. Both locking and Cortical screws 3.5 mm can be inserted in the shaft.

Lift-extra articular distal humerus plate



3. AO Principle

- In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation:

1. **Anatomic reduction**: Fracture Reduction and fixation to restore anatomical relationships.
2. **Stable fixation:** Fracture fixation providing absolute or relative stability, as required by the patient, the injury, and the personality of the fracture.
3. **Preservation of blood supply**: Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.
4. **Early, active mobilization**: Early and Safe Mobilization and rehabilitation of the injured part and the patient as a whole.

4. Indications

- Extra articular fracture of distal humerus
- Malunions of the distal humerus
- Non unions of the distal humerus

5. Intended Purpose

The distal humerus system consisting Distal humerus system is intended for temporary fixation, correction or stabilization in the Distal humerus anatomical region.

6. Contraindications

- Since external fixation devices are often used in emergency situations to treat patients with acute injuries, there are no absolute contraindications for use. The surgeon's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment for each individual patient. Whenever possible, the device chosen should be of a type indicated for the fracture being treated and/or for the procedure being utilized.
- Insufficient quantity or quality of bone which would inhibit appropriate fixation of the device.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or operative site.
- Previous history of infections.
- Any neuromuscular deficit which could interfere with the patient's ability to limit weight bearing.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Malignancy in the fracture area.
- Mental, physical or neurological conditions which may impair the patient's ability to cooperate with the post-operative regimen.
- Patients with a compromised immune system.
- Pre-existing internal fixation that prohibits proper pin placement

7. Surgical Steps

- **Preoperative Planning- General Technique**

1. Plate selection and contouring

The plates are available in various shapes and lengths which allow the surgeon to select fragment-specific treatment of distal humerus fractures. Decide on the desired articular approach and select the plates according to the fracture pattern and anatomy of the tibia. Contour the plates to the anatomy with the Plate Benders.

Precautions:

- The plate holes have been designed to accept some degree of deformation. The undercuts help ensure that the threaded holes will not be distorted with typical contouring. Significant distortion of the threaded holes will reduce locking effectiveness.
- Reverse bending or use of the incorrect instrumentation for bending may weaken the plate and lead to premature plate failure (e.g. breakage). Do not bend the plate beyond what is required to match the anatomy.
- Temporary fixation of fracture with K- wire
- Reduction can be preliminarily held with K-wires of 1.5mm or 1.8mm. A k wire introduced across the bone will fit into a plate.

2. Screw insertion

Determine whether cortical screws or locking screws will be used for Fixation in the shaft. Locking screws in the distal arm (head of the plate) may be an advantage to support the articular surface and prevent loss of reduction.

Recommendation: Use locking head screws in the distal arm of the plates, and locking head and/or cortical screws in the shaft of the plates. If a combination of cortical screws and locking head screws is used, a cortical screw should be used first to pull the plate to the bone.

Warning: If a locking head screw is used first, care should be taken to ensure that the plate is held securely to the bone, to avoid spinning of the plate.

- **Insertion of Cortical Screws:**

- **Pre-drill screw hole**

The insertion of cortical screws –3.5 mm is described using the example of a tibia plate. According to the selected screw diameter use the appropriate drill guide & tap guide 2.5mm/3.5mm to pre-drill the screw hole either neutrally

(buttress) or off-centre (compression). For the Cortical screw 3.5mm, use the 2.5mm drill bit for the gliding hole.

Determine screw length

Use the Depth Gauge for screws 3.5mm to determine the screw length.

- **Pick up screw**

Select and pick up the appropriate cortical screw using the Hexagonal Screwdriver 3.5mm Insert self-tapping Cortical Screw- 3.5mm

Insert the self-tapping cortical screw with the Hexagonal Screw Driver3.5mm.

Insertion of Locking Screws -3.5mm:

Insert Lift drill sleeve 2.8mm

The insertion of locking screws is described using the example of an extra articular distal humerus plate.

Screw the Locking Drill Sleeve for 3.5mm screws vertically into a threaded hole until fully seated. This is very much needed to ensure central drilling of the screw hole so that the final screw head shall fit into the plate's hole flushing to the plate and locking threads of the screws shall have engaged in plate firmly.

Predrill screw hole

With the Drill Sleeve for 3.5mm screws, use 2.8mm drill bit to drill to the desired depth.

Determine screw length

Use the Depth Gauge for screws 3.5mm to determine the screw length.

Pick up screw

Select and pick up the appropriate screw using the Hexagonal Screw Driver 3.5mm

Insert Locking screw 3.5mm

Insert the locking screw manually with the Hexagonal Screwdriver. Carefully tighten the locking screw, as excessive force is not necessary to produce effective screw locking. Alternatively, to apply the correct amount of torque use the
Torque Limit Screw Driver-3.5for torque up to 1.5Nm at the time of inserting final few threads of the screw.

8. Implant Removal

The LIFT extra articular distal humerus Plates should first be removed by following screw removal technique of cortical screws. Take care while removing locking screws, first unlock all screws from the plate with Hexagonal Screw Driver 3.5 mm then remove the screws completely from the bone. This prevents rotation of the plate when removing the last locking screw. Ensure that the tip of the screw driver sits fully into the head of the screws. Partial engagement may lead to wear out of screw head or screw driver tip. Don't use high torque while removing the screws. If screw head gets damaged during removal, use the screw removal instruments to remove damage head screws.

Note: The final decision of removing the implants shall be taken by the operating surgeon only. It is recommended that the implant used as an aid for healing should be removed once its service is over after proper consultation and examination by the operating surgeon in final follow up, particularly in younger and more active patients.

9. Caution

Used Implants:

Used implants which appear un-damaged may have internal and/or external defects. It is possible that individual stress analysis of each part fail to reveal the accumulated stress on the metals as a result of use within the body. This may lead ultimately to implant failure after certain point of time due to metal fatigue. Therefore, reuse of implants is strictly not recommended.

SINGLE BRAND USAGE: Implant components from one manufacture should not be used with those of another. Implants from each manufacture may have metal, dimensions and design differences so that the use in conjunction with different brands of devices may lead to inadequate fixation or adverse performances of the devices

10. Disposal of Implants

Every used or removed implant must be discarded after use and must never be re- used. It should be bent or scratched & then disposed of properly so that it becomes unfit for reuse. While disposing it off, it should be ensured that the discarded implant does not pose any threat to children, stray animals and environment. Dispose of the implants as per applicable medical practices and local, state and country specific regulatory requirement of Bio Medical Waste rules.

11. Packaging Material Disposal

The packaging material of this device is made special packing material and therefore if swallowed, may cause choking Hazards. Therefore, it should be disposed of in such a way that keep out of reach of children and stray animals.

12. MRI Information

IMPORTANT:

- Yogeshwar Implants (I) Pvt. Ltd. implants are manufactured from SS 316L and Titanium Grade 5 material both are non-magnetic material, hence it do not pose any safety risk.
- Patients should be directed to seek a medical opinion before entering potentially adverse environments that could affect the performance of the implants, such as electromagnetic or magnetic field or including a magnetic resonance environment.
- Doctor shall conduct a Risk Benefit Analysis before directing the patient to enter electromagnetic or magnetic fields or including a magnetic resonance environment.
- The Yogeshwar Implants (I) Pvt. Ltd. implants has not been evaluated for safety and compatibility in the MR environment but on the basis of literature study below mentioned points can be taken care during MRI
  - ✓ The minimum recommended time after the implantation that allows patients to safely undergo MRI examination or allowing the patient or an individual to enter the MRI environment is 6 (six) weeks.
  - ✓ The maximum recommended time limit for MRI examination in patients implanted with the evaluated device is 30 min with a scanner operating at 1.5T (Tesla) or less.

13. Note

This above surgical technique is also applicable for all below mention product	
Sr No.	Product Name
01	LIFT DISTAL HUMERUS PLATE WITH SUPPORT - RIGHT
	3H , 5H
	7H , 9H
02	LIFT DISTAL HUMERUS PLATE WITH SUPPORT - LEFT
	3H , 5H
	7H , 9H
03	LIFT DISTAL HUMERUS PLATE WITHOUT SUPPORT - RIGHT
	3H , 5H
	7H , 9H
04	LIFT DISTAL HUMERUS PLATE WITHOUT SUPPORT - LEFT
	3H , 5H
	7H , 9H
05	CLOVERLEAF PLATE
	3, 4 HOLES
	5, 6 HOLES
	7, 8 HOLES
06	LIFT - CLOVERLEAF PLATE - 3.5MM
	3H, 4H

	5H, 6H, 7H, 8H
	10H

Yogeshwar Implants (I) Pvt. Ltd.

Sr. No. 91 HISSA No. 1, "AR'" building,

Shobhana Complex, Rajlaxmi Compound,

Kalher Village, Tal. Bhiwandi, Thane – 421302, INDIA

E-mail: sales@yogeshwarimplants.com

Contact No: +91-9323927102

Website: www.yogeshwarimplants.com