YOGESHWAR IMPLANTS (I) PVT. LTD.

DISTAL FEMORAL PLATE AND LATERAL TIBIA PLATE

SURGICAL TECHNIQUE

Index

1. Description of Surgical Technique

Name- Lateral Tibia Plate and Distal Femur Plate

Lateral Tibia plate and Distal Femur Plate with combi-holes in the shaft

- Anatomically designed to recover femur & tibia fractures.
- Available in SS 316L & Tit. Grade 5

2. Feature & Benefits

- Both plates are in Left and Right direction
- Available in 5, 7, 9, 11, 13 and 15 combi-holes in the shaft

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

Lateral Tibia plate is indicated for the stabilization of fractures of the proximal tibia. These include:

- Proximal shaft fractures
- Meta physical fractures
- Intra-articular fractures
- Per prosthetic fractures

Distal Femur plate is indicated for the stabilization of fractures of the Distal Femur.

These Includes:

- Distal Femur Fractures
- Femur shaft Fracture

5. Intended Purpose

It is used in

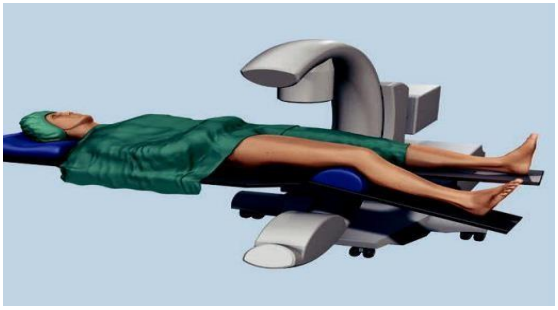
- It is used in Proximal shaft fractures
- Meta physical fractures
- Intra-articular fractures
- Per prosthetic fractures

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

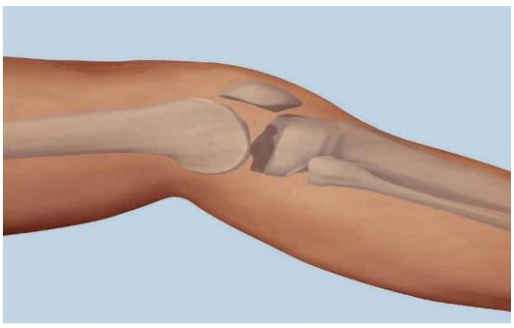
1. Position the patient supine on a radiolucent table. The leg should be freely movable. The contra lateral leg can be placed in an obstetric leg holder. Ensure that both a lateral and x-ray of the proximal tibia can be obtained in this position. Support the knee with towels to flex it into the appropriate position.



Depending on requirements, it is possible to perform either a curved (120° hockey stick) or a straight skin incision from a distal direction

2. Approximately half a centimeter from the tibia ridge, detach the anterior tibia muscle from the bone, retract it and insert the plate in the space between the periosteum and the muscle. To allow correct positioning of the proximal part of the plate, it is important to adequately dissect the muscle attachment site.

For complex intra-articular fractures, an anterolateral arthrotomy that provides good control of the reduction may be preferred.



3. For preliminary fixation of the plate, use a 2mm wire **through** the most proximal Kirschner wire hole, Insertion of 5.0 mm Drill Sleeve for 4.3 mm Drill Insertion of 4.3 mm Drill Bit **for** Drill the bone, and Carefully check the position of the plate and the length of the reduced injured

limb. Once the reduction has been successfully completed and the plate has been positioned correctly, the locking screws can be inserted and Tighten the screw manually with the 4.5mm Screwdrive

Insertion of Drill Sleeve for 4.3mm Drill, Insertion of 3.2/4.5mm Drill & Tap Sleeve Combined and Insertion of Drill Bit, Remove the Combined Sleeve and Insertion of 5.0 mm Depth Gauge for Check the Drill Depth, then Insertion of Locking Screw has been Successfully and tighten the Screw manually with 5mm Screw Driver.

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 - T PLATE - 4.5 / 5MM
	3H, 4H
	5H, 6H, 7H, 8H
02	LIFT - T BUTTRESS PLATE - 4.5 / 5MM
	5H, 6H, 7H, 8H
03	LIFT - L BUTTRESS PLATE - 4.5 / 5MM - RIGHT
	3H, 4H
	5H, 6H, 7H, 8H
	10H
04	LIFT - L BUTTRESS PLATE - 4.5 / 5MM - LEFT
	3H, 4H
	5H, 6H, 7H, 8H
	9H
05	T' BUTTRESS PLATE- A.O.TYPE
	4, 5 HOLES
	6, 7 HOLES

	8, 9 HOLES
	10HOLES
06	L' BUTTRESS PLATE(RIGHT & LEFT)
	4, 5 HOLES
	6, 7 HOLES
	8,9 HOLES
	10 HOLES

Lateral Tibial Head Plate

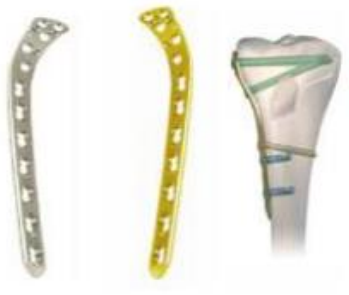
Cat No. For SS	0216
Cat No. For Tit.	1316
Available in	R/L
No. of Shaft Holes	5,7,9,11,13
Locking Screw	5.0 mm
Cortical Screw	4.5 mm
Cancellous Screw	5.0 mm

Profile
Thickness : 5.0 mm
Width : 16.0 mm
Fixation with 5.0 and 4.5 mm screw.

Indication
- Proximal shaft fractures of tibia.
- Metaphyseal fractures of tibia.
- Intra-articular fractures of tibia.
- Periprosthetic fractures of tibia.

Features
- Anatomically designed plate fits over proximal tibia from lateral side.
- Limited Contact plate design reduces the plate and bone contact, this feature reduces vascular trauma.

Use
Fracture for Proximal Lateral Tibia.



LIFT - K –WIRE 2.0 / 2.5 MM CAT NO. 1201

LIFT - DRILL GUIDE 3.2/4.5 MM CAT NO. 600.05

LIFT - BONE TAP 4.5 MM CAT NO. 600.03

Distal Femoral Plate

Cat No. For SS	0215
Cat No. For Tit.	1315
Available in	R/L
No. of Shaft Holes	5,7,9,11,13,15
Locking Screw	5.0 mm
Cortical Screw	4.5 mm
Cancellous Screw	5.0 mm

Profile
Thickness : 6.0 mm
Width : 16.0 mm
Fixation with 4.5 and 5.0 mm screw.

Indication
- Distal shaft fractures of femur
- Supracondylar fractures of femur
- Intra-articular fractures of femur
- Periprosthetic fractures of femur

Features
- The preshaped, low-profile plate minimizes potential issues with soft tissues and reduces need for plate contouring.
- A tapered, rounded plate tip facilitates a minimally invasive surgical technique

Use
Fracture for Distal Femur.

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