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#### The ULTRALOCK TECHNOLOGY

The following points distinguish treatment using ULTRALOCK screw technology:

- It allows fracture treatment using conventional plating with conventional Cortical or cancellous bone screws.
- An ULTRALOCK plate can also be used as an internal fixator and permits stable bridging over shattered zones.
- The ULTRALOCK system permits the combination of conventional and locking screws.
- Unicortical locking screws permit better vascularity.

#### **Important notes:**

The Ultra Lock Plating system applies to many different plate types and is therefore suitable for a large number of fracture types of large bones. For that reason, this Surgical Technique does not deal with any specific fracture type. Please refer to literatures of Principles of Fracture Management for specific fracture procedure.

#### **Indications**

The Ortho Max ULTROLOCK Plates — narrow and broad, are intended for fixation of various long bones, such as the humerus, femur and tibia. They are also for use in fixation of osteopenic bone and fixation of nonunions or malunions.

The Ortho Max ULTRALOCK Plates — T-Plates are intended to buttress metaphyseal fractures of the proximal humerus, medial tibial plateau and distal tibia-femur. They are also for use in fixation of osteopenic bone and fixation of nonunion and malunions.

The various options of plates in large fragment system are as under:

#### **Plates Options and Intended Use:**

- Dynamic Compression Locking Plates (DCLP) Narrow 12mm- For Fracture Fixation of Tibia
   & Humerus Shaft
- Dynamic Compression Locking Plates (DCLP) Broad 16mm For Fracture Fixation of Femur
- Buttress 'T' Locking Plates / Buttress 'L' Locking Plates For Internal Fixation of Proximal Tibial Condyle
- Lateral Tibial Head Locking Plates For Internal Fixation of Proximal Tibial Condyle

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- Peri-Articular Proximal Tibia LockingPlates For Internal Fixation of Proximal Tibial Condyle
- Proximal Medial Tibial LockingPlates For Internal Fixation of Proximal Tibial Condyle
- Antrolateral Distal Tibia Locking Plates For Internal Fixation of Lateral Distal Tibial Condyle
- Distal Tibia Locking Plates For Internal Fixation of Distal Medial Tibial Condyle
- Metaphyseal Distal Tibia Locking Plates For Internal Fixation of Medial Distal Tibial Condyle
- Low Bend Distal Tibia Locking Plates For Internal Fixation of Distal Medial Tibial Condyle
- Distal Femur Locking Plates For Internal Fixation of Distal Femur Condyle
- Proximal Femur Locking Plates For Internal Fixation of Proximal Femoral Condyle
- Richard's Barrel Locking Plates For Internal Fixation of Trochanter with Hip Screws
- Calcaneal Locking Plates For Internal Fixation of Calcaneal

#### **Contraindications:**

Do not use the Bone Plate, Bone Screw, Pins & Wires in cases of:

- Inadequate bone quantity and/or bone quality
- Hypersensitivity to metal or allergic reaction
- Early or Late Inspection, both deep and / or superficial
- Patients with limited blood supply
- Patient within whom co-operation or mental competence is lacking, thereby reducing patient compliance

#### **ADVERSE REACTIONS**

Adverse reactions may include but are not limited to:

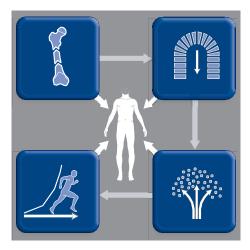
- Clinical failure (i.e. pain or injury) due to bending, loosening, breakage of implant, loose fixation, dislocation and/or migration
- Pain, discomfort, and/or abnormal sensations due to the presence of the implant.
- Primary and/or secondary infections.
- Allergic reactions to implant material.
- Necrosis of bone or decrease of bone density.
- Injury to vessels, nerves and organs.
- Elevated fibrotic tissue reaction around the surgical area.

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#### **AO Principles**

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



#### **Anatomic reduction**

Fracture reduction and fixation to restore anatomical

#### Stable fixation

Fracture fixation providing absolute or relative stability, as relationships.

#### Early, active mobilization

Early and safe mobilization and rehabilitation of the injured part and the patient as a whole. Required by the patient, the injury, and the personality of the fracture.

**Preservation of blood supply** Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

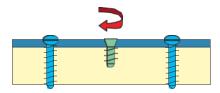
#### **Combined Internal Fixation**

The combination of conventional compression plating and locked plating techniques enhances plate osteosynthesis. The result is a combination hole that, depending on the indication, allows conventional compression plating, locked plating, or a combination of both.

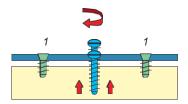
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#### Internal fixation using a combination of locking screws and standard screws



Note: If a combination of Cortical and locking screws is used, a cortical screw should be inserted first to pull the plate to the bone.

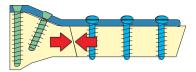


If locking screws (1) have been used to fix a plate to a fragment, subsequent insertion of a conventional screw

(2) In the same fragment without loosening and retight- ending the locking screw is NOT RECOMMENDED.

Note: If a locking 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 about the bone.

#### **Dynamic compression**



Once the Metaphyseal fragment has been fixed with locking screws, the fracture can be dynamically compressed using conventional screws in the DC hole portion of the ULTRALOCK hole.

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### **Locked and Conventional plating techniques**

- First, use lag screws to an atomically reconstruct the joint surfaces.
- The behavior of a locking screw is not the same as that of a lag screw. With the locked plating technique, the implant locks the bone segments in their relative positions regardless of how they are reduced.
- A plate used as a locked plate does not produce any additional compression between the plate and the bone.
- The unicortical insertion of a locking screw causes no loss of stability.

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#### **Surgical Technique (continued)**

#### 1. Plate selection

• The plates are available in various lengths and configurations as shown above similar to the Ortho Max Basic Plating Set.

#### 2. Contouring

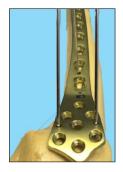
a. Use the Plate bender in Pair to contour the ULTRA LOCK Plate to the anatomy.



Note: The plate holes have been designed to accept some degree of deformation. When bending the plate, place the benders on two consecutive holes.

This ensures that the threaded holes will not be distorted. Significant distortion of the locking holes will reduce locking effectiveness.

#### 3. Reduction and temporary plate placement



The plate may be temporarily held in place with K wire holding in bony fragment.

Note: The middle of the plate should be positioned over the fracture site if compression of the fracture fragments is desired.

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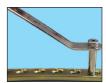


#### 4. Screw insertion

Insertion of a Cortical or cancellous bone screw

Use the 4.5 mm Drill & Tap Sleeve for an eccentric (compression) or neutral (buttress) insertion of cortical screws.

Determine whether conventional cortical screws, cancellous bone screws or locking screws will be used for fixation. A combination of all may be used.





Note: If a combination of Cortical, cancellous and locking screws is used, a conventional screw should be used first to pull the plate to the bone.

Warning: If a locking 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 about the bone.

#### Insertion of 4.0 mm and 5.0 mm Locking Screws

Note: The locking screw is not a lag screw. Use non locking screws when requiring a precise anatomical reduction (e.g., joint surfaces) or inter fragmentary compression. Before inserting the First locking screw, perform anatomical reduction and fix the fracture with lag screws, if necessary. After the insertion of locking screws, anatomical reduction will no longer be possible without loosening the locking screw.

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A. Screw the appropriate Threaded Locking Drill Sleeve for 4.0 mm or 5.0 mm screws into plate hole until fully seated.



- B. Use the appropriate Drill Bit (3.2 mm for 4.0 mm screws and 4mm for 5.0 mm screws) to drill to the desired depth.
- C. Remove the drill Sleeve.



D. Use the Depth Gauge 3.5 or 4.5mm to determine screw length.

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Note 1: Since the direction of a locking screw is determined by plate design, final screw position may be verified with a K wire prior to insertion. This becomes especially important when the plate has been contoured or applied in metaphysical regions around joint surfaces.

Warning: Do not try to bend the plate using the Locking Drill Sleeve because damage may occur to the hole's threads.



E. Insert the locking screw of respective dia. And length using the Torque Limit Screw driver of 4mm or 5mm.

Note: The screw is securely locked to the plate when an audible "click" is heard.



#### F. Alternative Method of Locking Screw Insertion

Use the Hexagonal Screw driver 3.5mm or 4.5mm to manually insert the appropriate locking screw.

Carefully tighten the locking screw, as excessive force is not necessary to produce effective screw-to- plate locking which can damage screw head and driver.

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### **Postoperative treatment**

Postoperative treatment with ULTRALOCK Plates does not differ from conventional internal fixation procedures.

#### **Implant removal:**

To remove the Ultra Lock Plates, unlock all screws from the plate; then remove the screws completely from the bone by following screw removal technique of cortical screws with the help of Hexagonal Screw Driver 3.5 OR 4.5mm. This prevents simultaneous rotation of the plate when removing the last locking screws .The following should be noted in order to avoid damage to the instrument or implants: Always engage the screw driver tip firmly into the head of screw to remove. Don't give extra quick torque to damage screw head. 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.

#### **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 reuses of implants are strictly not recommended.

#### **Disposal of Used 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.

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#### **PACKAGING MATERIAL DISPOSAL:**

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

#### **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.

#### **MRI SAFETY INFORMATION**

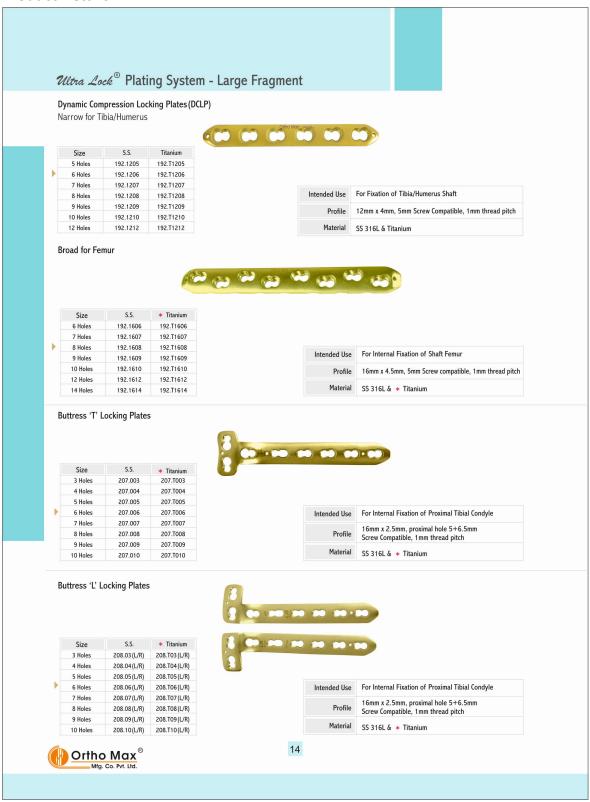
- Ortho Max Mfg. Co Pvt. Ltd. implants are manufactured from Titanium Gr.2, SS316L, SS316LVM material for Bone Plate & Titanium Gr.5, SS316L, SS316LVM material for Bone Screw, Pins & Wires, both are non-magnetic material, hence it do not pose any safety risk.
- Patients should be directed to seek a medical 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 Ortho Max Mfg. Co 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.

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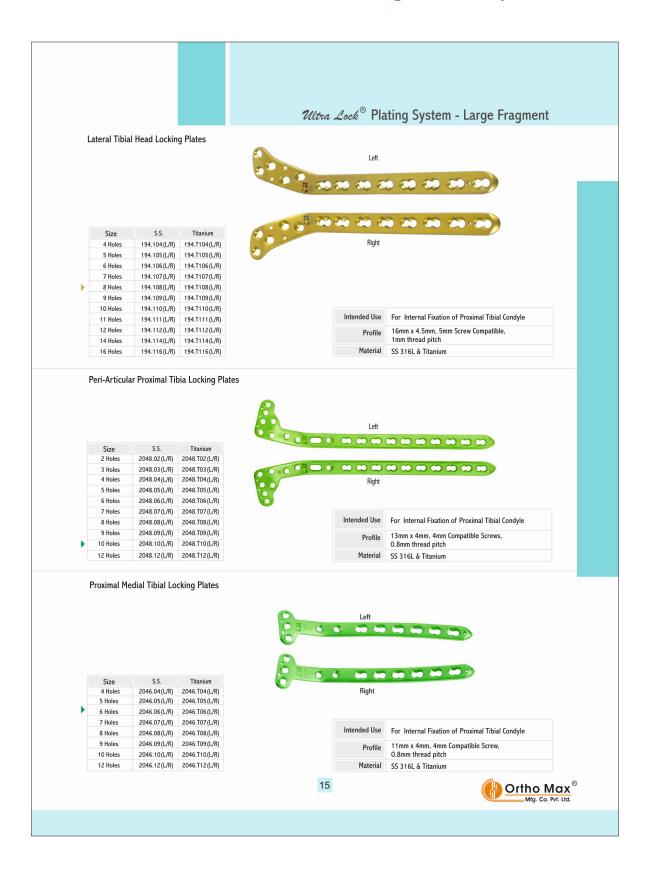
### LOCKING COMPRESSION PLATING SYSTEM FOR LARGE FRAGMENT – Surgical Technique

#### **Product Details:**



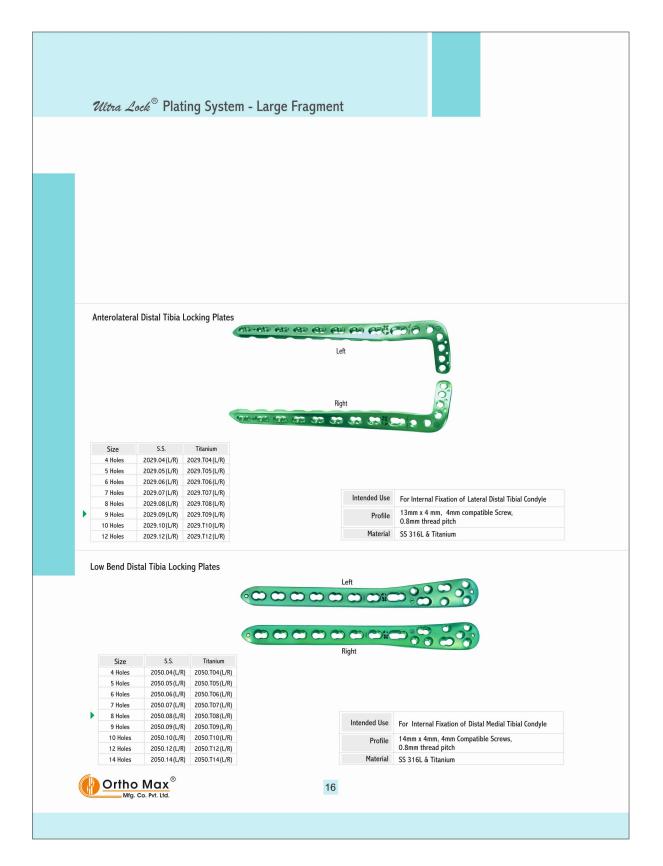
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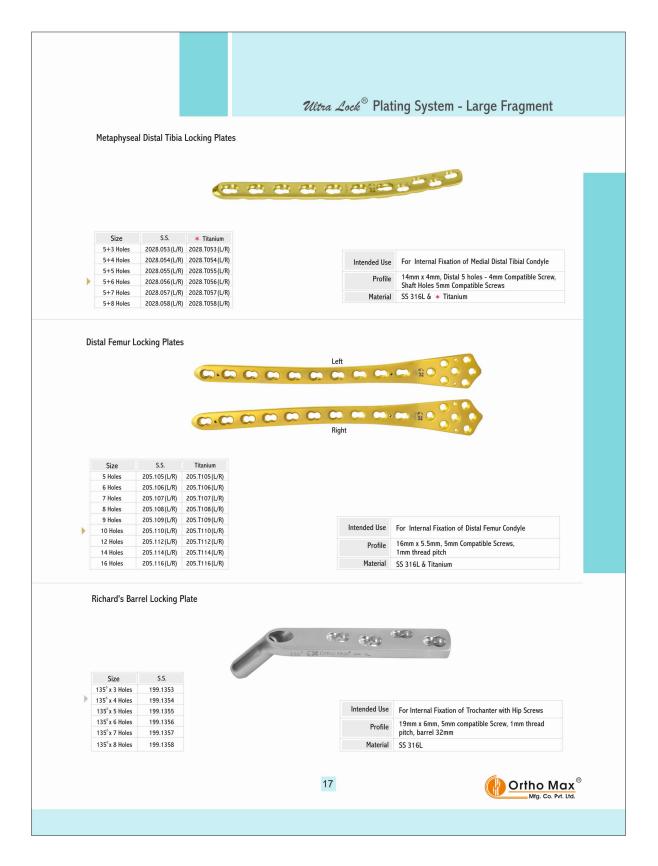
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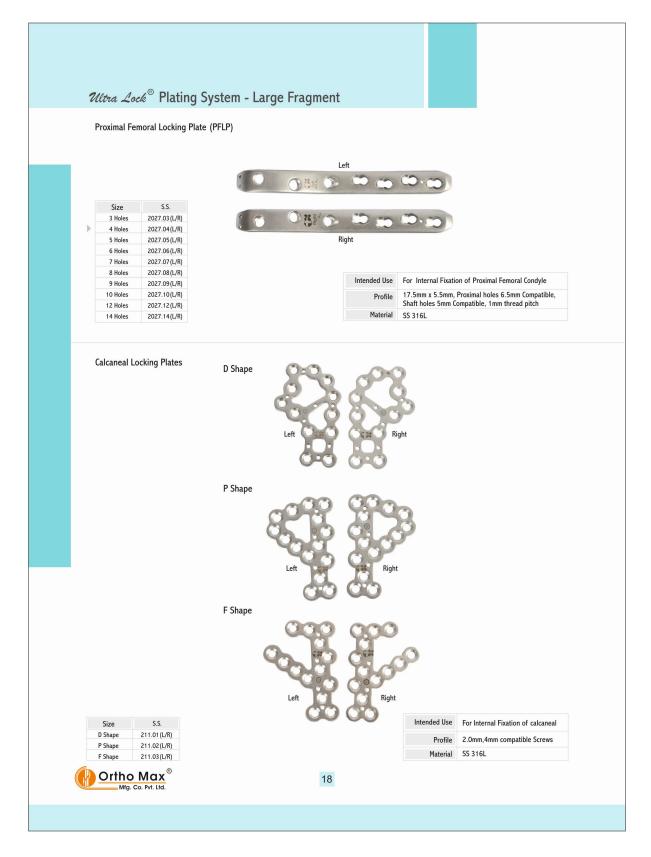
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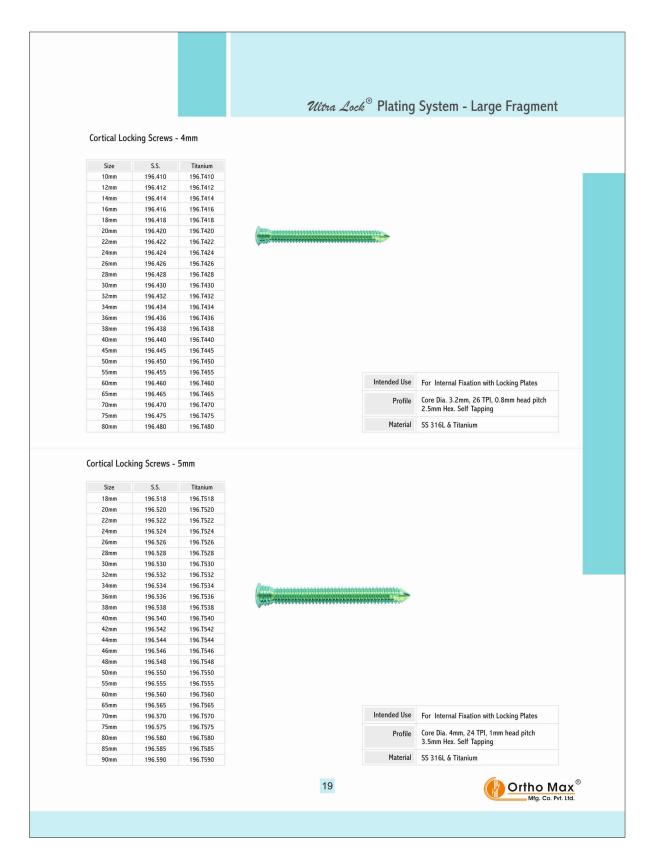
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### Ortho Max Mfg. Co. Pvt. Ltd.



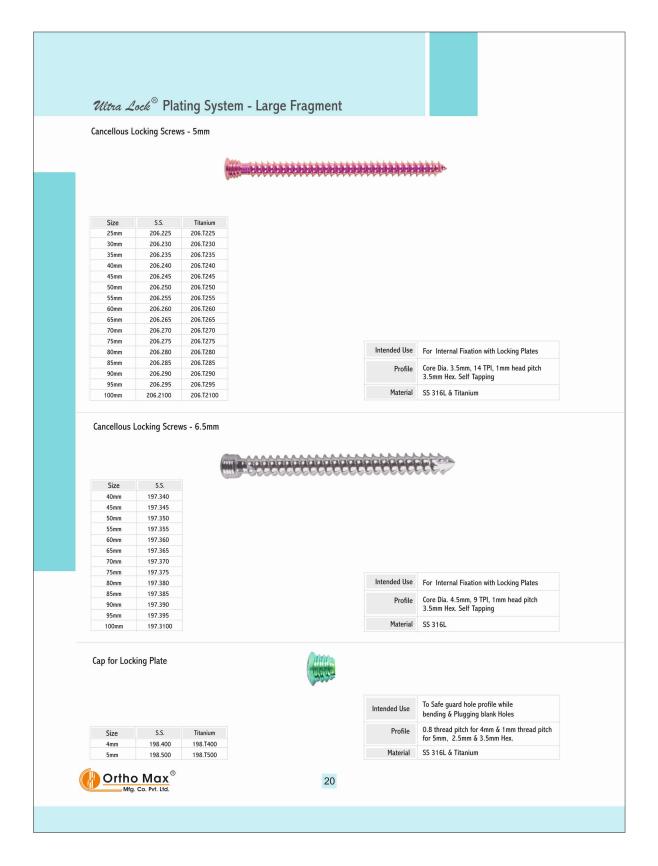
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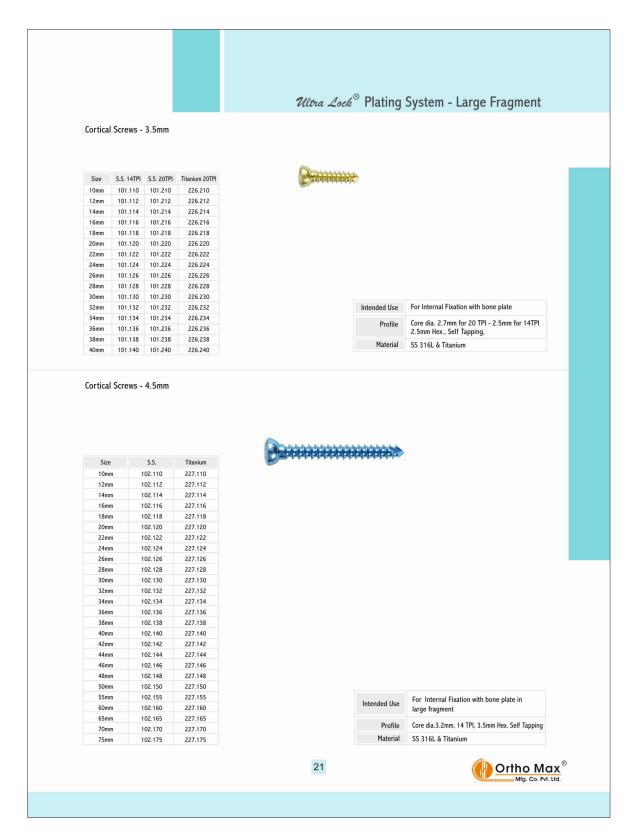
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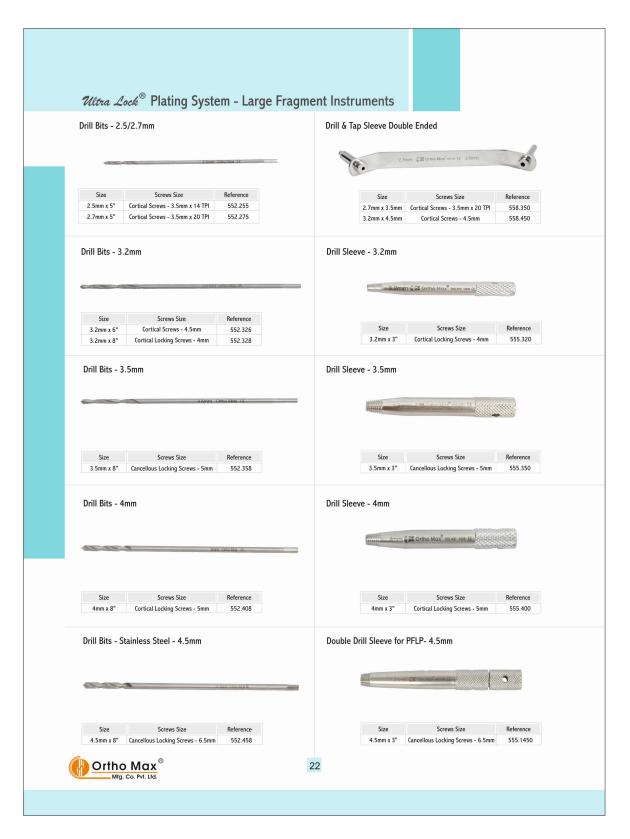
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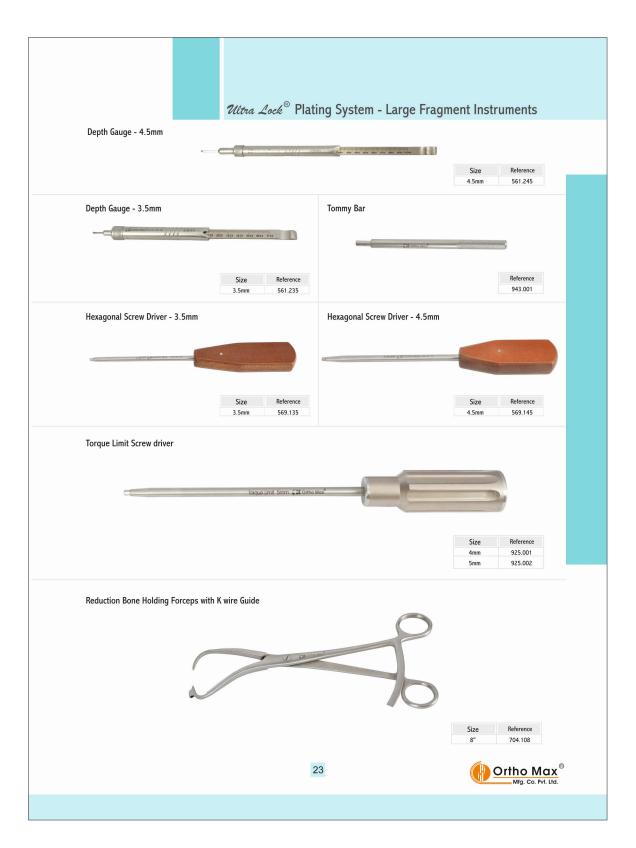
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### All in One "Ultra Lock" Large Fragment Set







#### Contents :

Implants	Size	Qty.
Lateral Tibial Head Locking Plates Left & Right	5H, 6H, 7H, 8H - 1 each 9H, 10H, 12H - 1 each	08 Nos
Anterolateral Distal Tibia Locking Plates Left & Right	6H, 8H - 1 each 10H, 12H - 1 each	04 No:
Low Bend Distal Tibial Locking Plates Left & Right	6H, 8H - 1 each 10H, 12H - 1 each	04 No 04 No
Distal Femur Locking Plates Left & Right	6H, 7H, 8H - 1 each 9H, 10H, 12H, 14H - 1 each	06 No 08 No
Proximal Medial Tibia Locking Plates Left & Right	4H, 5H, 6H, 8H - 1 each 10H - 1 each	08 No 02 No
Cortical Locking Screws	4mm x 24mm To 28mm - 10 each	30 No
	x 30mm To 40mm - 5 each	30 No
	x 45mm To 80mm - 5 each	40 No
	5mm x 24mm To 42mm - 10 each	100 N
	x 44mm To 50mm - 5 each	20 N
	x 55mm To 90mm - 5 each	40 N
Cancellous Locking Screws - Full Thread	5mm x 35mm To 100mm - 3 each	42 N
Cortical Screws 3.5mm x 20 TPI	22mm To 40mm - 5 each	50 N
Cortical Screws 4.5mm	24mm To 50mm - 10 each 55mm & 60mm - 5 each	140 N 10 N
Instruments Contents :-		
S.S. Drill Bits - 2.7mm x 5"	( For Cortical 3.5mm )	01 N
3.2mm x 6"	( For Cortical 4.5mm )	01 N
3.2mm x 8"	( For Lock. Cortical - 4mm)	02 N
3.5mm x 8"	( For Lock. Cancellous - 5mm)	01 N
4mm x 8"	( For Lock. Cortical - 5mm)	02 N
Drill & Tap Sleeve	2.7mm x 3.5mm	01 N
	3.2mm x 4.5mm	01 N
Drill Sleeve 3.2mm	( For Lock. Cortical - 4mm)	02 N
3.5mm	( For Lock. Cancellous - 5mm)	02 N
4.0mm	( For Lock. Cortical - 5mm)	02 N
Tommy Bar for Drill Sleeve		01 N
Depth Gauge - 3.5mm & 4.5mm - 1 each		02 N
Hexagonal Screw Driver - 3.5mm & 4.5mm - 1 each		02 N
Torque Limit Screw Driver - 4mm & 5mm - 1 each		02 N
Reduction Forceps Pointed with K Wire Guide 8"		01 N
Container For Witra Lock® Large Fragment Set		01 N

<sup>\*</sup>Available in SS 316L & Titanium

Reference 920.002





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Implants certified by ITC:  $\bigcup_{1023}^{\bullet}$ 

Instruments certified by self declaration:  $\mathbf{C} \in$ 



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