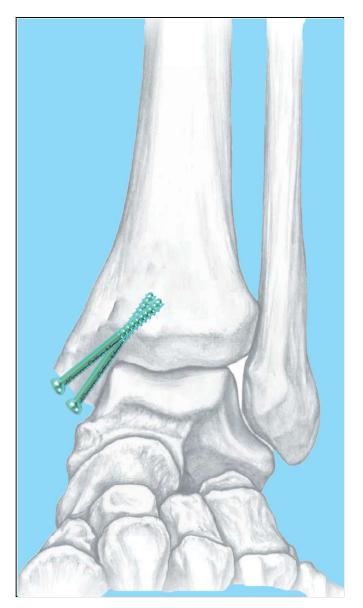


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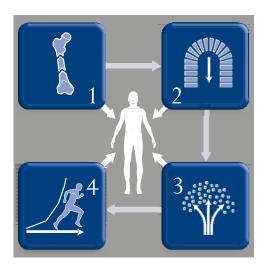


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AO Principles

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 relationships.

Early, active mobilization

Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

Stable fixation

Fracture fixation providing absolute or relative stability, as 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.

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INDICATIONS:

C.C. 4mm:

Fixation of fractures of medium fragments, e.g.:

- -Tarsal and metatarsal fractures and fixation in metatarsal and phalangeal osteotomies
- -Tarsometatarsal and metatarsophalangeal arthrodeses
- -Ligament fixations
- -Hallux valgus corrections

C.C. 6.5mm:

Fixation of fractures of large fragments, e.g.:

- -Femoral neck fractures
- -Intercondylar femoral fractures
- -Epiphyseolysis of the femoral head
- -Ankle arthrodeses
- -Iliosacral dislocations

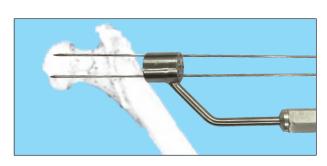
Warning: These screws are not recommended for screw fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Percutaneous Technique of C.C. Screws - 6.5mm

1. Reduce the fracture and make an incision of approx. 5 cm.

Insert multiple guide wire(s) using Parallel Guide.

Insert the Paralled guide through a stab incision and through the soft tissue to the bone. Select hole pattern and insert 1.8 mm guide wires through the preselected holes.



Note: The paralled guide will allow placement of washers when wires are placed through nonadjacent holes. Placement through adjacent holes will allow clearance

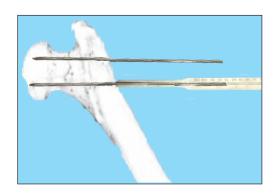
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for screws but not for washers.

2. Measure for screw length

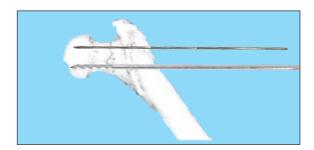
Remove parallel guide and slide the tapered end of the CC Direct Measuring Device over the guide wire. Read the scale at the end of 225mm wires to determine insertion depth of wire and appropriate screw length.



Notes:

- The reading indicates the screw length that will place the screw at the tip of the guide wire. Subtract appropriately for any anticipated interfragmentary compression resulting from screw insertion. Only use the guide wire in its original length to ensure correct measurement.

3. Drilling:



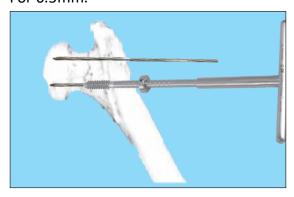
Even though the screws are self-tapping, the desired length must be predrilled with the cannulated drill bit of 4.5mm dia. The drill bit is having a calibration showing drill depth which can be considered as measure earlier.

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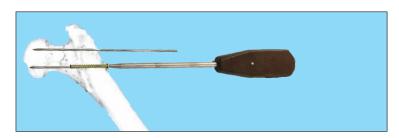
4. Tapping:

Where necessary, tap the near cortex with the cannulated tap For 6.5mm.



5. Insert screws:

Using the cannulated screwdriver 6.5mm, place the appropriate length screw over the guide wire and insert into the bone. Remove and discard the guide wire.



Procedure for osteoporotic bones:

In osteoporotic bone, the screw head can be prevented from sinking into the bone by using a washer. Avoid tightening the screw very firmly, because otherwise the thread may strip and the screw's grip in the bone could be compromised.

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Implant removal

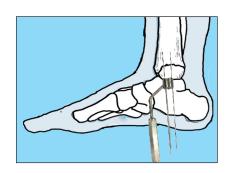
Expose the screw head and remove the screws using the Hexagonal screwdriver 4.5mm for the removal of cannulated screws.

Precaution: Do not use the cannulated screwdriver for implant removal as the tip of Cannulated screw driver may slip off during removal if extra force is applied.

PERCUTANEOUS INSERTION OF C.C. SCREWS- 4mm

1. Reduce fracture and insert guide wire:

After a stab incision, advance the drill sleeve or drill sleeve assembly through the soft tissues to the bone. Insert the guide wire through the Drill sleeve to the desired depth and position. Remove the drill sleeve and check the position of the guide wire of 1.2mm under the image Intensifier.



Use the adjustable parallel wire guide to place parallel wires at various distances from the first wire.



2. Measure for screw length:

Remove the two inner drill sleeves. Slide the tapered end of the cannulated screw direct measuring device over the guide wire to the bone. Read the scale at the end of the guide wire to determine appropriate screw length. This reading will show full length of the screw match with the guide wire tip and will not allow the threaded portion of the guide wire to remain in the bone during screw insertion.



e.g.: If the reading indicates 40mm, use a 35 mm screw to place the screw 5 mm short of the wire tip.

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3. Drilling:

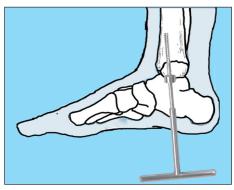
To pre-drill in dense bone, drill through the near cortex with the 3.2 mm cannulated drill bit on guide wire. Calibration marking is given on Drill bit to see the drill depth as desired.



4. Tapping:

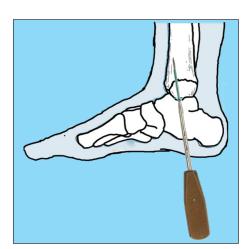
Where necessary, tap the near cortex with the cannulated tap

For 4mm.



5. Insert screw:

Place the appropriate length of screw over the guide wire. Use the cannulated screwdriver 4mm to insert the screw. Remove and discard the guide wire.



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Procedure for osteoporotic bones:

In osteoporotic bone, the screw head can be prevented from sinking into the bone by using a washer. Avoid tightening the screw very firmly, because otherwise the thread may strip and the screw's grip in the bone could be compromised.

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.

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

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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.

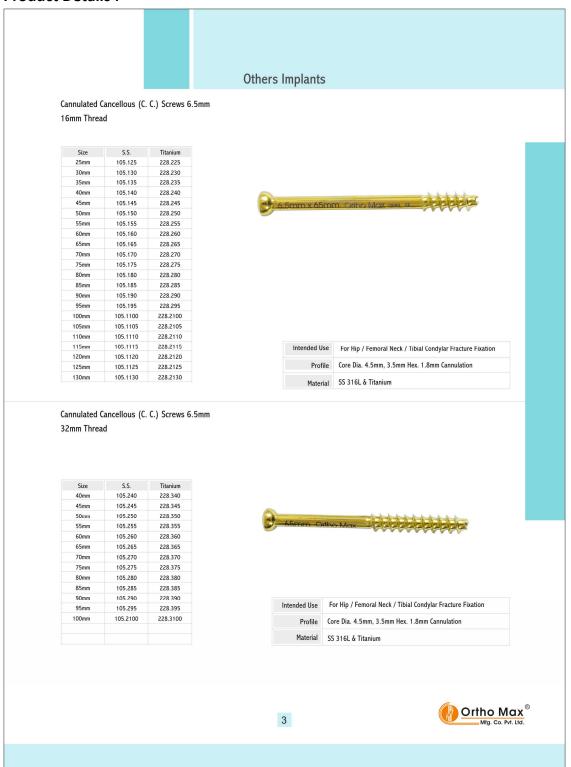
The maximum recommended time limit for MRI examination in patients implanted with the evaluated device is 30 min with a scanner operating at 1.5T (Tesla) or less.

END OF SURGICAL TECHNIQUE

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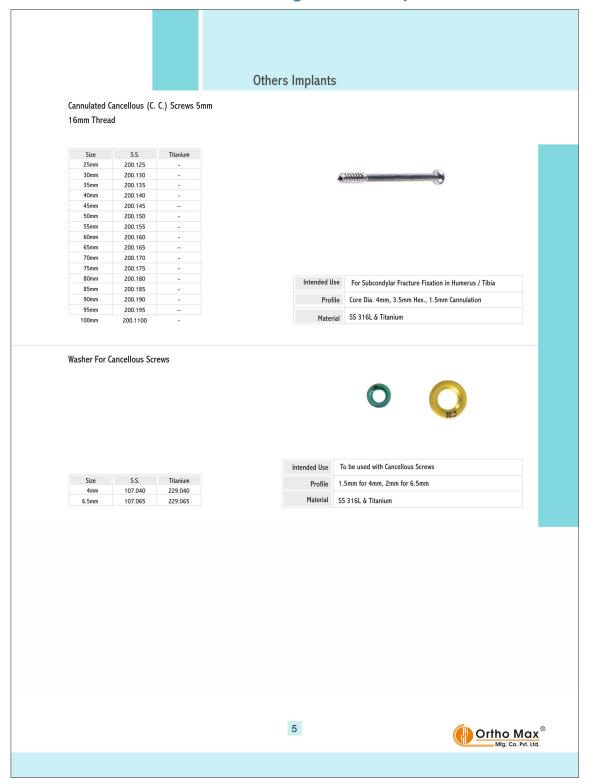
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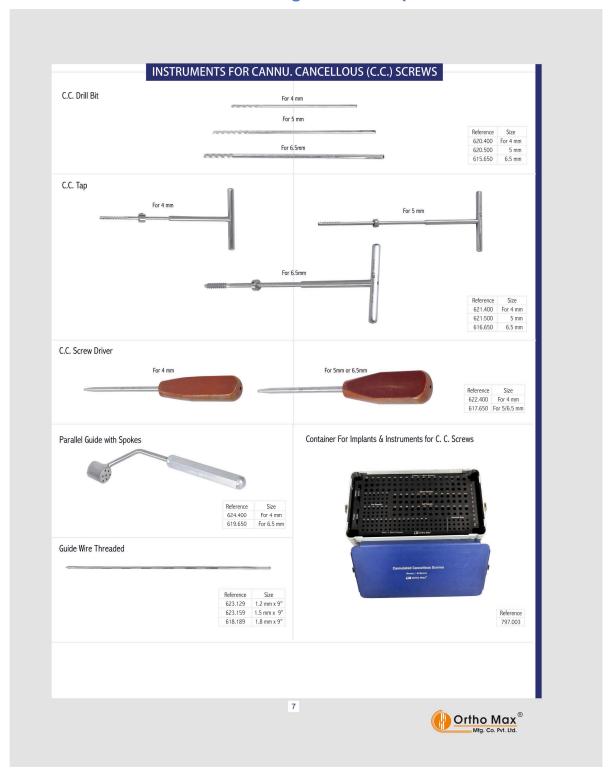
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Implants Certified by ITC:

Instruments Certified by Self Declaration :



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