YOGESHWAR IMPLANTS (I) PVT. LTD.

CISTA TIBIA NAIL

SURGICAL TECHNIQUE

Index

1. Description of Surgical Technique

Name: Cista Tibia Nail

Available for SS 316L and Titanium Grade 5 materials

2. Feature & Benefits

Design

- Anatomic design for easier insertion and improved fit
- Transverse locking holes to allow use of one nail in either left or right extremity
- threads for secure connection to insertion/extraction instruments
- Crimping for the best interference fit in the medullary canal& easy insertion.
- Designed to prevent penetration of posterior cortex during insertion, and to glide easily through medullary canal.
- Featured with both dynamic & static transverse.
- Two transverse locking holes and additional locking hole distally
- Anatomically correct bend and longer, flat proximal bend for easier insertion, better fit
- Beveled proximal end to prevent soft tissue irritation
- Wide range of available sizes: 8 mm to 10 mm diameters and 280 mm – 380 mm Length

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.

Early, active mobilization: Early and Safe Mobilization and rehabilitation of the injured part and the patient as a whole.

4. Indications

- TIBIA shaft as well as for metaphyseal.
- Distal 1/3 TIBIA fracture
- Proximal 1/3 TIBIA fracture

5. Intended Purpose

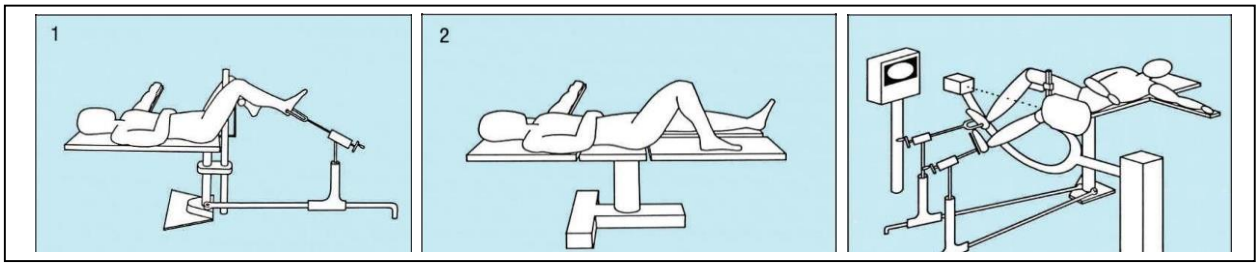
The Tibial Nail is designed to help treat various fractures of the tibia. Screws are placed through the nail to secure the implant in place and maintain length and alignment while healing occurs.

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

- **Patient Positing**



The fracture may be reduced using open or closed technique. Closed reduction is the preferred method, with the patient in the supine position on a fracture table or radiolucent operating table. An image intensifier is needed.

The patient is placed in the supine position, with the injured leg flexed 90° at the knee. The foot of the injured leg is placed in a cushioned boot, or supported by a calcaneal traction pin. For distal locking, the calcaneal traction pin must be used since the shoe extends too far proximally. The uninjured leg is positioned to allow free movement of the image intensifier from the AP to the lateral plane. The foot is placed in a cushioned boot.

The operating table must be radiolucent. The patient is placed in the supine position. The injured leg is positioned freely, with the knee flexed 90°. The uninjured leg is extended. The table should be adjusted to a comfortable operating height for the surgeon.

- **Use of the Image Intensifier**

An image intensifier is required for both closed reduction and distal locking techniques. The image intensifier allows controlled viewing of the fracture zone for insertion of the reaming rod, medullary reamer heads and universal nail. Proper positioning of the image intensifier is extremely important for locating the distal locking holes. With the patient in the supine position, the radiation source should be placed laterally to facilitate the aiming process, which is performed medially.

- **Finding of Entry point & medullary canal opening:**

Selecting the proper entry point is important to prevent rotation of the nail during insertion the entry point should be over the midline of the medullary canal and as superior as possible without causing damage to the anterior edge of the tibia plate. After finding entry point, bone awl used to open medullary canal.

- **Proximal Reaming:**

Proximal Reamer is followed by guide wire which is used to reaming the proximal portion of nail. Ø13.0 mm proximal reamer is use for reaming. The holding forceps is used to control the guide wire.

- **Nail and insertion handle assembly:**

After reaming proximal canal, nail is inserted in tibia bone. GTN excel jig is attached with nail with the use of in/ex bolt. For hammering purpose, force is applied by sliding the ram through extractor rod which pushes the jig so that nail can insert properly. Insertion Driving Head is an optional part locked with IN/EX bolt which also used for hammering.

- **Proximal Locking:**

Protection Sleeve 8.0 mm is passed through cistajig. With the use of pointer Ø8.0mm, entry point of drill identified. Trocar is passed through protection sleeve. Then after Pointer is replaced by Drill Sleeve 4.0 mm which is guide the drill bit 4.0mm. Depth gauge is used to measure the drill length. With the help of long screw driver, 4.9mm locking bolt is inserting in proximal holes.

- **Distal Locking:**

Protection Sleeve 8.0 mm is passed through distal jig. With the use of Pointer Ø8.0mm, entry point of drill identified. Pointer is passed through protection sleeve. Then after Pointer is replaced by Drill Sleeve 3.2 mm which is guide the drill bit 3.2 mm. Depth gauge is used to measure the drill length. 3.9mm locking bolt is inserting in proximal holes of nail through protection sleeve.

- **End-cap insertion:**

End cap is inserted with the use of screw driver at proximal threaded portion of CISTA NAIL.

END CAPS:

End Cap Prevents in growth of tissue & facilitates nail extraction

8. Implant Removal

In case of implant removal firstly remove the end cap with help of hex screw driver. Proceed by removing both locking bolt from the bone using hex screw driver.

Used extractor rod, handle for extractor & round hammer for nail removing.

Assemble the rod, handle & round hammer & back hammer the nail for removing.

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

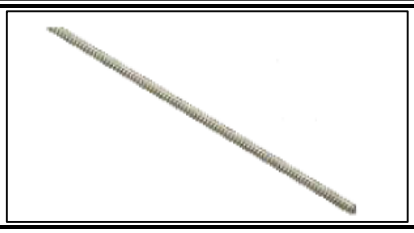
The packaging material of this device is made special packing material and therefore if swallowed, may cause choking Hazards. Therefore, it should be disposed of in such a way that keeps out of reach of children and stray animals.

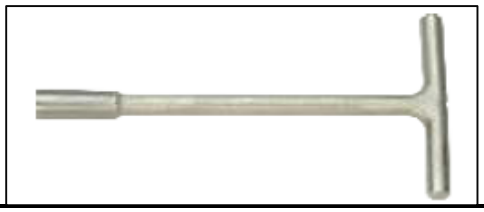
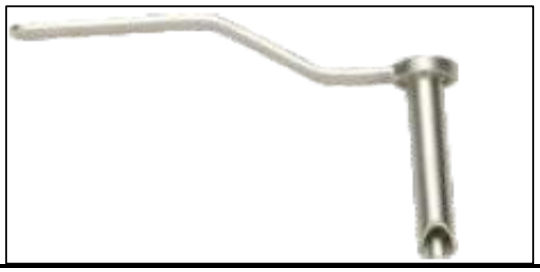
12. MRI Information

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.

Instruments

CISTA JIG WITH ATTCHMENT BOLT	
PROTECTION SLEEVE – 8 MM	
I.L.DRILL SLEEVE 3.2 MM	
I.L.DRILL SLEEVE 4 MM	
UNI INS/EX.BOLT FOR CISTA	
CURVED BONE AWL	
I.L. GUIDE WIRE- 2.5 MM X 900 MM	
S.S.DRILL BIT 3.2 MM X 200 MM **S.S.DRILL BIT 4 MM X 200 MM**	

DEPTH GUAGE	
EXTRACTOR ROD	
HANDLE FOR EXTRACTOR	
ROUND HAMMER	
SOCKET WRENCH-10 MM	
SOLAPUR SLEEVE –PLAIN	
HEAD FOR INTRODUCER	

Products

CISTA NAILS - S.S.
TITANIUM

1737
2008

	Dia	-	Length
1737 / 2008.828-838	8MM	-	280MM To 380MM
1737 / 2008.928-938	9MM	-	280MM To 380MM
1737 / 2008.1028-1038	10MM	-	280MM To 380MM
	(Difference of 10MM each)		

11MM & ODD SIZES ARE ON 'ORDER TO MAKE BASIS'

INTERLOCKING BOLTS

1702
1703

	Dia	-	Length
1702.3922-3938	3.9MM	-	22 TO 38MM (Difference of 2MM each)
1702.3940-3950	3.9MM	-	40 TO 50MM (Difference of 2MM each)
1703.4922-4938	4.9MM	-	22 TO 38MM (Difference of 2MM each)
1703.4940-4950	4.9MM	-	40 TO 50MM (Difference of 2MM each)
1703.4952-4960	4.9MM	-	52 TO 60MM (Difference of 2MM each)
1703.4964-4980	4.9MM	-	64,68,72,76,80MM
1703.4985-49100	4.9MM	-	85,90,95,100MM

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