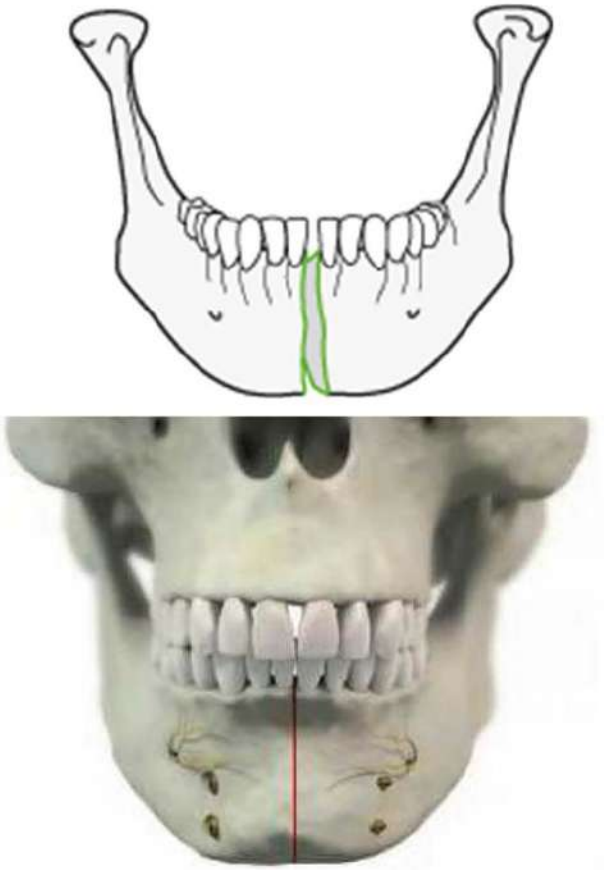


**Screw Features:**

- 316L stainless steel or Titanium Gr.5 for maximum strength
- Self- Tapping screws for easy insertion
- Low profile screw head ensure low projection
- Cross Drive or slotted head screw

**Intended use:**

Open reduction internal fixation (ORIF) is usually the method of choice for simple symphyseal fractures in order to avoid the drawbacks and inconveniences of MMF in the majority of patients.

It is recommended in all unstable fractures and noncompliant patients.

Closed treatment of simple fractures is still well accepted as an alternative to open treatment.

**Indications:**

Oblique or sagittal fractures where two lag screws can be placed from the buccal or lingual cortices

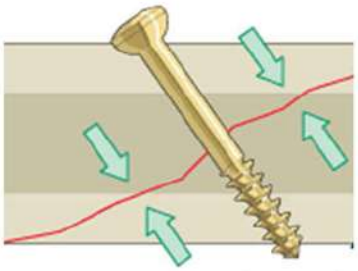
***Advantages:***

- Rapid application with a high level of stability
- Perfect bony reduction after interfragmentary compression
- Lower cost compared to plate and screw fixation
- Intraosseous location avoiding palpability

***Disadvantages:***

- Technically demanding (only one chance to get it right)
- Difficult implant removal (if needed)
- Lag screws can hardly be used in transverse fractures of the body.

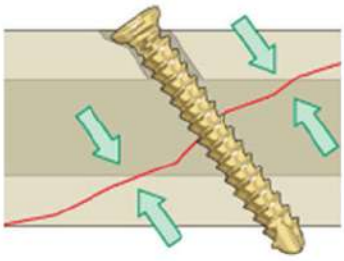
**Principles**



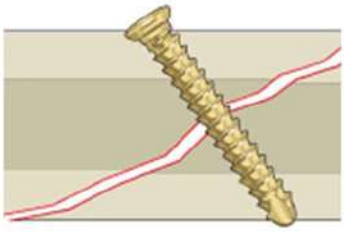
**Lag screw versus lag technique**

Lag screws and the lag technique compress the fracture fragments together. There are two methods by which to achieve this.

True lag screws (as illustrated here) have threads only on the terminal end of the screw. Therefore, when inserted across a fracture, the threads of the tip of the screw engage the far cortex and the head of the screw engages the near cortex, causing compression of the fracture fragments upon tightening.



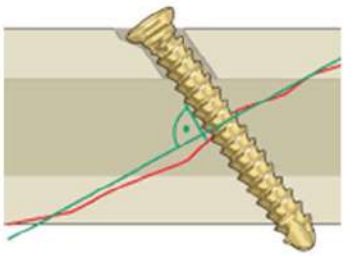
True lag screws are not available for CMF surgery. Instead, a lag technique is used. The lag technique involves overdrilling the near cortex to the size of the external diameter of the screw. When the screw is inserted, it glides through this overdrilled hole and the threads only engage the far cortex. As the screw is tightened the head of the screw engages the near cortex and the fracture fragments are compressed together.



Pitfall: no compression without overdrilling

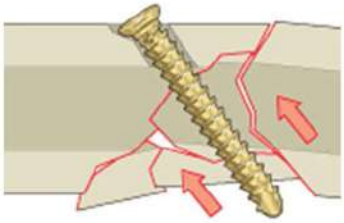
If the near cortex is not overdrilled, the threads of the screw will engage both near and far

cortices preventing compression of the fracture fragments.



**Perpendicular screw placement**

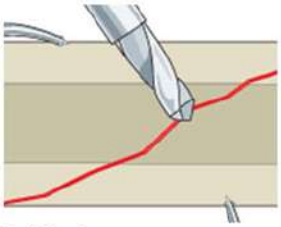
Because lag screw technique compresses the fracture fragments together, the screw must be placed perpendicular to the fracture plane. Otherwise, the fracture will displace when the screw is tightened.



**Contraindication - comminuted fractures**

Because lag screw technique compresses the fracture fragments together, the use of this technique is contraindicated in comminuted fractures.

## Lag technique



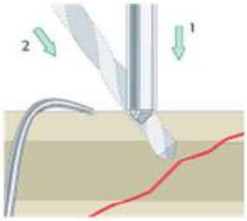
**Drill the near cortex to the external diameter of screw**

The first step is to determine that the drill is aligned perpendicular to the bevel of the fracture. The near cortex is perforated using a drill that is the same diameter as the external diameter of the screw. The gliding hole is taken to the fracture site or slightly beyond.

For example: when using a plating system 2.5mm, the external diameter of the screw is 2.5mm. The drill used to drill the near cortex is therefore 2.5 mm.

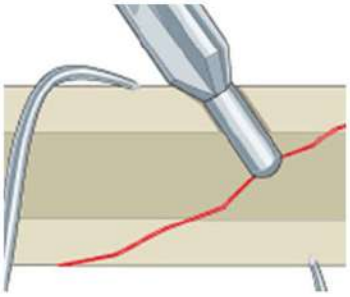
Pearl: It may be difficult for the surgeon to determine when the fracture site has been reached with the gliding hole. It may be advantageous to drill past the fracture site rather

than stay short of the fracture site. If the gliding hole is short of the fracture, compression of this fracture will not be obtained with lag screw technique.




Pearl: oblique surfaces

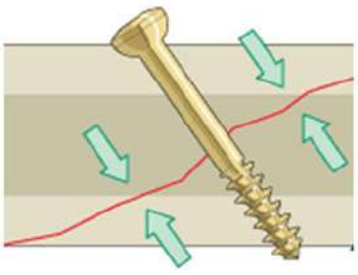
When drilling obliquely to the surface of the bone, the point of the drill can easily slide along the bone. It is helpful to first orient the drill perpendicular to the near cortex to create an initial hole before reorienting the drill perpendicular to the bevel of the fracture.



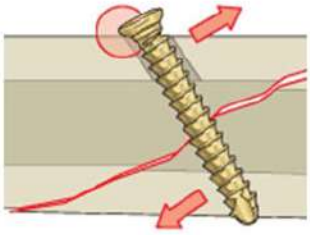
**Countersink near cortex**

A countersinking tool is used to create a platform in the near cortex.

Pearl: countersinking should be done by hand instrumentation. Use of power instruments can easily penetrate the outer cortex.

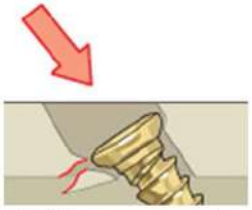


The hole created by the countersinking tool provides a platform into which the undersurface of the head of the screw will intimately contact when the screw is tightened.



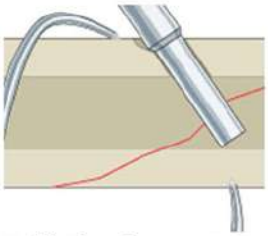
Pitfall: no countersinking

Failure to perform proper countersinking causes an eccentric force which can displace the fracture fragments upon tightening the screws.



Pitfall: too much countersinking

The medullary bone offers no resistance to the head of the screw. Therefore, it is imperative that countersinking does not remove all of the cortical bone around the circumference of the head of the screw. Otherwise, as the screw is tightened its head will enter the medullary space and provide no compression of the fracture fragments.

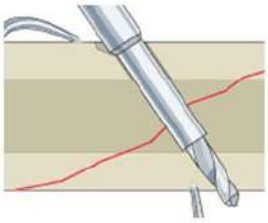


**Drill the far cortex to the inner diameter of the screw using "centering" drill guide**

A special drill guide is used to drill through the far cortex. This drill guide has an extension on its tip that is the same diameter as the external diameter of the screw. The drill guide snugly fits into the hole previously drilled through the near cortex.

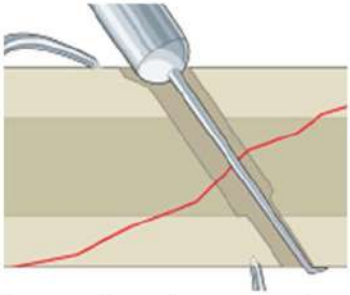
It is imperative that the fracture fragments be properly reduced prior to drilling through the far cortex.

Note: Gliding hole extends slightly past the fracture site as in the illustration, the drill guide is shown.



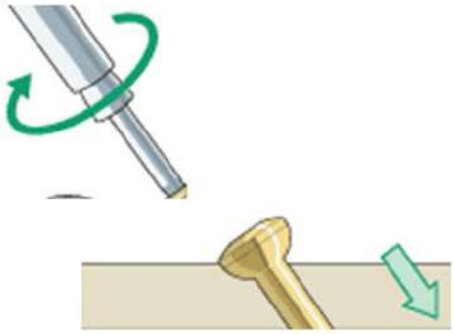
The drill guide centers the drill that will be used to drill the far cortex with the hole through the near cortex. This drill has the diameter that is similar to the inner diameter of the screw. For instance, when using a 2.5 mm screw, a 2mm drill is used to drill the far cortex.

When drilling, it is difficult to irrigate the tip of the drill. Therefore, it is imperative that the drill be repeatedly withdrawn so that the irrigant effectively cools the tip of the drill and washes away bony debris.



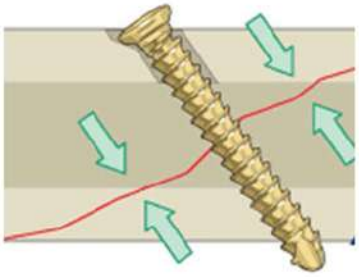
**Determine the screw length**

A depth gauge of 2.5mm size is used to determine the screw length. It is important to assure that the tip of the screw completely engages the far cortex. Because self-tapping screws have a point on their tips, it is important that the tip of the screw completely exits the far cortex so that the screw threads engage completely. Therefore, it is always better to select a screw that is slightly longer than the measurement recorded with the depth gauge.



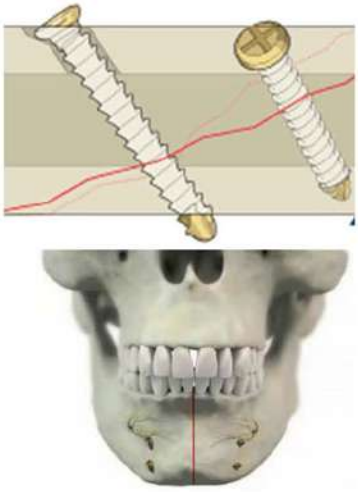
**Screw insertion**

The proper length screw is inserted and tightened. One should observe the near cortex as the screw is tightened to assure that cracking or crazing does not occur from over tightening.



Properly applied lag screw resulting in interfragmentary compression.

**Additional fixation**



In most cases, a single lag screw does not provide adequate three-dimensional stability. Additional means of fixation are therefore required. This could be in the form of another lag screw or a plate.

**Warnings, Precautions, General Adverse Events:**

**Warnings:**

- Using an internal fixation system on patients with active or latent infection may cause potential risks which may include construct failure and deterioration of infection. It is at the physician's discretion to evaluate the patient's medical conditions and select a fixation device most appropriate for the individual patient. It is also at the physician's discretion to consider all other necessary treatment methods to effectively manage the infection.
- Confirm the quality of bone at the selected screw / plate position. Using an internal fixation system on patients with insufficient quantity or quality of bone may cause potential risks which may include device loosening and construct failure. It is at the physician's discretion to evaluate the patient's Medical conditions and select a fixation device most appropriate for the individual patient.
- These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part should be removed. Be aware that implants are not as strong as native bone. Implants subjected to substantial loads may fail.
- Instruments, screws and cut plates may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Take care to remove all fragments that are not fixated during the surgery.
- While the surgeon must make the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished.

Implant removal should be followed by adequate post-operative management to avoid refracture.

**Precautions:**

- Confirm functionality of instruments and check for wear during reprocessing. Replace worn or damaged instruments prior to use.
- It is recommended to only use the instruments identified for use within the Wiring System of Ortho Max based on the surgical techniques recommended for implants.
- Always irrigate and apply suction for removal of debris potentially generated during implantation or removal.

**General Adverse Events**

As with all major surgical procedures, risks, side effectsand adverse events can occur. While many possible reactions may occur, some of the most common include: Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, nerve and/or tooth root damage or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hypersensitivity reactions, side effects associated with hardware prominence, loosening, bending, or breakage of the device, mal-union, non-union or delayed union which may lead to break age of the implant, reoperation.

**Device-specific Adverse Events**

Device-specific adverse events include but are not limited to:

- Malunion/ non-union that may be associated with:
- Implant inappropriately dimensioned for the intended use
- Construct failure due to inadequate strength design
- Construct strength too weak for post-operative loading forces
- Wrong implant material/design
- Misleading/incorrect label
- Information provided to the end-user (i.e. IFU)is insufficient, incorrect or imprecise
- Reverse and repeated bending applied
- Adverse Tissue Reaction that may be associated with:
- Instruments debris/particle created during cutting
- Instruments debris/particle created during implantation and/or removal

- Incorrect label i.e. wrong data provided on the LMD i.e. wrong text, missing symbols, wrong Mfg. date

• Damage to vital organs / surrounding structures that may be associated with:

- Insufficient structure
- Screw placement into nerve, tooth buds/roots and or any other critical structures
- Screw core diameter is too small leading to screw breakage post-operatively
- Screw deforms or breaks during insertion with generation of fragments that the surgeon is unaware of or unable to retrieve, potentially resulting in fragment migration
- Screw recess strips due to blade cam-out
- Burrs/sharp edges on edge of plate
- Screw breaks during insertion and fragments are not retrieved
- Screw break age post-operatively
- Blade comes-out of screw recess
- Screw passes completely through plate
- Generation of particle debris during surgical procedure
- Screw strips bone post-operatively
- Screw not safely retained resulting in loss of screw intra-operatively
- Screw or plate migrates or deforms post-operatively
- Implant loses functionality post-operatively
- Improper use of implant resulting in treatment failure
- Wrong screw or wire selection
- Incorrect screw position resulting in irreversible damage
- Inappropriate use of screws or drill bits
- Overheating of drill bit causing thermal necrosis of bone

• Loosening that may be associated with:

- Insufficient implant fixation
- Screw breakage post-operatively
- Inappropriate screw used

• Peripheral Nerve that may be associated with:

- Screws inserted into nerve, tooth buds/roots and or any other critical structures

• Soft Tissue Damage that may be associated with:

- Premature plate/mesh failure
- Screw breakage post-operatively
- Burrs/sharp edges on edge of plate

- Implant loses its function post-operatively
- Systemic Infection that may be associated with:
- Incomplete/incorrect processing leading to implantation of a non-sterile product
- Sterile barrier compromised leading to implantation of a non-sterile product
- Implantation of non-sterile product
- Implantation of non-sterile unclean product due to incorrect label
- Reuse of single use implant

**IMPLANTS REMOVAL**:

The Lag Screws should first be removed by following screw removal technique of cortical screws. Take care while removing the screws, Clear the slot of Single slotted or Cross Drive recess of 2mm or 2.5mm then remove the screws completely from the bone. 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.

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. Implant removal should be followed by adequate post-operative management to avoid refracture.

**MRI Information:**

It is recommended to pay particular attention to the following points:

– It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.

– Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.

– Generally, it is recommended to use an MRI system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.

– Using the ventilation system may further contribute to reduce temperature increase in the body

**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 the reuse 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 off 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 off 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 a way that keeps 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

**END OF SURGICAL TECHNIQUE**

Product Details:

OTHER IMPLANTS 19

Titanium Lag Screws

Cross Drive®

| 2mm dia. Reference | 2.5mm dia. Reference | Size |
|---|---|---|
| 050.208 | 050.258 | 8 mm |
| 050.2010 | 050.2510 | 10 mm |
| 050.2012 | 050.2512 | 12 mm |
| 050.2014 | 050.2514 | 14 mm |
| 050.2016 | 050.2516 | 16 mm |
| 050.2018 | 050.2518 | 18 mm |
| 050.2020 | 050.2520 | 20 mm |

Thd. Dia. : 2mm
Drill Size : 1.5mm
Gliding Hole Drill Size 1.8mm
Material : Titanium Grade V
& S.S. 316 L

Single Slotted

| 2mm dia. Reference | 2.5mm dia. Reference | Size |
|---|---|---|
| 081.208 | 081.258 | 8 mm |
| 081.2010 | 081.2510 | 10 mm |
| 081.2012 | 081.2512 | 12 mm |
| 081.2014 | 081.2514 | 14 mm |
| 081.2016 | 081.2516 | 16 mm |
| 081.2018 | 081.2518 | 18 mm |
| 081.2020 | 081.2520 | 20 mm |

Thd. Dia. : 2.5mm
Drill Size : 2mm
Gliding Hole Drill Size 2.3mm
Material : Titanium Grade V
& S.S. 316 L

S.S. Wire Reels

| Reference | Size |
|---|---|
| 033.024 | 24 Gauge |
| 033.026 | 26 Gauge |
| 033.028 | 28 Gauge |
| 033.030 | 30 Gauge |

Material : S.S. 316 L
Length : 10 mtrs.

Ortho Max®
Mfg. Co. Pvt. Ltd.

## LAG SCREWS KIT




| Reference |
|---|
| 1035S |

| Reference |
|---|
| 1035T |

Also available with Stainless Steel 316L implants

| Implants Contents: | Qty |
|---|---|
| **Titanium Lag Screws** | |
| 2mm x 14mm To 26mm - 2 Each | 14 Nos |
| 2.5mm x 14mm To 26mm - 2 Each | 14 Nos |
| **Instruments Contents** | |
| 1) S.S. Drill Bits 1.5,1.8, 2,2.3mm- 1 Each | 04 Nos |
| 2) Trocar / Drill Sleeve | 01 No |
| 3) Self Holding Screw Driver 2mm & 2.5mm | 02 Nos |
| 4) Ordinary Screw Driver 2mm & 2.5mm | 02 Nos |
| 5) Depth Gauge - 1.5mm & 2mm- 1 Each | 02 Nos |
| 6) Bone Holding Forceps - Pointed 6" | 01 No |
| 7) Counter Sink - 2mm & 2.5mm | 02 Nos |
| 8) Aluminium Anodised Box - Small with Tray | 01 No |

Instruments Certified : CE

**MFG. UNIT & REGD. OFFICE**
C-1-B/886/4, G.I.D.C. ESTATE
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VADODARA – 390 010 GUJ. INDIA

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