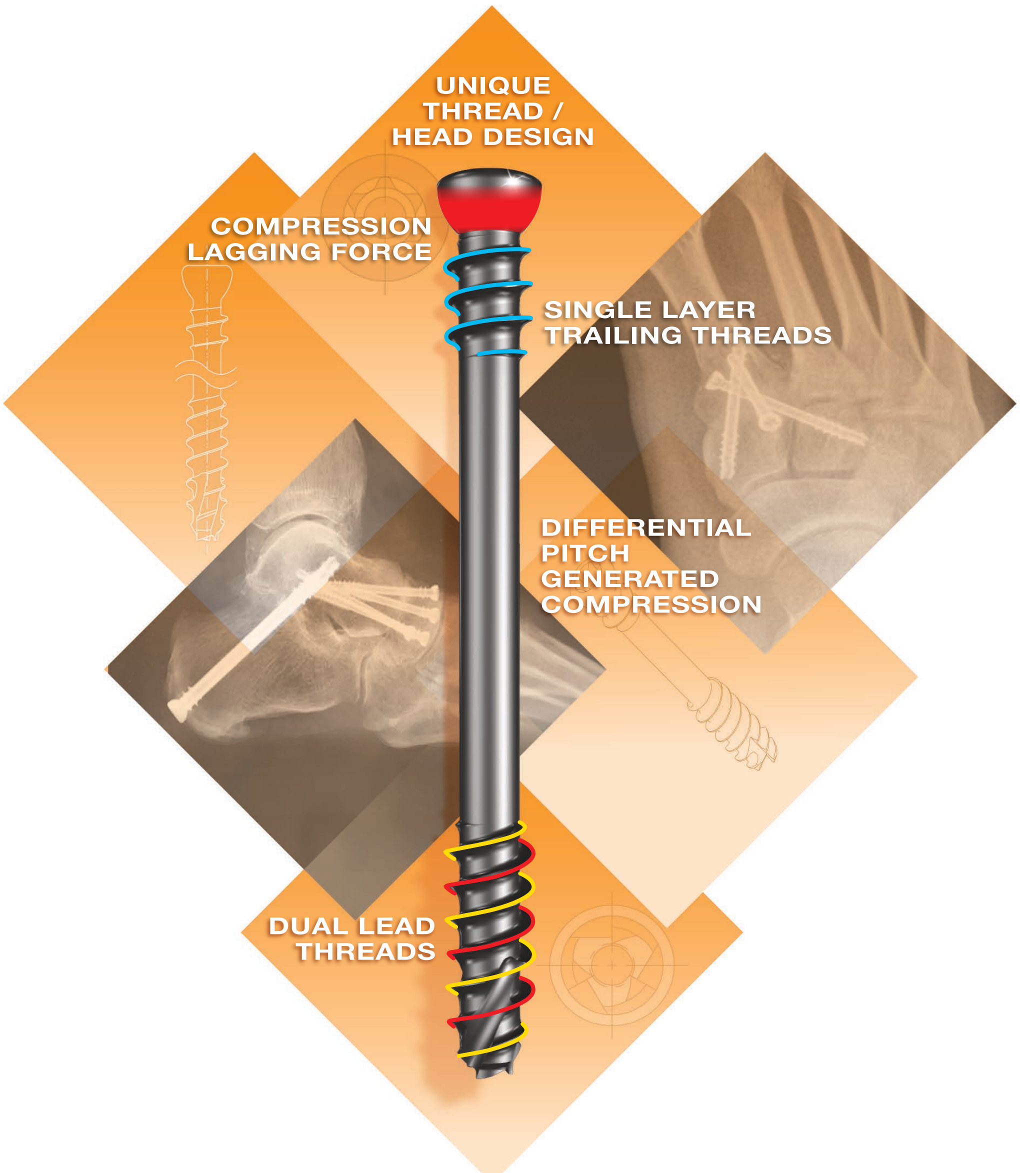
TECHNICAL MONOGRAPH

CoLag® CS Screws

Innovative Compressive Stability

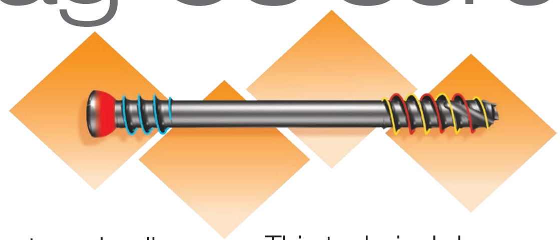


MOST SIGNIFICANT SCREW INNOVATION IN 25 YEARS

In2Bones

A GLOBAL EXTREMITY COMPANY

CoLag® CS Screws



Introduction During fracture and osteotomy healing, the mechanical forces applied to bone play a vital role[1-2]. The healing process is complex, involving structural, mechanical, and biological factors such as tension, friction, compression, stability, and vascularity - all of which act as stimuli for tissue regeneration.

This technical document discusses the mechanical properties and design features of the CoLag CS Screw System and how Compressive Stability may contribute to bone healing. The built in lag effect, compression of the differential thread pattern, and stability of the head create COMPRESSIVE STABILITY.

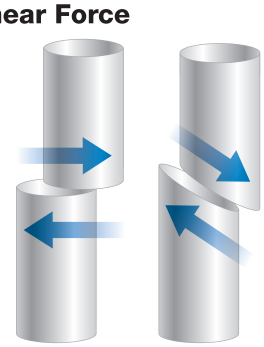
Stabilization and the Importance of Compression

It has been documented that primary bone healing occurs when bony fragments are tightly fixed together under compression[1]. Numerous studies show a positive correlation between compression and bone healing rates[2-3]. It is also reported that endochondral ossification and chondrogenesis occur only in compression based on mechanobiological regulation[4,5]. Therefore, the rate of compressive loading and the resultant stability are critically important to the bone healing process.

Studies have demonstrated that during the repair process, bones may fail to heal due to translational forces that stress the fracture site and cause shearing[6-8]. Furthermore, studies suggest that fractures may fail to heal due to shearing and subsequent fibrous tissue formation caused by instability at the fusion site[6]. Ⓐ

Interfragmentary stabilization after reduction of bony fragments via surgical intervention is of upmost importance with regard to how and why surgeons treat fractures. The primary goal of surgical intervention is that of stability and the elimination of displacement between the fragments. This is achieved by applying compression and friction to a fractured or surgically created bone segment. When the proper forces are applied, the surfaces will not move in relation to each other. Therefore, a significant concept in achieving this stability is the appropriate application of interfragmentary compression force and the durability of the fixation methods used during surgical intervention[9].

Ⓐ Shear Force



Translational forces cause shearing

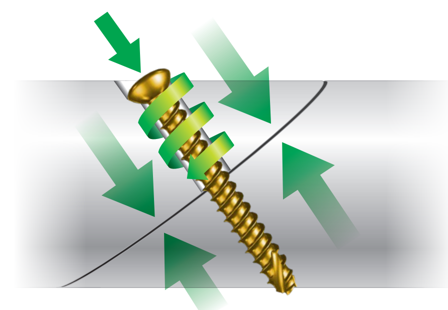
The Function of Screws

The function of a screw is to convert rotation to linear motion and rotational force to a linear force. This is accomplished by threads. As a screw advances, the head seats against the bones surface and further advancement of the screw compresses the fragments, creating a preload. This preload prevents separation from tension while friction between the bony surfaces opposes displacement by shear. Ⓑ

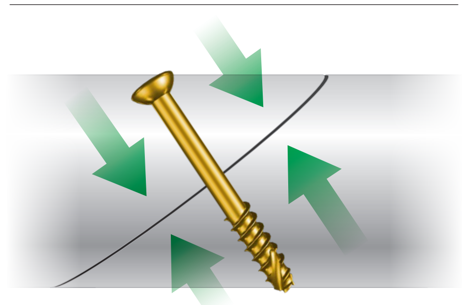
Traditional Lag Screws

Traditional lag screws have threads only on the leading end of the screw. Therefore, when inserted across a fracture or osteotomy, the threads at the tip of the screw engage the far segment and the head of the screw engages the near cortex, causing compression of the fragments upon tightening. Fixation by lag screws may provide an initial high compression force. However, their resistance to both bending and shearing forces may be insufficient in functional loading[10]. A study comparing lag screws to headless screws in subtalar joint fusions showed that lag screws were statistically inferior to headless compression screws[11]. Ⓒ

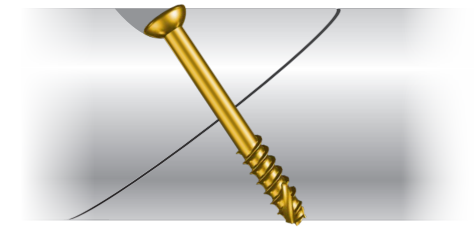
To improve the stability of lag screws and to spread the load of the head across the cortex, countersinking of the head into the near cortex is



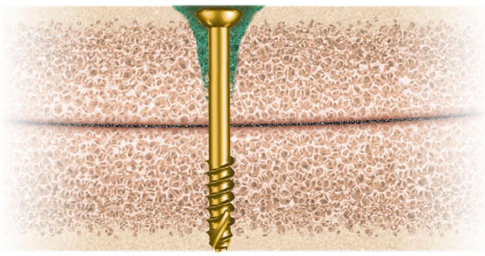
Ⓑ Screw threads convert rotation to linear motion and rotational force to a linear force



Ⓒ Traditional lag screw with partial threads engage the far segment while the head seats against the near segment creating compression



D **Countersinking of a headed lag screw**



E **Stress shielding around the proximal aspect of the screw which may contribute to instability**

commonly performed. The countersinking technique helps to improve screw stability within the near cortex and may increase a lag screw's resistance to eccentric forces. Failure to countersink could lead to high stress at the screw head / bone interface and cause screw loosening[10]. **D**

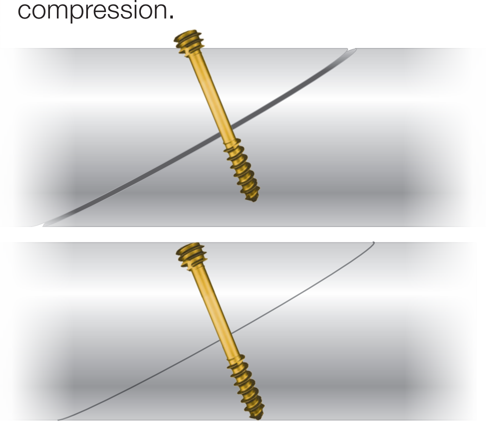
Countersinking does have pitfalls and is sensitive to technique. The cortical bone thickness and bone quality vary from patient to patient and therefore, it is imperative that countersinking does not remove all of the cortical bone around the circumference of the head of the screw. Otherwise, as the screw is tightened the head will enter softer bone and result in reduced compression of the fragments.

There are other potential downsides to the traditional lag screw. One is the tendency of the bone to stress shield around the proximal aspect of the screw which may contribute to near segment instability due to the loss of fixation by the screw[12]. The other is the higher rate of required removal when compared to other screw designs due to pain associated with screw head prominence[13]. **E**

Headless Compression Screws

Headless compression screws are available in many configurations and sizes. A unique advantage of the headless screw is that the screw head may be completely buried within the near cortex, eliminating any head prominence above the bone surface.

Traditional headless screws are designed with threads at either end with each thread possessing a different pattern. The pitch pattern of the leading thread is greater than that of the trailing or near thread. Therefore the leading thread advances further within the bone segment with each revolution of the screw compared to the near thread. **F** This design and the differential pitch between the leading and trailing thread allows for interfragmentary compression.



F **Headless screw design before and after insertion**

The Compressive Stability™ Difference

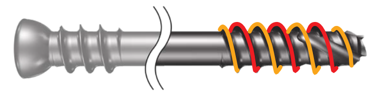
The newly designed CoLag CS Screw unites the stability of a headless compression screw with the compression force of a conventional headed lag screw.

This design allows the surgeon to generate initial compressive forces equal to or greater than traditional lag screws along with the added benefits of stability and resistance to cyclic loading of headless compression screws. By taking the best features of both types of traditional screws and uniting them in one unique revolutionary design, a new category of the bone screw has been created that offers heightened biomechanical performance.

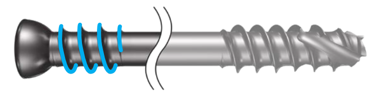
Compressive Stability™ by Design

G LEADING THREADS – The CoLag CS Screw design incorporates dual primary leading threads developed to provide fast screw advancement as they advance two threads at a time.

H TRAILING THREADS – The single trailing threads near the head of the screw advance one thread at a time and create initial compression similar to a headless screw due to the pitch differential.



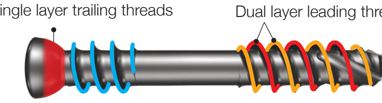
G **Dual layer leading threads**



H **Single layer trailing threads**

This is Compressive Stability™

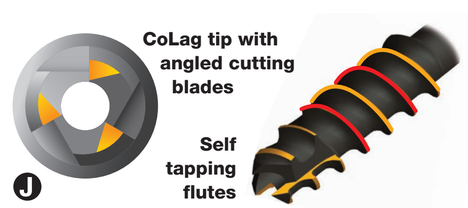
Dual distal lead threads advance at twice the rate of the trailing single proximal threads providing faster screw advancement. The distal and proximal thread pitches are not the same and this creates differential compression before the head engages.



I Compression lagging force

The unique low-profile head design provides a compression lag force. The thread pattern under the head prevents wobbling and adds stability. **I**

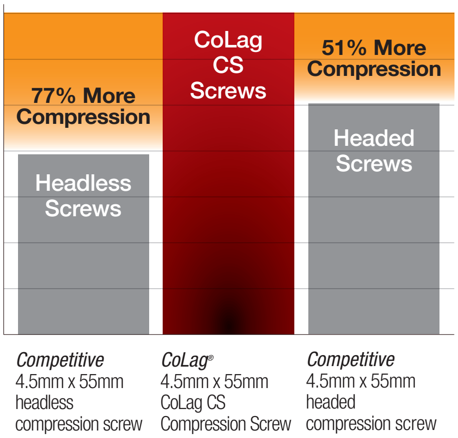
J SCREW TIP – The tip of the CoLag CS Screw has three angled drilling blades, self-tapping flutes and dual layer threads for efficient screw insertion and advancement.



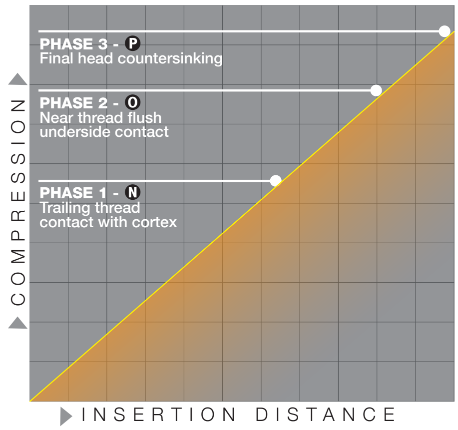
K SCREW HEAD – The CoLag CS Screw Head incorporates a Stick Fit Torx Drive within the head of the screw that ensures a secure connection with the driver shaft providing less chance of striping during high torque insertion.

Conclusion:

Ⓛ CoLag® CS Screw vs. Headless & Headed Screws



Ⓜ CoLag® CS Screw, Three Phases of Compression



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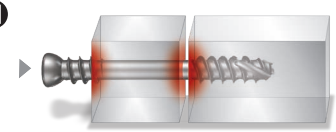

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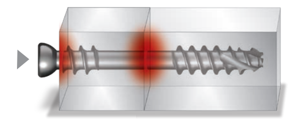

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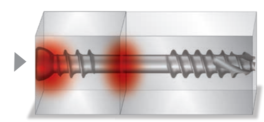

Superior Performance Over Standard Screws

In tests comparing traditional screws to the CoLag CS Screw, the CoLag CS Screw demonstrated significantly greater compression than both headless compression and headed lag screws. The results of these tests are represented in the chart Ⓛ.

Compression Phases During Insertion of the CoLag® CS Screw

Although the appearance of the CoLag CS Screw may appear simple, there is much more occurring during CoLag CS Screw insertion than standard compression screws. There are several measurable phases of compression during screw placement that act upon the bony fragments to create *Compressive Stability*™. Ⓜ

Ⓝ PHASE ONE – Initial compression occurs when the near threads under the head begin to engage the cortex of the near segment. This contact starts the compression that is generated from the thread differential between the leading dual threads and the near segment single threads.

Ⓞ PHASE TWO – As the CoLag CS Screw continues to advance, a further increase in compression occurs when the near threads are completely in the near cortex. The underside of the head begins to “lag” the segments and generates a spike in compression further pulling the fragments together.

Ⓟ PHASE THREE – Final compression is achieved during final screw insertion. By further advancing and countersinking the unique CoLag CS Screw head, a lagging compression “lock” is generated creating *Compressive Stability*™.

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