ACUMED®

Innovative Solutions

Olecranon Threaded Compression Rod

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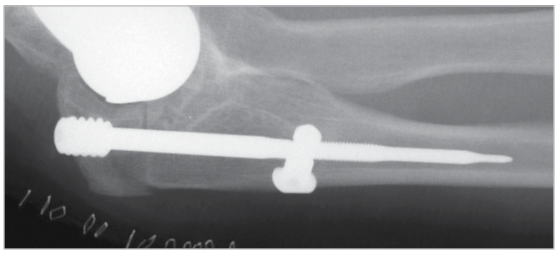
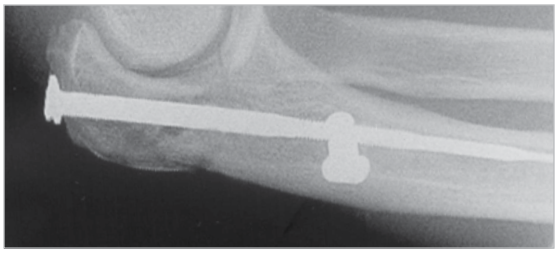
Since 1988, Acumed has been designing solutions to the demanding situations facing orthopaedic surgeons, hospitals and their patients. Our strategy has been to know the indication, design a solution to fit, and deliver quality products and instrumentation.





Acumed is dedicated to providing new, innovative options for the fixation of fractures and osteotomies in the elbow region. Orthopaedic surgeons have expressed the need to make surgeries less invasive, while continuing to maximize fixation. Our goal is to help surgeons get their patients moving and rehabilitating in a timely manner post-op.

Acumed strives to offer surgeons multiple solutions for an indication. Our pre-contoured Locking Olecranon Plates, Tension Band Pin System, Acutrak® Screws and the Olecranon Threaded Compression Rod provide surgeons with multiple fixation options to treat all types of olecranon fractures and osteotomy repair.

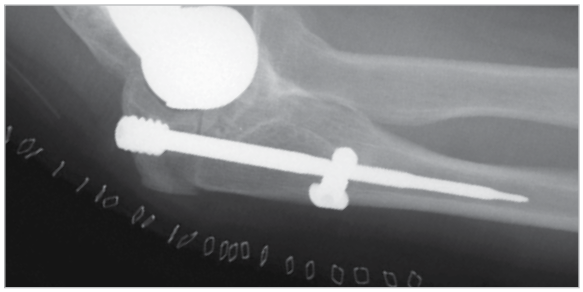
Designed in conjunction with Shawn O'Driscoll, Ph.D., M.D., the Olecranon Threaded Compression Rod provides surgeons with a new, innovative concept for treating olecranon osteotomies and transverse olecranon fractures. It is an intramedullary device that maximizes compression, minimizes hardware irritation and offers a minimally invasive, straightforward surgical technique.

There are several key benefits to using the Olecranon Threaded Compression Rod over traditional fixation techniques. The Olecranon Threaded Compression Rod provides a minimally invasive procedure with maximum compression across the osteotomy or fracture site. Because the rod's threads engage with the distal compression nut, the combination of the thread engagement and the head seating against a washer generate maximum compression and holding power. Minimized hardware prominence reduces soft tissue irritation on the subcutaneous surface of the ulna.

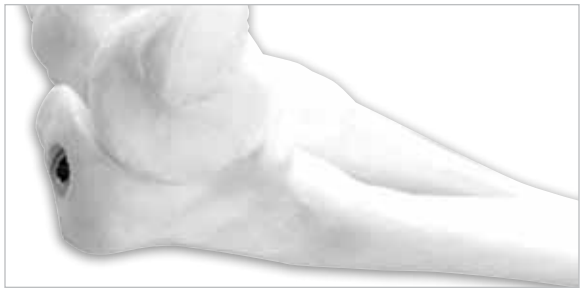
A compact instrumentation system with a straightforward surgical technique allows the rod to be implanted with both accuracy and minimal OR time. The system contains sterile-packed 316L stainless steel implants: the Olecranon Threaded Compression Rod, distal Compression Nuts (6mm, 8mm, 10mm), a Threaded Washer and a standard 1mm Olecranon Washer. A small, self-contained tray of instruments can be provided as a stand alone module or as a compliment to other Acumed systems.

Olecranon Threaded Compression Rod

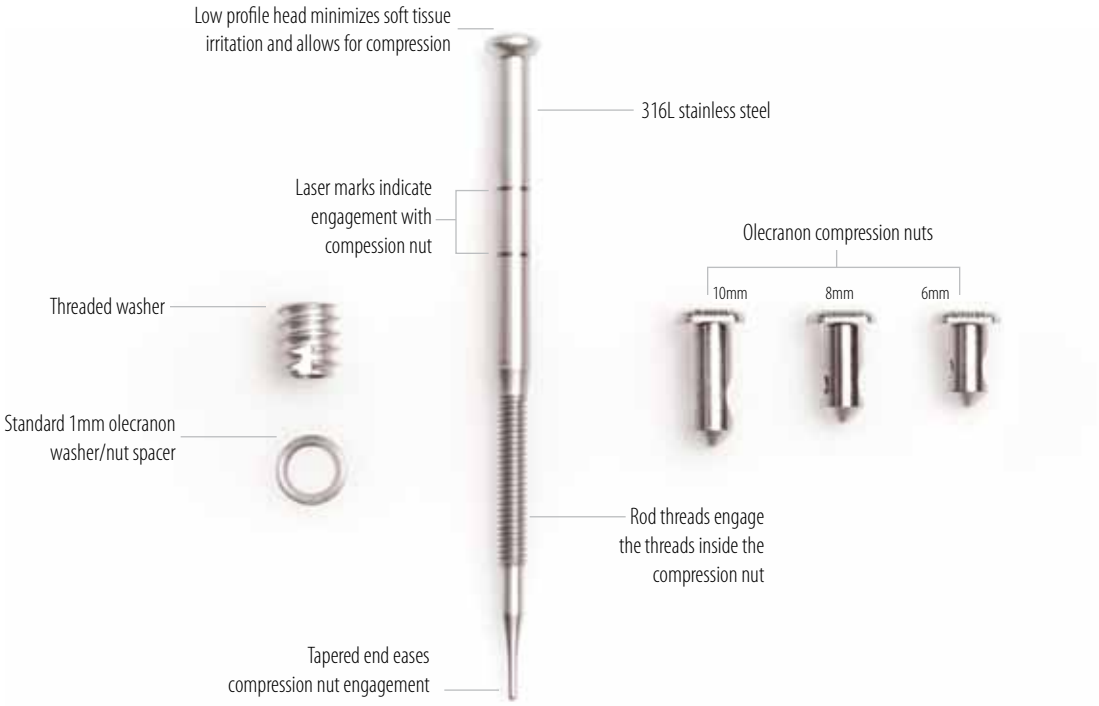
Maximized Compression and Holding Power is achieved with a combination of the rod's threads engaging with the distal compression nut and the head of the rod compressing against the threaded or standard washer. The Olecranon Threaded Compression Rod gains and maintains more compression than a standard tension band pinning technique with K-wires and cerclage wire placed in a figure-of-eight configuration[1].



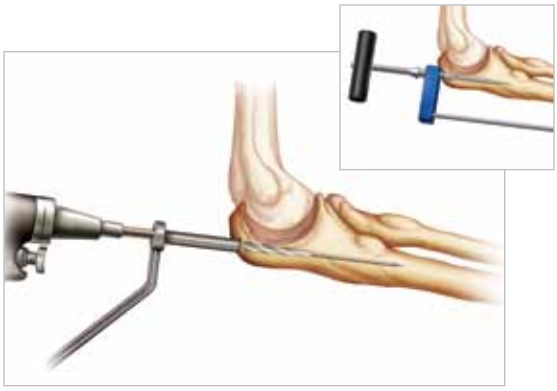
Minimally Invasive Technique allows maximized fixation with minimal exposure and soft tissue disruption. The Olecranon Threaded Compression Rod provides the benefits of an intramedullary device, and its low profile head offers significantly less hardware prominence than an olecranon plate, a traditional headed screw or tension band pins.



Straightforward Surgical Technique provides surgeons with a compact, user-friendly instrumentation set and a quick, reproducible means to implant the Olecranon Threaded Compression Rod. Our goal is for surgeons to be able to implant the rod quickly with a straightforward technique that provides reliable and consistent results every time. The targeting system and instrumentation is designed to make the procedure straightforward for the surgeon and OR staff.



Olecranon Threaded Compression Rod



Step 1: Cortex Perforation & Canal Preparation

Following exposure and dissection*, insert a 2.0mm guide wire (WS-2009ST) down the center of the canal approximately 8-10cm. Verify placement under an image intensifier in the A/P and lateral views. Ensure that the guide wire is not bent during insertion. Using the cannulated drill (80-0465), drill over the guide wire to the depth of the black laser band. A cannula (MS-2000) may be used to protect the soft tissues while drilling. Remove the guide wire after drilling.

Alternately, the awl (40-0022) may be used to perforate the cortex and prepare the canal. An axial alignment guide (80-0330) for the awl may be used to ensure straight alignment down the canal. The guide is aligned parallel with the ulna to ensure the awl passes straight into the canal (image inset).

Step 2: Insert Threaded Washer

If the threaded washer (40-0021-S) is selected, slide it onto the hex portion of the awl. The awl couples as a hex driver and is used to implant the washer into the bone. Bury the threaded washer to just below the cortex. The triceps tendon is thick and may hide a prominent washer. Use an image intensifier to confirm washer depth. If using the standard 1mm Olecranon Washer (40-0016-S), it will not be implanted until Step 8.

Warning: The threaded washer should not be used in patients with extremely osteoporotic bone or in patients with a small olecranon. In these cases, the standard 1mm Olecranon Washer (40-0016-S) should be used.

Step 3: Insert Targeting Guide & Cannula

Insert the targeting guide (40-0008) into ulna. Insert the cannula (40-0007) through the targeting guide. It is important that the cannula be fully seated against the cortex of the ulna during this step. The laser line on the cannula will align with (or between) the 6-, 8- and 10mm marks on the targeting guide. This will determine which size compression nut is used in a later step.

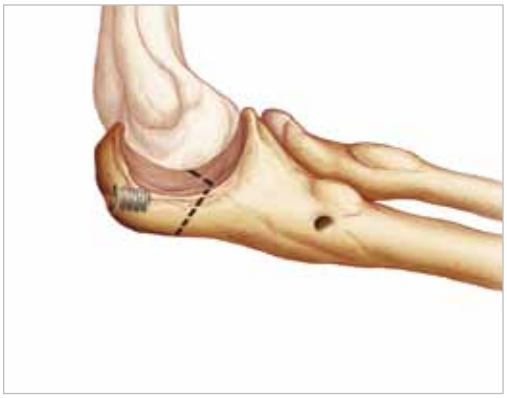
Step 4: Drill for Compression Nut

Drill through the cannula until the drill collar contacts the cannula and the drill cannot be advanced any further. Be sure that the cannula is fully seated against the bone while drilling. Note that the drill is not intended to exit the far cortex. Remove the targeting guide and cannula after drilling.

***** If using the Olecranon Threaded Compression Rod for fracture fixation, provisional fixation with K-wires and/or bone clamps is recommended.

Step 5: Create Osteotomy (if using OTCR for osteotomy repair)

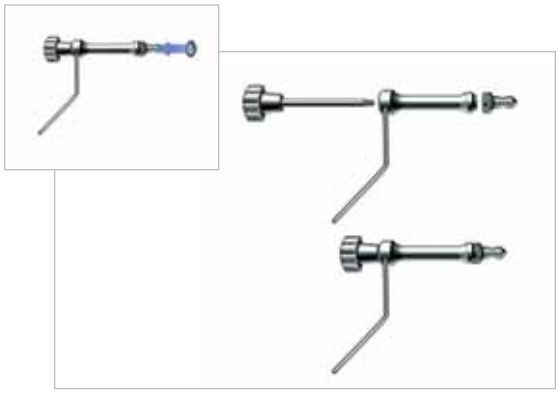
At this time, the osteotomy is made. A chevron osteotomy is recommended to aid with rotational alignment. The osteotomy is started with a fine oscillating saw and then finished by breaking the last few millimeters with an osteotome.



Step 6: Prepare Compression Nut

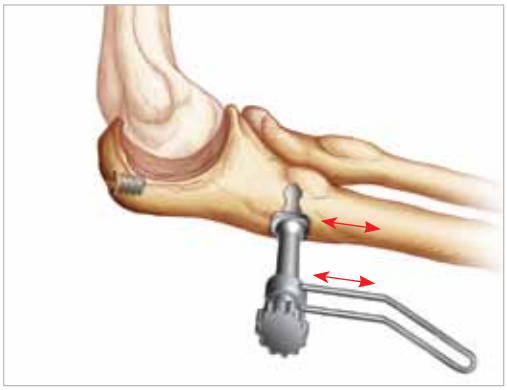
Attach the approprate size compression nut to the alignment guide (40-0003) with the locking bolt (40-0006). If a 9-, 7-, or 5mm size was indicated with the cannula in Step 3, a 1mm Olecranon Washer (40-0016-S) will need to be slid on to the compression nut prior to implanting:

9mm Use 10mm compression nut AND 1mm Olecranon Washer
7mm Use 8mm compression nut AND 1mm Olecranon Washer
5mm Use 6mm compression nut AND 1mm Olecranon Washer



Step 7: Insert Compression Nut

The handle on the alignment guide should be aligned parallel to the ulna to ensure proper orientation. Do not remove the alignment guide until after the Olecranon Threaded Compression Rod is inserted in the next step.

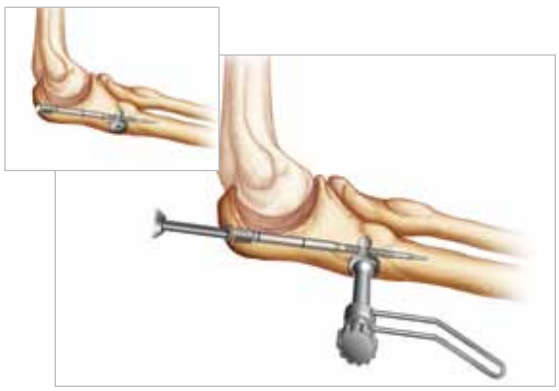


Step 8: Insert Olecranon Threaded Compression Rod

Insert the rod with the 3.5mm hex driver tip (80-0238) and driver handle (80-0175). If the standard 1mm Olecranon Washer was selected in Step 2, slide the washer (40-0016-S) onto the rod prior to inserting.

When inserting the rod, take care to ensure it is properly aligned and passes through (and not around) the compression nut. There are two laser bands on the rod. When the distal band enters the olecranon, the rod tip enters the compression nut. When the proximal band aligns with the cortex, the rod has passed completely through the compression nut. Confirm that the compression nut cannot be rotated more than a slight amount.

The nut alignment guide is then removed and the incision is closed at the surgeon's discretion. If threaded washer removal is necessary, the 5.0mm hex awl or standard 5.0mm hex driver is used.



Biomechanical Studies

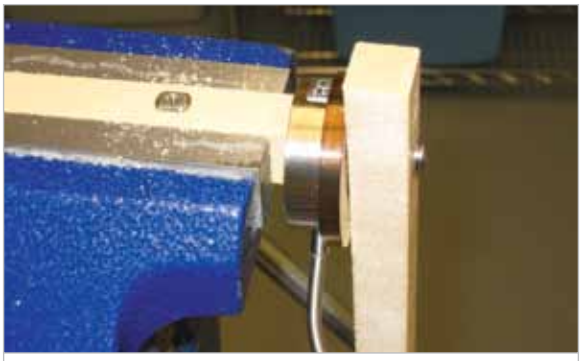


Figure 1

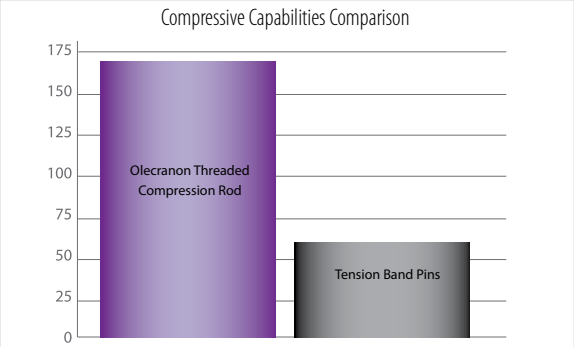


Chart 1: Maximum Loading Values -OTCR vs. TB Pins

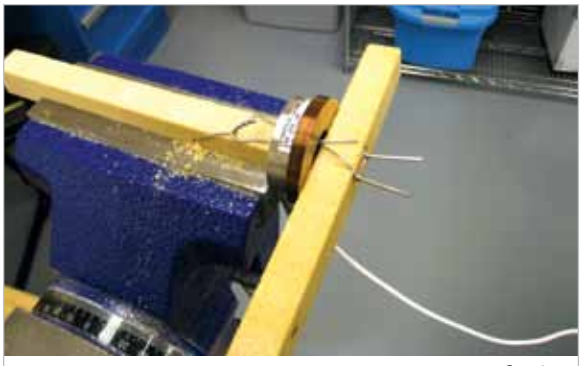


Figure 2

Figure 3

Internal mechanical testing was performed at Acumed comparing the compression force capability of the Olecranon Threaded Compression Rod to tension band pin fixation of an olecranon osteotomy. Foam with densities of 20lb/ft^3 and 30lb/ft^3 were used to simulate bone in the test. Acumed tested both the maximum and sustainable loads for both devices. The maximum load is the maximum compression loading that was achieved through the test for each sample. The sustainable load is the maximum load that each sample was able to sustain after being loaded and then left untouched.

The compressive capabilities of the two systems differed dramatically. The Olecranon Threaded Compression Rod samples easily sustained loads over 92 lbs, and could reach maximum loading values of over 170 lbs. *(Figure 1)* The tension band pins could only reach maximum values of 60 lbs and could not sustain loads over 32 lbs. When subjected to compressive forces, the cerclage wire that passed through the bone tunnel distally began to pull into the foam block. Proximally, the cerclage wire began to sink down into the foam block. *(Figure 2)*

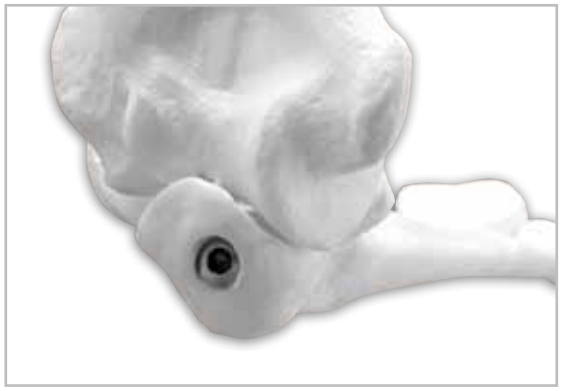
We also compared the pull-out strength between the Threaded Washer and the standard 1mm Olecranon Washer from the Olecranon Threaded Compression Rod System. Foam block samples with a density of 15lb/ft^3 were assembled with the appropriate washer and rod and placed into the test machine. From a set position, the machine then pulled the olecranon rod 20mm into the foam block and recorded the corresponding force. *(Figure 3)* The feedback force required to pull the washer through the foam block was recorded in real time.

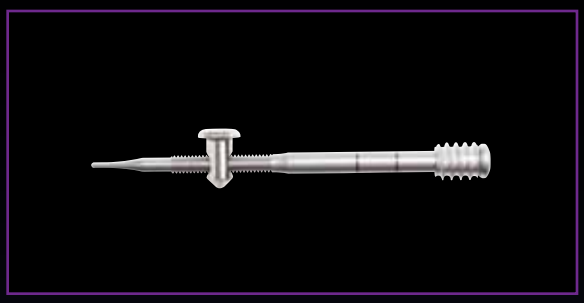
The peak values of failure between the threaded and standard washers were not significantly different. However, there is a clear difference between the loading behaviors of the two washers. As it's loaded, the standard washer resisted the force until it reached approximately 350N (78 lbs) to 400N (89 lbs) and then it began to cut into the foam block until the block fractured at an average of 618N (139 lbs). In contrast, the threaded washer immediately took the load and did not move or sink into the foam at all until the force peaked at an average of 616N (138 lbs). So while they both broke through the foam at nearly the same load, the standard washer begins to crush into the foam and displace at lower loads than the threaded washer.

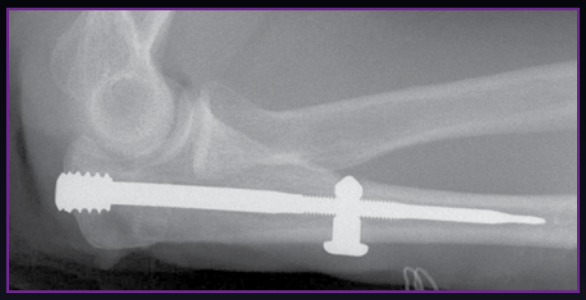
Ordering Information

Implants (Packaged Sterile)	
4.5mm Olecranon Threaded Compression Rod (89.5mm length)	40-0001-S
Olecranon Rod Threaded Insert	40-0021-S
1mm Olecranon Washer/Nut Spacer	40-0016-S
6mm Olecranon Compression Nut	40-0013-S
8mm Olecranon Compression Nut	40-0014-S
10mm Olecranon Compression Nut	40-0015-S

Instrumentation	
5mm Hex Awl	40-0022
Targeting Guide Assembly	40-0008
Targeting Guide Drill Cannula	40-0007
Olecranon Compression Nut Drill	40-0012
Olecranon Nut Guide Assembly	40-0003
Olecranon Locking Bolt	40-0006
3.5mm Quick Release Hex Driver Tip	80-0238
Ratcheting Driver Handle	80-0175
Awl Alignment Guide Assembly	80-0330
Olecranon Rod Cannulated Drill	80-0465
2.0mm x 9" ST Guide Wire	WS-2009ST
Generic Cannula Assembly	MS-2000
Tray Insert with Lid	80-0312







REFERENCES

1. Data on file at Acumed.

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