

# AEUMED<sup>®</sup>

Innovative Solutions

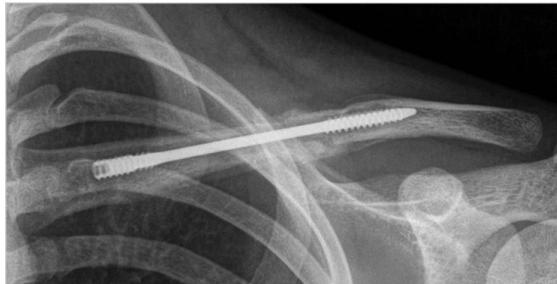


**Dual-Trak  
Clavicle Screw**

# Dual-Trak Clavicle Screw System

Acumed® is a global leader of innovative orthopaedic and medical solutions.

We are dedicated to pioneering products, service methods and approaches that improve patient care.



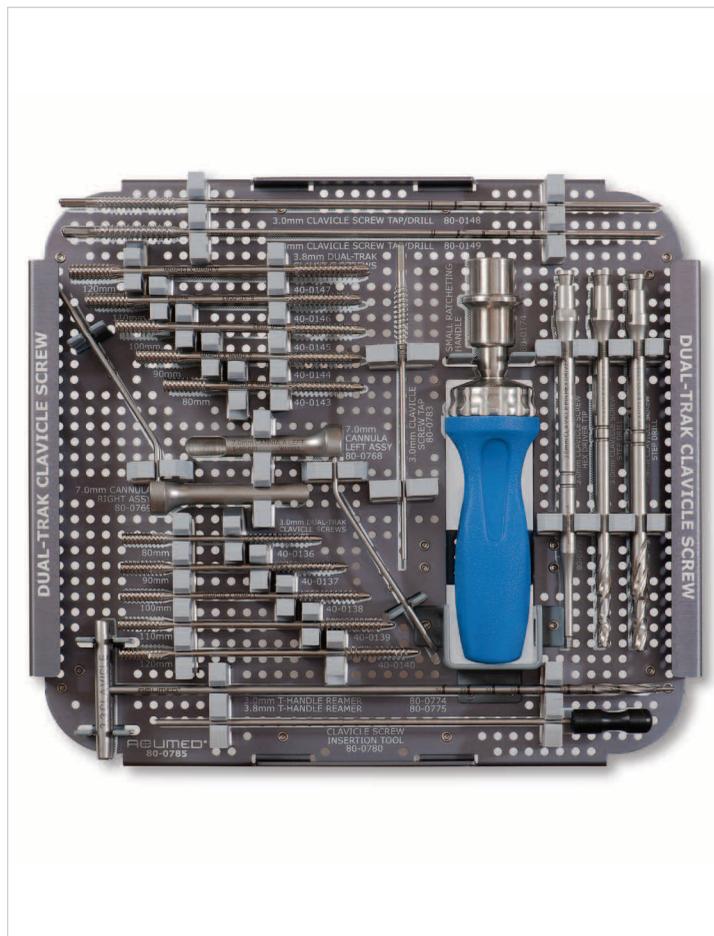
Aligning with our goal to provide surgeons with innovative solutions, Acumed® has designed the Dual-Trak Clavicle Screw System as an intramedullary option to treat middle third clavicle fractures.

Numerous attempts have been made to find less invasive techniques to provide rapid pain relief, simplify surgery and minimize complications by reducing surgical time and soft-tissue stripping. However, these techniques are fraught with post-operative complications, some as high as 50%, including implant migration or failure, painful prominent hardware, unstable fixation, infection, and refracture after hardware removal.<sup>(1-6)</sup>

The Acumed® Dual-Trak Clavicle Screw design targets the complications of previous intramedullary clavicle fixation techniques. Designed to provide excellent fracture stability and restoration of anatomical alignment, this minimally invasive implant offers several advantages which lead to improved patient outcomes.

## CONTENTS

Introducing the System	2
System Features	3
Lateral Entry Surgical Technique	4
Medial Entry Surgical Technique	7
Ordering Information	11



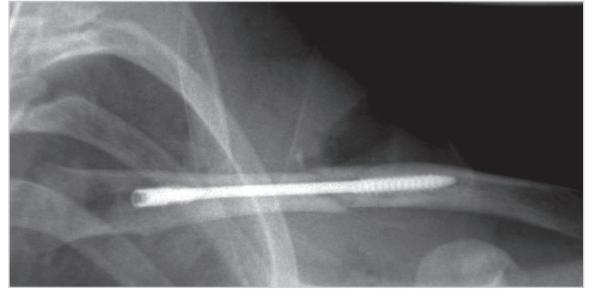
Designed in conjunction with Robert M. Orfaly, M.D., the Dual-Trak Clavicle Screw provides a novel surgical solution for acute fractures, malunions, and nonunions of the clavicle. The Dual-Trak Clavicle Screw is a completely intramedullary device that provides and maintains superior compression, eliminates hardware irritation, and offers a minimally invasive surgical technique – all of which benefits both the patient and surgeon.

Implanted entirely within the canal of the clavicle, the subosseous Dual-Trak Clavicle Screw preserves the periosteum and surrounding soft tissue and minimizes tissue trauma. Moreover, minimized hardware prominence reduces soft tissue irritation and increases patient acceptance. Unlike other implants on the market, the Dual-Trak Clavicle Screw does not require any extra-medullary means of fixation in order to maintain compression or prevent implant migration. User-friendly surgical techniques and instrumentation eases the procedure for both surgeon and OR staff and minimizes overall surgery time.

The Dual-Trak Clavicle Screw System is housed in a well organized, comprehensive tray with all the instruments necessary to implant the screw. The versatility of the system allows it to be used as either a stand-alone system or in conjunction with the Acumed® Locking Clavicle Plate System, to create one complete clavicle solution system for surgeon and hospital convenience.

## Dual-Trak Clavicle Screw System Features

**Minimally Invasive Technique** offers a limited surgical exposure thereby reducing soft-tissue dissection, periosteal stripping, and unsightly or painful scarring. User-friendly instrumentation and multiple surgical techniques allow for reliable and reproducible results, a shorter recovery time, and a faster return to daily activities.



**Fully Intramedullary Implant** eliminates painful prominent hardware, skin breakdown related to hardware prominence, and reduces risk of infection. The Dual-Trak Clavicle Screw also reduces the need for hardware removal which in turn reduces the potential of refracture due to a stress riser. This is achieved via the headless design and multiple lengths provided. With five lengths ranging from 80 mm-120 mm, the system offers numerous options to optimize the stability of fixation by obtaining sufficient thread engagement across the fracture fragments in the S-shaped medullary canal.



**Maximized Holding Control and Compression** is provided by differential pitch threads on the tip and tail ends of the Dual-Trak Clavicle Screw. This interfragmental compression effect is superior to other intramedullary implants because the threads exert an axial compression force at the fracture site. The Dual-Trak Clavicle Screw does not require any extra-medullary means of fixation to maintain compression or prevent implant migration, unlike other implants on the market.



Differential Pitch prevents implant migration and provides up to 3 mm of compression.

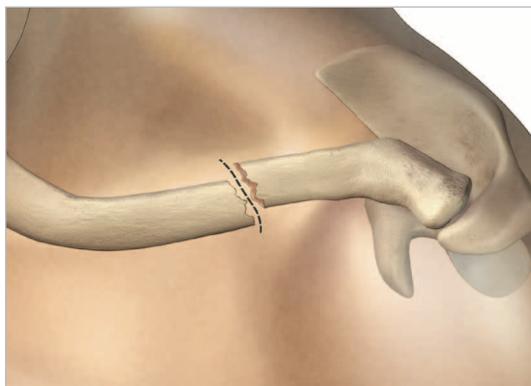
Composed of high grade titanium-alloy, the biocompatible Dual-Trak Clavicle Screw offers superior strength and a modulus of elasticity that maintains alignment of the fracture without overly rigid fixation.

Cutting Flutes on both the tip and tail ease insertion.



A comprehensive array of screw diameters (3.0 mm and 3.8 mm) and lengths (80 mm to 120 mm) in 10 mm increments provide numerous options to best accommodate the various sizes of patient medullary canals.

# Lateral Entry Surgical Technique

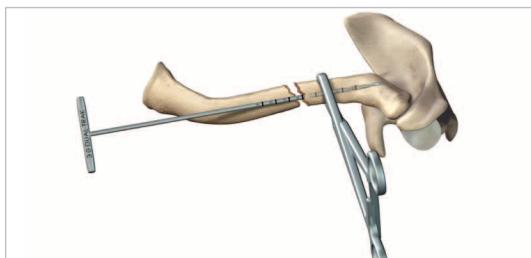


## 1 EXPOSURE

With the patient in the beach chair position, make a 3 cm vertical incision in Langer's lines over the distal end of the medial fragment. Incise the deltotracheal fascia horizontally to expose the fracture fragments. Butterfly fragments can be left with their soft tissue attachments while the major medial and lateral fragments are exposed.

Alternatively, the patient may be positioned flat in the center of the bed. This positioning will avoid any fluoroscopy imaging disturbances from the bed itself and any possible contamination of the surgical field.

In either position, place a bolster between the patient's shoulder blades and head allowing the injured shoulder girdle to retract posteriorly. This will facilitate reduction by bringing the clavicle anterior to restore length and improve exposure.



## 2 REAM LATERAL FRAGMENT

First place a spinal needle into the posterior AC joint. Aiming slightly offset, the needle provides an aiming point to optimize screw purchase in the lateral fragment and ensure that the instrumentation does not exit the clavicle into the AC joint. To ensure instrumentation maintains the correct path, under fluoroscopy, hold the lateral fragment with a serrated clamp and use a 2.8 mm drill to open up the canal.



Insert the 3.0 mm T-Handle Reamer into the lateral portion of the fracture and ream in a medial to lateral direction, making sure not to exit the bone. If the reamer is engaging cortex, it signifies that a 3.0 mm diameter Dual-Trak Clavicle Screw should be inserted. If the reamer is not fully engaging the cortex, use the 3.8 mm T-Handle Reamer to prepare the canal. In this instance, a 3.8 mm diameter Dual-Trak Clavicle Screw will be used to achieve fracture fixation.

Each reamer is laser marked in 10 mm increments. Note the final depth measurement of the reamer to help determine the length of the device to be implanted later.

**TIP:** Fluoroscopy helps ensure a precise posterior-lateral exit point. Otherwise, the drill may exit the superior surface of the clavicle.

**NOTE:** In cases with small-boned patients who have a minimal medullary canal and dense bone, proceed with caution. As an alternative in these cases, the surgeon may opt to plate the clavicle using the Acumed Locking Clavicle Plate System.

## Lateral Entry Surgical Technique

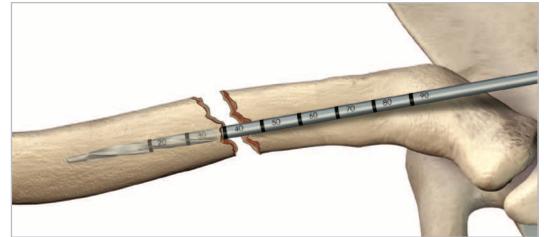
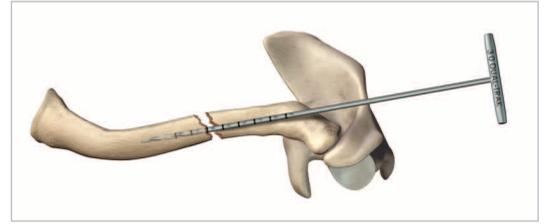
### 3 REAM MEDIAL FRAGMENT

To ensure instrumentation maintains the correct path, hold the medial fragment with a serrated clamp and use a 2.8 mm drill to open up the canal.

Next, insert the 3.0 mm T-Handle Reamer into the medial fragment. Ream in a lateral to medial direction making sure not to exit the bone. If the reamer is not engaging cortex, use the 3.8 mm T-Handle Reamer to finish preparing the canal.

Note the final depth measurement of the reamer. Add the reamer depths from Step 2 and Step 3 respectively to obtain the final screw length.

TIP: If the isthmus is located in the medial fragment, the order of reaming may be reversed to determine the proper screw diameter as the medial fragment will usually have a wider canal than the lateral fragment.

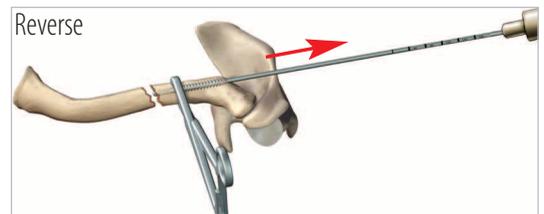
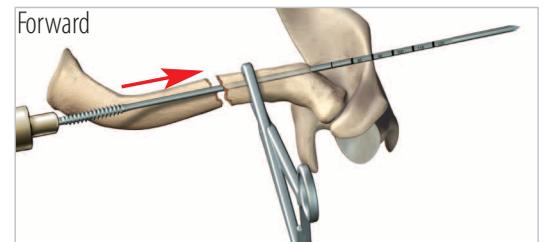


### 4 DRILL & TAP LATERAL FRAGMENT

Chuck the Clavicle Tap/Drill by the blunt tip nose just past the tap threads. Holding the lateral fragment with a serrated clamp, insert the drill portion of the Clavicle Tap/Drill into the fragment. Drill **forward** in a medial to lateral direction, advancing the drill through the lateral cortex of the clavicle. As the skin begins to tent, make a stab incision. Advance the drill out of the skin laterally until the drill approaches the fracture site. Un-chuck the Clavicle Tap/Drill from the tap end and re-chuck laterally over the exposed drill on the region with tri-flat contours. **Reverse** out the Clavicle Tap/Drill laterally until the tap portion is completely within the lateral fragment.

TIP: Fluoroscopy helps ensure a precise posterior lateral exit point.

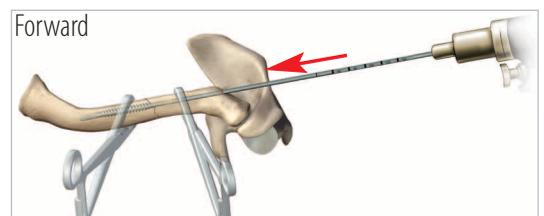
TIP: A #11 blade will create a cleaner cut for the stab incision as opposed to a #15 or #20 blade.



### 5 TAP MEDIAL FRAGMENT

Holding the fragments with serrated clamps, reduce the fracture and under fluoroscopy, advance the Clavicle Tap/Drill **forward** into the medial fragment to the desired placement. Keep the Clavicle Tap/Drill in place as this will serve to maintain reduction until after Step 7.

NOTE: When tapping medially, we recommend that the entire length of tap threads engage the medially fragment. Stop tapping prior to exiting the bone.



## Lateral Entry Surgical Technique

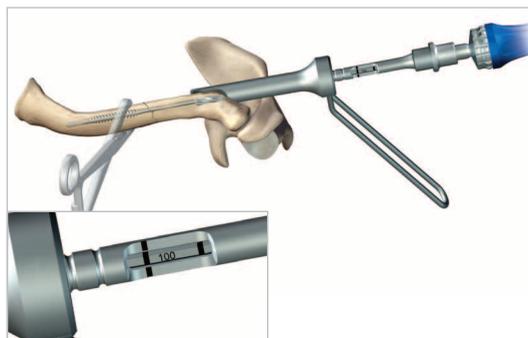
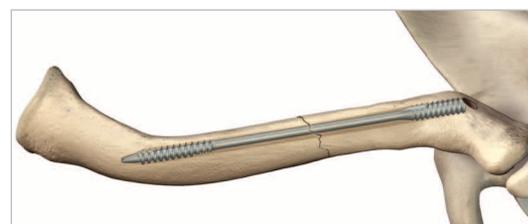
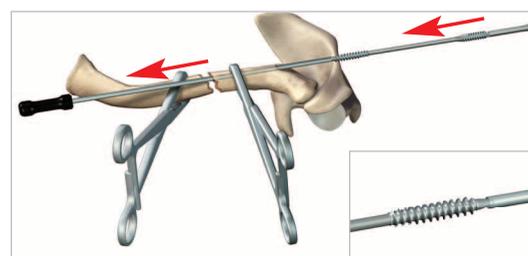
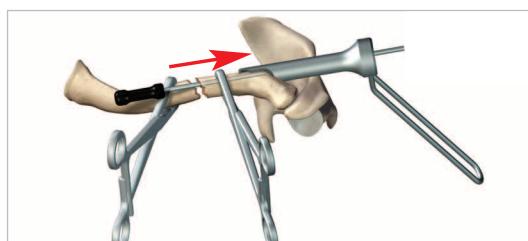


Figure A



Figure B



### 6 PREPARE MEDULLARY CANAL

Slide the appropriate sided Cannula over the exposed portion of the Clavicle Tap/Drill. Rotate the Cannula so that the nose is flush with the bone. Insert the cannulated Clavicle Step Drill over the Clavicle Tap/Drill and through the Cannula.

Next, determine the amount of compression desired for the surgery. The Dual-Trak Clavicle Screw offers an opportunity to achieve up to 3 mm of compression.

**SCREW MEASUREMENT:** The Clavicle Step Drill has a built-in window. Note the alignment of the laser mark on the Clavicle Tap/Drill with the laser marks on the Clavicle Step Drill (inset). If the length is between sizes, downsize to the shorter screw length.

**FOR MAXIMUM COMPRESSION:** Advance the Clavicle Step Drill in a lateral to medial direction until the **FIRST GROOVE** on the drill shaft aligns with the back end of the Cannula (Figure A). Upon screw insertion, insert the Hex Driver until the **FIRST GROOVE** on the driver shaft aligns with the back end of the Cannula.

**FOR REDUCED COMPRESSION:** Advance the Clavicle Step Drill until the **SECOND GROOVE** on the drill shaft aligns with the back end of the Cannula (Figure B). Upon screw insertion, insert the Hex Driver until the **FIRST GROOVE** on the driver shaft aligns with the back end of the Cannula.

### 7 SECURE LATERAL ENTRY POINT

Remove the Clavicle Step Drill from the medullary canal. Next, holding the fragments with serrated clamps **reverse** the Clavicle Tap/Drill out from the medial and lateral fragments. Place the Insertion Tool through the fracture site in a medial to lateral direction so that it advances out of the lateral clavicle and skin. This identifies the entry site and eases the process of inserting the Dual-Trak Clavicle Screw into the medullary canal.

### 8 SCREW INSERTION

First connect the Hex Driver to the Hudson Adapter. Place the nose of the Dual-Trak Clavicle Screw into the concave portion of the Insertion Tool (inset). Thread the Dual-Trak Clavicle Screw into the medullary canal while withdrawing the Insertion Tool. As the screw approaches the fracture site, remove the Insertion Tool and reduce the fracture. Holding the medial fragment with a serrated clamp, advance the Dual-Trak Clavicle Screw until the most medial screw threads cross the fracture site and are completely implanted into the medial fragment. Advance the screw until the **FIRST GROOVE** on the Hex Driver aligns with the back end of the Cannula. This alignment will signify the screw is flush with the bone.

**NOTE:** If the Clavicle Step Drill was advanced to the **SECOND GROOVE** to achieve reduced compression (determined in step 6), advancing the Hex Driver to the **SECOND GROOVE** will result in maximum compression with the implant buried 5 mm beneath the surface of the bone.

If the Clavicle Step Drill was advanced only to the **FIRST GROOVE** to achieve maximum compression (determined in step 6), advancing the Hex Driver to the **SECOND GROOVE** may result in distraction of the fracture.

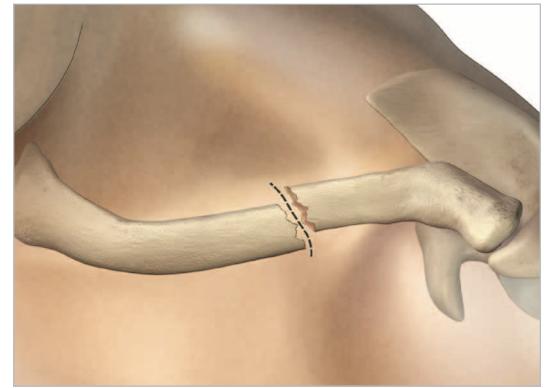
## Medial Entry Surgical Technique

### 1 EXPOSURE

With the patient in the beach chair position, make a 3 cm vertical incision in Langer's lines over the distal end of the medial fragment. Incise the deltotrapezial fascia horizontally to expose the fracture fragments. Butterfly fragments can be left with their soft tissue attachments while the major medial and lateral fragments are exposed.

Alternatively, the patient may be positioned flat in the center of the bed. This positioning will avoid any fluoroscopy imaging disturbances from the bed itself and any possible contamination of the surgical field.

In either position, place a bolster between the patient's shoulder blades and head allowing the injured shoulder girdle to retract posteriorly. This will facilitate reduction by bringing the clavicle anterior to restore length and improve exposure.



### 2 REAM LATERAL FRAGMENT

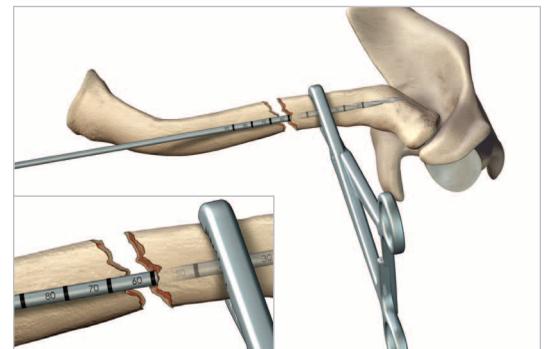
First place a spinal needle into the posterior AC joint. Aiming slightly offset, the needle provides an aiming point to optimize screw purchase in the lateral fragment and ensures that the instrumentation does not exit the clavicle into the AC joint. To ensure instrumentation maintains the correct path, under fluoroscopy, hold the lateral fragment with a serrated clamp and use a 2.8 mm drill to open up the canal.

Insert the 3.0 mm T-Handle Reamer into the lateral portion of the fracture, and ream in a medial to lateral direction, making sure not to exit the bone. If the reamer is engaging cortex, it signifies that a 3.0 mm diameter Dual-Trak Clavicle Screw will be inserted. If the reamer is not fully engaging the cortex, use the 3.8 mm T-Handle Reamer to prepare the canal. In this instance, a 3.8 mm diameter Dual-Trak Clavicle Screw will be used to achieve fracture fixation.

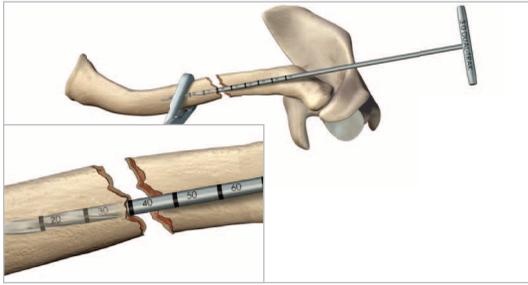
**SCREW MEASUREMENT:** Each reamer is laser marked in 10 mm increments. Note the final depth measurement of the reamer.

**TIP:** Fluoroscopy helps ensure a precise posterior-lateral positioning. Otherwise, the drill may exit the superior surface of the clavicle.

**NOTE:** In cases with small-boned patients who have a minimal medullary canal and dense bone, proceed with caution. As an alternative in these cases, the surgeon may opt to plate the clavicle using the Acumed Locking Clavicle Plate System.



## Medial Entry Surgical Technique



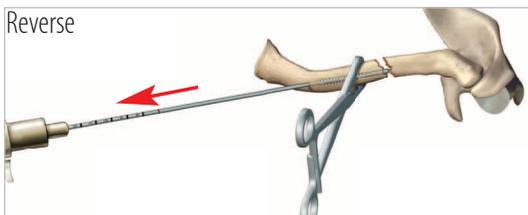
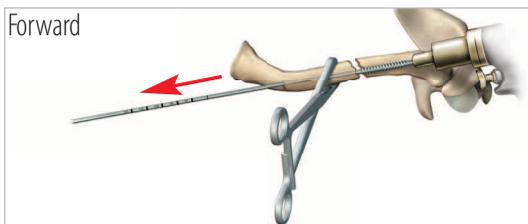
### 3 REAM MEDIAL FRAGMENT

To ensure instrumentation maintains the correct path, hold the medial fragment with a serrated clamp and use a 2.8 mm drill to open up the canal.

Next, insert the 3.0 mm T-Handle Reamer into the medial fragment. Ream in a lateral to medial direction making sure not to exit the bone. If the reamer is not engaging cortex, use the 3.8 mm T-Handle Reamer to finish preparing the canal.

**SCREW MEASUREMENT:** Note the final depth measurement of the reamer. Add the reamer depths from Step 2 and Step 3 respectively to obtain the final screw length.

**TIP:** If the isthmus is located in the medial fragment, the order of reaming may be reversed to determine the proper screw diameter as the medial fragment will usually have a wider canal than the lateral fragment.



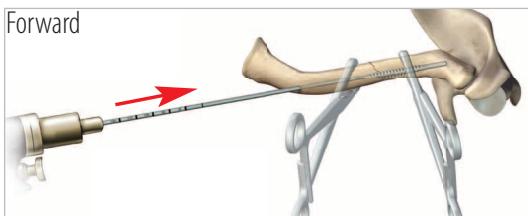
### 4 DRILL & TAP MEDIAL FRAGMENT

Chuck the Clavicle Tap/Drill by the blunt tip nose just past the tap threads. Holding the medial fragment with a serrated clamp, insert the drill portion of the Clavicle Tap/Drill into the fragment. Drill **forward** in a lateral to medial direction, advancing the drill through the anterior cortex of the medial clavicle. As the skin begins to tent, make a stab incision. Advance the drill out of the skin anteriorly until the drill approaches the fracture site. Un-chuck the Clavicle Tap/Drill from the tap end and re-chuck medially over the exposed drill on the region with tri-flat contours.

**Reverse** the Clavicle Tap/Drill medially until the tap portion is completely within the medial fragment.

**TIP:** Fluoroscopy helps ensure a precise anterior medial exit point.

**TIP:** A #11 blade will create a cleaner cut for the stab incision as opposed to a #15 or #20 blade.



### 5 TAP LATERAL FRAGMENT

Holding the fragments with serrated clamps, reduce the fracture and under fluoroscopy, advance the Clavicle Tap/Drill **forward** into the lateral fragment to the desired placement. Keep the Clavicle Tap/Drill in place as this will serve to maintain reduction until after Step 7.

**NOTE:** When tapping laterally, we recommend that the entire length of tap threads engage the lateral fragment. Stop tapping prior to exiting the bone.

## Medial Entry Surgical Technique

### 6 PREPARE MEDULLARY CANAL

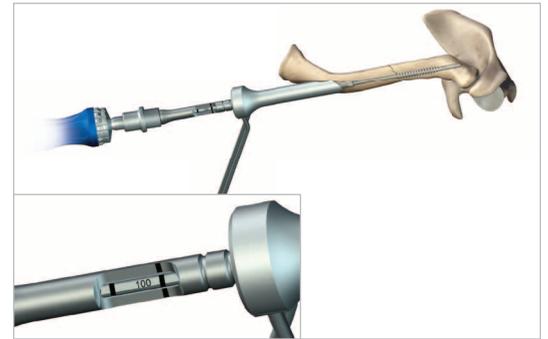
Slide the appropriate sided Cannula over the exposed portion of the Clavicle Tap/Drill. Rotate the Cannula so the nose is flush with the bone. Insert the cannulated Clavicle Step Drill through the Cannula and over the Clavicle Tap/Drill.

The Dual-Trak Clavicle Screw offers an opportunity to achieve up to 3 mm of compression.

**SCREW MEASUREMENT:** The Clavicle Step Drill has a built-in window. Note the alignment of the laser mark on the Clavicle Tap/Drill with the laser marks on the Clavicle Step Drill (inset). If the length is between sizes, downsize to the shorter screw length.

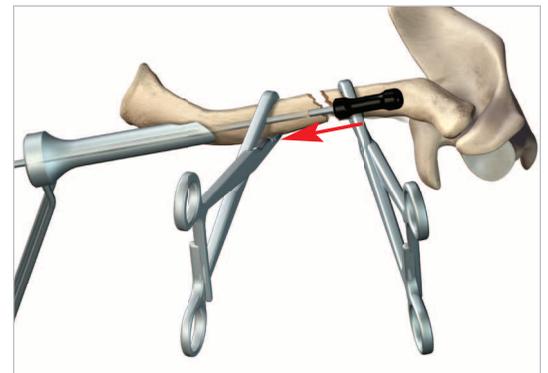
**FOR MAXIMUM COMPRESSION:** Advance the Clavicle Step Drill in a medial to lateral direction until the **FIRST GROOVE** on the drill shaft aligns with the back end of the Cannula (Figure A). Upon screw insertion, insert the Hex Driver until the **FIRST GROOVE** on the driver shaft aligns with the back end of the Cannula.

**FOR REDUCED COMPRESSION:** Advance the Clavicle Step Drill until the **SECOND GROOVE** on the drill shaft aligns with the back end of the Cannula (Figure B). Upon screw insertion, insert the Hex Driver until the **FIRST GROOVE** on the driver shaft aligns with the back end of the Cannula.

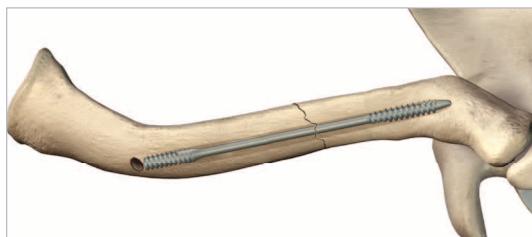
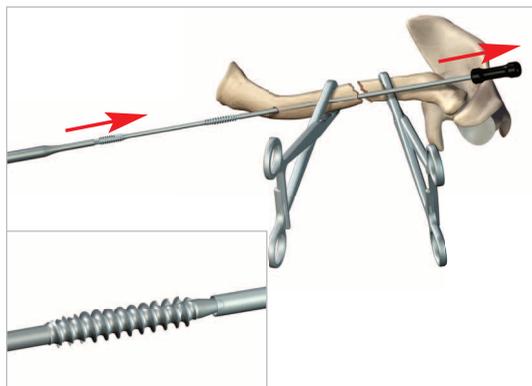


### 7 SECURE MEDIAL ENTRY POINT

Remove the Clavicle Step Drill from the medullary canal. Next, holding the fragments with serrated clamps **reverse** the Clavicle Tap/Drill out from the medial and lateral fragments. Place the Insertion Tool through the fracture site (concave end first) in a lateral to medial direction so that it advances out of the medial fragment and skin. This identifies the entry site and eases the process of inserting the Dual-Trak Clavicle Screw into the medullary canal.



## Medial Entry Surgical Technique



### 8 SCREW INSERTION:

First connect the Hex Driver to the Hudson Adapter. Place the nose of the Dual-Trak Clavicle Screw into the concave portion of the Insertion Tool (inset). Thread the Dual-Trak Clavicle Screw into the medullary canal while withdrawing the Insertion Tool. As the screw approaches the fracture site, remove the Insertion Tool and reduce the fracture. Holding the lateral fragment with a serrated clamp, advance the Dual-Trak Clavicle Screw until the screw threads cross the fracture site and are completely implanted into the lateral fragment. Advance the screw until the FIRST GROOVE on the Hex Driver aligns with the back end of the Cannula. This alignment will signify the screw is flush with the bone.

NOTE: If the Clavicle Step Drill was advanced to the SECOND GROOVE to achieve reduced compression (determined in step 6), advancing the Hex Driver to the SECOND GROOVE will result in maximum compression with the implant buried 5 mm beneath the surface of the bone.

If the Clavicle Step Drill was advanced only to the FIRST GROOVE to achieve maximum compression (determined in step 6), advancing the Hex Driver to the SECOND GROOVE may result in distraction of the fracture.

## 3.0 mm Dual-Trak Clavicle Screw Implants

3.0 mm x 80 mm Dual-Trak Clavicle Screw	40-0136
3.0 mm x 90 mm Dual-Trak Clavicle Screw	40-0137
3.0 mm x 100 mm Dual-Trak Clavicle Screw	40-0138
3.0 mm x 110 mm Dual-Trak Clavicle Screw	40-0139
3.0 mm x 120 mm Dual-Trak Clavicle Screw	40-0140

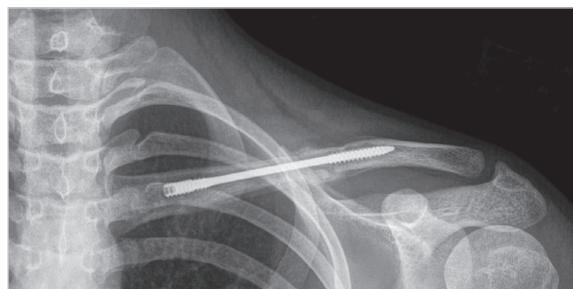
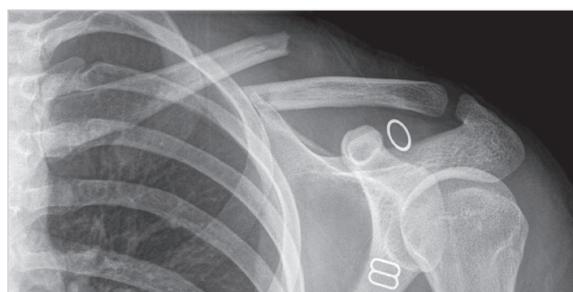
## 3.8 mm Dual-Trak Clavicle Screw Implants

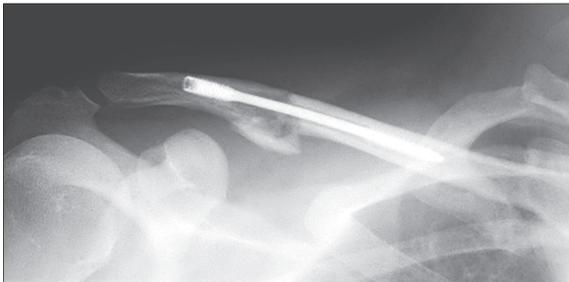
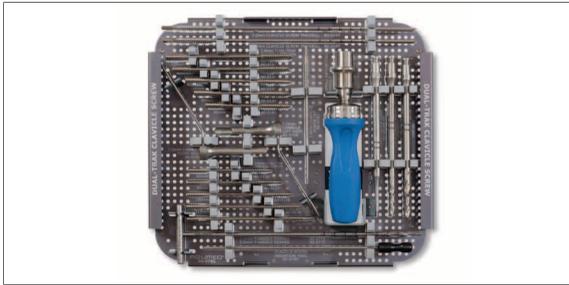
3.8 mm x 80 mm Dual-Trak Clavicle Screw	40-0143
3.8 mm x 90 mm Dual-Trak Clavicle Screw	40-0144
3.8 mm x 100 mm Dual-Trak Clavicle Screw	40-0145
3.8 mm x 110 mm Dual-Trak Clavicle Screw	40-0146
3.8 mm x 120 mm Dual-Trak Clavicle Screw	40-0147

## Dual-Trak Clavicle Screw Instrumentation

7.0 mm Cannula Left Assembly	80-0768
7.0 mm Cannula Right Assembly	80-0769
3.0 mm Clavicle Screw Step Drill	80-0772
3.8 mm Clavicle Screw Step Drill	80-0773
3.0 mm Clavicle Screw Tap/Drill	80-0148
3.8 mm Clavicle Screw Tap/Drill	80-0149
Small Ratcheting Handle w/Large Hudson Connection	80-0174
3.0 mm T-Handle Reamer	80-0774
3.8 mm T-Handle Reamer	80-0775
Clavicle Screw Insertion Tool	80-0780
3.0 mm Clavicle Screw Hex Driver Tip	80-0779
3.0 mm Clavicle Screw Tap	80-0783
Universal Tray Clavicle Screw Base	80-0785
Universal Tray Shoulder Solutions Lid	80-0786

These implants are available nonsterile or sterile-packed. Add -S to product number for sterile products. To order, contact your local Acumed® Representative.





## REFERENCES

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6. Closed Reduction with Intramedullary Fixation for Midclavicular Fractures. Chen, et al. Orthopedics May 2004 Volume 27 Number 5.

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