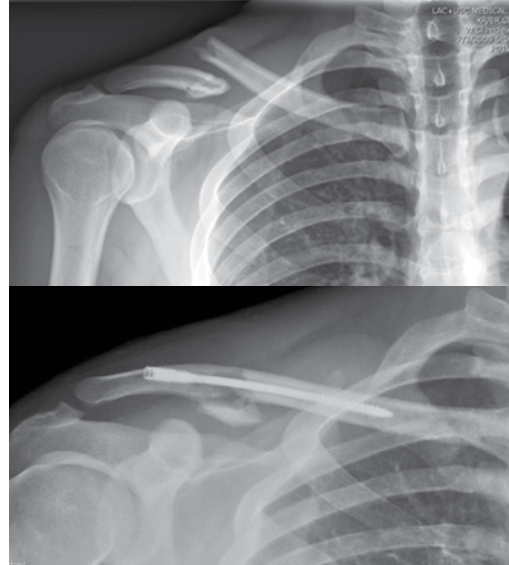




Acumed® is a global leader of innovative orthopaedic and medical solutions.

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



Dual-Trak Clavicle Screw
Design Surgeon
[Robert M. Orfaly, M.D.](#)

Acumed® Dual-Trak Clavicle Screw

The Acumed Dual-Trak Clavicle Screw System offers fully intramedullary implants intended to reduce hardware prominence when compared to plating, provide stable fracture fixation, and anatomic reduction of clavicle fractures. Designed in conjunction with Robert M. Orfaly, M.D., the Dual-Trak Clavicle Screw System includes all of the necessary instrumentation for proper canal preparation and implant sizing. The versatile design of the tray allows it to be placed in the Acumed Clavicle Plating System for a complete clavicle fixation solution.

The differential pitch threads on the tip and tail ends of the Dual-Trak Clavicle Screw allow a range from zero to three millimeters of compression. The implants are available in shaft diameters of 3.0 and 3.8 mm and in lengths ranging from 80 to 120 mm to accommodate the various patient anatomies. All Dual-Trak Clavicle Screws are made of titanium alloy per ASTM F136 and are available in sterile and nonsterile forms.

Indications for use: The Acumed Dual-Trak Clavicle Screw System is designed for fusions and fixation of the clavicle.

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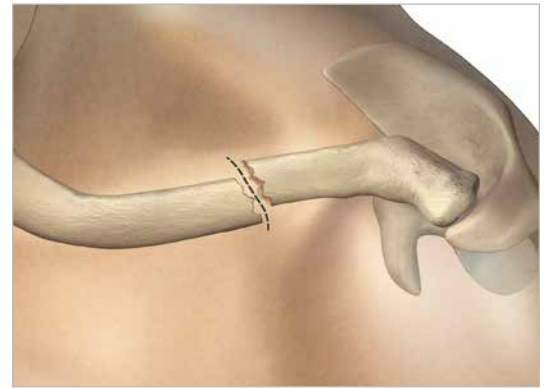
Lateral Entry Surgical Technique

1 PATIENT POSITIONING AND EXPOSURE

The patient may be placed in the beach chair position or flat in the center of the bed. These positions may minimize fluoroscopy imaging disturbances from the bed itself.

With the patient in either position, place a bolster between the shoulder blades and head to allow the injured shoulder girdle to retract posteriorly. This will help facilitate fracture reduction by bringing the clavicle anteriorly to restore length and improve exposure.

Next, locate the distal end of the medial fragment and make a 3 cm vertical incision along Langer's lines. Incise the deltotracheal fascia horizontally to expose the fracture. Butterfly fragments may be left with soft tissue attached while the major medial and lateral fragments are exposed.



2 REAM LATERAL FRAGMENT

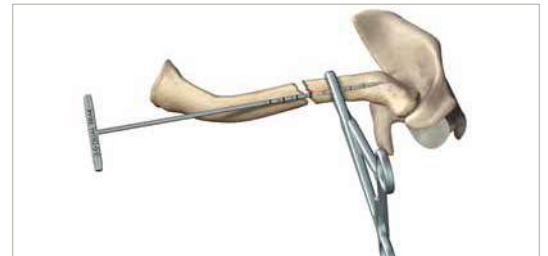
Place a spinal needle into the posterior acromioclavicular joint. This provides an aiming point to optimize screw purchase in the lateral fragment and ensures that the instrumentation does not exit the clavicle and violate the joint.

Tip: The use of fluoroscopy throughout this step can assist in a precise posterolateral exit point and may minimize the possibility of a drill or reamer exiting the superior surface of the clavicle.

Create a pilot hole for instrumentation to follow by holding the lateral fragment with a serrated clamp* and under fluoroscopy using a 2.8 mm drill bit*, drill into the medullary canal.

***Note:** The serrated clamp and 2.8 mm drill bit are not included in the Dual-Trak platter. These instruments can be found in the Acumed Clavicle Plating System or other general orthopaedic surgical sets.

Insert the 3.0 mm T-Handle Reamer (80-0774) into the lateral fragment and ream in a medial-to-lateral direction, being careful not to exit the lateral end of the clavicle.



DETERMINING SCREW DIAMETER

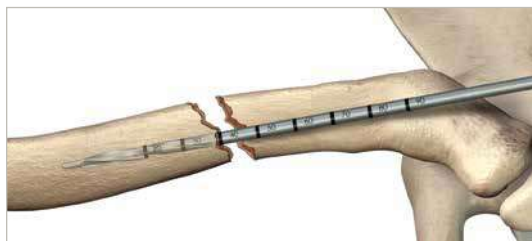
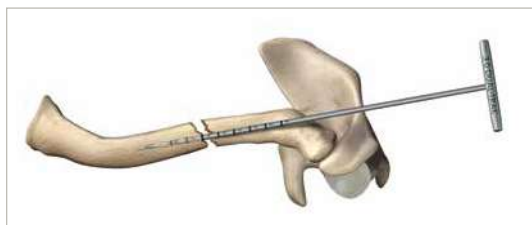
If the 3.0 mm diameter T-Handle Reamer engages the cortex, a 3.0 mm diameter Dual-Trak Clavicle Screw is recommended.

If the 3.0 mm diameter T-Handle Reamer does not fully engage the cortex, use the 3.8 mm T-Handle Reamer (80-0775) to finish preparing the medullary canal. A 3.8 mm diameter Dual-Trak Clavicle Screw should be used in these cases.

Caution: Proceed with caution in cases with patients who may have a minimal medullary canal and dense bone. As an alternative option, the surgeon may choose to plate the clavicle using the Acumed Clavicle Plating System.

DETERMINING SCREW LENGTH

Each T-handle Reamer is marked in 10 mm increments. Take careful note of the final depth measurement on the reamer, measure at the entry point of the fragment, as this will assist in determining screw length at the end of Step 3.



3 REAM MEDIAL FRAGMENT

Hold the medial fragment with a serrated clamp and use a 2.8 mm diameter drill to open the medullary canal. This will create a pilot hole for instrumentation to follow.

Tip: The use of fluoroscopy throughout this step can assist in positioning and may minimize the possibility of a drill or reamer exiting the clavicle.

Next, insert the 3.0 mm T-Handle Reamer (80-0774) into the medial fragment and ream in a lateral-to-medial direction, being careful to not exit the medial end of the clavicle.

If the larger diameter reamer was utilized in Step 2, use the 3.8 mm T-Handle Reamer (80-0775) to finish preparing the medullary canal.

Each T-handle Reamer is laser marked in 10 mm increments. Once again, take note of the depth measurement on the reamer. To estimate the screw length, add this depth reading to the depth measurement taken in Step 2.

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.

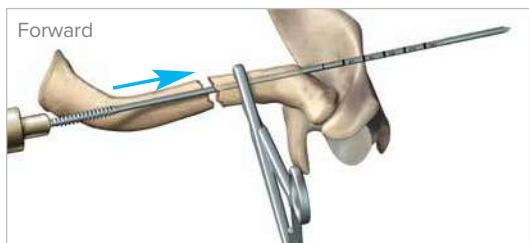


Figure 1

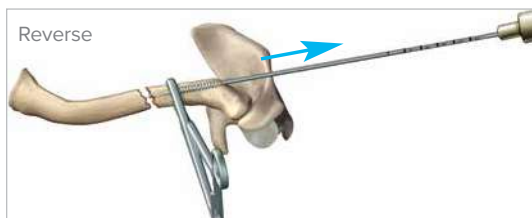


Figure 2

4 DRILL AND TAP LATERAL FRAGMENT

Select the appropriately sized Clavicle Screw Tap/Drill and insert the blunt-tipped nose, located just beyond the tap threads, into the chuck of a surgical drill.

Dual-Trak Screw Diameter (As determined in Step 2)	Corresponding Clavicle Screw Tap/Drill
3.0 mm	Part No. 80-0148
3.8 mm	Part No. 80-0149

Hold the lateral fragment with a serrated clamp and insert the Clavicle Screw Tap/Drill into the fragment. Drill **forward** in a medial-to-lateral direction, advancing the drill through the lateral cortex of the clavicle (see Figure 1). When the skin begins to tent, make a stab incision, and advance the Clavicle Screw Tap/Drill out of the skin laterally until the tap threads engage the fracture site.

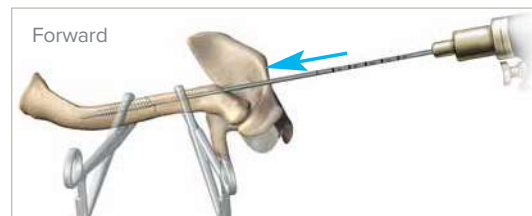
Detach the Clavicle Screw Tap/Drill from the power drill and reattach the power drill laterally over the exposed end with the tri-flat contours (see Figure 2). Next, **reverse** the Clavicle Screw Tap/Drill laterally until the threads on the tap portion are completely within the medullary canal of the lateral fragment.

- Tips:**
- The use of fluoroscopy throughout this step may help ensure a precise posterolateral exit point.
 - A #11 blade will create a cleaner cut for the stab incision as opposed to a #15 or #20 blade.

5 TAP MEDIAL FRAGMENT

While under fluoroscopy, hold both fragments with serrated clamps and reduce the fracture. Next, advance the Clavicle Screw Tap/Drill forward into the medial fragment to the desired depth. Leave the Clavicle Screw Tap/Drill in place, as this will serve to maintain reduction going forward.

Note: When tapping medially, we recommend the entire length of tap threads engage the medial fragment. However, stop tapping prior to exiting the bone.



6 PREPARE LATERAL MEDULLARY CANAL

At the lateral end of the clavicle, slide the appropriate right or left 7.0 mm Cannula over the exposed portion of the Clavicle Screw Tap/Drill, rotating it so the nose of the Cannula is flush to the bone. Next, place the appropriately sized cannulated Clavicle Screw Step Drill over the Clavicle Screw Tap/Drill and through the 7.0 mm Cannula until it comes in contact with the bone.

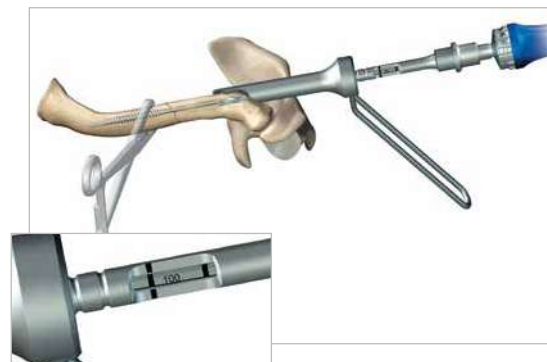


Figure 1

Dual-Trak Screw Diameter (As determined in Step 2)	Corresponding Clavicle Screw Tap/Drill	Corresponding Clavicle Screw Step Drill
3.0 mm	Part No. 80-0148	Part No. 80-0772
3.8 mm	Part No. 80-0149	Part No. 80-0773

Note: The Dual-Trak Clavicle Screw is designed to achieve up to 3 mm of compression.

TO ACHIEVE MAXIMUM COMPRESSION

Advance the Clavicle Screw Step Drill until the first groove on the drill shaft aligns with the backend of the Cannula (see Figure 2).

TO ACHIEVE REDUCED COMPRESSION

Advance the Clavicle Screw Step Drill until the second groove on the drill shaft aligns with the backend of the Cannula (see Figure 3).

SCREW LENGTH

The built-in window on the Clavicle Screw Step Drill includes markings on either side of the window (see Figure 1, inset). Once the Clavicle Screw Step Drill has been inserted to the desired depth, the reading closest to the markings on the Clavicle Screw Step Drill signifies the length of screw to implant.

If the reading falls between two markings on the Clavicle Screw Tap/Drill, downsize to the shorter length.



Figure 2



Figure 3

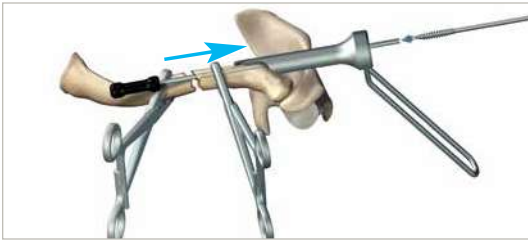


Figure 1

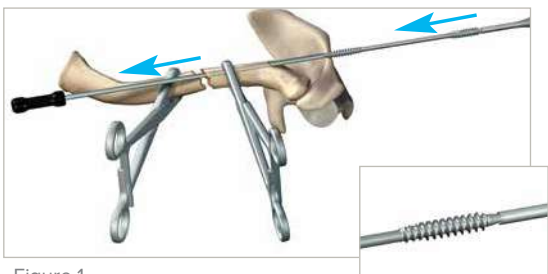


Figure 2



Figure 3

7 SECURE LATERAL ENTRY POINT

Holding both fragments with serrated clamps, remove the Clavicle Screw Step Drill from the medullary canal, and then **reverse** the Clavicle Screw Tap/Drill out laterally from both fragments.

Next, place the Clavicle Screw Insertion Tool (80-0780), concave end first, into the lateral fragment through the fracture site. Advance the tool in a medial-to-lateral direction, so it advances out through the lateral fragment and skin. This identifies the entry site for the implant and eases the process of inserting the Dual-Trak Clavicle Screw into the medullary canal.

8 SCREW INSERTION

Note: The procedures in steps 2 and 3 determined the diameter and Step 6 determined the length of the screw to implant.

Attach the 3.0 mm Clavicle Screw Hex Driver Tip (80-0779) to the Small Ratcheting Handle with Large Hudson Adapter (80-0174).

Next, place the nose of the selected Dual-Trak Clavicle Screw into the concave portion of the Clavicle Screw Insertion Tool (80-0780) (see Figure 1, inset) and advance the Dual-Trak Clavicle Screw into the clavicle. As the screw is advanced, the Insertion Tool will slowly withdraw (see Figure 1). Once the screw approaches the fracture site, remove the Insertion Tool entirely.

Holding the medial fragment with a serrated clamp, reduce the fracture, then advance the Dual-Trak Clavicle Screw until the first groove on the Hex Driver Tip aligns with the backend of the Cannula (see Figure 2). This alignment signifies the screw is flush with the bone.

If, in Step 6, the Clavicle Step Drill was advanced to the first groove to achieve maximum compression, advancing the Hex Driver Tip in this step to the second groove may result in distraction of the fracture.

If, in Step 6, the Clavicle Step Drill was advanced to the second groove to achieve reduced compression, advancing the Hex Driver Tip to the second groove will result in maximum compression with the implant buried 5 mm beneath the surface of the bone.

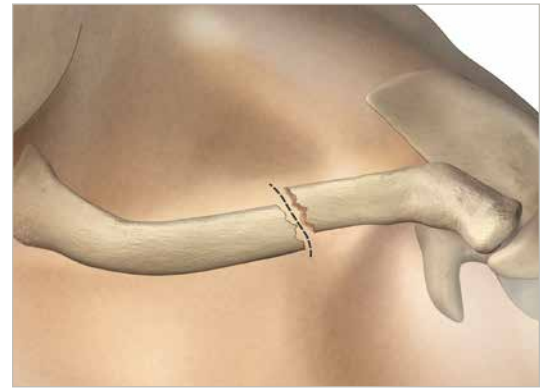
Medial Entry Surgical Technique

1 PATIENT POSITIONING AND EXPOSURE

The patient may be placed in the beach chair position or flat in the center of the bed. These positions may minimize fluoroscopy imaging disturbances from the bed itself.

With the patient in either position, place a bolster between the shoulder blades and head to allow the injured shoulder girdle to retract posteriorly. This will help facilitate fracture reduction by bringing the clavicle anteriorly to restore length and improve exposure.

Next, locate the distal end of the medial fragment and make a 3 cm vertical incision along Langer's lines. Incise the deltotrapezial fascia horizontally to expose the fracture. Butterfly fragments may be left with soft tissue attached while the major medial and lateral fragments are exposed.



2 REAM LATERAL FRAGMENT

Place a spinal needle into the posterior acromioclavicular joint. This provides an aiming point to optimize screw purchase in the lateral fragment and ensures that the instrumentation does not exit the clavicle and violate the joint.

Tip: The use of fluoroscopy throughout this step can assist in posterolateral positioning and may minimize the possibility of a drill or reamer exiting through the superior surface of the clavicle.

Create a pilot hole for instrumentation to follow by holding the lateral fragment with a serrated clamp* and under fluoroscopy using a 2.8 mm drill bit*, drill into the medullary canal.

***Note:** The serrated clamp and 2.8 mm drill bit are not included in the Dual-Trak platter. These instruments can be found in the Acumed Clavicle Plating System or other general orthopedic surgical sets.

Insert the 3.0 mm T-Handle Reamer (80-0774) into the lateral fragment and ream in a medial-to-lateral direction, being careful not to exit the lateral end of the clavicle.

DETERMINING SCREW DIAMETER

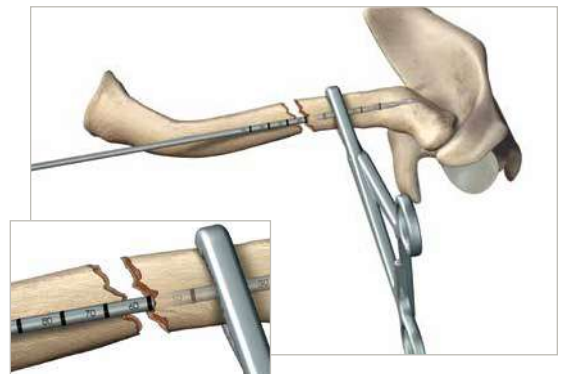
If the 3.0 mm diameter T-Handle Reamer engages the cortex, a 3.0 mm diameter Dual-Trak Clavicle Screw is recommended.

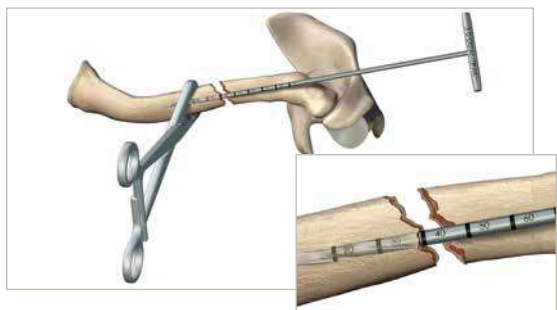
If the 3.0 mm diameter T-Handle Reamer does not engage the cortex, use the 3.8 mm T-Handle Reamer (80-0775) to finish preparing the medullary canal. A 3.8 mm diameter Dual-Trak Clavicle Screw should be used in these cases.

Caution: Proceed with caution in cases with patients who may have a minimal medullary canal and dense bone. As an alternative option, the surgeon may choose to plate the clavicle using the Acumed Clavicle Plating System.

DETERMINING SCREW LENGTH

Each T-handle Reamer is marked in 10 mm increments. Take careful note of the final depth measurement on the reamer, measure at the entry point of the fragment, as this will assist in determining screw length at the end of Step 3.





3 REAM MEDIAL FRAGMENT

Hold the medial fragment with a serrated clamp and use a 2.8 mm diameter drill to open the medullary canal. This will create a pilot hole for instrumentation to follow.

Tip: The use of fluoroscopy throughout this step can assist in positioning and may minimize the possibility of a drill or reamer exiting the clavicle.

Next, insert the 3.0 mm T-Handle Reamer (80-0774) into the medial fragment and ream in a lateral-to-medial direction, being careful to not exit the medial end of the clavicle.

If the larger diameter reamer was utilized in Step 2, use the 3.8 mm T-Handle Reamer (80-0775) to finish preparing the medullary canal.

Each T-handle Reamer is marked in 10 mm increments. Once again, take note of the depth measurement on the reamer. To estimate the screw length, add this depth reading to the depth measurement taken in Step 2.

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.



Figure 1

4 DRILL AND TAP MEDIAL FRAGMENT

Select the appropriately sized Clavicle Screw Tap/Drill and insert the blunt-tipped nose, located just beyond the tap threads, into the chuck of a surgical drill.

Dual-Trak Screw Diameter (As determined in Step 2)	Corresponding Clavicle Screw Tap/Drill
3.0 mm	Part No. 80-0148
3.8 mm	Part No. 80-0149



Figure 2

Hold the medial fragment with a serrated clamp and insert the Clavicle Screw Tap/Drill into the fragment. Drill **forward** in a lateral-to-medial direction, advancing the Clavicle Screw Tap/Drill through the anterior cortex of the medial clavicle (see Figure 1). When the skin begins to tent, make a stab incision, and advance the Clavicle Screw Tap/Drill out of the skin anteriorly until the tap threads engage the fracture site.

Detach the Clavicle Screw Tap/Drill from the power drill and reattach the power drill medially over the exposed end with the tri-flat contours (see Figure 2). Next, **reverse** the Clavicle Screw Tap/Drill medially until the threads on the tap portion are completely within the medullary canal of the medial fragment.

Tip: • The use of fluoroscopy throughout this step may help ensure a precise anterior medial exit point.

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

5 TAP LATERAL FRAGMENT

While under fluoroscopy, hold both fragments with serrated clamps, and reduce the fracture. Next, advance the Clavicle Screw Tap/Drill **forward** into the lateral fragment to the desired depth. Leave the Clavicle Screw Tap/Drill in place, as this will serve to maintain reduction going forward.

Note: When tapping laterally, we recommend the entire length of tap threads engage the lateral fragment. However, stop tapping prior to exiting the bone.



6 PREPARE MEDIAL MEDULLARY CANAL

At the medial end of the clavicle, slide the appropriate left or right 7.0 mm Cannula over the exposed portion of the Clavicle Screw Tap/Drill, rotating it so the nose of the Cannula is flush to the bone. Next, place the appropriately sized cannulated Clavicle Screw Step Drill over the Clavicle Screw Tap/ Drill and through the 7.0 mm Cannula until it comes in contact with the bone.



Figure 1

Dual-Trak Screw Diameter (As determined in Step 2)	Corresponding Clavicle Screw Tap/Drill	Corresponding Clavicle Screw Step Drill
3.0 mm	Part No. 80-0148	Part No. 80-0772
3.8 mm	Part No. 80-0149	Part No. 80-0773

Note: The Dual-Trak Clavicle Screw is designed to achieve up to 3 mm of compression.

TO ACHIEVE MAXIMUM COMPRESSION

Advance the Clavicle Screw Step Drill until the first groove on the drill shaft aligns with the backend of the Cannula (see Figure 2).

TO ACHIEVE REDUCED COMPRESSION

Advance the Clavicle Screw Step Drill until the second groove on the drill shaft aligns with the backend of the Cannula (see Figure 3).

SCREW LENGTH

The built-in window on the Clavicle Screw Step Drill includes markings on either side of the window (see Figure 1, inset). Once the Clavicle Screw Step Drill has been inserted to the desired depth, the reading closest to the markings on the Clavicle Screw Step Drill signifies the length of screw to implant.

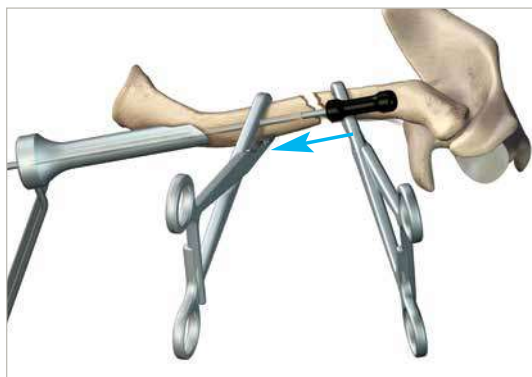
If the reading falls between two markings on the Clavicle Screw Tap/ Drill, downsize to the shorter length.



Figure 2



Figure 3



7 SECURE MEDIAL ENTRY POINT

Holding both fragments with serrated clamps, remove the Clavicle Screw Step Drill from the medullary canal, and then **reverse** the Clavicle Screw Tap/Drill out medially from both fragments.

Next, place the Clavicle Screw Insertion Tool (80-0780), concave end first, into the medial fragment through the fracture site. Advance the Insertion Tool in a lateral-to-medial direction, so it advances out through the medial fragment and skin. This identifies the entry site for the implant and eases the process of inserting the Dual-Trak Clavicle Screw into the medullary canal.

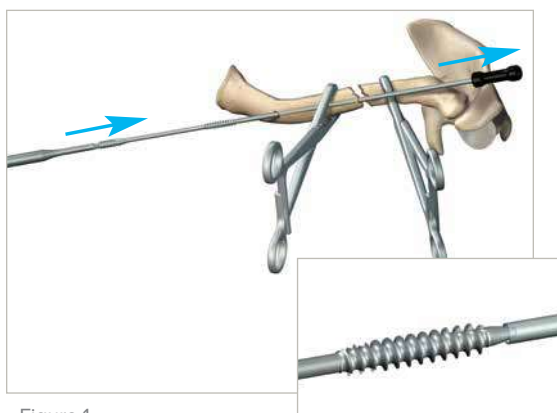


Figure 1

8 SCREW INSERTION

Note: The procedures in steps 2 and 3 determined the diameter and Step 6 determined the length of the screw to implant.

Attach the 3.0 mm Clavicle Screw Hex Driver Tip (80-0779) to the Small Ratcheting Handle with Large Hudson Adapter (80-0174).

Next, place the nose of the selected Dual-Trak Clavicle Screw into the concave portion of the Clavicle Screw Insertion Tool (80-0780) (see Figure 1, inset) and advance the Dual-Trak Clavicle Screw into the clavicle. As the screw is advanced, the insertion tool will slowly withdraw (see Figure 1). Once the screw approaches the fracture site, remove the Insertion Tool entirely.

Holding the lateral fragment with the serrated clamp, reduce the fracture, then advance the Dual-Trak Clavicle Screw until the first groove on the Hex Driver Tip aligns with the backend of the Cannula (see Figure 2). This alignment signifies the screw is flush with the bone.



Figure 2

If, in Step 6, the Clavicle Step Drill was advanced to the first groove to achieve maximum compression, advancing the Hex Driver Tip in this step to the second groove may result in distraction of the fracture.

If, in Step 6, the Clavicle Step Drill was advanced to the second groove to achieve reduced compression, advancing the Hex Driver Tip to the second groove will result in maximum compression with the implant buried 5 mm beneath the surface of the bone.

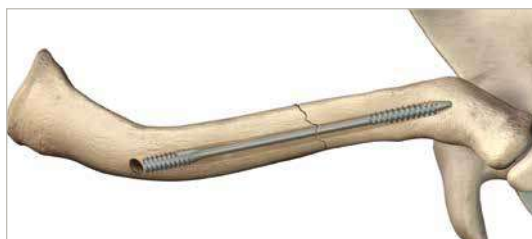


Figure 3

Ordering Information

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

Instrumentation - Nonsterile

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 Connector	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 learn more about the full line of Acumed® innovative surgical solutions, please contact your local Acumed sales representative, call 888.627.9957, or visit acumed.net.



SHD00-03-C

Effective: 09/2014

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