

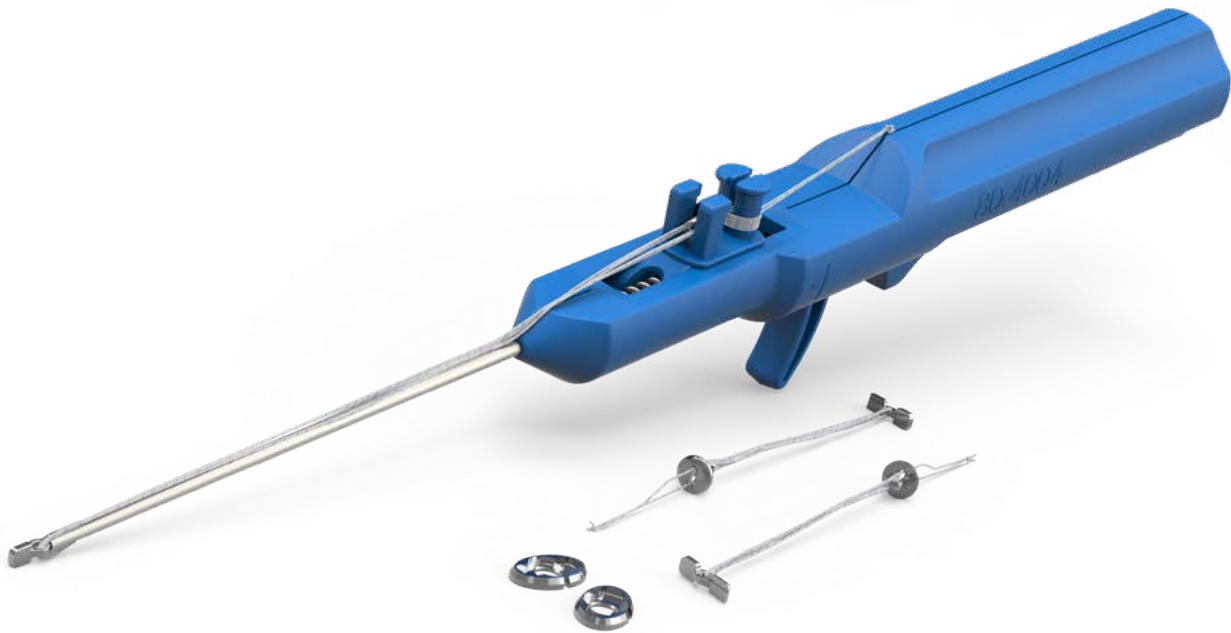
Surgical Technique



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.



Acumed® Ankle Syndesmosis Repair System with Acu-Sinch® Knotless

The tibiofibular syndesmosis is disrupted in approximately 10–20% of ankle fracture cases and requires repair.^{1,3} For decades, screw fixation of the syndesmosis has been the gold standard for treatment.¹ However, emerging clinical evidence has demonstrated that flexible, suture-based syndesmosis repairs have successful clinical outcomes and may reduce complications associated with malreduction of the syndesmosis when fixed with screws.^{2,3,4}

Designed in conjunction with Alastair Younger, MB, Ch.B., M.Sc., Ch.M., FRCS(C); Selene Parekh, MD, MBA; and Steven Morgan, MD, the Acu-Sinch Knotless Implant enables the dynamic stabilization of laxity or syndesmotic disruptions to the tibiofibular joint.

The Acu-Sinch Knotless buttons may be augmented with a washer or may be used in conjunction with the Acumed and OsteoMed® fibula fracture fixation plates and intramedullary nails with 3.5 mm nonlocking screw holes. Our patent pending release mechanism gives the user control to place the medial button subcutaneously without the need for direct visualization.

	Definition
Warning	Indicates critical information about a potential serious outcome to the patient or the user.
Caution	Indicates instructions that must be followed in order to ensure the proper use of the device.
Note	Indicates information requiring special attention.

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System Features

Acu-Sinch® Knotless System 3.5 mm



Low-profile titanium Round Button is compatible with a variety of titanium fibula plates with 3.5 mm nonlocking screw holes

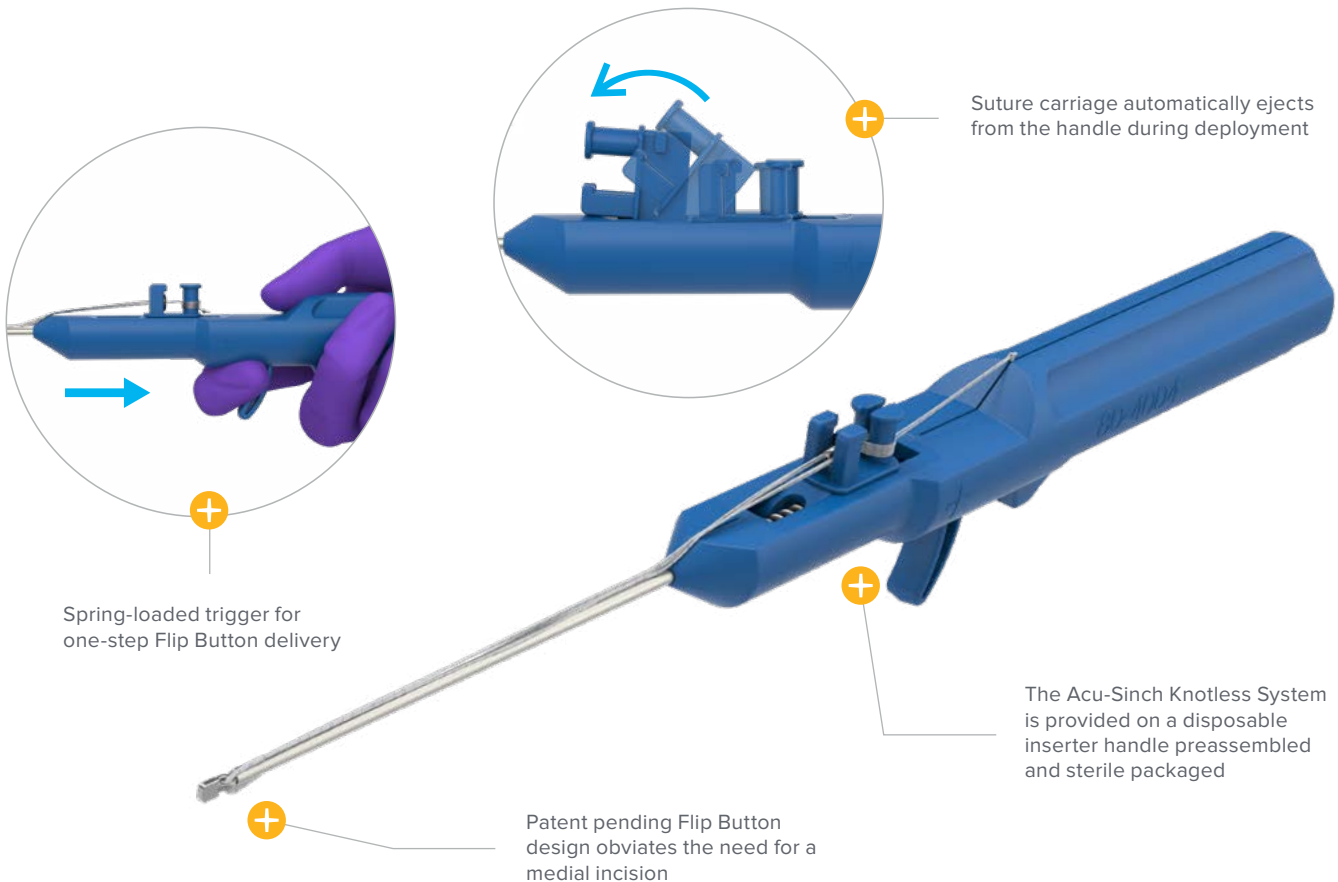
Self-locking suture loop made from #2 UHMWPE nonabsorbable HS Fiber enables an adjustable knotless repair

Titanium Flip Button is designed to pass through a 3.5 mm bone tunnel, plates, or intramedullary nails with a nonlocking 3.5 mm hole

Acu-Sinch Washer 3.5 mm



Slotted titanium washer is designed for assembly over the suture after the Acu-Sinch Knotless has been deployed, for increased surface area on the bone



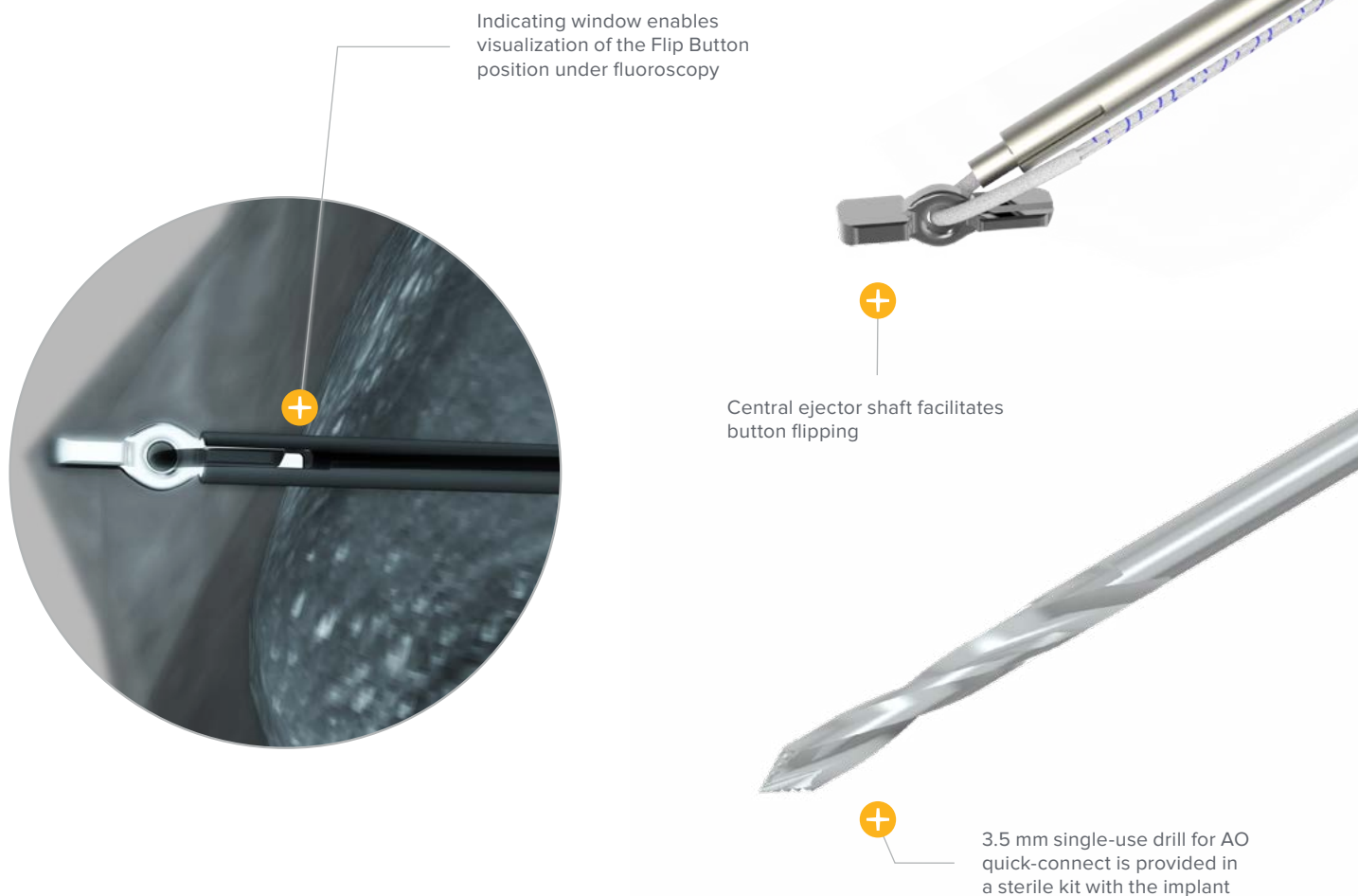
Spring-loaded trigger for one-step Flip Button delivery

Suture carriage automatically ejects from the handle during deployment

Patent pending Flip Button design obviates the need for a medial incision

The Acu-Sinch Knotless System is provided on a disposable inserter handle preassembled and sterile packaged

System Features [continued]



Indications for Use:

The Ankle Syndesmosis Kit is intended to be used as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated. It is also intended to be used as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the Ankle Syndesmosis Kit is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis disruption in connection with Weber B and C ankle fractures.

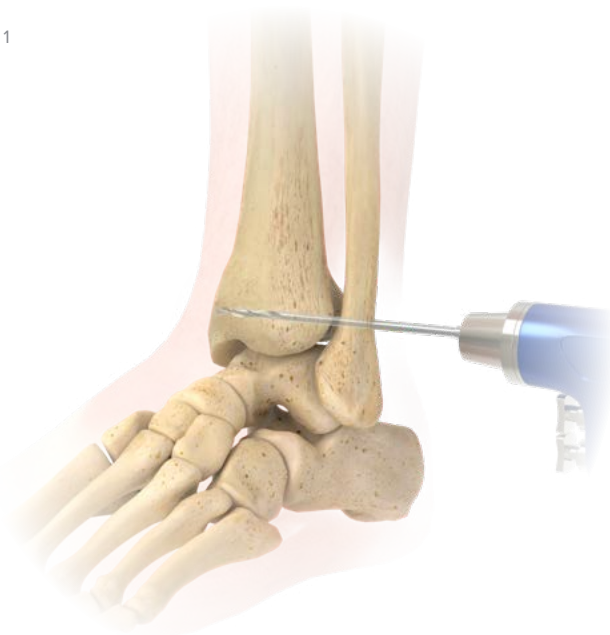
The Acu-Sinch Knotless is compatible with implants from with Acumed and OsteoMed® fibula fracture fixation products:

- ▶ Acumed Ankle 3 Lateral Fibula Plates
- ▶ Acumed 1/3 Tubular Plates
- ▶ Acumed Locking Ankle System (LPL) Fibula Plates
- ▶ Acumed Fibula Rods
- ▶ Acumed Fibula Nail 2
- ▶ OsteoMed ExtremiLock™ Ankle Lateral Fibula Plate
- ▶ OsteoMed 1/3 Tubular Plates

The Acu-Sinch Knotless devices may be used alone, or in conjunction with titanium plates and nails designed to accept 3.5 mm nonlocking screws.

Ankle Syndesmosis Repair System Surgical Technique

Figure 1



1 Reduction and Drill

Ensure the distal fibula is anatomically reduced within the tibia incisura as viewed in the A/P and lateral X-rays. Accurate restoration of the anatomic relationship between the distal fibula and tibia is critical. After soft tissue exposure at the appropriate level, drill through all four cortices of the fibula and tibia targeting the center of the tibia in the transmalleolar plane approximately 1–2 cm above the tibial plafond, using the Single Use 3.5 mm Fluted Drill (80-3914)* provided in the Acu-Sinch® Knotless System w/Inserter 3.5 mm Kit (46-0023-S).

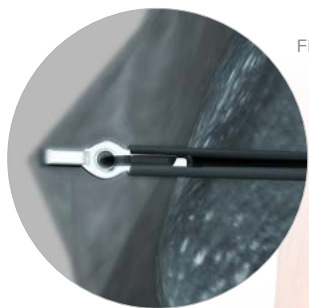
Note: Acumed 3.5 mm drills MS-DC35**, MS-DC35-S†, and 80-2503‡ may also be used in place of 80-3914.

**PKGI-24-N

†PKGI-52-N

‡PKGI-57-K

Figure 2



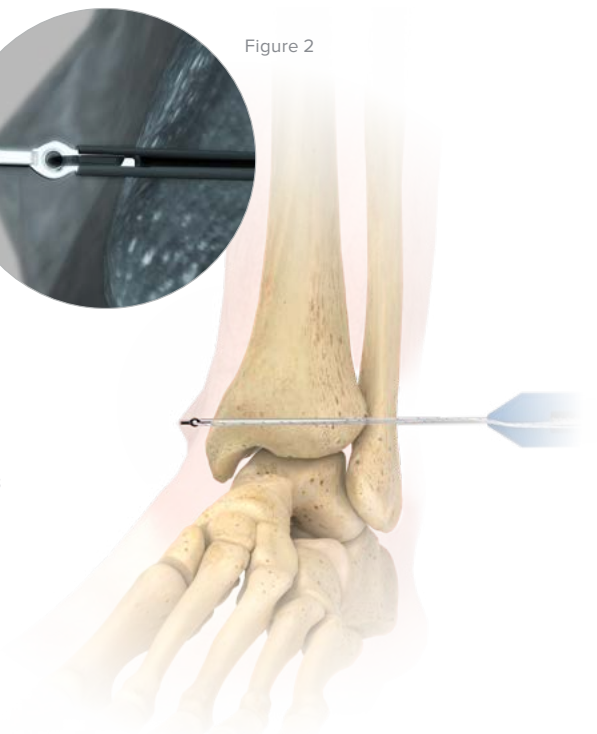
2 Device Insertion

Pass the Flip Button through all four cortices until the entire button can be seen protruding (or palpated) through the medial tibial cortex under fluoroscopy.

Note: The Acu-Sinch Knotless System 3.5 (5502-0200)* is provided preloaded onto the Acu-Sinch Knotless Inserter 3.5 mm (80-4004)* in 46-0023-S (with drill) or 46-0024-S* (implant only).

Note: Under fluoroscopic visualization in anterior-posterior view, a gap can be seen between the button and inserter to indicate Flip Button orientation and location. This feature should be outside the tibial cortex (Figure 2).

Figure 3



Single Use 3.5 mm Fluted Drill (80-3914)



Acu-Sinch Knotless System w/ Inserter 3.5 mm Kit (46-0023-S)



Acu-Sinch Knotless System 3.5 mm (5502-0200)



Acu-Sinch Knotless Inserter 3.5 mm (80-4004)



Acu-Sinch Knotless System w/ Inserter 3.5 mm (46-0024-S)

Ankle Syndesmosis Repair System Surgical Technique [continued]

3 Flip Tibial Button

Pull the trigger on the handle of the Acu-Sinch® Knotless Inserter 3.5 mm (80-4004)* firmly to flip the tibial button and then pull back on the insertion handle to seat the button against the medial tibia cortex.

Note: A medial incision may be useful for visualizing the Flip Button to ensure no soft tissue interposition between the bone and button, or to add a washer. Dissect to the level of periosteum, taking precautions to protect the saphenous vein.

Figure 4

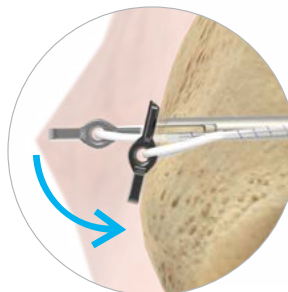
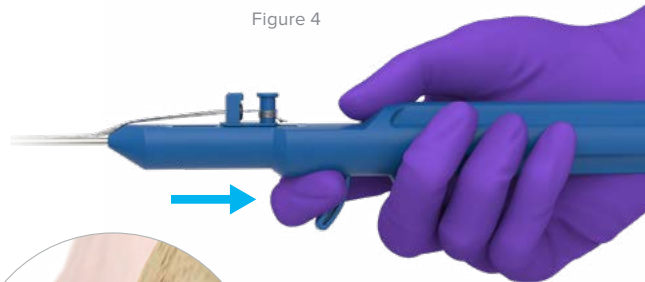


Figure 5

4 Release from Inserter

Confirm that the button is flush against the medial tibia cortex under fluoroscopy. Continue pulling the inserter handle laterally and in a direction away from the Flip Button to release the Acu-Sinch Knotless System from the inserter.

Note: There is no need to unwrap the sutures from the inserter. The suture carriage automatically releases to unfurl the suture and Round Button.

Note: Use one handle to stabilize the leg while pulling the handle during the release.

Figure 6

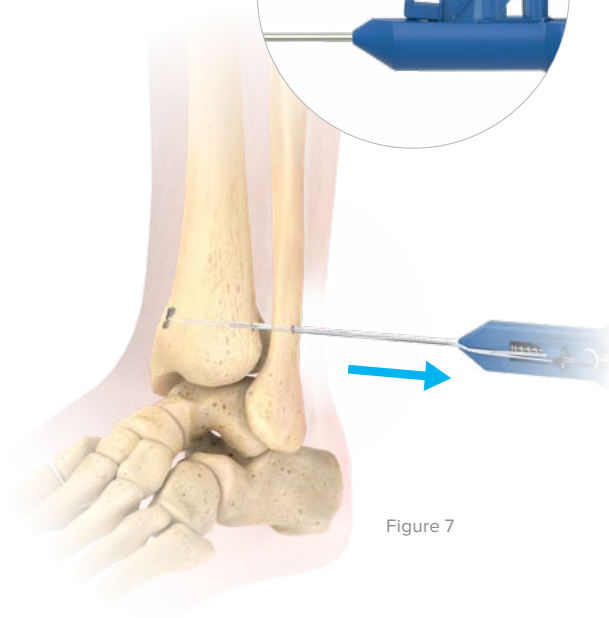
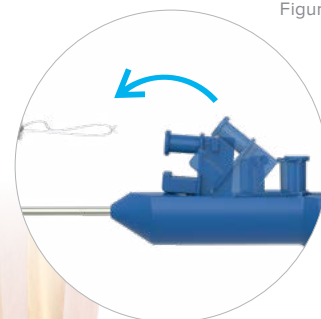


Figure 7



Acu-Sinch
Knotless Inserter
3.5 mm
(80-4004)

*Component parts not sold individually.

Ankle Syndesmosis Repair System Surgical Technique [continued]

Figure 8



5 Reduction

Pull the adjustment loop to reduce the Round Button to the fibular cortex. Ensure that any suture loops that form during the cinching process are pulled completely through the button prior to final tightening.

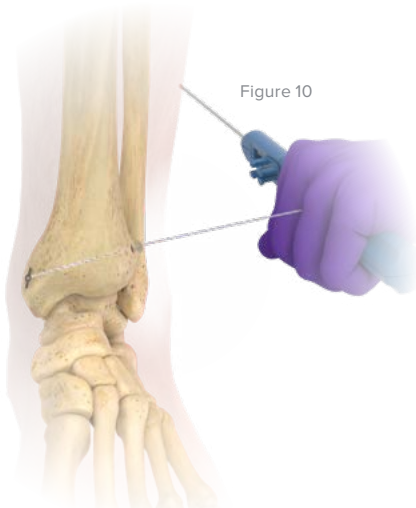
Note: Guide the Round Button to the bone with slight tension to maintain suture alignment during initial adjustment as shown in Figure 8.

Note: Prior to suture loop adjustment, a washer (provided separately) may be placed under the Round and/or Flip Button to increase contact area on the tibial or fibular cortex. If the washer is to be placed under the Flip Button, a medial incision will be required. See the technique on page 10 for washer implantation instructions.

Figure 9



Figure 10



After fully seating the Round Button on the fibular cortex, wrap the adjustment loop around the handle of the Acu-Sinch® Knotless Insertor 3.5 mm or other instrument and pull to the desired repair tension.

Figure 11



5A Optional Medial Incision

A medial incision may be useful for visualizing the Flip Button to add a washer or to confirm no soft tissue is entrapped between the Flip Button and the bone. Dissect to the level of periosteum, taking precautions to protect the saphenous vein.

Ankle Syndesmosis Repair System Surgical Technique

[continued]

6 Trim

The adjustment loop may be cut flush with the Round Button once the desired tension is reached.

Note: The Acu-Sinch Knotless System (5502-0200)* consists of a self-locking suture (knotless), therefore tying a knot over the Round Button is not required.



Figure 12

7 Optional Additional Fixation

If a second point of fixation is desired, an Acu-Sinch Knotless System w/Inserter 3.5 mm (46-0024-S) may be used. Drill a second hole approximately 2 cm proximal and parallel to the first implant using the Single Use 3.5 mm Fluted Drill (80-3914) from the Acu-Sinch Knotless System Kit. Implant the Acu-Sinch Knotless System (5502-0200) as described in Steps 1 through 6.



Figure 13



Acu-Sinch
Knotless System
(5502-0200)



Acu-Sinch
Knotless System
w/ Inserter 3.5 mm
(46-0024-S)



Single Use
3.5 mm
Fluted Drill
(80-3914)

*Component parts not sold individually.

Ankle Syndesmosis Repair System Nail Surgical Technique

Fibular Intramedullary Nail



Figure 1

1 Reduction and Drill

Syndesmotic reduction, either open or closed, should ensure the distal fibula is anatomically reduced within the tibia incisura as viewed in the A/P and lateral X-rays. Accurate restoration of the anatomic relationship between the distal fibula and tibia is critical. Once anatomic length, rotation, and alignment of the fibula fracture has been established and the fracture stabilized with the appropriate intramedullary nail, syndesmotic reduction can proceed using an Acu-Sinch® Knotless System w/Inserter 3.5 mm Kit (46-0023-S). Select a non-threaded nail hole meant for a 3.5 mm cortical screw approximately 1–2 cm above the tibial plafond. Using the targeting system provided with the fibula nail system, drill a pilot hole through the four cortices of the fibula and tibia to include the selected hole.

Note: If an implant from the Acumed FFN 2 System is used, the Acu-Sinch Knotless System should be placed through the distal Lateral/Medial screw hole which is non-threaded. Assemble the targeting guide as shown in the Acumed Fibula Nail 2 System with Tip-Loc™ Technology Surgical Technique and form the pilot hole by drilling through the FFN 2.8 mm Drill Guide (80-2505) using the FFN 2.8 mm Drill (80-2471) provided in the system tray.

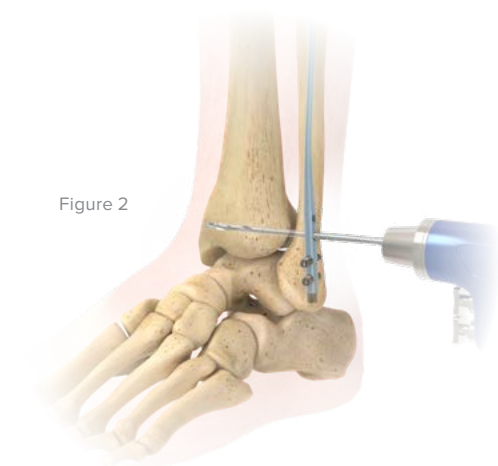


Figure 2

2 Drill

Remove the targeting guide hardware and enlarge the pilot hole using the Single Use 3.5 mm Fluted Drill (80-3914) provided in the Acu-Sinch Knotless Kit.

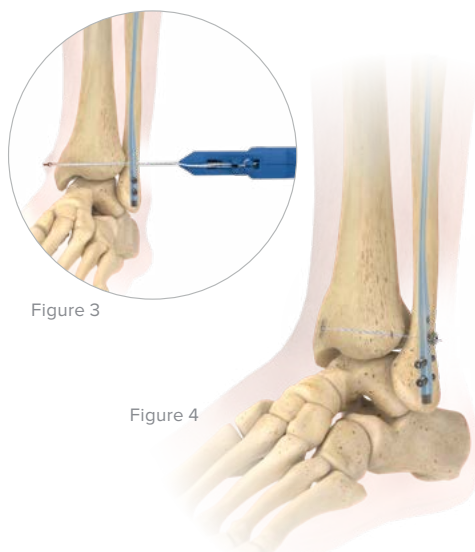


Figure 3

Figure 4

3 Device Insertion

Implant the Acu-Sinch Knotless System through the fibula and tibia (including the intramedullary nail), tension, and trim as previously described. See steps 1–7 from Ankle Syndesmosis Repair System Surgical Technique on pages 4–7.

Note: A washer (provided separately) may be placed under the Round and/or Flip Button prior to reduction to increase contact area on the tibial or fibular cortex. See technique on page 10 for washer implantation instructions.



Acu-Sinch Knotless System w/ Inserter 3.5 mm Kit (46-0023-S)



FFN 2.8 mm Drill Guide (80-2505)



FFN 2.8 mm Drill (80-2471)



Single Use 3.5 mm Fluted Drill (80-3914)

*Component parts not sold individually.

Ankle Syndesmosis Repair System Surgical Technique

Fibular Plate

1 Reduction

Syndesmotic reduction, either open or closed, should ensure the distal fibula is out to length and anatomically reduced within the tibia incisura as viewed in the A/P and lateral X-rays. Accurate restoration of the anatomic relationship between the distal fibula and tibia is critical. Once anatomic length, rotation, and alignment of the fibula fracture have been established and the fracture stabilized with appropriate fibula plate, syndesmotic reduction can proceed using an Acu-Sinch® Knotless System w/Inserter 3.5 mm Kit (46-0023-S). Select the appropriate plate hole or holes approximately 1–2 cm above the tibial plafond for the Acu-Sinch Knotless System (5502-0200).

Note: Acu-Sinch Knotless can be used with a variety of ankle plates with holes that accept a 3.5 mm drill.

Note: Plate holes in the Acumed Ankle 3 family compatible with the Acu-Sinch Knotless System are marked with an "S".

2 Drill

Drill through the selected hole in the plate and all four cortices, aiming approximately 30 degrees anterior to target the center of the tibia in the transmalleolar plane using the 3.5 mm Drill (80-3914) provided in the Kit.

3 Device Insertion and Reduction

Implant the Acu-Sinch Knotless System (5502-0200) through the fibula and tibia including the fibular plate, and reduce as previously described. See steps 1–7 from the Ankle Syndesmosis Repair System Surgical Technique on pages 4–7. Once the Round Button is fully seated on the plate, pull the suture loop to achieve the desired repair tension. Cut the suture limbs flush with the fibula button.

Note: A Washer is not recommended between the Round Button and fibular plate.

Note: If a second point of fixation is desired, an Acu-Sinch Knotless System w/Inserter 3.5 mm (46-0024-S) may be used through an appropriate hole, and implanted as previously described.

Figure 1



Figure 2

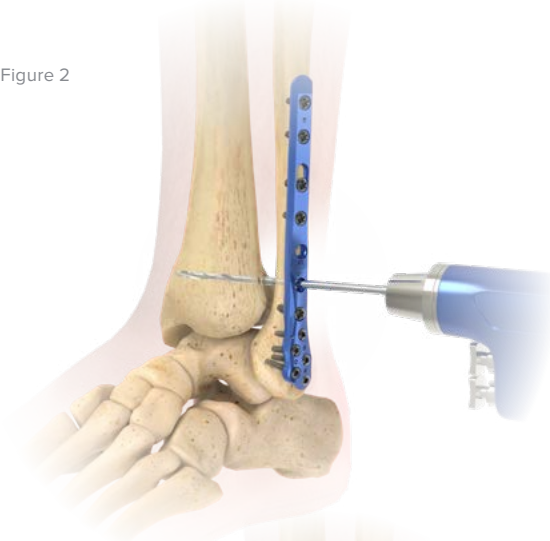


Figure 3

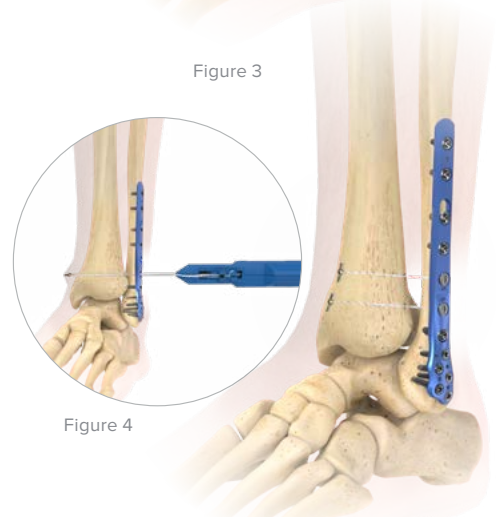


Figure 4



Acu-Sinch
Knotless System
w/ Inserter
3.5 mm Kit
(46-0023-S)



Acu-Sinch
Knotless System
(5502-0200)



Single Use
3.5 mm Fluted
Drill
(80-3914)



Acu-Sinch
Knotless System
w/ Inserter 3.5 mm
(46-0024-S)

*Component parts not sold individually.

Optional Washer Implantation Surgical Technique

For use on either the tibia side or the fibula side

Figure 1



1 Placement

After deploying the implant as shown in steps 1–4 on pages 4–5, ensure the button is away from the bone with the suture clearly visible.

Note: Use of an Acu-Sinch® Washer 3.5 mm (5502-0205-S) on the tibial cortex requires a medial incision. Dissect to the level of periosteum, taking precautions to protect the saphenous vein.

Figure 2



2 Implant Washer

Pull the round or Flip Button away from the cortex to provide working space, and then slide the Acu-Sinch Washer 3.5 mm (5502-0205-S) over the suture lines with the recess facing the button so the suture lines pass through the slot and arrive in the center hole of the washer.

Figure 3

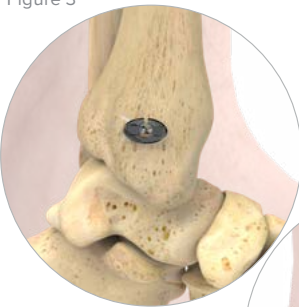


Figure 4



3 Reduction

Pull the adjustment loop to reduce the button down onto the washer until the button and washer are flush against the bone. Ensure the button is sitting flush within the recess of the washer and the washer is properly oriented prior to final tensioning. Provide the desired adjustment tension as described in step 5 on page 6 and cut the adjustment loop flush with the Round Button.



Acu-Sinch Washer
3.5 mm
(5502-0205-S)

Removal Surgical Technique

1 Incise Skin

Palpate the skin near the distal tibia to find the Flip Button and mark the location of the device on the skin. Make a surgical incision over the device.

2 Dissect to Periosteum

Dissect to the level of the periosteum, taking precautions to protect the saphenous vein. Find the Flip Button and expose the device.

3 Cut Suture and Remove

Use a scalpel to cut the suture in the doughnut eyelet of the Flip Button. Remove the button from the tibia.

4 Round Button Removal

Incise through the existing fibula incision over the Round Button, and dissect down to the button. Pull out and remove the Round Button and attached sutures.

Figure 1



Figure 2

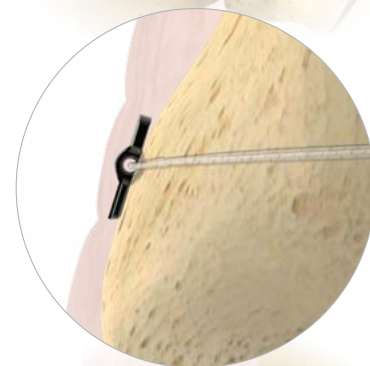


Figure 3

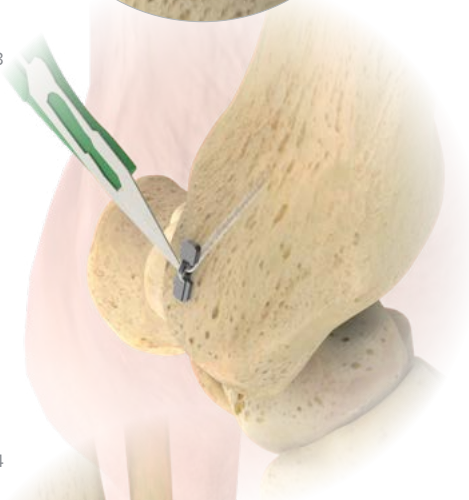
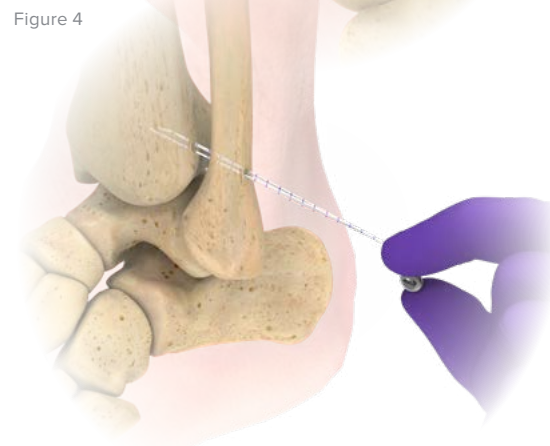


Figure 4



Ordering Information

Tray Components

Acu-Sinch® Knotless Ankle Syndesmosis Repair System

1	Acu-Sinch Knotless System w/ Inserter 3.5 mm Kit	46-0023-S
2	Acu-Sinch Knotless System w/ Inserter 3.5 mm	46-0024-S
3	Acu-Sinch Washer 3.5 mm Kit	5502-0205-S

Note: To learn more about the full line of Acumed innovative surgical solutions, please contact your authorized Acumed distributor, call 888.627.9957, or visit www.acumed.net.



References

1. Schepers T. Acute distal tibiofibular syndesmosis injury: a systematic review of suture-button versus syndesmotic screw repair. *Int Orthop*. 2012;36(6):1199-1206. doi:10.1007/s00264-012-1500-2
2. Raeder B, Figved W, Madsen J, Frihagen F, Jacobsen S, Andersen M. Better outcome for suture button compared with single syndesmotic screw for syndesmosis injury: five-year results of a randomized controlled trial. *Bone Joint J*. 2020;102-B(2):212-219. doi:10.1302/0301-620X.102B2.BJJ-2019-0692.R2.
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