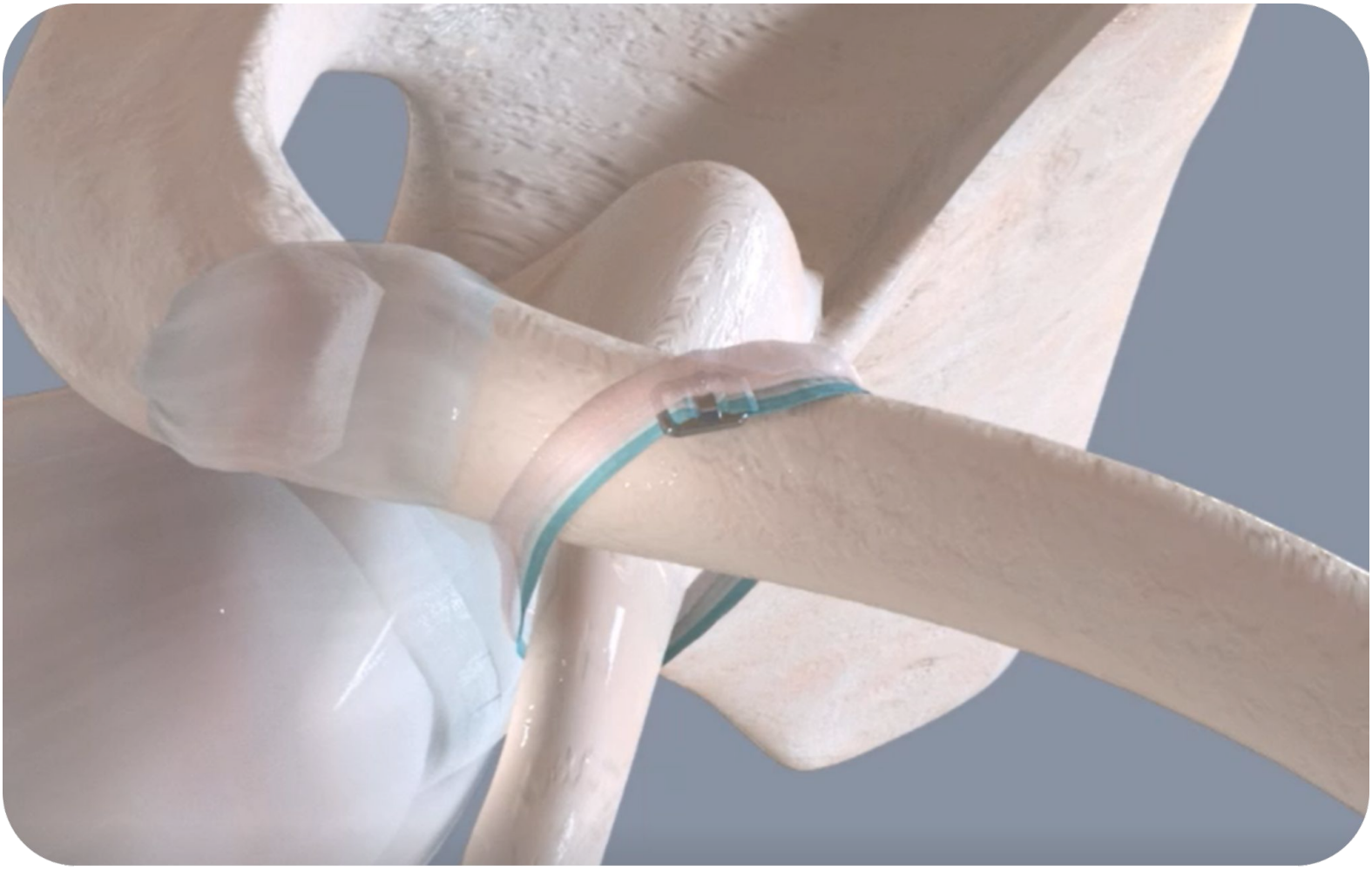
NoviCOID AC Joint Repair System

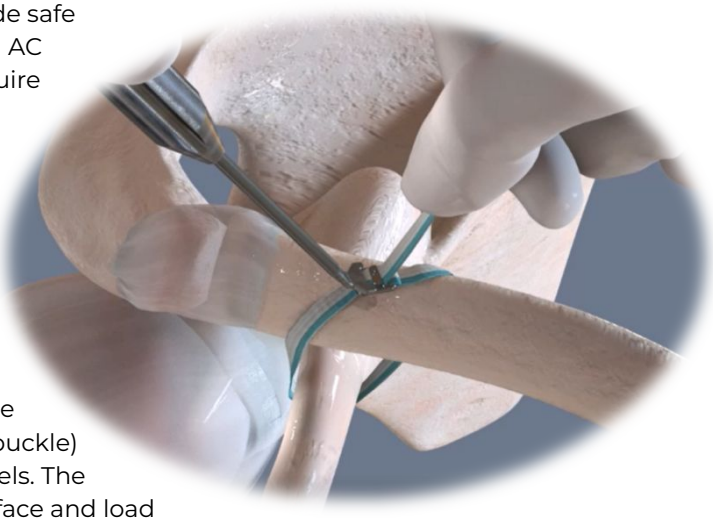
Technology Guidelines and Surgical Technique



ORTHONOVIS
ELEVATING SURGERY®

NoviCOID AC Joint Repair System and Use

The NoviCOID AC Joint Repair System is designed to provide safe and reproducible fixation during the healing of Grade IV–VI AC separations, as well as those Grade III injuries that may require surgical intervention. It is not intended to serve as the sole means of reconstruction for chronic AC separations, which should always include a biologic component.



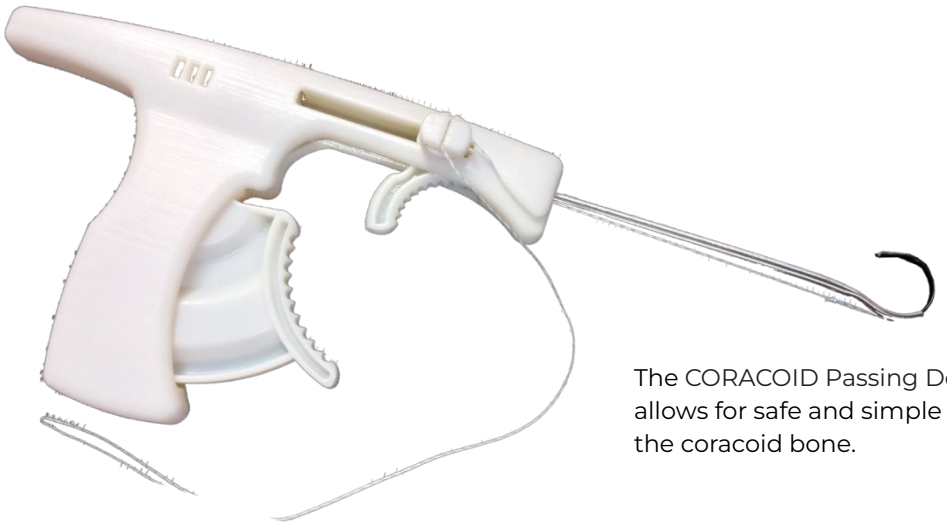
Preoperatively, patients should be examined to assess for AP clavicular instability. Preoperative x-rays should include clavicle x-rays and three-view shoulder x-rays, including axillary views.

The NoviCOID AC Joint Repair System is built around a wide prosthetic woven band with a low-profile knotless fixator (buckle) and facilitates AC repair without compromising bone tunnels. The woven band is specifically designed for optimal bone interface and load distribution. Its placement around the coracoid and over the clavicle provides “compliant constraint,” avoiding the suboptimal biomechanical binding of point-to-point fixation found with other products.

The NoviCOID Acromioclavicular Device comes in 4mm and 7mm (shown) versions

The included Punch Tool provides easy, repeatable final locking of the buckle.

The included Counter Traction Tool provides stabilization of the buckle during fixation.



The CORACOID Passing Device (sold separately) allows for safe and simple passage under/around the coracoid bone.

Surgical Technique - Open

This procedure may be completed using standard open or arthroscopically- assisted techniques. The arthroscopically-assisted approach will be described here. Similar results may be obtained by adapting the arthroscopic aspects described to the open technique.

The patient is positioned in the beach-chair position for both the arthroscopic and open procedure. Ensure that there is adequate access to allow for C-Arm visualization of the clavicle and AC joint. The middle third of the clavicle, at least, should be sterile in the operative field. As with any positioning, it is critical to ensure safe and proper neck position and provide padding for all bony prominences. An arm-holder is recommended to help facilitate reduction of the AC joint. Insure that the head stabilizer permits access to the operative field and if necessary, reposition the patient to allow routine posterior arthroscopy placement.

1. Preparation of the Coracoid and Clavicle

Incision, Clavicle, and Coracoid Preparation:

An open exposure should be performed over the superior aspect of the clavicle. A 4–8 cm incision in Langer's lines ("sabre cut" approximately 4 cm medial to the AC joint, or a 4–8 cm incision parallel to the clavicle extending medially from the AC joint) may be made. The deltotrapezial fascia is then incised in line with the clavicle. The clavicle should be exposed anteriorly and posteriorly along its length for approximately 4 cm.

Care should be taken when considering distal clavicle excision. While this may facilitate clavicle reduction, it may also substantially increase the risk of anterior-posterior (AP) instability. If possible, the distal clavicle should be preserved. Careful blunt dissection under the clavicle, starting from the distal end, may assist with reduction. Take care to avoid injury to the subclavian vessels.

Once the distal clavicle is exposed, attention is turned to the coracoid. The deltoid is released from its attachment on the anterior aspect of the clavicle. Dissection should be performed carefully to allow identification of the base of the coracoid process. Once identified, the medial and lateral aspects of the coracoid should be carefully exposed. ***It is critical to stay on bone and avoid straying into the soft tissues to prevent damage to neurovascular structures.*** A blunt clamp may aid in opening a tract for passage of the suture underneath the coracoid process. Ensure that the coracoid is well exposed and free of soft tissue that could impede passage of the graft and the NoviCOID AC Joint Repair System.

Avoid dissection at the tip of the coracoid to protect the conjoint tendon.

Graft Preparation

The NoviCOID AC Joint Repair System is often used in combination with an allograft or autograft (see Illustration D below). The graft should be at least 250 mm in length to accommodate passage beneath the coracoid process and over the clavicle. It should be approximately 4–6 mm in diameter to recreate the anatomy of the conoid and trapezoid ligaments. The graft should be whipstitched at either end for approximately 25 mm (not the full length, as this may impede passage).

Surgical Technique - Open

2. Subcoracoid Passage and Subclavicular passage of Suture, NoviCOID Acromioclavicular Device and Graft

Once a tract has been established, the CORACOID Passing Device is introduced. The loaded device is inserted along the medial aspect of the clavicle near its base, approximately 4 cm medial to the distal clavicle. The CORACOID Passing Device is then advanced down the previously established tract from the clavicle to the coracoid until the tip can be visualized (via the scope) below the coracoid.

The device is incrementally deployed to advance the attached shuttle suture under the coracoid process. Care must be taken to pass the device from medial to lateral. ***It is critical to have good exposure of the coracoid process to see the passage of the CORACOID Passing Device.*** If there is any question about the direction of the nitinol strip, the CORACOID Passing Device should be retracted and repassed. Once the tip of the nitinol strip and suture are seen laterally, the suture is retrieved, completing the subcoracoid passage.

Once the loop has been passed under the coracoid process, it is then passed under the clavicle. Blunt dissection should be used to clear a path under the clavicle, approximately 4 cm medial to the distal clavicular tip. The CORACOID Passing Device is used again for the subclavicular passage.

After the shuttle suture is passed under both the coracoid and the clavicle, the NoviCOID AC Joint Repair System and the graft may be pulled into place. Always pass the free (non-buckle) end first. The sutures of the graft are placed through the shuttle suture loop and pulled under the coracoid process and clavicle. We recommend passing an additional shuttle suture in case a secondary passage is needed. The NoviCOID AC Joint Repair System and sutures should be passed first, followed by the graft.

Note: Once the NoviCOID AC Joint Repair System is pulled into place, ensure it moves freely back and forth. If it is constrained, remove it, clear any obstructing soft tissue, and repeat the passage.

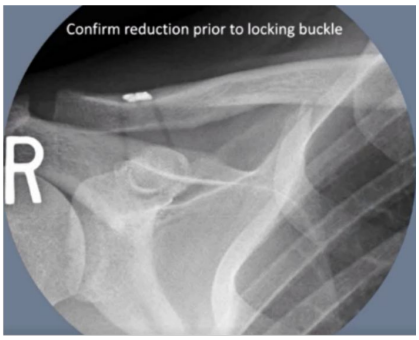
Surgical Technique - Open

3. AC Reduction and NoviCOID Acromioclavicular Device Fixation

Once the NoviCOID AC Device and graft have been passed beneath the coracoid and under the clavicle, the AC joint should be reduced. Placing upward pressure on the arm and downward pressure on the clavicle can facilitate reduction of the AC joint. If there is significant resistance to reduction, then the surgeon should ensure that there is no soft tissue block or other impediments to reduction. It is recommended that fluoroscopy and direct vision should be used to ensure proper reduction.

Affix the NoviCOID AC Device over the clavicle by passing the lead end of the band through the slanted slot in the buckle. The strap is tightened around the clavicle by pulling up firmly on the free end. The Counter Traction Tool may be used to push the buckle down flush onto the clavicle (A) and to stabilize the buckle while the free end of the band is secured under the cleat. To engage the Counter Traction Tool with the buckle, align the black hash mark on the Counter Traction Tool with the black hash mark on the buckle. Once desired reduction is achieved and the NoviCOID AC Device is snug around the clavicle, the NoviCOID AC Device construct may be stabilized by applying light downward pressure on the Counter Traction Tool. This allows the free end of the band to be placed under the buckle cleat, thus creating stable provisional fixation. Radiographic assessment of the reduction may then be accomplished. This fixation will not be adequate for final fixation.

Note: The NoviCOID AC Device construct and the Counter Traction Tool are not designed to generate reduction of the clavicle; rather, they maintain reduction once it has been achieved by other means.

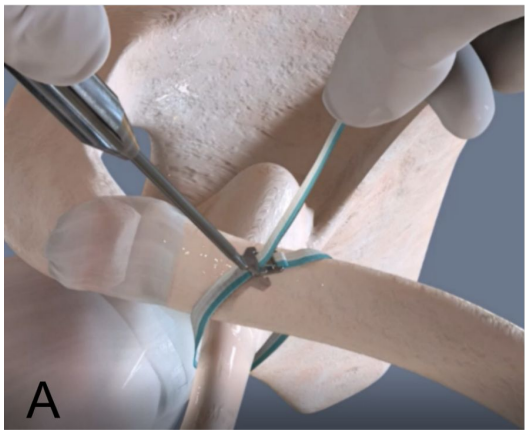


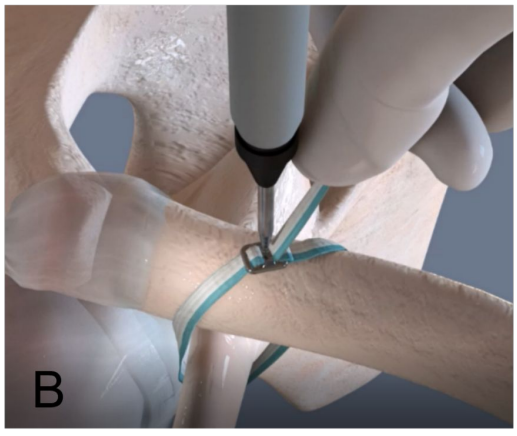
At this point, the surgeon should assess the reduction by direct vision and fluoroscopy. Use of fluoroscopy is recommended to ensure proper restoration of the coracoclavicular distance.

Once proper reduction has been confirmed, the NoviCOID AC Device should be secured in its final position. The tip of the Locking Punch should be placed in the corresponding dimple in the buckle cleat (B). Once engaged securely in the dimple, the buckle cleat should be deflected downward by lightly tapping the back of the punch with a mallet. Visually confirm that the cleat is deflected down and sits flush with the buckle edge (see “Buckle Locking” insert below).

Note: It may be necessary to tap the punch multiple times in order to fully deflect the cleat.

If the surgeon has not previously used the NoviCOID AC Device, it is recommended that the Locking Punch be deployed once on the back table, as a trial, so the surgeon will have experience with the normal tactile feedback of the securing punch. Using two hands while activating the punch may help stabilize it.

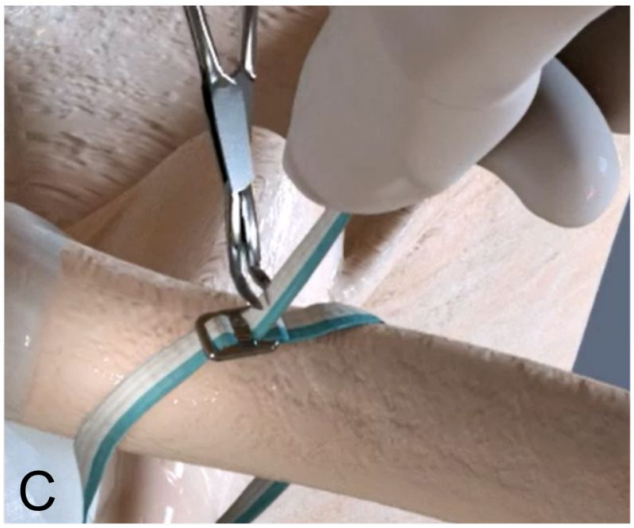


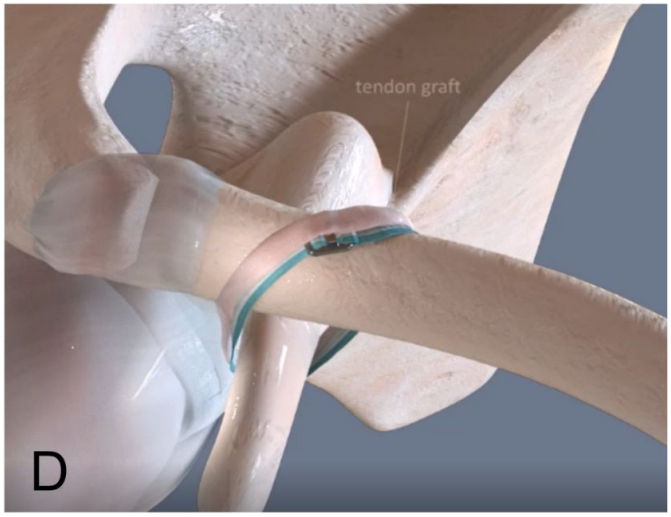


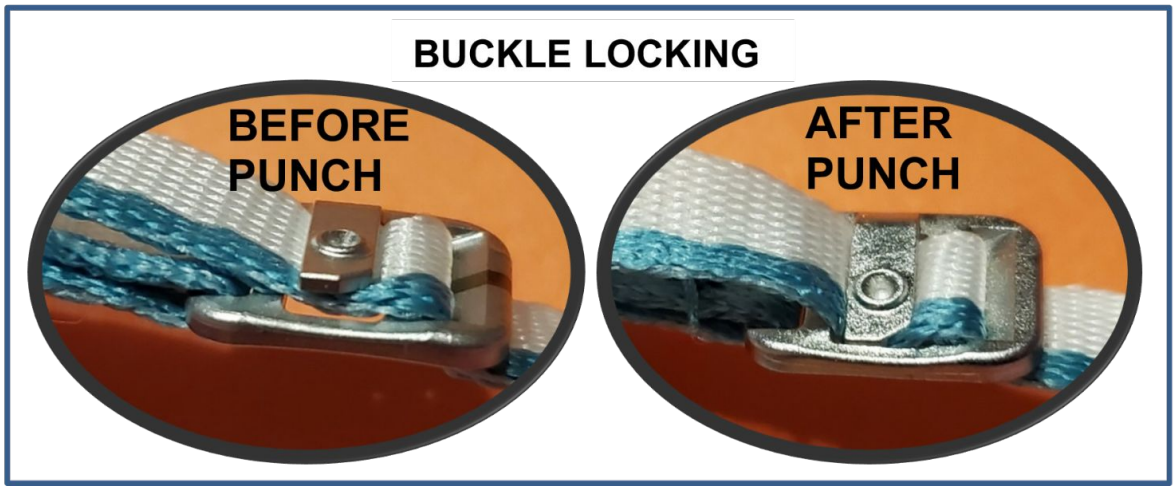
Surgical Technique - Open

The tail of the NoviCOID AC Device is then trimmed at least 7-10mm from the deflected cleat (C).

Once pulled together over the clavicle (D), the graft is sewn onto itself or tied into a knot which is then reinforced with nonabsorbable sutures. Once secured, the excess ends of the graft are cut. The construct can be evaluated arthroscopically in the subcoracoid space to ensure proper placement of the NoviCOID AC Device and graft. There is no specific recommendation about orientation of graft and NoviCOID AC Device below the coracoid.







Surgical Technique - Open

4. Postoperative Protocol and Clinical Follow-up

The shoulder is protected in a sling for 6 weeks. Since the surgery is a “resuspension,” patients must be instructed to avoid the arm hanging for 6 weeks. Patients should not actively use the shoulder during this time. Passive range of motion in the plane of the scapula, pendulums and table slide exercise may be performed. Active range of motion is initiated at 6 weeks when the sling is discontinued. Strengthening is begun at 10 – 12 weeks and after the patient has achieved full range of motion. The patient should avoid contact sports for a minimum of 4 -6 months.

It is recommended that the patients be seen at regular postoperative intervals for follow-up both clinically and with radiographs. The duration of follow up is at the discretion of the surgeon. Supervised follow-up, to include x-rays is suggested for a minimum of 6 months. It is recommended that x-rays include both AP and Axillary views of the clavicle/shoulder. Surveillance should be maintained for evidence of bony wear of the clavicle (AP view) or coracoid (Axillary view). If evidence is seen of excessive clavicular or coracoid erosion, then consideration should be given to removal of the NoviCOID AC Device Buckle to relieve the stress on the bone.

Surgical Technique - Arthroscopically-Assisted

The arthroscopically-assisted approach will be described here. Similar results may be obtained by adapting the arthroscopic aspects described to the open technique.

The patient is positioned in the beach chair position for the arthroscopic and open procedure. Ensure that there is adequate access to allow for C-Arm visualization of the clavicle and AC joint. The middle third of the clavicle, at least, should be sterile in the operative field. As with any positioning, it is critical to ensure safe and proper neck position and provide padding for all bony prominences. An arm-holder is recommended to help facilitate reduction of the AC joint. Ensure that the head stabilizer permits access to the operative field and if necessary, reposition the patient to allow routine posterior arthroscopy placement.

Surgical Technique - Arthroscopically-Assisted

1. Preparation of the Coracoid and Clavicle

Coracoid Process Preparation

To access the coracoid process, first resect the soft tissue in the rotator interval. Once this has been accomplished, the coracoid process will be seen medial to the anterior portal. Proceed with dissection of the coracoid process to its base. This may be achieved with a shaver and ablation device in alternating fashion as necessary. Thorough debridement and good visualization of the coracoid will facilitate passage and proper positioning of the NoviCOID AC Device and graft as well as ensure adherence to the bone.

To ensure sufficient exposure of the coracoid process, it is recommended to establish an accessory, anterior portal 2-3cm below and 2-3 cm lateral to the standard anterior portal. This should be established after the coracoid process has been exposed. This can be established using an “outside-in” technique with a needle to ensure that exposure can proceed parallel to the coracoid process. The use of a 70-degree scope from the posterior portal or the placement of the arthroscope in one of the anterior portals may enhance visualization of the subcoracoid space.

During dissection, the surgeon must preserve the attachment of the strap muscles on the lateral tip of the coracoid process. To accomplish this, the surgeon should identify the attachment and stay medial to it. The pectoralis minor attachment and the coracoacromial ligament may be released. Dissection should proceed until the curve of the base of the coracoid process is identified. It is critical to ensure that the coracoid process is well exposed and there is no soft tissue which may impede the passage of the NoviCOID AC Device and graft. During dissection, it is necessary that the surgeon understands the position of the adjacent neurovascular structures and studiously avoids and protect them.

Graft Preparation

The NoviCOID AC Device is often used in combination with an allograft or autograft (D). The graft should be at least 250mm in length to accommodate passage beneath the coracoid process and over the clavicle. It should be approximately 4-6mm in diameter to recreate the anatomy of the conoid and trapezoid ligaments. The graft should be whipstitched on either end for approximately 25mm (not the full length, as this may impede passage) with No 2 suture.

Clavicle Preparation

Following arthroscopic coracoid exposure, one should perform a mini-open exposure of the apical clavicle. A 4-6 cm incision in Langer’s lines (“sabre cut” approximately 4cm medial to the AC joint or a 4-6 cm incision parallel to clavicle extending medial from the AC joint) may be made. The deltotrapezial fascia is then incised in line with the clavicle. The clavicle should be exposed anteriorly and posteriorly along its length for approximately 4cms. It is not necessary to expose the coracoid process.

Once the distal clavicle is exposed, assess the need to perform a distal clavicle excision. Distal Clavicle Excision may help in allowing reduction of the clavicle. However, there is also a risk of potential Anterior-Postereior (AP) instability. If possible, the distal clavicle should be preserved. Careful blunt dissection under the clavicle proceeding from the distal clavicle may help with reduction. Care must be taken to avoid the subclavian vessels.

Surgical Technique - Arthroscopically-Assisted

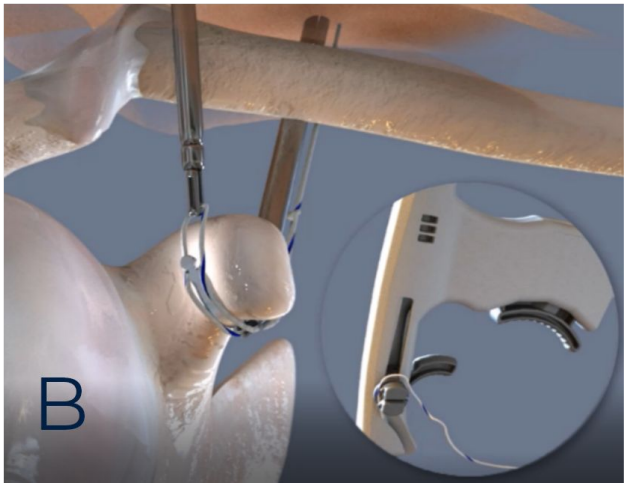
2. Subcoracoid Passage and Subclavicular

Following clavicle exposure, the arthroscope is reintroduced into the joint. The surgeon should obtain visualization of the coracoid base and body. A 70-degree arthroscope from the posterior portal or a 30-degree portal through an anterior portal may aid in this.

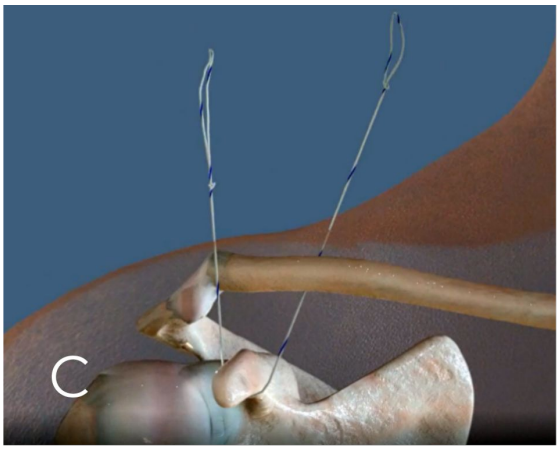
From the medial clavicle, establish a pathway to the coracoid process by using a blunt instrument through the mini-incision over the clavicle. A tract free of soft tissue along the medial clavicle and lateral clavicle should be created to allow for passage of the CORACOID Passing Device and for suture retrieval. A split in the deltoid may need to be performed with blunt dissection. It is critical to use blunt dissection to avoid damage to any neurovascular structure and ensure that the deltoid will not block passage of the suture, graft, or NoviCOID AC Device. Dissection with an electrocautery device may be necessary to free up a passage. It is imperative to stay immediately on bone while dissecting the coracoid process to avoid neurovascular injury.

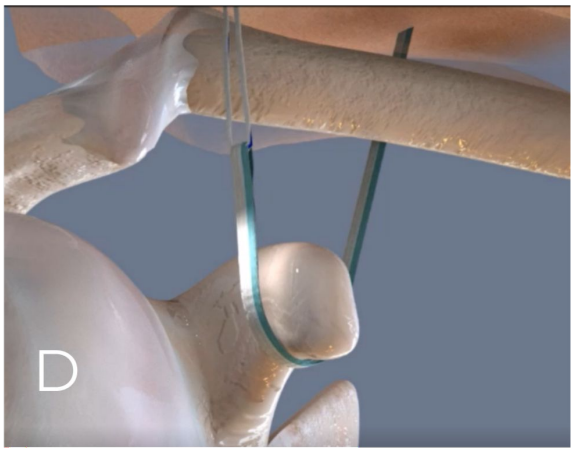
Once a tract has been established, the CORACOID Passing Device is introduced. The loaded CORACOID Passing Device is introduced along the anterior aspect of the clavicle approximately 4cm medial to the distal clavicle (A). It is critical to visualize the CORACOID Passing Device at all times during this step. The CORACOID Passing Device is advanced down the previously established tract from the clavicle to the coracoid until the tip of the CORACOID Passing Device can be visualized (via the scope) below the coracoid. The CORACOID Passing Device is then incrementally deployed to advance the attached shuttle suture around the coracoid to the extent that it may be retrieved using standard graspers/suture grabber which have been advanced from the mini-open incision from the lateral aspect of the clavicle (B). Alternatively, an intermediate passage may be completed via an anterior inferior portal, before ultimately passing the shuttle suture up through the mini-incision at the anterior aspect of the clavicle. Once the shuttle suture is retrieved, the nitinol loop is retracted

Once the loop has been passed under the coracoid process, it is then passed under the clavicle. Blunt dissection should be used to clear a path under the clavicle, approximately 4cm distal to the distal clavicular tip. Following this, the CORACOID Passing Device is passed from the posterior clavicle anteriorly. A suture will be used for passage of the subcoracoid suture. The medial limb of the subcoracoid suture is passed under the clavicle.



Surgical Technique - Arthroscopically-Assisted





Once the loop has been passed under the coracoid process, it is then passed under the clavicle. Blunt dissection should be used to clear a path under the clavicle, approximately 4cm distal to the distal clavicular tip. Following this, the CORACOID Passing Device is passed from the posterior clavicle anteriorly. A suture will be used for passage of the subcoracoid suture. The medial limb of the subcoracoid suture is passed under the clavicle.

After the Shuttle Suture is passed under the coracoid and the clavicle, the NoviCOID AC Device and graft may be pulled into place. The free (non-buckle end), along with the sutures of the graft are placed through the Shuttle Suture loop and pulled under the coracoid process and under the clavicle. We recommend passing an additional passing suture in the event that another passage under the coracoid process and clavicle is necessary. The NoviCOID AC Device and sutures should be passed first, followed by the graft.

Note: Once the NoviCOID AC Device is pulled into place, ensure that it moves freely back-and-forth. If it is constrained, remove the NoviCOID AC Device and clear additional soft tissue from the path.

3. AC Reduction and NoviCOID AC Device Fixation

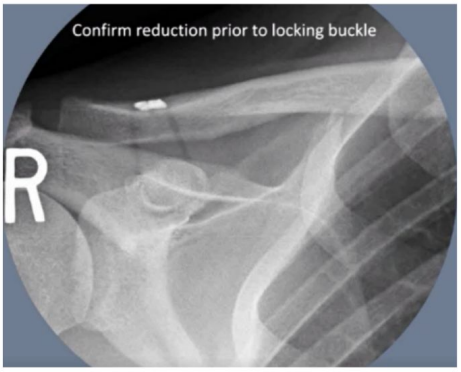
Once the NoviCOID AC Device and graft have been passed beneath the coracoid and under the clavicle, the AC joint should be reduced. Placing upward pressure on the arm and downward pressure on the clavicle can facilitate reduction of the AC joint. If there is significant resistance to reduction, then the surgeon should ensure that there is no soft tissue block or other impediments to reduction. It is recommended that fluoroscopy and direct vision should be used to ensure proper reduction.

Affix the NoviCOID AC Device over the clavicle by passing the lead end of the band through the slanted slot in the buckle. The strap is tightened around the clavicle by pulling up firmly on the free end. The Counter Traction Tool may be used to push the buckle down flush onto the clavicle (A) and to stabilize the buckle while the free end of the band is secured under the cleat. To engage the Counter Traction Tool with the buckle, align the black hash mark on the Counter Traction Tool with the black hash mark on the buckle. Once desired reduction is achieved and the NoviCOID AC Device is snug around the clavicle, the NoviCOID AC Device construct may be stabilized by applying light downward pressure on the Counter Traction Tool. This allows the free end of the band to be placed under the buckle cleat, thus creating stable provisional fixation. Radiographic assessment of the reduction may then be accomplished. ***This fixation will not be adequate for final fixation.***

Note: The NoviCOID AC Device construct and the Counter Traction Tool are not designed to generate reduction of the clavicle, rather they maintain reduction once it has been achieved by other means.

Surgical Technique - Arthroscopically-Assisted

At this point, the surgeon should assess the reduction by direct vision and fluoroscopy. Use of fluoroscopy is recommended to ensure proper restoration of the coracoclavicular distance.



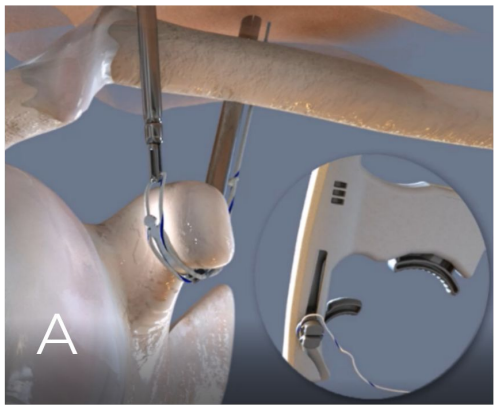
Once proper reduction has been confirmed, the NoviCOID AC Device should be secured in its final position. The tip of the Locking Punch should be placed in the corresponding dimple in the buckle cleat (B). Once engaged securely in the dimple, the buckle cleat should be deflected downward by lightly tapping the back of the punch with a mallet. Visually confirm that the cleat is deflected down and sits flush with the buckle edge (see “Buckle Locking” insert below).

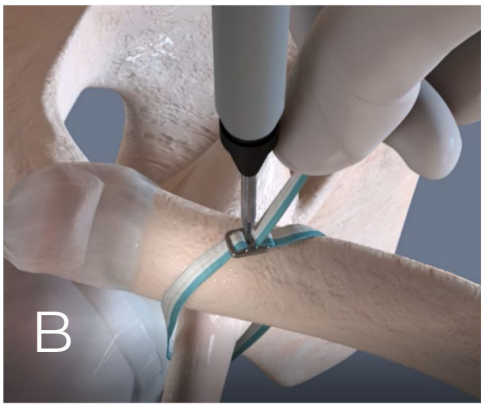
Note: It may be necessary to tap the punch multiple times in order to fully deflect the cleat.

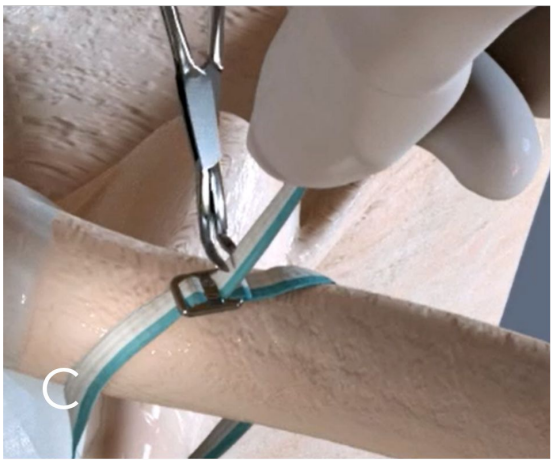
If the surgeon has not previously used the NoviCOID AC Device it is recommended that the Locking Punch be deployed once on the back table, as a trial, so the surgeon with have experience with the normal tactile feedback of the securing punch. Using two hands while activating the punch may help stabilize it.

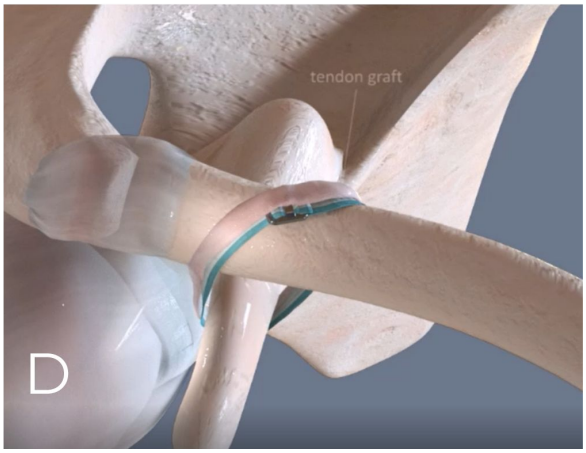
The tail of the NoviCOID AC Device is then trimmed at least 7-10mm from the deflected cleat (C).

Once pulled together over the clavicle (D), the graft is sewn onto itself or tied into a knot which is then reinforced with nonabsorbable sutures. Once secured, the excess ends of the graft are cut. The construct can be evaluated arthroscopically in the subcoracoid space to ensure proper placement of the NoviCOID AC Device and graft. There is no specific recommendation about orientation of graft and NoviCOID AC Device below the coracoid.

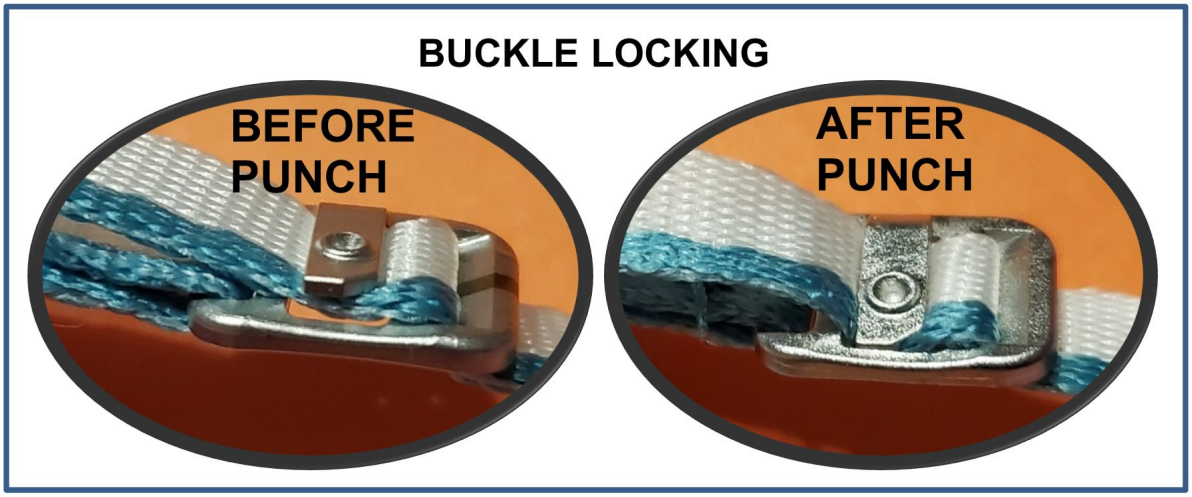








Surgical Technique - Arthroscopically-Assisted



4. Postoperative Protocol and Clinical Follow-up

The shoulder is protected in a sling for 6 weeks. Since the surgery is a “resuspension,” patients must be instructed to arm hanging for 6 weeks. Patients should not actively use the shoulder during this time. Passive range of motion in the plane of the scapula, pendulums and table slide exercise may be performed. Active range of motion is initiated at 6 weeks when the sling is discontinued. Strengthening is begun at 10 – 12 weeks and after the patient has achieved full range of motion. The patient should avoid contact sports for a minimum of 4 -6 months.

It is recommended that the patients be seen at regular postoperative intervals for follow-up both clinically and with radiographs. The duration of follow up is at the discretion of the surgeon. Supervised follow-up, to include x-rays is required suggested for a minimum of 6 months. It is recommended that x-rays include both AP and Axillary views of the clavicle/shoulder. Surveillance should be maintained for evidence of bony wear of the clavicle (AP view) or coracoid (Axillary view). If evidence is seen of excessive clavicular or coracoid erosion, then consideration should be given to removal of the NoviCOID AC Device Buckle to relieve the stress on the bone.

Ordering Information

Catalog Number	Description
NC4	NOVICOID Acromioclavicular, 4mm Stainless Steel w/Accessories
NC7	NOVICOID Acromioclavicular, 7mm Stainless Steel w/Accessories
NCJP	CORACOID Passing Device

The technique described herein was prepared with the input of health care professionals and is intended as a reference guide and educational tool for licensed health care professionals. The surgeon is responsible for determining the appropriate techniques, devices, and postoperative care for individual patients based on their own judgement, training, and experience. Individual results will vary.

For complete information regarding indications, contraindications, warnings, cautions, etc., please reference our website, www.OrthoNovis.com.