ORTHONOVIS
ELEVATING SURGERY®

NOVICOID Acromioclavicular Device

INSTRUCTIONS FOR USE

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Carefully read all instructions prior to use. Observe all warnings and precautions contained in these instructions. Failure to do so may result in complications.

Product Description
The NOVICOID Acromioclavicular Device is a polyester suture band with a pre-attached metal (titanium or stainless steel) connector/button. The Connector/Button is designed to provide temporary fixation and permanent fixation once proper reduction is verified. The **NOVICOID** Accessory Tools included are a Counter Traction Tool and Punch Tool. The Counter Traction Tool aids in stabilizing the Connector/Button and reducing the coracoclavicular interspace during reduction. Upon verifying proper reduction of the clavicle, the Punch Tool is used to deploy the permanent fixation feature on the Connector/Button.

The NOVICOID Device (Fig 1) should be used in combination with the NOVICOID Accessory Tools (Fig 2), which consists of the Counter Traction Tool and Punch Tool.

These Instructions for Use apply to the single use System Components noted in the table below. The components are supplied sterile:

	Catalog No.	Description
REF	NC4	NOVICOID Acromioclavicular, 4mm Stainless Steel w/Accessories
REF	NC7	NOVICOID Acromioclavicular 7mm Stainless Steel w/Accessories

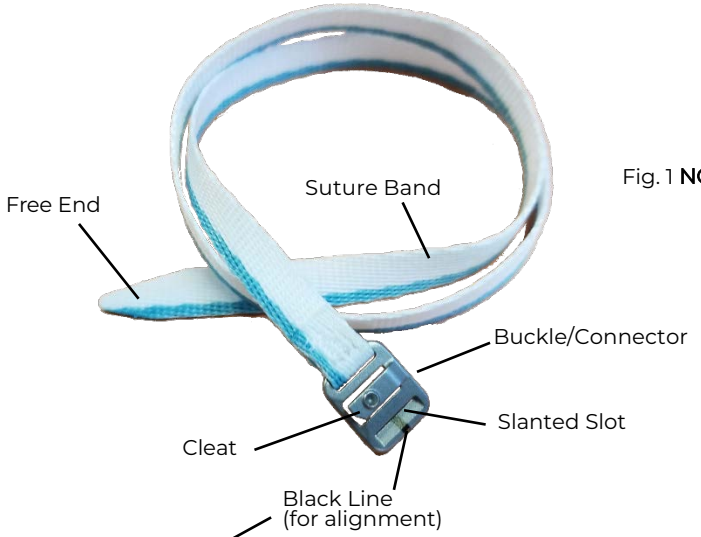

Fig. 1 **NOVICOID D**evice

Fig. **2 NOVICOID** Accessory Tools; Counter Traction Tool (*top*), Punch Tool (*bottom*)

Indications for Use:
The **OrthoNovis NOVICOID** Acromioclavicular Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as acromioclavicular separations due to coracoclavicular ligament disruption.

Contraindications:

Contraindications include, but are not limited to:

1. Insufficient quality or quantity of bone.
2. Blood supply limitations and previous infections which may retard healing.
3. Foreign body sensitivity to implant materials. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Any active infection.
5. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt the growth plate(s).
7. Do not use for indications other than those indicated.

Possible Adverse Effects:

1. Infection, both deep and superficial
2. Allergies and other reactions to device materials that are listed in Material Specifications section.
3. Loosening or migration of the implant
4. Allergic reaction to a foreign body
5. Pain, discomfort, or abnormal sensation due to presence of the device
6. Nerve damage due to surgical trauma
7. Necrosis of bone or tissue
8. Inadequate healing
9. Intraoperative or postoperative bone fracture and/or postoperative pain

Warnings:

1. Contact of the metal NOVICOID Buckle/Connector component with other metal components used in the procedure should be avoided.
2. Do not use this device as the sole means of reconstructing a chronic acromioclavicular joint dislocation.
3. Post-operatively, until healing is complete the fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the implant.
4. Detailed instructions on the use and limitations of the device should be given to the patient.
5. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management.
6. Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device.
7. The appropriate OrthoNovis NOVICOID Accessory Tools (Counter Traction Tool and Punch) are required for proper insertion of the implant.
8. Once open, discard any unused suture band, or repair system materials.
9. Do not expose polyester suture band to heat.
10. This is a single use device. Reuse of this device could result in failure of the device to perform as intended and could cause harm to the patient and/or user.
11. Patient sensitivity to the device materials should be considered prior to implantation. See Adverse Effects.
12. This device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. This device has not been tested for heating or migration in the MR environment.

Packaging and Labeling:

1. OrthoNovis NOVICOID and Accessory Tools should be accepted only if the factory packaging and labeling arrive intact.
2. Contact Customer Service if package has been opened or altered.

Sterilization:
The NOVICOID, and Accessory Tools are supplied sterile by exposure to Ethylene Oxide (EO) Gas. Do not re-sterilize. Do not use past expiration date.

Material Specifications:

- NOVICOID Suture Band: High-Tenacity Polyethylene Terephthalate (PET).
- NOVICOID Buckle/Connector: 316L Stainless Steel

Storage and Handling:

- Products must be stored in the original unopened packaging, away from moisture and extreme temperature, and should not be used after the expiration date. Handle the NOVICOID with care.

Precautions:

1. Carefully inspect the package prior to use for any breach of the sterile barrier or damage to the contents. If the sterile barrier integrity is compromised or the contents damaged, DO NOT USE and contact your OrthoNovis representative.
2. For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.

Directions for Use:

1. Using standard surgical technique, prepare the coracoid process and clavicle to allow for passage and positioning of the NOVICOID.
2. Pass the free end of the NOVICOID device under the coracoid process and around clavicle in the desired configuration. Insure that there are no twists in the suture band and that the coracoid and clavicle are encompassed.
3. With the Buckle/Connector over the clavicle, thread the free end of the NOVICOID suture band through the open (slanted) slot of the Buckle/Connector. Pull the free end until all the slack is removed, then pull firmly straight up to effectively tighten the band and reduce the clavicle. Manual downward pressure on the distal clavicle will aid in reduction and band tightening.
   Note: manual manipulation of the patient's arm, lifting the arm in a cephalad direction, may be used to aid in reduction
4. Once reduction of the clavicle is achieved and the NOVICOID buckle/connector is flush against superior surface of the clavicle, use the Counter Traction Tool to hold the Buckle/Connector in place. This is done by aligning the black line at the end of the tool with the black line of the Buckle/Connector, ensuring that the free end of the suture band resides above (not under) the tool. While maintaining light downward pressure on the tool, grasp the free end of the suture band and ensure it is free of the tool.
5. Temporary fixation is achieved by sliding the free end of the band under the cleat of the Buckle/Connector while maintaining light downward pressure on the tool. Ensure the entire width of the band is under the cleat.
6. If adjustment in clavicle reduction is required, slide the Suture Band from beneath the Cleat and repeat Steps 3 and 4.
7. After verifying desired reduction, the Punch Tool is used to permanently lock the NOVICOID by engaging the tip of the punch into the dimple on the Buckle/Connector and pushing down while holding the punch perpendicular to the buckle. An audible pop/click indicates that the punch was fully activated.
   Note: Always verify that the Buckle/Connector cleat is deflected flush with the buckle. Additional punches may be employed if needed.
8. Trim excess weave leaving at least 0.5" (12mm) beyond Cleat.

Symbols:

	**Catalog Number**
	**Lot Number**
	**Single Use Only**
	**Do not re-sterilize**
	**Manufacturer**

	**Sterile by Ethylene Oxide**
	**Use By**
	**Follow Instructions for Use**

Manufactured for:

ORTHONOVIS
ELEVATING SURGERY®

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