ORTHONOVIS
ELEVATING SURGERY®

CORACOID Passing 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 CORACOID Passing Device is a manual passer designed to pass a shuttle suture around bony structures to aid in placement of a biological graft, prosthetic or other device on/around the bony structure. The device consists of:

- A disposable pistol-shaped hand piece with an elongated cannula that retractably deploys a shape-memory loop.
- A disposable, non-implantable shuttle suture with a loop on each end that is placed by the shape memory loop and used to pull a prosthetic band, suture or biological graft into place.

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	NCJP	CORACOID Passing Device

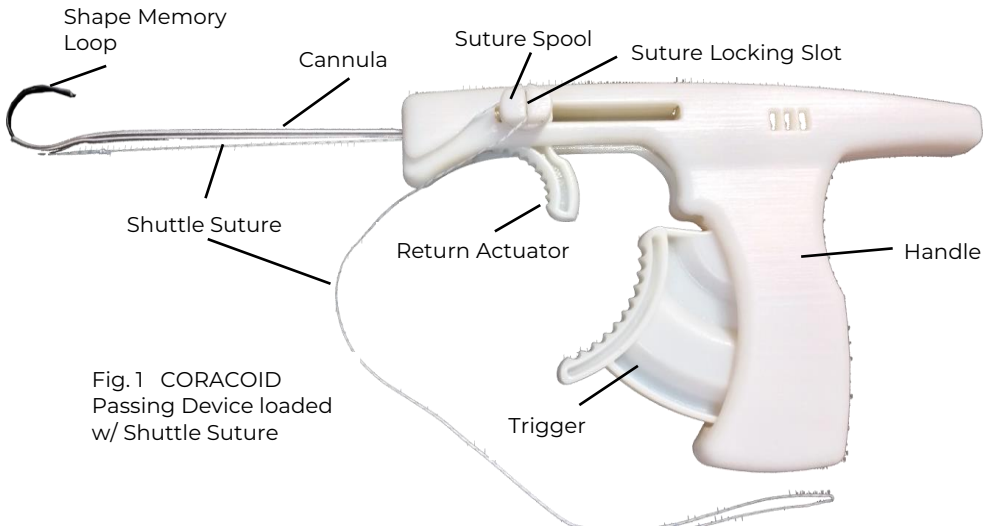


Fig. 1 CORACOID Passing Device loaded w/ Shuttle Suture

Indications for Use:
The CORACOID Passing Device is intended to aid in the placement of grafts and/or prostheses during orthopedic procedures.

Contraindications:
Contraindications include, but are not limited to:

1. Pathological conditions in the bone or surrounding soft tissue which would adversely affect prosthesis/graft retention.
2. Physical conditions, blood supply limitations and previous infections which may retard healing.
3. Any active infection.
4. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
5. Do not use for indications other than those indicated.
6. This device or any component thereof is not intended to be implanted.

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. Allergic reaction to a foreign body
4. Nerve damage due to surgical trauma
5. Inadequate healing

Warnings:

1. This device or any component thereof is not intended to be implanted.
2. This device is not intended for tissue dissection. Proper site preparation is required and may include tissue removal or dissection in order to facilitate placement of cannula and shape memory loop.
3. Avoid lateral stresses and bending of the instrument or the device function may be compromised and unintentional patient injury may result.
4. Pre-operative and operating procedures, including knowledge of surgical techniques are important considerations in the successful utilization of this device.
5. 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.
6. Direct or arthroscopic visualization of the cannula tip and shape memory loop must be maintained at all times during the use of this device. Failure to visualize the tip of the device or loop may result in unintentional patient injury.

Packaging and Labeling:

1. The CORACOID Passing Device 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 CORACOID Passing Device and Shuttle Sutures are supplied sterile by exposure to Ethylene Oxide (EO) Gas. Do not re-sterilize. Do not use past expiration date.

Material Specifications:
Refer to the package label for materials.

- Shuttle Suture: Ultra-High Molecular Weight Polyethylene (UHMWPE)
- Cannula: Stainless Steel
- Shape Memory Loop: Nitinol
- Handle: ABS and/or Polycarbonate

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 CORACOID Passing Device 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.
3. Use only the Shuttle Suture provided for loading on the CORACOID Passing Device device.

Directions for Use:

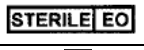
<u>Loading</u>

1. After carefully examining the device for damage, use the Return Actuator to retract the Shape Memory Loop until only 4 - 6mm of the Loop protrudes from the cannula mouth.
2. Place one loop of the Shuttle Suture over the protruding tip of the Shape Memory Loop. Apply light tension to the Shuttle Suture while locating the loop into the notches on the sides of the Shape Memory Loop tip.
3. While maintaining tension on the Shuttle Suture, pull it down along the underside of the cannula situating it in the v-notch on the back of the Cannula tip, then along the cannula, through the angled slot at the distal end of the passer handle to the Suture Spool.
4. Wrap the Shuttle Suture at least two full revolutions around the Suture Spool before pulling it into the Locking Slot on the Suture Spool.
5. Verify that the Shuttle Suture is still under tension, then use the Return Actuator to retract the tip of the Shape Memory Loop fully into the Cannula.

6. Place the Cannula tip into the surgical site and abut it to the bone so that the bone nestles in the curved portion of the Cannula.
7. While visualizing the tip of the device, squeeze the Trigger one time. After verifying that the Loop is extending properly under/around the bone.
8. While keeping the cannula curve and Shape Memory Loop snug to the bone squeeze the Trigger, stopping after each squeeze to verify location of the tip of the Shape Memory Loop.
9. Once the tip reaches a point where it may be accessed, release the proximal end of the Shuttle Suture from the Suture Spool.
10. Grasp the Shuttle Suture from the tip of the Shape Memory Loop. Retract the Shape Memory Loop using the Return Actuator and remove the device from the surgical site.
11. Suture Bands, Grafts or other prostheses may now be placed through the loop at either end of the Shuttle Suture and pulled into position.

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®

OrthoNovis, Inc.
One Hargrove Grade, 2f Palm Coast, FL 32137