

Shoulder Options, Inc.

Cuff Repair Plate (CRP)[™] System

It is recommended that the operating surgeon intending to use a product marketed by Shoulder Options review and understand the following recommendations concerning the products' safe and effective use. All contraindications, indications, warnings, and precautions provided herein should be considered and adhered to. Additionally, available product-specific information (i.e. technique guides, product literature, applicable journal articles, etc.) should be referenced for a more thorough understanding concerning the use of the product. Such information may be found on the Shoulder Options web site (www.shoulderoptions.com). Shoulder Options is not liable for complications related to the use of the device if it is used beyond its specified indications, without consideration to the recommended technique, by way of poor surgical judgment, and/or any similar condition beyond the control of Shoulder Options, Inc.

Description of Device

The Shoulder Options Cuff Repair Plate System is a plate and locking bolt system. The low-profile plate is anatomically contoured with threaded holes to "lock" the anchor bolts in a fixed angle relative to the plate. The superior periphery of the plate has holes, with an undercut surface to allow for the passage of sutures through the plate before and/or after the device has been anchored to the bone.

The plates and anchor bolts are manufactured from titanium alloy Ti-6Al-4V ELI.

Indications for Use

The Cuff Repair Plate is indicated for augmentation of transosseous rotator cuff repair, especially in massive tears and re-ruptures in proximity to osteopenic bone.

- Primary rotator cuff repair augmentation
- Revision rotator cuff repair augmentation

Contraindications

- Not intended for use in fracture management
- Do not use in the presence of infection
- Do not use in the presence of insufficient bone stock
- Not for use in the spine

Warnings & Precautions

- Shoulder Options devices are not intended to be reused.
- Bending the plate near the "locking" hole could deform the hole, rendering it unable to thread together with the locking anchor bolt.
- Avoid scratching, notching, hitting, or otherwise damaging the device.
- The device is a temporary internal fixation device designed to augment rotator cuff healing to the bone during the normal healing process. After the repair has healed, the device should be removed as it provides no further functionality

Adverse Effects

The following adverse effects may occur:

- Postoperative plate and/or anchor bolt breakage, loosening, or pullout failure
- Cold welding of the anchor bolt to the plate
- Suture and/or bone breakage resulting in failure of the tendon-to-bone repair
- Soft tissue irritation or damage
- Post-traumatic osteoarthritis
- Osteonecrosis
- Inflammation, infection, and/or pain
- Metal sensitivity
- Corrosion of metal components

Sterilization Instructions

The devices for this system are provided non-sterile. Therefore, these devices must be sterilized prior to using following the recommendations below. More detailed instructions can be found in "Shoulder Options Recommendations for Processing and Sterilization of Orthopedic Instruments and Devices" (Order # 00-LT-PS001).

Type	Minimum Temperature	Minimum Exposure Time	Minimum Dry Time
Prevacuum	132°C/270°F	4 minutes	30 minutes
Gravity Displacement	Not Recommended	Not Recommended	Not Recommended

Discussions with Patients

It is important for the physician to discuss the limitations of orthopedic procedures and devices. Complications of orthopedic surgery utilizing internal fixation devices have an increased probability if patients have unrealistic expectations of outcome, are overweight, are inappropriately physically active, and/or do not follow the recommended rehabilitation protocol. All of the aforementioned situations can result in loosening, wear, and/or failure of the device. The patient should have a clear understanding regarding postoperative activity restrictions. The patient should also understand that the medical implant is not intended to stay in the body permanently and may need to be removed.



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