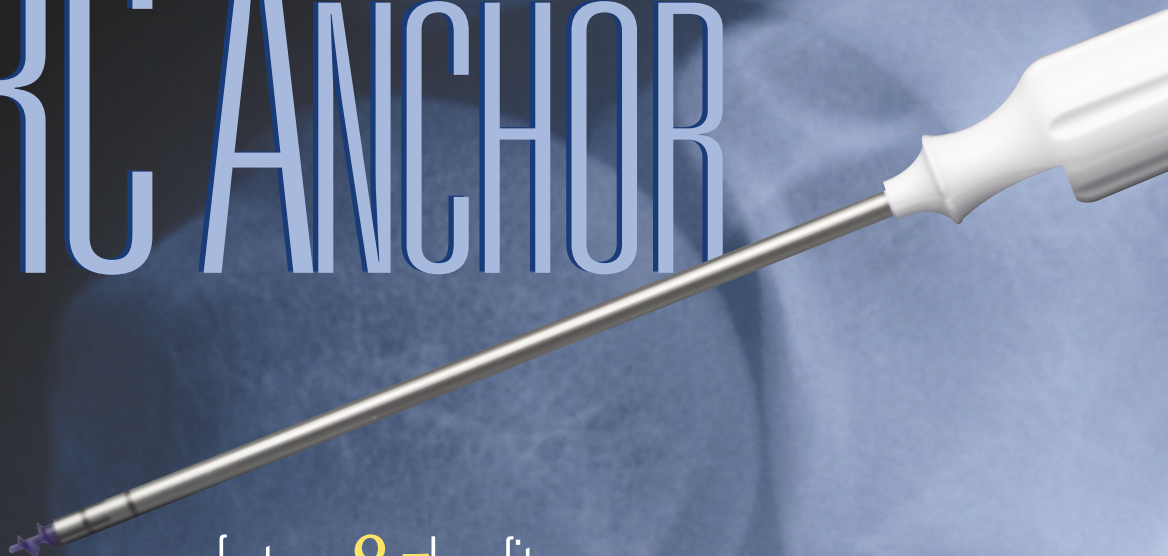




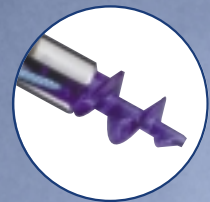
BIOFASTIN^{*}

RC ANCHOR



features & benefits

- Achieves excellent soft-bone purchase.
- Made from bioabsorbable, radiolucent PLA.
- Dual-suture anchor to distribute tension on the repair.
- Independent suture eyelets for improved suture sliding.
- Delivery guide, Introducer and Obturator are ideal for arthroscopic Rotator Cuff Repair.



Mitek
WORLDWIDE
a Johnson & Johnson company

BIOFASTIN RC

ANCHOR

INDICATIONS:

SHOULDER: Rotator Cuff Repair.

CONTRAINDICATIONS

1. Surgical procedures other than those listed in the INDICATIONS section.
2. Pathological conditions of bone, such as cystic changes or severe osteopenia, which would compromise secure anchor fixation.
3. Pathological conditions in the soft tissue to be attached which would impair secure fixation by suture; comminuted bone surface, which would compromise secure anchor fixation.
4. Physical conditions which would eliminate, or tend to eliminate, adequate implant support or retard healing, i.e., blood supply limitation, infection, etc.
5. Conditions which tend to preempt the patient's ability to heal or the healing period, such as senility, mental illness, or alcoholism; attachment of intracapsular knee ligaments (ACL & PCL).

WARNINGS

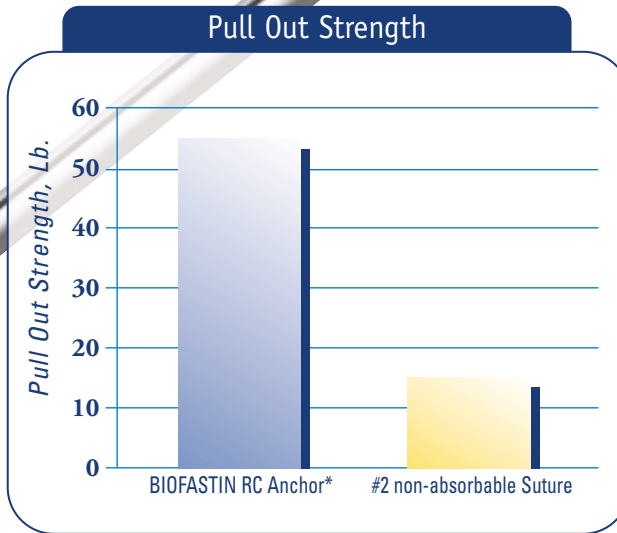
1. Mitek anchors are designed to lock into cortical or cancellous bone. Bone stock must be adequate to allow proper and secure anchor placement.
2. Immediate range of motion should be avoided to allow biological bony/soft tissue healing.
3. Do not use where pre-healing suture tension will exceed 20 lbs. for size #2 suture, as suture may fail.
4. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the thoracic or lumbar spine.
5. Inspect all instruments for damage before use. Do not attempt to repair.

PRECAUTIONS

A surgeon should not begin clinical use of a Mitek anchor without reviewing the instructions for use and practicing the procedure in a skills laboratory.

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a physician.



Data on file at Mitek Worldwide



Position Delivery Guide at desired implant site.



Insert Tap and turn clockwise until depth mark reaches cortical surface.



After removing Tap, insert anchor by twisting clockwise, applying slight forward pressure, insert until depth mark is at the cortical surface.



Remove inserter by pulling straight back, which will expose the suture and swaged needles.



Complete repair.

ORDERING INFORMATION

Cat. No.	Description	Qty.	Order Qty.
222821	BIOFASTIN RC with ETHIBOND* (Green)	1/box	_____
222841	BIOFASTIN RC with PANACRYL* (White)	1/box	_____
213210	BIOFASTIN RC Insertion Guide	1/box	_____
219075	Tap Screw	1/box	_____
219077	Guide Introducer	1/box	_____

Surgeon's Signature

Date

For more information, call your Mitek representative at 1-800-382-4682 or visit us at www.mitek.com. Mitek Worldwide, a Division of ETHICON, Inc., 249 Vanderbilt Avenue, Norwood, MA 02062

Mitek, BIOFASTIN, PANACRYL and ETHIBOND are trademarks of Ethicon, Inc., a Johnson & Johnson company, or its Mitek Worldwide Division. These products are covered by the following U.S. Patents: 4,632,100, 4,994,074, 5,814,051. Other Patents Pending. P/N is 900685. Rev. A 10/02.

*tested in 15 lb./ft.³ foam