

PANALOK ANCHOR

INDICATIONS

ANKLE — Lateral instability, medial instability, achilles tendon repair/reconstruction.

ELBOW — Biceps tendon reattachment.

KNEE — Medial collateral ligament, lateral collateral ligament, posterior oblique ligament capsule to tibia, joint capsule closure to anterior proximal tibia, extra capsular reconstruction, ITB tenodesis, patellar ligament and tendon avulsion repair.

SHOULDER — Bankart repair, rotator cuff repair, SLAP lesion repair, biceps tenodesis, acromio clavicular capsule shift/capsulolabral reconstruction.

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 inhibit the drilling of a precise hole or compromise secure anchor fixation.
3. Pathologic conditions in the soft tissue to be attached, which would impair secure fixation by suture.
4. Comminuted bone surface, which would compromise secure anchor fixation.
5. Conditions that would: eliminate, or tend to eliminate, adequate implant support or retard healing, e.g. blood supply limitation, infection, etc; tend to compromise the patient's ability to heal such as cognitive state, (need clarification) require prolonged approximation of tissues under stress, such as when wound healing is expected to be delayed (e.g., steroid therapy, chemotherapy, etc).
6. Attachment of artificial ligaments or other implants.

WARNINGS

As the anchor is absorbable, immobilization by external support should be employed. The Mitek PANALOK 3.5mm Absorbable Anchor is designed to lock into cancellous bone. After removing the inserter, apply nominal tension on the suture lengths to completely set the anchor. Do not use excessive tension or overload the suture as either could lead to bone breakage and subsequent device pullout or suture breakage.

Do not use this anchor with a drill bit that is not 3.5mm in diameter and that does not generate a precise diameter drill hole of at least 18 mm in depth.

In the event that a Mitek PANALOK 3.5mm Absorbable Anchor must be removed, over-drill the original insertion hole or use curettes or osteotomies to open the cortical surface. Carefully remove the cancellous bone to expose the anchor. Use a needle holder or forceps to grasp the anchor and remove it.

A Mitek PANALOK 3.5mm Absorbable Anchor must never be reused. In the event the anchor should dislodge from the inserter or bone site, do not attempt to reattach the anchor to the inserter. In this case, the anchor and inserter should be discarded and a new anchor should be utilized. Acceptable surgical practice should be followed for the management of infected or contaminated wounds.

Do not re-sterilize. Once its package has been opened an unused suture anchor should be discarded. Re-sterilization compromises the integrity of the Anchor system and/or Anchor and may lead to serious surgical consequences.

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

Mitek[®]
PRODUCTS

ETHICON
a Johnson & Johnson company



Absorbable Soft Tissue Anchor

PANALOK[®]

Ordering Information

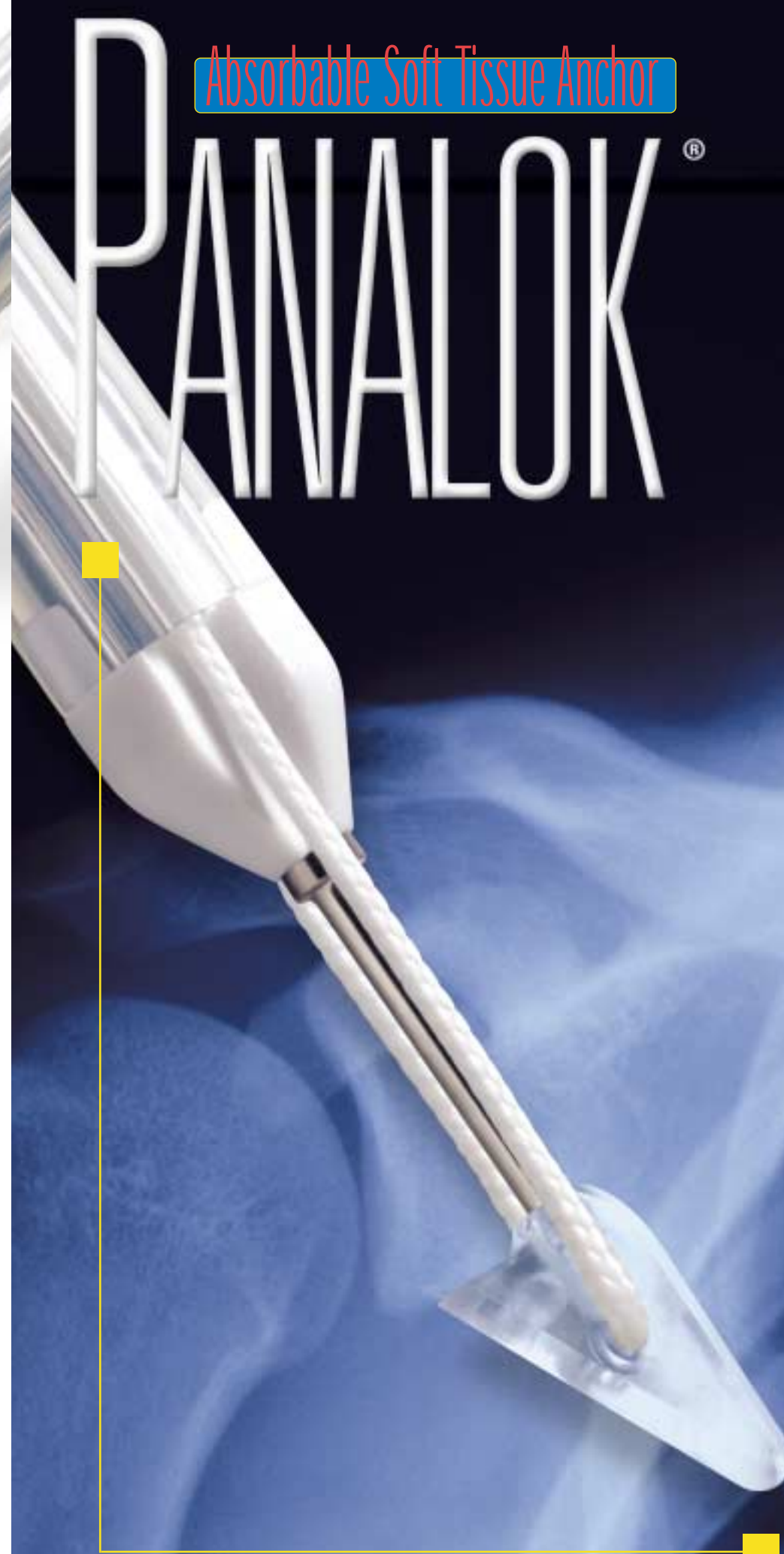
Cat. No.	Description	Qty.	Order Qty.
210725	PANALOK Anchor w/#2 PANACRYL Suture	1/box	_____
210025	PANALOK Anchor w/#2 ETHIBOND™ Suture (green)	1/box	_____
210026	PANALOK Anchor w/#2 ETHIBOND Suture (white)	1/box	_____
211026	PANALOK Drill Bit 3.5mm	1/box	_____
213025	PANALOK Slotted Drill Guide, Fishmouth	1/box	_____
213026	PANALOK Slotted Drill Guide, Sawtooth	1/box	_____

Surgeon's Signature

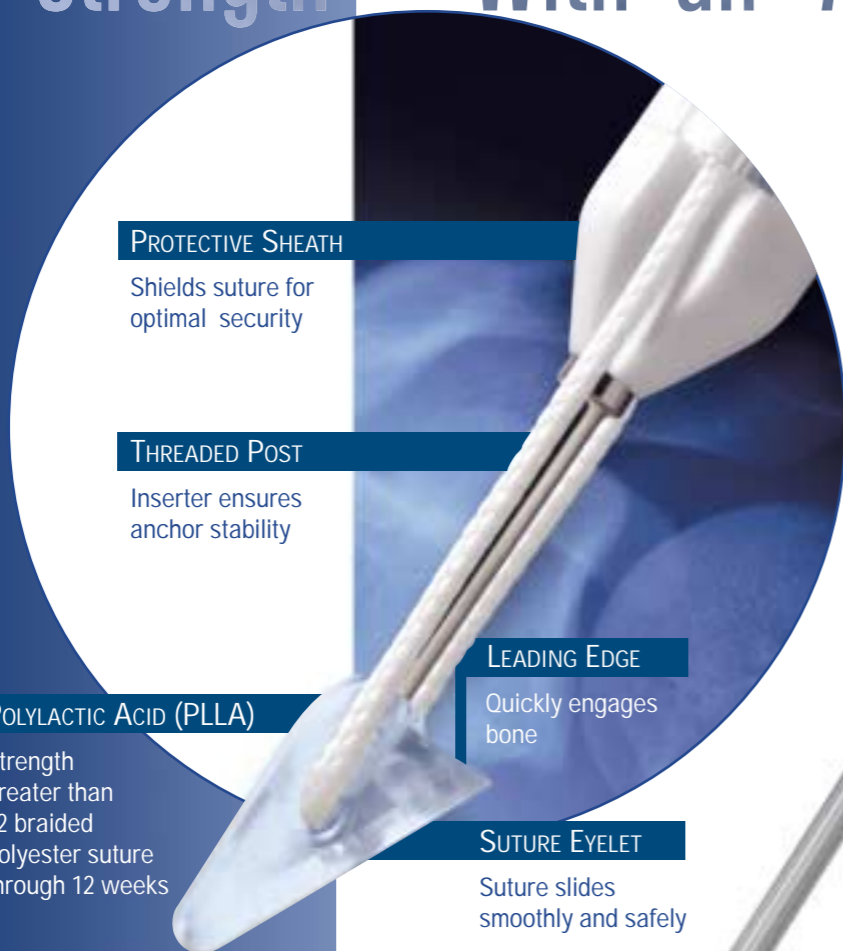
Date

For more information, call your Mitek representative at 1-800-382-4682 or visit our website at www.mitek.com. Mitek Products, Division of ETHICON, Inc., 60 Glacier Drive, Westwood, Massachusetts 02090

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Anchor Strength - With an Absorbing Advantage



PROTECTIVE SHEATH

Shields suture for optimal security

THREADED POST

Insertor ensures anchor stability

LEADING EDGE

Quickly engages bone

SUTURE EYELET

Suture slides smoothly and safely

POLYLACTIC ACID (PLLA)

Strength greater than #2 braided polyester suture through 12 weeks

Clinical studies show that PANALOK® soft-tissue anchors provide results equivalent to fixation using non-absorbable suture and suture anchors. Constructed of the highest quality PLLA (polylactic acid), biocompatible PANALOK anchors absorb slowly and safely leaving no permanent foreign material presence.

Only Mitek anchors are pre-loaded with PANACRYL™, long-term braided absorbable suture from ETHICON®.



Preloaded #2 PANACRYL Suture

Clinical Results Prove Effectiveness

Clinical outcome studies demonstrate that PANALOK anchors are as effective as non-absorbable anchors and sutures in reconstruction of the shoulder.¹

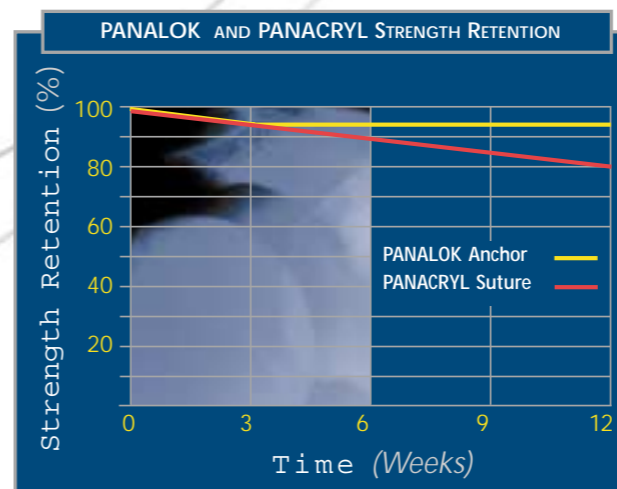
Safe, Bioabsorbable Construction

Composed of highly purified PLLA material, PANALOK anchors offer maximum strength retention and a slow rate of absorption for optimal healing.

PANACRYL Long Term Suture

Only PANALOK anchors are pre-loaded with PANACRYL, the first long-term braided absorbable suture. PANACRYL retains up to 80% of its strength through twelve weeks of healing.

¹ Data on file.



PANALOK anchor and PANACRYL suture retain strength through the soft tissue healing period.



Anchor slides smoothly into hole, without tapping



Anchor turns, pin bends to fit hole



Pin memory forces leading edge to engage cancellous bone



Withdrawal motion spins anchor, using leading edge as a fulcrum



Insertor separates from anchor; suture tensioning further locks anchor within bone hole



Mitek
PRODUCTS

Innovation Defined by Experience