Surgical Techniques

Arthroscopic Rotator Cuff Repair

A Simplified Approach

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SURGICAL TECHNIQUE

DePuy Mitek
a Johnson & Johnson company

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SIMPLIFIED APPROACH

MITEK VAPR SYSTEM

INDICATIONS

The Mitek VAPR System is intended for resection, ablation and excision of soft tissue, and hemostasis of blood vessels in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow and wrist. Arthroscopic surgery could include, for example, the following: Knee, Meniscectomy, Lateral Release, Chondroplasty, Synovectomy, ACL, Debridement, Plica Removal, Meniscal Cystectomy, Ankle, Fracture Debridement, Excision of Scar Tissue, Synovectomy, Chondroplasty, Wrist, Synovectomy, Cartilage Debridement, Fracture Debridement, Shoulder, Labral Tear Resection, Synovectomy Excision of Scar Tissue, Acromioplasty, Bursectomy, Subacromial Decompression, Chondroplasty, Elbow, Synovectomy, Tendon Debridement, Chondroplasty.

CONTRAINDICATIONS

The Mitek VAPR System is contraindicated in any non-arthroscopic surgical procedure and in procedures where saline or Ringer's lactate is not used as an irrigant. The System is also not appropriate for patients for whom an arthroscopic procedure is contraindicated for any reason. Use of the System is also contraindicated in patients with heart pacemakers or other electronic device implants.

WARNING

Hazardous Electrical Output: This equipment is capable of producing a physiological effect and is for use only by licensed physicians, trained in the use of this device.

Fire/Explosion Warnings

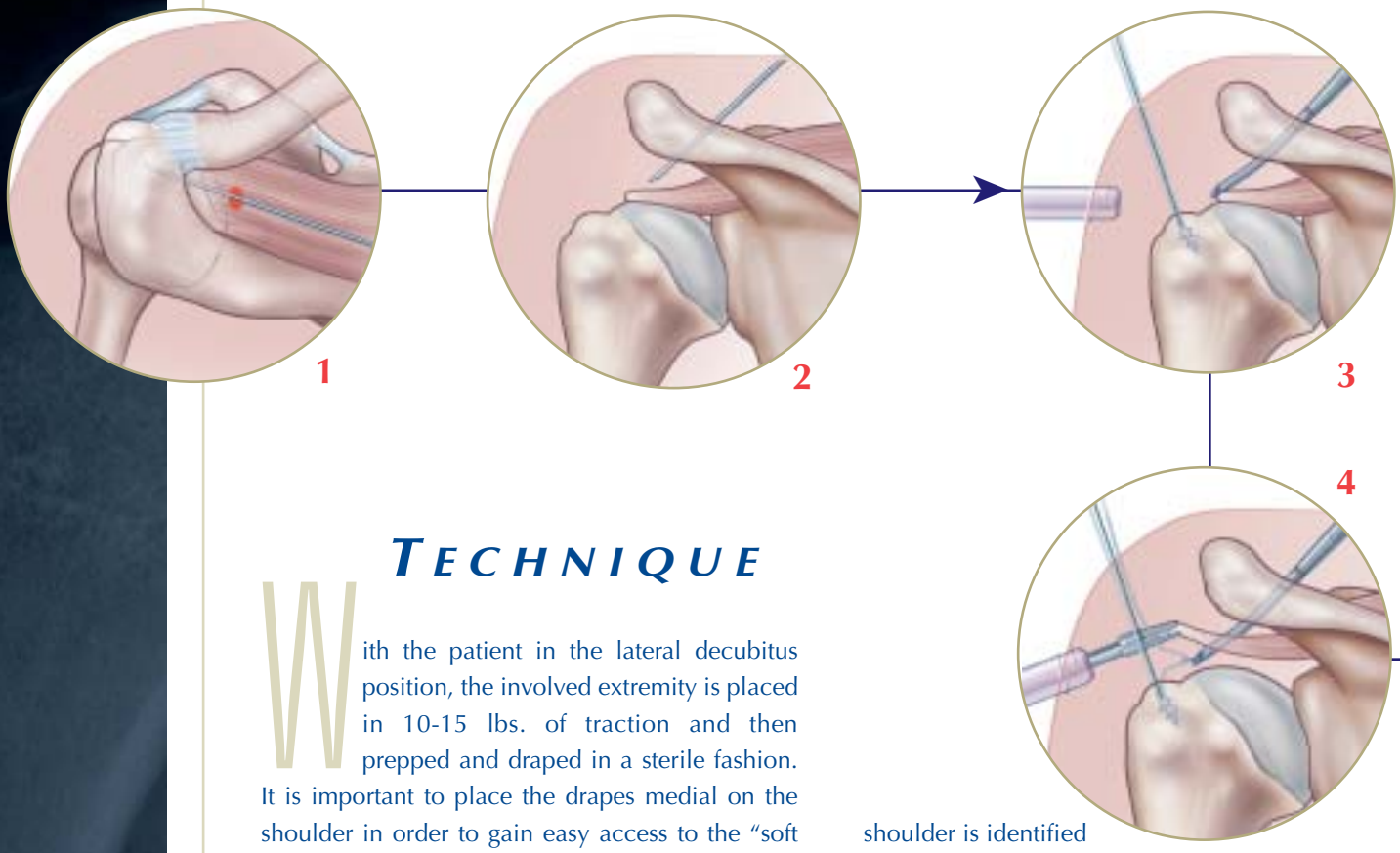
- As with all electrosurgical devices, do not use in the presence of flammable anesthetics or oxidizing gases, such as nitrous oxide, oxygen or endogenous gases which have accumulated in body cavities. An electrosurgical device has the potential for providing a source for ignition.
- Nonflammable substances should be used for cleaning and disinfecting. Use of flammable substances, such as alcohol-based skin prepping agents and tinctures should also be avoided.
- All oxygen connections must be leak free for the duration of the surgical procedure. Pathways, such as endotracheal tubes, must be leak free and properly sealed to prevent oxygen leaks.
- Electrosurgical accessories which are activated or hot from use can be a potential fire hazard if placed near or in contact with flammable materials. Some materials, such as gauze, cotton or wool, when saturated with flammable liquids, can be ignited by sparks produced during the normal use of electrosurgical devices.

Surgical Techniques

Surgical Technique in Arthroscopic Rotat

Overview

The Nevaiser portal or superior medial portal was first described by Thomas J. Nevaiser in 1987 as an "operative" portal for arthroscopy of the glenohumeral joint. The Nevaiser portal is situated in the soft spot of the shoulder and is bordered by the AC joint anteriorly, the acromion laterally, and the scapular spine posteriorly (Fig. 1). More recently, the superior medial portal has been used to access the subacromial space during arthroscopic rotator cuff repair. After establishing this portal with an 18 gauge spinal needle, the MITEK 30 degree suture retriever can be used to pass sutures through the supraspinatus tendon, with ease and efficiency. In addition, the superior medial portal aids with suture management and also enables



Technique

With the patient in the lateral decubitus position, the involved extremity is placed in 10-15 lbs. of traction and then prepped and draped in a sterile fashion. It is important to place the drapes medial on the shoulder in order to gain easy access to the "soft spot". A standard posterior portal is established and the arthroscope is inserted into the glenohumeral joint. After establishing an anterior portal, any necessary debridement of the labrum/rotator cuff may be performed. The arthroscope is then placed in the subacromial space and a lateral portal is established under direct visualization. A bursectomy is performed with the MITEK VAPR® system and the rotator cuff and tuberosity are debrided. If necessary, mobilization of the rotator cuff can be carried out at this time. The soft spot of the shoulder is identified and a spinal needle is inserted into the subacromial space. By placing the needle slightly more medially or by briefly abducting the arm to 50 or 55 degrees, access to the subacromial space and rotator cuff is facilitated **(Fig. 2)**. The spinal needle is removed, a 2 mm incision is made, and the 30 degree MITEK suture retriever is inserted. The spinal needle is then used to localize the appropriate placement of the FASTIN® RC suture anchor (usually off of the anterolateral border of the acromion) and an anchor is inserted at

TOR CUFF REPAIR

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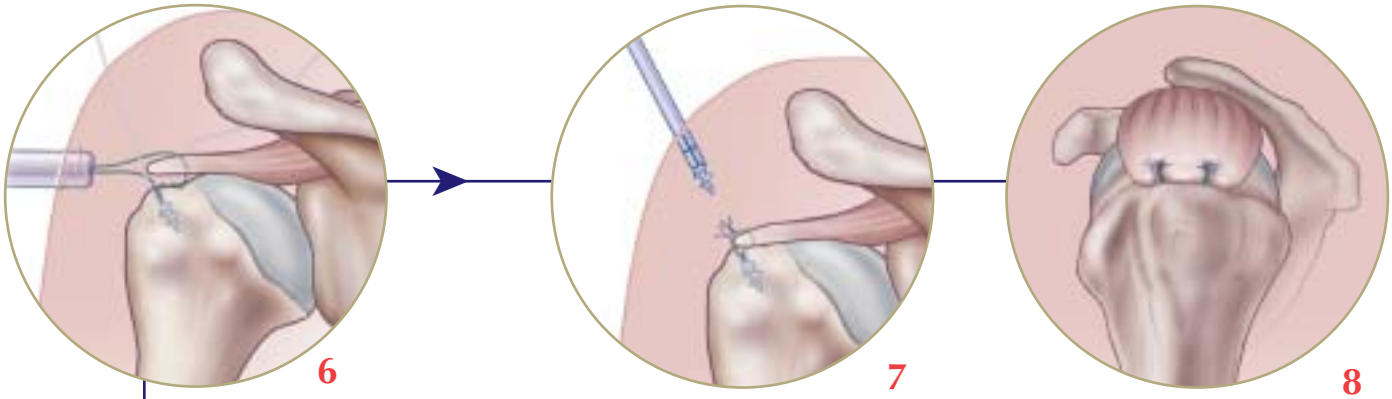
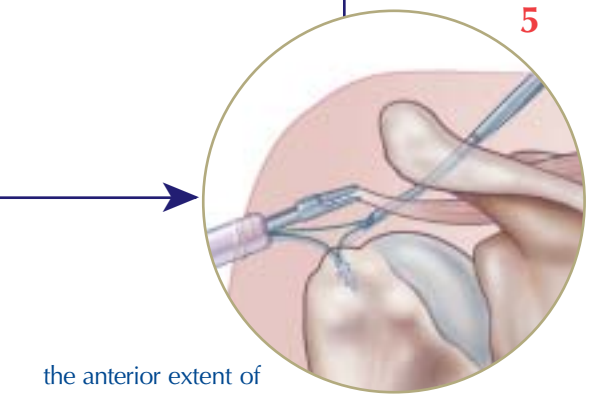
the surgeon to keep the arthroscope in the posterior portal while passing instruments through the lateral portal. The low profile design of the MITEK suture retrievers allows unimpeded access to the subacromial space and helps avoid many of the difficulties encountered when using other bulky suture retrievers with handles.

A SIMPLIFIED APPROACH





the anterior extent of the tear into the tuberosity.

A 6mm cannula is placed into the lateral portal. The suture retriever is then inserted through the supraspinatus tendon and one limb of the green suture is pulled through the tendon and out of the Nevaiser portal **(Fig. 3 & 4)**. (Suture passing is facilitated by using the suture grasper to lift the tendon and manipulate the sutures.) One limb of the white suture is then passed through the tendon in a similar fashion **(Fig. 5)**. The green sutures are then brought out of the lateral cannula and tied using a sliding, self-locking knot **(Fig. 6)**. The green suture is then cut and the white sutures are then tied and cut in a similar fashion **(Fig. 7)**. A second anchor is then inserted, posterior to the first. The sutures are then passed through the tendon and tied in a similar fashion **(Fig. 8)**. After repair of the rotator cuff is completed, a subacromial decompression is performed and the wounds are closed. The patient is placed into a sling and discharged the same day.

This method of arthroscopic rotator cuff repair facilitates the passing of suture through the supraspinatus tendon and prevents many of the pitfalls frequently encountered with poor suture management.

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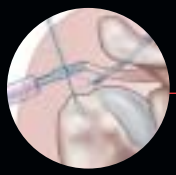

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MITEK VAPR SYSTEM

Electrical Safety Considerations

- Examine all accessories and connections to the VAPR Generator before use. Ensure that the accessories function as intended. Improper connection may result in arcing, sparking, or malfunction of the Electrode or Handpiece, any of which can result in an unintended surgical effect, injury, or product damage.
- Unless specified in the instructions for use accompanying an approved VAPR accessory, the VAPR System should only be activated with the working tip of the electrode accessory completely immersed in 0.9% w/v; 150 mmol/l sodium chloride or Ringer's lactate solutions. For convenience, these will be referred to within the remainder of this manual as normal saline or Ringer's, respectively. Performance will be suppressed by use of other irrigating solutions such as Glycine, Sorbitol, Dextrose, Mannitol or other solutions containing a non-physiological concentration of electrolytes.

Electrosurgical Smoke Caution

- Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to surgical personnel. Use appropriate surgical masks or other means of protection.

PRIOR TO SURGERY

Operator Safety Warnings

- Electric Shock Hazard: Do not connect wet accessories to the handpiece or generator. Ensure that all accessories are securely and properly connected.
- Electric Shock Hazard: Do not remove or tamper with the Generator housing. Contact Mitek technical service for assistance.
- The power cord must meet all requirements for safe grounding. Do not use extension cords, multiple point plugs or 2 to 3 pronged adapters.
- Do not reuse or resterilize accessories labeled "SINGLE USE," as malfunction, injury or cross-infection may result.

Operator Safety Cautions

- Inspect the insulation of all cords for cracks, nicks and breaks. Inspect all connectors for damaged or missing parts.
- Use default power levels to test Electrode performance. Confirm proper default power settings with package insert information before proceeding with surgery.
- Accessories labeled "REUSABLE" must only be processed according to the recommended procedures provided in this manual.
- Provide as much distance as possible between the electrosurgical generator and other electronic equipment (such as monitors) because an activated electrosurgical generator may cause interference with them.

DURING SURGERY NOTE

For the purposes of safety procedures, and despite the absence of a conventional return pad, the VAPR System should still be treated as a high power electrosurgical device.

CAUTION

Failure of the HF SURGICAL EQUIPMENT could result in an unintended increase of output power.

Operator Safety Warnings

- Observe extreme caution when using electrosurgery in close proximity to or in direct contact with any metal objects. The majority of arthroscopes and arthroscopic instruments are metal. Do not activate the electrode while any portion of the electrode tip is in contact with another metal object; localized heating of the electrode and the adjacent metal object may result in product damage.
- Do not wrap Handpiece, Footswitch or Generator power cord around metal objects. Wrapping cables around metal objects may induce currents that could lead to shock, fire or injury to patient or surgical personnel.
- During an electrosurgical procedure, the patient should not be allowed to come into direct contact with grounded metal objects such as surgical table frame, instrument table, etc.
- Confirm proper default generator power settings before proceeding with surgery. Always check that the automatic default settings shown on the display match those indicated on the package insert of the Electrode being used.
- Caution should be used when overriding the default power settings. Use the lowest power setting and the minimum tissue contact time necessary to achieve the appropriate surgical effect.
- Visually inspect the Handpiece and Electrode to ensure that they are clean and dry and free of damage prior to inserting the Electrode. Damage to the connectors or the presence of fluid may cause a hazardous electrical short.
- Ensure that the Electrode is fully seated in the handpiece prior to use. Improper connection could result in non-activation of the Electrode and fluid leakage which may produce an electrical short.
- Introducing the Electrode without an instrument cannula may result in tissue injury and/or product damage.
- Do not insert, withdraw or touch the active tip of the Electrode when power is being applied.
- When not in use, place the active Electrode in a clean, dry, nonconductive, and highly visible area not in contact with the patient. Inadvertent activation while in contact with the patient may result in burns.

Operator Safety Cautions

- Maintain the generator volume control to a level that will be audible in a normal operating room environment. The activation tone is heard while the foot pedal is depressed, indicating the electrode is activated.
- If possible, avoid the use of needle style electrodes for any physiological monitoring equipment that may be connected to the patient during electrosurgery.
- Where practical, only use monitoring equipment that incorporates high frequency current limiting devices during electrosurgical procedures.
- The Handpiece cable should be positioned so that it avoids contact with the patient and any other leads.
- Should a power supply interruption occur, the generator power settings will revert to the minimum values when power is re-established should the accessory combination still be connected.

Potential Hazards for Arthroscopic Procedures

As visualization may be impaired during arthroscopy, be particularly alert to these potential hazards:

- An activated Electrode tip may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Maintain the active Electrode in the field of view at all times. Injuries to the patient may result from inadvertent activation or movement of an activated Electrode outside the field of view.
- Use care when inserting and withdrawing the Electrode from a cannula to avoid the possibility of damage to the devices and/or injury to the patient.
- Continuous flow of irrigant is recommended. Fluid flow assists in removing vaporization by-products as well as reducing the temperature of the electrode tip between activations.
- Ensure that the Electrode tip is completely surrounded by irrigant solution during use.
- Outflow is important, especially in small joint spaces.
- Prolonged or unnecessary activation when not in contact with tissue may result in unintentional damage to surrounding tissue.

AFTER SURGERY

WARNING

Electric shock hazard: Turn off the Generator and unplug the power cord from the AC source prior to cleaning Generator.

EQUIPMENT DISPOSAL

- The VAPR System Generator contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.
- Dispose of any system accessories according to normal institution practice relating to potentially contaminated items.

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

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

MITEK FASTIN RC

INDICATIONS

The MITEK FASTIN RC threaded titanium alloy suture anchor is preloaded on a disposable inserter assembly intended for fixation of two strands of #2 suture to bone in the surgical repair of the rotator cuff.

CONTRAINDICATIONS

Surgical procedures other than those listed in the INDICATIONS section. Pathologic conditions of bone, such as cystic changes or severe osteopenia, which would impair its ability to securely fix the MITEK Anchor. Pathological changes in the soft tissues sutured to the bone which would prevent its secure fixation by the suture. Comminuted bone surface, which would compromise secure fixation of the MITEK Anchor. Physical conditions that would eliminate or tend to eliminate adequate implant support or retard healing, i.e., blood supply limitation, previous infections, etc. Conditions which tend to preempt the patient's ability or the healing period, such as senility, mental illness or alcoholism are contraindicated. Attachment of artificial ligaments or other implants. Reattachment of intracapsular knee ligaments (ACL & PCL).

WARNINGS

MITEK Anchors are designed to lock into cortical or cancellous bone. Bone stock must be adequate to allow proper and secure anchor placement. Nominal tension (about 8 lbs.) should be applied on the suture lengths to set the Anchor. DO NOT USE EXCESSIVE TENSION OR OVERLOAD THE ANCHOR. This could lead to device pullout or suture breakage. In the event a MITEK FASTIN RC Anchor must be removed, locate the Anchor by identifying the suture tract or with radiographic assistance. Remove any suture material remaining in the suture eyelet. Place the FASTIN RC inserter over the anchor hex and turn counter-clockwise to remove. If the anchor has been countersunk and can not be reached by the inserter, remove cortical bone with a small curette until the inserter fits into the anchor. Immediate range of motion should be avoided to allow biological bony/soft tissue healing. Do not use where pre-healing suture tension will exceed 20 lbs. for size #2 suture, as suture may fail. This device is not approved for screw attachment or fixation to the posterior element (pedicles) of the thoracic or lumbar spine. Inspect all instruments for damage before use. Do not attempt to repair. A surgeon should not begin clinical use of the MITEK Anchor without reviewing the instructions for use and practicing the procedure in a skills laboratory. As a braided, long-term suture, which is essentially absorbed over 1.5 to 2.5 years, PANACRYL long-term suture may act as a foreign body over an extended period of time. The surgeon should consider whether use of a long-term absorbable braided suture is appropriate in specific situations such as in wounds that carry an increased risk of infection or contamination.

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