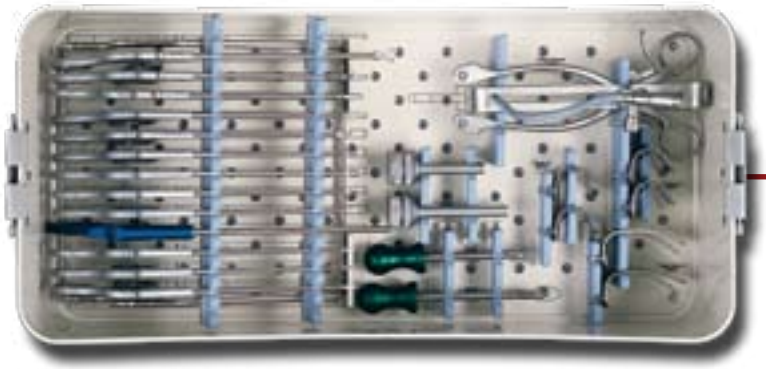
CHARLOTTE™
SHOULDER SYSTEM

ARTHROTEK®
A Biomet Company

Finally...

a complete

INSTRUMENTS



Tray 1
Hand Instruments
and RC Retractor

Tray 2
Portal Placement/
Miscellaneous Tray

Tray 3
Anchor Instrumentation/
Suture Management

shoulder system.

IMPLANTS

CHARLOTTE™ SHOULDER SYSTEM

In the last decade, orthopaedic surgeons have witnessed the development of arthroscopic techniques to manage labral tears, shoulder instability, and rotator cuff tears. Clinical results are now being reported that compare favorably to our traditional open procedures. As we learn and adapt these arthroscopic techniques to our own practices, operating rooms must have the necessary instrumentation available to efficiently address these shoulder lesions.

We have all experienced sending the circulating nurse scurrying out of the room to search for the equipment needed to repair an unanticipated labral lesion or to accomplish an arthroscopic rotator cuff repair. The Charlotte™ Shoulder System was designed to eliminate this problem via a comprehensive and versatile shoulder instrument set which can be utilized for carrying out the spectrum of arthroscopic and mini-open shoulder procedures. Resorbable screw-in suture anchors (for both cortical and cancellous bone) and disposable cannulas are available to complement the system.

We hope this system assists you and your operating room staff in performing successful arthroscopic shoulder surgery.

Patrick M. Connor, M.D.
Donald F. D'Alessandro, M.D.
Ortho Carolina, Charlotte, NC

Precision Hand Instruments

- Over 50 different instruments to choose from
- Tapered tube and shaft
- Oversized, ergonomic handle
- Dual cutting tips

Biters

- *Low profile, biting basket forceps allow easy access in tight spaces*
- *Many different types and angles to choose from including BackBiter® device right and left biter*

ArthroPasser™ Suture Retriever

- *Three different angles: 0°, 15° up, 45° up*
- *passes any type of suture*
- *sharp tip to assist in passing suture through tissue*

Suture Grasper

- *Dual-purpose ring suture grasper can either grasp the suture directly or retrieve suture by allowing it to slide freely through the ring*

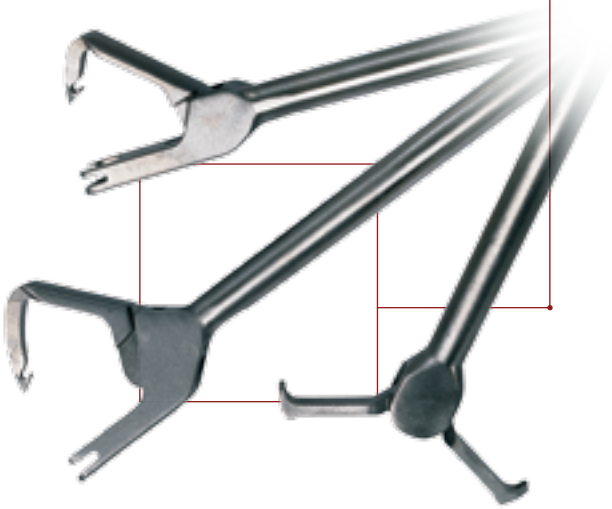
CHARLOTTE™ SHOULDER SYSTEM

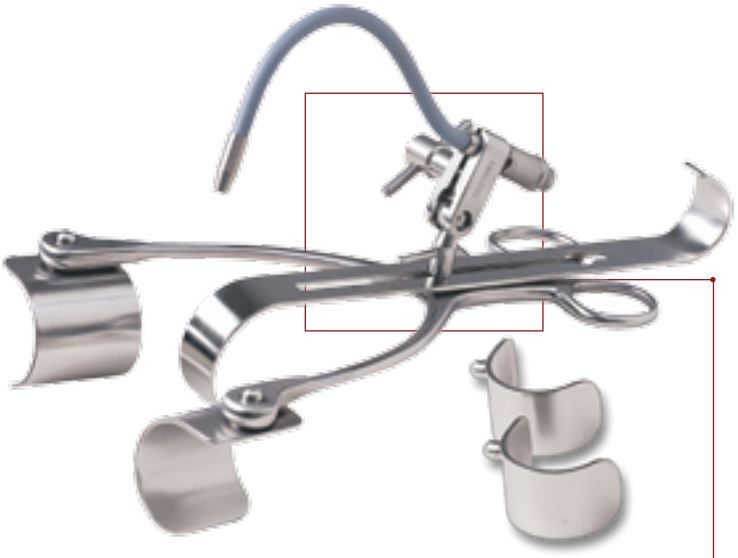
Caspari™ Suture Punch

- *Ability to pass any type of suture through soft tissue enabling placement of either mattress or simple stitches*
- *Does not require the use of shuttle relays*
- *Two sizes and various angles*
- *Can be utilized with any anchor that has a sliding suture*

Nordt™ Knot Tightener

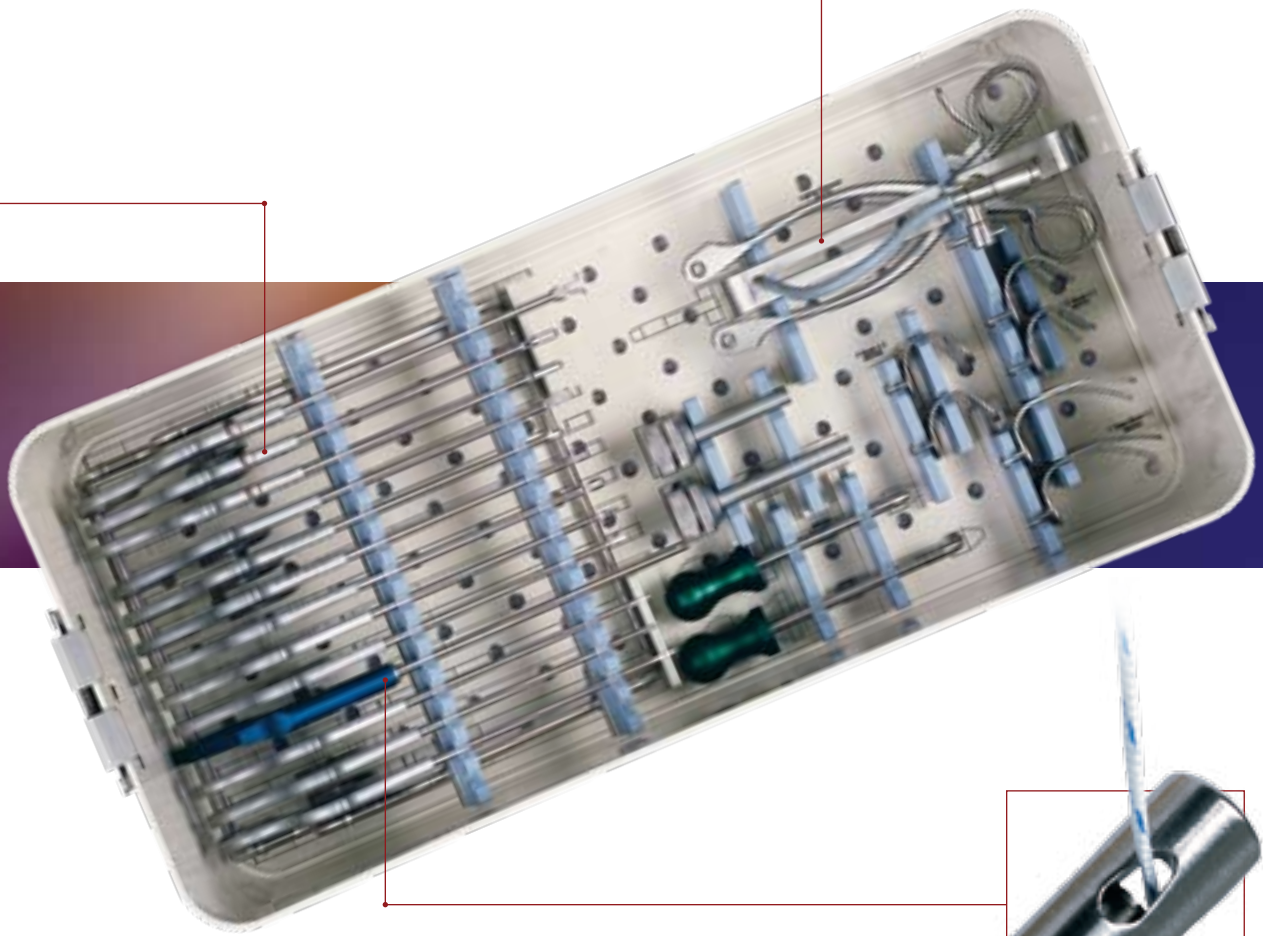
- *Allows both pushing and spreading of knots, reproducing the same technique used when tying traditional open knots.*
- *It can be used with any type of suture, and obviates the need to thread the suture through an eyelet*





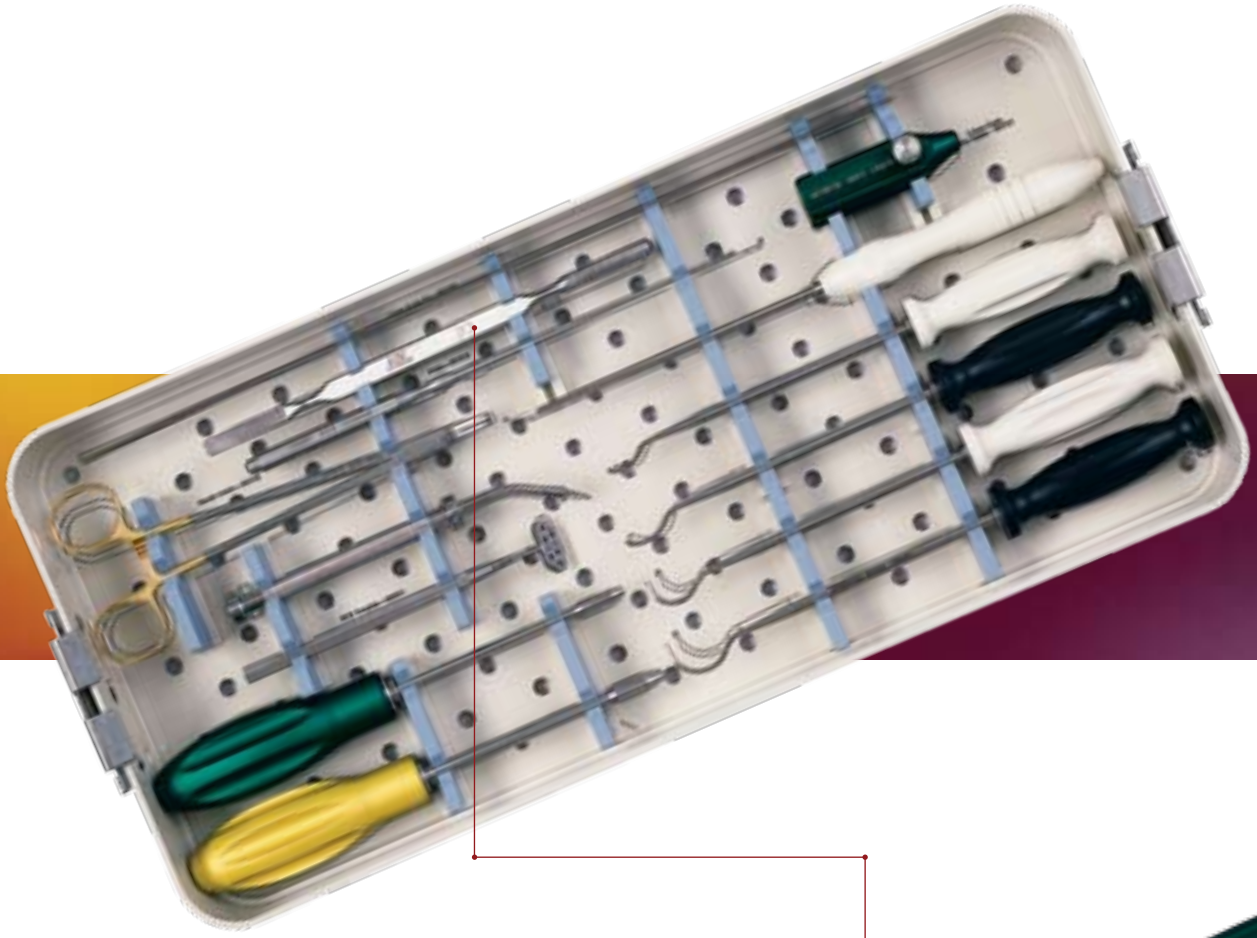
RC Retractor

- Several blade sizes allow for superficial or deep muscle retraction.
- Permits retraction in three different directions (medial, lateral, and inferior), ideal for open and mini-open repairs.
- The fiberoptic light cable is compatable with all arthroscopic light sources.



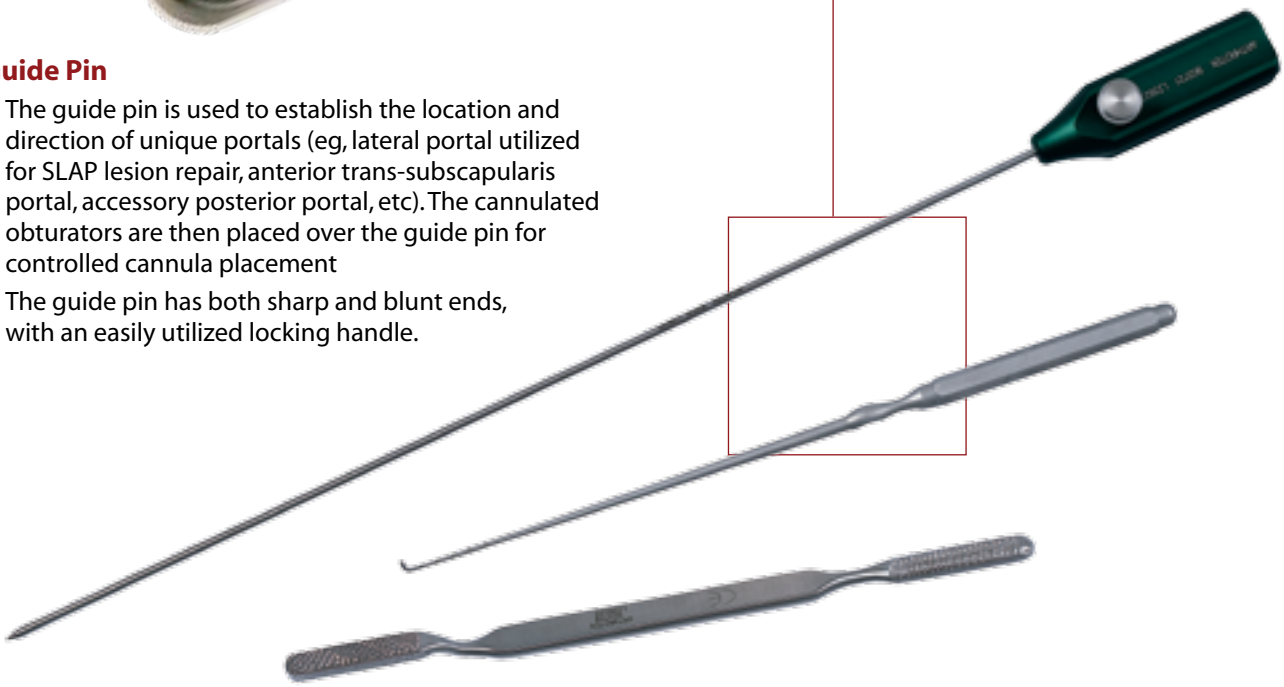
MaxCutter™ Suture Cutter

- Cuts any size and type of suture
- Ergonomic spring loaded handle
- Built-in knot pusher



Guide Pin

- The guide pin is used to establish the location and direction of unique portals (eg, lateral portal utilized for SLAP lesion repair, anterior trans-subscapularis portal, accessory posterior portal, etc). The cannulated obturators are then placed over the guide pin for controlled cannula placement
- The guide pin has both sharp and blunt ends, with an easily utilized locking handle.

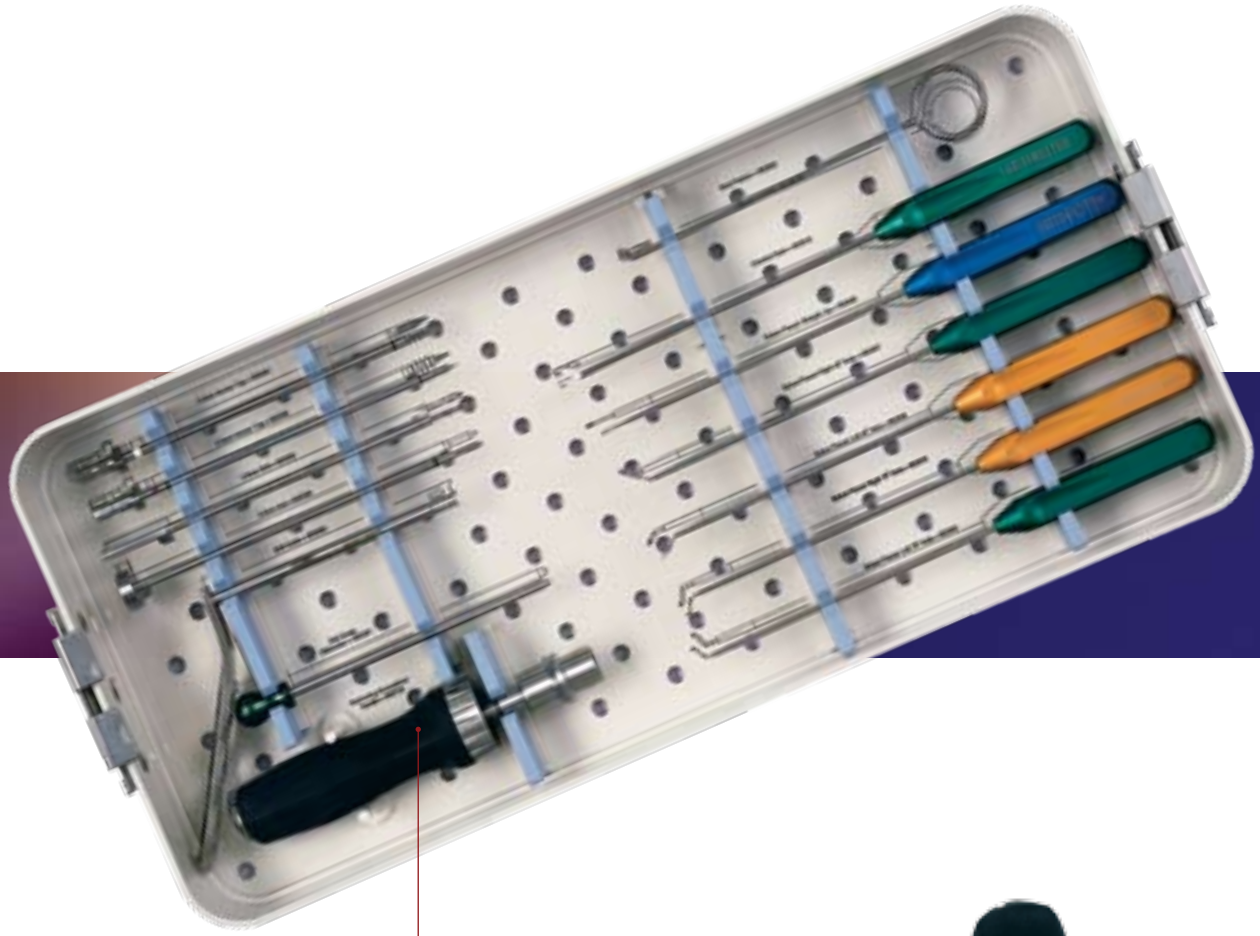


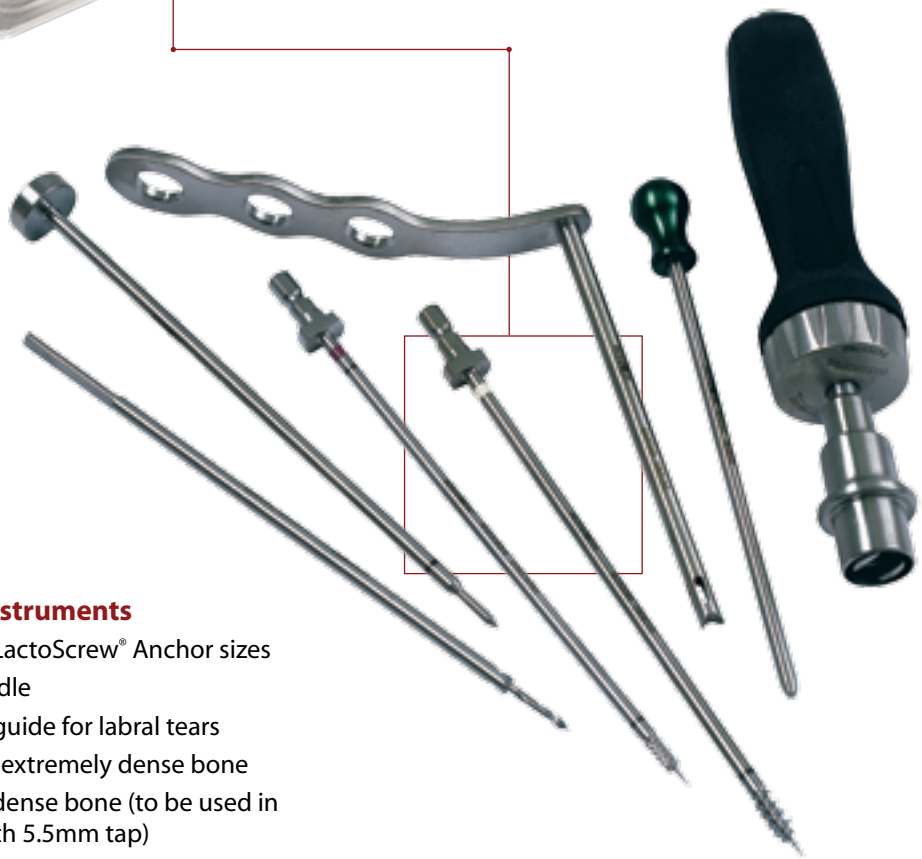
Calibrated Probe

- Ergonomically designed calibrated probe allows the surgeon to accurately quantify pathology.

Acromial Rasp

- Acromial rasp has aggressive teeth on one side and finer teeth on the other. In addition, offset and straight ends facilitate smooth, parallel planing of bony resection.





LactoScrew® Instruments

- Drill-tap for all LactoScrew® Anchor sizes
- Ratcheting handle
- Obturator and guide for labral tears
- 3.5 mm drill for extremely dense bone
- 5.5mm awl for dense bone (to be used in conjunction with 5.5mm tap)

LactoScrew® Suture Anchors

- 2.8, 3.5, 5.5, 6.8mm sizes for various indications
- LactoSorb® L15 material
- Simple insertion—Drill-tap only
- 5.5, 6.8mm available with or without needles
- Available with MaxBraid™ PE suture, Osteoprene™ resorbable suture or polyester suture

LactoSorb® L15 Material

- Low crystalline material
- Amorphous
- Maintains 80% of its strength at eight months[1]
- Resorbs in approximately 16 – 24 months[1]
- Clear radiographs
- Does not retard pediatric skeletal growth

1. Data on file at Arthrotek, Inc.

Ti-Screw Suture Anchors

Ti-Screw Suture Anchors with EasySlide™ Process

- 3.0, 5.0, 6.5mm sizes for various indications
- One step insertion – No drill or tap
- Can be repositioned if unsatisfied with initial location
- Tremendous pull-out strength[1]
- All sizes are available with two sutures
- All sizes are available with or without needles
- Available with MaxBraid™ PE Suture or polyester Suture

Ti-Screw SP Suture Anchors with EasySlide™ Process

- Independent eyelets ease suture sliding and management
- Double or triple suture loaded
- Fully threaded to achieve cortical fixation
- 5.0mm and 6.5mm options

EasySlide™ Surface Treatment

- More than doubles (132% increase) suture life during sliding[1]
- Increased performance of sliding knots
- Minimizes suture abrasion
- Does not alter the chemical or biological characteristics of the titanium alloy.

Ti-Screw SP Suture Anchor

1. Data on file at Arthrotek, Inc.
2. Data supplied by DSM Dyneema
3. Data on file at Arthrotek, Inc.

MaxBraid™ PE Suture

- 100% polyethylene
- Braided Dyneema® Purity Fibers are 15x stronger than steel on a weight for weight basis[2]
- Silky smooth feel is gentle on tissue and gloves
- Unique braid allows suture to lie flat and improves knot security

Osteoprene™ Resorbable Suture

- One of two sutures indicated for orthopedic indications
- Composed of 88% L-Lactide and 12% Trimethylene Carbonate (TMC)
- 73% loss of strength at three months and 52% at six months[3]
- Available as a #2 in white or violet
- Available on 3.5, 5.5mm LactoScrew® Suture Anchors

Package Inserts

Arthrotek, Inc.
A Wholly Owned Subsidiary of Biomet, Inc.
56 East Bell Drive
Warsaw, Indiana 46582 USA

01-50-1072
Date: 02/05

ARTHROTEK® SOFT TISSUE ANCHORING DEVICES
ATTENTION OPERATING SURGEON

DESCRIPTION

The Arthrotek® Soft Tissue Anchoring Devices are resorbable repair devices used to attach soft tissue to bone. LactoSorb® Soft Tissue Screw and Washer and MicroMax™ Suture Anchor are used with or without a suture. LactoSorb® L-15 Screw Anchors consist of a screw and head design and are used with a suture. The devices are implanted into a predrilled bone hole and are made of a resorbable copolymer, a polyester derivative of lactic acid and glycolic acid. Polylactic/polyglycolic acid copolymer degrades and resorbs *in vivo* by hydrolysis to lactic and glycolic acids, which are then metabolized by the body.

MATERIALS

Poly-L-Lactic Acid/Polyglycolic Acid
Ultra-High Molecular Weight Polyethylene (UHMWPE)
Polyester
Polypropylene

INDICATIONS

1. LactoScrew® L-15 Screw Anchor (85% PLLA/15% PGA):
   - **Shoulder**
     - Bankart repair
     - SLAP lesion repair
     - Acromio-clavicular separation
     - Rotator cuff repair
     - Capsule repair or capsulolabral reconstruction
     - Biceps tenodesis
     - Deltoid repair
   - **Wrist/Hand**
     - Scapholunate ligament reconstruction
     - Ulnar/radial collateral ligament reconstruction
   - **Ankle/Foot**
     - Lateral stabilization
     - Medial stabilization
     - Achilles tendon repair/reconstruction
     - Hallux valgus reconstruction
     - Mid- and forefoot reconstruction
   - **Elbow**
     - Tennis elbow repair
     - Ulnar or radial collateral ligament reconstruction
     - Biceps tendon reconstruction
   - **Knee**
     - Medial collateral ligament repair
     - Lateral collateral ligament repair
     - Posterior oblique repair
     - Joint capsule closure
     - Iiotibial band tenodesis
     - Patellar ligament/tendon repair

2. LactoSorb® L-15 Screw and Washer (85% PLLA/15% PGA) and MicroMax™ Suture Anchor:
   - **Shoulder Indications**
     - Bankart Repair
     - SLAP Lesion Repair
     - Acromio-clavicalur Separation Repair
     - Rotator Cuff Repair
     - Capsule Repair and Capsulolabral Reconstruction
     - Biceps Tenodesis
     - Deltoid Repair
   - **Wrist Indications**
     - Scapholunate ligament reconstruction
   - **Elbow Indications**
     - Tennis Elbow Repair
     - Biceps Tendon Reattachment
     - Medial and Lateral Repairs
     - Ulnar or Radial Collateral Ligament Reconstruction
   - **Knee Indications**
     - Extra-Capsular Repair
     - Medial Collateral Ligament Repair
     - Lateral Collateral Ligament Repair
     - Posterior Oblique Ligament Repair
     - Joint Capsule Closure
     - Iliotibial Band Tenodesis Reconstruction
     - Patellar Ligament/Tendon Repair
     - Vastus Medialis Obliquus (VMO) Muscle Advancement

LactoSorb® L-15 Screw and Washer and MicroMax™ Suture Anchor are preloaded with suture for use at the discretion of the physician.

CONTRAINDICATIONS

1. Active infection.
2. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
3. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone, or latent infections.
4. Pathologic soft tissue conditions, which would prevent secure fixation.

WARNINGS

Arthrotek® internal fixation devices provide the surgeon with a means to aid in the management of soft tissue to bone reattachment procedures. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy soft tissue or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of incomplete healing. Therefore, it is important that immobilization (use of external support, sling, etc.) of the treatment site be maintained until healing has occurred. Surgical implants are subject to repeated stresses in use, which can result in fracture or damage to the implant. Factors such as the patient's activity level and adherence to weight bearing or load bearing instructions have an affect on the service life of the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and polymeric aspects of the surgical implants.

1. Correct selection of the implant is extremely important. The potential for success in soft tissue to bone fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, the device is not designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
2. The implants can loosen or be damaged when subjected to increased loading associated with inadequate healing. If healing is delayed, or does not occur, the implant or the procedure may fail. Loads produced by weight bearing and activity levels may dictate the longevity of the implant.
3. Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or tissue supported by the device. Sufficient bone quantity and quality are important for adequate fixation and success of the procedure. Bone quality must be assessed at the time of surgery. Adequate fixation in diseased bone may be more difficult. Patients with poor quality bone, such as osteoporotic bone, are at greater risk of device loosening and procedure failure.
4. Care is to be taken to assure adequate soft tissue fixation at the time of surgery. Failure to achieve adequate fixation or improper positioning or placement of the device can contribute to a subsequent undesirable result.
5. The use of appropriate immobilization and postoperative management is indicated as part of the treatment until healing has occurred.
6. Correct handling of implants is extremely important. Do not modify implants. Do not notch or bend implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage. Intraoperative fracture of devices can occur if excessive force (torque) is applied while seating.
7. DO NOT USE if there is loss of sterility of the device.
8. Discard and DO NOT USE opened or damaged devices, and use only devices that are packaged in unopened or undamaged containers.
9. Ensure contact of tissue to bone when implanting. DO NOT OVERTIGHTEN the screw. Structural damage to the tissue and implant may occur if the screw is overtightened.
10. Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful soft tissue management. Patients affected with senility, mental illness, alcoholism, and drug abuse may be at a higher risk of device or procedure failure. These patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports that are intended to immobilize the repair site and limit weight bearing or load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy tissue, and that the device can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing. The patient is to be made aware and warned of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.
11. MicroMax™ Suture Anchor – Loss of bone fixation may occur if flanged wings are not properly deployed.

PRECAUTIONS

Instruments are available to aid in the accurate implantation of internal fixation devices. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Arthrotek recommends that all instruments be regularly inspected for wear and disfigurement.

If device contains MaxBraid™ suture, refer to manufacturer package insert for further information.

POSSIBLE ADVERSE EFFECTS

1. Infection can lead to failure of the procedure.
2. Neurovascular injuries can occur due to surgical trauma.
3. Bending, fracture, loosening, rubbing, and migration of the implant may occur as a result of excessive activity, trauma, or load bearing.
4. Implantation of foreign materials can result in an inflammatory response or allergic reaction.
5. Inadequate healing.
6. Pain, discomfort, or abnormal sensation due to the presence of the device.
7. Necrosis of the bone or tissue.

STERILITY

Arthrotek® resorbable implants are sterilized by exposure to Ethylene Oxide (ETO) Gas. Do not resterilize. Do not use past expiration date.

STORE AT OR BELOW ROOM TEMPERATURE. DO NOT EXPOSE PRODUCT TO TEMPERATURES GREATER THAN 120°F OR 49°C.

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

Authorized Representative:
Biomet U.K., Ltd.
Waterton Industrial Estates
Bridgend, South Wales
CF31 3XA U.K.
CE 0086

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Arthrotek at the contact information provided herein.

Distributed by:
Arthrotek, Inc.
A Wholly Owned Subsidiary of Biomet, Inc.
56 East Bell Drive
Warsaw, Indiana 46582 USA

01-50-1134
Date: 08/05

MaxBraid™
POLYETHYLENE SUTURE
Non-absorbable Surgical Suture
U.S.P. except for oversized diameter.

Sterile: Contents sterile unless package has been opened or damaged. Single Use Only, Do Not Resterilize.

DESCRIPTION

MaxBraid™ Polyethylene Surgical Suture is a nonabsorbable, sterile surgical suture composed of ultra high molecular weight polyethylene. MaxBraid™ Polyethylene Suture is provided braided as a co-braid of undyed polyethylene and blue monofilament polypropylene or undyed (white). MaxBraid™ sutures are U.S.P. except for diameter in the following sizes:

Suture Size	USP Ave Diameter Specification (mm) <861>	Maximum Oversize Average Diameter (mm)	Maximum Oversize Average Diamter from USP (mm)
2-0	0.300 – 0.339	0.363	0.024
0	0.350 – 0.399	0.459	0.060
1	0.400 – 0.499	0.574	0.075
2	0.500 – 0.599	0.617	0.018

MaxBraid™ sutures exceed USP specifications for diameter.

INDICATIONS

MaxBraid™ Polyethylene Nonabsorbable Surgical Sutures are indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

ACTIONS

MaxBraid™ Polyethylene Surgical Suture elicits a minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue.

WARNINGS

Do not resterilize. Do not use if package is opened or damaged. Discard open, unused sutures.

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing Polyethylene Surgical Suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in urinary or biliary tracts, may result in calculus formation. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

PRECAUTIONS

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders. Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon.

Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

This device should be handled and disposed of in accordance with all applicable regulations including, without limitation, those pertaining to human health and safety and the environment.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include: wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infected wounds, minimal acute inflammatory tissue reaction, and transitory local irritation.

HOW SUPPLIED

MaxBraid™ Polyethylene Surgical Suture is available in USP sizes 2-0 through 2 (metric sizes 3 through 5). MaxBraid™ Surgical Suture is provided sterile as a co-braid of undyed polyethylene and blue monofilament polypropylene or undyed (white).

The suture is provided in a variety of lengths, with and without needles, with or without pledgets, and may be supplied in a variety of cut lengths or on ligating reels. Finished suture may be packaged in cartons as single packs, multipacks, or procedure packs.

STERILITY

MaxBraid™ Polyethylene Nonabsorbable Surgical Sutures are sterilized by exposure to Ethylene Oxide (ETO) Gas. Do not resterilize. Do not use past expiration date.

MaxBraid™ is a trademark of Arthrotek, Inc.

Caution: Federal law (USA) limits this device to sale or use by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-1683.

Manufacturer: Teleflex Medical
600 Airport Road
Fall River, MA 02720 USA
508-677-6600

Telephone 800-367-7874 (USA only)
+1-508-677-6600

Suture CE marked by Teleflex

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Arthrotek at the contact information provided herein.

Package Inserts

Arthrotek, Inc. 01-50-1018
A Wholly Owned Subsidiary of Biomet, Inc.
P.O. Box 587 Date: 09/05
56 East Bell Drive
Warsaw, Indiana 46581 USA

Arthrotek® Internal Fixation Devices
Attention Operating Surgeon

DESCRIPTION

Arthrotek manufactures a variety of internal fixation devices intended to aid in arthroscopic and orthopedic reconstructive procedures requiring soft tissue fixation, due to injury or degenerative disease. Implants used for this application include: screws, washers, anchors, pins, and suture. Specialty implants are available for specialized treatments.

Materials:

316 LVM Stainless Steel
Titanium Alloy
Ultra-High Molecular Weight Polyethylene (UHMWPE)
Polyester

INDICATIONS

The Metal Screw Anchor and the Harpoon® Suture Anchor are indicated for use in soft tissue reattachment procedures in the shoulder, wrist, elbow, and knee. Specific indications as follows:

Shoulder Indications—Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair.

Wrist/Hand Indications—Scapholunate ligament reconstruction, ulnar/radial collateral ligament reconstruction.

Ankle/Foot Indications—Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, mid- and forefoot reconstruction.

Elbow Indications—Ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction.

Knee Indications—Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis, and patellar ligament/tendon repair.

Bone Mulch® Screws are intended for use in fixation of semitendinous and/or gracile tendon grafts in ACL reconstruction, only.

Interference Screws and Set Screws are intended for use in fixation of patellar bone-tendon-bone grafts in ACL reconstruction.

Screw and Washers are indicated for soft tissue fixation to bone, and bone to bone fixation in orthopedic procedures specifically during Ligament reconstruction.

Toggle anchors (ie. toggle buttons and EZLoc™) are indicated for use for fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) Reconstruction.

Patient selection factors to be considered include: 1) need for soft tissue to bone fixation, 2) ability and willingness of the patient to follow postoperative care instructions until healing is complete, and 3) a good nutritional state of the patient.

CONTRAINDICATIONS

1. Infection.
2. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone or soft tissue.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

WARNINGS

Arthrotek® internal fixation devices provide the surgeon with a means to aid in the management of soft tissue to bone reattachment procedures. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of nonunion, delayed union, or incomplete healing. Therefore, it is important that immobilization (use of external support, walking aids, braces, etc.) of the treatment site be maintained until healing has occurred. Surgical implants are subject to repeated stresses in use, which can result in fracture or damage to the implant. Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the service life of the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and metallurgical aspects of the surgical implants.

1. Correct selection of the implant is extremely important. The potential for success in soft tissue to bone fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, neither the device nor grafts, when used are designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
2. The implants can loosen or be damaged and the graft can fail when subjected to increased loading associated with nonunion or delayed union. If healing is delayed, or does not occur, the implant or the procedure may fail. Loads produced by weight bearing, and activity levels may dictate the longevity of the implant.
3. Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or tissue supported by the device. Sufficient bone quantity and quality are important to adequate fixation and success of the procedure. Bone quality must be assessed at the time of surgery. Adequate fixation in diseased bone may be more difficult. Patients with poor quality bone, such as osteoporotic bone, are at greater risk of device loosening and procedure failure.
4. Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants. Every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e., screws and plates.
5. Correct handling of implants is extremely important. Do not modify implants. Do not notch or bend implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage. Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws.
6. Do not use excessive force when inserting suture anchors. Excessive force (long hard hammer blows) may cause fracture or bending of the device. When encountering hard cortical bone, predrill with a 3/32 or 1/8 inch drill prior to inserting suture anchors.
7. Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful fracture management. Patients effected with senility, mental illness, alcoholism, and drug abuse may be at a higher risk of device or procedure failure. These patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports, walking aids, and braces that are intended to immobilize the fracture site and limit weight bearing or load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing. The patient is to be made aware and warned of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.

PRECAUTIONS

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat with implants that have been even momentarily placed in a different patient.

Instruments are available to aid in the accurate implantation of internal fixation devices. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Arthrotek recommends that all instruments be regularly inspected for wear and disfigurement.

If device contains MaxBraid™ suture, refer to manufacturer package insert for further information.

POSSIBLE ADVERSE EFFECTS

1. Nonunion or delayed union, which may lead to breakage of the implant.
2. Bending or fracture of the implant.
3. Loosening or migration of the implant.
4. Metal sensitivity, or allergic reaction to a foreign body.
5. Pain, discomfort, or abnormal sensation due to the presence of the device.
6. Nerve damage due to surgical trauma.
7. Necrosis of bone or tissue.
8. Inadequate healing.
9. Intraoperative or postoperative bone fracture and/or postoperative pain.

STERILITY

Arthrotek® internal fixation implants are typically supplied sterile and are sterilized by exposure to a minimum dose of 25kGy of gamma radiation or by Ethylene Oxide Gas (ETO) if device contains MaxBraid™ PE suture. If supplied sterile, do not resterilize the implant.

If not supplied sterile, metallic internal fixation devices must be sterilized prior to surgical use. Do not sterilize UHMWPE implants using steam autoclaving methods. Do not use implants after expiration date.

Pre-VacuumSteam (HI-VAC) -- wrapped or unwrapped

Temperature	270°-275° F (132°-135°C)
Exposure Time	5 Minutes
Drying Time	8 Minutes

Since Arthrotek is not familiar with individual hospital handling methods, cleaning methods and bioburden, Arthrotek cannot assume responsibility for sterility even though the guideline is followed.

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

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estates,
Bridgend, South Wales
CF31 3XA, U. K.

CE 0086

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Arthrotek at the contact information provided herein.

Ordering Information

2.8mm LactoScrew® Suture Anchors	
905494	Long with one #2 MaxBraid™ Suture
905495	Short with One #2 MaxBraid™ Suture with Needles

3.5mm LactoScrew® Suture Anchors	
905573	One #2 Blue Polyester Suture
905570	One #2 MaxBraid™ Suture
905591	One #2 MaxBraid™ Suture with AutoKnot™ Pre-Tied Knot

3.5mm LactoScrew® LS Suture Anchors	
905482	Two 2-0 MaxBraid™ Sutures
905493	One, #2 MaxBraid™ Suture
905483	One #2 Polyester Suture
CP9055593	One #2 Osteoprene™ Resorbable Suture

5.5mm LactoScrew® Suture Anchors	
905571	Two #2 MaxBraid™ Sutures with Needles
905572	Two #2 MaxBraid™ Sutures
905575	Two #2 MaxBraid™ Sutures with Cutting Needles
905592	Two #2 MaxBraid™ Sutures with AutoKnot™ Pre-Tied Knot
905491	Two #2 MaxBraid™ Sutures with Needles (Pkg. 2)

5.5mm LactoScrew® LS Suture Anchors	
905490	Two #2 MaxBraid™ Sutures (Pkg. 2)
905496	Two #2 MaxBraid™ Sutures
CP905596	Two #2 Osteoprene™ Sutures with Needles
CP905597	Two #2 Osteoprene™ Suture

6.8mm LactoScrew® Suture Anchors	
905580	Two #2 MaxBraid™ Sutures
905581	Two #2 MaxBraid™ Sutures with Cutting Needles

3.0mm Ti-Screw Suture Anchors	
902554	One #2 Blue Suture

5.0mm Ti-Screw Suture Anchors	
902556	Two #2 Blue Suture

3.0mm Ti-Screw EasySlide™ Suture Anchors	
902574	One #2 Blue Suture
902578	One #2 Blue Suture with Needles
902482	Two 2-0 MaxBraid™ Sutures
902482	Two 2-0 MaxBraid™ Sutures
902569	One #2 MaxBraid™ Sutures with Needles
902570	One #2 MaxBraid™ Suture

5.0mm Ti-Screw EasySlide™ Suture Anchors	
902576	Two #2 Sutures
902579	Two #2 Sutures with Needles
902571	Two #2 MaxBraid™ Sutures with Needles
902572	Two #2 MaxBraid™ Sutures
902596	Two #2 MaxBraid™ Sutures with Needles

6.5mm Ti-Screw EasySlide™ Suture Anchors	
902580	Two #2 Sutures with Needles
902573	Two #2 MaxBraid™ Sutures
902587	Two #2 MaxBraid™ Sutures with Needles

5.0mm Ti-Screw SP Suture Anchors	
902588	Two #2 MaxBraid™ Sutures with Needles
902591	Two #2 MaxBraid™ Sutures
902597	Three #2 MaxBraid™ Sutures
902598	Three #2 MaxBraid™ Sutures with Needles

6.5mm Ti-Screw SP Suture Anchors	
902589	Two #2 MaxBraid™ Sutures with Needles
902592	Two #2 MaxBraid™ Sutures with Needles
902599	Three #2 MaxBraid™ Sutures
902600	Three #2 MaxBraid™ Sutures with Needles

Ordering Information

Tray #1—Hand Instruments/ RC Retractor

Charlotte™ Shoulder System Tray #1

903730

Charlotte™ Shoulder System Retractor

903705	Body
903704	Deep Blade, 1 Pair
903706	Small Blade, 1 Pair
903707	Large Blade, 1 Pair

Grasper

902075	2.75mm
902083	3.4mm

15˚ Angulated Up Low Profile Biter

902733	3.4mm

Nordt™ Knot Tightener

901477

MicroShears

902076	2.75mm

Caspari™ Suture Punch

901070	Straight
902070	Mini

Oval Cannula

900419	50mm Small
900421	70mm Small

Oval Cannulated Obturator

900459	50mm Small
900461	70mm Small

ArthroPasser™ Retreiving Device

902800	2.75mm 15 ˚ Up
902801	2.75mm Straight
902802	2.75mm 45˚ Up

Tray #2—Portal Placement/ Miscellaneous

Charlotte™ Shoulder System Tray #2

903731

Charlotte™ Shoulder System Shoulder Rasp

903709

Guide Pin

903720	Pin
903721	Handle

Calibrated Probe

901010

Charlotte™ Shoulder System Needle Driver

903708

RC Buttress Template

905971

RC Buttress Awl

905972

Curved Rasp with Elevator

903719

Reusable Cannula Obturator

900328	7mm
900370	9mm

Charlotte™ Shoulder System Tunnel Awl

903710	Small
903712	Large

Charlotte™ Shoulder System Tunnel Retriever

903714	Small
903716	Large

Tray #3—Anchor Instrumentation/ Suture Management

Charlotte™ Shoulder System Tray #3

903732

LactoScrew® Tap

905584

Screw/Anchor Tap

905586	5.5mm

LactoScrew® Drill

905585	3.5mm

Screw/Anchor Awl

905588	5.5mm

Drill Guide Obturator

905561

Ratchet Handle

909733

Open Knot Pusher

902803

Suture Crochet Hook

903610

SpeedPass™ Suture Retriever—Reusable

902804	70˚ Left Pigtail—Reusable
902805	70˚ Right Pigtail—Reusable
902806	45˚ Left Pigtail—Reusable
902807	45˚ Right Pigtail—Reusable
902808	70˚ Straight Up—Reusable

Miscellaneous

Charlotte™ Shoulder System Tray #5

903734

Charlotte™ Shoulder System Tray Lid

903740

Caspari™ Suture Punch

Caspari™ Suture Punch

901070	Straight
901070HP	Straight—High Performance

Caspari™ Mini Suture Punch

902070	Straight
902070HP	Straight—High Performance
902071	Left
902071HP	Left—High Performance
902072	Right
902072HP	Right—High Performance
902073	15˚ Up
902073HP	15˚ Up—High Performance

Caspari™ Suture Punch/ Hand Instrument Case

902095

Nordt™ Knot Tightener

Nordt™ Knot Tightener

901477
901477HP High Performance

Ti-Screw Instruments

1.5mm Drill Bit

Ordering Information

902562

Ti-Screw Anchor Tap

902565	5.0mm
902566	3.0mm

Additional LactoScrew® Instruments

LactoScrew® Anchor Tap

905587	6.8mm
905497	2.8mm

LactoScrew® Anchor Drill

905492	2.8mm

ARTHROTEK®

A BIOMET COMPANY

P.O. Box 587, Warsaw, IN 46581-0587 • 800.348.9500 ext. 1501 •
web site: www.arthrotek.com • eMail: arthrotek@arthrotek.com
Form No. Y-BMT-960/033106/K

INVENTING THE FUTURE OF ARTHROSCOPY