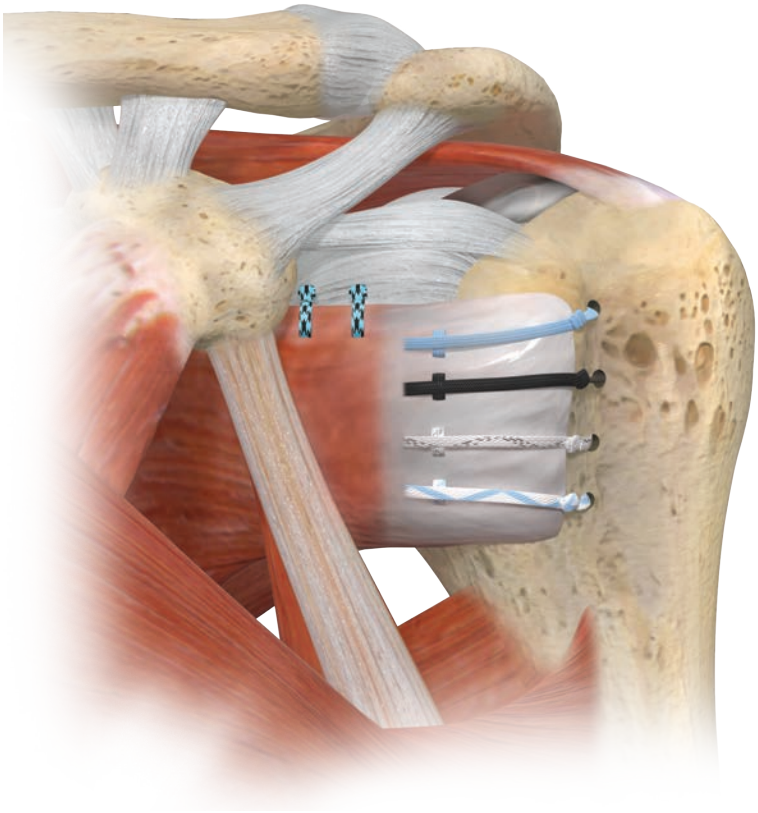
ZIMMER BIOMET

Subscapularis Repair Kit for TSA and RSA

Basic Kit (Modified Mason-Allen Stitch)

Surgical Technique



Introduction

The Zimmer Biomet Subscapularis Repair Kit was designed to facilitate transosseous subscapularis repair during Total Shoulder Arthroplasty (TSA) and Reverse Shoulder Arthroplasty (RSA).

The sterile kits give the surgeon a comprehensive suture and tape configuration for soft tissue and fracture management with multiple needle and color configurations.

Intended for a standard Mason-Allen stitch technique, the Basic Subscapularis Repair Kit includes 9 total sutures with a drill bit:

- 2 Tagging Sutures – USP 2 MaxBraid™ strands with 36mm tapered needles
  - Intended to "tag" the subscap and mobilize at the beginning of total shoulder case
- 2 Shuttle Sutures – USP 2 MaxBraid™ strands with an 8" working length and 5" loop length
  - One 36mm reverse cutting needle
  - One 48mm conventional cutting needle
    - Shuttles are intended to pass suture through bone tunnels. There are two different needle options as well
- 4 Repair Strands – 1.5mm BroadBand™ Tape repair strands with tapered needles
- 1 Closure Suture – 1.5 mm BroadBand™ Tape with 36mm tapered needles
- 1 Drill Bit – 2mm drill bit to drill suture tunnels

Descriptions

- BroadBand™ / MaxBraid™ sutures are non-absorbable, sterile, surgical sutures composed of ultra high molecular weight polyethylene (UHMW PE). These braided sutures are available uncoated or coated uniformly with polybutylene adipate or silicone to increase surface lubricity, thereby enhancing the handling characteristics, ease of passage through tissue, and knot run-down properties for security. BroadBand™ / MaxBraid™ sutures are inert and elicit only minimal local tissue reaction. The suture braid is available undyed (white), dyed blue, dyed black or with trace filaments of black, blue or green suture for color. BroadBand™ / MaxBraid™ sutures meet all requirements established by the United States Pharmacopeia (USP) for non-absorbable surgical sutures except where indicated on the individual unit package.
- Single use drill bits are composed of medical grade stainless steel. The drill bits are available in 50mm - 200mm lengths and 0.25mm – 6.5mm diameters. Single use drill bits should only be used in conjunction with a compatible standard power drill.

Indications and Contraindications

BroadBand™ Tape MaxBraid™ Suture

INDICATIONS: BroadBand™ / MaxBraid™ sutures are indicated for use in general soft tissue approximation and/or ligation and the use of allograft tissues for orthopedic surgeries, but are not for use in cardiovascular procedures. BroadBand™ / MaxBraid™ sutures are intended for one-time use only, and are not to be re-sterilized.

ACTIONS: BroadBand™ / MaxBraid™ sutures elicit a minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. BroadBand™ / MaxBraid™ sutures are not absorbed, nor is there any significant change in tensile strength retention known to occur in vivo.

CONTRAINDICATIONS: None known.

WARNINGS: As with any foreign body, prolonged contact of any suture with salt solutions may result in calculus formation. Discard opened or unused sutures. Do not resterilize. Users should be familiar with surgical procedures and techniques involving sutures before employing BroadBand™ / MaxBraid™ non-absorbable sutures for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used. 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. The use of additional throws may be particularly appropriate when knotting monofilaments.

Single Use Drill Bit

INDICATIONS: Single use drill bits are indicated for use in general orthopedic procedures to manipulate tissue, or for use with other devices in orthopedic surgery. Single use drill bits are intended for one-time use only, and are not to be re-sterilized, reprocessed, or implanted.

CONTRAINDICATIONS: None known.

WARNINGS: Discard opened or unused drill bits. Do not resterilize. Do not use more than once as there is risk of metal fatigue or transfer of biological material. For proper aseptic presentation, inspect pouch immediately before use and carefully open pouch at the top flap until almost the entire drill bit is free to remove. Do not use if the sterility may be compromised as there can be an increased risk of infection. Users should be familiar with surgical procedures and techniques involving drill bits before employing single use drill bits in orthopedic procedures. Do not grab single use drill bits by the sharp body including point end. Users should always use caution when handling the sharp instruments to avoid any injury and/or damage to protective gears. Patients with known sensitivity or allergy to single use drill bits materials should not use this device. No drill bit material should be left in the body. Do not use single use drill bit after its expiration date.

Surgical Technique

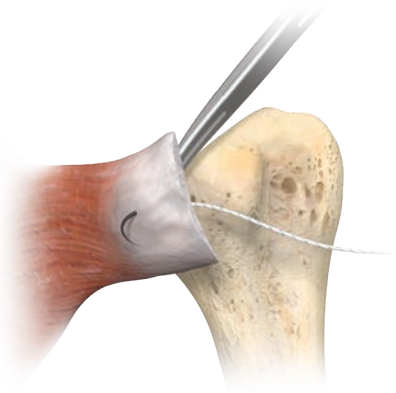


Figure 1

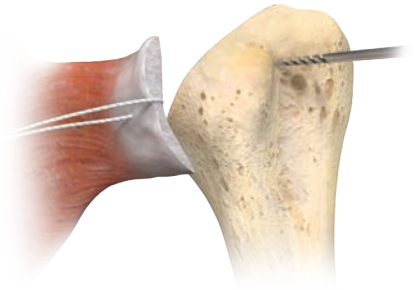


Figure 3

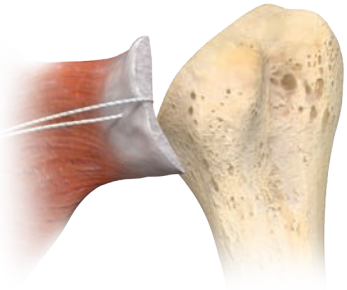


Figure 2

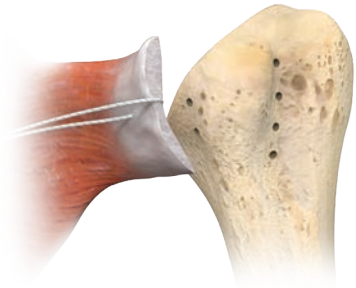


Figure 4

1. Prepare the Humerus and Tag Subscapularis

Mobilize the subscapularis tendon using TAG suture.

Prepare the humerus following standard total shoulder arthroplasty techniques (Figures 1 and 2).

2. Transosseus Tunnel Preparation

Drill four lateral transosseus holes in the bicipital groove using the 2.0mm drill bit and two medial holes on the provided edge of the lesser tuberosity (Figures 3 and 4).

Note: The quantity and location of the fixation points is dependent on the surgeon's preferences. Tie patterns can differ from surgeon to surgeon.

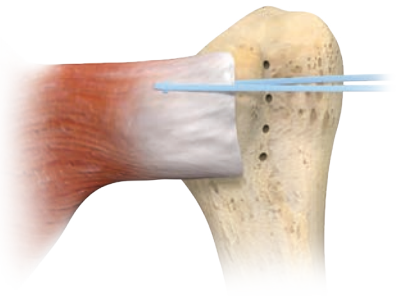


Figure 5

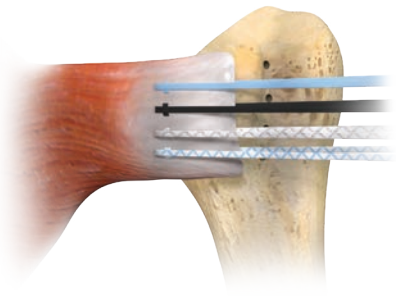


Figure 6

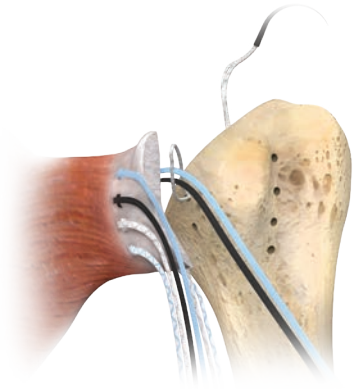


Figure 7

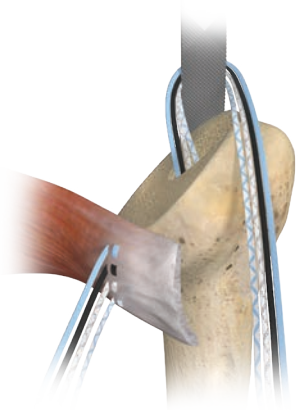


Figure 8

3. Stitch Subscapularis with Four Modified Mason-Allen Stitches

Pass repair suture tape in the subscapularis tendon using modified Mason-Allen stitch pattern and remove needle (Figure 5).

Repeat with the remaining repair strands (Figure 6).

Note: Location and type of stitch may vary from surgeon to surgeon.

4. Shuttle Repair Strands Through Medial Tunnels.

Shuttle one suture limb from each of the two superior repair strands through the superior medial tunnel and into the intramedullary canal using the suture shuttles from the kit (Figure 7).

Shuttle one suture limb from each of the two inferior repair strands through the inferior medial tunnel and into the intramedullary canal using the suture shuttles.

Note: Ensure the correct suture tape limbs are shuttled through the tunnels.

Leave slack so the sutures can loop around the stem. A retractor may be used to hold the sutures and help in suture management (Figure 8).

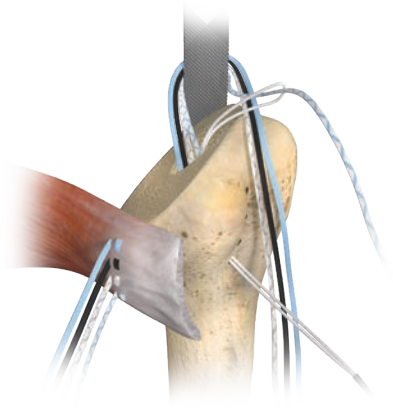


Figure 9

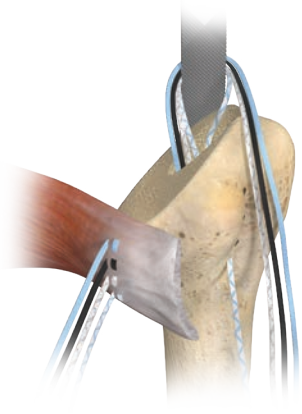


Figure 10

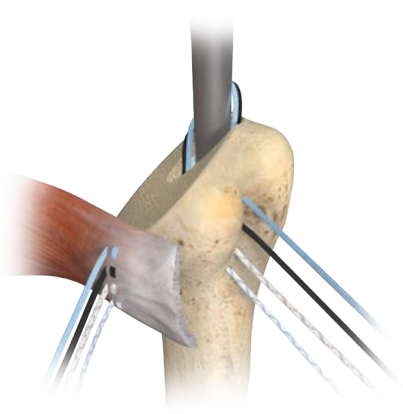


Figure 12

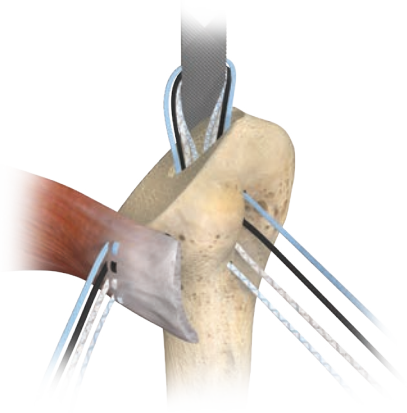


Figure 11

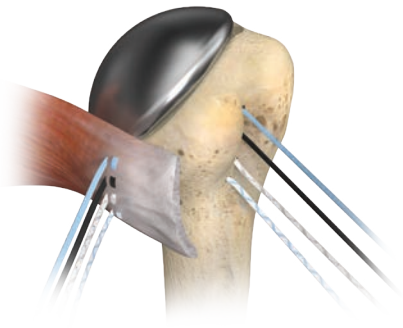


Figure 13

5. Shuttle Repair Strands Through Lateral Tunnels

Shuttle the inferior stitch suture through the most inferior lateral tunnel (Figures 9 and 10).

Repeat the steps for the remaining sutures so that one repair strand is through each lateral tunnel (in the same inferior to superior order in which they were passed through the subscap) (Figure 11).

6. Insert Stem

Insert the stem: The suture strands should wrap around the stem.

Remove slack from sutures.

Impact the stem into the humerus, securing the sutures in place (Figures 12 and 13).

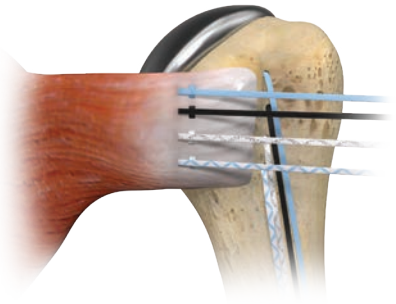


Figure 14

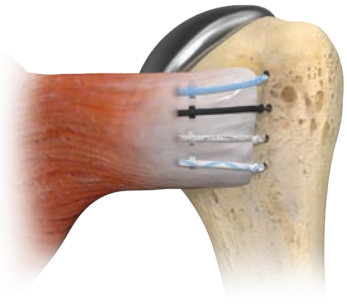


Figure 15

7. Repair the Subscapularis

Reduce tissue and tie knots between like colored repair sutures to complete the repair.

Place the knots in the bicipital groove (Figures 14 and 15).

Note: Desired tie pattern may differ from surgeon to surgeon.

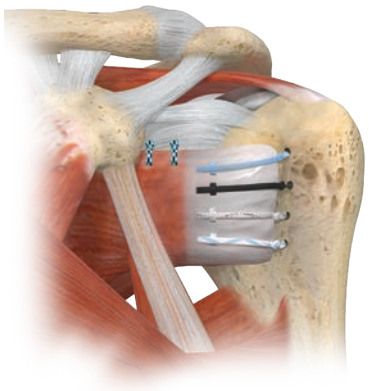


Figure 16

8. Close Rotator Cuff Interval

Close rotator cuff interval with closing sutures if preferred (Figure 16).

Ordering Information

Basic Subscapularis Repair Kit for TSA and RSA

Part #	Description
110046602	Basic Subscapularis Repair Kit for Mason-Allen Stitch, 9 sutures

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Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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ZIMMER BIOMET

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