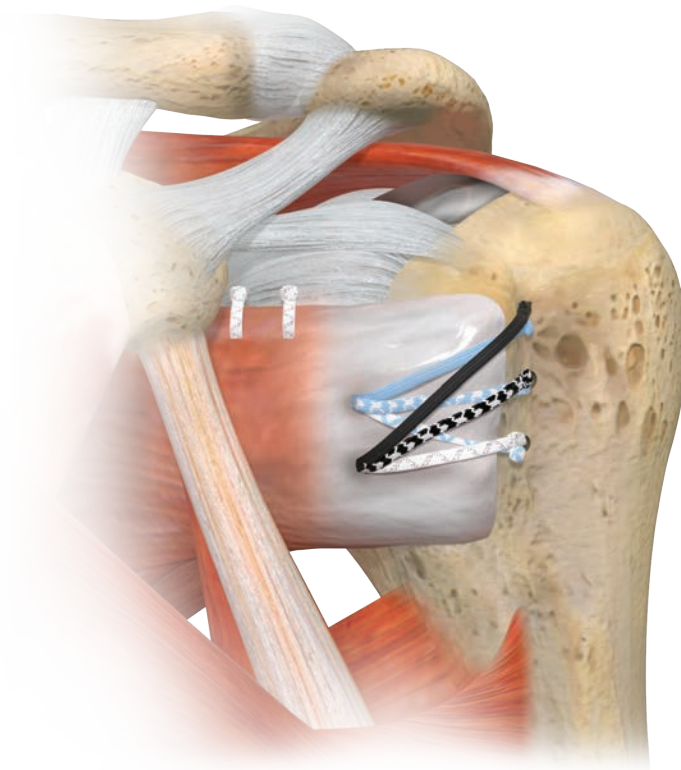


Subscapularis Repair Kit for TSA and RSA

Ultra Kit - Large Footprint Compression Repair

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 more in-depth subscap peel technique, the Ultra Subscapularis Repair Kit includes 13 total sutures with 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
- 3 Shuttle Sutures – USP 2 MaxBraid™ strands with an 8” working length and 5” loop length
 - One 36mm Reverse Cutting Needle
 - One 40mm Taper Needle
 - One 48mm Conventional Cutting Needle
- 3 Dual BroadBand™ Strand Repair Sutures (6 total repair strands)
- 2 Closure Sutures – 1.5 mm BroadBand™ Tape with 36mm tapered needles
- One 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

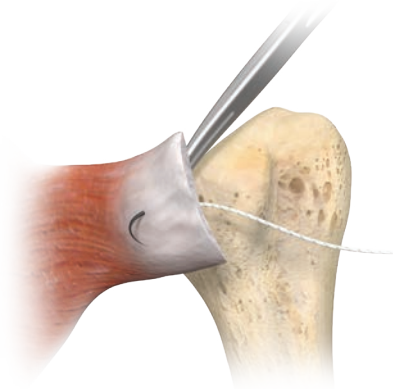


Figure 1

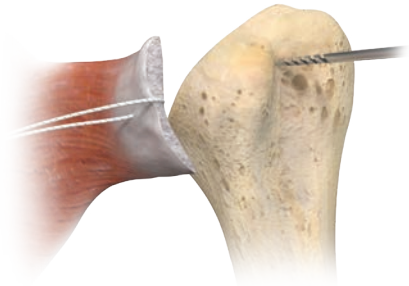


Figure 3

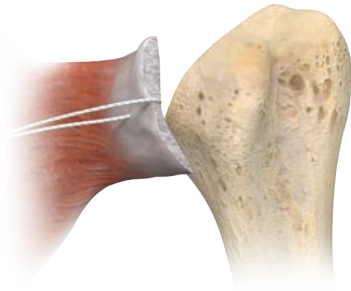


Figure 2

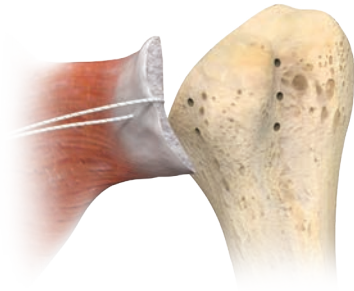


Figure 4

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 three lateral transosseus holes in the bicipital groove using the 2.0mm drill bit and two medial holes in the proximal 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.

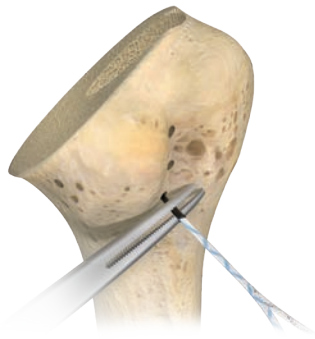


Figure 5

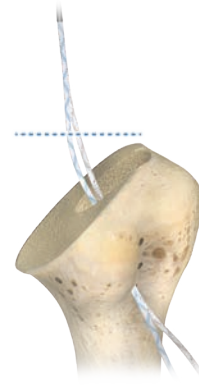


Figure 7

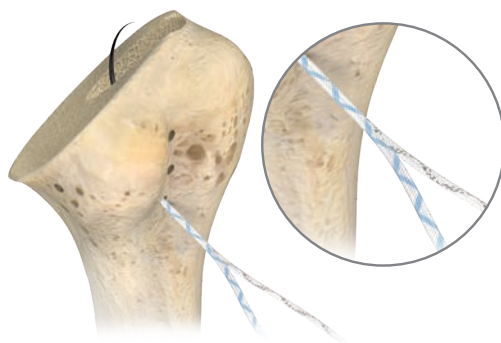


Figure 6



Figure 8

3. Pass Repair Strands Through the Lateral Tunnels

Use the curved needle to pass the dual-strand suture tape through the inferior hole in the bicipital groove and into the intermedullary canal (Figures 5 and 6).

Separate sutures into individual strands by cutting off the needle after the suture junction (Figure 7).

Repeat the steps with the additional repair suture tapes through other lateral tunnels.

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

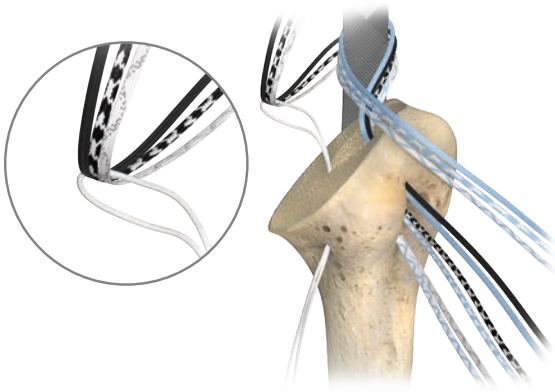


Figure 9

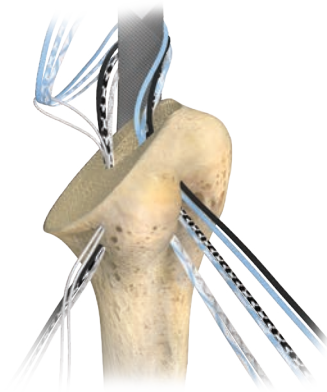


Figure 11

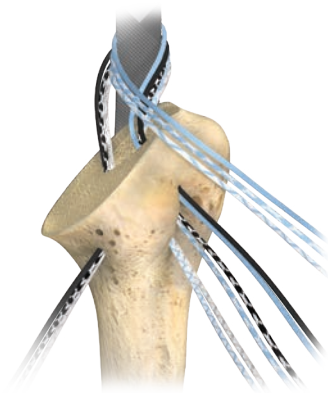


Figure 10

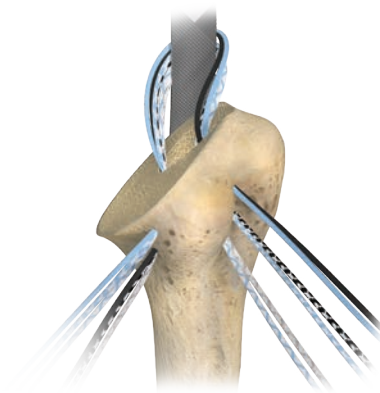


Figure 12

4. Shuttle Repair Strands Through Medial Tunnels

Shuttle the three black and white sutures through the inferior hole in the lesser tuberosity (Figures 9 and 10).

Shuttle the three blue and white sutures through the superior hole in the lesser tuberosity (Figures 11 and 12).

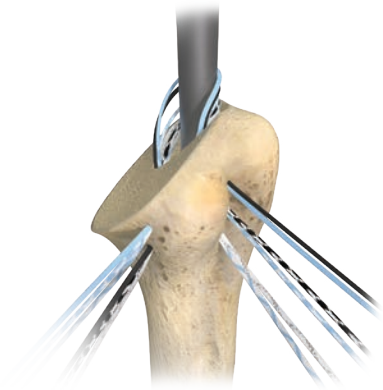


Figure 13

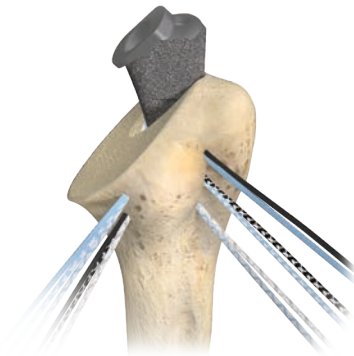


Figure 14

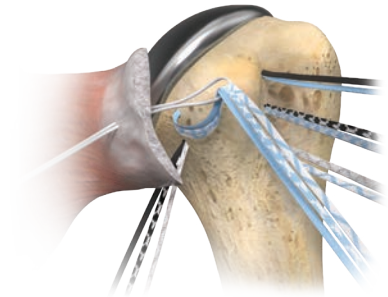


Figure 16

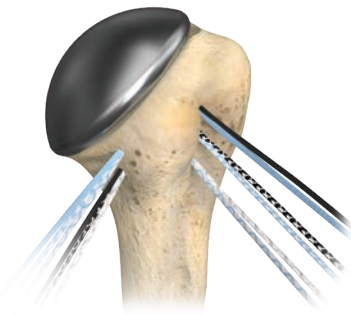


Figure 15

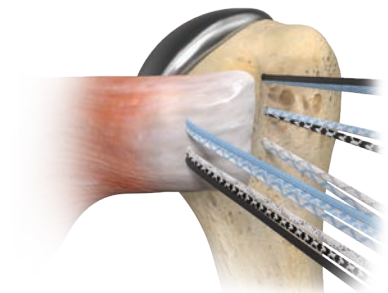


Figure 17

5. Insert Stem

Insert the stem. The repair strands should wrap around the stem.

Remove the slack from the sutures.

Mallet the stem into the humerus, securing the sutures in place (Figures 13, 14, 15).

6. Shuttle Suture Tapes Through the Subscapularis

Shuttle the superior medial suture tapes through the subscapularis (Figure 16).

Repeat the steps with the inferior medial suture tapes. Allow proper suture tape spacing for optimal footprint restoration (Figure 17).

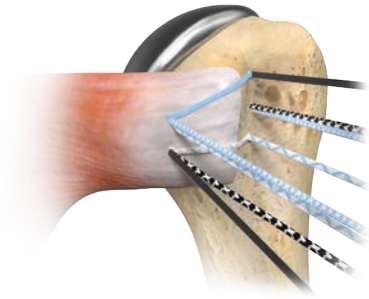


Figure 18

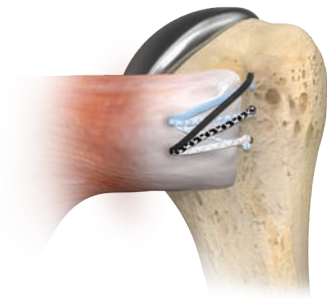


Figure 19

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.

Remove tag sutures if applicable (Figures 18 and 19).

Note: Desired pattern can differ from surgeon to surgeon.



Figure 20

8. Close the Rotator Interval

Close the rotator interval with the closing sutures, if preferred (Figure 20).

Ordering Information

Ultra Subscapularis Repair Kit for TSA and RSA

Part #	Description
110046455	Ultra Subscapularis Repair Kit with 13 sutures, needles and drill bit

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