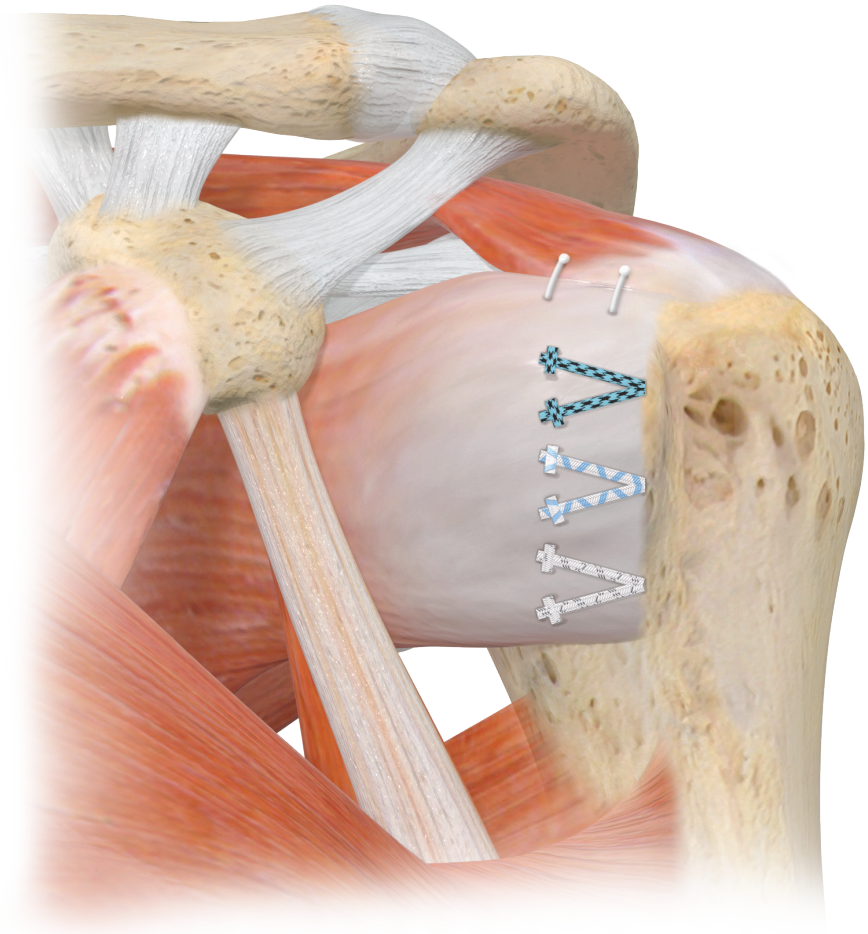
ZIMMER BIOMET

OsseoFit Suture (Bone Tunnel) Subscapularis Repair Kit

Bone Tunneling Technique

Surgical Technique



Introduction

The Zimmer Biomet OsseoFit™ Suture (Bone Tunnel) Subscapularis Repair Kit was designed to facilitate the reattachment of the Subscapularis tendon after Total Shoulder Arthroplasty (TSA) utilizing the OsseoFit™ Stemless Shoulder System

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

TAG

Maxbraid™ (1) White/Green USP #2 Suture w/MO-4 curved needle – 39" Length | **Qty 1 Needle**
Total 1 MO-4 Curved Needle

SHUTTLE

Passing Needle polypropylene loop MO-4 curved needle | **Qty 1 Needle**
Passing Needle polypropylene loop MO-4 curved needle | **Qty 1 Needle**
Total 2 MO-4 Curved Needles

REPAIR

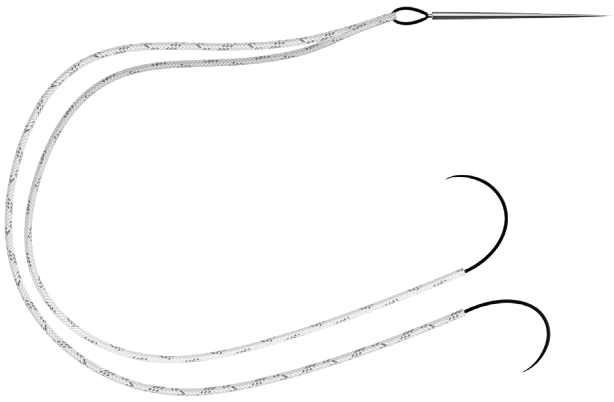
Double Armed BroadBand™ (1) White/Black Tape (1.5mm) w/(2) MO-4 Curved Needles, (1) ST-2 Straight Passing Needle | **Qty 3 Needles**
Double Armed BroadBand™ (1) White/Blue Tape (1.5mm) w/(2) MO-4 Curved Needles, (1) ST-2 Straight Passing Needle | **Qty 3 Needles**
Double Armed BroadBand™ (1) Blue/Black Tape (1.5mm) w/(2) MO-4 Curved Needles, (1) ST-2 Straight Passing Needle | **Qty 3 Needles**
Total 6 MO-4 Curved Needles
Total 3 ST-2 Straight Passing Needles

CLOSURE

Maxbraid™ (1) White/Blue USP #2 Suture w/MO-4 Curved Needle 39" Length | **Qty 1 Needle**
Maxbraid™ (1) White/Blue USP #2 Suture w/MO-4 Curved Needle 39" Length | **Qty 1 Needle**
Total 2 MO-4 Curved Needles

NEEDLES DETAILS

ST-2 Taper Point Straight 35mm
MO-4 cobra black Taper Point 1/2c 36mm



Double Armed BroadBand™ (1) White/Black Tape (1.5mm) w/ (2) MO-4 Curved Needles, (1) ST-2 Straight Passing Needle

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INDICATIONS

OsseoFit™ Bone Tunnel Constructs are intended for use in soft tissue to bone fixation for the following indications:

Shoulder

- Rotator Cuff Repair

CONTRAINDICATIONS

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

Descriptions

OsseoFit™ Bone Tunnel Construct

DEVICE DESCRIPTION: The OsseoFit™ Bone Tunnel Construct is comprised of a double armed suture with a preassembled passing loop. The Bone Tunnel Construct are intended for use in soft tissue to bone fixation when used as a shoulder arthroplasty adjunct by passing through the bone or OsseoFit™ stemless implant slot. Suture materials are Ultra-High Molecular Weight Polyethylene. Passing loop materials are polypropylene.

Surgical Steps

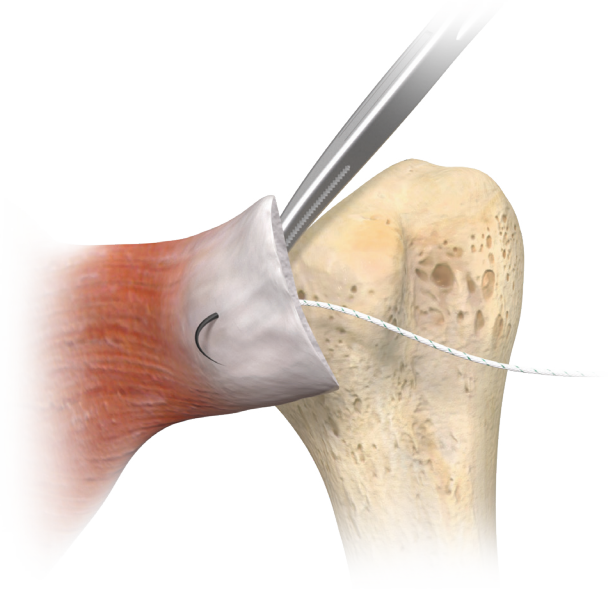

Figure 1

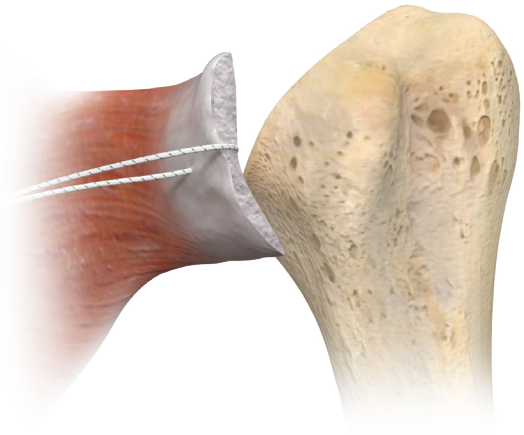

Figure 2

1. Subscapularis Detachment

Mobilize and tag the subscapularis tendon using the "TAG" Suture (Maxbraid™ White/Green USP #2 w/ MO-4 curved needle) (Figures 1 and 2).

Prepare the humerus following standard total shoulder arthroplasty techniques.

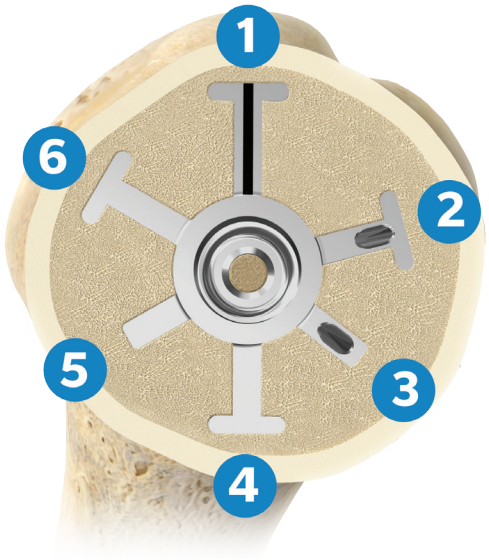

Figure 3

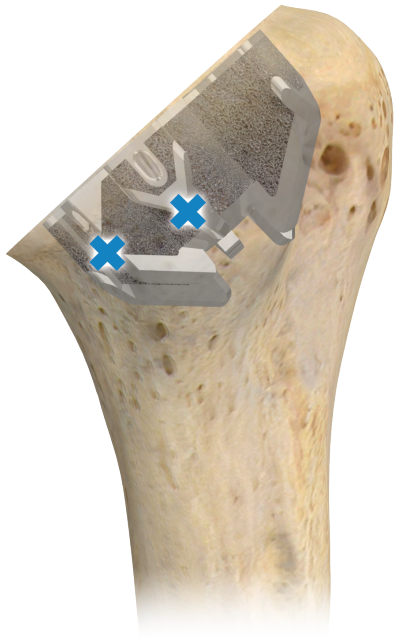

Figure 4

2. Identify the fixation points to repair the Subscapularis

Examine the Subscapularis repair site and identify the ideal locations of each fixation point to complete the repair (3 maximum fixation points based on the number of repair constructs in the kit). These fixation points may vary depending on surgeon preference and technique used to mobilize the subscapularis (i.e. peel, LTO). This step is important in guiding where the sutures will pass in Step 3.

Note: The Blue X's (figure 4) indicate the approximate fixation points if the Double Armed BroadBand™ ST-2 Straight Passing Needle Repair Constructs are passed through the slots on fins 2 and 3. If these fixation points are not desirable to accommodate your preferred repair technique, passing the sutures in between the fins is acceptable to meet the desired location of the fixation points for repair.

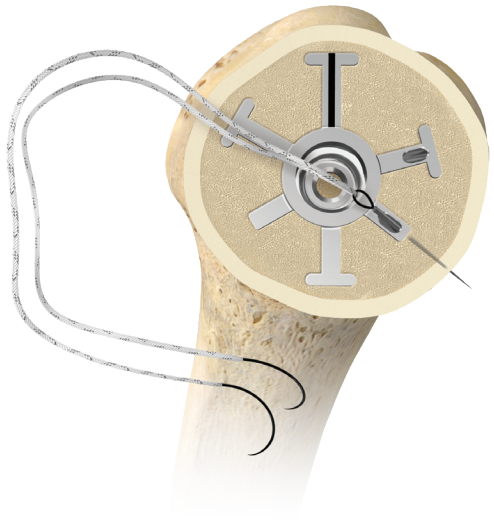

Figure 5

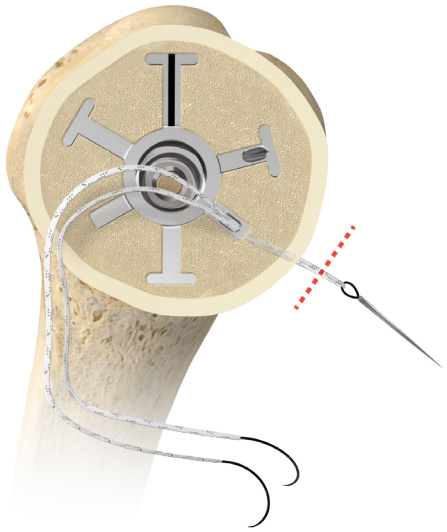

Figure 6

3. Suture Repair Construct Management

Once the preferred fixation points are known, pass the REPAIR construct through the implant or bone utilizing a needle holder and a mallet if necessary. If the fixation points desired do not align with the implant slots 2 & 3 it is ok to pass the suture in between the fins of the OsseoFit™ Implant. **(Continued on next page)**

- **Note:** Separate sutures into individual strands by cutting the suture loop. (Figure 6)
- **Note:** Repeat the steps with the second and third double stranded constructs.
- **Note:** Do NOT mallet the needle directly, instead lightly mallet the needle holder that is grasping the needle.

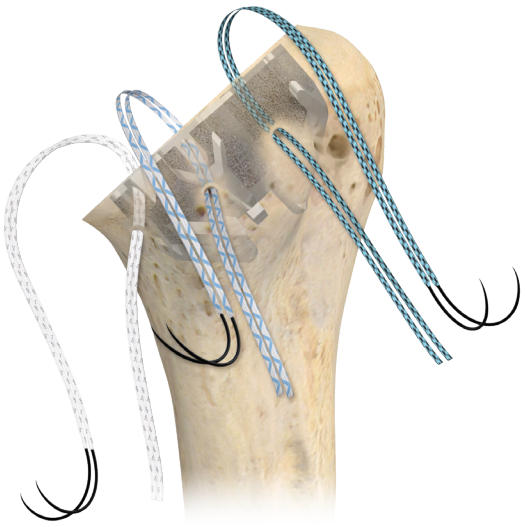

Figure 7

3. Suture Repair Construct Management (cont.)

Note: It is not necessary to pass needles through the OsseoFit™ slots. For this example, "REPAIR" constructs were passed through the slots in fins 2 & 3, and one construct was passed directly through bone between fins 1 and 2, as shown in Figure 7. All constructs can pass through the bone and not the implant if that is the preferred method. It is possible for sutures to loosen in cancellous bone since they are not reinforced by the implant.

Note: The geometry for both slots 2 & 3 on the Onlay OsseoFit™ Implant are 45° relative to the resection, and the Inlay OsseoFit™ Implant has a 45° slot in fin 2 and a 35° slot in fin 3. It is important to align the passing needle close to these angles when passing through the implant as to not apply unnecessary forces to the OsseoFit™ Anchor.

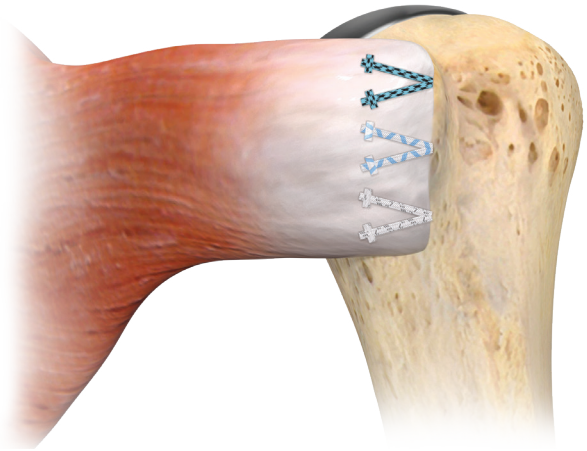

Figure 8

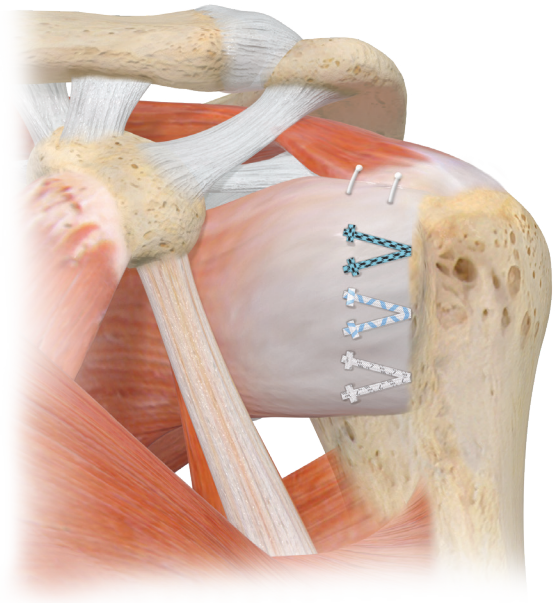

Figure 9

4. Subscapularis Reattachment

Repair the subscapularis tendon utilizing the suture color of choice (White/Black, White/Blue, Blue/Black) in preferred sequential order. Approximate the Subscapularis to the repair site and tie down sequentially in preferred progression.

Remove excess suture from repair site and test range of motion. Ensure repair is in an acceptable position and has appropriate tensioning and balance.

Allow proper spacing between sutures for optimal footprint restoration.

5. Rotator Interval Closure

Utilize remaining Maxbraid™ White/Blue USP #2 Suture w/MO-4 curved needle to close the rotator cuff interval as desired. Figure 9

- **Note:** Utilize the Tapestry® Biointegrative Implant for biologic augmentation if desired.
- **Note:** Refer to IFU for indications and contraindications

POSSIBLE ADVERSE EFFECTS: Adverse effects associated with the use of this device include: Nonunion or delayed union, which may lead to breakage of the implant, Bending or fracture of the implant, Loosening or migration of the implant, Allergic reaction to a foreign body, Pain, discomfort, or abnormal sensation due to the presence of the device, Nerve damage due to surgical trauma, Necrosis of bone or tissue, Inadequate healing, Intraoperative or postoperative bone fracture and/or postoperative pain.

WARNINGS: The OsseoFit™ Bone Tunneling Construct internal fixation device provides the surgeon with a means to aid in the management of soft tissue to bone reattachment for shoulder arthroplasty 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, 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 material aspects of the surgical implants. 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.

3) a good nutritional state of the patient. When using bone tunneling construct as an adjunct to a stemless implant, inspect adjunct metal implant for burrs and sharp edges prior to implanting. Do not use adjunct metal implants with burrs and sharp edges. Do not pass construct through stemless implant channels until the stemless implant is implanted and positioned in bone. 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.

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. Improper selection, placement, positioning, and fixation of the device can lead to failure of the device or the procedure. The surgeon is to be familiar with the device, the method of application and the surgical procedure prior to performing surgery. The surgeon must select a type, or types of internal fixation devices appropriate for treatment.

3. The implants can loosen or be damaged and the graft repair 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.

4. 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.

5. Care is to be taken to ensure 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.

6. The use of appropriate immobilization and postoperative management is indicated as part of the treatment until healing has occurred.

7. Do not modify implants.

8. Correct handling of the device is extremely important. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders. Avoid disturbing the device once implanted. This could lead to failure requiring additional surgery and device removal.

9. Inspect adjunct metal implant for burrs and sharp edges prior to implanting. Do not use adjunct metal implants with burrs and sharp edges.

10. Do not use excessive force when inserting the device. Excessive force may cause damage to the device and/or adversely affect its performance.

11. The device can break or be damaged due to excessive activity or trauma. This could lead to failure requiring additional surgery and device removal.

12. DO NOT USE if there is a loss of sterility of the device.

13. DO NOT USE opened or damaged devices. Use only devices that are packaged in unopened or undamaged containers.

14. Ensure contact of tissue to bone when implanting.

15. 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 future management.

• Patients with senility, mental illness, alcoholism, or drug abuse may be at higher risk of device failure. These patients may ignore instructions and activity restrictions.

• The patient is to be instructed in the use of external supports (slings, braces, etc.) that are intended to immobilize the treatment 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 or be damaged as a result of stress, activity, load bearing, or weight bearing.

• The patient is to be made aware of the surgical risks and possible adverse effects prior to surgery, and warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.

• The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.

• Patients that engage in stressful physical activities are to be warned that injury at or near the implant site can lead to failure of the device and/or the treatment.

Ordering Information:

Osseofit™ Suture (Bone Tunnel) Kit

Description	Part Number
OsseoFit™ Suture (Bone Tunnel) Kit	120002051
Quattro GT Suture Passer	CM-9010GT
Quattro GTS Side Loading Passer	CM_9010GTS
Quattro Suture Passer Needle	CM-9011
30 x 30 mm, Implant Only	TP-3030-01
40 x 30 mm, Implant Only	TP-4030-01
70 x 50 mm, implant with Insertion Sleeve	TP-7050-02

Notes

Zimmer Biomet does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons.

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.

Check for country product clearances and reference product specific instructions for use.

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