

Low-Profile/Trans-Cuff PASTA Repair

with JuggerKnot® Soft Anchor-1.5 mm
(with Percutaneous Instrumentation)

Surgical Technique
by Shabi Kahn, M.D.

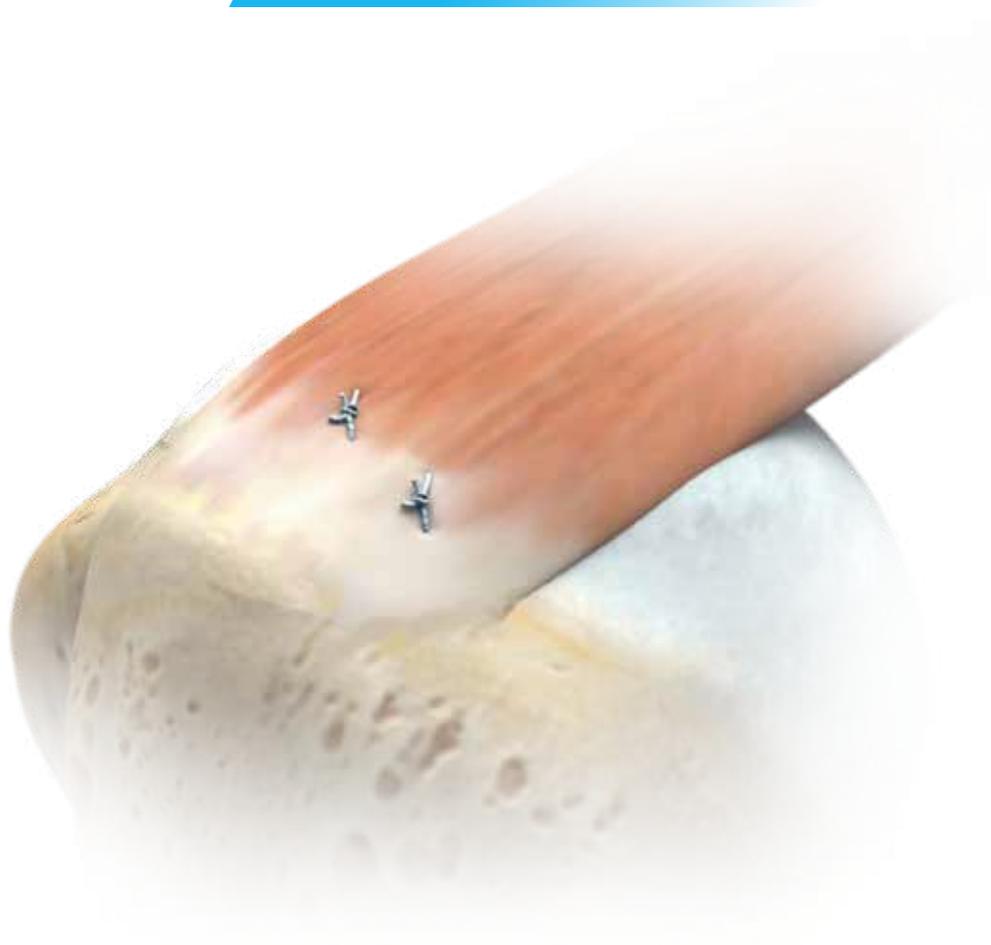


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Surgical Technique



Figure 1



Figure 2

Patient Positioning and Portal Placement

Place the patient in either the beach chair or lateral decubitus position depending upon surgeon preference (Figure 1). Insert a 30° arthroscope through the posterior portal. Carefully assess all anatomy including any associated chondral, rotator cuff, biceps and labral abnormalities. Place a 7 mm AquaLoc® cannula anteriorly through the rotator interval either from an outside in or inside out technique. At this point identify the under-sided rotator cuff tear, likely in the supraspinatus. There is usually an articular side, slightly retracted, draped over a portion of the tendon visualized. Some torn and frayed intermediate fibers are usually seen.

Prepare the Rotator Cuff Surface

Utilize a curved shaver through the anterior portal to prepare the cuff surface. Two aspects of the preparation are required. First, debride the torn edge of the articular portion of the supraspinatus tendon. Second, create a channel of bleeding cortical bone just medial to the insertional fibers of the intermediate or bursal side of the tendon to create a small trough (Figure 2). Abduct and slightly externally rotate the arm to help with appropriate position and contact of the shaver with the bone bed.

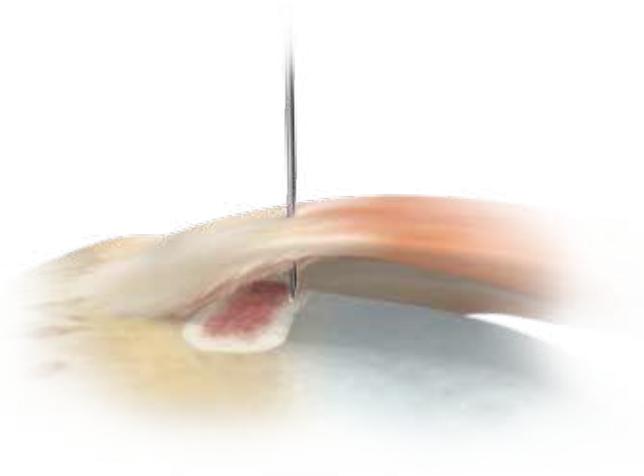


Figure 3

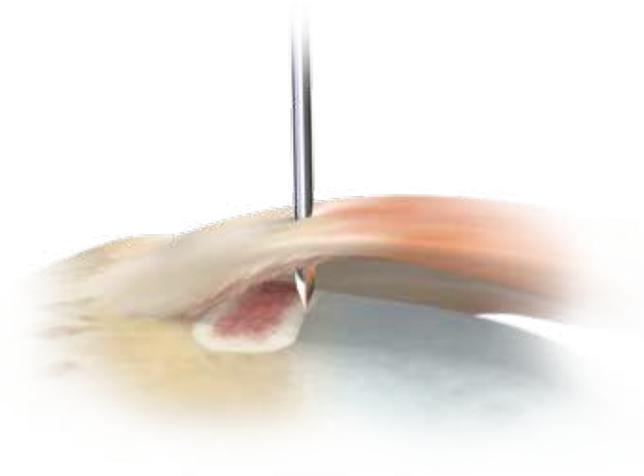


Figure 4

Placement of Percutaneous Guide

When repairing the rotator cuff using an all inside PASTA technique, utilize a third transcutaneous incision and portal. Use a spinal needle through an anterolateral percutaneous area, adjacent to the anterolateral acromion, to identify the appropriate angle. Visualize the spinal needle penetrating through the attached bursal side of the tendon and more lateral to the torn edge of the intra-articular portion of the tendon (Figure 3). Next place a small stab incision, smaller than a portal incision, through the skin.

Insert the rigid trocar for the percutaneous guide at the same angle as the previously identified spinal needle through the skin incision (Figure 4). Then insert the percutaneous guide over the trocar.

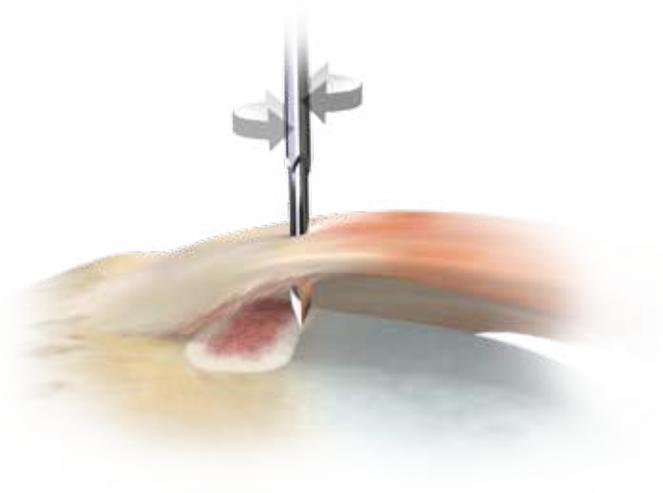


Figure 5

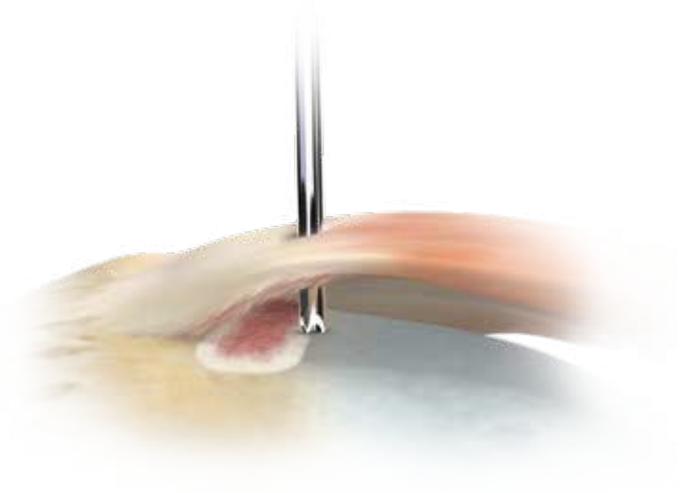


Figure 6

Placement of Percutaneous Guide (cont.)

Utilize a rotating motion back and forth to penetrate through both the subcutaneous tissue and rotator cuff tendon into the intra-articular space (Figure 5).

Remove the rigid trocar and appropriately place the guide on the pre-prepared medial edge of the greater tuberosity along the trough created (Figure 6). Keep the angle of the guide as vertical as possible, as not to penetrate the articular surface of the humeral head during drilling.

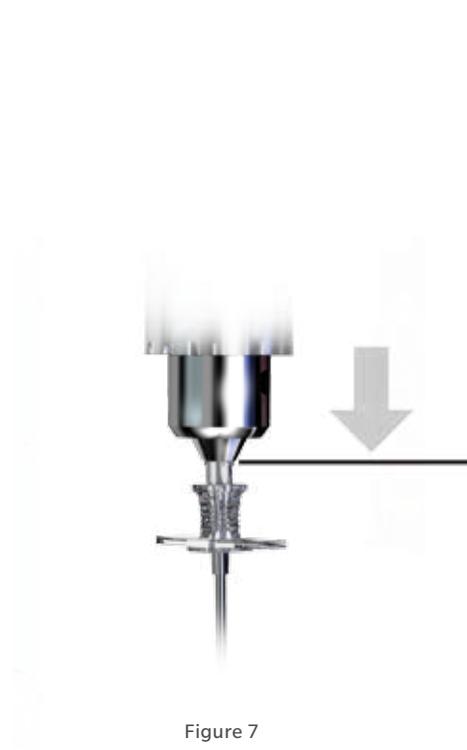


Figure 7

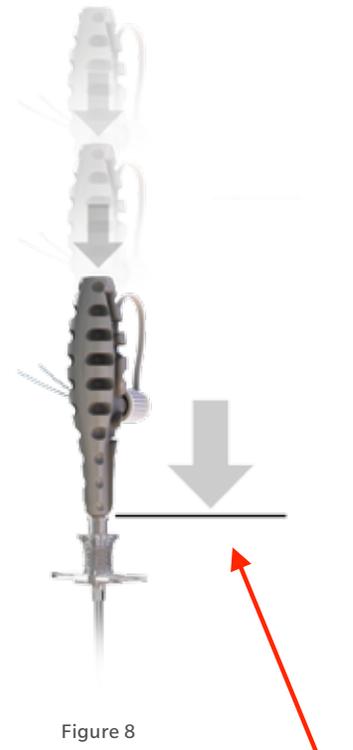


Figure 8

Pilot Hole and Anchor Placement

Chuck the drill bit to the proximal laser etch line. Advance the drill under power until the drill bottoms out on the top of the guide (Figure 7). Remove the drill. Next insert the JuggerKnot Soft Anchor–1.5 mm through the guide until it makes contact with the surface of the bone.

ⓘ **Note:** Be sure to maintain the precise position of the guide, including the angle, over the drill hole.

5 pirkimo dalis, reikalavimas nr. 2 - įvedimo būdas - įkalamas.

Insert the JuggerKnot 1.5 mm anchor through the guide until seated at the entry of the pilot hole. Utilize a small mallet to insert the JuggerKnot anchor in the bone. Advance the inserter until it bottoms out on the top of the guide handle (Figure 8).

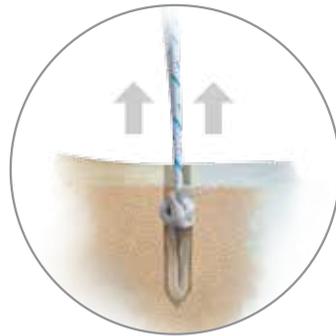


Figure 9a

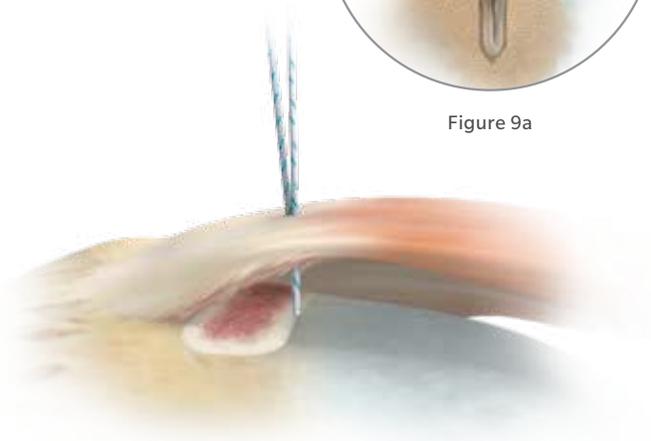


Figure 9

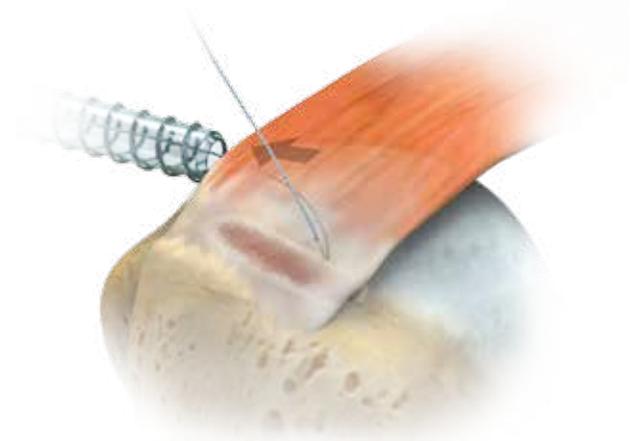


Figure 10

5 pirkimo dalis, reikalavimas nr. 6 - Atsukamas siūlo tvirtinimas ant vienkartinio įvedėjo

Anchor Deployment

Unscrew the white luer-lock cap to release the sutures from the inserter. Remove the anchor inserter handle and assembly. Remove the guide and seat the anchor by lightly pulling back on both sutures (Figure 9 & 9a). Check to verify the sutures slide within the anchor.

↑ 5 pirkimo dalis, reikalavimas nr. 1 - Paruoštas implantas su vienu #2 storio, slankiojančiu, nesirezorbuojančiu ultra aukštos molekulinės masės polietileno pagrindu siūlu

Suture Retrieval

Through the anterior portal utilize a suture retriever to grasp one limb of the suture, leaving the opposite limb still trans-cuff (Figure 10).

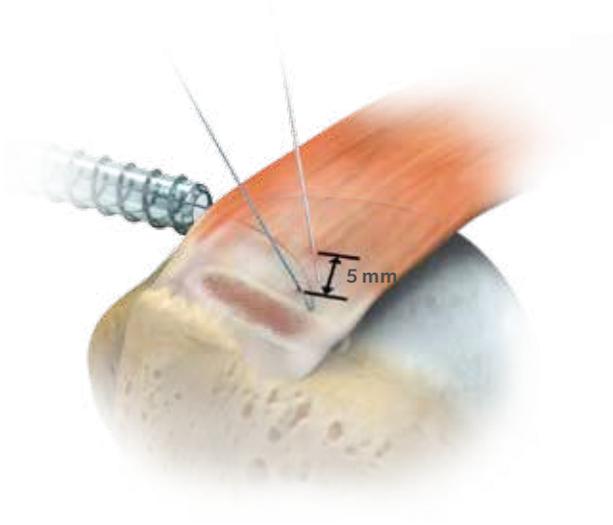


Figure 11

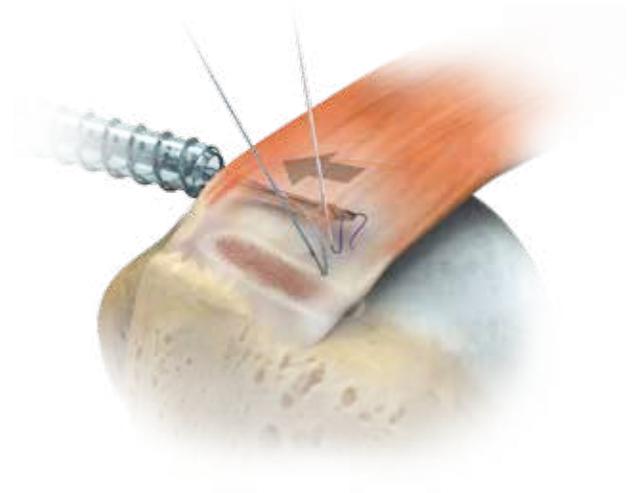


Figure 12

Suture Retrieval (cont.)

At times, it is useful to use a probe, while abducting and externally rotating and/or internally rotating the arm, to guide the suture towards the probe. Then insert a spinal needle adjacent to the previous anterolateral stab incision and penetrate it through a 5 mm more medial portion of the articular side of the slightly retracted tendon (Figure 11).

Pass a PDS suture through the spinal needle and utilize a tissue grasper through the anterior portal to retrieve the PDS suture anteriorly (Figure 12). Tie the PDS to the existing limb of the MaxBraid™ suture exiting the portal. Pull the PDS and the single limb of the MaxBraid suture through the articular side of the tendon and out the skin.

Repeat the same procedure to provide two passes of the single loaded JuggerKnot anchor with the plan for a mattress type repair as opposed to a simple knot.



Figure 13

Assess Need for Second Anchor

At this point, carefully seesaw the limbs of the suture back and forth, confirming the torn edge of the tendon fully contacts and is nicely opposed to the previously prepared bone bed.

☰ **Note:** The least amount of tension will be visualized if the arm is in the adducted position.

If a second anchor is to be used, the same procedure is followed with a recommendation for a mattress type of placement of both limbs of the MaxBraid suture.

Knot Tying

Insert the arthroscope into the subacromial position. As noted above, the subacromial decompression and bursectomy have been performed to maximize visualization in the subacromial space. The arm is kept in the adducted position to reduce the pull of the articular side of the tendon against the untied sutures. A cannula is inserted through the lateral portal and both sutures are retrieved.

To secure the tissue place standard single knots and/or a slip knot followed by half hitches in the usual fashion (Figure 13). The knots are cut flush with a small tail.

Follow the same procedure if a second anchor was placed. As an optional maneuver, insert the scope through the posterior portal to visualize a nicely opposed articular side repair of the tendon.

Fixation is complete.

Ordering Information

Implants

Part Number	Description
912030	1.4 mm JuggerKnot Single Loaded
912010	1.4 mm JuggerKnot Package of 10
912031	1.5 mm JuggerKnot Single Loaded
912015	1.5 mm JuggerKnot Package of 10

Instruments

Part Number	Description
912140C	1.4 mm JuggerKnot Curved Guide Disposable Kit with Centering Sleeve
912141C	1.5 mm JuggerKnot Curved Guide Disposable Kit with Centering Sleeve
912040P	1.4/1.5 mm JuggerKnot Percutaneous Kit

INDICATIONS FOR USE

The JuggerKnot Soft Anchors are intended to be used for soft tissue to bone fixation for the following indications:

Shoulder

Bankart lesion repair
SLAP lesion repair
Acromio-clavicular repair
Capsular shift/capsulolabral reconstruction
Deltoid repair
Rotator cuff tear repair
Biceps tenodesis

Foot and Ankle

Medial/lateral repair and reconstruction
Mid-and forefoot repair
Hallux valgus reconstruction
Metatarsal ligament/tendon repair or reconstruction
Achilles tendon repair

Elbow

Ulnar or radial collateral ligament reconstruction
Lateral epicondylitis repair
Biceps tendon reattachment

Knee

Extra-capsular repair: MCL, LCL,
and posterior oblique ligament
Iliotibial band tenodesis
Patellar tendon repair
VMO advancement
Joint capsule closure

Hand and Wrist

Collateral ligament repair
Scapholunate ligament reconstruction
Tendon transfers in phalanx
Volar plate reconstruction

Hip

Acetabular labral repair

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 or patients who are otherwise unwilling or incapable of doing so.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

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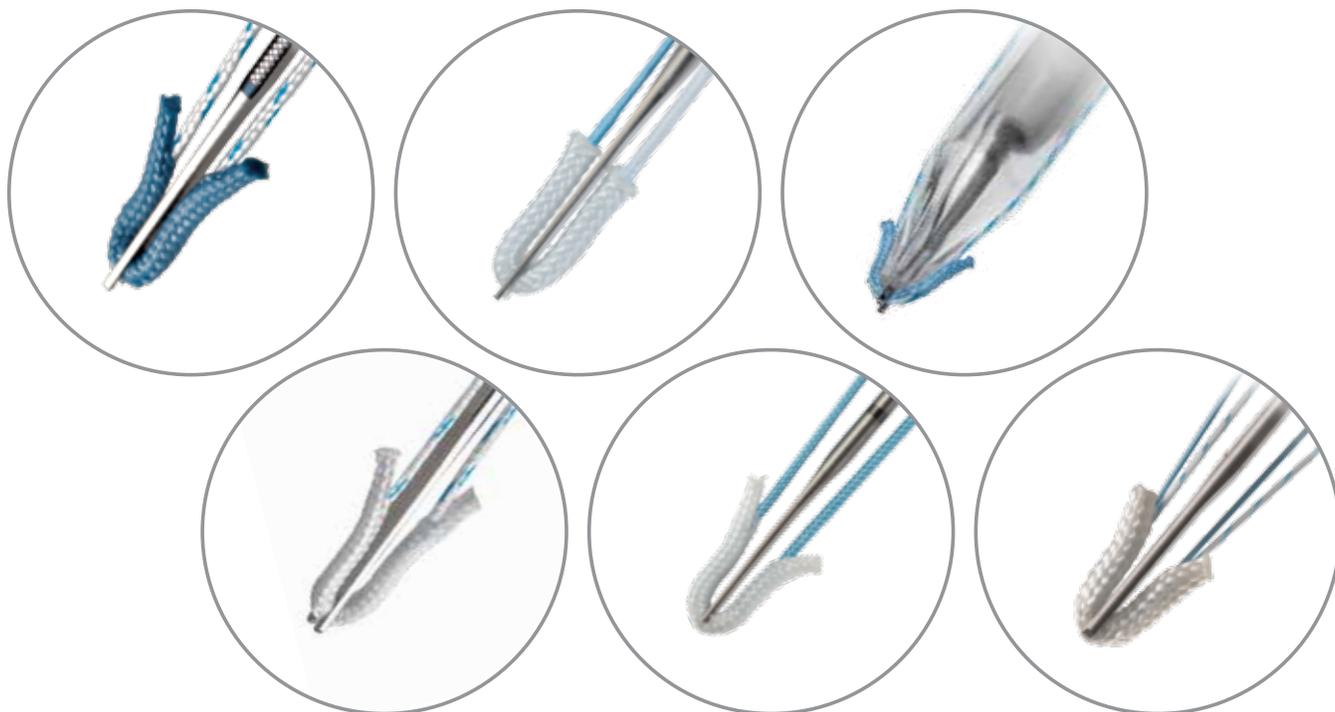
www.zimmerbiomet.com

CE 0086

CE mark on a surgical technique is not valid unless there is a CE mark on the product label.

JuggerKnot[®] and JuggerKnotless[®] Soft Anchor

All-Inclusive Brochure



JuggerKnot Soft Anchor

The Leader in All-Suture Anchors¹

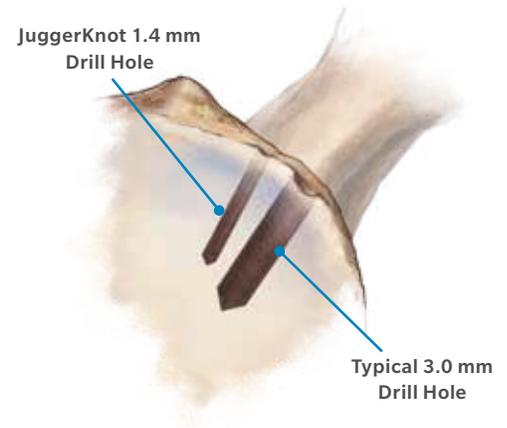
Zimmer Biomet has completely redefined how soft tissue repair is performed with the design of the JuggerKnot Soft Anchor. An article published by *PRWeb* in March 2013 stated, “There are currently two major developments in the U.S. orthopedic device market that are making drastic impacts, both in the soft tissue and orthopedic biomaterials market. Due to technological innovations by the market leader Zimmer Biomet, patients with shoulder labrum tears or rotator cuff damage from sports or age-related injuries can now expect better quality restoration.”¹

The award winning JuggerKnot Soft anchor began with a 1.4 mm diameter, 100% suture based anchor system and has quickly evolved into a family of anchors that offer sizing options for many different procedures.



They're Small

- The volume of bone that is removed with a 3.0 mm drill is equivalent to four JuggerKnot 1.4 mm anchor drill holes⁹
- Reduces the removal of bone
- Smaller diameter drill size reduces the likelihood of intersecting anchor tunnels when placing multiple anchors
- Allows for multiple points of fixation when repairing soft tissue to bone



They're Strong

- Strength is equal or greater than some anchors two or three times larger²
- High pullout strength^{3,4}

They're All-Suture

- Soft anchor deployment system with no rigid component
- Eliminates the possibility of rigid material loose bodies in the joint
- Allows blood to repair site
- Facilitates revision surgery

And Now They're Knotless

- Ability to control anchor tension
- Built on the clinical history of the JuggerKnot Soft Anchor
- No hand tied knots
- JuggerKnotless demonstrated 57 lbs of pullout strength⁵

JuggerKnotless Soft Anchor

First All-Suture Knotless Anchor

The clinical experience of the JuggerKnot Soft Anchor and innovative knotless design of the ZipLoop™ Technology has paved the foundation for the development of the JuggerKnotless Soft Anchor.

The JuggerKnotless Soft Anchor is designed for the reattachment of soft tissue to bone without the hassle of tying surgical knots. It is the first all-suture knotless anchor on the market. The design of the anchor allows surgeons the ability to control the tension of the anchor with their hands. In addition, this design provides for a one size fits all option, which may reduce the need to carry multiple sizes in inventory.

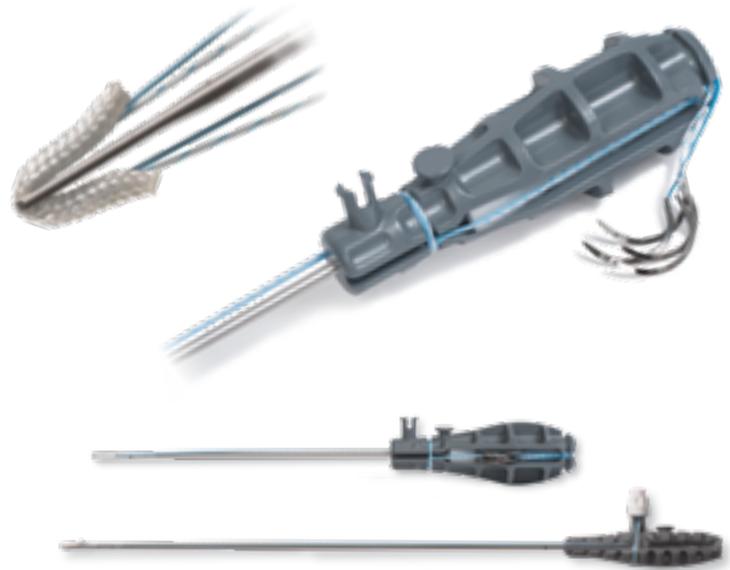


Rotator Cuff Repair – Soft Anchor Systems

JuggerKnot Soft Anchors – 2.9 mm

Features

- Available with and without needles for arthroscopic and mini-open repairs
- Tapered and cutting needle options available
- Manual deployment method



JuggerKnot Soft Anchors	
912029	2.9 mm, (2) #2 MaxBraid
912529	2.9 mm, (2) #2 MaxBraid (10 Pack)
110005093	2.9 mm Short, Cutting Needles
110005096	2.9 mm Short, Tapered Needles
110005241	2.9 mm Short, Cutting Needles (10 Pack)
110005242	2.9 mm Short, Tapered Needles (10 Pack)

JuggerKnot 2.9 mm Instruments	
912091	Drill Bit, Disposable
912057	Disposable Straight Kit (Guide, Drill)
912064	In Guide Punch, Reusable
912090G	Straight Guide, Reusable
912092G	Obturator, Reusable
912093G	Trocar, Reusable

JuggerKnot 2.9 mm Short & 2.9 mm Short with Needles Instruments	
110005306	Drill Bit, Disposable
912059	Punch, Reusable
110016951	Straight Guide, Reusable

Educational Materials

Ref. Number	Description
0395.1-GLBL-en-REV0916	Arthroscopic and Mini-Open Rotator Cuff Repair with JuggerKnot Soft Anchor – 2.9 mm Surgical Technique
0393.1-GLBL-en-REV0416	JuggerKnot and JuggerKnotless Soft Anchor – All-Inclusive Brochure
0391.1-GLBL-en-REV0416	JuggerKnot Soft Anchor – FAQ
0410.1-GLBL-en-REV0516	JuggerKnot Soft Anchor – 2.9 mm with Needles Flyer
0763.1-US-en REV0117	Soft Anchor Selling Guide

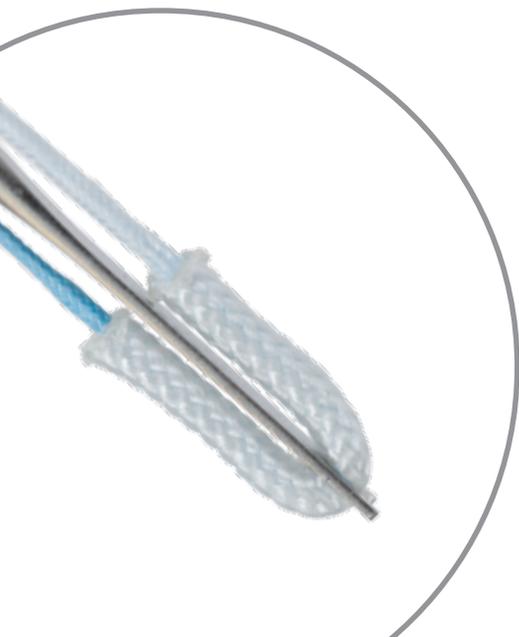
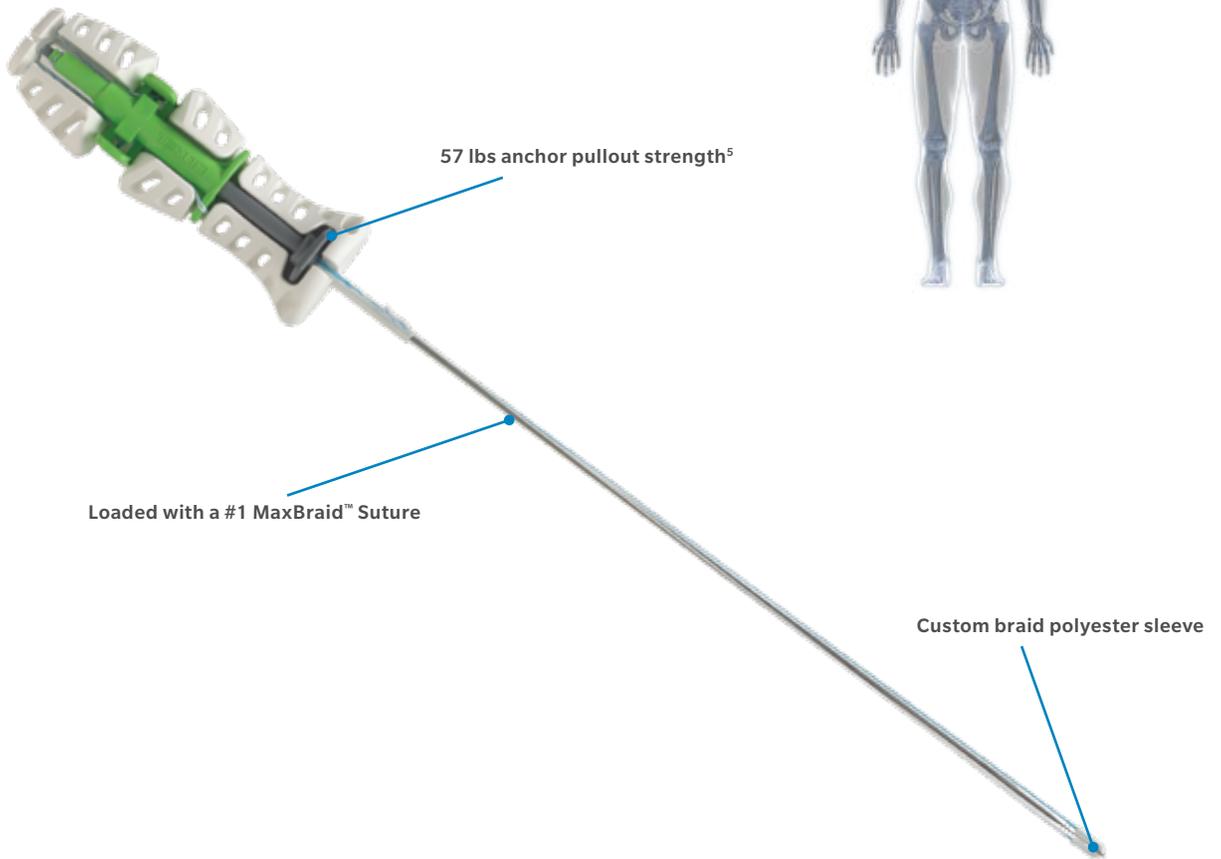
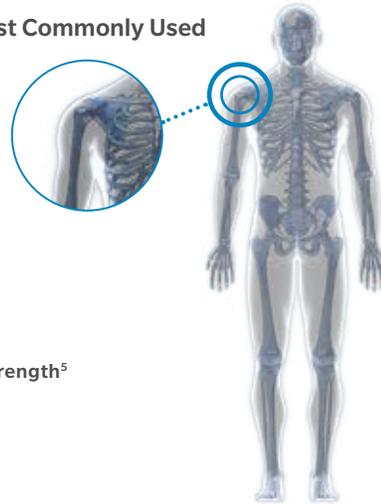
Sample Products

Part Number	Description
912029S	2.9 mm JuggerKnot Blue Sample
912029SR	2.9 mm JuggerKnot Blue Sample Reload (5 Pack)
912050S	2.9 mm JuggerKnot Sample
912050SR	2.9 mm JuggerKnot Sample Reload (5 Pack)
110005243	2.9 mm JuggerKnot Cutting Needles Sample
110005244	2.9 mm JuggerKnot Tapered Needles Sample

JuggerKnotless Soft Anchor 2.1 mm

JuggerKnotless
Soft Anchor Inserters

Most Commonly Used

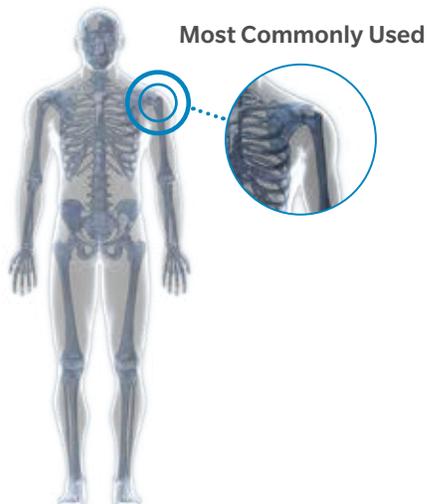


Surgical Technique available for:

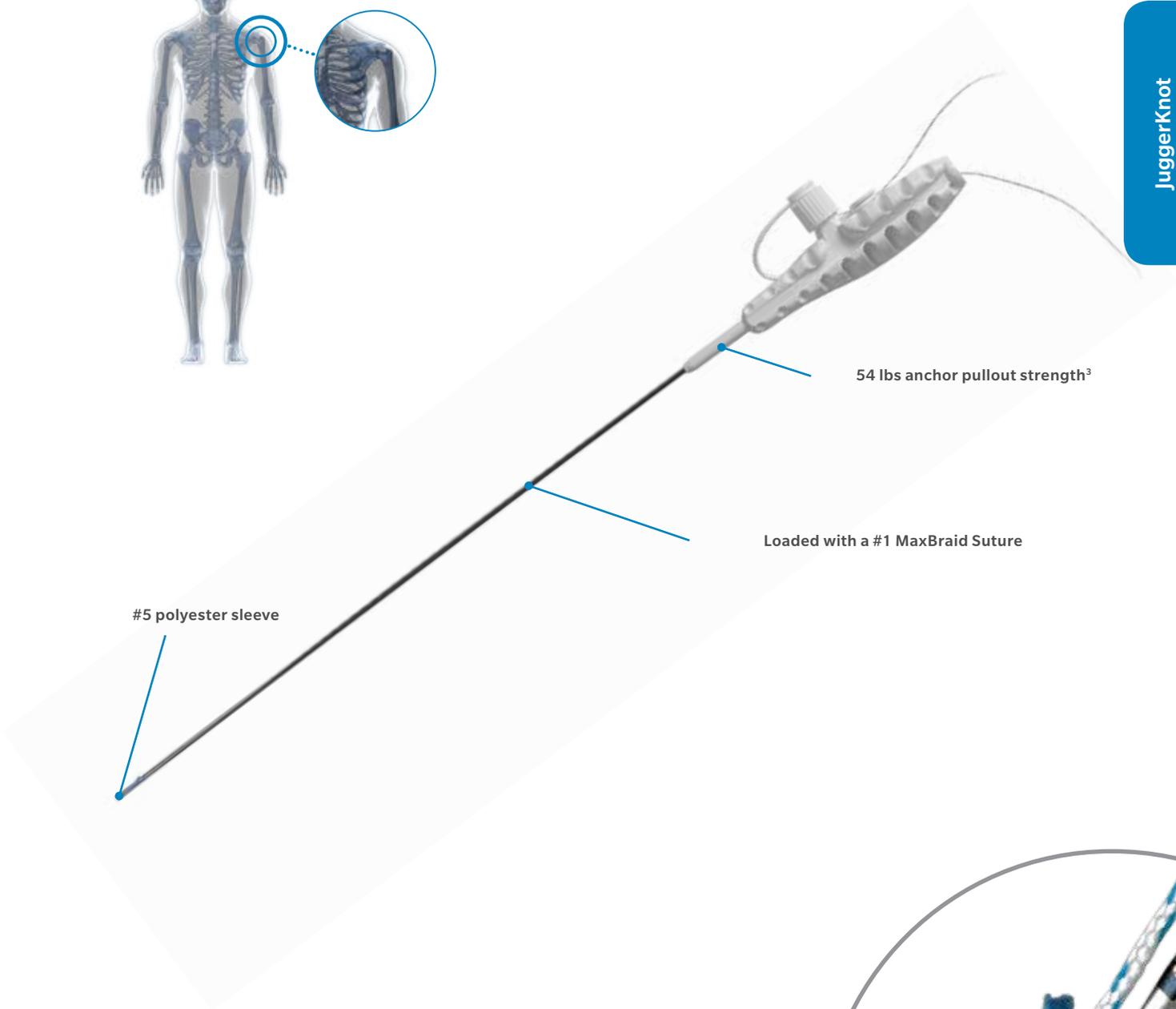
- Labral Repair

Instrumentation and Ordering Information
for JuggerKnotless Soft Anchor 2.1 mm
can be found on pages 16–17.

JuggerKnot Soft Anchor 1.4 mm

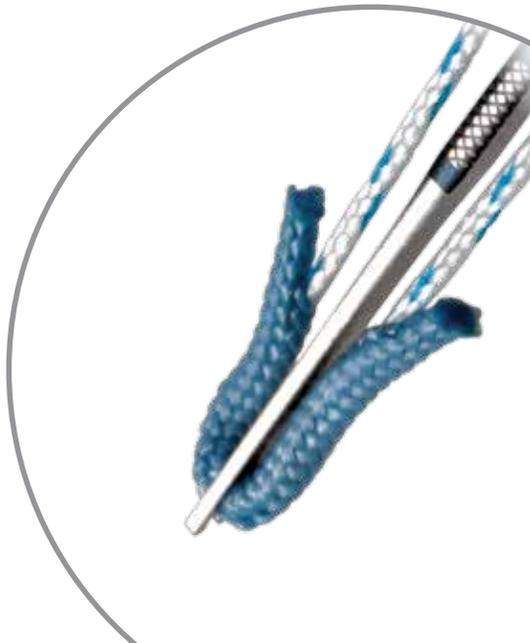


JuggerKnot
Soft Anchor Inserters



Surgical Technique available for:

- Labral Repair
- Curved Delivery for Bankart/SLAP Lesion Repair
- Percutaneous Instrumentation for Low Profile/Trans-Cuff SLAP Repair



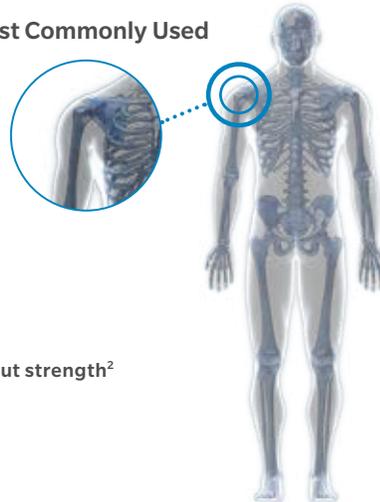
Instrumentation and Ordering Information for JuggerKnot Soft Anchor 1.4 mm can be found on pages 18–19.

JuggerKnot Soft Anchor 1.5 mm

5 pirkimo dalis, reikalavimas nr. 5 - Implantų išmatavimai: storis 1,5 mm.

JuggerKnot
Soft Anchor Inserters

Most Commonly Used



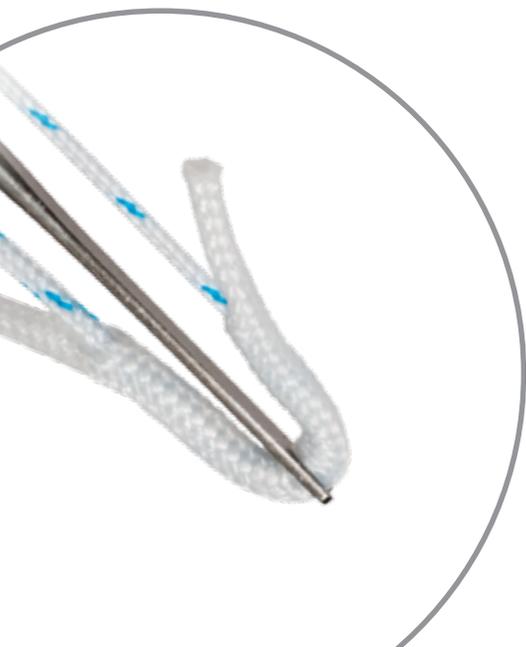
65 lbs anchor pullout strength²

Loaded with a #2 MaxBraid Suture

5 pirkimo dalis, reikalavimas nr. 1 - Paruoštas implantas su vienu #2 storio, slankiojančiu, nesirezorbuojančiu ultra aukštos molekulinės masės polietileno pagrindu siūlu

5 pirkimo dalis, reikalavimas nr. 3 - Inkaruojančios dalies cheminė sudėtis - poliesteris.

#6 polyester sleeve



Surgical Technique available for:

- Curved Delivery for Bankart/SLAP Lesion Repair
- Percutaneous Instrumentation for Low Profile/Trans-Cuff SLAP Repair
- Percutaneous Instrumentation for Low Profile/Trans-Cuff PASTA Repair

Instrumentation and Ordering Information for JuggerKnot Soft Anchor 1.5 mm can be found on pages 18–19.

Shoulder Labral Repair – Soft Anchor Systems

JuggerKnot Soft Anchors – 1.4 mm & 1.5 mm

Features

- Single-loaded with #1 or #2 MaxBraid suture
- Smaller anchor allows minimal bone removal in the glenoid and provides for tissue to bone contact
- Smaller anchor allows for curved guide deployment which are designed to minimize the quantity of portals



JuggerKnot 1.4 & 1.5 mm Soft Anchors	
912030	1.4 mm, (1) #1 MaxBraid Suture
912010	1.4 mm, (1) #1 MaxBraid Suture (10 Pack)
912000	1.4 mm System (2 Implants, Straight Guide, Drill Bit)
912031	1.5 mm, (1) #2 MaxBraid Suture
912015	1.5 mm, (1) #2 MaxBraid Suture (10 Pack)

Educational Materials

Ref. Number	Description
0394.1-GLBL-en-REV0416	Low Profile/Trans-Cuff SLAP Repair with the JuggerKnot Soft Anchor 1.4/1.5 mm (with Percutaneous Instrumentation)
0396.1-GLBL-en-REV0416	Low-Profile/Trans-Cuff PASTA Repair with JuggerKnot Soft Anchor 1.5 mm (with Percutaneous Instrumentation)
0393.1-GLBL-en-REV0416	JuggerKnot and JuggerKnotless Soft Anchor – All-Inclusive Brochure
2736.1-US-en	Shoulder Labrum Portfolio

Sample Products

Part Number	Description
912030S	1.4 mm JuggerKnot Sample
912030SR	1.4 mm JuggerKnot Reload Sample (10 Pack)
912031S	1.5 mm JuggerKnot Sample
912031SR	1.5 mm JuggerKnot Reload Sample (10 Pack)

JuggerKnot 1.4 mm and 1.5 mm disposables and instrumentation on following page.

MaxBraid™ PE Suture

The “incredible strength” suture

5 pirkimo dalis, reikalavimas nr. 1 - Paruoštas implantas su vienu #2 storio, slankiojančiu, nesirezorbuojančiu ultra aukštos molekulinės masės polietileno paviršiumi siūlu

MaxBraid™ Suture is made from 100% polyethylene with specific features including:

- Unique braid which allows the suture to lie flat and improves knot security
- Silky smooth feel is gentle on tissue and gloves
- Braided with Dyneema® Purity fiber
- Range of sizes to fit a variety of needs

Strength Comparison (lbs.):

- Ethibond™ Excel #2 tensile strength is 27.01 lbs with 21.61 lbs of knot security.²
- Fiberwire™ Suture tensile strength is 60.96 lbs with 29.83 lbs of knot security.²
- MaxBraid™ Suture tensile strength is 69.18 lbs with 39.45 lbs of knot security.³



Dyneema® Purity is ultra-high molecular weight polyethylene-based. It is 15 times stronger than steel on a weight for weight basis.¹ The fiber possesses benefits such as outstanding flexibility, pliability, and surgical ease-of-use.

BIOMET[®]
SPORTS MEDICINE

Ordering Information

*Needles are actual size. Suture sold as boxes of 12.



MaxBraid™ Suture 900312	
Suture	#5 Blue
Needles	Cutting K-60



MaxBraid™ Suture 900284	
Suture	#2 Blue
Needles	Cutting KHC-5



MaxBraid™ Suture 900333	
Suture	#2 White
Needles	Tapered HC-5



MaxBraid™ Suture 900334	
Suture	#2 Blue
Needles	Tapered HC-5



MaxBraid™ Suture 900335	
Suture	#2 Blue
Needles	Tapered C-7



MaxBraid™ Suture 900267	
Suture	#0 Blue
Needles	Tapered T-2



MaxBraid™ Suture 900336	
Suture	2-0 Blue
Needles	Tapered AT-2



MaxBraid™ Suture 900252	
Suture	3-0 Blue
Needles	Tapered T-2



MaxBraid™ Suture 900244	
Suture	4-0 Blue
Needles	Tapered T-1

References

1. Data supplied by DSM Dyneema.
2. Testing performed by Arthrex, Oct. 2000.
3. Data supplied by Teleflex Medical.

For description, materials, indications, contraindications and warnings, see the following package inserts at www.biomet.com/sportsmedicine: 01-50-1134 or 21404001 MaxBraid™ Polyethylene Suture Non-absorbable Surgical Suture.

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Shoulder Labral Repair – Soft Anchor Systems

JuggerKnot Soft Anchor Instrumentation – 1.4 mm & 1.5 mm

1.4 mm Disposable Instrumentation

Part Number	Description	Components
912000	2 Implant Kit System	2 implants, guide, drill bit
912040	Disposable Straight Kit	Guide & drill bit
912040C	Disposable Curved Kit	Curved guide & flex drill bit
912040P	Disposable Percutaneous Kit	Guide, 13G guide pin & drill bit
912140C	Disposable Curved Kit with Centering Sleeve	Curved guide, centering sleeve, & flex drill bit
912045	Centering Sleeve Kit	Centering sleeve & drill bit
912036R	Large Shank Rigid Drill Bit	
912036	Flexible Spade Drill Bit	
912136	Sterile Flexible Spade Drill Bit	



Straight Guide



Curved Guide

1.5 mm Disposable Instrumentation

Part Number	Description	Components
912041	Disposable Straight Kit	Guide & drill bit
912041C	Disposable Curved Kit	Curved guide & flex drill bit
912141C	Disposable Curved Kit with Centering Sleeve	Curved guide, centering sleeve, & flex drill bit
912046	Centering Sleeve Kit	Centering sleeve & drill bit
912037R	Large Shank Rigid Drill Bit	
912037	Flexible Drill Bit	



Reusable Straight Fishmouth Guide

1.5 mm Reusable Instrumentation

Part Number	Description
912035	Reusable Straight Guide
912038	Reusable Straight Trocar
912038P	Reusable Percutaneous Trocar
912039	Reusable Obturator
912035C	Reusable Curved Guide
912038C	Flexible Trocar
912039C	Flexible Obturator



Centering Sleeve Drill Bit



Flexible Drill Bit

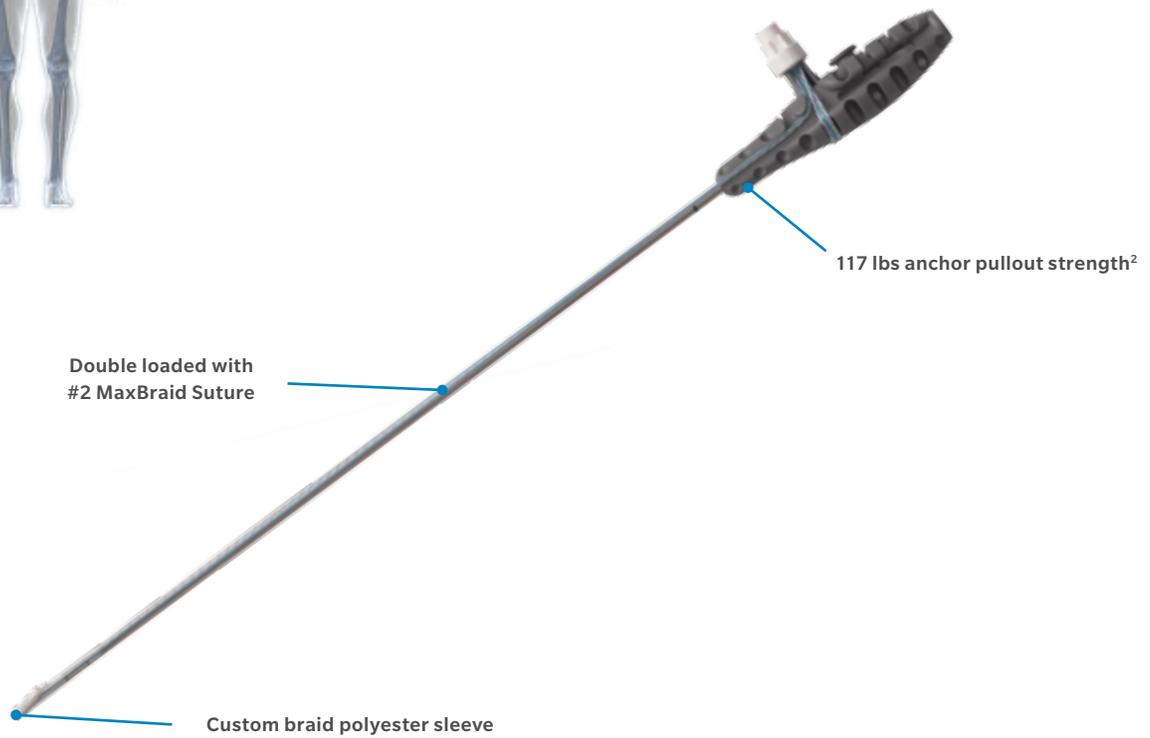
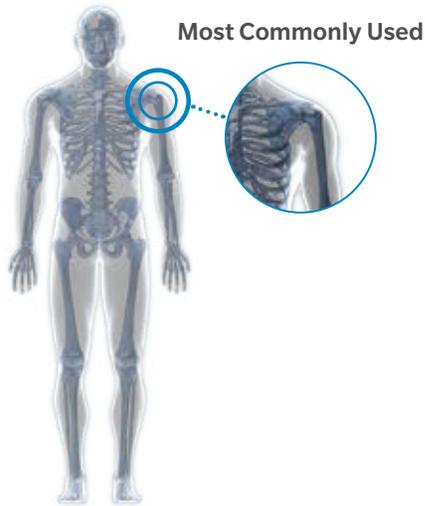
1.4 mm & 1.5 mm Sample Instrumentation

Part Number	Description	Components
912040S	1.4 mm Disposable Kit Sample	Guide, drill, obturator
912040CS	1.4 mm Curved Kit Sample	Curved guide, drill, obturator
912040PS	Percutaneous Kit Sample	Perc Guide, drill, guide pin, long trocar
912041S	1.5 mm Straight Kit Sample	Guide, drill, obturator
912041CS	1.5 mm Curved Kit Sample	Curved guide, drill, obturator



Rigid Drill Bit

JuggerKnot Soft Anchor 2.9 mm

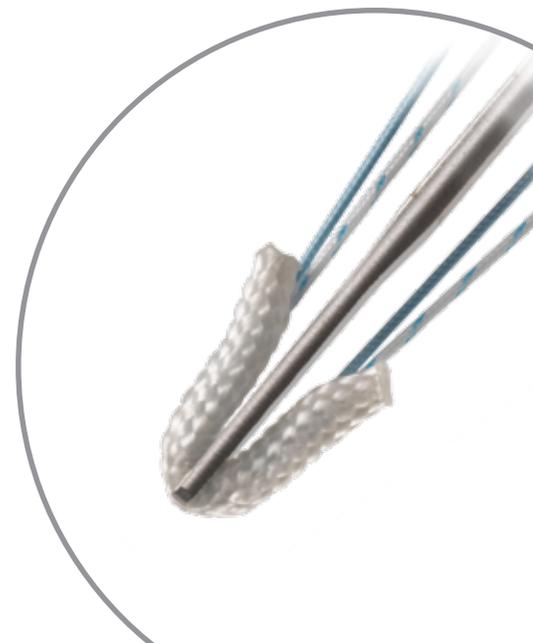


JuggerKnot
Soft Anchor Inserters

Surgical Technique available for:

- Arthroscopic and Mini-Open Rotator Cuff Repair

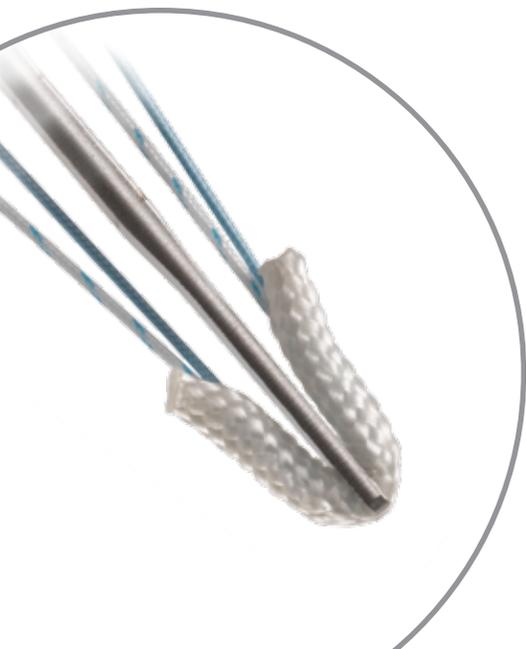
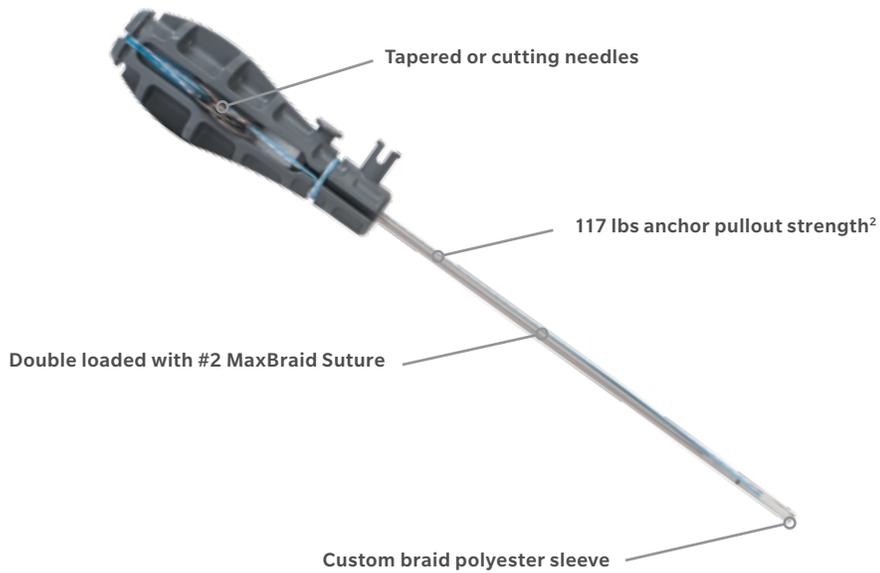
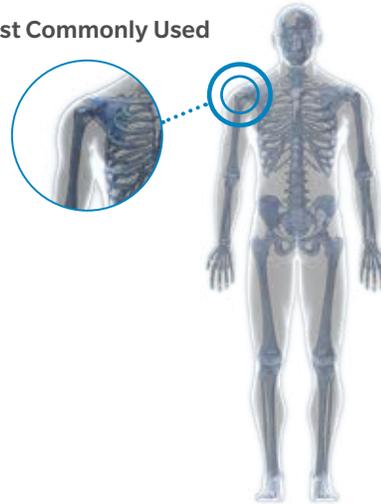
Instrumentation and Ordering Information for JuggerKnot Soft Anchor 2.9 mm can be found on pages 20–21.



JuggerKnot Soft Anchor 2.9 mm with Needles

JuggerKnot
Soft Anchor Inserters

Most Commonly Used

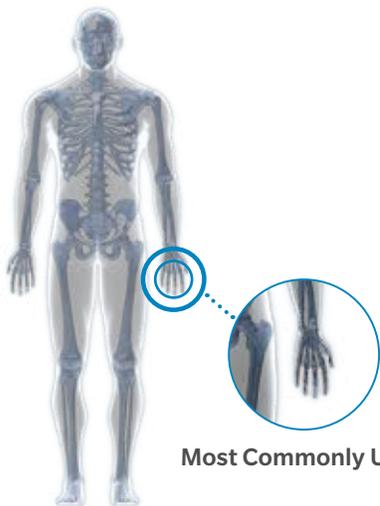


Surgical Technique available for:

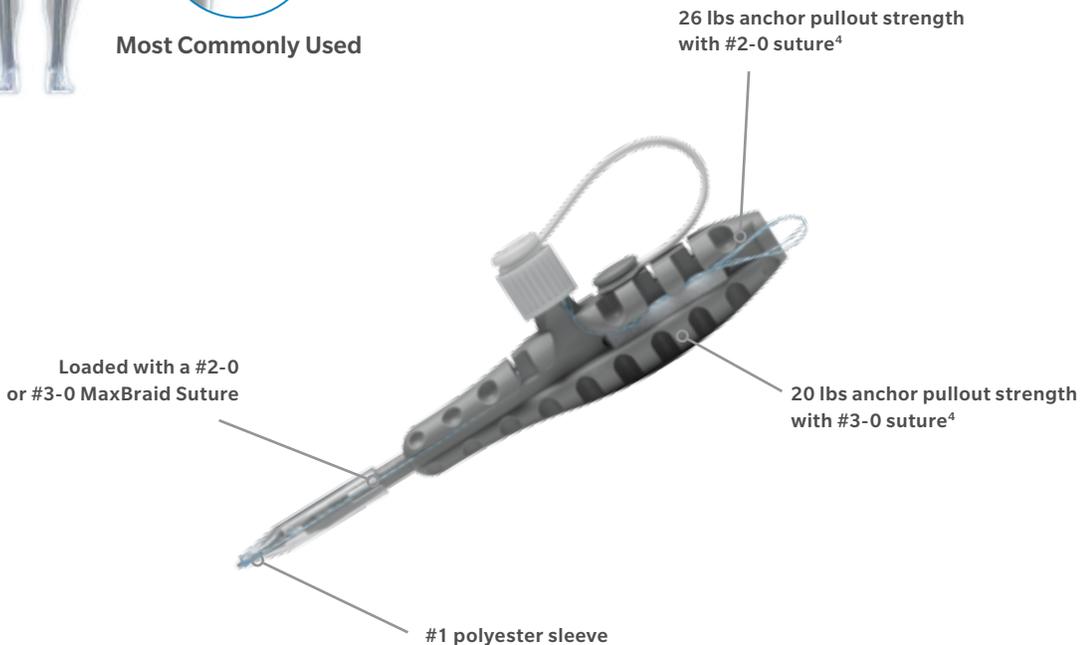
- Arthroscopic and Mini-Open Rotator Cuff Repair

Instrumentation and Ordering Information for JuggerKnot Soft Anchor 2.9 mm with Needles can be found on pages 20–21.

JuggerKnot Soft Anchor 1.0 mm Mini



Most Commonly Used

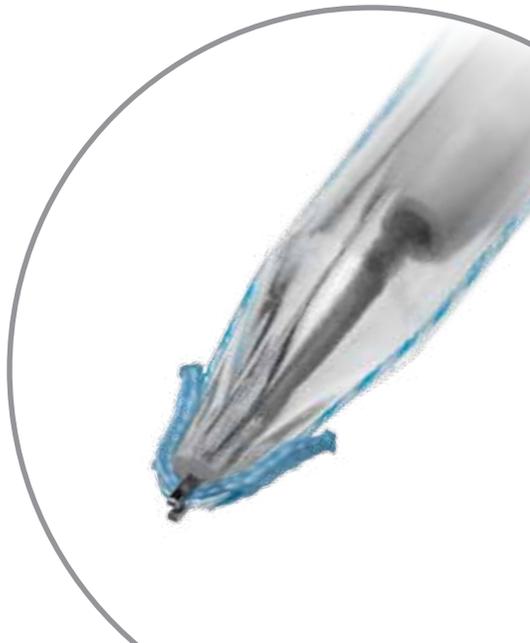


Surgical Technique available for:

- Scapholunate Ligament Repair
- Ulnar Collateral Ligament Repair

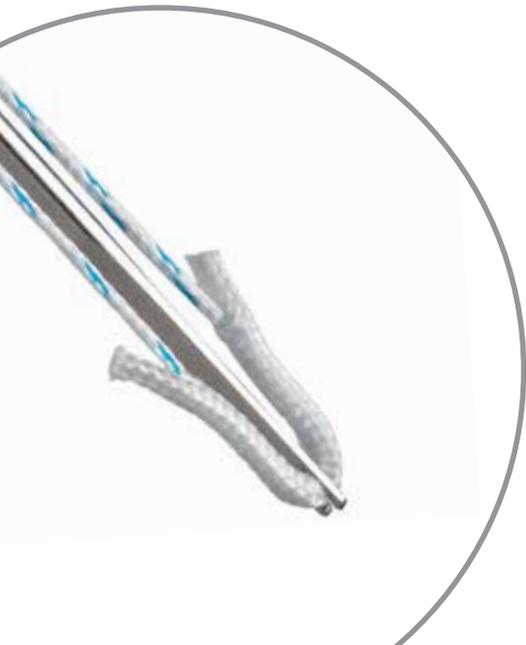
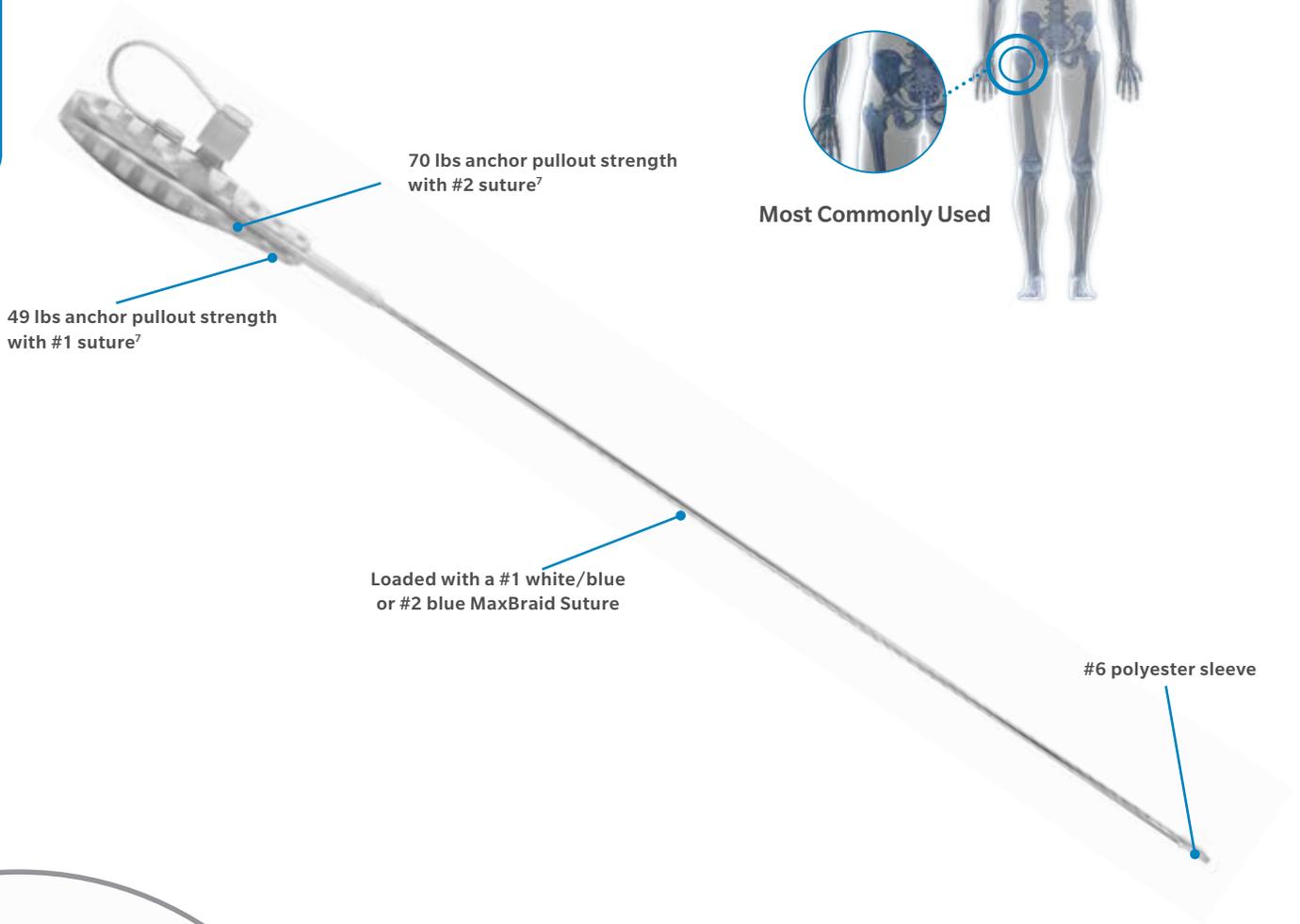
Instrumentation and Ordering Information for JuggerKnot Soft Anchor 1.0 mm Mini can be found on pages 22–23.

JuggerKnot
Soft Anchor Inserters



JuggerKnot 1.45 mm Long Soft Anchor

JuggerKnot
Soft Anchor Inserters

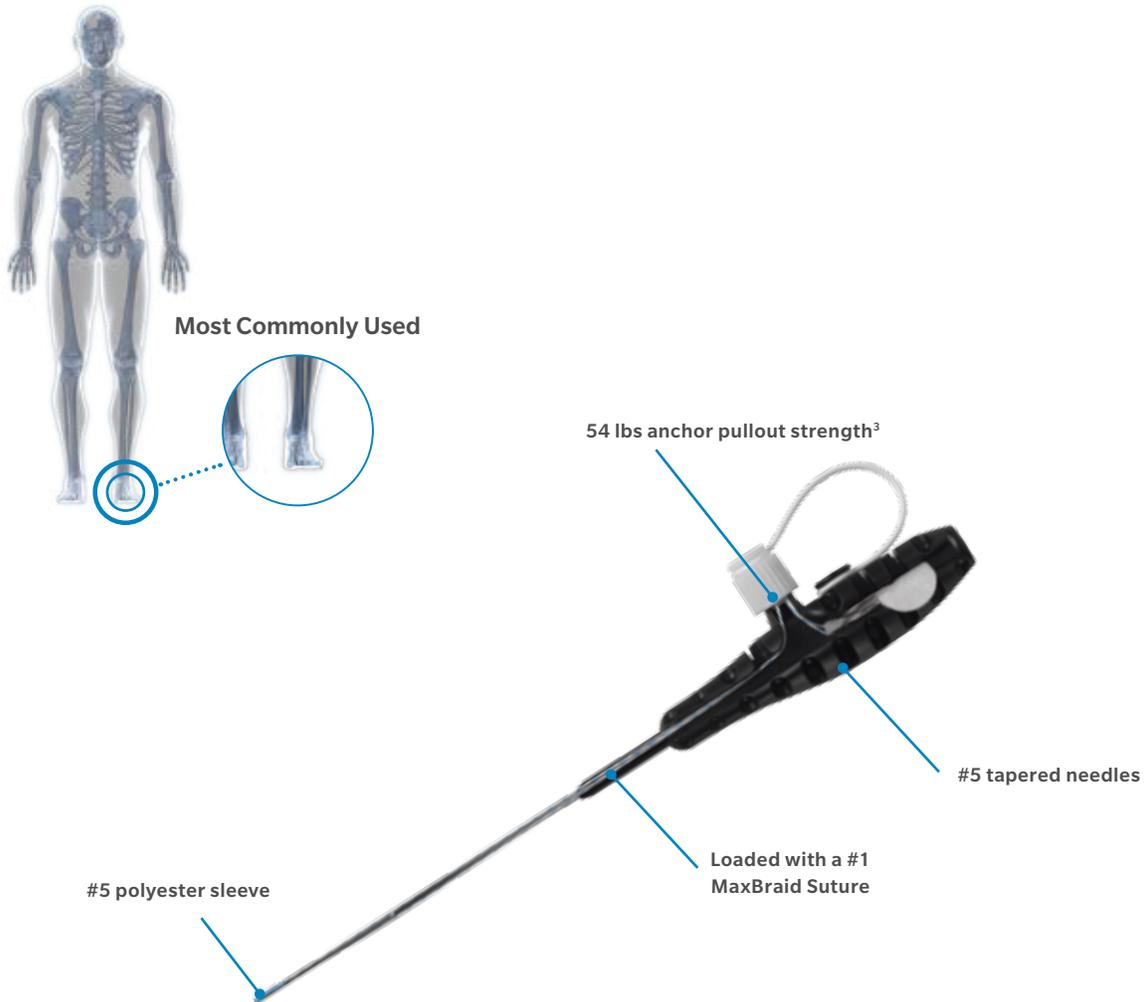


Surgical Technique available for:

- Hip Acetabular Labral Repair

Instrumentation and Ordering Information for JuggerKnot 1.45 mm Long Soft Anchor can be found on pages 22–23.

JuggerKnot Soft Anchor 1.4 mm Short

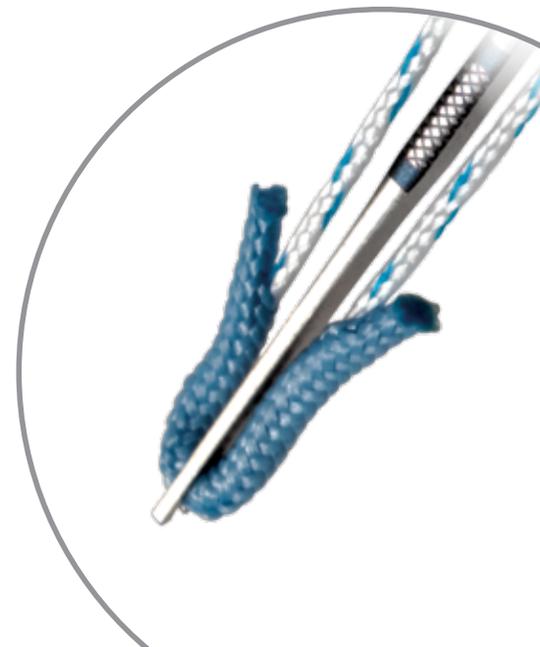


JuggerKnot
Soft Anchor Inserters

Surgical Technique available for:

- Lateral Epicondylitis Repair
- Midfoot Repair
- Lateral Ankle Repair
- Achilles Tendon Repair

Instrumentation and Ordering Information for JuggerKnot Soft Anchor 1.4 mm Short can be found on pages 24–25.



JuggerKnot Soft Anchor 1.45 mm Short Rigid

JuggerKnot
Soft Anchor Inserters



Most Commonly Used

52 lbs anchor pullout strength
with #1 suture⁸

78 lbs anchor pullout strength
with #2 suture⁸

#5 tapered needles

Loaded with a #1 blue/white
or #2 blue MaxBraid Suture

#5 polyester sleeve



Instrumentation and Ordering Information
for JuggerKnot Soft Anchor 1.45 mm Short
Rigid can be found on page 24–25.

JuggerKnotless Soft Anchor 2.1 mm Instrumentation

2.1 mm Disposable Kit



JuggerKnotless Disposable Kit

2.1 mm Reusable Instruments



Reusable Low Profile Obturator

Reusable Low Profile Trocar

Reusable Low Profile Four-Prong Guide

Reusable Low Profile Fishmouth Guide

Fishmouth Guide



Four-Prong Guide



Ordering Information

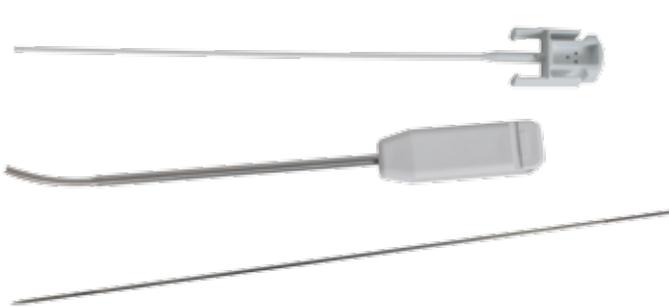
Implants

Part Number	Description
110005198	JuggerKnotless SS Implant
110005199	JuggerKnotless SS Implant (Package of 10)

Instrumentation

Part Number	Description
110003182	JuggerKnotless Disposable Low Profile Drill Bit (Sterile)
110003172	JuggerKnotless Disposable Kit
110017436	JuggerKnotless Reusable Low Profile Fishmouth Guide
110017434	JuggerKnotless Reusable Low Profile Obturator
110017433	JuggerKnotless Reusable Low Profile Trocar
110003181	JuggerKnotless Reusable Low Profile Four-Prong Guide

JuggerKnot Soft Anchor 1.4 mm and 1.5 mm Instrumentation

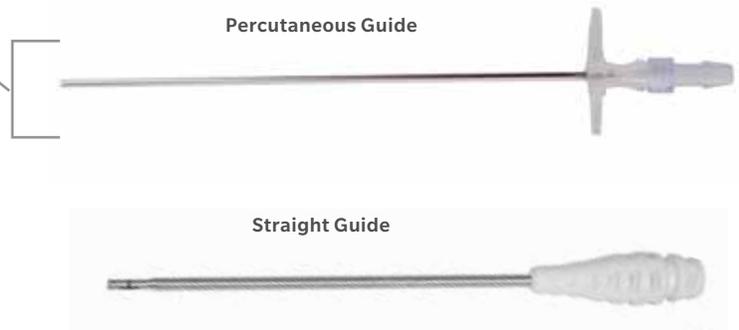


1.4/1.5 mm Curved Instrumentation

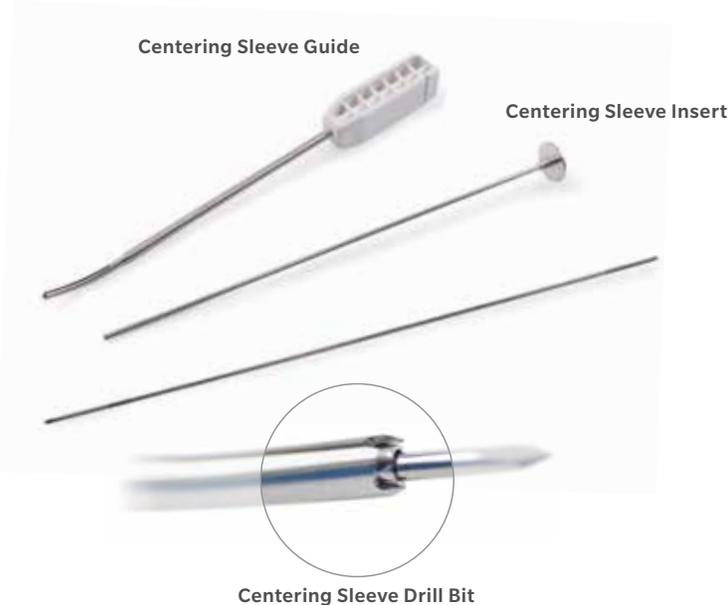
- 23° curvature
- Ability to drill a hole perpendicular to bone surface at anchor site
- Allows anchor to be placed through interval portals without compromising the rotator cuff.
- Kit also available with Straight Guide

1.4/1.5 mm Percutaneous Instrumentation

- Allows anchor to be inserted into the skin through a 2.4 mm diameter guide, minimizing tissue trauma
- Allows for multiple access points for labral tear repair
- No need for cannula



JuggerKnot
Soft Anchor
Instrumentation



1.4/1.5 mm Centering Sleeve Instrumentation

- Assists with consistent anchor placement via the curved guide by centering anchors in the drill hole

Ordering Information

Implants

Part Number	Description
912000	JuggerKnot Soft Anchor- 1.4 mm 2 Implant Pack (Guide, Drill Bit)
912030	JuggerKnot Soft Anchor- 1.4 mm Single Loaded Implant
912010	JuggerKnot Soft Anchor- 1.4 mm (Package of 10)
912031	JuggerKnot Soft Anchor-1.5 mm Single Loaded Implant
912015	JuggerKnot Soft Anchor-1.5 mm (Package of 10)

Instrumentation

Part Number	Description
912038	Reusable Trocar
912036R	Rigid Drill Bit
912039	Reusable Obturator
912038P	Percutaneous Trocar
912035C	Reusable Curved Guide
912038C	Flexible Trocar
912036	Flexible Drill Bit
912039C	Flexible Obturator
912136	Sterile Single Flexible Drill Bit
912040	Disposable Kit (Guide, Flex Drill Bit)
912040R	Disposable Kit (Guide, Rigid Drill Bit)
912040C	Disposable Curved Kit (Curved Guide, Flex Drill Bit)
912040P	Percutaneous Kit (Guide, Drill Bit)
912140C	1.4 mm Centering Sleeve Kit (Curved Guide with Drill Sleeve)
912045	1.4 mm Centering Sleeve Kit (Flex Drill Bit with Drill Sleeve)
912035	Straight Reusable Guide
912037R	Rigid Drill (Gold)
912035C	Curved Reusable Guide
912037	Flex Drill (Black)
912041	Straight Disposable Kit (Guide, Large Shank Drill)
912041C	Curved Disposable Kit (Guide, Drill Bit)
912141C	1.5 mm Centering Sleeve Kit (Curved Guide with Drill Sleeve)
912046	1.5 mm Centering Sleeve Kit (Flex Drill Bit with Drill Sleeve)

JuggerKnot Soft Anchor 2.9 mm with and without Needles Instrumentation

2.9 mm/2.9 mm with Needles Instrumentation



2.9 mm and 2.9 with Needles In Guide Punch



2.9 mm with Needles Reusable Short Guide

2.9 mm Instrumentation



2.9 mm Disposable Guide



2.9 mm Reusable Guide



2.9 mm Disposable Kit



Ordering Information

Implants

Part Number	Description
912029	JuggerKnot Soft Anchor-2.9 mm Double Loaded #2 MaxBraid Suture BL/WH-BL-Single Loaded
912529	JuggerKnot Soft Anchor-2.9 mm Double Loaded #2 MaxBraid Suture BL/WH-BL (Package of 10)
110005093	JuggerKnot Soft Anchor- 2.9 mm with Needles with Cutting Needles
110005096	JuggerKnot Soft Anchor-2.9 mm with Needles with Tapered Needles
110005241	JuggerKnot Soft Anchor-2.9 mm with Needles with Cutting Needles (Package of 10)
110005242	JuggerKnot Soft Anchor-2.9 mm with Needles with Tapered Needles (Package of 10)

Instrumentation

Part Number	Description
912090G	Reusable Drill Guide
912091	Sterile Disposable Drill Bit
912092G	Reusable Obturator
912093G	Reusable Trocar
912064	Reusable In-Guide Punch
912057	JuggerKnot Soft Anchor- 2.9 mm Disposable Instrument Kit (Guide, Obturator, Drill Bit)
110005306	JuggerKnot Soft Anchor- 2.9 mm with Needles Drill Bit Short Shaft Sterile Pack
912059	JuggerKnot Soft Anchor- 2.9 mm with Needles Short Punch
1100016951	JuggerKnot Soft Anchor- 2.9 mm with Needles Reusable Short Guide

JuggerKnot Soft 1.0 mm Mini and 1.45 mm Long Anchor Instrumentation

1.0 mm Mini Instrumentation



Drill Bit

1.45 mm Long Anchor Instrumentation



Straight Guide



Flexible Drill Bit



Rigid Drill Bit (Large Shank)

1.45 mm Long Anchor Curved Instrumentation



Curved Guide



Centering Sleeve

JuggerKnot
Soft Anchor
Instrumentation

Ordering Information

Implants

Part Number	Description
912076	JuggerKnot Soft Anchor-1.0 mm Mini with 2-0 Needles with Drill
912080	JuggerKnot Soft Anchor-1.0 mm Mini with 2-0 Needles (Package of 10)
912082	JuggerKnot Soft Anchor-1.0 mm with 3-0 Needles with Drill
912084	JuggerKnot Soft Anchor-1.0 mm with 3-0 Needles (Package of 10)
916030	JuggerKnot Long Soft Anchor #1 Single Loaded
010000334	JuggerKnot Long Soft Anchor #1 (Package of 10)
010000324	JuggerKnot Long Soft Anchor #2 Single Loaded
010000335	JuggerKnot Long Soft Anchor #2 (Package of 10)

Instrumentation

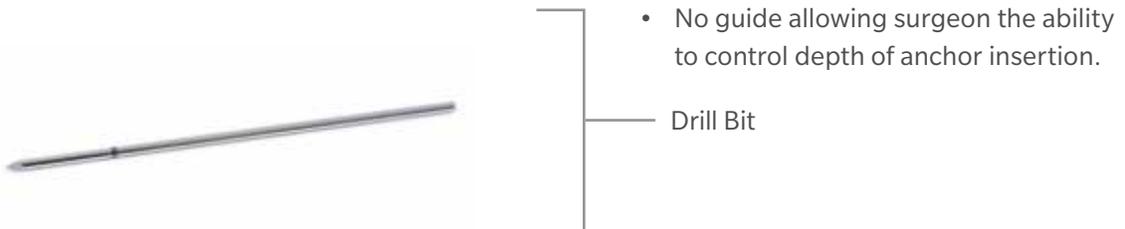
Part Number	Description
912077	JuggerKnot Soft Anchor 1.0 mm Mini Step Drill
110002759	JuggerKnot Long Soft Anchor 1.45 mm Reusable Fishmouth Guide
916020	JuggerKnot Long Soft Anchor 1.45 mm Disposable Curved Set (Guide, Centering Sleeve, and Flexible Drill Bit)
916034	JuggerKnot Long Soft Anchor 1.45 mm Reusable Curved Guide
916035	JuggerKnot Long Soft Anchor 1.45 mm Reusable Straight Four-Prong Guide
916036	JuggerKnot Long Soft Anchor 1.45 mm Disposable Flex Drill
916037	JuggerKnot Long Soft Anchor 1.45 mm Disposable Rigid Drill
916038	JuggerKnot Long Soft Anchor 1.45 mm Reusable Flex Trocar
916039	JuggerKnot Long Soft Anchor 1.45 mm Reusable Flex Obturator
916040	JuggerKnot Long Soft Anchor 1.45 mm Disposable Straight Guide Kit (Guide and Rigid Drill)
110016992	JuggerKnot Long Soft Anchor 1.45 mm Disposable Flex Drill with Centering Sleeve

JuggerKnot Soft 1.4 mm Short and 1.45 mm Short Rigid Instrumentation

1.4 mm Short Instrumentation



1.45 mm Short Rigid Instrumentation



Ordering Information

Implants

Part Number	Description
912068	JuggerKnot 1.4 mm Short #1 Single Loaded
912069	JuggerKnot 1.4 mm Short #1 (Package of 10)
110005307	JuggerKnot 1.45 mm Short Rigid #1 Implant with Drill Bit
110005315	JuggerKnot 1.45 mm Short Rigid #2 Implant with Drill Bit
110005319	JuggerKnot 1.45 mm Short Rigid #1 Implant (Package of 10)
110005320	JuggerKnot 1.45 mm Short Rigid #2 Implant (Package of 10)

Instrumentation

Part Number	Description
912071	Sterile Disposable Drill Bit
912072	Reusable guide
912073	JuggerKnot 1.4 mm Short Disposable Kit with Guide and Drill Bit
912075	JuggerKnot 1.4 mm Short Disposable Kit with Implant and Guide
110005323	JuggerKnot 1.45 mm Short Rigid Drill (Package of 5)

JuggerKnot Soft Anchor

INDICATIONS FOR USE

Intended for soft tissue to bone fixation for the following Indications:

Shoulder

- Bankart lesion repair
- S.L.A.P. lesion repair
- Acromio-clavicular repair
- Capsular shift / capsulolabral reconstruction
- Deltoid repair
- Rotator cuff tear repair
- Biceps tenodesis

Elbow

- Ulnar or radial collateral ligament reconstruction
- Lateral epicondylitis repair
- Biceps tendon reattachment

Hand and Wrist

- Collateral ligament repair
- Scapholunate ligament reconstruction
- Tendon transfers in phalanx
- Volar plate reconstruction

Hip

- Acetabular labral repair

Knee

- Extra-capsular repair: MCL, LCL, and posterior oblique ligament
- Iliotibial band tenodesis
- Patellar tendon repair
- VMO advancement
- Joint capsule closure

Foot and Ankle

- Medial / lateral repair and reconstruction
- Mid- and forefoot repair
- Hallux valgus reconstruction
- Metatarsal ligament/tendon repair or reconstruction
- Achilles tendon repair

JuggerKnot Mini Soft Anchor

INDICATIONS FOR USE

Intended for soft tissue to bone fixation for the following Indications:

Shoulder

- Bankart repair

Hand and Wrist

- Ulnar or lateral collateral ligament reconstruction
- Repair/reconstruction of collateral ligaments
- Flexor and extensor tendon at the PIP, DIP, and MCP joints for all digits.
- Scapholunate ligament reconstruction

Foot and Ankle

- Midfoot reconstruction
- Hallux valgus reconstruction

JuggerKnotless Soft Anchor

INDICATIONS FOR USE

Indicated for soft tissue reattachment procedures for the following indications:

Shoulder

- Acromio-clavicular Separation
- Anterior Shoulder Instability Repair
- Bankart lesion repair
- Biceps tenodesis
- Capsule Repair or Capsulolabral Reconstruction
- Deltoid Repair
- Rotator Cuff Repair
- S.L.A.P. Lesion Repair

Elbow

- Biceps Tendon Reattachment
- Biceps Tendon Reconstruction
- Lateral/Medial Repairs
- Lateral Epicondylitis Repair (Tennis Elbow Repair)
- Ulnar & Radial Collateral Ligament Reconstruction

Hand and Wrist

- Collateral Ligament Repair (Gamekeeper's Thumb)
- Scapholunate Ligament Reconstruction
- Tendon Transfers in Phalanx
- Volar Plate Reconstruction

Hip

- Labral

Knee

- Iliotibial Band Tenodesis
- Joint Capsule Closure
- Lateral/Medial Collateral Ligament Repair
- Patellar Ligament Repair
- Patellar Tendon Repair
- Patellar Realignment/Repair
- Posterior Oblique/Ligament Repair
- VMO Advancement

Foot and Ankle

- Medial / lateral stabilization repairs and reconstruction
- Mid- and forefoot reconstruction/repairs
- Hallux valgus reconstruction
- Achilles tendon repair/reconstruction

CONTRAINDICATIONS

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

References

1. PRWeb. Biomet, Terumo, and Arterioocyte Trail Blaze in US Orthopedic Device Markets, Claiming Nearly Entire Market Share Reports iData Research. March 13, 2013. <http://www.prweb.com/releases/prweb2013/3/prweb10519419.htm>.
2. Barber FA, M.D, Herbert MA, Ph.D. "Cyclic Loading Biomechanical Analysis of the Pullout Strengths of Rotator Cuff and Glenoid Anchors: 2013 Update." Arthroscopy 2013, Article in Press. Bench test results are not necessarily indicative of clinical results.
3. Barber FA, Herbert MA, Hapa O, Rapley JH, Barber CA, Bynum JA, Hrnack SA. "Biomechanical Analysis of Pullout Strength of Rotator Cuff and Glenoid Anchors. 2011 Update." Arthroscopy 2011. Bench test results are not necessarily indicative of clinical results.
4. Data on file at Biomet Sports Medicine. Test Report BSM03. Bench test results are not necessarily indicative of clinical results.
5. Data on File at Biomet Sports Medicine. Biomechanical Evaluation of the Biomet Sports Medicine Juggernaut Soft Anchor. BMET0769.0-GBL. Bench test results are not necessarily indicative of clinical results.
6. Data on file at Biomet Sports Medicine. Test Report AT47D. Bench test results are not necessarily indicative of clinical results.
7. Data on file at Biomet Sports Medicine. Test Report BSM4. Bench test results are not necessarily indicative of clinical results.
8. Data on file at Biomet Sports Medicine. Test Report BSM17. Bench test results are not necessarily indicative of clinical results.
9. Email Chain Data on file at Biomet Sports Medicine.

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Biomet Sports Medicine
P.O. Box 587
56 E. Bell Drive
Warsaw, Indiana 46581-0587
USA

www.zimmerbiomet.com

0393.1-GLBL-en-REV0416

Technical File – Declaration of Conformity

Technical File: SM-JGK-003

We the Manufacturer:	Authorized European Community Representative and Location of Responsible Person:
Biomet Sports Medicine 56 East Bell Drive PO Box 587 Warsaw, IN 46581-0587 USA ☎800-348-9500	Biomet U.K. Limited Waterton Industrial Estate South Wales Bridgend CF 31 3XA United Kingdom ☎44-1656-655221 📠 44-1656-645454

Declaration:	We hereby declare under our sole responsibility that the following products meet the classification, requirements, relevant directive provisions, harmonized standards, normative documents, registrations and certifications referenced below and within the technical file referenced above.
Product Group:	Sterile Single-Use Implants Sterile Single-Use Instruments Non-Sterile Single-Use Instruments Non-Sterile Reusable Instruments
Product Family:	JuggerKnot Soft Anchor Implants and Instrumentation
Product Schedule:	Part number listing below
Classification:	Refer to part number listing below

Directives:	Council Directive 93/42/EEC and subsequent amendments concerning medical devices, i.e, Medical Device Directive – MDD:	
	Annex I Essential Requirements	
	Annex VII EC Declaration of Conformity Technical Documentation	
	Annex II EC Declaration of Conformity Full QAS – (Section 4 exception)	
Registrations and Certifications:	Certificate No.	Type
	CE 02271	EC Certificate – Full Quality Assurance
	MDSAP 667872	MDSAP Certificate
Notified Body:	Notified Body:	Notified Body No.:
	BSI Product Services Kitemark Court Davy Avenue, Knowlhill Milton Keynes, MK5 8PP United Kingdom	0086
Biomet Responsible Authority	Signature: 	Date: 20 Mar 2019
	Jared Cooper, Sports Medicine, Manager, Regulatory Affairs	

Declaration of Conformity Prepared Date: 19 March 2019

Form: INST 2.1.2.2 Rev 4

Ref: SOP 2.1.2 Tech File, Master Record, Product Master Record Procedure

Page: 1 of 7

MASTER maintained electronically within EtQ Reliance,

PROPRIETARY & CONFIDENTIAL

Technical File – Declaration of Conformity

Catalog / Product No.	Description	Sterile / Non-sterile	Reusable? Yes or No	Classification	Classification Rule Number per Annex IX	GMDN Code (This column may be removed if not required)
912035	JuggerKnot Reusable Guide	Non-Sterile	Yes	I	Rule 6	47831
912035C	JuggerKnot Reusable curved guide	Non-Sterile	Yes	I	Rule 6	47831
912038	JuggerKnot Reusable Trocar	Non-Sterile	Yes	I	Rule 6	47457
912038P	JuggerKnot Percutaneous Trocar	Non-Sterile	Yes	I	Rule 6	47457
912039	JuggerKnot Reusable Obturator	Non-Sterile	Yes	I	Rule 6	33997
912064	JuggerKnot IN-Guide Punch 2.9mm	Non-Sterile	Yes	I	Rule 6	47831
912072	JuggerKnot 1.4 Short Reusable Guide	Non-Sterile	Yes	I	Rule 6	47831
912090G	JuggerKnot 2.9 Reusable Guide	Non-Sterile	Yes	I	Rule 6	47831
912092G	JuggerKnot 2.9 Reusable Obturator	Non-Sterile	Yes	I	Rule 6	33997
912093G	JuggerKnot 2.9 Reusable Trocar	Non-Sterile	Yes	I	Rule 6	47457
916034	JuggerKnot Long Reusable Curved Guide	Non-Sterile	Yes	I	Rule 6	47831
916035	JuggerKnot Long Reusable Straight 4 Prong Guide	Non-Sterile	Yes	I	Rule 6	47831
916038	JuggerKnot Long Reusable Trocar	Non-Sterile	Yes	I	Rule 6	47457
916039	JuggerKnot Long Reusable Obturator	Non-Sterile	Yes	I	Rule 6	33997
110002759	JuggerKnot Long Straight Fishmouth Guide	Non-Sterile	Yes	I	Rule 6	47831
110016951	JuggerKnot 2.9 Short Reusable Guide	Non-Sterile	Yes	I	Rule 6	35095
912036	JuggerKnot Single Loaded Drill Bit	Non-Sterile	No	IIa	Rule 6	47563
912036R	JuggerKnot 1.4 Rigid Drill Bit	Sterile	No	IIa	Rule 6	43390
912037	JuggerKnot 1.5 Flex Drill Bit	Sterile	No	IIa	Rule 6	43390

Declaration of Conformity Prepared Date: 19 March 2019

Form: INST 2.1.2.2 Rev 4

Ref: SOP 2.1.2 Tech File, Master Record, Product Master Record Procedure

Page: 2 of 7

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Technical File – Declaration of Conformity

912037R	JuggerKnot 1.5 Rigid Drill Bit	Sterile	No	Ia	Rule 6	43390
912038C	JuggerKnot Flex Trocar	Sterile	No	Ia	Rule 6	47457
912039C	JuggerKnot Flex Obturator	Sterile	No	Ia	Rule 6	33997
912040	JuggerKnot 1.4 Disposable Set	Sterile	No	Ia	Rule 6	44052
912040C	JuggerKnot 1.4 Curved Kit	Sterile	No	Ia	Rule 6	44052
912040P	JuggerKnot 1.4 Percutaneous Kit	Sterile	No	Ia	Rule 6	44052
912040R	JuggerKnot 1.4 Disposable Kit with Rigid Drill Bit	Sterile	No	Ia	Rule 6	44052
912041	JuggerKnot 1.5 Disposable Kit	Sterile	No	Ia	Rule 6	44052
912041C	JuggerKnot 1.5 Curved Kit	Sterile	No	Ia	Rule 6	44052
912045	JuggerKnot Flex Drill Bit with Drill Sleeve 1.4mm	Sterile	No	Ia	Rule 6	44052
912046	JuggerKnot Flex Drill Bit with Drill Sleeve 1.5mm	Sterile	No	Ia	Rule 6	44052
912057	JuggerKnot 2.9 Disposable Kit	Sterile	No	Ia	Rule 6	44052
912071	JuggerKnot 1.4 Short Single Loaded Drill Bit	Sterile	No	Ia	Rule 6	43390
912073	JuggerKnot 1.4 Short Instrument Kit	Sterile	No	Ia	Rule 6	44052
912091	JuggerKnot 2.9 Drill Bit	Sterile	No	Ia	Rule 6	43390
912136	JuggerKnot 1.4mm Disposable Flexible Drill	Sterile	No	Ia	Rule 6	43390
912140C	JuggerKnot Curved Kit with Drill Sleeve 1.4mm	Sterile	No	Ia	Rule 6	44052
912141C	JuggerKnot Curved Kit with Drill Sleeve 1.5mm	Sterile	No	Ia	Rule 6	44052
916036	JuggerKnot Long Flex Drill Bit	Sterile	No	Ia	Rule 6	43390
916037	JuggerKnot Long Rigid Drill Bit	Sterile	No	Ia	Rule 6	43390
916040	JuggerKnot Long Disposable Straight Kit (Straight Guide, Obturator, rigid drill)	Sterile	No	Ia	Rule 6	44052
110005306	JuggerKnot 2.9 Short Drill	Sterile	No	Ia	Rule 6	43390
110005323	JuggerKnot 2.9 Direct Insert (Rigid) Drill – 1.4/1.5 5 pack	Sterile	No	Ia	Rule 6	43390

Declaration of Conformity Prepared Date: 19 March 2019

Form: INST 2.1.2.2 Rev 4

Ref: SOP 2.1.2 Tech File, Master Record, Product Master Record Procedure

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Technical File – Declaration of Conformity

110016992	JuggerKnot Long Flex Drill with Sleeve	Sterile	Yes	Ia	Rule 6	44052
912000	JuggerKnot System Two Implants / One Instrument Set (Size 1, 1.4mm w/ Blue/White MaxBraid Suture)	Sterile	No	Iib	Rule 8	45062
912010	JuggerKnot Size1 1.4mm w/ Blue/White MaxBraid Suture 10 Pack	Sterile	No	Iib	Rule 8	45062
912015	JuggerKnot Single Loaded Anchor Size 2, 1.5mm w/ Blue/White MaxBraid Suture 10 Pack	Sterile	No	Iib	Rule 8	45062
912029	JuggerKnot Soft Anchor- 2.9 (blue and white/blue MaxBraid sutures)	Sterile	No	Iib	Rule 8	45062
912030	JuggerKnot Single Loaded Anchor Size 1, 1.4mm w/ Blue/White MaxBraid Suture	Sterile	No	Iib	Rule 8	45062
912031	JuggerKnot Single Loaded Anchor Size 2, 1.5mm w/ Blue/White MaxBraid Suture	Sterile	No	Iib	Rule 8	45062
912050	2.9mm JuggerKnot w/ 2 #2 MaxBraid Sutures (White and Blue/White)	Sterile	No	Iib	Rule 8	45062
912068	JuggerKnot 1.4mm Short Size 1 Blue/White MaxBraid Suture and Needles	Sterile	No	Iib	Rule 8	45062
912069	JuggerKnot 1.4mm Short Size 1 Blue/White MaxBraid Suture and Needles 10 Pack	Sterile	No	Iib	Rule 8	45062
912075	JuggerKnot Short Implant System	Sterile	No	Iib	Rule 8	45062
912529	JuggerKnot Soft Anchor- 2.9 (blue and white/blue MaxBraid sutures)- 10 pack	Sterile	No	Iib	Rule 8	45062
916030	JuggerKnot Long Single Loaded #1 Blue/White MaxBraid	Sterile	No	Iib	Rule 8	45062
010000324	JuggerKnot Long Single Loaded Size 2 Blue/White MaxBraid	Sterile	No	Iib	Rule 8	45062
010000334	JuggerKnot Long Single Loaded #1 Blue/White MaxBraid 10 Pack	Sterile	No	Iib	Rule 8	45062
010000335	JuggerKnot Long Single Loaded Size 2 Blue/White MaxBraid 10 Pack	Sterile	No	Iib	Rule 8	45062

5 pirkimo dalis, reikalaujamas nr. 4 - Sterilus įpakavimas, sterilioje pakuotėje

Technical File – Declaration of Conformity

110005093	JuggerKnot Soft Anchor – 2.9 with Cutting Needles	Sterile	No	Iib	Rule 8	45062
110005241	JuggerKnot Soft Anchor – 2.9 with Cutting Needles 10 pack	Sterile	No	Iib	Rule 8	45062
110005096	JuggerKnot Soft Anchor – 2.9 with Tapered Needles	Sterile	No	Iib	Rule 8	45062
110005242	JuggerKnot Soft Anchor – 2.9 with Tapered Needles 10 pack	Sterile	No	Iib	Rule 8	45062
110005307	JuggerKnot Soft Anchor – 1.4 Short Rigid Implant and Drill	Sterile	No	Iib	Rule 8	45062
110005315	JuggerKnot Soft Anchor – 1.5 Short Rigid Implant and Drill	Sterile	No	Iib	Rule 8	45062
110005319	JuggerKnot Soft Anchor – 1.4 Short Rigid 10 pack	Sterile	No	Iib	Rule 8	45062
110005320	JuggerKnot Soft Anchor – 1.5 Short Rigid 10 pack	Sterile	No	Iib	Rule 8	45062
916020	JuggerKnot Long Curved Disposable Set	Sterile	No	Iia	Rule 6	44052

GMDN Code(s):

33997: Obturator

45062: Soft tissue anchor, non-bioabsorbable

35095: Surgical drill guide, reusable

47457: Orthopaedic trocar, reusable

32390: Fluted surgical drill, reusable

43390: Fluted surgical drill, single-use, sterile

47831: Surgical instrument sleeve, reusable

44052: Orthopaedic surgical procedure kit, non-medicated, single-use

Technical File – Declaration of Conformity

<u>REV</u>	<u>DATE</u>	<u>REVISION HISTORY</u>
A	27January2014	Initial Release
B	24April2014	Transfer of Juggerknot Soft Anchor Implants and Instrumentation from technical files INSTR-SM-003, INSTR-SM-004 and SM-003. Remove part numbers 912001, 912060, 912090, 912092, 912093. Addition of part numbers 912136, 912045, 912046, 912141C, 916034, 916038-40, 110002759, 110016992.
C	23February2015	Addition of part number 916020. Administrative change to include Annex VII to DoC on page 1 for class I devices only.
D	23September2016	Updated GMDN codes for part numbers 912000, 912010, 912015, 912029, 912030, 912031, 912050, 912068, 912069, 912075, 912529, 916030, 010000324, 010000334, 010000335, 110005093, 110005241, 110005096, 110005242, 110005307, 110005315, 110005319, 110005320 from 57874 to 45062. 3 year Technical File Review. Updated GMDN codes for part numbers 912035, 912035C, 912064, 912072, 912090G, 916034, 916035, and 110002759 from 32311 to 47831. Updated GMDN codes for part numbers 912038, 912038P, 912093G, 916038, and 912038C from 14154 to 47457.
E	07November2017	Updated GMDN code for 912059 from 32859 to 35287. Updated GMDN code for part number 912036 from 32852 to 47563. Updated GMDN codes for part numbers 912036R, 912037, 912037R, 912071, 912091, 912136, 916036, 916037, 110005306, and 110005323 from 32852 to 43390. Updated GMDN codes for part numbers 912040, 912040C, 912041C, 912040P, 912040R, 912041, 912057, 916040, 912073, and 916020 from 33961 to 44052. Updated GMDN codes for part numbers 912045, 912046, 912140C, 912141C, and 110016992 from 32852 to 44052.
F		Remove 912059 from scope Change CMDCAS Certificate to MDSAP 667872 Removed GMDN code reference 35287

Technical File – Declaration of Conformity

G

Section 8 – Added Sterigenics-Salt Lake City as an EO sterilization site. Removed Centurion from list of sterilization sites.