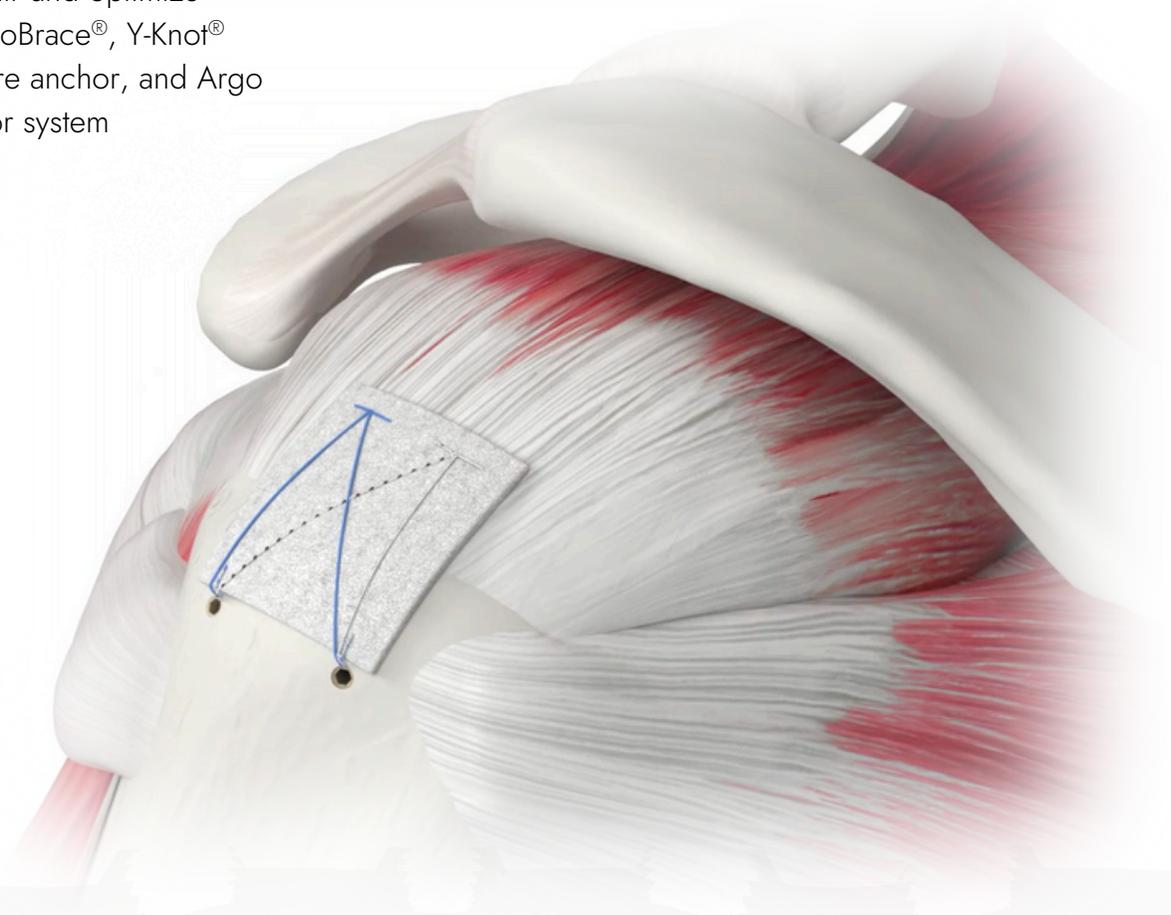




BioBrace[®]

Rotator Cuff Augmentation Surgical Technique Guide

Technique options to strengthen your rotator cuff repair and optimize healing using BioBrace[®], Y-Knot[®] PRO RC all-suture anchor, and Argo Knotless[®] anchor system



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Technique Preface

Retear rates for full-thickness rotator cuff tears can range anywhere from 7.2% to 94%, with insufficient biologic healing of the native tendon tissue and mechanical failure at the suture tendon interface as the leading causes of retear.¹⁻⁶

BioBrace[®] is a novel reinforced biocomposite implant. Augmenting a rotator cuff repair with BioBrace[®] increases time-zero strength by 34% and reduces cyclic creep by 23% in an ovine model.⁷⁻⁸

The following outlines techniques for augmenting rotator cuff repairs with BioBrace[®], to alleviate stress from the tendon and reduce rotator cuff repair failure at the suture-tendon interface.

BioBrace[®] was designed to be compatible with a variety of rotator cuff repair techniques. The following techniques outline a simple and efficient way to augment with BioBrace[®].

Technique's Covered

On-lay Augmentation of a Single Row Repair:

Medial BioBrace[®] Suture Passed Prior to Primary Repair Completion

Rotator Cuff Augmentation using Y-Knot[®] PRO RC, Argo Knotless[®] SP, and BioBrace[®]

Integrated Augmentation of a Double Row Repair:

BioBrace[®] Integrated Into Primary Repair

Rotator Cuff Augmentation using Y-Knot[®] RC PRO, Argo Knotless[®] SP, and BioBrace[®]

BioBrace[®] Integrated Following Primary Repair Reduction

Rotator Cuff Augmentation using Argo Knotless[®] GENESYS[™] and BioBrace[®]

Procedural Setup Recommendations

The following recommendations are agnostic to patient positioning

Cannula Selection and Placement

- A minimum 8mm diameter cannula should be utilized for the lateral portal. The lateral portal will be utilized to insert BioBrace® into the joint. Larger cannula sizes reduce friction during insertion.
- The lateral cannula should be placed more lateral than standard. Insertion and fixation of BioBrace® is made easiest when BioBrace® is inserted parallel to the rotator cuff. Use of a spinal needle to confirm that cannula placement is inline with the rotator cuff is recommended

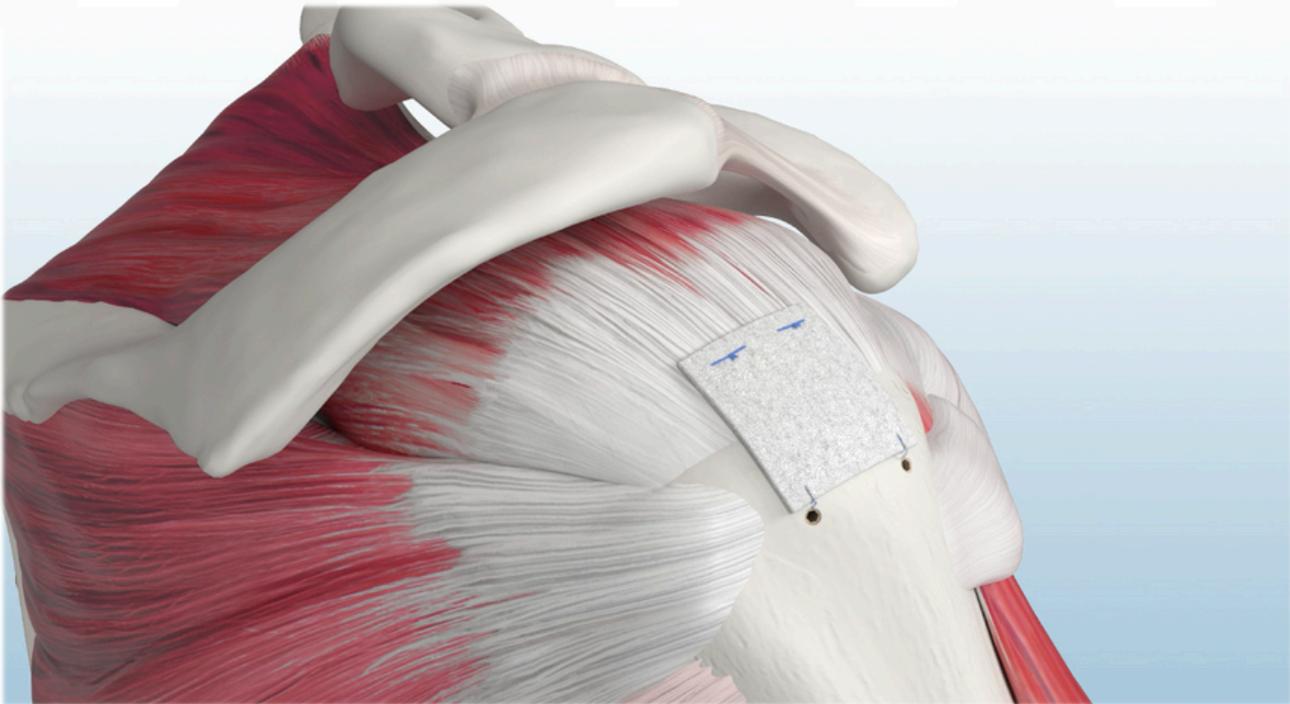
Accessory Portals

- Accessory portals are recommended for suture management. When not actively passing and/or tying suture, it is beneficial to have all suture docked through an accessory portal to reduce the risk of suture tangling.
- The use of anterolateral and posterolateral accessory portals are the most beneficial for suture management.
- Anchor insertion through accessory portals increases efficiency through decreasing suture docking steps.

BioBrace® Preparation

- It is beneficial to mark BioBrace® with a surgical marker for orientation under the scope. Designate the superficial side of BioBrace and the location of suture passage prior to passing suture through BioBrace®.
- BioBrace® can be trimmed length-wise and maintain mechanical strength. For smaller patient anatomies, consider reducing the length of BioBrace® to fit the patient's anatomical needs.
- The sutures utilized to secure BioBrace® laterally may be passed inside or outside the joint, depending on user preference. It is easier to pass suture through BioBrace® outside the joint. Passage of suture inside the joint reduces the quantity of sutures that require management at one time.

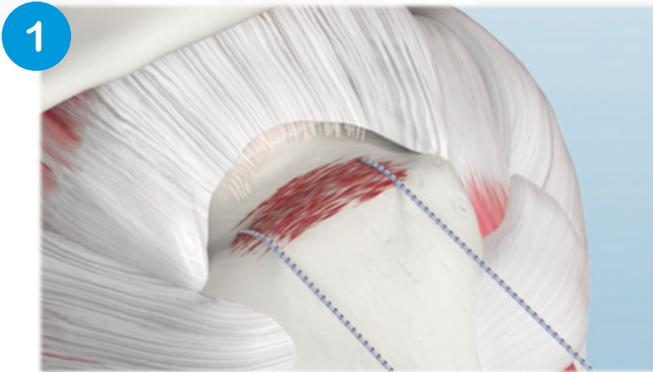
On-lay Augmentation of a Single Row Repair



Ordering Information

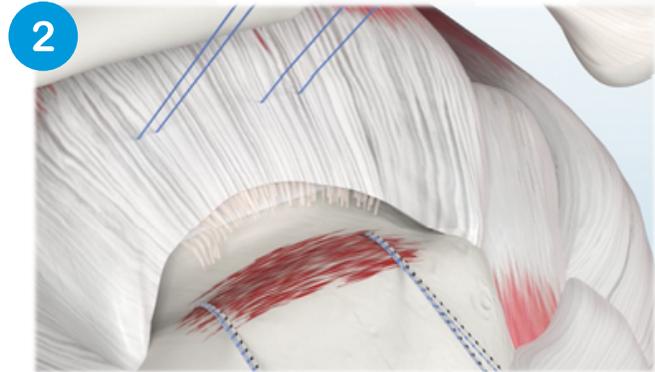
Description	Catalog Number	Quantity
BioBrace® 23mm x 30mm	BB23X30	1
Y-Knot® PRO RC w/ two #2 Hi-Fi® Sutures (Blue, White/Black)	YPRC02	2
4.75mm Argo Knotless® Self-Punching Anchor with 1mm Hi-Fi® Ribbon	SPK475	2
Hi-Fi® Passing Loop	HL7000	2

On-lay Augmentation of a Single Row Repair



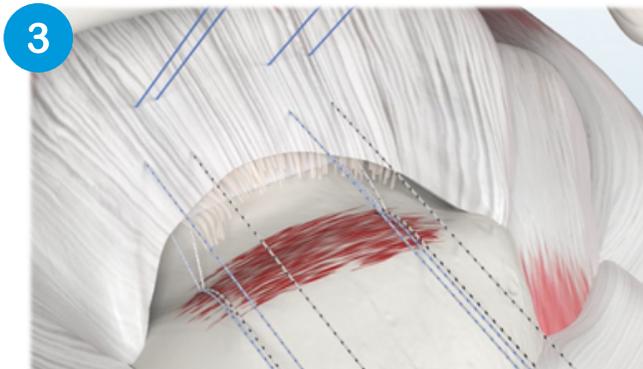
Insert Medial Anchors

- Insert two Y-Knot® PRO RC Suture Anchors double loaded with #2 Hi-Fi® Suture.
- Dock all suture through an accessory portal after anchor insertion.
- Anchor insertion through anterolateral and posterolateral accessory portals will reduce suture docking steps.



Pass Free Suture Through the Rotator Cuff

- Using a free suture, place two mattress stitches in the medial aspect of the tendon.
- The medial mattress stitches will be utilized to secure BioBrace® medially. It is recommended to pass these sutures more medial to where you will pass your primary fixation suture.
- Dock all suture through an accessory portal after suture passage.



Pass the Hi-Fi® #2 Suture Through the Rotator Cuff

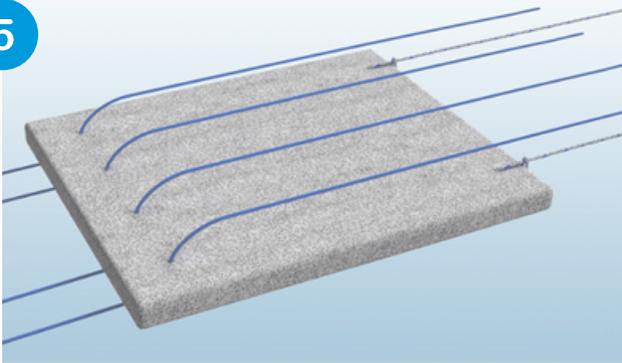
- Individually pass each limb of sliding #2 suture originating from the Y-Knot® PRO RC Suture Anchors (blue & white/black) in simple fashion through the medial aspect of the tendon.
- It is recommended to dock all suture through an accessory portal when not actively passing.



Complete Single Row Repair

- Tie and cut each set of Hi-Fi® #2 suture from each Y-Knot® PRO RC Suture Anchor to complete the rotator cuff repair.
- Cut the remaining suture limbs, using the Katana™ High Strength Suture Cutter.

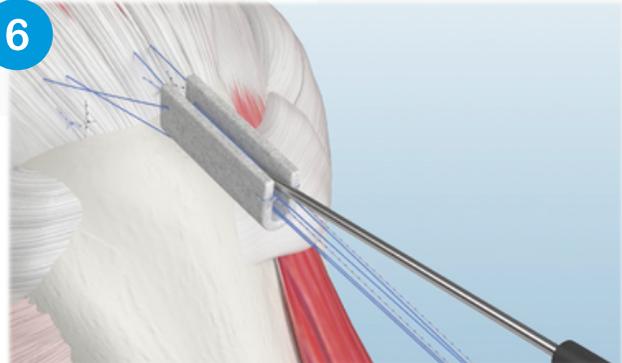
5



Pass Suture Through BioBrace®

- Use a ring grasper to pull all four suture limbs from the medial mattress stitches through the lateral portal.
- Pass all four limbs through the leading edge of BioBrace®, leaving a 5mm border to prevent suture pull-through.
- Create two luggage tags on the opposite end of BioBrace® using the Hi-Fi® Passing Loop.
- Pearl: Run a ring grasper along each suture limb before and after passing through BioBrace® to avoid tangles.

6



Deliver BioBrace® Into Joint

- Load the two center suture limbs into a knot pusher. Utilize the knot pusher to slide the BioBrace® through the cannula and into place.
- Maintain tension on all four suture limbs to enable BioBrace® to glide along the suture.
- Alternatively, a ring grasper may be utilized instead of a knot pusher, or a back grasper may be utilized to hold BioBrace® and slide it into the joint.

7



Secure BioBrace® Medially

- Tie, then cut the mattress stitches on the medial aspect of BioBrace®, using a Katana™ High Strength Suture Cutter.
- It is recommended to dock one set of suture while tying the other.

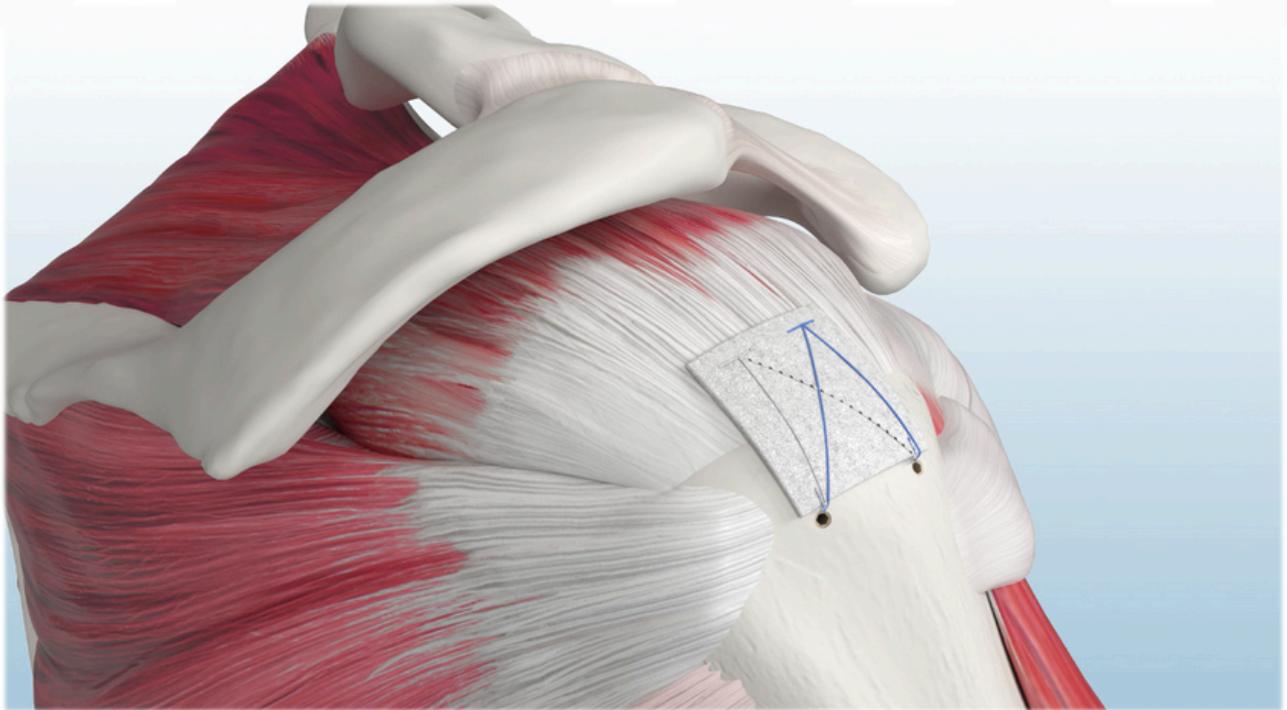
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Secure BioBrace® Laterally

- Secure the luggage tag using the Argo Knotless® Self-Punching Suture Anchor.

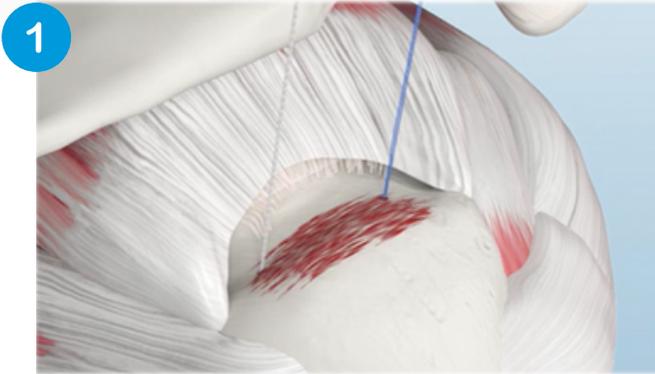
BioBrace® Integrated Into Primary Repair



Ordering Information

Description	Catalog Number	Quantity
BioBrace® 23mm x 30mm	BB23X30	1
Y-Knot® PRO RC w/ two #2 Hi-Fi® Sutures (Blue, White/Black)	YPRC02	2
4.75mm Argo Knotless® Self-Punching Anchor with 1mm Hi-Fi® Ribbon	SPK475	2
Hi-Fi® Passing Loop	HL7000	2

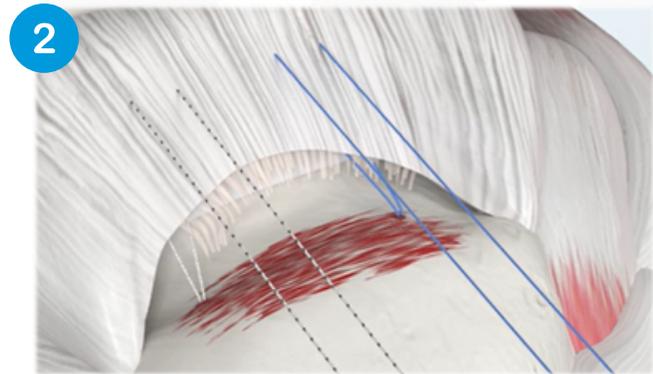
BioBrace[®] Integrated Into Primary Repair



1

Insert Medial Anchors

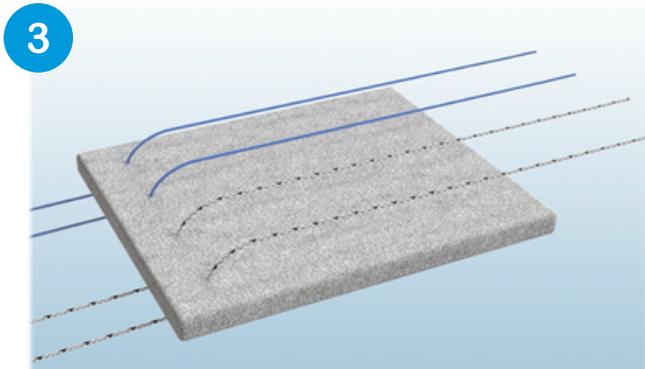
- Insert two Y-Knot[®] PRO RC Suture Anchors double loaded with #2 Hi-Fi[®] Suture.
- Optionally remove one suture from each anchor.
- Dock all suture through an accessory portal after anchor insertion.
- Anchor insertion through anterolateral and posterolateral accessory portals will reduce suture docking steps.



2

Pass Suture Through the Rotator Cuff

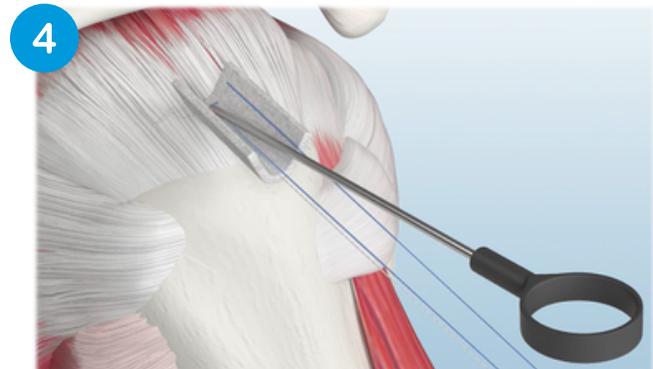
- Individually pass each limb of sliding #2 suture in simple fashion through the medial aspect of the tendon.
- It is recommended to dock all suture through an accessory portal when not actively passing.



3

Pass Suture Through BioBrace[®]

- Pass all four limbs of #2 suture from the medial anchors through the leading edge of BioBrace[®], leaving a 5mm border around the edges of BioBrace[®] to prevent suture pull-through.
- Pearl: Run a ring grasper along each suture limb prior to and after passage through BioBrace[®], to ensure there are no suture tangles.



4

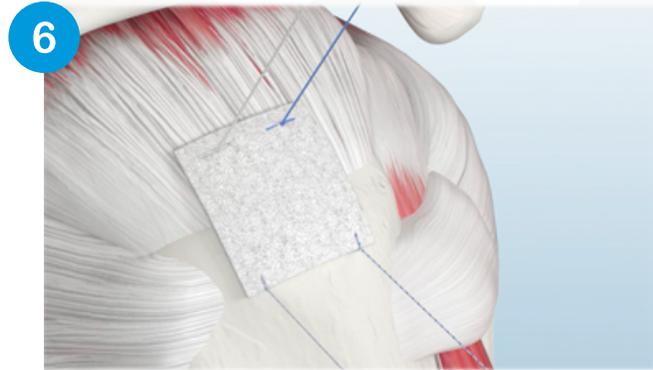
Deliver BioBrace[®] Into Joint

- Load the two center suture limbs into a knot pusher. Utilize the knot pusher to slide the BioBrace[®] through the cannula and into place.
- Maintain tension on all four suture limbs to enable BioBrace[®] to glide along the suture.
- Alternatively, a ring grasper or suture retriever may be utilized instead of a knot pusher.



Secure BioBrace® Medially

- Tie mattress stitches on the medial aspect of BioBrace®.
- It is recommended to dock one set of suture while tying the other.



Pass Lateral Stitches Through BioBrace®

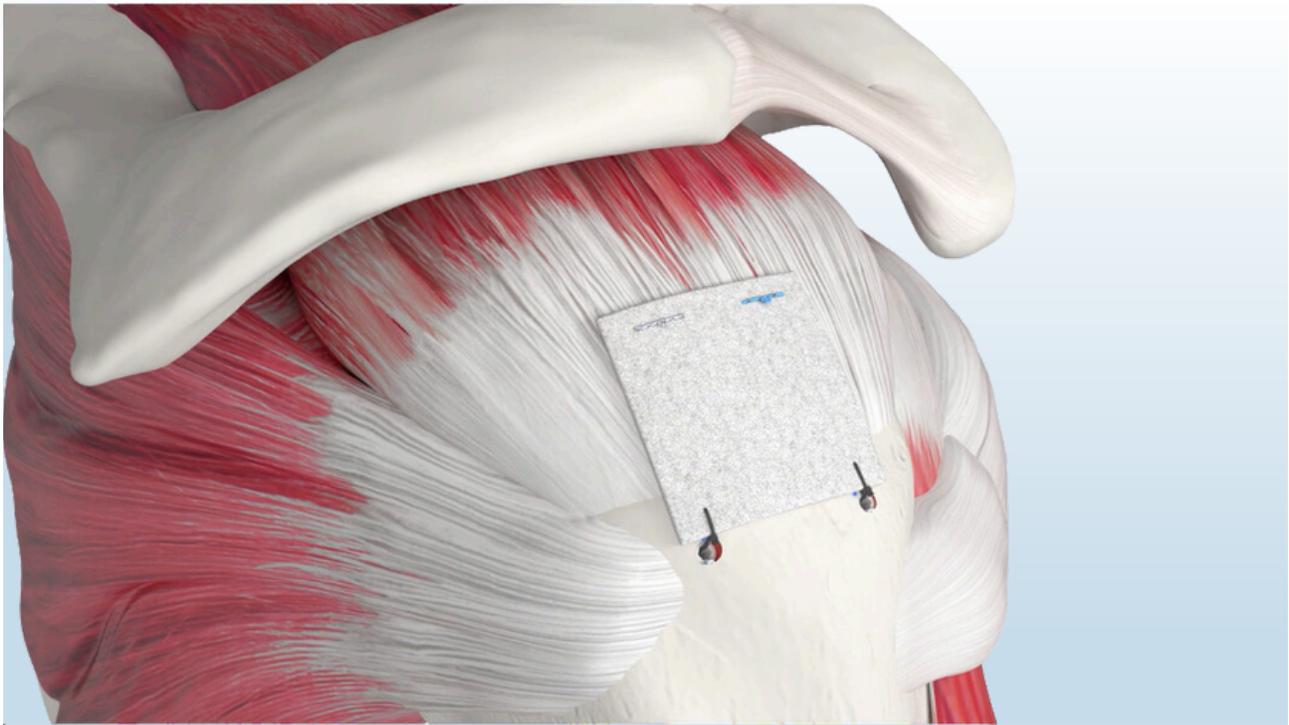
- Create two luggage tags on lateral edge of BioBrace® using the Hi-Fi® Passing Loop.



Secure BioBrace® Laterally

- Secure one limb of #2 suture from each medial anchor using the Argo Knotless® Suture Anchor to complete the rotator cuff repair and augmentation.
- Cut the remaining suture limbs, using the Katana™ Flush Cutter.

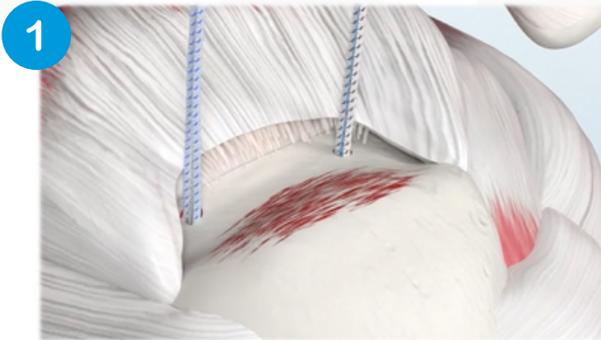
BioBrace[®] Integrated Following Primary Repair Reduction



Ordering Information

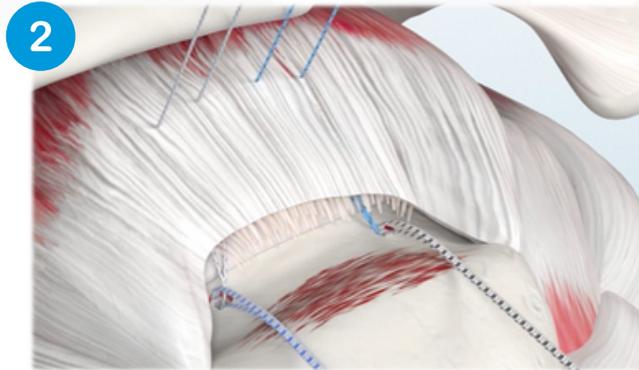
Description	Catalog Number	Quantity
BioBrace [®] 23mm x 30mm	BB23X30	1
4.75mm Argo Knotless [®] GENESYS [™] Anchor, Hi-Fi [®] Tape, Blue/Blue	KBC475TB	1
4.75mm Argo Knotless [®] GENESYS [™] Anchor, Hi-Fi [®] Tape, White/Black	KBC475TW	1
4.75mm Argo Knotless [®] GENESYS [™] Anchor with #2 Hi-Fi [®] Suture	KBC475	2

BioBrace® Integrated Following Primary Repair Reduction



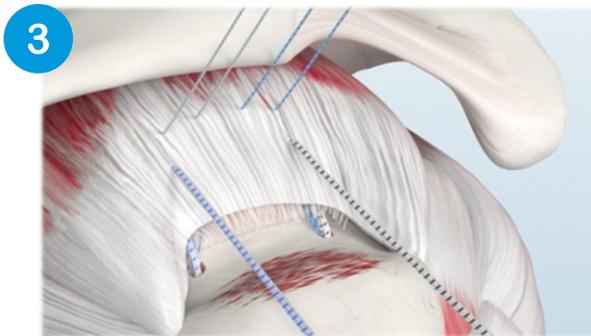
1 Insert Medial Anchors

- Insert two Argo Knotless® GENESYS™ Suture Anchors preloaded with Hi-Fi® Tape.
- Dock all suture through an accessory portal after anchor insertion.
- Anchor insertion through anterolateral and posterolateral accessory portals will reduce suture docking steps.



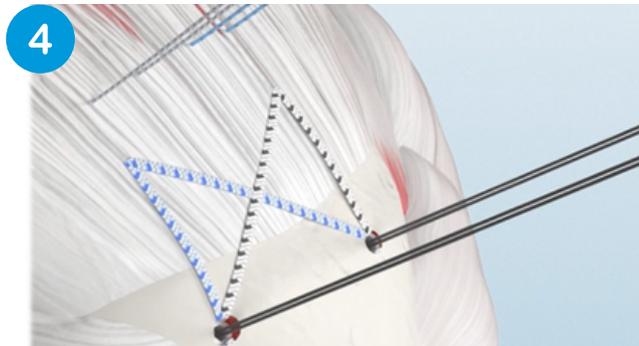
2 Pass the #2 Suture Through the Rotator Cuff

- Individually pass each limb of sliding #2 suture in simple fashion through the medial aspect of the tendon.
- The sliding #2 suture will be used to secure BioBrace® medially. It is recommended to pass these sutures more medial to where you will pass your primary fixation suture.
- It is recommended to dock all suture through an accessory portal when not actively passing.



3 Pass Swaged Tape Through Cuff

- Pass the swaged tape from each medial anchor through the remaining rotator cuff tissue, lateral to the mattress stitches.
- After passage through the cuff, cut the suture tape below the swage point, separating the tape limbs.

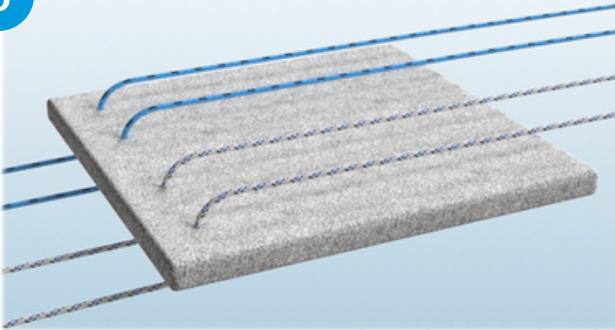


4 Secure Tape Laterally

- Secure one limb of Hi-Fi® Tape from each medial anchor using the Argo Knotless® GENESYS™ Suture Anchor to complete the rotator cuff repair.
- Cut the remaining suture tape limbs, using the Katana™ Flush Cutter. Use caution not to cut the sliding #2 suture from the lateral anchors as they will be utilized for augmentation.
- Dock the black sliding #2 suture in an accessory portal

BioBrace® Integrated Following Primary Repair Reduction (Cont.)

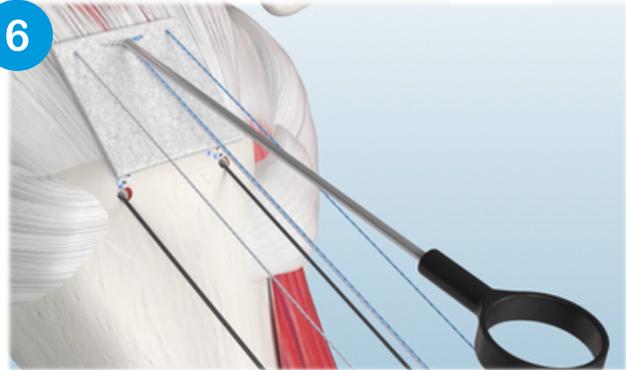
5



Pass Medial Retention Suture Through BioBrace®

- Pass all four limbs of #2 suture from the medial anchors through the leading edge of BioBrace®, leaving a 5mm border around the edges of BioBrace® to prevent suture pull-through.
- Pearl: Run a ring grasper along each suture limb prior to and after passage through BioBrace®, to ensure there are no suture tangles.

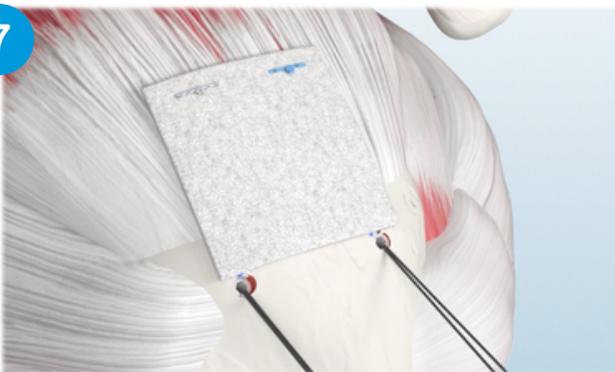
6



Deliver BioBrace® Into Joint

- Load the two center suture limbs into a knot pusher. Utilize the knot pusher to slide the BioBrace® through the cannula and into place.
- Maintain tension on all four suture limbs to enable BioBrace® to glide along the suture.
- Alternatively, a ring grasper may be utilized instead of a knot pusher.

7



Secure BioBrace® Medially

- Tie, then cut the mattress stitches on the medial aspect of BioBrace®, using a Katana™ High Strength Suture Cutter.
- It is recommended to dock one set of suture while tying the other.

8



Secure BioBrace® Laterally

- Pass a simple stitch through the lateral aspect of BioBrace®.
- Tie, then cut the lateral stitches to complete your repair.
- Alternatively, lateral mattress stitches may be utilized, if BioBrace® extends beyond the lateral anchor.

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8. Walsh, WR, AJ Carter, V Lovric, J Crowley, D Wills, T Wang, G Kanski, R Stanton, S Arnoczky, and R Arciero. 2021. "TissueEngineered Augmentation of A Rotator Cuff Tendon Using A Novel Bio-Inductive Biocomposite Scaffold: A Preliminary Study In Sheep." Presented at the Orthopaedic Research Society (ORS) 2021 Annual Meeting; February 12-16, 2021, Virtual.



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