smith&nephew

Tibial Fixation

Using the BIOSURE◇ SYNC Tibial Fixation Device

A Knee Series Technique Guide

Introduction

The Smith & Nephew BIOSURE° SYNC Tibial Fixation Device is an intra-tunnel device that provides superior tibial fixation strength, compared to that of standard fixation devices, when used to secure soft tissue grafts to bone during cruciate ligament reconstruction[1]. The BIOSURE SYNC Tibial Fixation Device provides the following unique features to enhance healing opportunity:

- Sheath wings that capture up to four soft-tissue grafts, compressing them against the tibial tunnel, allowing 360° bone-to-graft contact.
- A cortical tab that engages the cortex for rigid fixation and to prevent the sheath from migrating into the tunnel
- Barbs on each sheath wing designed to help discourage graft slippage and prevent post-operative laxity

The BIOSURE SYNC Tibial Fixation Device is made from PEEK-OPTIMA® material from Invibio® for use with BIOSURE PK Screws (25 mm length) and is designed to accommodate a variety of arthroscopic ligament reconstruction techniques. As a result, surgeons should use preferred methods for patient positioning and portal placement.

Procedure

1. Prepare the tibial and femoral tunnels in accordance with standard surgical practice. Ensure that the tibial tunnel is a minimum of 40 mm long.
2. Prepare the soft tissue grafts in a double-loop fashion by individually whip-stitching the distal strands.

   Note: In order to easily identify the matched ends of the grafts, it is recommended that each end of one graft be whip-stitched with the same color suture. Use a different color suture for the second graft.
3. Using the desired method, securely fix the proximal end of the graft in the femoral tunnel **(Figure 1)**.
4. Separate and tension the distal strands of the graft in line with the tibial tunnel.

   Note: To ensure that the graft strands are not twisted or crossed in the tibial tunnel, align the strands of like-colored suture as they exit the tibial tunnel.

Figure 1.

Figure 2.

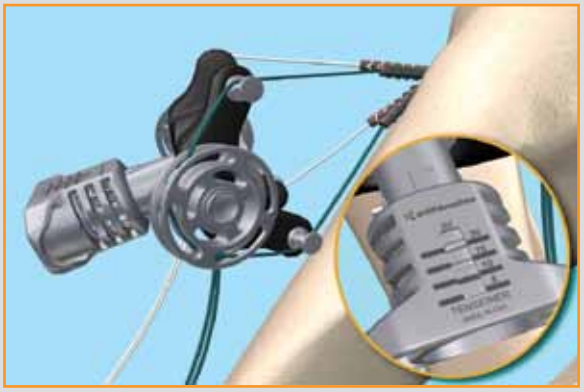

Figure 3.

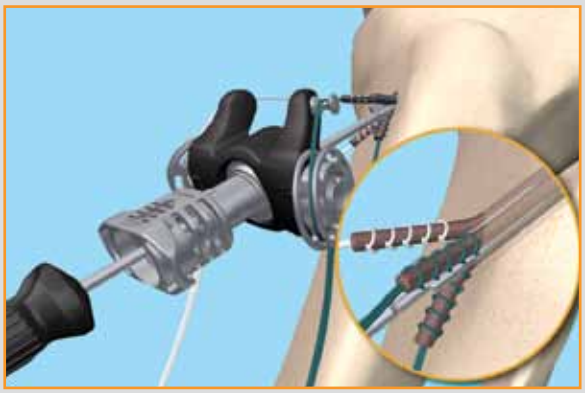

Figure 4.

5. If using the BIOSURE® SYNC Tensioner:
   a. Identify a matched pair of tendons and pull the sutures taut in line with the tunnel. Tie the suture tails together to create a closed loop approximately 4" from the tunnel opening (Figure 2).
   b. Repeat this process for the second pair of matched tendons (if applicable).

      Note: A suture loop longer than 4.25" from the tunnel opening may inhibit the reach of instruments to the tibial tunnel.

      Note: A suture loop shorter than 3.25" from the tunnel opening may prevent the placement of the suture loops onto the pulleys.
   c. Place one suture loop over each pulley, being sure to capture the suture management posts with each strand (Figure 3).
   d. Pull on the tensioner until desired tension is achieved as measured in either newtons or pounds-force.
   e. Insert all instrumentation through the center channel of the tensioner.
6. To separate and compress the grafts, introduce the appropriate size BIOSURE SYNC Dilator between the graft strands until the depth stop contacts the superior aspect of the tibial tunnel entrance.

Tunnel Diameter (mm)	BIOSURE SYNC (mm)	Dilator (mm)	BIOSURE PK Screw (X mm x 25 mm)
5	5–6	5–6	6
6	5–6	5–6	6
7	7–8	7–8	7
8	7–8	7–8	8
9	9–10	9–10	9
10	9–10	9–10	10
11	11–12	11–12	11
12	11–12	11–12	11

It is not necessary to pound the depth stop into the bone. Remove the dilator (Figure 4).

Note: Failure to use the dilator may cause difficulty inserting the fixation device into the tibial tunnel.

7. There are two options for inserting the BIOSURE◇ SYNC Tibial Fixation Device into the tibial tunnel.

   Option 1: Insert a Smith & Nephew 1.2 mm x 18” guide wire through the center channel of the tensioning device and into the tibial tunnel between the graft strands **(Figure 5)**. Place the fixation device on the inserter, ensuring that the cortical tab of the device is aligned with the notch on the inserter **(Figure 6)**. The inserter and fixation device are now prepared to pass over the guide wire and into the tibial tunnel.

   Option 2: Place the fixation device onto the inserter, ensuring that the cortical tab of the device is aligned with the notch on the inserter. Place a Smith & Nephew 1.2 mm x 18" guide wire through the inserter in order to simultaneously place the guide wire with the fixation device. This technique is desirable because the implant is self-centering and will ensure accurate placement of the guide wire.

8. Orient the fixation device so the four tendons are separated into the quadrants and the tab is aligned as closely to the 12 o’clock position as the grafts will permit. While maintaining tension on the graft strands, insert the fixation device into the tunnel until the cortical tab is flush with the superior aspect of the distal tibial tunnel **(Figure 7)**.

Figure 5.

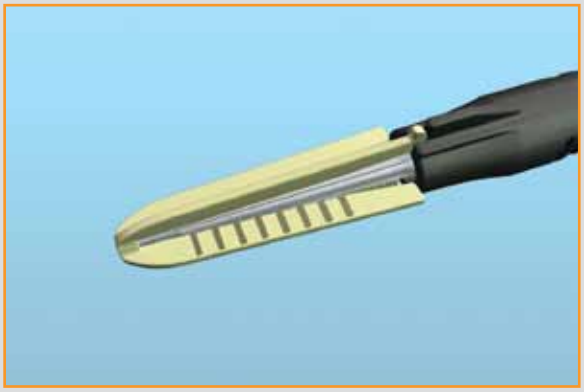

Figure 6.

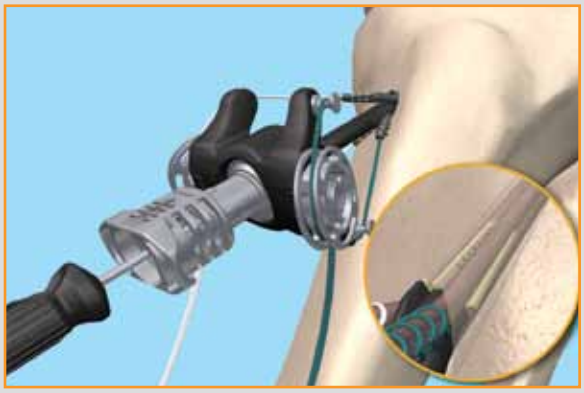

Figure 7.

Figure 8.

Figure 9.

Figure 10.

9. Remove the inserter, taking care to maintain the position of the guide wire.
10. Twist and release the J-lock feature of the inserter to convert to use as a driver (Figure 8).
11. Place the appropriate size BIOSURE® PK Screw onto the inserter.

Tunnel Diameter (mm)	BIOSURE SYNC (mm)	Dilator (mm)	BIOSURE PK Screw (X mm x 25 mm)
5	5–6	5–6	6
6	5–6	5–6	6
7	7–8	7–8	7
8	7–8	7–8	8
9	9–10	9–10	9
10	9–10	9–10	10
11	11–12	11–12	11
12	11–12	11–12	11

Pass the screw over the guide wire. While maintaining tension on the graft strands, insert the screw into the fixation device until it is flush with the tunnel (Figure 9).

12. Remove the driver and guide wire.
13. Trim any excess graft (Figure 10).

Additional Instruction

Prior to performing this technique, consult the instruction for use documentation provided with individual components – including indications, contraindications, warnings, cautions, and instructions.

Pearls

- The tibial tunnel length should be at least 40 mm long (sheath length is 32 mm).
- Avoid twisting the grafts within the tibial tunnel.
- Ensure that the guide wire remains in place after insertion of the sheath.
- If the guide wire dislodges prior to the screw insertion, using the inserter to replace it may help to ensure that it stays centered in the sheath.
- BIOSURE° PK Screw length should not exceed 25 mm.
- PEEK-OPTIMA® material from Invibio® is lubricious and a "squeak" during screw insertion is not common. Also, the purchase may not feel similar to that of absorbable devices. Neither of these characteristics of PEEK-OPTIMA material correlates to pullout strength.

References

1. Greaves L, Al-Beik J, Shaw W, BIOSURE SYNC Tibial Fixation Device: A Biomechanical Study of Fixation Strength (REF 10600681).

All data on file at Smith & Nephew, April 2010;
ITR 4235, *Initial Fixation Strength of BIOSURE SYNC vs. Intrafix: Bovine Tibia Model*;
ITR 4219, *Initial Fixation Strength of BIOSURE SYNC vs. Intrafix: Porcine Tibia Model*.

Ordering Information

To order the instruments used in this technique, call +1 800 343 5717 in the U.S. or contact an authorized Smith & Nephew representative.

BIOSURE° SYNC Tibial Fixation Devices

REF	Description
72202744	BIOSURE SYNC Tibial Fixation Device 5–6 mm
72202745	BIOSURE SYNC Tibial Fixation Device 7–8 mm
72202746	BIOSURE SYNC Tibial Fixation Device 9–10 mm
72202747	BIOSURE SYNC Tibial Fixation Device 11–12 mm

BIOSURE SYNC Instrument System (72202843)

Includes 1 each of the following:

REF	Description
72202752	BIOSURE SYNC Inserter
72202754	BIOSURE SYNC Tensioner
72202755	BIOSURE SYNC Dilator 5–6 mm
72202756	BIOSURE SYNC Dilator 7–8 mm
72202757	BIOSURE SYNC Dilator 9–10 mm
72202758	BIOSURE SYNC Dilator 11–12 mm
72202753	BIOSURE SYNC Instrument Tray

BIOSURE SYNC Interference Screws

REF	Description
72202260	BIOSURE PK Screw 6 x 25 mm
72202263	BIOSURE PK Screw 7 x 25 mm
72202267	BIOSURE PK Screw 8 x 25 mm
72202272	BIOSURE PK Screw 9 x 25 mm
72202276	BIOSURE PK Screw 10 x 25 mm
72202279	BIOSURE PK Screw 11 x 25 mm
72201201	Guide Wire, 1.2 mm x 18", box of 5, sterile

CAUTION: *U.S. Federal law restricts these devices to sale by or on the order of a physician.*

Courtesy of Smith & Nephew, Inc., Endoscopy Division

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