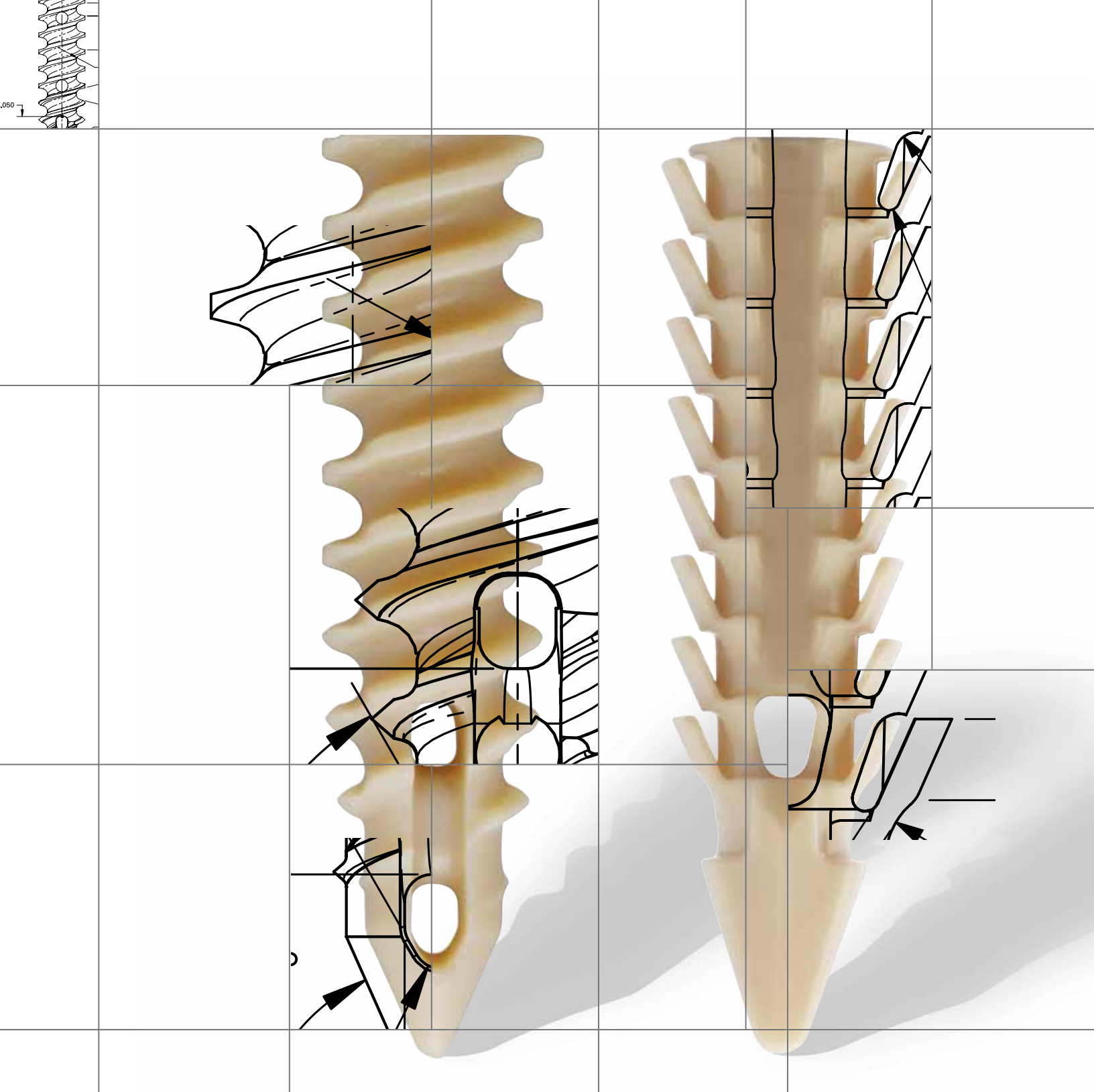




Rotator Cuff Solution

Combined Strengths.
Precise Control.

 **smith&nephew**
TWINFIX[®] Ultra
FOOTPRINT Ultra
Suture Anchors

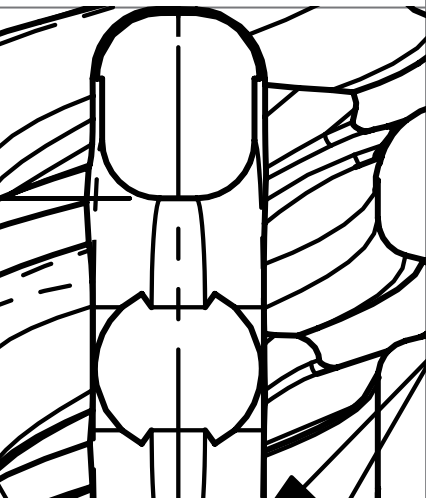


TWO ANCHORS. One precisely controlled rotator

Shoulder surgeons can rely on Smith & Nephew for rotator cuff repair solutions that provide *easy, secure* and *strong* repairs with *precise* control over final tensioning. This two anchor solution combines the benefits of our newest shoulder anchors, the TWINFIX[®] Ultra and FOOTPRINT Ultra Suture Anchors.

Reduce Cuff Displacement and Suture Slippage with a customizable repair

By combining the individual strengths of each anchor product into one solution we've created a **customizable** repair that facilitates complete rotator cuff footprint control. Strong pullout strength in the medial row with suture security and the ability to tension in the lateral row means a solution that can help reduce cuff displacement and suture slippage.*



cuff solution.

TWINFIX[◇] Ultra Suture Anchor

Medial Row solutions with TWINFIX Ultra Suture Anchors

Available in a choice of non-absorbable PEEK, absorbable HA, and titanium materials, as well as in a variety of size options and a choice of suture configurations, TWINFIX Ultra suture anchors can be used for primary or double row repairs and for the medial row of a suture bridging technique.

- **Ideal Fixation Strength:**

Transitional thread design provides secure fixation with distal “cutting” threads for easier insertion and proximal “locking” threads for stronger pull-out strength, even in poor bone quality.¹

ULTRABRAID[◇] suture provides stronger knot strength than competitive suture and a low profile knot stack.²

Internal driver supports anchor to optimize force transfer during insertion into all qualities of bone.

- **Optimal Versatility:**

Numerous anchor sizes, 4.5 mm, 5.5 mm and 6.5 mm facilitates rotator cuff repairs in patients. Multiple suture configurations, with double or triple ULTRABRAID sutures, provides flexibility for surgeon.

HA and PK: Multiple hole preparation instruments to address differing humeral bone quality.

Ti: Elongated distal trocar tip allows anchor to be self-tapping; without the need to predrill in most bone qualities

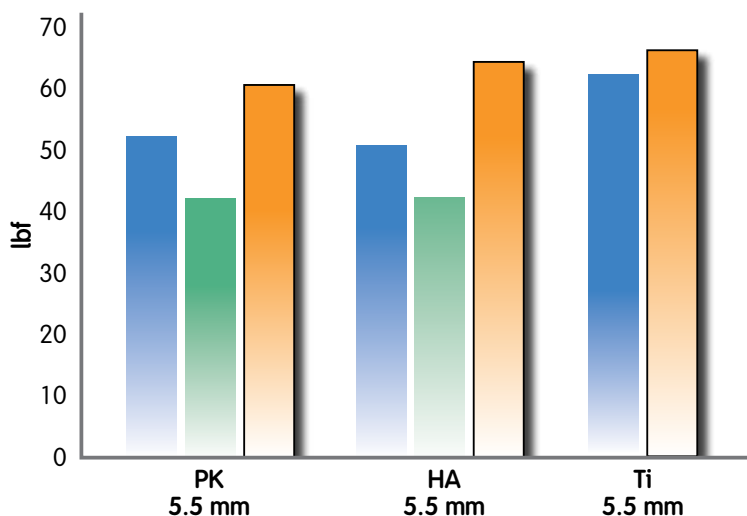
TWINFIX Ultra PK

TWINFIX Ultra Ti

TWINFIX Ultra HA

Average Fixation Strength¹

25/5 pcf bone block



Smith & Nephew TWINFIX Ultra
Mitek™ Healix™ PK
Arthrex™ Corkscrew™ FT PK

1) Data on file at Smith & Nephew, ITR-4091, ITR-4039, ITR-3952, 2009

2) Lo, Burkhart, Chan, and Kyriacos Athanasiou, "Arthroscopic Knots: Determining the Optimal Balance of Loop Security and Knot Security," Arthroscopy 20, no. 5 (May-June 2004): 489-502

FOOTPRINT Ultra Suture Anchor

Lateral row solutions with FOOTPRINT Suture Anchors

Available in two sizes, 4.5 and 5.5, the FOOTPRINT Ultra PK anchor is intended for use in the lateral row in double row suture bridging techniques.

- Uniquely designed, inner plug adjustability means more **precise** fixation and suture **tensioning** of final repair
- **Reduced suture slippage** means less gap formation and rotator cuff displacement³
- Exclusive tap-in anchor design with offset barbed geometry threads means **strong pullout** and **easy insertion**.³

Hidden Retention Suture

Runs parallel to the inserter and adds stability to the anchor/inserter interface

Torque Limiter

Incorporates positive stop technology to drive the inner plug a specific distance confirming suture is secured within anchor body

Elongated Handle

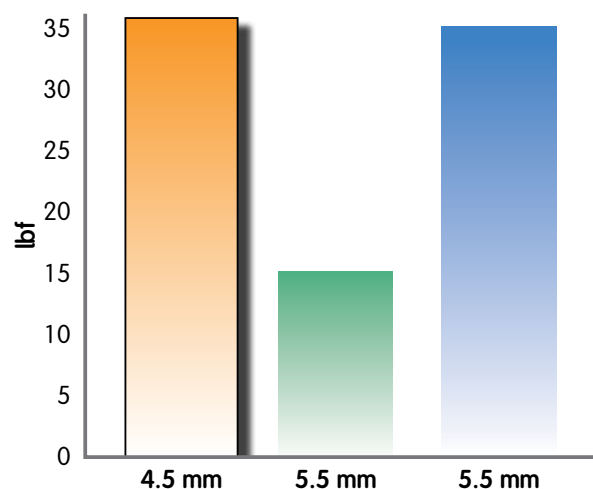
Ergonomic handle designed for surgeon comfort and ease of use

Integrated Suture Management

Ergonomic and easy to use suture docking tabs for final suture tensioning

Average Fixation Strength⁴

25/5 pcf bone block



Smith & Nephew FOOTPRINT Ultra PK

Arthrex™ PEEK PushLock™

Arthrex™ PEEK Swivel-Lock™

³ Data on file at Smith & Nephew, ITR-3679, 2008

⁴ Data on file at Smith & Nephew, ITR-4202, 2010; ITR-3557, 2007; ITR-3784, 2008

Offset Barbed Geometry

Unique barbed anchor design provides optimal pull-out strength for a tap-in anchor design

Preferred Anchor Size

4.5 mm and 5.5 mm anchor size offerings accommodate a variety of repair techniques

Trusted materials

Absorbable

Our absorbable HA suture anchor combines poly-L-lactic acid (PLLA) with hydroxyapatite (HA), a calcium phosphate similar to the mineral compound of bone. Once absorbed, it has the fracture resistance of human cortical bone.* HA is a natural bone mineral shown to promote bone replacement.

Non-absorbable

Our non-absorbable PK suture anchor incorporates PEEK-OPTIMA® polymer from Invibio®. With a modulus similar to cortical bone, PEEK-OPTIMA exhibits an ideal combination of strength, biocompatibility, revisability and inherent radiolucent characteristics.

Metallic

Titanium (Ti) suture anchors exhibit ideal fixation strength and anchor stability. Catering to surgeon's preference, titanium material brings a reliable solution that caters to both the needs of the patient and surgeon.

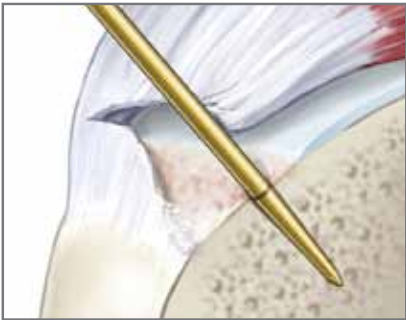
* Akao, M., Aoki, H. and Kato, K., Mechanical properties of sintered hydroxyapatite for prosthetic applications. *Journal of Material Science*: 16, 809-812, (1981).



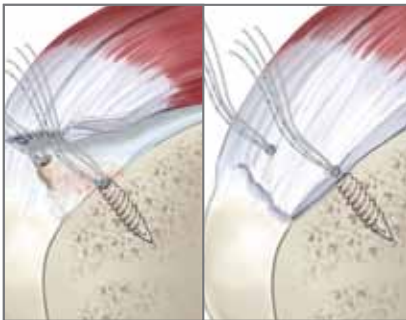
Procedural Techniques



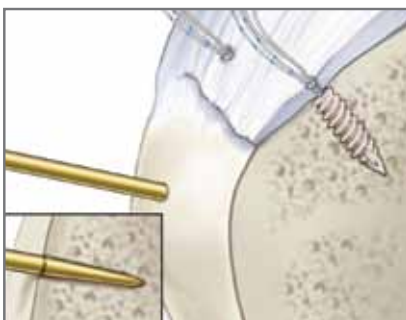
STEP 1: Identify the rotator cuff tear and confirm the rotator cuff tissue is mobile. Prepare the repair site utilizing the Whirlwind RF probe to remove any excess tissue from the articular margin of the humeral head to ensure proper visualization of the hole preparation site.



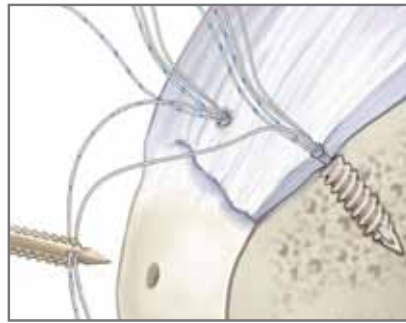
STEP 2: Use the 3.8 mm Tapered Awl (or recommended hole preparation device based on anchor material and bone quality) to prepare an anchor hole at the desired site on the medial border of the rotator cuff footprint which is slightly lateral to the articular margin. The proper hole depth is achieved when the laser depth mark on the distal end of the awl contacts the bone surface.



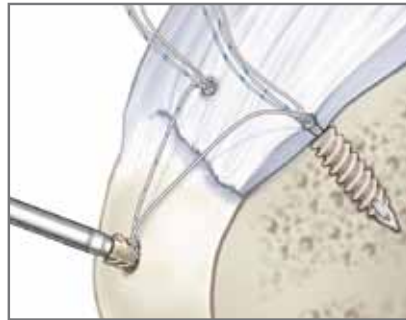
STEP 3: Insert the TWINFIX® Ultra PK suture anchor at a 45 degree angle, so it is partially under the articular surface. Insert by twisting the anchor until the laser mark is flush with the cortical bone layer. This places the suture anchor approximately 1 mm below the bone surface. Repeat this process to place a second TWINFIX Ultra PK suture anchor. Use a Smith & Nephew ELITE® PASS Suture Shuttle to pass sutures through the rotator cuff from an anterior to posterior position, then tension and tie the sutures as desired.



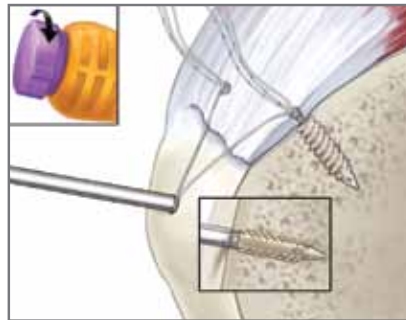
STEP 4: Place the distal tip of the awl/drill onto the bone at the desired implantation site of the FOOTPRINT Ultra PK suture anchor at or slightly distal to the lateral margin. Hold the awl in place and use a mallet to tap the proximal end to prepare the insertion site. The proper hole depth is achieved when the laser depth mark on the distal end of the awl contacts the bone surface.



STEP 5: Select the appropriate limb(s) of suture(s) from the TWINFIX Ultra PK medial row suture anchors. Thread the free medial row suture ends through the FOOTPRINT Ultra PK suture anchor using the blue suture threading loop.



STEP 6: Establish and maintain axial alignment of the suture anchor to the prepared insertion site, and place the tip of the anchor into the prepared hole. Using a mallet tap the FOOTPRINT Ultra PK suture anchor inserter handle until the laser mark is flush with the cortical bone.



STEP 7: Apply tension to each free limb of suture individually to establish the desired suture tension over the rotator cuff tissue and secure suture limbs on the inserter handle suture management tabs. While maintaining slight downward pressure on the inserter handle turn the torque limiter knob in the clockwise direction until audible clicks are heard locking the suture within the anchor body.



STEP 8: Slowly disengage the suture anchor from the inserter by pulling straight back or tapping the distal end with a mallet. Cut the excess suture.

Ordering Information

Reference # Description

TWINFIX® Ultra PK Suture Anchor

72202595	TWINFIX Ultra PK 4.5 mm Anchor with two #2 sutures (white, COBRAID-blue) sterile
72202623	TWINFIX Ultra PK 4.5 mm Anchor with two #2 sutures (COBRAID-blue, COBRAID-black) sterile
72202599	TWINFIX Ultra PK 5.5 mm Anchor with two #2 sutures (white, COBRAID-blue) sterile
72202625	TWINFIX Ultra PK 5.5 mm Anchor with two #2 sutures (COBRAID-blue, COBRAID-black) sterile
72202600	TWINFIX Ultra PK 5.5 mm Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black) sterile
72202605	TWINFIX Ultra PK 6.5 mm Anchor with two #2 sutures (white, COBRAID-blue) sterile
72202630	TWINFIX Ultra PK 6.5 mm Anchor with two #2 sutures (COBRAID-blue, COBRAID-black) sterile
72202606	TWINFIX Ultra PK 6.5 mm Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black) sterile

Instruments

72202621	3.8 Tapered Awl – Disposable for use with general hole preparation for normal bone quality
72201915	3.8 Tapered Awl – Reusable for use with general hole preparation for normal bone quality
72202633	4.5 Awl – Dilator for use with 4.5 mm Anchor hole preparation for hard bone
72202634	5.5/6.5 Awl – Dilator for use with 5.5/6.5 mm Anchor hole preparation for hard bone
72202116	3.5 mm Spade Tip Drill for use with 4.5 mm Anchor hole preparation for hard bone
72201707	4.5 mm Spade Tip Drill for use with 5.5 mm Anchor hole preparation for hard bone
72201708	5.5 mm Spade Tip Drill for use with 6.5 mm Anchor hole preparation for hard bone

TWINFIX Ultra HA Suture Anchor

72202597	TWINFIX Ultra HA 4.5 mm Anchor with two #2 sutures (white, COBRAID-blue) sterile
72202624	TWINFIX Ultra HA 4.5 mm Anchor with two #2 sutures (COBRAID-blue, COBRAID-black) sterile
72202602	TWINFIX Ultra HA 5.5 mm Anchor with two #2 sutures (white, COBRAID-blue) sterile
72202626	TWINFIX Ultra HA 5.5 mm Anchor with two #2 sutures (COBRAID-blue, COBRAID-black) sterile
72202603	TWINFIX Ultra HA 5.5 mm Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black)
72202608	TWINFIX Ultra HA 6.5 mm Anchor with two #2 sutures (white, COBRAID-blue) sterile
72202631	TWINFIX Ultra HA 6.5 mm Anchor with two #2 sutures (COBRAID-blue, COBRAID-black) sterile
72202610	TWINFIX Ultra HA 6.5 mm Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black)

Instruments

72202633	4.5 Awl-Dilator for use with 4.5 mm Anchor hole preparation
72202634	5.5/6.5 Awl-Dilator for use with 6.5 mm Anchor hole preparation
72202116	3.5 mm Spade Tip Drill for use with 4.5 mm Anchor hole preparation device for hard bone
72201707	4.5 mm Spade Tip Drill for use with 5.5 mm Anchor hole preparation device for hard bone
72201708	5.5 mm Spade Tip Drill for use with 6.5 mm Anchor hole preparation device for hard bone

Endoscopy

Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810 USA

www.smith-nephew.com

T +1 978 749 1000
US Customer Service: +1 800 343 5717
International Customer Service: +1 978 749 1140

Reference # Description

TWINFIX Ultra Ti Suture Anchor

72202893	TWINFIX Ultra Ti 4.5 mm Anchor with two #2 sutures (white, COBRAID-blue) sterile
72202894	TWINFIX Ultra Ti 4.5 mm Anchor with two #2 sutures (COBRAID-blue, COBRAID-black) sterile
72202895	TWINFIX Ultra Ti 5.5 mm Anchor with two #2 sutures (white, COBRAID-blue) sterile
72202896	TWINFIX Ultra Ti 5.5 mm Anchor with two #2 sutures (COBRAID-blue, COBRAID-black) sterile
72202897	TWINFIX Ultra Ti 5.5 mm Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black)
72202898	TWINFIX Ultra Ti 6.5 mm Anchor with two #2 sutures (white, COBRAID-blue) sterile
72202899	TWINFIX Ultra Ti 6.5 mm Anchor with two #2 sutures (COBRAID-blue, COBRAID-black) sterile
72202900	TWINFIX Ultra Ti 6.5 mm Anchor with three #2 sutures (white, COBRAID-blue, COBRAID-black)

Instruments

72202116	3.5 mm Spade Tip Drill for use with 4.5 mm Anchor hole preparation device for hard bone
72201707	4.5 mm Spade Tip Drill for use with 5.5 mm Anchor hole preparation device for hard bone
72201708	5.5 mm Spade Tip Drill for use with 6.5 mm Anchor hole preparation device for hard bone
72202621	3.8 mm Tapered Awl-Disposable
72201915	3.8 mm Tapered Awl-Reusable

FOOTPRINT Ultra PK Suture Anchor

72202901	FOOTPRINT Ultra 4.5 mm Suture Anchor
72202902	FOOTPRINT Ultra 5.5 mm Suture Anchor

Instruments

72202621	3.8 mm Tapered Awl-Disposable
72201915	3.8 mm Tapered Awl-Reusable
72202116	3.5 mm Spade Tip Drill for use with the 4.5 mm Anchor hole preparation device for hard bone
72201707	4.5 mm Spade Tip Drill for use with the 5.5 mm Anchor hole preparation device for hard bone
72201450	3.8 mm Straight Awl-Reusable
72202986	3.8 mm Straight Awl-Disposable

SHOULDER ARTHROSCOPY INSTRUMENTATION

72202503	ELITE® PREMIUM II Shoulder Arthroscopy System
7211020	ELITE PASS Premium Arthroscopic Suture Shuttle with Ratchet EA
7211021	ELITE PASS Premium Arthroscopic Suture Shuttle without Ratchet EA
72201840	ELITE PASS Long Bite EA
7210693	ELITE PASS Shuttle Needle, box of 5, sterile BX
72202589	Suture Cutter EA

RESECTION

7205962	DYONICS® BONECUTTER® ELECTROBLADE® Resector 5.5 mm, sterile 3/BX
72202213	DYONICS BONECUTTER ELECTROBLADE Resector 4.5 mm, sterile 3/BX
7210380	VULCAN® Generator Adaptor, non-sterile, reusable
72202139	DYONICS RF-S WHIRLWIND 90 degree Probe; 3.75 mm shaft; 90 degree shaft angle
72202149	DYONICS Generator System

PATIENT POSITIONING

7210996	T-Max System BX
7210994	SPIDER System (Beach Chair) BX
7210995	SPIDER System (Lateral Decubitus) BX
72201428	Lateral Jack EA
72202466	Lateral Jack, sterile cover, box of 25 BX
7210573	Shoulder Stabilization Kit, disposable, box of 12, sterile BX

®Trademark of Smith & Nephew. Certain marks Reg US Pat & TM Off. All trademarks acknowledged. ©2010 Smith & Nephew, Inc. All rights reserved. Printed in USA.
09/10 10600547 Rev. C