

Rotator Cuff Solution

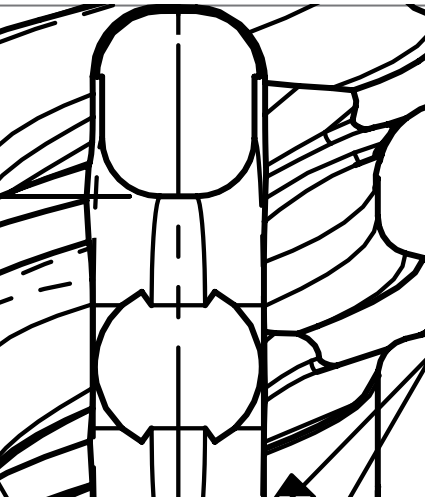
Combined Strengths.  
Precise Control.

 **smith&nephew**  
**TWINFIX<sup>®</sup> 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<sup>◊</sup> 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<sup>◇</sup> 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.<sup>1</sup>

ULTRABRAID<sup>◇</sup> suture provides stronger knot strength than competitive suture and a low profile knot stack.<sup>2</sup>

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

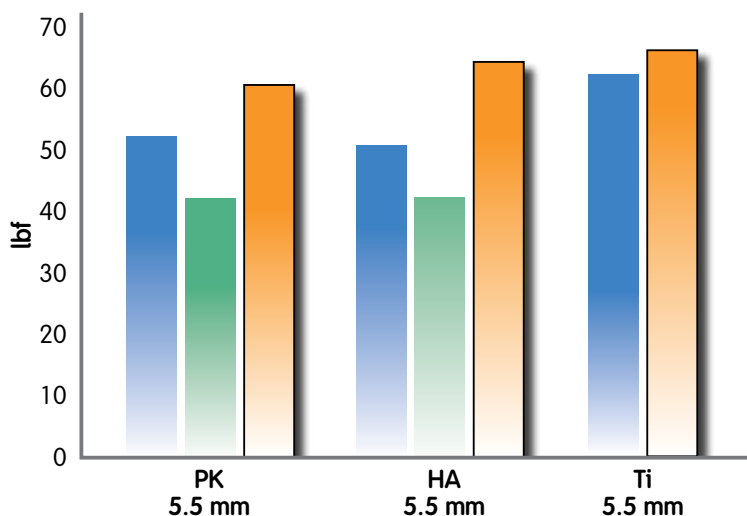
TWINFIX Ultra Ti

TWINFIX Ultra HA



### Average Fixation Strength<sup>1</sup>

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

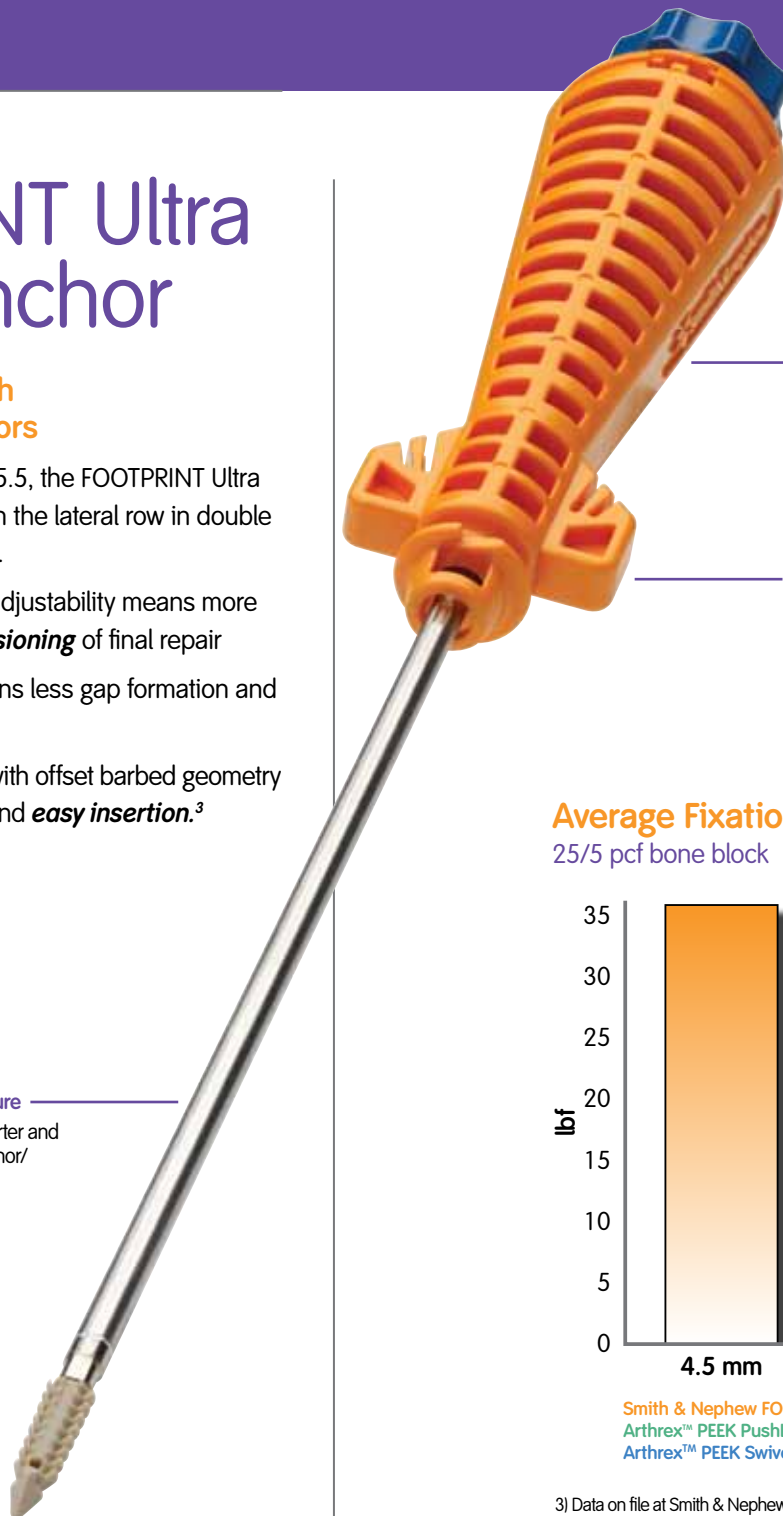
## Lateral row solutions with FOOTPRINT Suture Anchors

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 displacement<sup>3</sup>
- Exclusive tap-in anchor design with offset barbed geometry threads means **strong pullout** and **easy insertion**.<sup>3</sup>

### 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

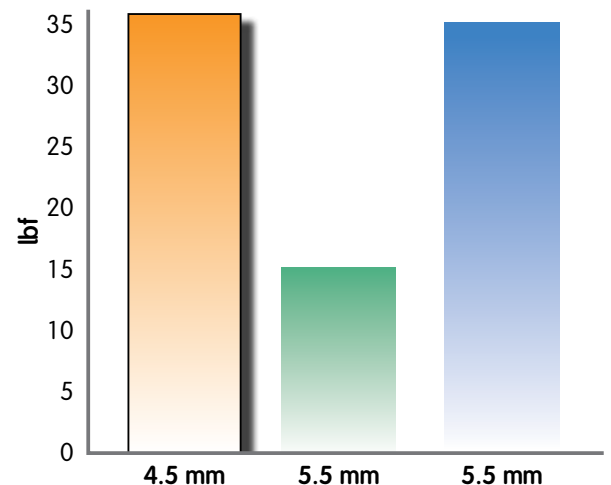
Ergonomic handle designed for surgeon comfort and ease of use

### Integrated Suture Management

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

## Average Fixation Strength<sup>4</sup>

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.

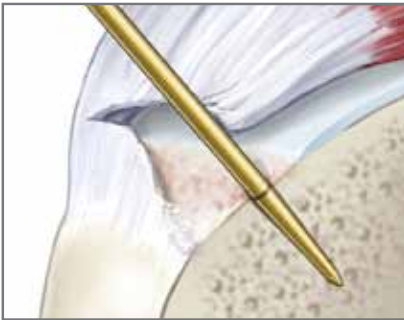
\* Akao, M., Aoki, H. and Kato, K., Mechanical properties of sintered hydroxyapatite for prosthetic applications. *Journal of Material Science*: 16, 809-812, (1981).



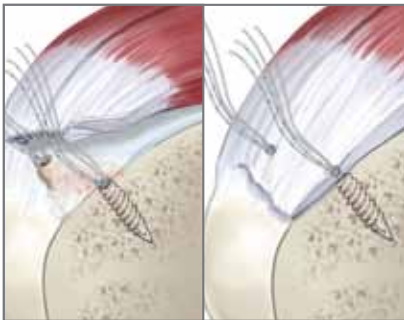
# Procedural Techniques



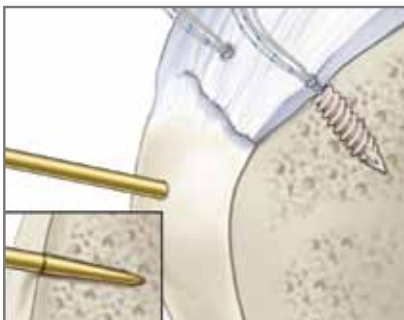
**STEP 1:** Identify the rotator cuff tear and confirm the rotator cuff tissue is mobile. Prepare the repair site utilizing the Whirlwind RF probe to remove any excess tissue from the articular margin of the humeral head to ensure proper visualization of the hole preparation site.



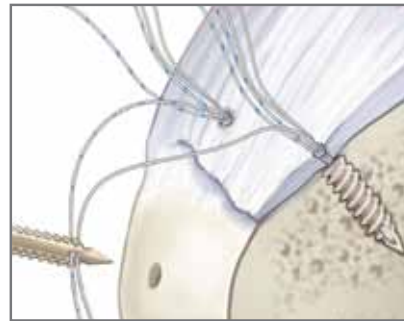
**STEP 2:** Use the 3.8 mm Tapered Awl (or recommended hole preparation device based on anchor material and bone quality) to prepare an anchor hole at the desired site on the medial border of the rotator cuff footprint which is slightly lateral to the articular margin. The proper hole depth is achieved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



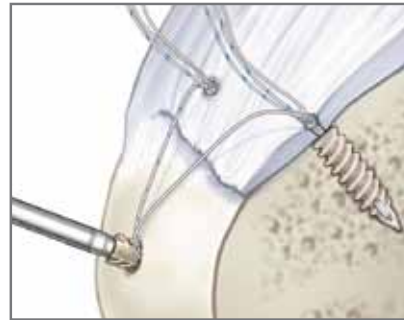
**STEP 3:** Insert the TWINFIX® Ultra PK suture anchor at a 45 degree angle, so it is partially under the articular surface. Insert by twisting the anchor until the laser mark is flush with the cortical bone layer. This places the suture anchor approximately 1 mm below the bone surface. Repeat this process 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.



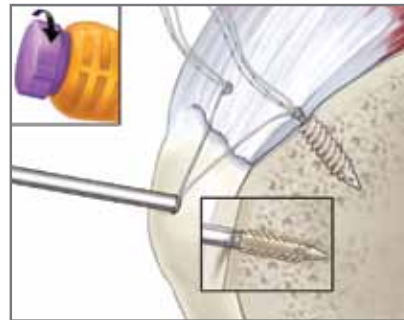
**STEP 4:** Place the distal tip of the awl/drill onto the bone at the desired implantation site of the FOOTPRINT Ultra PK suture anchor at or slightly distal to the lateral margin. Hold the awl in place and use a mallet to tap the proximal end to prepare the insertion site. The proper hole depth is 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   |
|--|---|
| <b>TWINFIX® Ultra PK Suture Anchor</b> |   |
| 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   |
|---------------------------------------|---|
| <b>TWINFIX Ultra Ti Suture Anchor</b> |   |
| 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 |

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