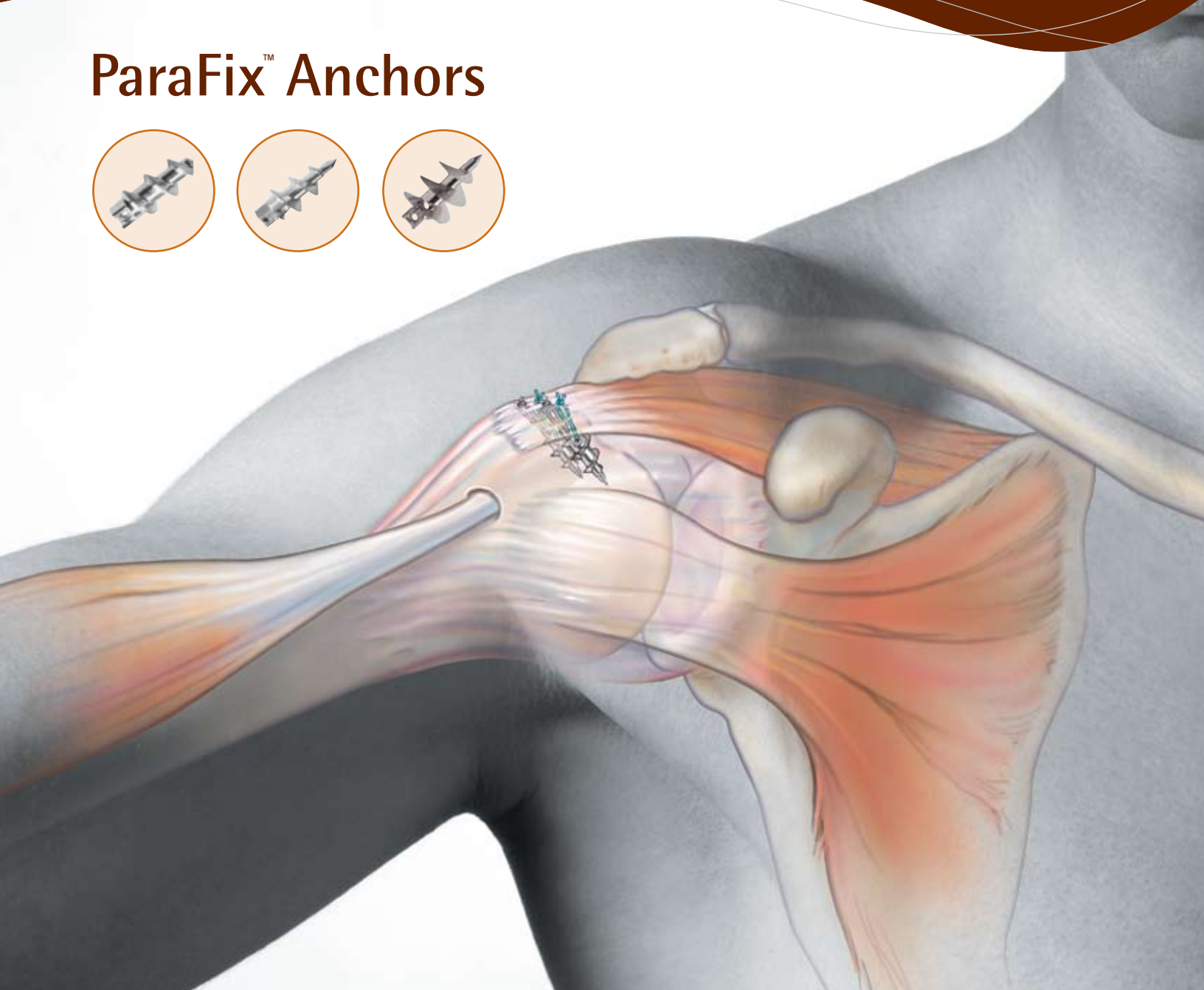


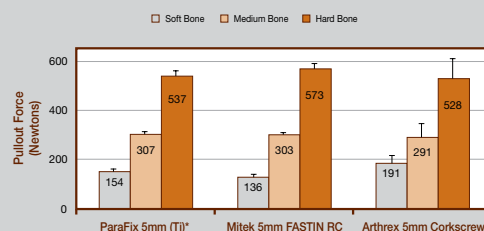
# ParaFix™ Anchors



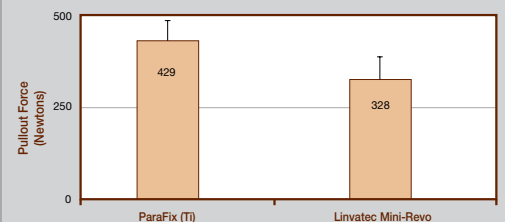
## THE ATLANTECH® COLLECTION

- Titanium Suture Anchors
- Patented Elliptical Eyelets
- Pre-loaded with MagnumWire®

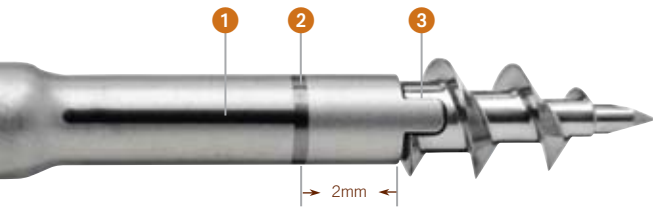
Competitive Analysis—5mm ParaFix Titanium Anchor



Competitive Analysis—3mm ParaFix Titanium Anchor



The ParaFix Anchor is a titanium suture anchor designed for soft tissue repair. The anchors feature the patented Elliptical Eyelets that eliminate suture binding, minimizes suture damage, and allows for easier suture manipulation. ParaFix Anchors are available with #2 polyester braided suture or MagnumWire suture which is 3 times stronger than an equivalent size braided polyester suture.



ParaFix Anchor

## 5mm and 6.5mm ParaFix Anchors

These titanium anchors have a unique self-starting thread design which allows for a quicker and easier start into bone and eliminates the need for a tap. The bone compacting threads compact the bone longitudinally and vertically. The eyelets allow both sutures to be aligned in the same direction and to slide separately. For extremely hard bone an optional bone punch is available which helps to break through the bone cortex.

### 1 Marked Eyelet Orientation

- Allows for precise directional placement of the suture.

### 2 Depth Indicator

- Laser marked for direct insertion into the humerus, not the cuff.
- When the anchor is inserted to this depth, it is buried 2mm below the bone surface.

### 3 Suture Protection Tabs

- Protect suture from damage during insertion.
- Clear bone fragments from bone hole, for improving suture glide



Suture Anchor Needles

## 5mm and 6.5mm Anchors with Needles

### Suture Anchor Needles

The 5mm and 6.5mm ParaFix anchors are available with needles swaged on each end of the suture strands for use in open rotator cuff procedures:

### 4 Suture Retaining Ring

### 5 Tab of Needle Sleeve

### 6 Suture Retaining Cleat



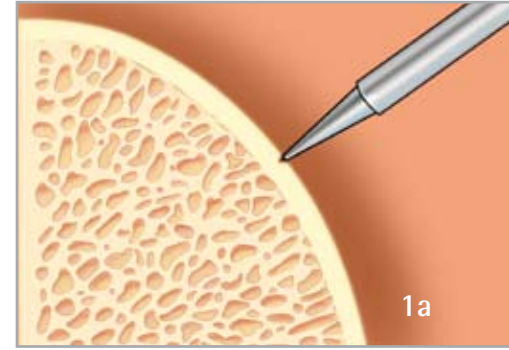
Suture Anchor

## Parafix Rotator Cuff Technique

The 5mm and 6.5mm anchors are self-tapping; it is unnecessary to make a pilot hole (except in the case of hard cortical bone). In hard bone, start with Step 1a, otherwise start with Step 1b.

### Step 1a

- In the event of extremely hard cortical bone, use the bone punch to start the pilot hole. Place the 5mm bone punch at the desired location. Drive the bone punch into the bone using a mallet.
- The punch will insert into the bone to the stop/collar on the instrument.

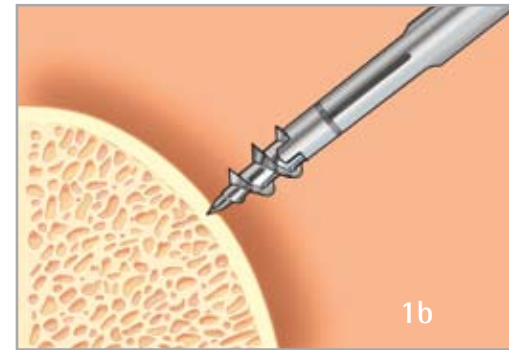


### Step 1b

- Remove the preloaded anchor from the package.
- Thread the self-tapping anchors into the bone.

### Step 2

- Thread the anchor into the bone until the horizontal laser mark is at the surface of the bone. Orient the vertical laser mark perpendicular to the soft tissue.

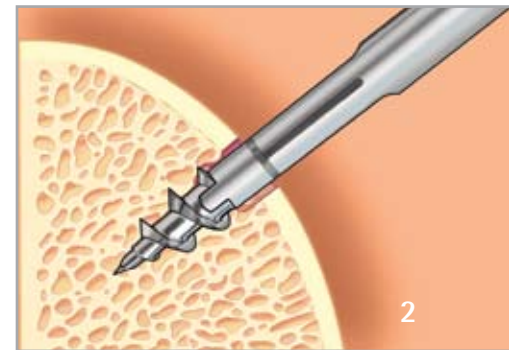


**NOTE:** The orientation of the suture exiting the eyelet is indicated by the vertical line on the driver tip.

**WARNING:** Do not apply excessive bending force to the driver as it may damage the anchor or driver tip.

### Step 3

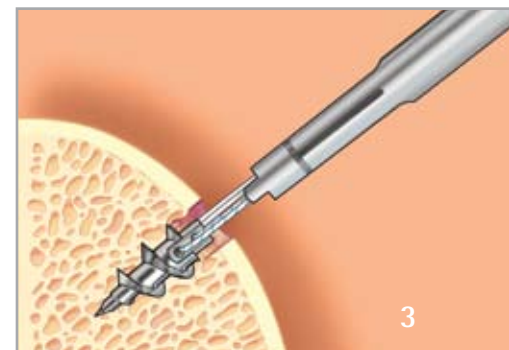
- Remove the suture retaining ring from the end of the driver.
- Remove the driver from the surgical site.
- Pass the ends of the sutures through the tissue and secure with a knot.



**TIP:** Use the PerfectPasser™ suture shuttles (OM-1000CS) to pass the free ends of the suture throughout the cuff. For anchors with needles pass the needles through the tissue and secure.

## Technique using Anchors with Needles

- Remove the needle sleeve from the driver handle by pulling on the exposed tab (bullet 5 on previous page).
- Grasp the suture below the needle sleeve and lightly pull the suture cleat from the driver shaft.
- Pass the needles through the window on the distal end of the driver.
- Remove the driver from the surgical site and pass the needles through the tissue and secure.



## Instruments



Bone Punch (22-5004)



Removal Tube (22-5003)



Capture Tube (22-5003)

### Bone Punch (22-5004)

A tap is not required for the 5mm or 6.5mm titanium anchor due to the self-starting thread design. In the case of very hard cortical bone, the bone punch is recommended before placing the anchor.

### Removal Tool and Capture Tube (22-5003)

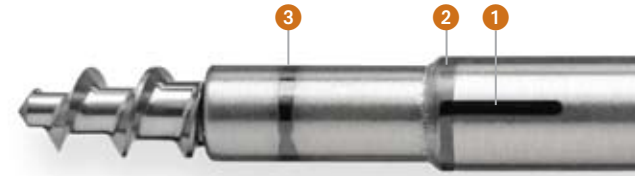
The Removal Tool is a reusable anchor driver to be used when an anchor needs to be extracted. This can be used to remove the 5mm ParaFix anchors from the bone.

### Technique to remove 5mm anchors using the Removal Tool and Capture Tube

- Remove the suture strands from the inserted anchor.
- Slide the capture tube over the shaft of the removal tool, knurled end first.
- The distal tip of the removal tool engages on the anchor head.
- The capture tube needs to remain firm on the cortical bone surface. The inside of the capture tube has two bent tabs on the distal end. These tabs act as a continuation of the threads cut into the bone, allowing the anchor to thread up into and become captured within the tube.
- While applying pressure (with the removal tool) onto the anchor, rotate the removal tool counter-clockwise until anchor is backed out.
- This ensures safe removal of the anchor.

## 3mm ParaFix Anchor

The 3mm ParaFix anchor is used in the glenoid for Bankart and SLAP lesion. This titanium anchor has a single eyelet and is available pre-loaded with a strand of either #2 polyester braided suture or MagnumWire. The instrumentation includes a tap and a drill guide.



ParaFix Anchor

### 3mm ParaFix Features:

#### 1 Marked Eyelet Orientation

- Allows for precise directional placement of the suture.

#### 2 Depth Indicator

- Insert with drill guide.
- When the drill guide is used and the 3mm anchor is inserted to the second line, it is buried 1mm below the bone surface.

#### 3 Depth Indicator

- Insert without drill guide.
- When the 3mm anchor is inserted to the first line, it is buried 1.5mm below the bone surface.

## Instruments

### 3mm Tap (22-5009)

The 3mm tap must be used prior to 3mm ParaFix insertion. The depth indicators on the tap are for use with and without the drill guide.

3mm Tap (22-5009)

### Drill Guide and Obturator (22-5005)

The distal tip of the guide is designed with a 'Fish Mouth™' and 'Walrus Teeth™'. The 'Fish Mouth' is designed to straddle the glenoid rim as well as position the center of the guide on the edge of the glenoid. The 'Walrus Teeth' feature is on the opposite plane to the 'Fish Mouth.' The three sharp and pointed teeth are intended to "dig in" and prevent the guide from sliding or moving along the rim of the glenoid between tapping and inserting the anchor into the hole. The drill guide rotates, which aids in precise placement on the glenoid.



Fish Mouth Design



Walrus Tooth Design



Obturator (22-5005)

Drill Guide (22-5005)

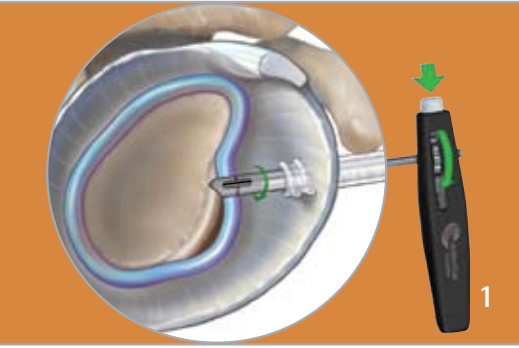
## 3mm ParaFix Implant Technique

### Step 1

- Insert the 3mm drill guide to the site and orient the two smaller teeth on the articular margin near the rim of the glenoid with the larger tooth on the articular surface.

**NOTE:** This orientation will place the anchor approximately 2mm onto the articular surface.

For correct drill guide handle orientation, depress the button on the top of the drill guide and rotate wheel.



### Step 2

- Tap a hole in the bone utilizing the 3mm tap while maintaining the position of the drill guide.
- Tap until the second depth indicator line on the tap lines up with the indicator notches in the window on the drill guide.
- Remove the tap.

**NOTE:** The drill guide window is extended to allow for accurate depth indication beyond the recommended depth. The Tap should not bottom out on the top of the drill guide.

When the drill guide is not utilized, tap until the first indicator line on the Tap is at the surface of the bone and insert the anchor to the first indicator line on the driver.

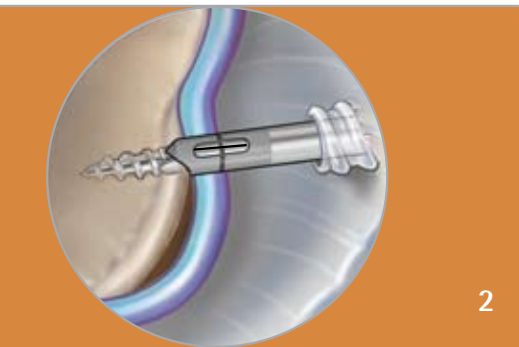
**WARNING:** The anchor must be inserted to the same depth as the anchor tap.

### Step 3

- Remove the anchor from the package. The orientation of the suture exiting the eyelet is indicated by the vertical line on the driver tip and the flats on the driver handle.
- Thread the anchor into the pre-tapped hole until the second indicator line on the driver lines up with the indicator notches on the drill guide.

**NOTE:** If the hole was over tapped in Step 2, the anchor must also be over inserted to the same depth.

**WARNING:** Do not apply excessive bending force to the driver as it may damage the anchor or driver tip.



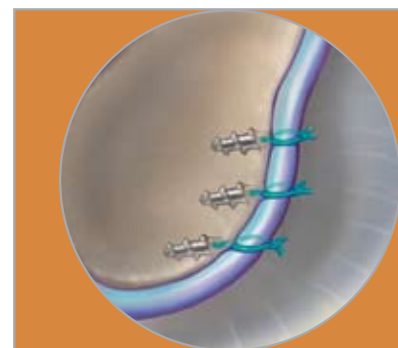
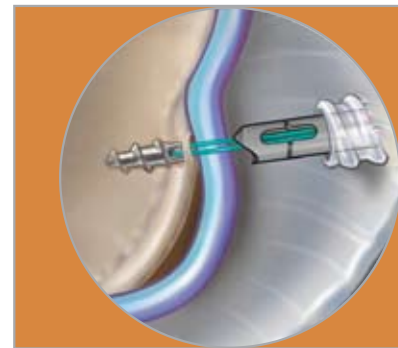
## 3mm ParaFix Implant Technique (Continued)

### Step 4

- Orient the vertical indicator line perpendicular to the Labrum.
- Remove the suture retaining ring from the end of the driver.
- Remove the driver from the surgical site.

### Step 5

- Pass and secure sutures according to surgeon preference.
- Place further anchors using the above technique to achieve the desired repair.



## Ordering Information

Number	Description
22-5001	5mm ParaFix Anchor (5mm x 14.5mm) – 2 strands of #2 braided suture
22-5002	3mm ParaFix Anchor (3mm x 9mm) – single strand of #2 braided suture
22-5010	3mm ParaFix Anchor – single strand of MagnumWire
22-5011	5mm ParaFix Anchor – 2 strands of MagnumWire
22-5011N	5mm ParaFix Anchor – 2 strands of MagnumWire with Needles
22-5012	6.5mm ParaFix Anchor – 2 strands of MagnumWire
22-5012N	6.5mm ParaFix Anchor – 2 strands of MagnumWire with Needles
22-5000	ParaFix Instrumentation Set Includes: <ul style="list-style-type: none"><li>22-5003 Removal Tool and Capture Tube, 5mm</li><li>22-5004 Bone Punch, 5mm</li><li>22-5005 Drill Guide and Obturator, 3mm</li><li>22-5006 Tap, 3mm</li><li>22-5007 Sterilization Tray</li></ul>
0M-8000	SmartStitch® Handle
0M-8010	PerfectPasser Connector
0M-1000CS	Suture Shuttles

