Razek®

Giving value where it really matters

FASTFIT RAZEK

INDICATIONS

FastFit Razek family implants are composed of a flexible suture anchor and a cortical plate, interconnected by an adjustable suture, and are indicated for reapproximation and stabilization between bone structures in different arthroscopic or conventional orthopedic surgical procedures. The unique combination of the flexible suture anchor and the cortical plate results in a hanging fastener element that acts as a stabilizing or distributing pole for tensile loads. The adjustable suture, in turn, has an adjustable knot for quick regulation of the fastening tension of the assembly and the distance between bone structures.

When compared to traditional button-button fixation systems, FastFit Razek has the advantage of preserving the 4th cortical bone, resulting in a mounting process with reduced biological material removal and fewer protrusions.

Images merely illustrative

INPI Patented Product

PATENT

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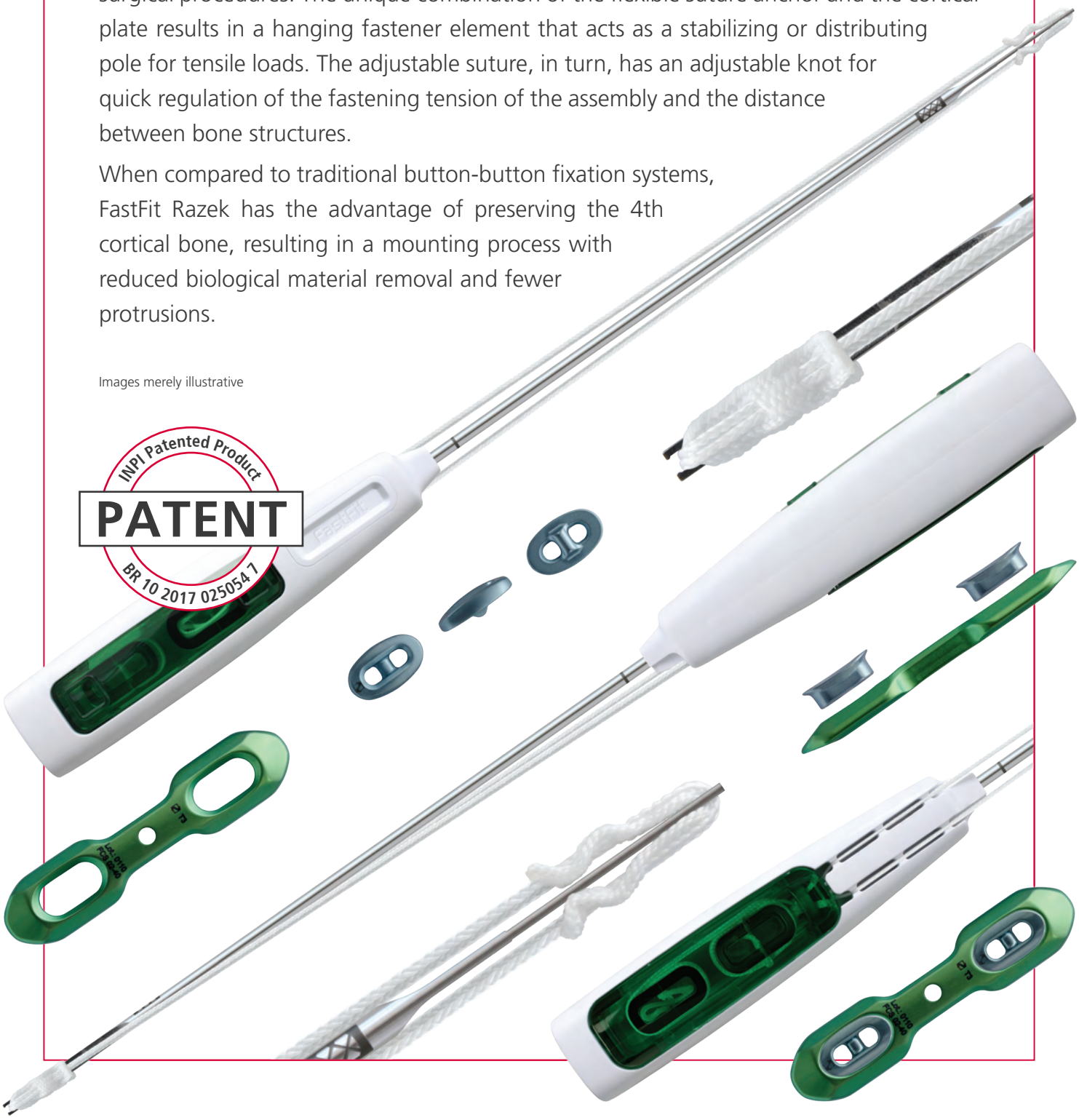
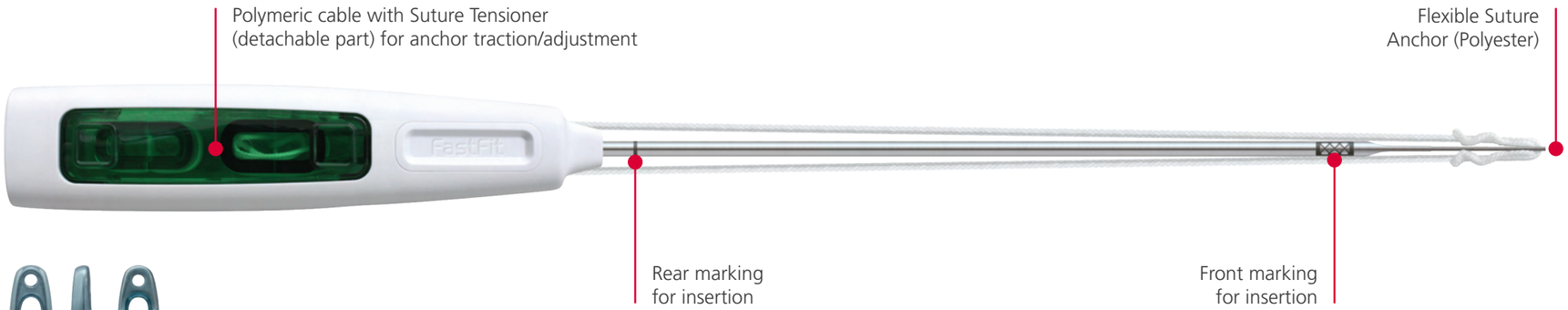
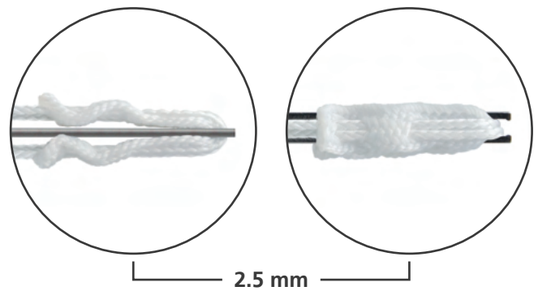
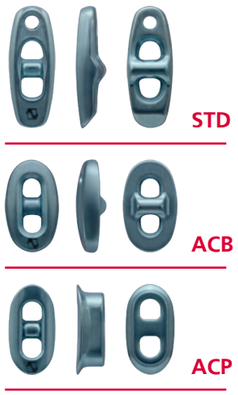
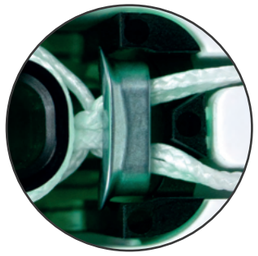


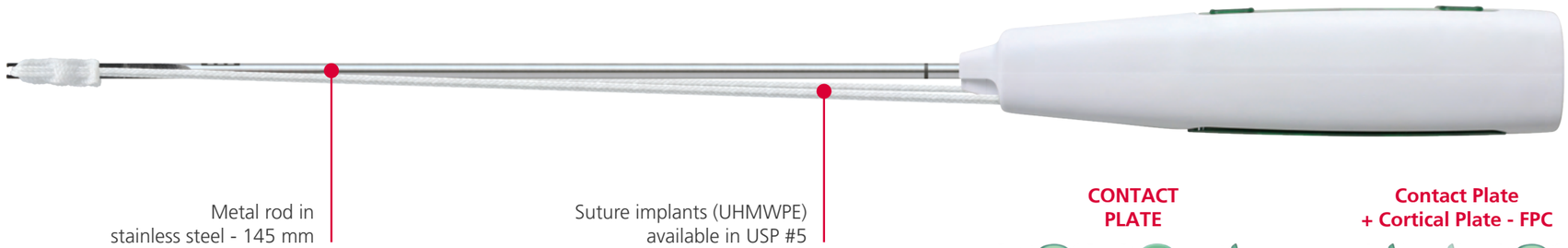






CORTICAL PLATE





CONTACT PLATE

Contact Plate + Cortical Plate - FPC

Auxiliary instruments with
a channel for passing
suture threads

FASTFIT RAZEK +
FASTFIT GUIDE - BIPARTITE

CHARACTERISTICS OF ANCHORS

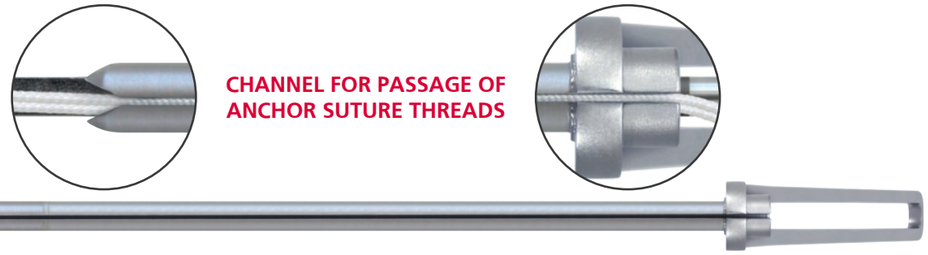
- Available in **2.5 mm** diameter: loaded with very high resistance wires (UHMWPE ** ForceFiber® Teleflex **);
- **Reduced bone removal** - the smaller diameter drill makes the hole created for the implant much smaller. Consequently, there is a greater preservation of the **bone-tissue** contact surface, in addition to less aggression, considerably decreasing pain during the post-surgery period;
- Complications such as fractures, ostolysis and synovitis **are minimized**, which can occur with other materials, mainly in bioabsorbables;
- The **reduced diameter** of the anchor reduces the need for greater bone perforations, common in metallic, peek and bioabsorbable anchors, causing complications such as bone fragility and relections to be minimized. In addition, in cases where more anchors are needed, there will be less chance of complicationsand greater possibility for its proper positioning.

CHARACTERISTICS OF CORTICAL PLATES

- Cortical Plates available in **3 models**, for different applications;
- The **STD** cortical plate's geometry allows its passage through a bone tunnel with the aid of the passage suture. Typical **EasyFlip** design that makes it unnecessary to use additional sutures to tumble the device;
- The **ACB** cortical plate's geometry allows its **perfect fit** into a wide range of different bone structures, with a large surface area and excellent distribution of tensions on the cortical surface;
- The **ACP** cortical plate's geometry allows its fit into the holes of the **Contact Plates**, which are part of the FastFit Razek family, and in the compression holes of the plates of the **Rigid Mounting System UpperTreat RZ**, giving the surgeon the option of performing a **combined repair**;
- Cortical Plates and Contact Plates made of ASTM F136 titanium alloy.

FastFit Guide - Bipartite + FastFit Obturator

FastFit Guide - Bipartite + Drill



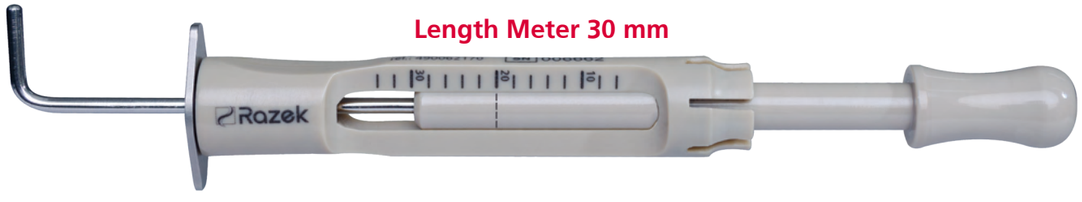
Cannulated Drills

Non-Cannulated Drills

* 2.5mm diameter drill only

Positioner Pin Ø 1.6 x 140 mm - Trocar Tip

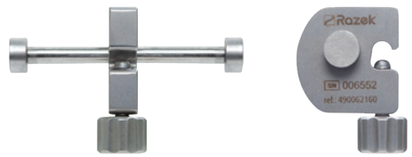
Length Meter 30 mm



FastFit Drilling Limiter

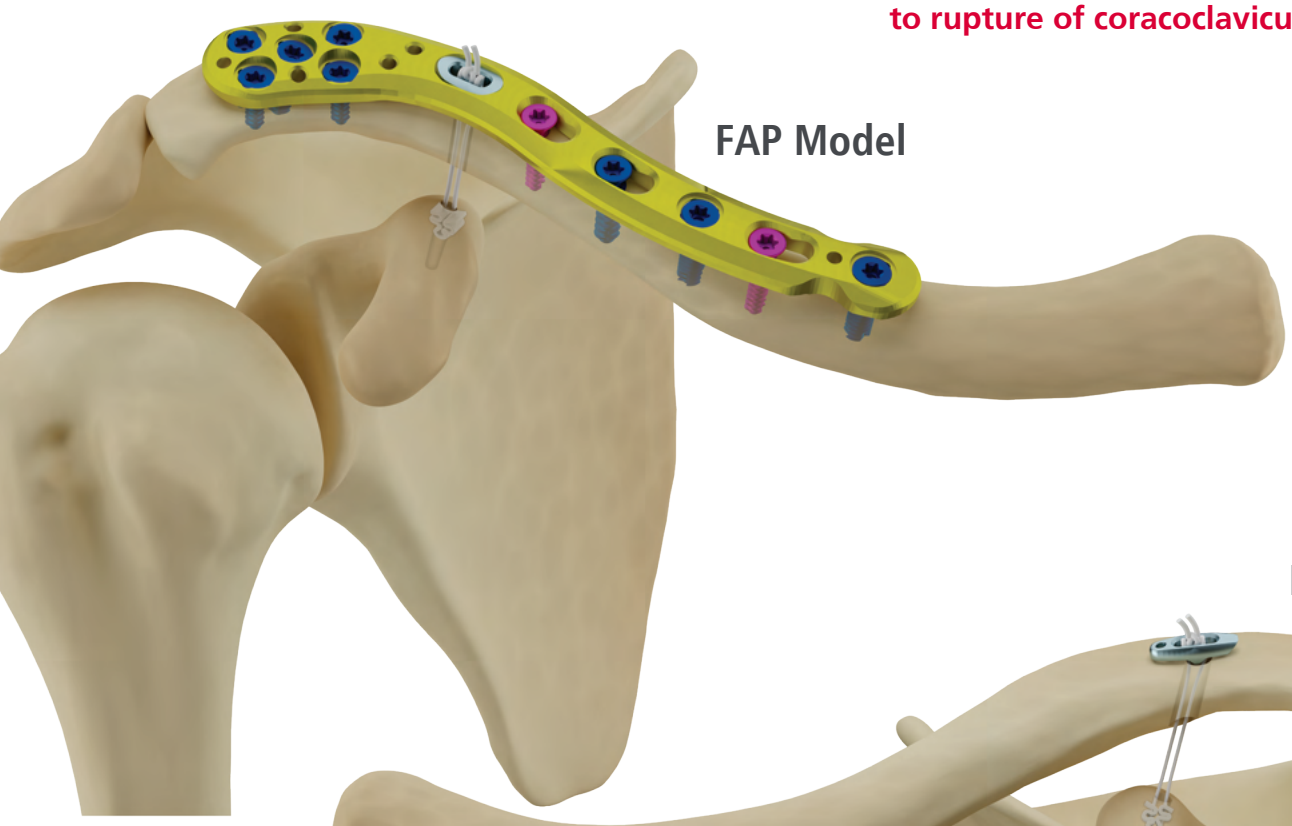
FastFit Razek + FastFit Insertion Limiter

FastFit Insertion Limiter



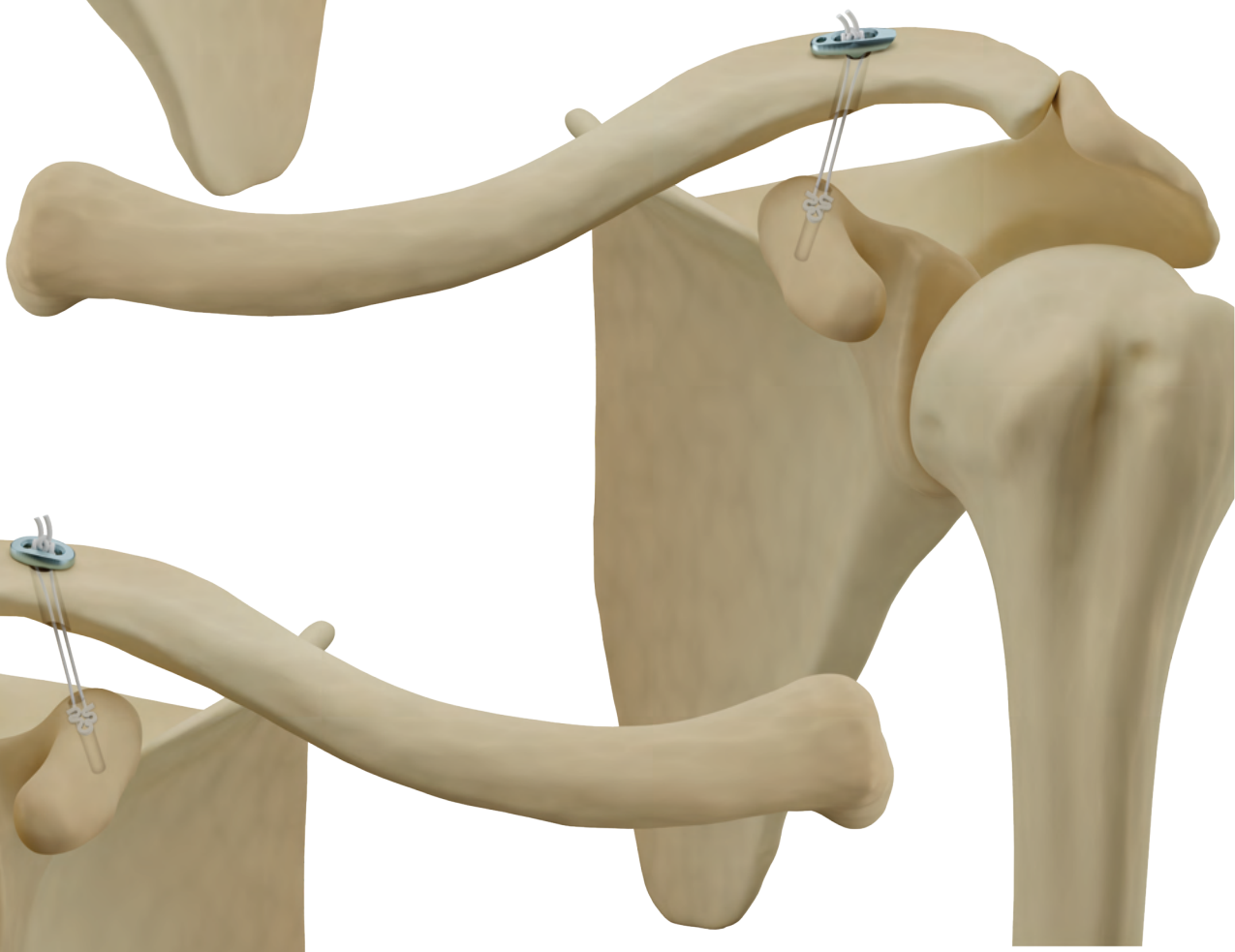
Indications for Use

Repair of acromioclavicular separation due to rupture of coracoclavicular ligament

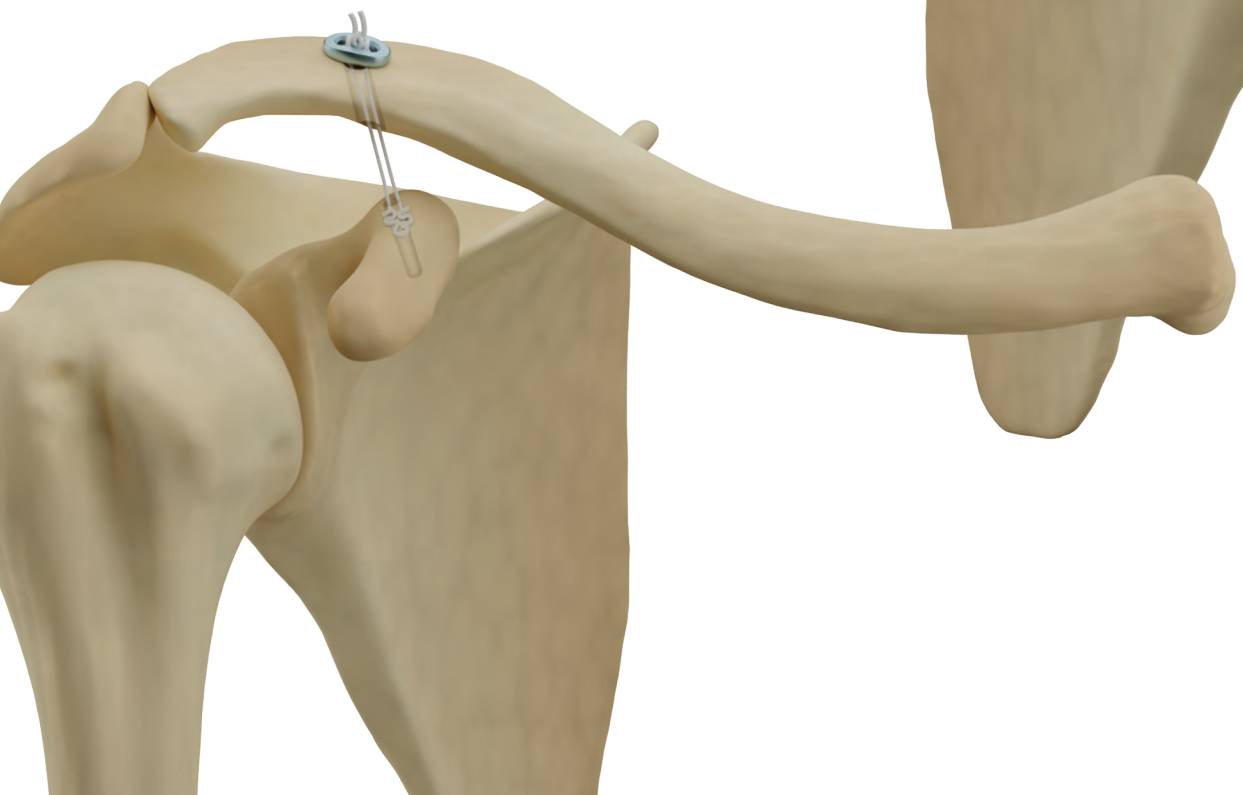


FAP Model

FST Model



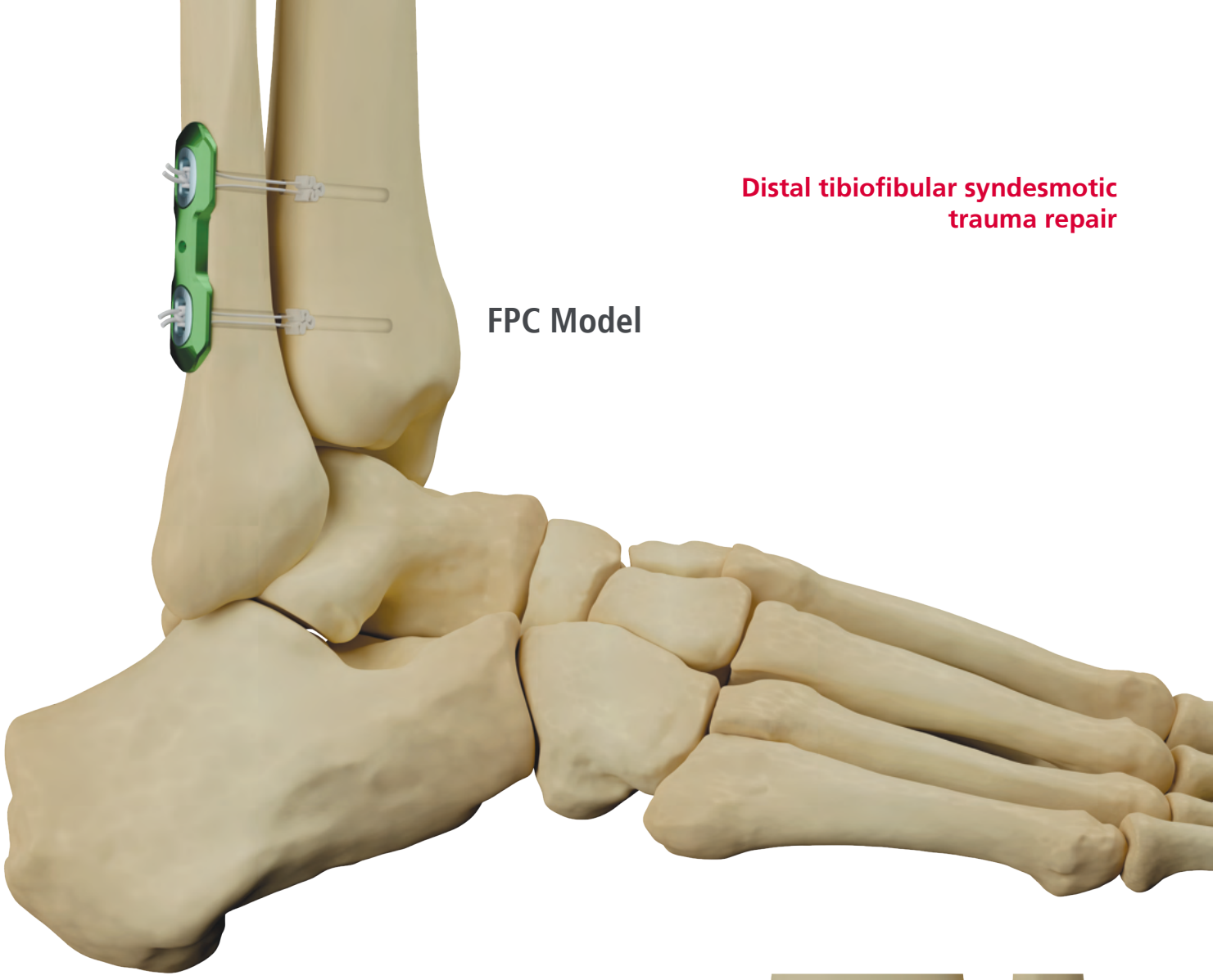
FAB Model



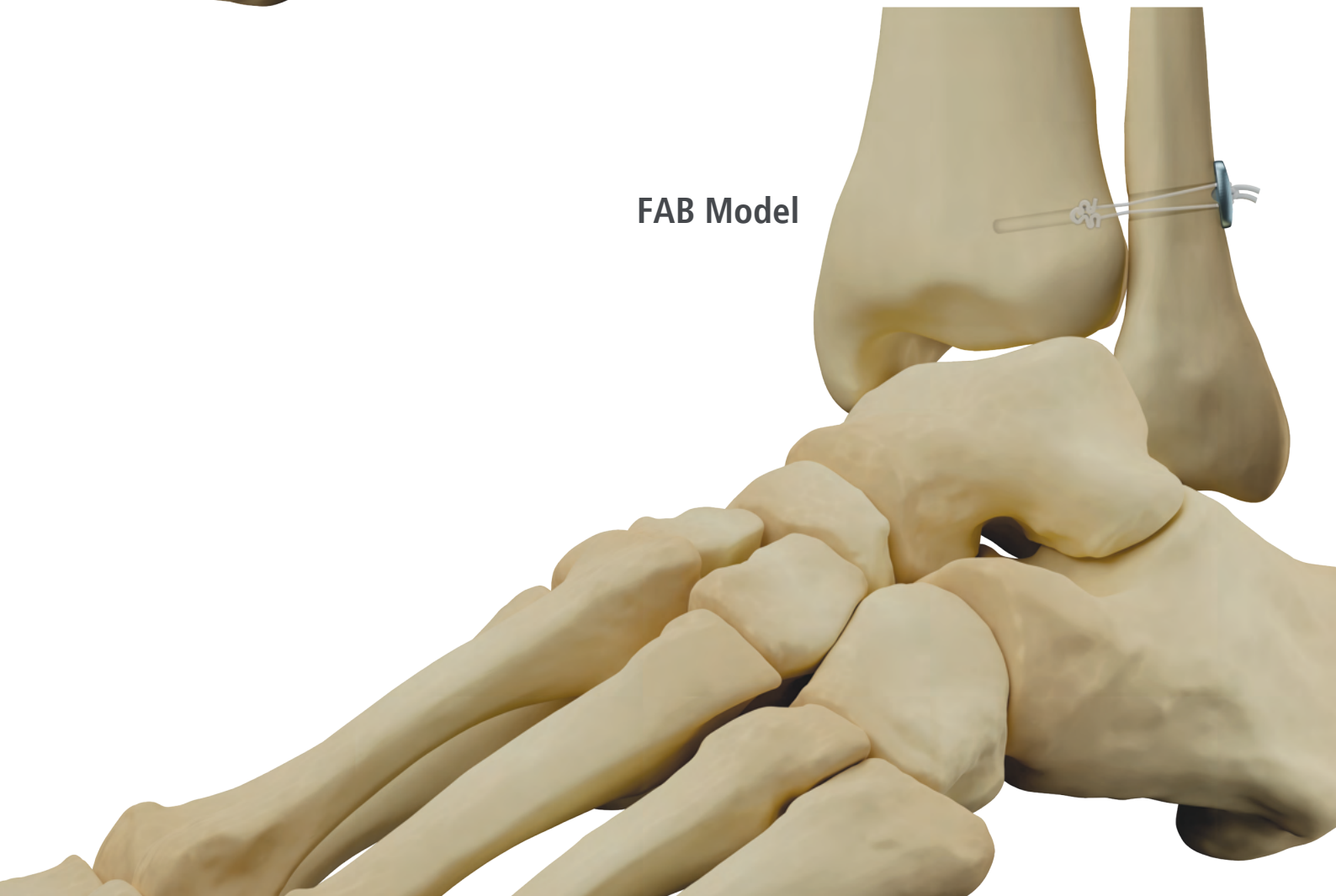
Images merely illustrative

Distal tibiofibular syndesmotic trauma repair

FPC Model



FAB Model



MODELS - FASTFIT RAZEK

Code	Description	Pre-hole diameter (mm)	Characteristics
500120015	**2.5 Adjustable (FST 15-25M)**	**2.5**	**FastFit Razek - 2.5 Adjustable STD (1 unit):** ▪ Disposable Inserter (1 unit) ▪ White Braided UHMWPE Suture Thread USP 5 x 1,3 m (1 unit) ▪ Cortical Plate STD 12,5 x 4,5 x 2,8 mm (1 unit) ▪ Flexible Anchor 14 mm (1 unit) ▪ Passage Suture - Polyester Suture Thread (PET) Green Braided USP 5 x 0,9m (1 unit)
500120020	**2.5 Adjustable (FAP 15-25M)**	**2.5**	**FastFit Razek - 2.5 Adjustable ACP (1 unit):** ▪ Disposable Inserter (1 unit) ▪ White Braided UHMWPE Suture Thread USP 5 x 1,3 m (1 unit) ▪ Cortical Plate ACP 9,5 x 5 x 2,9 mm (1 unit) ▪ Flexible Anchor 14 mm (1 unit)
500120021	**2.5 Adjustable (FPC 15-32M)**	**2.5**	**FastFit Razek - 2.5 Adjustable ACP (2 units):** ▪ Disposable Inserter (1 unit) ▪ White Braided UHMWPE Suture Thread USP 5 x 1,3 m (1 unit) ▪ Cortical Plate ACP 9,5 x 5 x 2,9 mm (1 unit) ▪ Flexible Anchor 14 mm (1 unit) ▪ Contact Plate 32 mm (FCS 02-32) (1 unit)
500120022	**2.5 Adjustable (FPC 15-36M)**	**2.5**	**FastFit Razek - 2.5 Adjustable ACP (2 units):** ▪ Disposable Inserter (1 unit) ▪ White Braided UHMWPE Suture Thread USP 5 x 1,3 m (1 unit) ▪ Cortical Plate ACP 9,5 x 5 x 2,9 mm (1 unit) ▪ Flexible Anchor 14 mm (1 unit) ▪ Contact Plate 36 mm (FCS 02-36) (1 unit)
500120023	**2.5 Adjustable (FPC 15-40M)**	**2.5**	**FastFit Razek - 2.5 Adjustable ACP (2 units):** ▪ Disposable Inserter (1 unit) ▪ White Braided UHMWPE Suture Thread USP 5 x 1,3 m (1 unit) ▪ Cortical Plate ACP 9,5 x 5 x 2,9 mm (1 unit) ▪ Flexible Anchor 14 mm (1 unit) ▪ Contact Plate 40 mm (FCS 02-40) (1 unit)
500120030	**2.5 Adjustable (FAB 15-25M)**	**2.5**	**FastFit Razek - 2.5 Adjustable ACB (1 unit):** ▪ Disposable Inserter (1 unit) ▪ White Braided UHMWPE Suture Thread USP 5 x 1,3 m (1 unit) ▪ Cortical Plate ACB 10 x 6 x 2,8 mm (1 unit) ▪ Flexible Anchor 14 mm (1 unit)

Note: The models identified as M have a metal rod of the Inserting Device with length of 145 mm.

MODELS - FASTFIT RAZEK SUPPORT INSTRUMENTS

Code	Description
490062160	FastFit Insertion Limiter
490062170	Length Gauge 30 mm
490061870	Cannulated Bone Drill Ø 2,5 x 170 mm
490062180	Cannulated Bone Drill Ø 3,8 x 155 mm
490062190	Cannulated Bone Drill Ø 4,6 x 155 mm
490062200	FastFit Drill Limiter
490061850	Bone Drill Ø 3,8 x 155 mm
490061860	Bone Drill Ø 4,6 x 155 mm
490061040	Quick Coupling Chuck
490061830	FastFit Drill 2,5 - M
490061900	FastFit Guide 2,5 - Split M
490062070	FastFit Obturator 2,5 - Split M
490061730	Positioning Pin Ø 1,6 x 140 mm - Trocar Tip

Suggested Use - FastFit Razek
FST Models

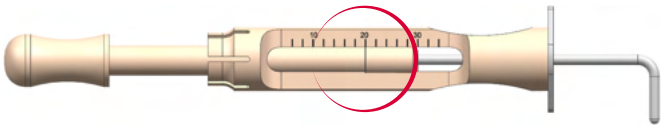
1 | After incision, perform the preparation of the bone surface;

2 | Select the **FastFit Razek** model to be used;

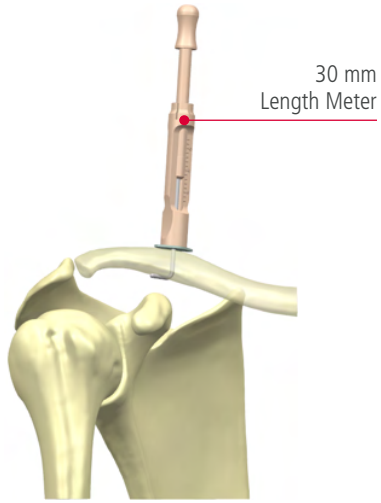
FastFit Razek Model	Code
2.5 Adjustable (FST 15-25M)	500120015

Note 1: **FastFit Razek** anchors have a pre-bore diameter equal to Ø 2.5 mm;

3 | Measure the dimension of the first bone structure using the **30 mm Length Meter**;

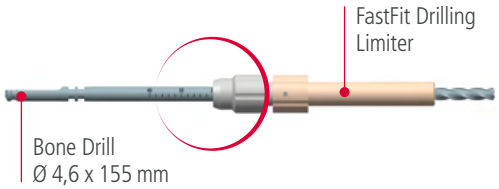


Instrument	Code
30 mm Length Meter	490062170



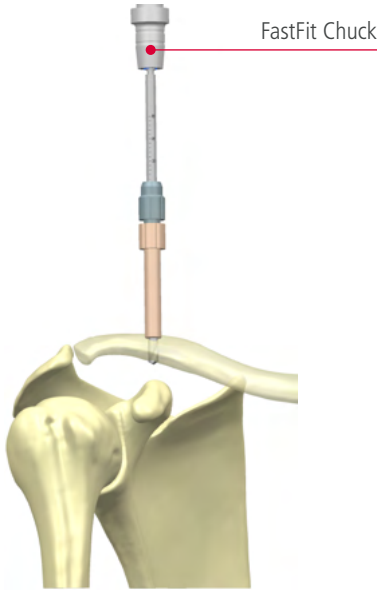
4 | Attach the **FastFit Drilling Limiter** to the **Bone Drill Ø 4.6 x 155 mm**, positioning it on the scale according to the measurement of the first bone structure previously performed;

Instrument	Code
Bone Drill Ø 4.6 x 155 mm	490061860
FastFit Drilling Limiter	490062200



5 | Drill the first bone structure, 1st and 2nd cortical, using the **Bone Drill Ø 4.6 x 155 mm** coupled to the driller and the **FastFit Chuck** . The **FastFit Drilling Limiter** offers safety and precision to the surgeon, so that the 3rd cortical is not damaged;

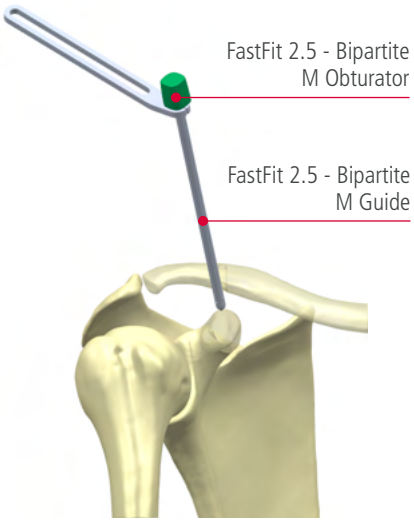
Instrument	Code
FastFit Chuck	490061040



6 | Insert the **FastFit 2.5 - Bipartite M Guide** with the **FastFit 2.5 - Bipartite M Obturator** inside, at the anchor insertion site.

Note: The insertion of the **2.5 FastFit Bipartite M Guide** should not be performed through the previously prepared bone tunnel.

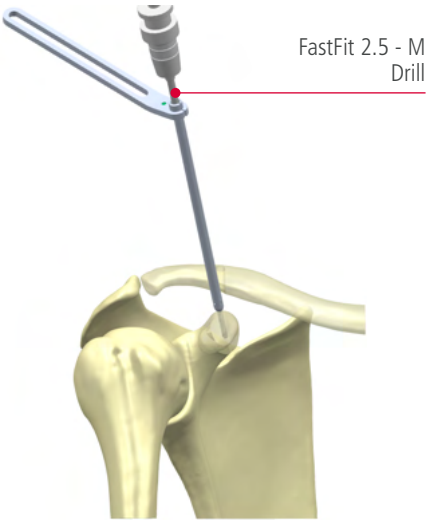
Instrument	Code
FastFit 2.5 - Bipartite M Guide	490061900
FastFit 2.5 - Bipartite M Obturator	490062070



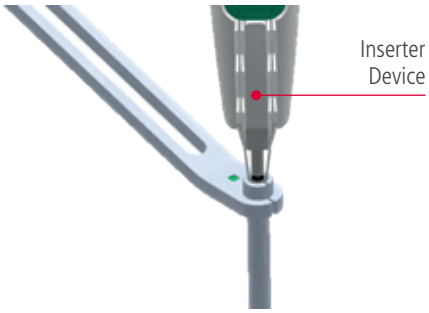
7 | Remove the **FastFit 2.5 - Bipartite M Obturator** from the inside of the **FastFit 2.5 - Bipartite M Guide**;

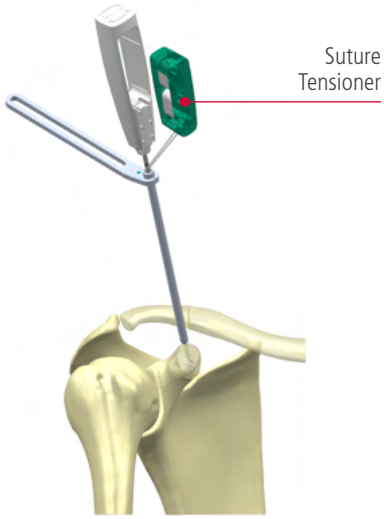
8 | Perform the drilling for insertion of the flexible anchor using the **FastFit 2.5 - M Drill** coupled to the driller and the **FastFit Chuck** , through the **FastFit 2.5 - Bipartite Guide M**. The **FastFit 2.5 - M Drill** has a mechanical stop that indicates the exact drilling depth;

Instrument	Code
FastFit 2.5 - M Drill	490061830



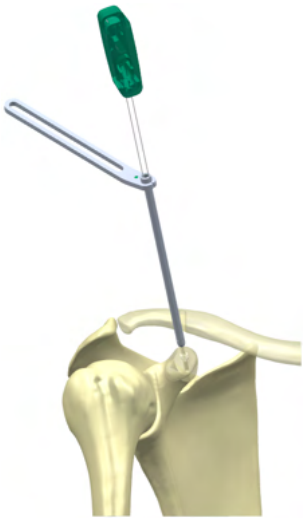
9 | Impact the **Inserter Device**, through the **FastFit 2.5 - Bipartite M Guide**, in order to completely insert the anchor into the spongy bone tissue. The anchor must be inserted until the marking present on the rod of the **Inserter Device**, as shown on the side.

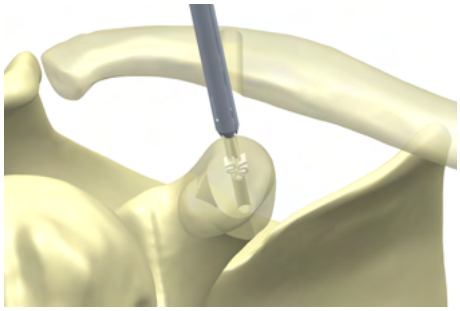




10 | Detach the **Suture Tensioner** and pull the assembly 1 to 3 times. Ideally, the assembly should still be pulled with the **Inserter Device** inserted, in order to ensure that the anchor is correctly conformed and completely fixed to the bone cortical;

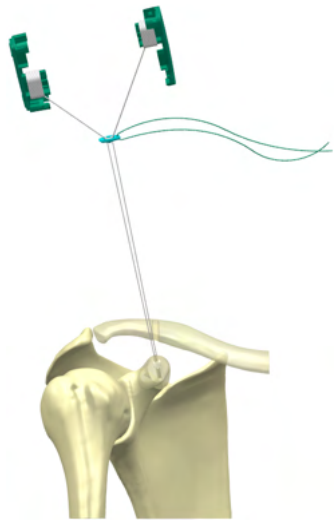
11 | Remove the **Inserter Device**, keeping the sutures tensioned;



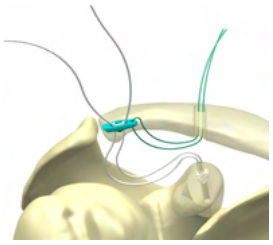


12 | After removing the **Inserter Device**, pull the assembly again without excess load. During this procedure the anchor can move a few millimeters, reaching its final attachment point. Without this procedure there may be deleterious micro movements to the result of the suture;

13 | Remove the **2.5 FastFit Guide - Bipartite M**.
The **2.5 FastFit Guide - Bipartite M** has a front tear for suture removal;

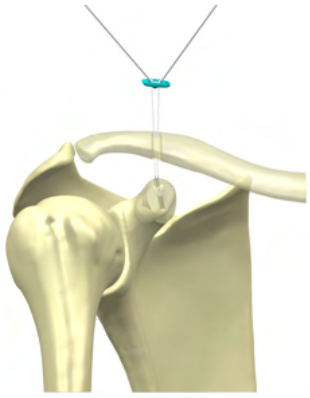


14 | Remove the **Cortical Plate** from the inside of the **Suture Tensioner**;



15 | Pass the **Cortical Plate** through the previously prepared bone tunnel, with the aid of the passing suture;

Note: After the passage of the **Cortical Plate** through the bone tunnel, the passing suture must be removed, not remaining implanted.



16 | Traction of sutures to achieve desired stabilization and reduction. Adjustment is best accomplished by pulling one wire at a time, as follows:

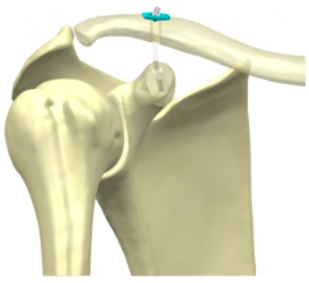
a. Pull a wire about 3 to 5 mm;

b. Traction the other wire in the same way;

c. Repeat the above procedure until the desired initial stabilization is achieved and the **Cortical Plate** is properly accommodated on the bone surface;

17 | Perform final reduction on **FastFit Razek**. After final reduction, it is recommended that the surgeon tie a knot using the adjustment sutures;

18 | Cut the adjustment wires using an appropriate suture cutter. The cutting of the wires must be carried out at a minimum safety distance above the knot.



Suggested Use - FastFit Razek
FPC Models

1 | After incision, perform the preparation of the bone surface;

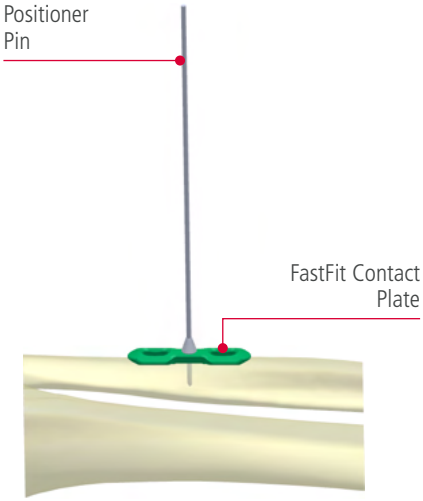
2 | Select the **FastFit Razek** model to be used;

Note 1: FastFit Razek models with **Contact Plate** are available in 3 contact plate lengths, as shown in the table:

FastFit Razek Model	Code	Contact Plate
2.5 Adjustable (FPC 15-32M)	500120021	Contact Plate 32 mm (FCS 02-32)
2.5 Adjustable (FPC 15-36M)	500120022	Contact Plate 36 mm (FCS 02-36)
2.5 Adjustable (FPC 15-40M)	500120023	Contact Plate 40 mm (FCS 02-40)

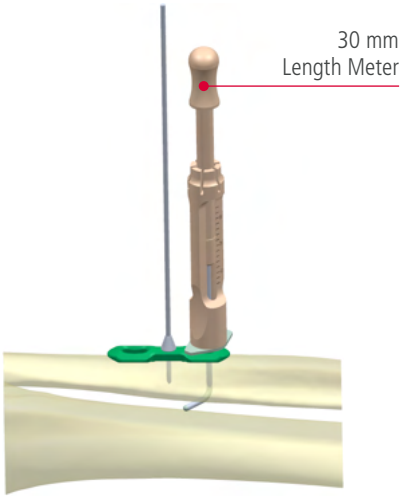
Note 2: FastFit Razek anchors have a pre-bore diameter equal to Ø 2.5 mm

3 | Position the **FastFit Contact Plate** chosen by the surgeon through the incision. Temporary fixation of the **FastFit Contact Plate** to the bone structure using a **Positioner Pin** is recommended;

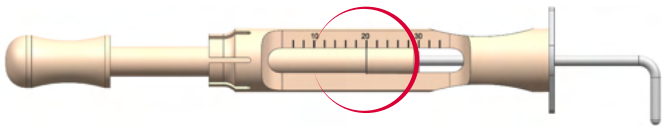


Instrument	Code
Positioner Pin Ø 1,6 x 140 mm - Trocar Tip	490061730

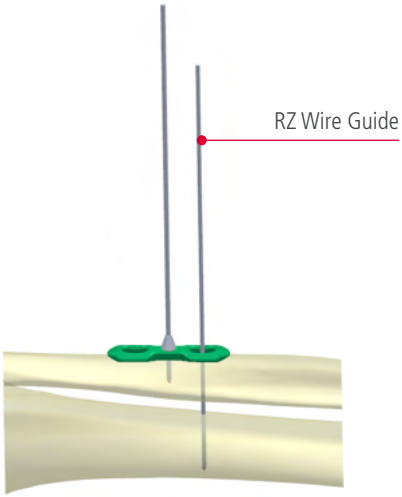
4 | Measure the dimension of the first bone structure using the **30 mm Length Meter**;



Instrument	Code
30 mm Length Meter	490062170



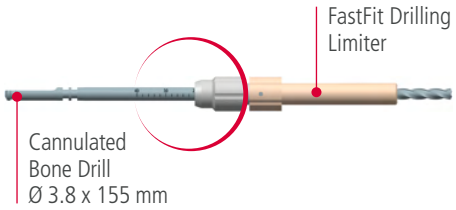
5 | Insert the **RZ Wire Guide** through the first hole of the **FastFit Contact Plate** to the height of the 4th cortical, without crossing it;



Instrument	Code
RZ Wire Guide Trocar Tip - 1,4 x 150 mm	742593920

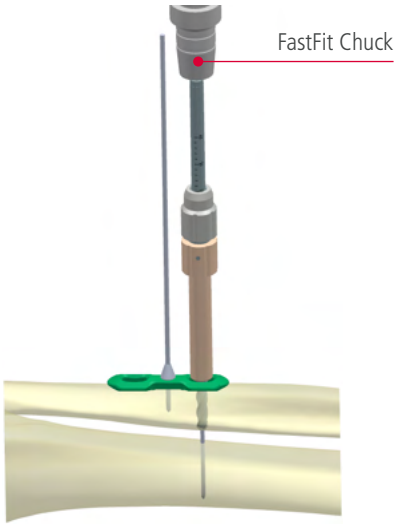
6 | Attach the **FastFit Drilling Limiter** to the **Cannulated Bone Drill Ø 3.8 x 155 mm**, positioning it on the scale according to the measurement of the first bone structure previously performed;

Instrument	Code
Cannulated Bone Drill Ø 3.8 x 155 mm	490062180
FastFit Drilling Limiter	490062200



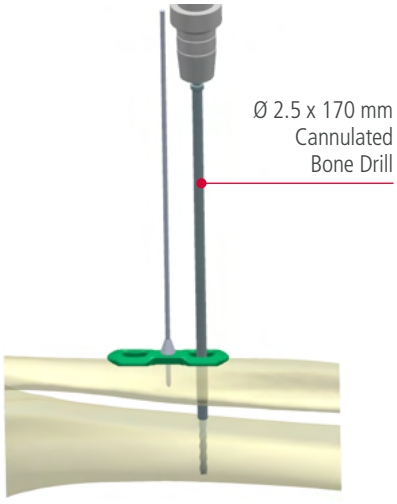
7 | Drill the first bone structure, 1st and 2nd cortical, using the **Cannulated Bone Drill Ø 3.8 x 155 mm**, coupled to the driller and the **FastFit Chuck** , through the **RZ Wire Guide**. The **FastFit Drilling Limiter** offers safety and precision to the surgeon, so that the 3rd cortical is not damaged;

Instrument	Code
FastFit Chuck	490061040



8 | Drill to insert the flexible anchor using the **Ø 2.5 x 170 mm Cannulated Bone Drill**, coupled to the driller and the **FastFit Chuck** , through the **RZ Wire Guide**. The **Cannulated Bone Drill Ø 2.5 x 170 mm** has a mechanical stop that provides the exact drilling depth;

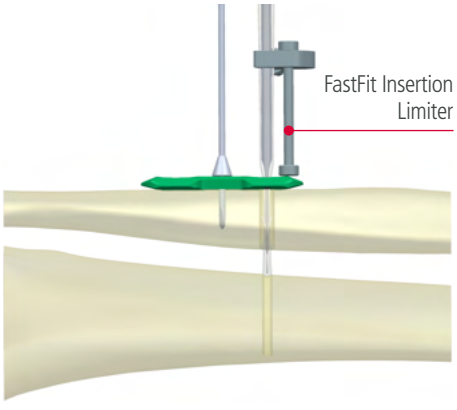
Instrument	Code
Ø 2.5 x 170 mm Cannulated Bone Drill	490061870



9 | Remove the **RZ Wire Guide**;

10 | Insert the anchor through the hole of the first bone structure to the height of the 3rd cortical. Then, fix the **FastFit Insertion Limiter** according to the image on the side;

Instrument	Code
FastFit Insertion Limiter	490062160



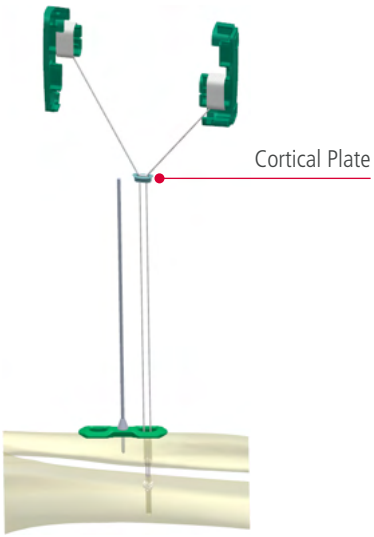
11 | Impact the **Inserter Device** to completely insert the anchor into the cancellous bone tissue. **Note:** the **FastFit Insertion Limiter** must reach its limit, according to the image on the side;

12 | Remove the **FastFit Insertion Limiter**;

13 | Detach the **Suture Tensioner** and pull the assembly 1 to 3 times. Ideally, the assembly should still be pulled with the **Inserter Device** inserted, in order to ensure that the anchor has conformed and completely fixed on the bone cortex;

14 | Remove the **Inserter Device**, keeping the sutures tensioned;

15 | After removing the **Inserter Device**, pull the assembly again without excess load. During this procedure the anchor can move a few millimeters, reaching its final attachment point. Without this procedure, there may be deleterious micro movements to the result of the suture;



16 | Remove the **Cortical Plate** from the inside of the **Suture Tensioner**;

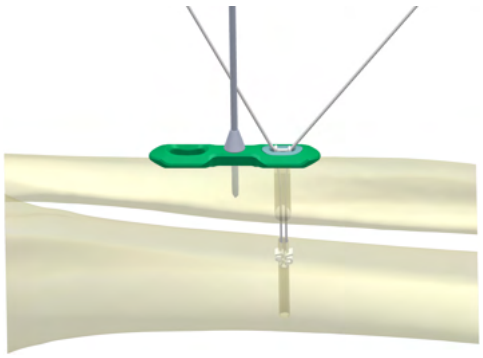
17 | Using the **Suture Tensioner**, pull the sutures to achieve the desired stabilization and reduction. Adjustment is best accomplished by pulling one wire at a time, as follows:

a. Pull a wire about 3 to 5 mm;

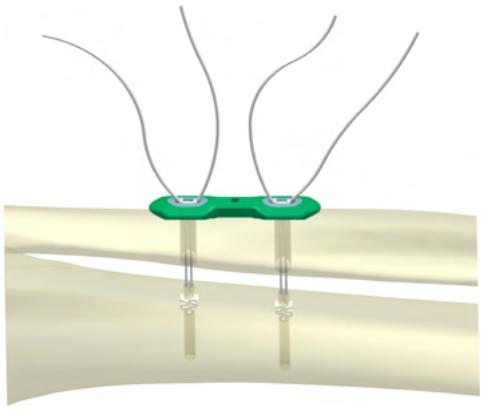
b. Traction the other wire in the same way;

c. Repeat the above procedure until the desired initial stabilization is achieved and the **Cortical Plate** is properly accommodated on the **Contact Plate**;

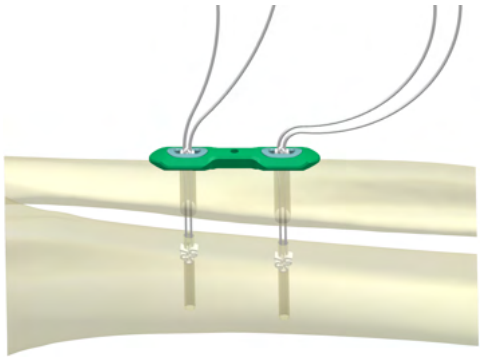
Note: Tying of the knot and cutting of the adjustment sutures should only be performed after insertion of the second FastFit Razek and completion of the desired final reduction.



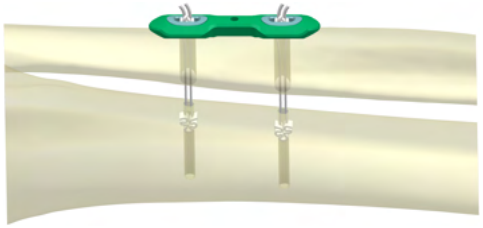
18 | Perform the above procedures for the second **FastFit Razek**;



19 | Perform the final reduction on both **FastFit Razek**. After final reduction, it is recommended that the surgeon tie a knot using the fitting sutures;



20 | Cut the adjustment wires using an appropriate suture cutter. The cutting of the wires must be carried out at a minimum safety distance above the knot.



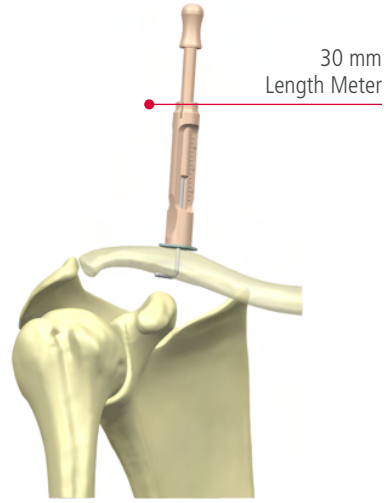
Suggested Use - FastFit Razek
FAB Models

1 | After incision, perform the preparation of the bone surface;

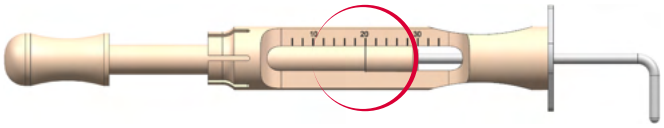
2 | Select the **FastFit Razek** model to be used;

FastFit Razek Model	Code
2.5 Adjustable (FAB 15-25M)	500120030

Note 1: FastFit Razek anchors have a pre-bore diameter equal to Ø 2.5 mm;



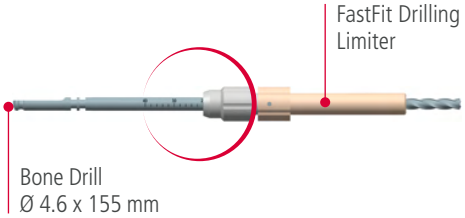
3 | Measure the dimension of the first bone structure using the **30 mm Length Meter**;

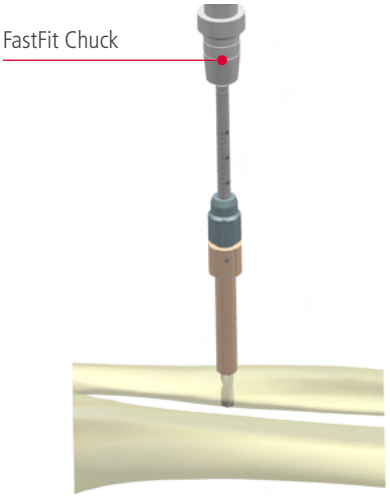


Instrument	Code
30 mm Length Meter	490062170

4 | Attach the **FastFit Drilling Limiter** to the **Bone Drill Ø 4.6 x 155 mm**, positioning it on the scale according to the measurement of the first bone structure previously performed;

Instrument	Code
Bone Drill Ø 4.6 x 155 mm	490061860
FastFit Drilling Limiter	490062200





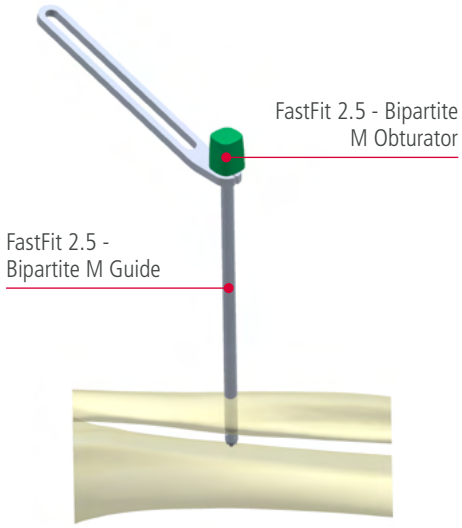
5 | Drill the first bone structure, 1st and 2nd cortical, using the **Bone Drill Ø 4.6 x 155 mm**, coupled to the driller and the **FastFit Chuck** . The **FastFit Drilling Limiter** offers safety and precision to the surgeon, so that the 3rd cortical is not damaged;

Instrument	Code
FastFit Chuck	490061040

6 | Insert the **FastFit 2.5 - Bipartite M Guide**, through the drilling previously performed, with the **FastFit 2.5 - Bipartite M Obturator** inside;

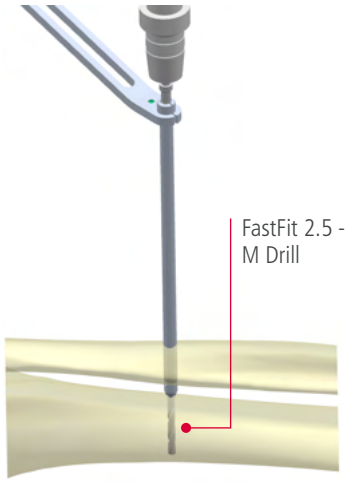
Instrument	Code
FastFit 2.5 - Bipartite M Guide	490061900
FastFit 2.5 - Bipartite M Obturator	490062070

7 | Remove the **FastFit 2.5 - Bipartite M Obturator** from the inside of the **FastFit 2.5 - Bipartite M Guide**;

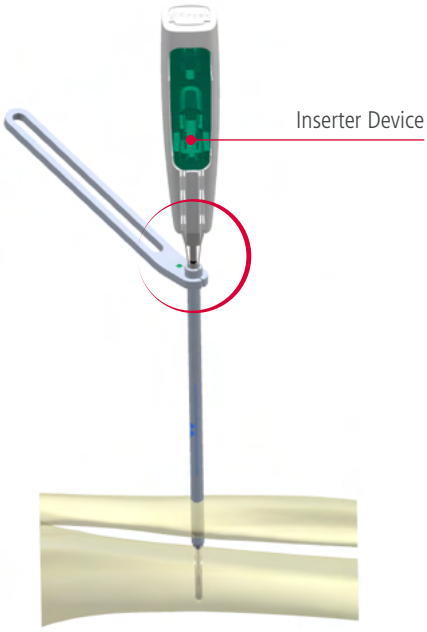


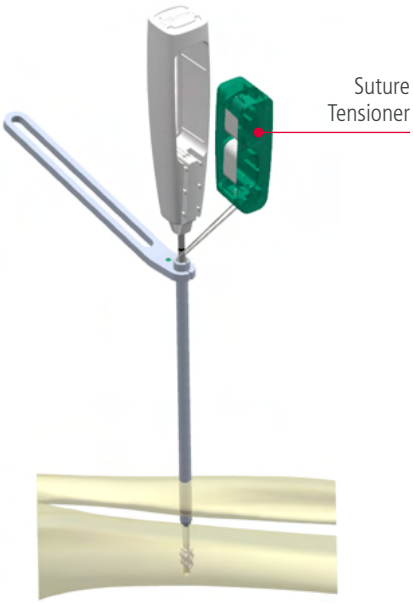
8 | Perform the drilling for insertion of the flexible anchor using the **FastFit 2.5 - M Drill** coupled to the driller and the **FastFit Chuck** , through the **FastFit 2.5 - Bipartite Guide M**. The **FastFit 2.5 - M Drill** has a mechanical stop that provides the exact drilling depth;

Instrument	Code
FastFit 2.5 - M Drill	490061830



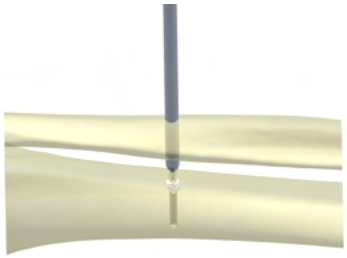
9 | Impact the **Inserter Device**, through the **FastFit 2.5 - Bipartite M Guide**, in order to completely insert the anchor into the spongy bone tissue. The anchor must be inserted until the marking present on the rod of the **Inserter Device**, according to the image on the side;





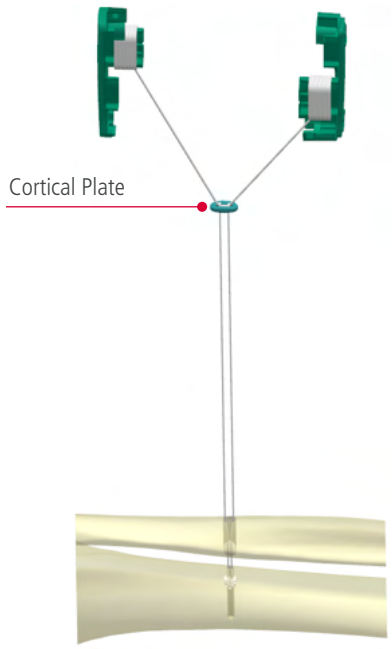
10 | Detach the **Suture Tensioner** and pull the assembly 1 to 3 times. Ideally, the assembly should still be pulled with the **Inserter Device** inserted, in order to ensure that the anchor has conformed and completely fixed to the bone cortex;

11 | Remove the **Inserter Device**, keeping the sutures tensioned;

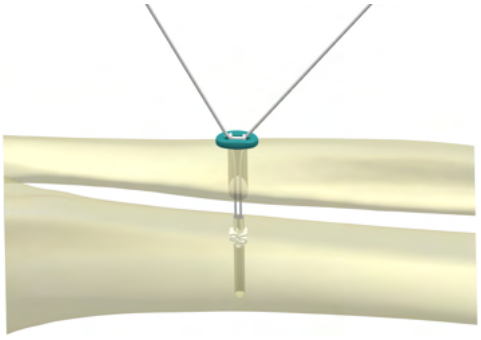


12 | After removing the **Inserter Device**, pull the assembly again without excess load. During this procedure the anchor can move a few millimeters, reaching its final attachment point. Without this procedure there may be deleterious micro movements to the result of the suture;

13 | Remove **2.5 FastFit Guide - Bipartite M**. The **FastFit 2.5 - Bipartite M Guide** has a frontal tear for suture removal;



14 | Remove the **Cortical Plate** from the inside of the **Suture Tensioner**;

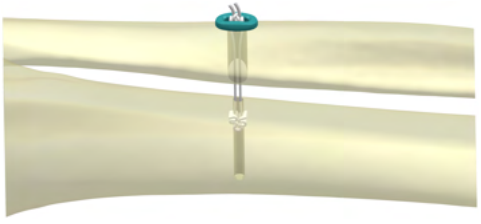


15 | Using the **Suture Tensioner**, pull the sutures to achieve the desired stabilization and reduction. Adjustment is best accomplished by pulling one wire at a time, as follows:

a. Pull a wire about 3 to 5 mm;

b. Traction the other wire in the same way;

c. Repeat the above procedure until the desired initial stabilization is achieved and the **Cortical Plate** is properly accommodated on the bone surface;



16 | Perform the final reduction on **FastFit Razek**. After final reduction, it is recommended that the surgeon tie a knot using the adjustment sutures;

17 | Cut the adjustment wires using an appropriate suture cutter. The cutting of the wires must be carried out at a minimum safety distance above the knot.

Suggested Use - FastFit Razek
FAB Model - with Wire Guide

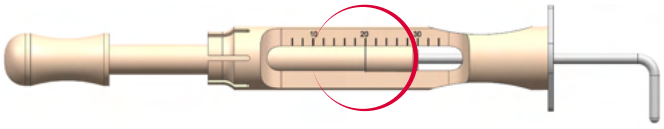
1 | After incision, perform the preparation of the bone surface;

2 | Select the **FastFit Razek** model to be used;

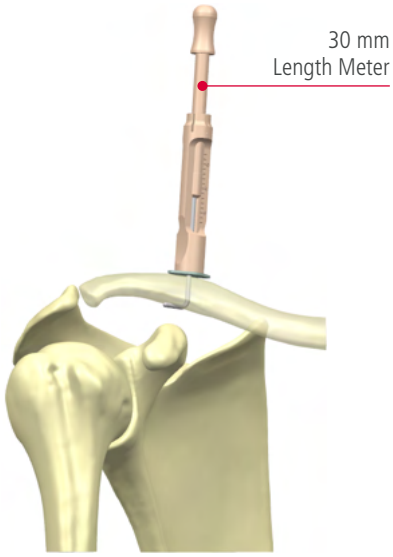
Model FastFit Razek	Code
2.5 Adjustable (FAB 15-25M)	500120030

Note 1: FastFit Razek anchors have a pre-bore diameter equal to Ø 2.5 mm;

3 | Measure the dimension of the first bone structure using the **30 mm Length Meter**;

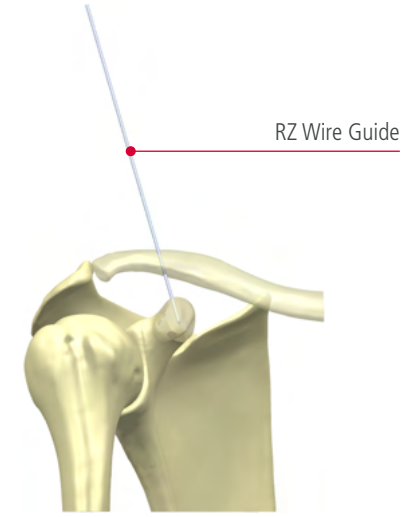


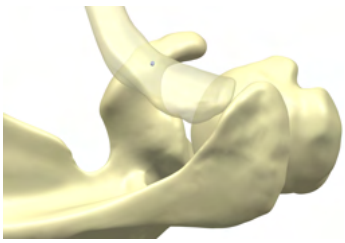
Instrument	Code
30 mm Length Meter	490062170



4 | Insert the **RZ Wire Guide** up to the height of the 4th cortical, without crossing it;

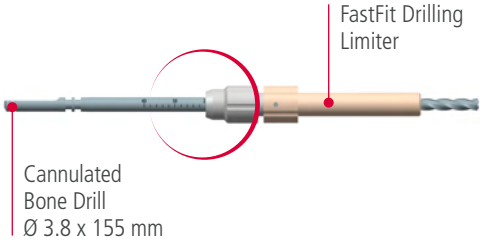
Instrument	Code
RZ Wire Guide Trocar Tip - 1,4 x 150 mm	742593920





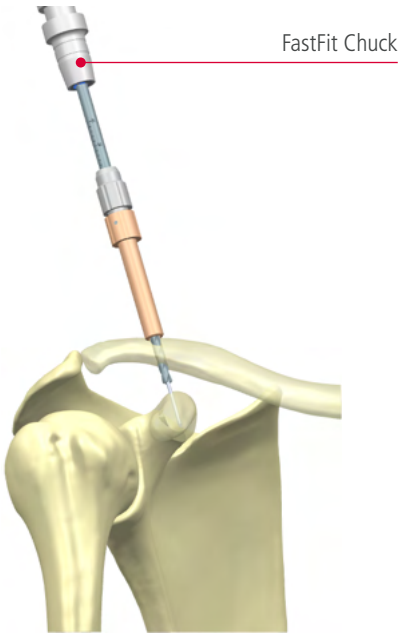
5 | Attach the **FastFit Drilling Limiter** to the **Cannulated Bone Drill Ø 3.8 x 155 mm**, positioning it on the scale according to the measurement of the first bone structure previously performed;

Instrument	Code
Cannulated Bone Drill Ø 3.8 x 155 mm	490062180
FastFit Drilling Limiter	490062200



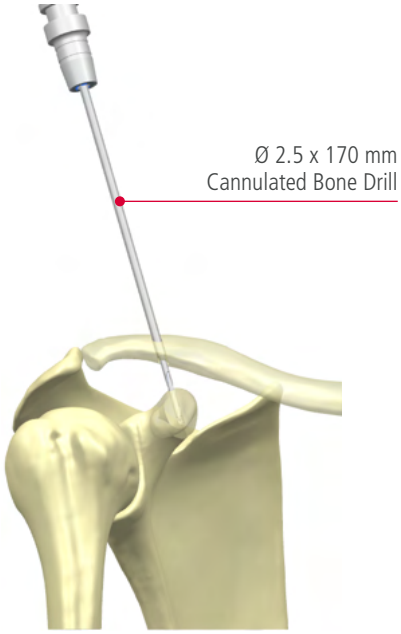
6 | Drill the first bone structure, 1st and 2nd cortical, using the **Ø 3.8 x 155 mm Cannulated Bone Drill**, coupled to the driller and the **FastFit Chuck** , through the **RZ Wire Guide**. The **FastFit Drilling Limiter** offers safety and precision to the surgeon, so that the 3rd cortical is not damaged;

Instrument	Code
FastFit Chuck	490061040



7 | Drill to insert the flexible anchor, using the **Ø 2.5 x 170 mm Cannulated Bone Drill**, coupled to the driller and the **FastFit Chuck** , through the **RZ Wire Guide**. The **Cannulated Bone Drill Ø 2.5 x 170 mm** has a mechanical stop that provides the exact drilling depth;

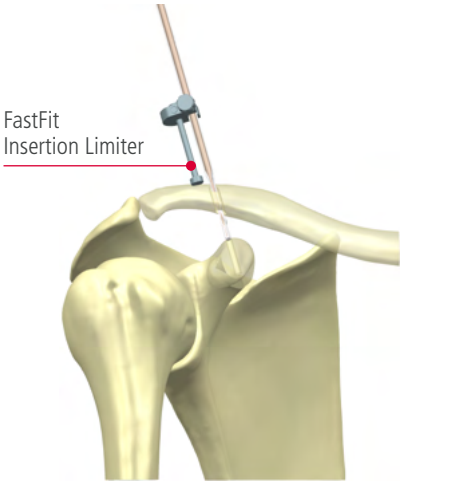
Instrument	Code
Ø 2.5 x 170 mm Cannulated Bone Drill	490061870



8 | Remove the **RZ Wire Guide**;

9 | Insert the anchor through the hole of the first bone structure to the height of the 3rd cortical. Then, fix the **FastFit Insertion Limiter** as shown on the side;

Instrument	Code
FastFit Insertion Limiter	490062160



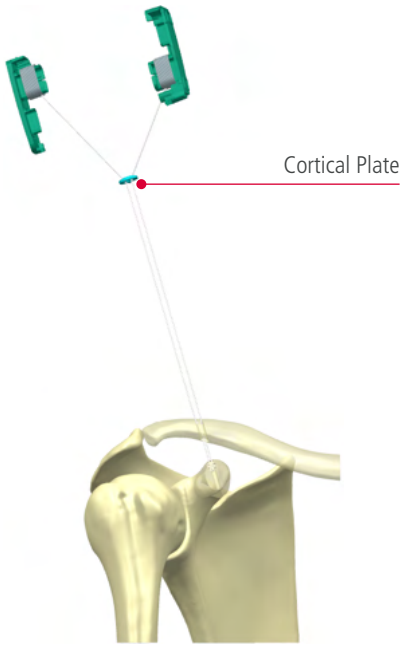
10 | Impact the **Inserter Device** to completely insert the anchor into the cancellous bone tissue. **Note:** the **FastFit Insertion Limiter** must reach its limit, as shown on the side;

11 | Remove the **FastFit Insertion Limiter**;

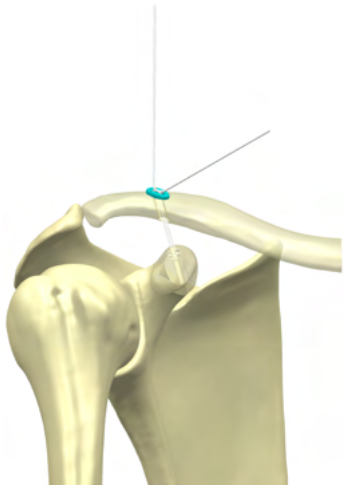
12 | Detach the **Suture Tensioner** and pull the assembly 1 to 3 times. Ideally, the assembly should still be pulled with the **Inserter Device** inserted, in order to ensure that the anchor has conformed and completely fixed to the bone cortex;

13 | Remove the **Inserter Device**, keeping the sutures tensioned;

14 | After removing the **Inserter Device**, pull the assembly again without excess load. During this procedure the anchor can move a few millimeters, reaching its final attachment point. Without this procedure there may be deleterious micro movements to the result of the suture.



15 | Remove the **Cortical Plate** from the inside of the **Suture Tensioner**;

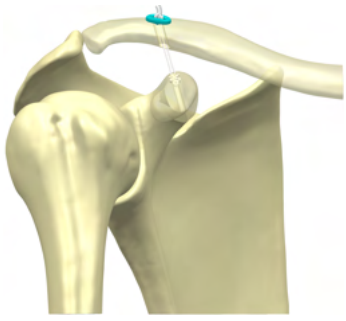


16 | Using the **Suture Tensioner**, pull the sutures to achieve the desired stabilization and reduction. Adjustment is best accomplished by pulling a wire at a time, as follows:

a. Pull a wire about 3 to 5 mm;

b. Traction the other wire in the same way;

c. Repeat the above procedure until the desired initial stabilization is achieved and the **Cortical Plate** is properly accommodated on the bone surface;



17 | Perform the final reduction in **FastFit Razek**. After final reduction, it is recommended that the surgeon tie a knot using the fitting sutures;

18 | Cut the adjustment wires using an appropriate suture cutter. The cutting of the wires must be carried out at a minimum safety distance above the knot.