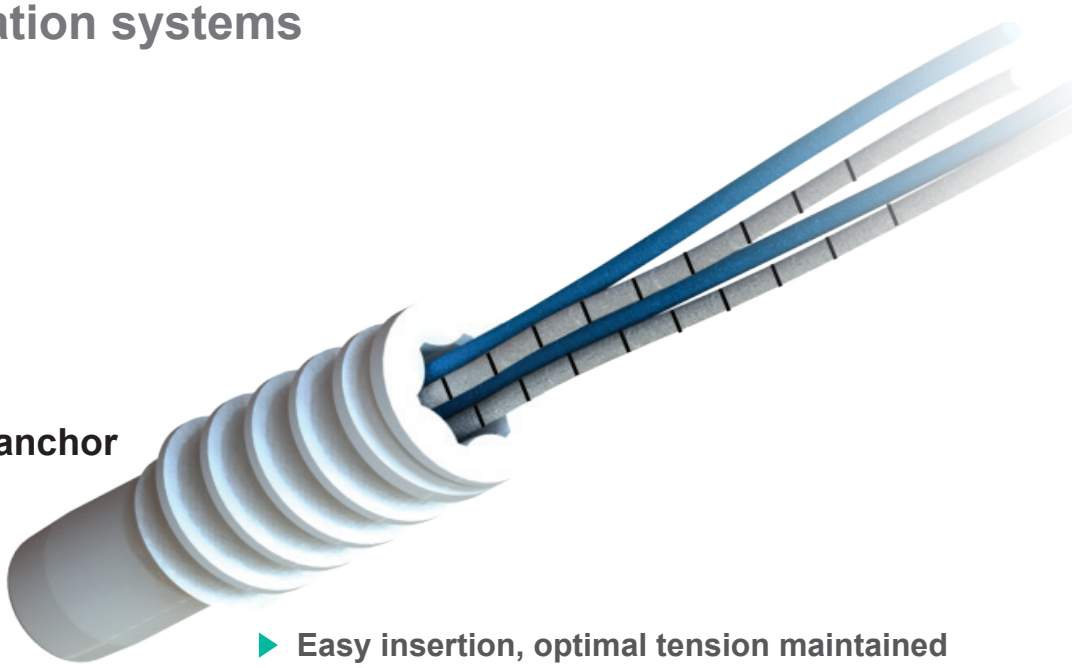
Rotator cuff repair

Bioabsorbable fixation systems

FIXIT®

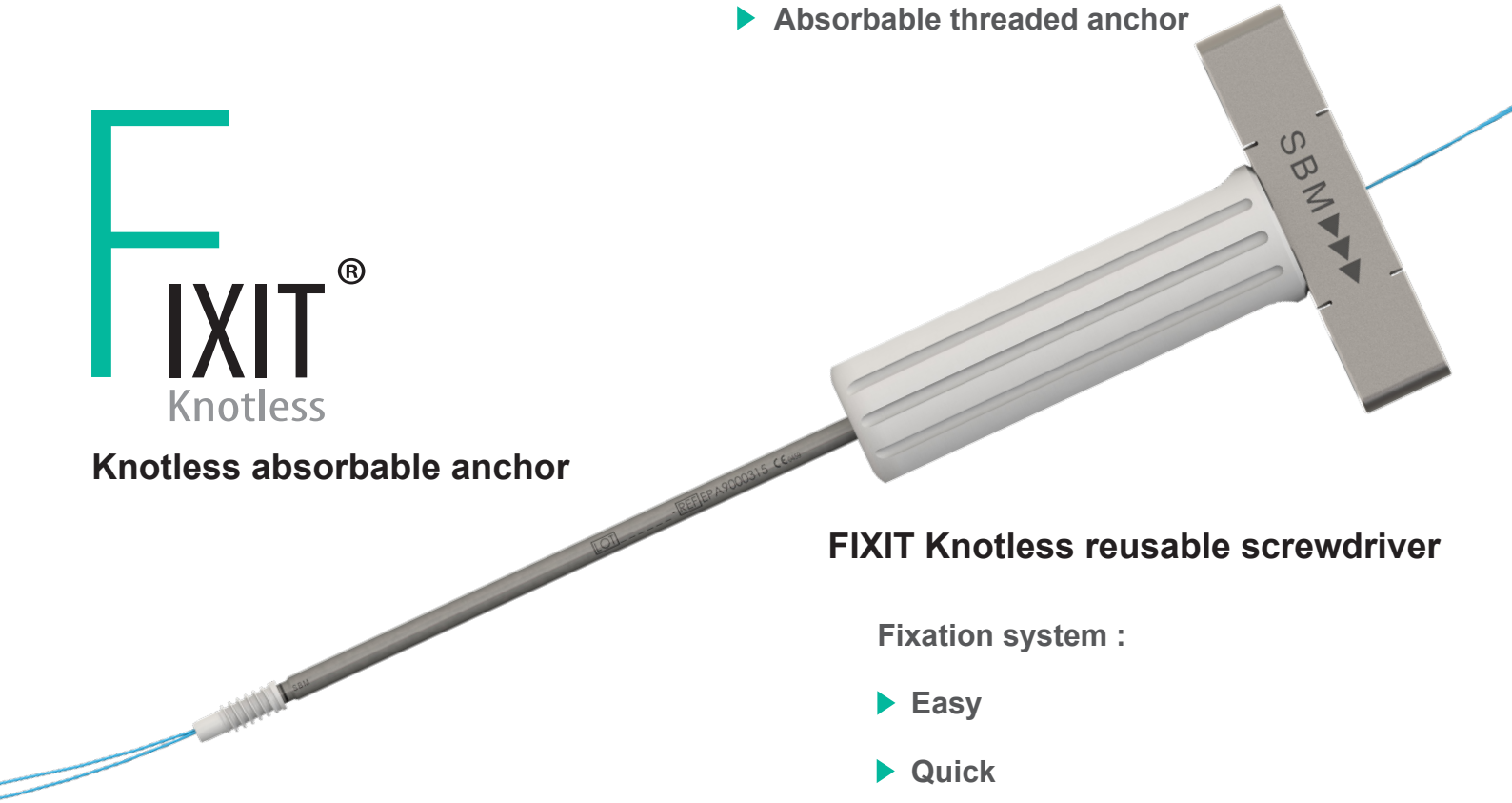
Pre-loaded absorbable anchor



- Easy insertion, optimal tension maintained on the suture
- Available from size 4.5 mm
- Absorbable threaded anchor

FIXIT® Knotless

Knotless absorbable anchor



FIXIT Knotless reusable screwdriver

Fixation system :

- Easy
- Quick
- Reproducible
- Accomodates up to 4 suture strands

+ complete instrumentation

SBM
Science & Bio Materials

Osteoconductive, bioabsorbable and high-strength…

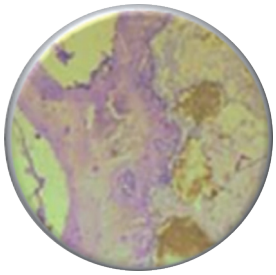
FIXIT® is a line of ready-to-use anchors for tendinous tissue fixation in arthroscopic rotator cuff repair. Available in three different sizes, each with sutures and knotless versions, this system was designed to be quick and easy to use.

Made exclusively in Duosorb®, a biocomposite material, these osteoconductive and bioabsorbable anchors offer remarkable mechanical performances when compared with other bioabsorbable anchors on the market. The FIXIT® system promotes bone healing and facilitates revision surgery. This adaptable high performance system is the solution of choice for all your arthroscopic rotator cuff repairs, no matter what technique you use.

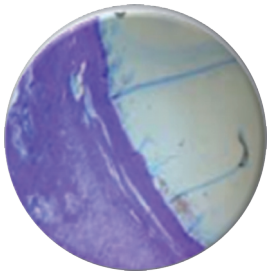
Bone healing

Osteoconductive material [1]

FIXIT® anchors are made with Duosorb®, a biocomposite material composed of: **30% β-TCP** and **70% PLDL**. This balance between strength and elasticity makes Duosorb® both osteoconductive and bioabsorbable, and its high β-TCP content limits inflammatory responses.



Duosorb®
Toluidine blue x400 - 3 months



Pure PLDL
Toluidine blue x400 – 1 week

Atraumatic design

FIXIT® and FIXIT® KNOTLESS systems have atraumatic threaded anchors that can be reliably inserted. The eyelet is hidden inside the FIXIT® anchors which avoids friction with sutures and makes the device stronger.

Quick and reproducible

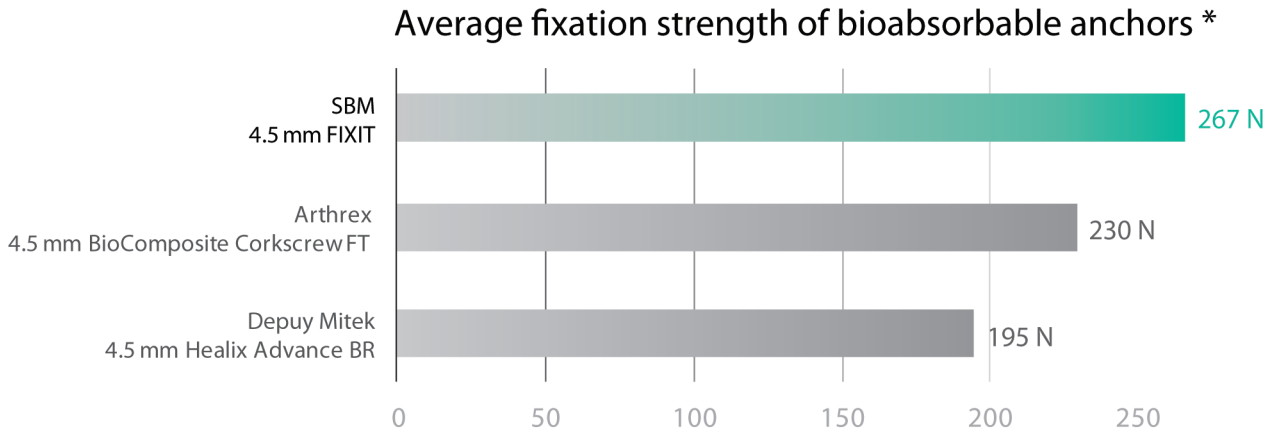
FIXIT®

FIXIT® anchors are pre-assembled with two UHMWPE suture, and pre-loaded on a disposable screwdriver for tensioning the sutures. FIXIT® anchors are specially designed to make their insertion easy thanks to a conical nose perfect for locating the pilot-hole.

FIXIT® KNOTLESS

The knotless version of the FIXIT® anchors are used with a non-disposable insertion pin which makes passing the sutures through the anchor and the screwdriver quick and easy. In addition, the sutures allow good interference and the design of the anchor facilitates its insertion thanks to the conical nose which makes finding the pilot hole much easier.

High-strength [2]



[1] Biological performance of a new β-TCP/PLLA composite material for applications in spine surgery: In vitro and in vivo studies, AUNOBLE S., CLEMENT D., FRAYSSINET P., HARMAND M-F., LE HUEC J-C. Journal of Biomedical Materials Research, Part A, Art. 30749, 1-7, 2006.

[2] Data on file, SBM.

...for all your techniques

FIXIT®

Pre-loaded anchor

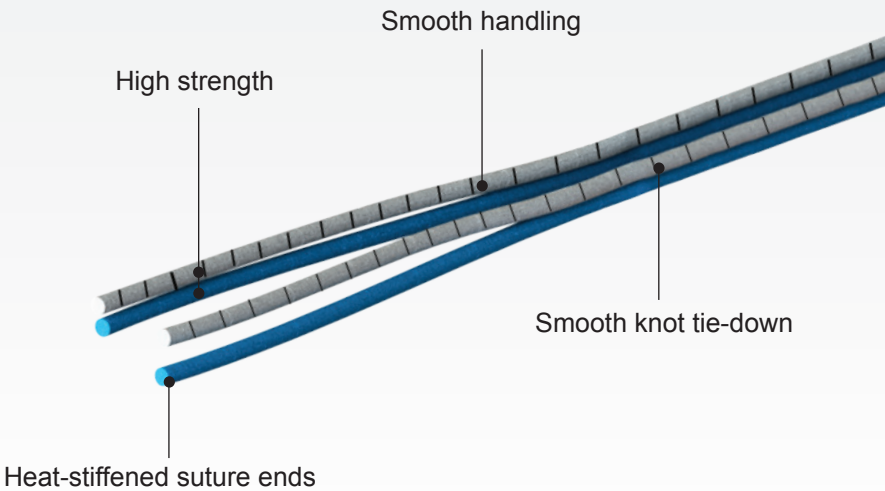
Composed of a bioabsorbable anchor and two UHMWPE sutures, the system is pre-loaded on a disposable screwdriver which allows a quick and reproducible implantation.

Punch Tap

POWERTEX®

UHMWPE sutures

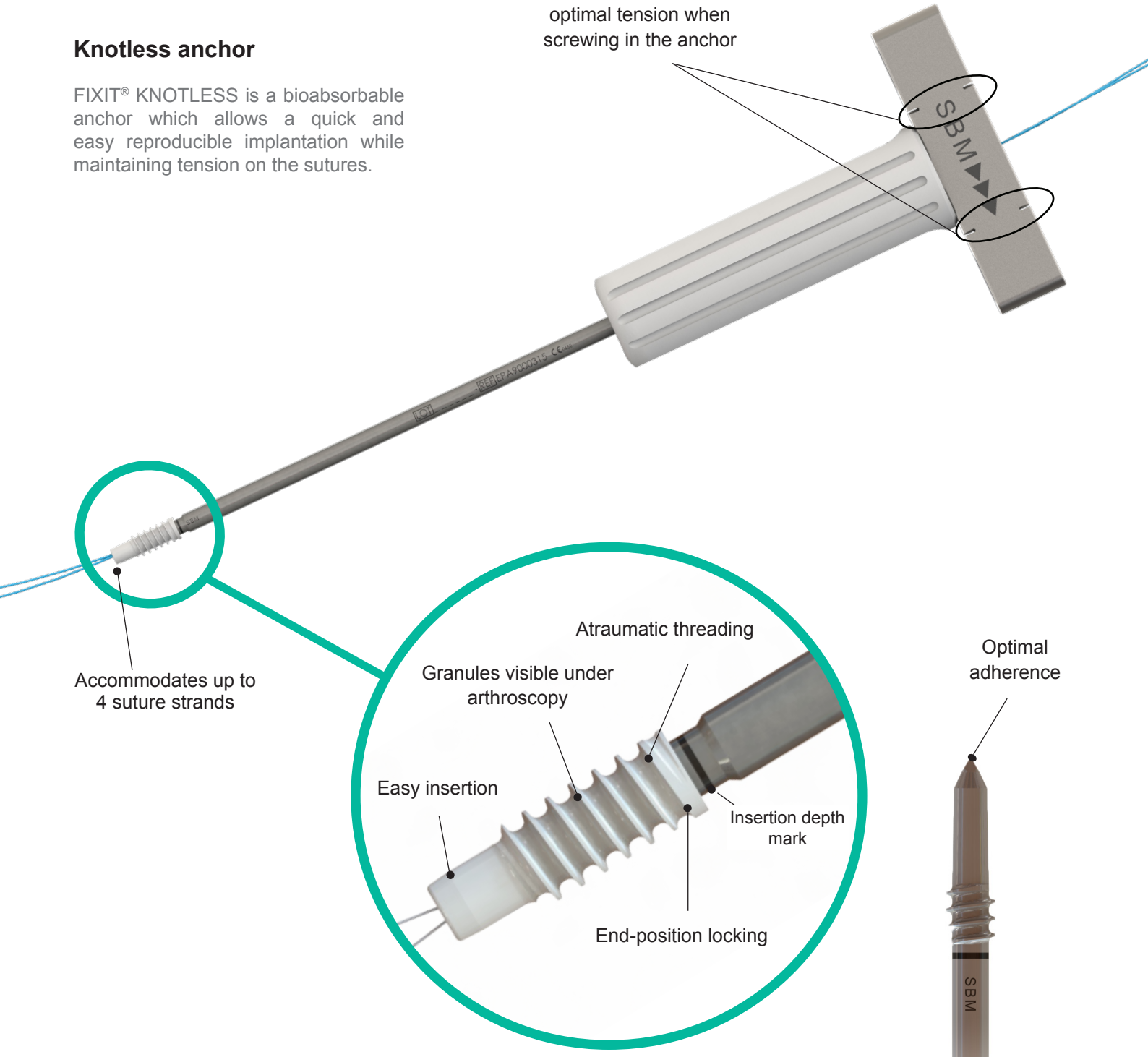
Size USP #2 POWERTEX® sutures are incredibly strong latest-generation sutures, made of UHMWPE (Ultra High Molecular Weight PolyEthylene).



FIXIT®
Knotless

Knotless anchor

FIXIT® KNOTLESS is a bioabsorbable anchor which allows a quick and easy reproducible implantation while maintaining tension on the sutures.



Punch Tap

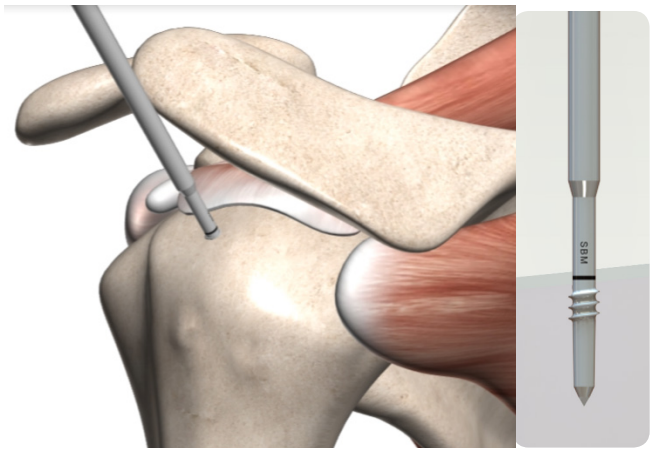
Surgical technique - Double Row Rotator Cuff Repair

Medial row

0 Prerequisites

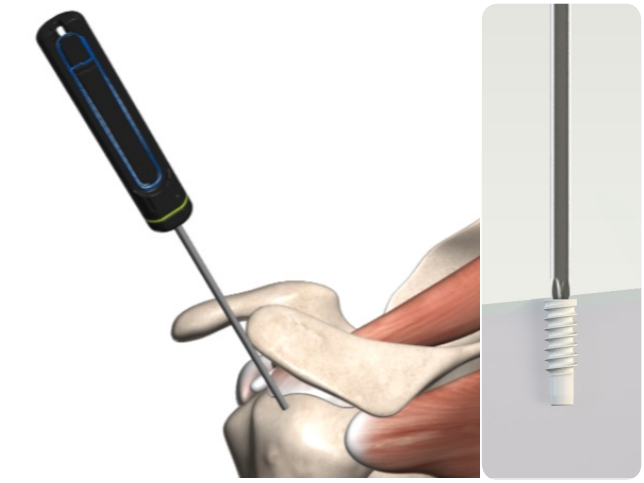
Incision.
Assess the type of shoulder injury.
Arthroscopic evaluation.
Clean the humeral head with a shaver.

1 Make a pilot-hole



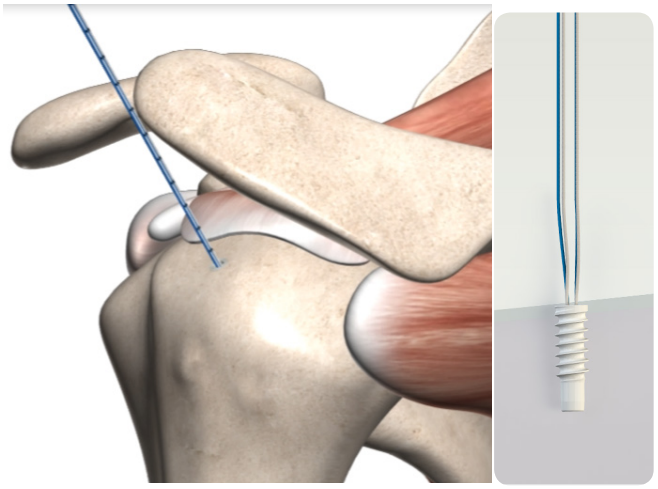
Make a pilot-hole by impacting the punch tap with a hammer (punch tap 4.5 for 4.5 anchor, 5.5 for 5.5 and 6.5 anchors) then tap until the mark is inserted inside the bone.

2 Insert the anchor



Remove the punch tap and insert a FIXIT® anchor up to the mark. Two vertical marks are engraved on the screwdriver to indicate the sutures orientation. These marks must be positioned along the frontal plane when the screw is completely inserted in the bone.

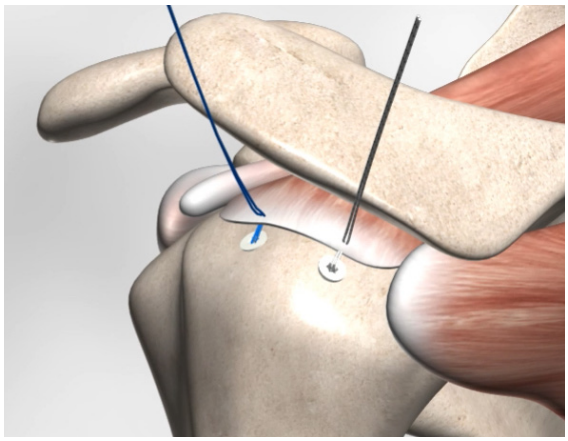
3 Remove the screwdriver



Unlock the sutures from the screwdriver handle and pull out the screwdriver.
The sutures are now free.

The FIXIT® anchor can be used as a 1st row anchor and as a single row anchor in the tension-band technique with the tendon pulled laterally

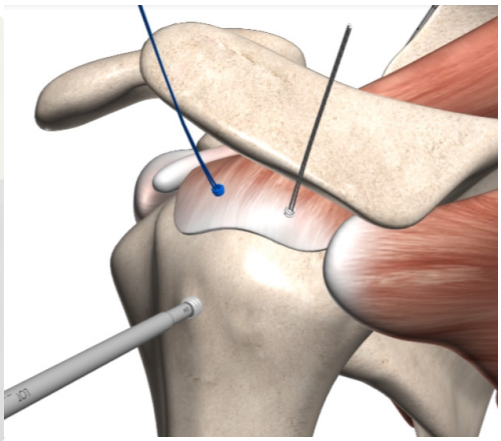
0 Prerequisites:



Incision.
Arthroscopic evaluation.
Clean the humeral head with a shaver.
Insert two FIXIT® anchors in the medial row.

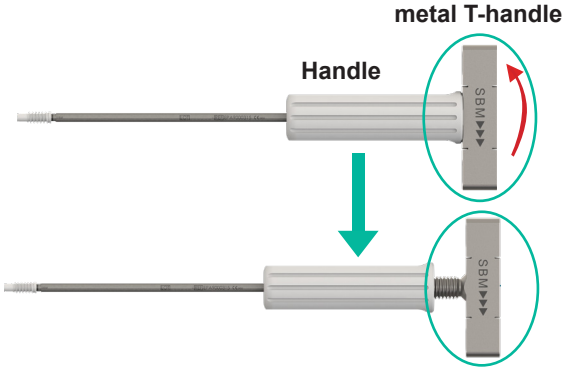
Lateral row

1 Make a pilot-hole



Make a pilot hole for the posterior most lateral FIXIT® Knotless anchor through the lateral portal by using the FIIXT® punch tap with a diameter 1 mm less than that of the anchor to be inserted, unless the bone is very dense in which case you should use the FIXIT® punch tap which fits the size of the knotless anchor: for a 4.5 mm anchor, use a 4.5 mm punch tap.
Do not use the tap part of the punch tap for the lateral row.

2 Prepare the FIXIT® Knotless screwdriver

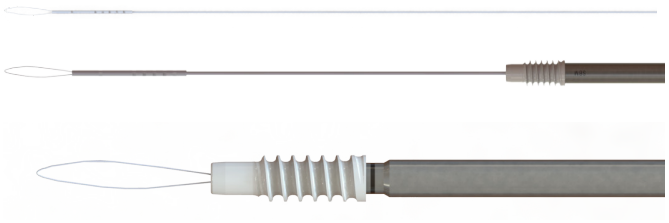


Unscrew the metal T-handle by turning it clockwise until it comes to a stop, all the while keeping the straight handle still.

3 Put the implant on the screwdriver

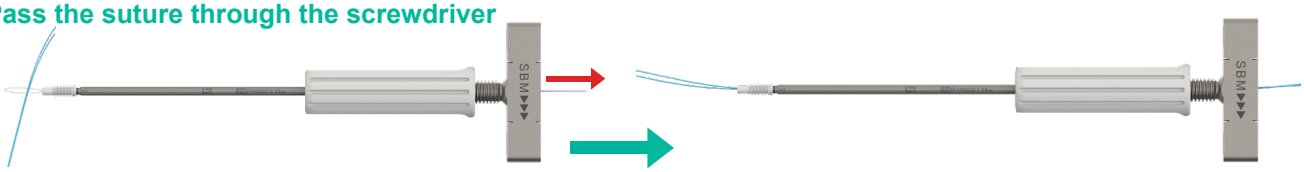
Open the implant holder.
Place the anchor on the FIXIT® Knotless screwdriver.

4 Pass the suture retriever pin



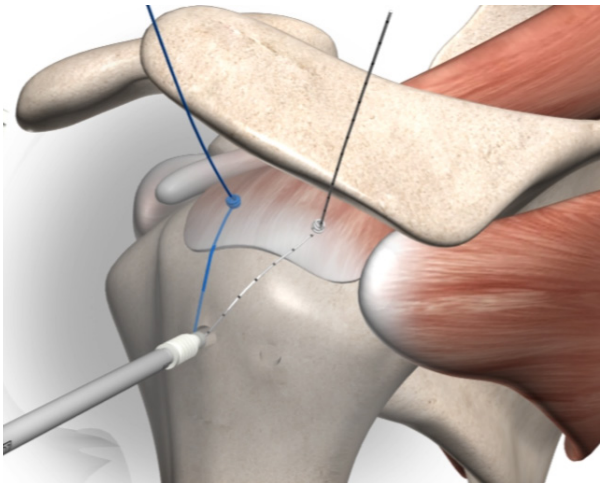
Pass the suture retriever pin (present in the ancillary instrumentation set) through the screwdriver so that the loop protrudes from the distal extremity of the anchor.

5 Pass the suture through the screwdriver



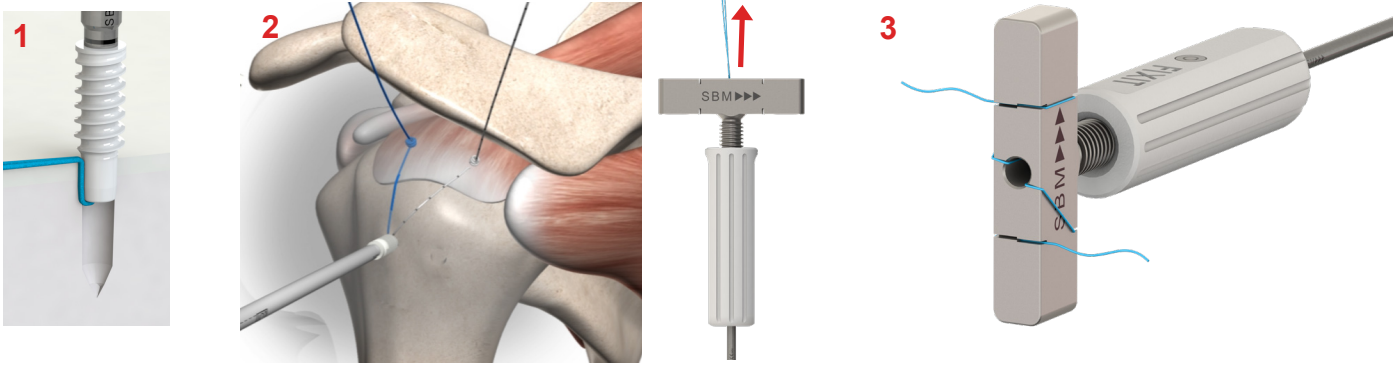
Pull one suture limb from the posterior/medial anchor and one suture from the anterior/medial anchor.
Pass a few centimeters only of each suture end through the loop of the suture retriever pin, then pull on the pin to shuttle the suture ends through the Fixit Knotless screwdriver.
A maximum of 4 suture limbs can be passed with the suture retriever pin.

6 Position the anchor



Pass the screwdriver carrying the anchor through the lateral portal and position the anchor relative to the posterior lateral pilot hole.

7 Insert the anchor

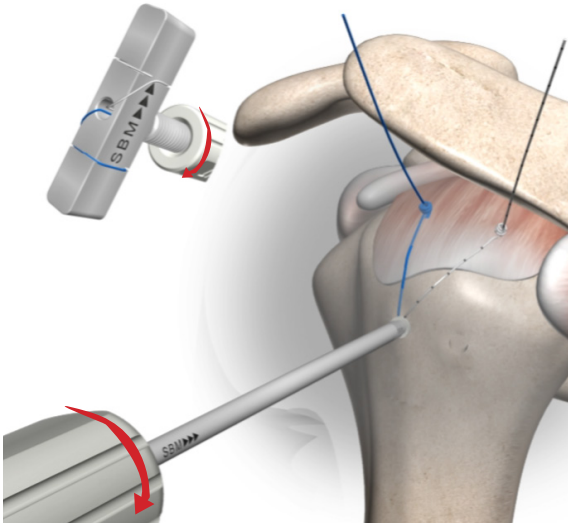


To ensure smooth anchor insertion, maintain the same angle of insertion as the pilot hole.
Push the nose of the anchor into the bone.

Maintain the sutures under tension.
Wedge the sutures in the slots of the screwdriver metal T-handle.

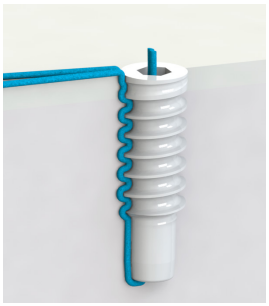
CAREFUL ! Apply maximum tension at this point, no additional tension can be added once the anchor has been screwed in.

8 Insert the anchor



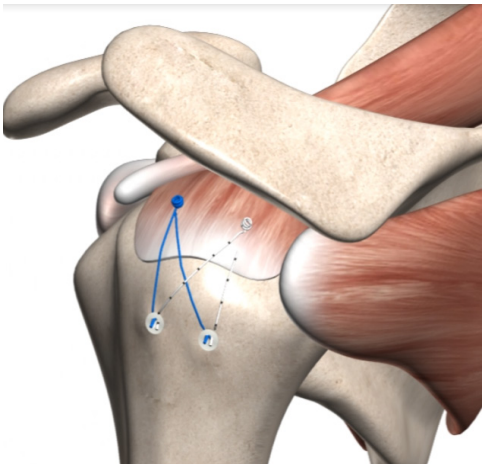
While maintaining the metal T-handle still and applying a pushing force on it, turn the handle clockwise until the anchor arrives flush with the bone surface.

9 Finish securing the first anchor



Unwedge the suture strands from the slots.
The screwdriver can be pulled out of the anchor and the free suture ends can be cut.

10 Last step

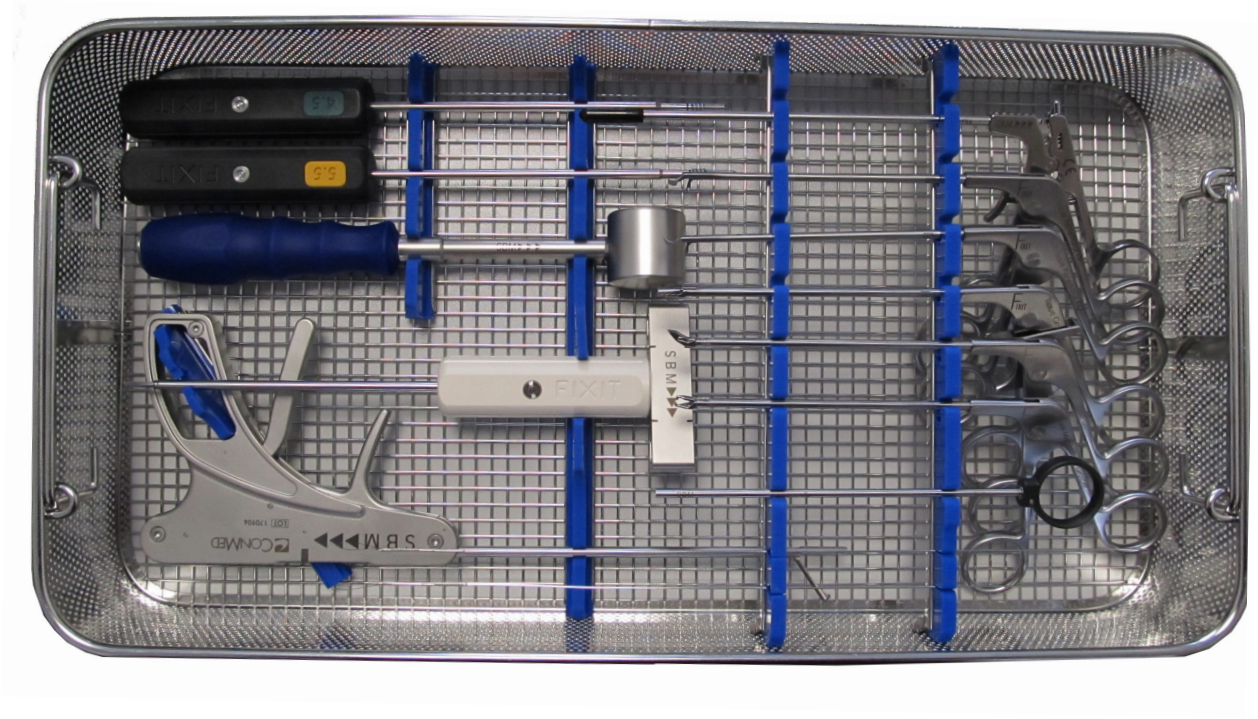


Take the remaining sutures from the lateral row and repeat the steps for securing the sutures to a lateral/anterior knotless anchor.

Alternative configurations can be used.

Instrumentation

FIXIT® instruments



Complete FIXIT® basket - 1st + 2nd row with automatic grasper
EPA9000004

Punch tap
For anchor ø 4.5 - EPA9000240

Punch tap
For anchors ø 5.5 & 6.5 mm - EPA9000241

FIXIT® mallet
EPA9000247

Tissue Grasper
EPAGR00074

Penetrating Grasper 30° Up
EPAGR00174

Clever Hook Right
328332bs

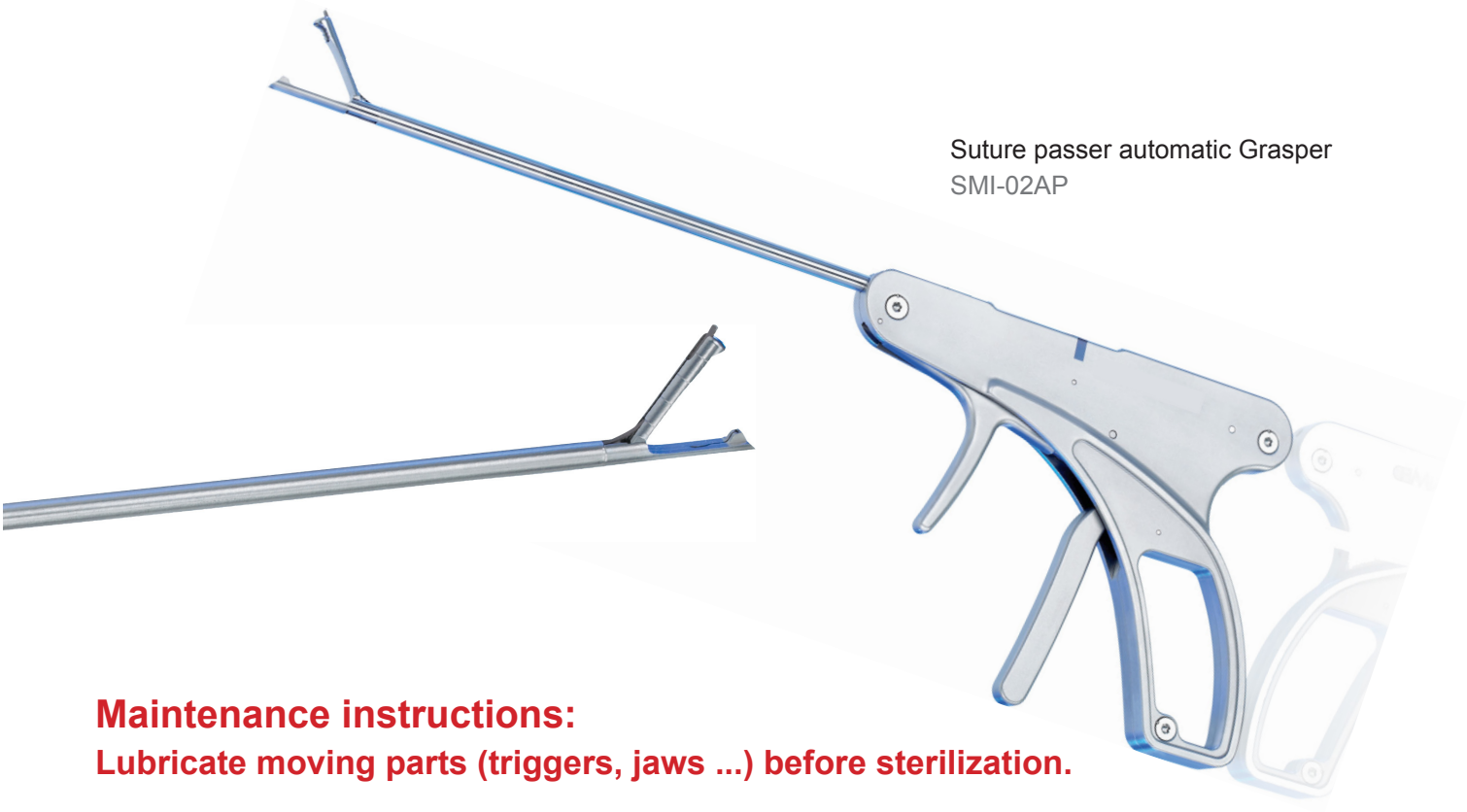
Clever Hook Left
328342bs

Suture Manipulator Grasper
EPAGR00274

Suture Cutter
231400BS

Knot pusher
EPAKN00074

OPTION

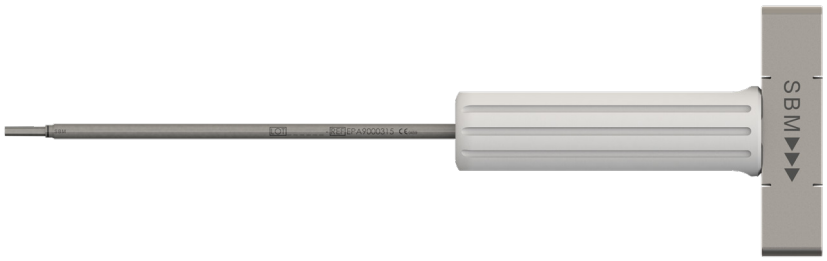


Suture passer automatic Grasper
SMI-02AP

Maintenance instructions:
Lubricate moving parts (triggers, jaws ...) before sterilization.

Box of 5 automatic grasper disposable Needles
SMI-02N

SECOND Row



FIXIT® knotless screwdriver
NOT DISPOSABLE
EPA9000315

Suture retriever pin
NOT DISPOSABLE
EPA9000303

Ordering information

FIXIT® bioabsorbable threaded anchors

Codes	Designation	Packaging
EPA0047CLA	FIXIT® ø 4.5 mm threaded anchor mounted on screwdriver	1
EPA0055CLA	FIXIT® ø 5.5 mm threaded anchor mounted on screwdriver	1
EPA0065CLA	FIXIT® ø 6.5 mm threaded anchor mounted on screwdriver	1

FIXIT® KNOTLESS bioabsorbable threaded anchors

Codes	Designation	Packaging
EPAV245KNO	FIXIT® knotless threaded anchor single interference - Ø 4.5	1
EPAV255KNO	FIXIT® knotless threaded anchor single interference - Ø 5.5	1
EPAV265KNO	FIXIT® knotless threaded anchor single interference - Ø 6.5	1

FIXIT® instruments for rotator cuff repair

Codes	Designation	In the basket
EPA9000240	FIXIT® punch tap - ø 4.5 mm	1
EPA9000241	FIXIT® punch tap - ø 5.5 mm and ø 6.5 mm	1
EPA9000247	FIXIT® mallet	1
231200BS	Suture Cutter	1
EPAGR00074	Tissue Grasper	1
EPAGR00274	Suture Manipulator Grasper	1
328332bs	Clever Hook Right	1
328342bs	Clever Hook Left	1
EPAGR00174	Penetrating grasper 30° up	1
EPAKN00074	Knot pusher	1
EPA9000101	FIXIT® stainless steel basket with silicones	1
EPA9000201	FIXIT® stainless steel basket lid	1
EPA9000001	Complete FIXIT® basket - 1st row	

FIXIT® Knotless specific instrumentation

Codes	Designation	In the basket
EPA9000315	FIXIT® knotless screwdriver	1
EPA9000303	Suture retriever pin	2
EPA9000002	Complete FIXIT® basket - 1st + 2nd row	

Optional FIXIT® instruments for rotator cuff repair

Codes	Designation	In the basket
SMI-02AP	Suture passer automatic grasper	1
EPA9000003	Complete FIXIT® basket - 1st row with automatic grasper	
EPA9000004	Complete FIXIT® basket - 1st + 2nd row with automatic grasper	

CONSUMABLE

Codes	Designation	Packaging
SMI-02N	Box of 5 automatic grasper disposable Needles	1

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CE 0459

ISO 13485

Carefully read the instructions for use that comes with the medical device or labeling provided to medical professionals. Class III devices.
Document not legally binding - Can be modified without prior notice.

S.B.M. SAS

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