QUICK REFERENCE GUIDE

XCaliber™

Bone Screws

The XCaliber Cylindrical Bone Screws

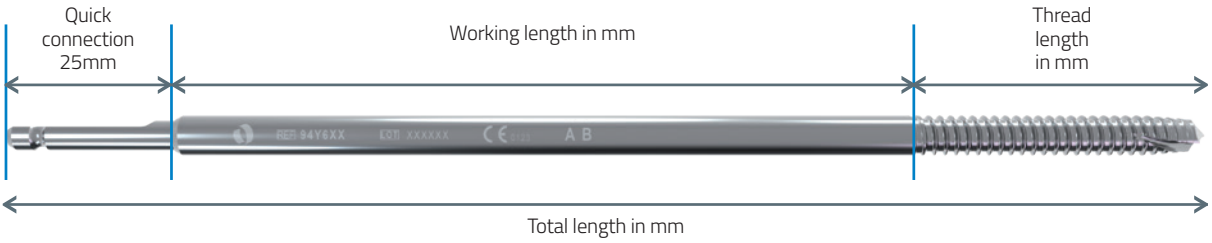
insertion and removal technique

ORTHOFIX®
ORTHOPEDICS

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please kindly refer to the product IFU PQSCR and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.

XCALIBER™ CYLINDRICAL BONE SCREWS

XCaliber™ Cylindrical Bone Screws are self-drilling and self-tapping, suitable for use in both cancellous and cortical bone. They are supplied in five different lengths (100mm, 120mm, 150mm, 180mm and 260mm) with Quick Connection. They are cut to the appropriate length after insertion. Screws are supplied in four thread diameters (6mm, 5mm, 4mm and 3mm) and different thread lengths as shown in the table below. All screws are available uncoated in stainless steel.



SHAFT DIAMETER 6mm, THREAD DIAMETER 6mm										
	Thread length (mm)									
Total length (mm)	**25**	**30**	**35**	**40**	**45**	**50**	**60**	**70**	**80**	**90**
180 QC	99-941625	99-941630	99-941635	99-941640	99-941645	99-941650	99-941660	99-941670	*	*
260 QC	99-942625	99-942630	99-942635	99-942640	99-942645	99-942650	99-942660	99-942670	*	*

SHAFT DIAMETER 6mm, THREAD DIAMETER 5mm										
	Thread length (mm)									
Total length (mm)	**25**	**30**	**35**	**40**	**45**	**50**	**60**	**70**	**80**	**90**
150 QC	-	-	-	99-944540	-	-	-	-	-	-
180 QC	99-941525	99-941530	99-941535	99-941540	99-941545	99-941550	99-941560	99-941570	-	-
260 QC	99-942525	99-942530	99-942535	99-942540	99-942545	99-942550	99-942560	99-942570	*	*

SHAFT DIAMETER 6mm, THREAD DIAMETER 4mm					
	Thread length (mm)				
Total length (mm)	**25**	**25**	**30**	**35**	**40**
100 QC	99-943420	-	99-943430	-	99-943440
120 QC	99-944420	-	99-944430	-	99-944440
150 QC	99-945420	99-945425	99-945430	99-945435	99-945440
180 QC	99-946420	-	99-946430	-	99-946440

SHAFT DIAMETER 4mm, THREAD DIAMETER 3mm					
	Thread length (mm)				
Total length (mm)	**15**	**20**	**25**	**30**	**35**
100 QC	_	99-947320	99-947325	-	_
120 QC	99-948315	99-948320	99-948325	99-948330	99-948335

All screws are also available packaged non sterile. They can be ordered using the above code numbers without 99- [e.g. 942560]
* Upon request.

INSTRUMENTS

CODE	Description
91150	Universal T Wrench
93161	Screw Hand Drill QC
93162	Screw T Wrench QC

Standard Instrumentation for Screw Insertion

STERILE	R

Contents sterile unless package opened or damaged; Do not use if package is opened or damaged.

The cylindrical screws can be backed out if not properly inserted.

Fig. 1

The screws all have a pointed tip and flute which allow them to be inserted self-drilling by using a power drill or a hand drill.

When insertion of self-drilling screws is performed in diaphyseal bone, pre-drilling might be recommended; use a drill bit through a drill guide (4.8mm drill bit for 6mm thread diameter screws, 3.2mm drill bit for 5mm thread diameter screws, 3.2mm drill bit for 4mm thread diameter screws, 2.7mm drill bit for 3mm thread diameter screws).

XCaliber™ Cylindrical bone screws of 6mm thread diameter can be used in any situation where the diameter of the bone at the point of insertion is greater than 20mm. If it is less than 20mm, 5mm, 4mm or 3mm thread diameter screws should be used according to bone diameter. Care should be taken that the screw is inserted in the center of the bone axis. If it is too peripheral the bone may be weakened.

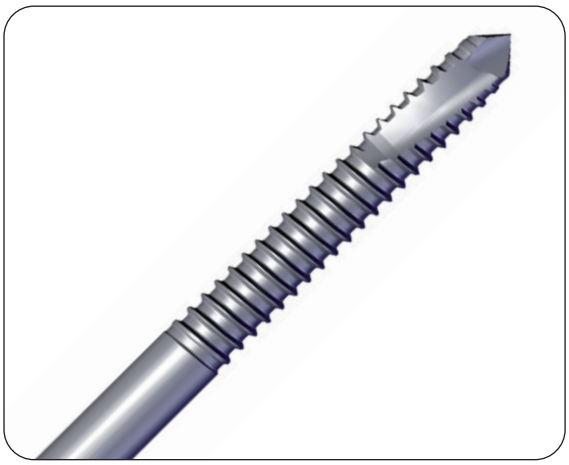


Fig. 2

XCaliber™ Cylindrical Screw Insertion

The following operative steps are related to 6mm and 5mm thread bone screws. The same operative steps can be followed also for 4mm and 3mm thread bone screws insertion.

Make a 15-20mm incision so that the skin around each screw is not too tight. The underlying tissues also require broad blunt dissection down to the bone.

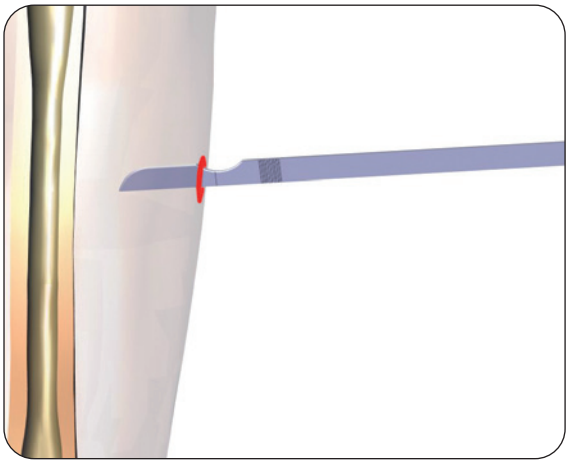


Fig. 3

Insert a screw guide perpendicular to the longitudinal axis of the bone. Use a trocar to locate the midline by palpation. Keep the screw guide in contact with the cortex by gentle pressure, withdraw the trocar, and tap the screw guide lightly to anchor its distal end.

PRECAUTION: Diaphyseal bone screws should always be inserted perpendicular to and in the centre of the bone axis to avoid weakening it.

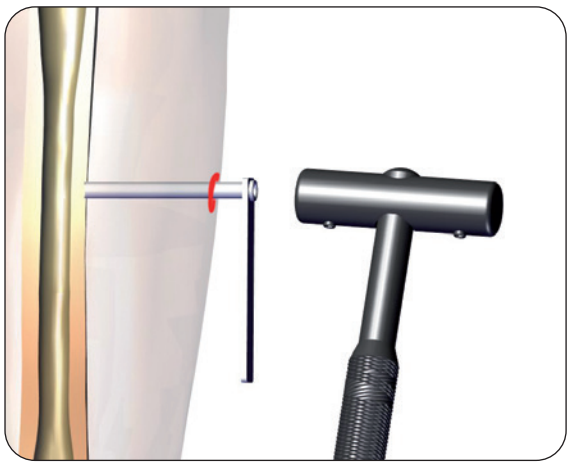


Fig. 4

Insert a screw through the screw guide into the bone directly using the power drill. While drilling, the power drill should be held steady so that the drilling direction is maintained throughout the procedure. Once the second cortex has been reached, reduce the drilling speed.

Alternatively a screw might be inserted manually with the hand drill QC or the T-wrench QC.

In diaphyseal bone, the screw should protrude 2mm beyond the distal cortex. In cancellous bone, there is no need for the screw to protrude from the second cortex.

In all cases the surgeon should be mindful of the amount of torque required to insert the screw. In general, it is advisable to pre-drill the diaphyseal bone using a drill bit (4.8mm drill bit for 6mm thread diameter screws, 3.2mm drill bit for 5mm thread diameter screws).

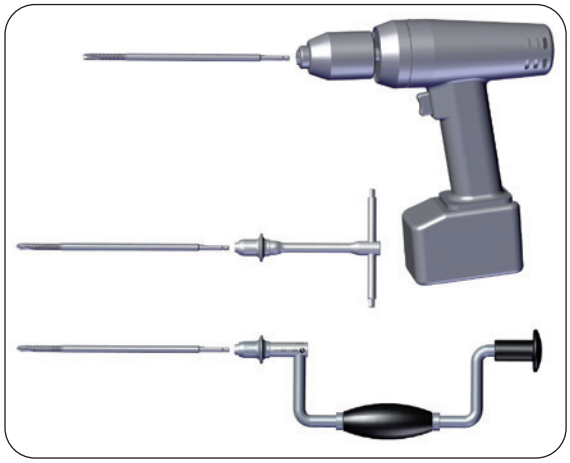


Fig. 5

PRECAUTION: Diaphyseal bone screws should always be inserted perpendicular to and in the centre of the bone axis to avoid weakening it.

WARNING: Do not excessively penetrate the second cortex with any type of screws to avoid soft tissue damage.

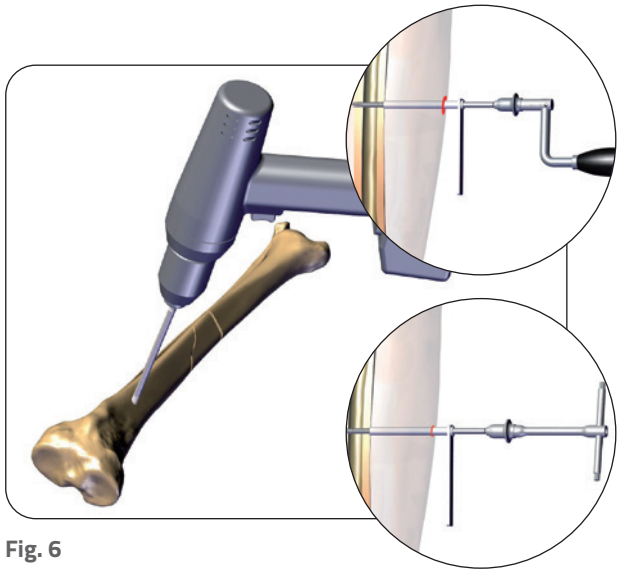


Fig. 6

When Inserted After Pre-Drilling

Insert the 3.2mm or 4.8mm drill guide into the screw guide, and introduce a 3.2mm or 4.8mm drill bit. Drill at 500-600 rpm through the first cortex, checking that the drill bit is at right angles to the bone. The force applied to the drill should be firm and the drilling time as short as possible to avoid thermal damage. Ensure that the drill bit completely penetrates the second cortex.

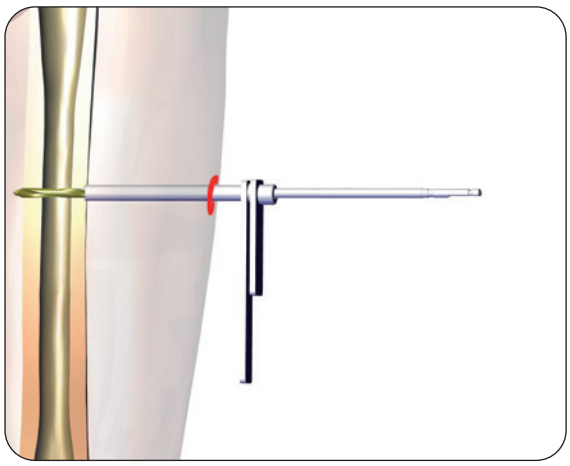


Fig. 7

Remove the drill bit and drill guide, keeping pressure on the handle of the screw guide. The screw is inserted with the T-Wrench QC or hand drill QC until it reaches the second cortex. Ensure that about 2mm of the screw protrudes beyond the second cortex.

WARNING: Do not excessively penetrate the second cortex with any type of screws to avoid soft tissue damage.

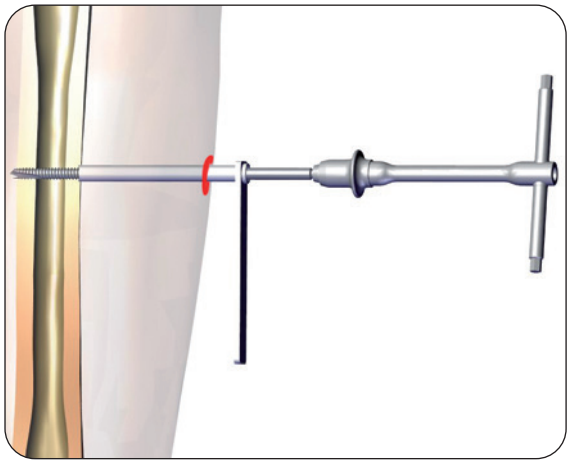


Fig. 8

CUTTING THE BONE SCREW SHAFTS TO LENGTH

When all screws have been inserted and the screw guides removed the fixator is applied. After the fixator clamps have been securely locked over the screws, the screw shafts can be cut with the bone screw cutter. It is important that all of the screws are inserted first, and the fixator applied with the clamps tightened firmly over the screws, about 20mm from the skin. The cutter can then be slid over the screw shafts in turn and the screws cut close to the fixator clamps. This will normally result in about 6mm of screw shaft protruding from the fixator. The cut ends of the screws can then be protected with screw caps. When cutting the screws, the arms of the cutter should be extended for greater efficiency, and the outer end of the screw held to prevent it causing injury.

PRECAUTION: XCaliber™ screws should be cut before screw insertion or after they have all been inserted with the fixator applied and the clamp locking screws firmly tightened. Cutting must be performed with the appropriate cutter.

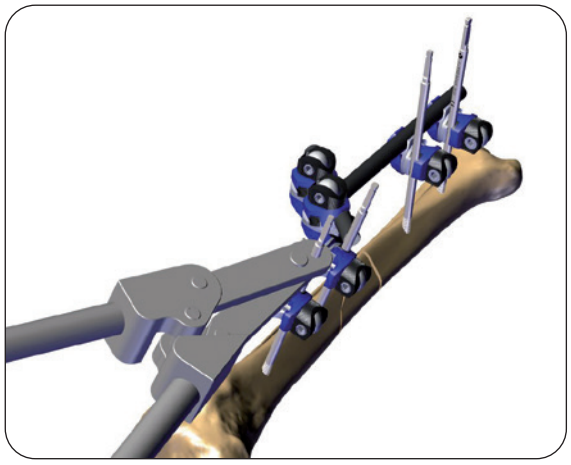
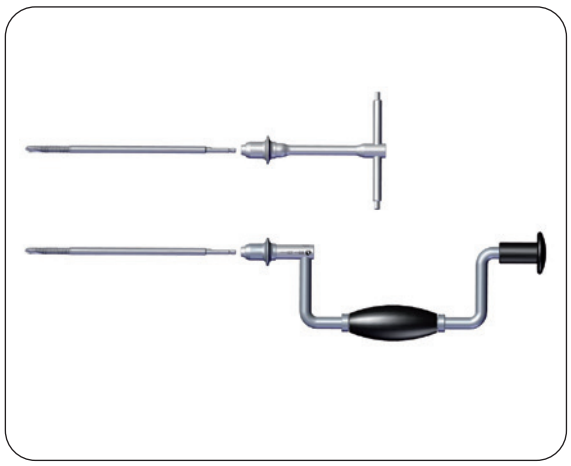


Fig. 9

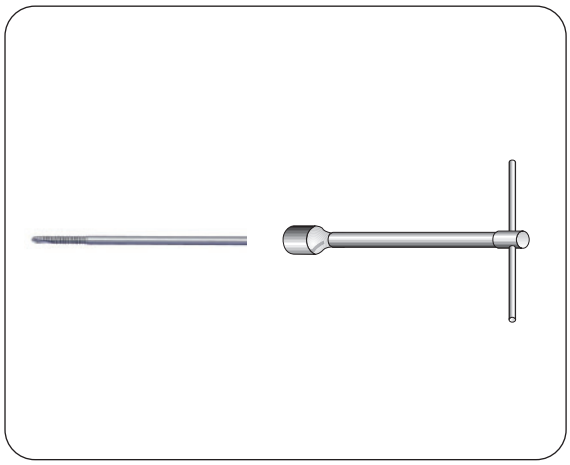
REMOVAL

Part #	Description
91150	Universal T-Wrench 6 mm
93175	Universal T-Wrench 4 mm
93161	Screw Hand Drill QC
93162	Screw T-Wrench QC

XCaliber Cylindrical Bone Screws should be removed on-hand using the T-Wrench QC or hand drill QC. To engage, slide the T-Wrench QC or hand drill QC over the screw-shaft until a positive-stop is reached and rotate counter-clockwise.



XCaliber Cylindrical Bone Screws, which have been cut, should be removed on-hand using the 4 mm or 6 mm Universal T-Wrench. To engage, slide the Universal T-Wrench over the screw-shaft until a positive-stop is reached and rotate counter-clockwise.



Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, possible adverse events, MRI (Magnetic Resonance Imaging) safety information and sterilization.

Electronic Instructions for use available at the website http://ifu.orthofix.it

Electronic Instructions for use - Minimum requirements for consultation:
- Internet connection (56 Kbit/s)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50 Mbytes

Free paper copy can be requested from customer service (delivery within 7 days):
tel: +39 045 6719301, fax: +39 045 6719370
e-mail: customerservice@orthofix.it

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.

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