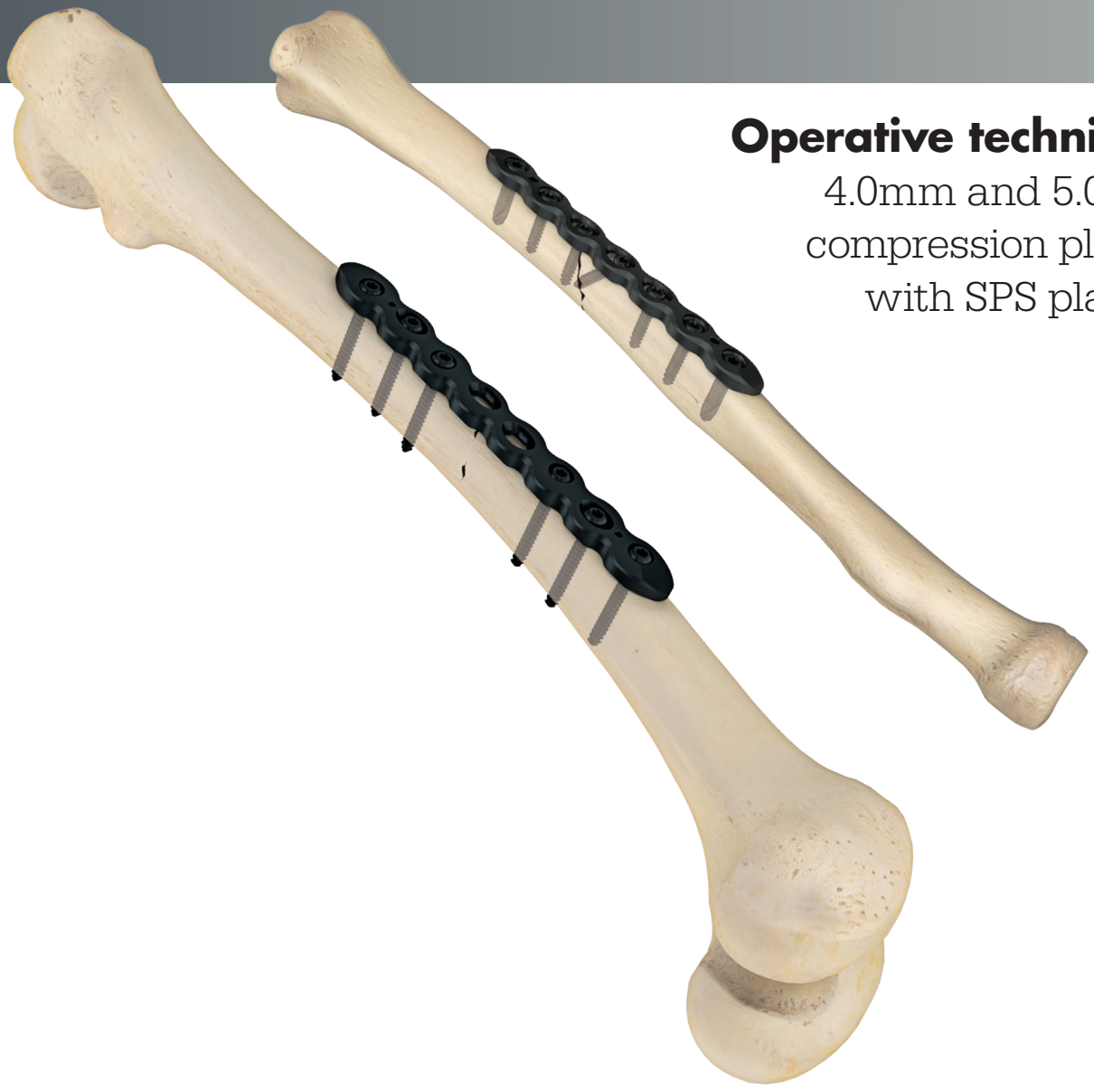
stryker

AxSOS 3® Titanium
Locking Plate System



Operative technique

4.0mm and 5.0mm
compression plates,
with SPS plating

AxSOS 3 Titanium Locking Plate System

4.0mm and 5.0mm compression plates, with SPS plating

Contents

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to first surgery. All non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our reprocessing guide (OT-RG-1). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

See instruction for use V15011, V15020, V15246 and V15013 for a complete list of potential adverse effects, contraindications, warnings and precautions.

The surgeon must discuss all relevant risks, including the finite lifetime of the device with the patient.

Introduction

The AxSOS 3 Titanium Locking Plate System is intended for long bone fracture fixation.

The system allows for the use of locking and non-locking screws.

This operative technique contains a step-by-step procedure for the implantation of AxSOS 3 Titanium Compression Plates and SPS Titanium Small Fragment plates using the ORIF instrumentation.

Additionally, the non-locking screws of the AxSOS 3 Titanium System are compatible with the Titanium SPS Small Fragment plates. Several Titanium SPS screws are also compatible with the AxSOS 3 Titanium Plates. Please refer to the compatibility table on page 31 showing SPS and AxSOS 3 Titanium compatibility.

Please note that AxSOS 3 Titanium and SPS Titanium are made out of anodized type II titanium alloy (Ti6Al4V) and are not compatible with SPS Stainless Steel plates and screws.

Introduction

A) Small fragment plates:

Plates and screws used in
this operative technique guide:

**4.0mm compression plate,
2 to 20-hole plates**

AxSOS 3 Titanium screws used with the AxSOS 3 Titanium 4.0mm Compression Plates:

4.0mm cancellous full thread | **4.0mm cancellous partial thread** | **3.5mm cortex shaft** | **3.5mm cortex screw** | **4.0mm locking screw**

All of the above AxSOS 3 Titanium Screws have a T15 screw head interface. Please refer to the compatibility table on page 31 showing SPS and AxSOS 3 Titanium compatibility.

SPS Titanium Small Fragment ISO screws used with the AxSOS 3 Titanium 4.0mm Compression Plates:

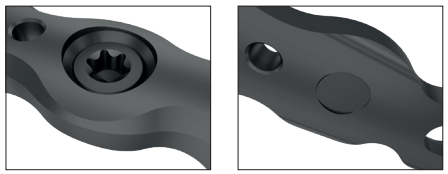
4.0mm cancellous full thread | **4.0mm cancellous partial thread** | **3.5mm cortex screw**

All of the above SPS Titanium Small Fragment ISO screws have a Hex 2.5 screw head interface. Please refer to the compatibility table on page 31 showing SPS and AxSOS 3 Titanium compatibility.

4.0mm blind screws

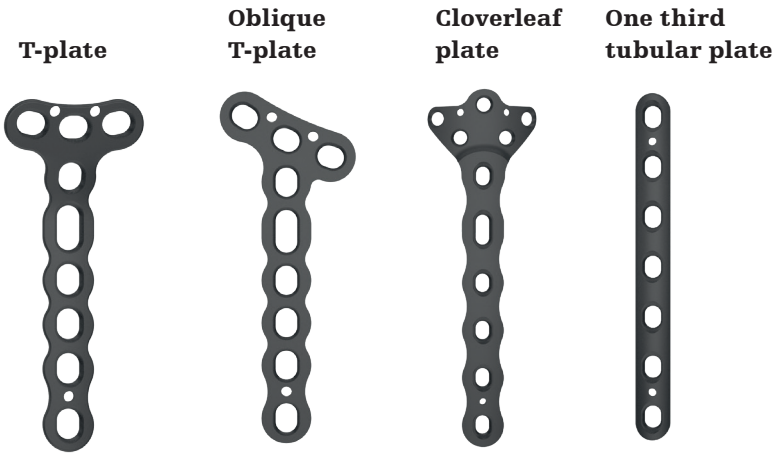
These optional inserts may be placed
in empty universal screw holes.

4.0mm

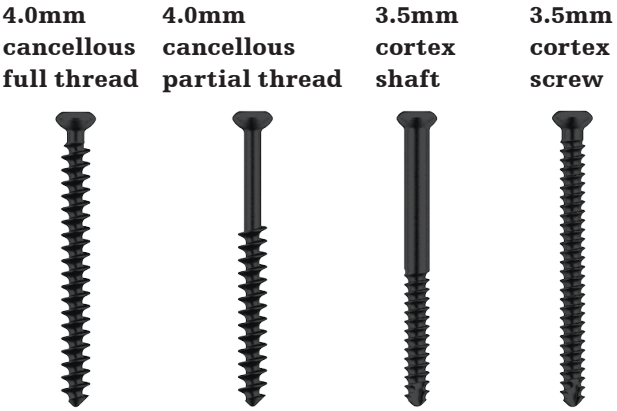


Introduction

SPS Titanium Small Fragment plates:

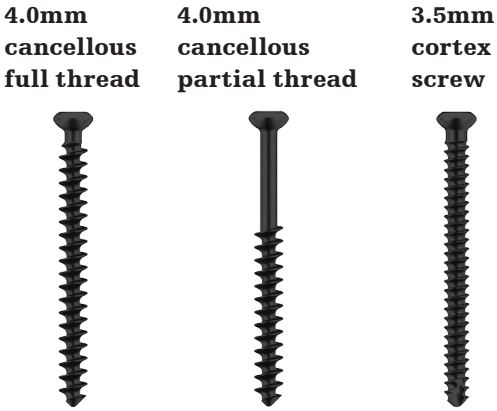


AxSOS 3 Titanium Screws used with the SPS Titanium Small Fragment Plates:



All of the above AxSOS 3 Titanium Screws have a T15 screw head interface. Please refer to the compatibility table on page 31 showing SPS and AxSOS 3 Titanium compatibility.

SPS Titanium Small Fragment ISO screws used with the SPS Titanium Small Fragment plates:



All of the above SPS Titanium Small Fragment ISO screws have a Hex 2.5 screw head interface. Please refer to the compatibility table on page 31 showing SPS and AxSOS 3 Titanium compatibility.

Introduction

B) Large fragment plates:

AxSOS 3 Titanium 5.0mm Compression Plates

5.0mm broad compression plate, 6 to 22-hole plates

5.0mm narrow compression plate, 2 to 22-hole plates

5.0mm blind screws

These optional inserts may be placed in empty universal screw holes.

5.0mm

5.0mm cable plug

The 5.0mm cable plug allows for a stable positioning of a cerclage cable on the plate and helps prevent slipping in oblique cable applications.

5.0mm Variable Angle Extension Arm*

The extension arm allows the variable angle placement of 4.0mm AxSOS 3 Titanium Locking Screws next to the plates, thus enabling the surgeon to go around an implant blocking the medullary canal.

*** This product is not CE marked in accordance with applicable EU regulations and directives. Stryker is not marketing or distributing this product in the EU. Any reference to this product is for presentation purposes only.**

AxSOS 3 Titanium Screws used with the AxSOS 3 Titanium 5.0mm Compression Plates:

6.0mm cancellous full thread

6.0mm cancellous 32mm thread

6.0mm cancellous 16mm thread

4.5mm cortex shaft

4.5mm cortex screw

5.0mm locking screw

5.0mm periprosthetic locking screw

SPS Titanium Basic Fragment ISO screws used with the AxSOS 3 Titanium Large Fragment Plates:

4.5mm cortex screw

All of the above AxSOS 3 Titanium screws have a T20 screw head interface. Please refer to the compatibility table on page 31 showing SPS and AxSOS 3 Titanium compatibility.

All of the above SPS Titanium Basic Fragment ISO screws have a Hex 3.5mm screw head interface. Please refer to the compatibility table on page 31 showing SPS and AxSOS 3 Titanium compatibility.

Indications, precautions and contraindications

Indications for use

AxSOS 3 Titanium is intended for long bone fracture fixation. Indications include:

- Diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- Non-unions and malunions
- Normal and osteopenic bone
- Osteotomies
- Periprosthetic fractures of the femur and proximal tibia

The AxSOS 3 Titanium Waisted Compression Plates are also indicated for fracture fixation of:

- Periprosthetic fractures
- Diaphyseal and metaphyseal areas of long bones in pediatric patients
- The 4mm waisted compression plate indications also include fixation of the scapula and the pelvis

Intended use

AxSOS 3 Titanium is intended for long bone fracture fixation.

Indications for the SPS Stryker Plating System:

SPS Small Fragment Set:

The SPS Small Fragment Set is indicated for fractures of the metaphysis and/or the diaphysis of the following:

One third tubular plate: fibula, metatarsals, metacarpals

Fibular plate: fibula

Compression plate: radius, ulna, distal tibia, fibula, distal humerus, clavicle

Oblique T-plate: distal radius

T-plate: distal radius, calcaneus, lateral clavicle

Cloverleaf plate: proximal humerus, distal tibia

Calcaneal plate: calcaneus

Reconstructive plate: humerus, pelvis

Screws are used either to fasten plates or similar devices onto bone, or, as lag screws, to hold together fragments of bone.

SPS Basic Fragment Set:

The Basic Fragment Set is intended for use in long bone fracture fixation. Reconstruction plates, wide and narrow straight and waisted compression plates are indicated for fixation of long bone fractures including but not limited: to fractures of the femur, the tibia, the humerus and the pelvis. T-plates, T-buttress plates and L-buttress plates are indicated for fractures at the proximal or distal end of long bones including but not limited to: fractures of the femoral condyles, the tibial plateau, the distal tibia and the proximal humerus.

⚠ CAUTION

The AxSOS 3 Titanium 4.0mm and 5.0mm Waisted Compression plates should not cross the growth plates of pediatric patients.

Indications, precautions and contraindications

Precautions

MRI Safety Information

AxSOS 3 Titanium System (no periprosthetic indication)

Non-clinical testing has demonstrated the Stryker AxSOS 3 Titanium System is MR Conditional.
A patient with these devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 and 3.0T
- Maximum spatial field gradient of 3000 gauss/cm (30T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Stryker AxSOS 3 Titanium System is expected to produce a maximum temperature rise of less than 7.1°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 32mm from the Stryker AxSOS 3 Titanium System when imaged with a gradient echo pulse sequence and a 3.0T MRI system.

AxSOS 3 Titanium System (periprosthetic indication of the femur)

Non-clinical testing has demonstrated the Stryker AxSOS 3 Titanium System is MR conditional.
A patient with these devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 and 3.0T
- Maximum spatial field gradient of 2000 gauss/cm (20T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)
- Scan time restriction: maximum 6 minutes of continuous scanning
- Only in combination with MR conditional Stryker hip implants

Under the scan conditions defined above, the Stryker AxSOS 3 Titanium System is expected to produce a maximum temperature rise of less than 8.9°C after 6 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 45mm from the Stryker AxSOS 3 Titanium System when imaged with a gradient echo pulse sequence and a 3.0T MRI system.

⚠ CAUTION

The MRI safety information provided is based on testing which did not include supplementary devices. If there are supplementary devices (i.e. plates, screws, wires, prosthesis etc.) present in proximity to the system, this could result in additional MRI effects and the information provided above may not apply.

Indications, precautions and contraindications

Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment.

Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices
- Material sensitivity, documented or suspected
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself
- Patients having inadequate tissue coverage over the operative site
- Implant utilization that would interfere with anatomical structures or physiological performance
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care
- Other medical or surgical conditions which would preclude the potential benefit of surgery

Detailed information is included in the instructions for use attached to every implant.

See instructions for use for a complete list of potential adverse effects and contraindications. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient.

Principles of fracture management

Following the OTA/AO principles of fracture management[1] the AxSOS 3 Compression Plates and associated implants of the AxSOS 3 System are utilized to reconstruct the anatomy and restore its function:

1. Fracture reduction to restore anatomical relationships.
2. Fracture fixation providing absolute or relative stability as the "personality" of fracture, patient and injury requires.
3. Preservation of blood supply to soft tissues and bone.
4. Early and safe mobilization of the injured part and the patient as a whole.

For long bone fracture fixation as well as diaphyseal and metaphyseal areas in pediatric patients and also for scapula and the pelvis the following steps are performed to achieve fracture fixation providing absolute or relative stability:

1. Diagnosis, identification of the indication and severity of fracture.
2. Prepare operation (pre-operative planning).
3. Approach (incision, access to fractured area).
4. Fracture reduction.
5. Plate selection - size (width, length), type and selection of screw configuration.
6. Contouring of the plate (if necessary).
7. Fixation (according to the different techniques described: compression, neutralization, and bridge plating).

1) AO Principles of Fracture Management Thomas Rüedi , Richard E. Buckley, Christopher G. Moran Vol. 1: Principles, Vol. 2: Specific fractures

Operative technique
Pre-operative planning

Use of the X-ray template or E-templates can assist in the selection of an appropriately sized implant.

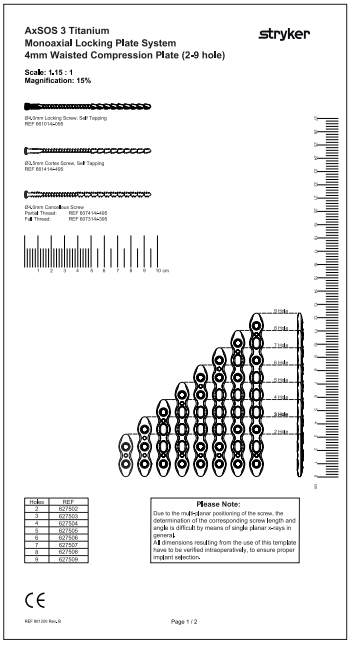
Ref 981206 - 4mm compression plate

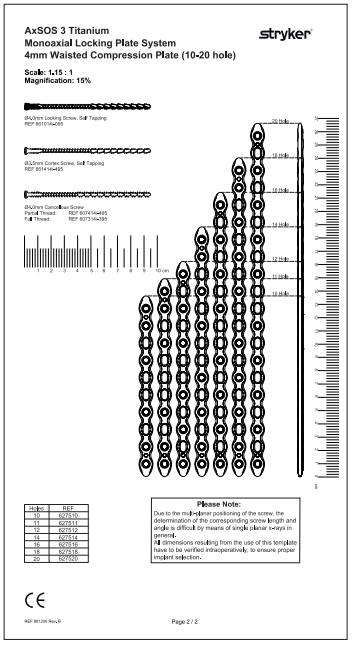
Ref 981207 - 5mm narrow compression plate

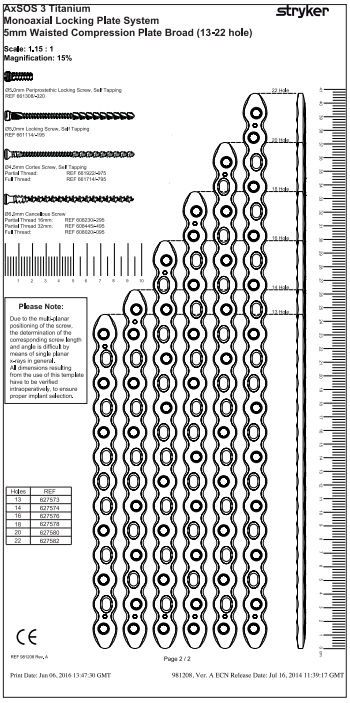
Ref 981208 - 5mm broad compression plate

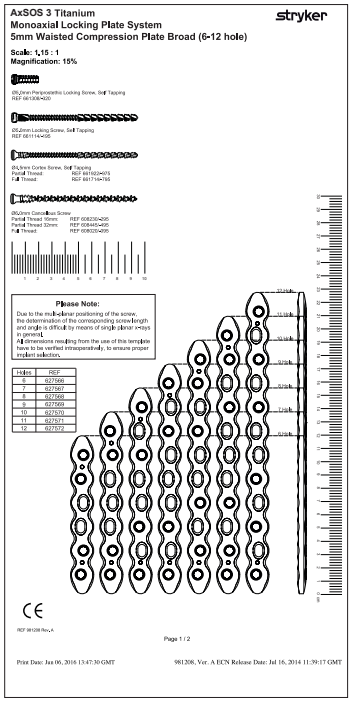
NOTICE

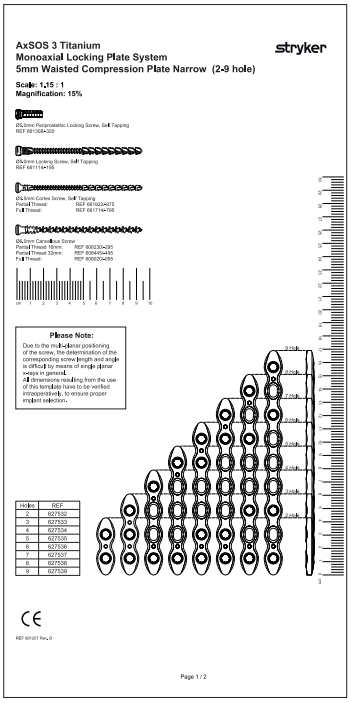
For conventional templates, the scale is 1:1.15 which usually matches with analogous X-rays. If digital X-ray images are used, correct magnification has to be verified prior to use.

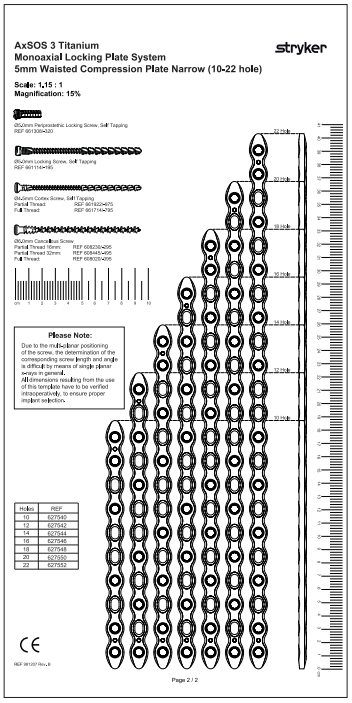












Operative technique
4.0mm and 5.0mm compression plates, SPS Small Fragment plates

As the compression plates have numerous indications, this operative technique does not describe the patient positioning and surgical approach in detail. Rather, the operative technique explains the three main fracture fixation techniques: compression, neutralization, and bridge plating. The 4.0mm plates are illustrated in this section; however, the same principles apply to the 5.0mm plates and the SPS Titanium as well.

Compression technique

Plate fixation/screw insertion

The plate is centered over the fracture site. Temporary plate fixation can be performed using a 2.0mm K-wire through the K-wire holes in the plate. Alternatively, the temporary plate fixator pin (ref 705019-1) may be inserted bi–cortically through one of the shaft holes (fig. 1). The sleeve (ref 705019) is then applied over the pin and threaded to push the plate to the bone. A neutral non-locking screw is placed in the plate using the appropriate drill guide, drill, and screwdriver. This can either be in an oblong hole or a universal hole.

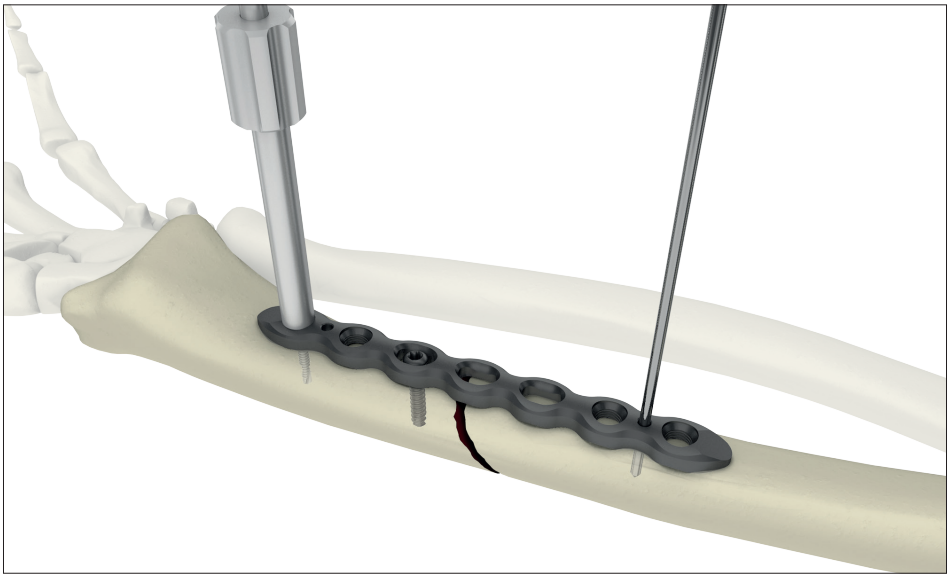


Fig. 1

Operative technique

4.0mm and 5.0mm compression plates, SPS Small Fragment plates

Choose an oblong hole on the opposite side of the fracture to obtain compression. The chosen oblong hole is normally the one closest to the fracture. Use the compression/neutral drill guide (ref 705024 for 4mm plates and ref 705033 for 5mm plates), which correctly places the drill hole in the eccentric position (fig. 2).

An arrow is etched onto the drill guide. This arrow must be aiming towards the fracture line to correctly drill the hole.

For SPS Titanium Plates use the double drill guide Ø3.5mm / Ø2.5mm (ref 705023) to drill an eccentric hole (away from the fracture line) for compression.

Measure the screw depth and insert the appropriate non-locking screw until seated. Prior to firmly tightening the screw, remove any provisional plate fixation on this side of the fracture to allow for sliding of the plate in relation to the bone. Then, firmly tighten the screw. The maximum shift per compression hole is approximately 1mm (fig. 3).

After compression is achieved, the remaining holes of the plate are filled in the neutral position. If desired, locking screws may be used in the universal holes (fig. 4).

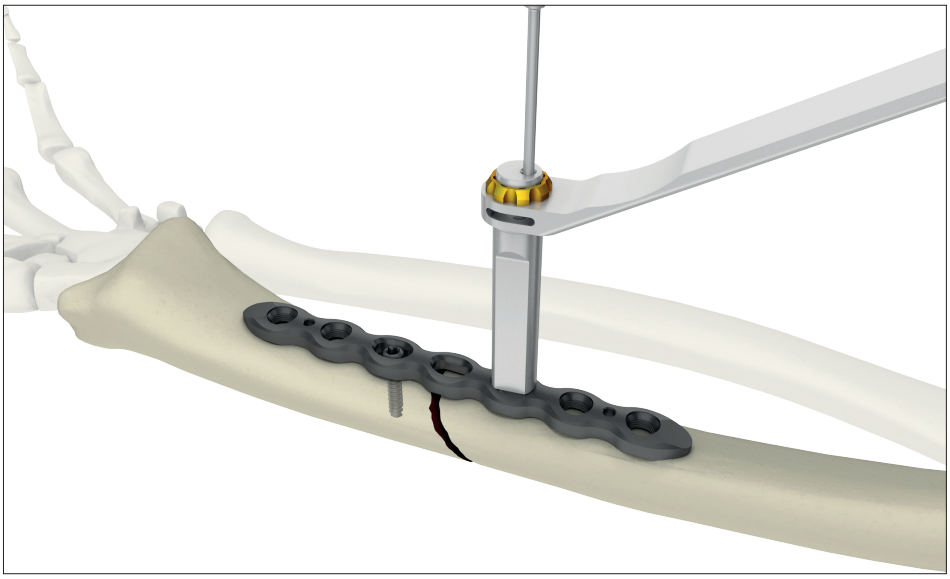


Fig. 2

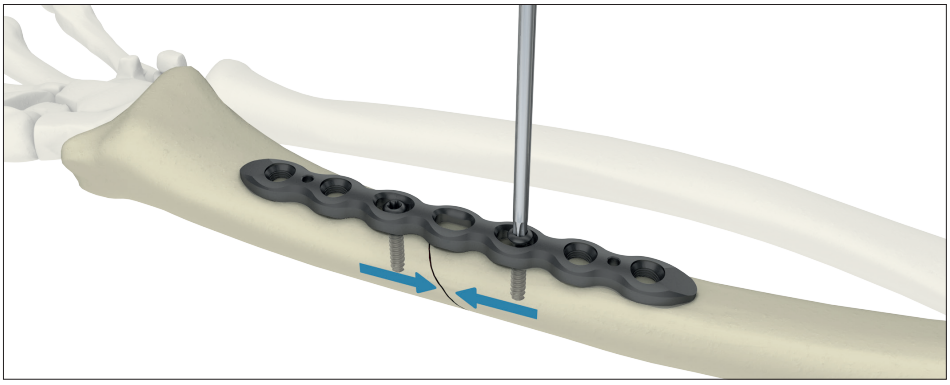


Fig. 3

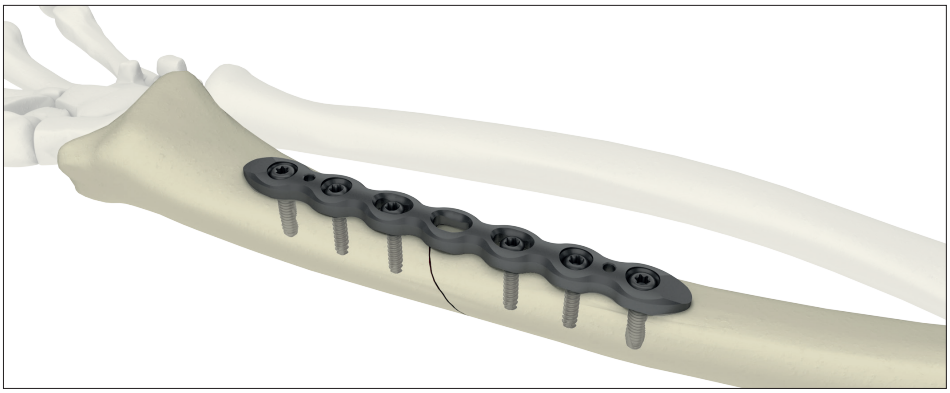


Fig. 4

Operative technique
4.0mm and 5.0mm compression plates, SPS Small Fragment plates

Lag screw and neutralization plating

In addition to the standard drills and drill guides, a number of instruments are also available to perform a lag screw technique both independently or through a plate (fig. 5 and fig. 6). Lag screw placement is dependent on the fracture orientation. The instruments are described in the instrumentation guideline section of this operative technique.

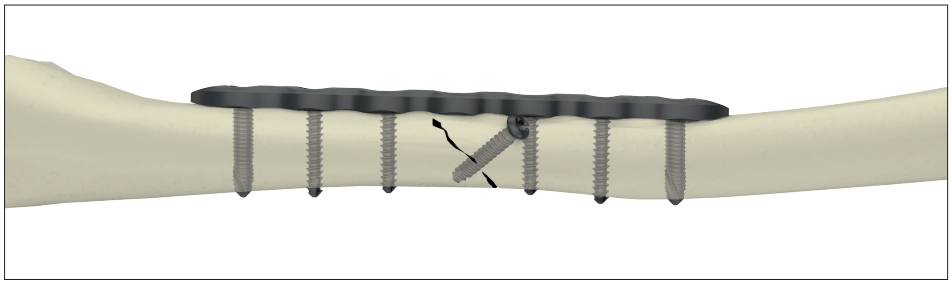


Fig. 5

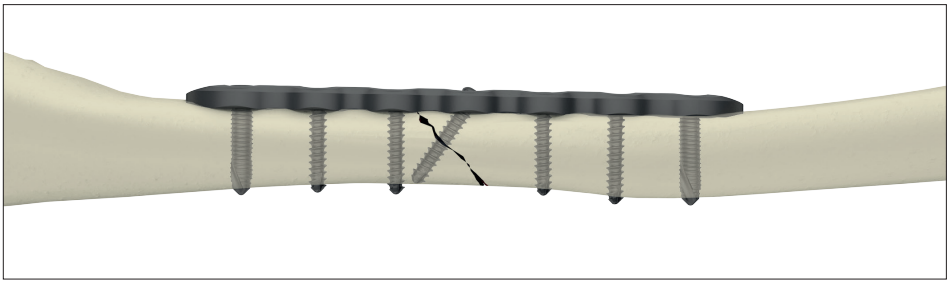


Fig. 6

Operative technique
4.0mm and 5.0mm compression plates, SPS Small Fragment plates

Bridge plating

When the fracture is not amenable to compression or lag screws due to a zone of comminution at the fracture site, the bridging technique may be used (fig. 7). Contrary to compression and lag screw techniques which rely on absolute fracture reduction and compression, bridge plating in effect splints the fracture. Length, alignment, and rotation are maintained by the plate, and secondary bone healing consolidates the fracture.

In general, longer plates are used in these cases so that proper bridging of the fracture can occur. Non-locking screws or locking screws may be used or a combination of both (fig. 8).

If both screw types are used, ensure that the non-locking screws are inserted before any locking screws. Normally, the zone of comminution is left undisturbed; however, a surgeon may choose to fixate a larger fragment within the zone to provide more relative stability. Care is taken not to disrupt blood supply.

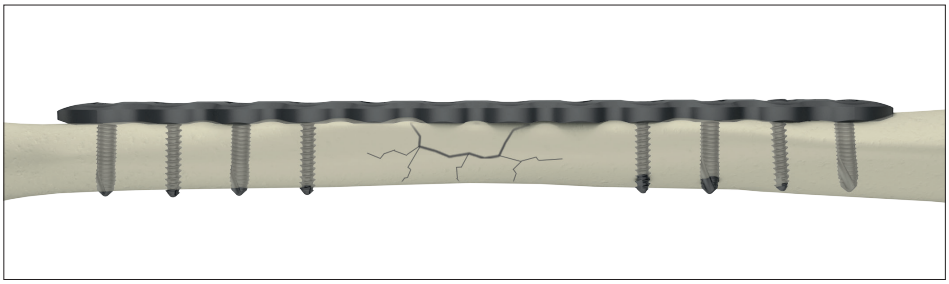


Fig. 7

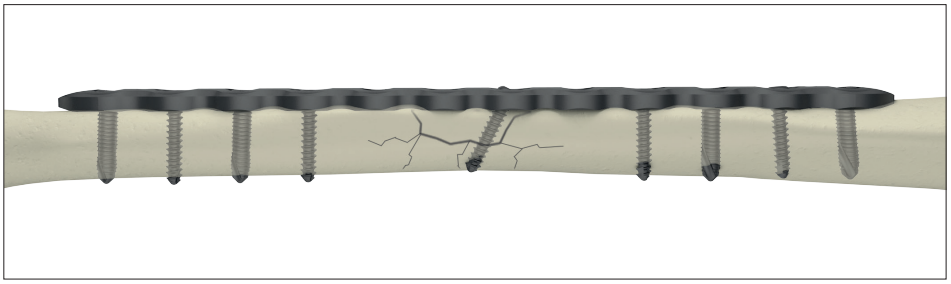


Fig. 8

Operative technique

T-plate

In this plate the oblong hole allows the plate to be re-adjusted before final tightening. The bi-directional compression holes offer not only axial compression but compression across the T-section, for articular reduction. For temporary fixation the K-wire holes allow for Ø1.6mm or Ø2.0mm K-wires (fig. 9).

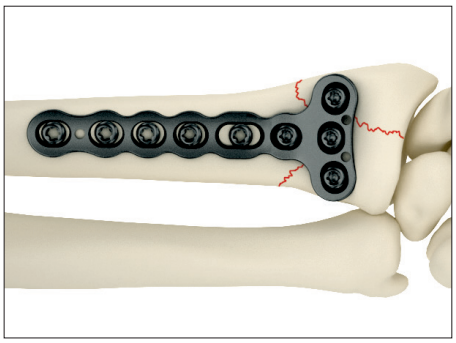


Fig. 9

Oblique T-plate

This plate offers the same options as the standard T-plate. The 20° offset angle of the head of this plate additionally offers a more anatomic fit along the radial styloid. For temporary fixation the K-wire holes allow for Ø1.6mm or Ø2.0mm K-wires (fig. 10).

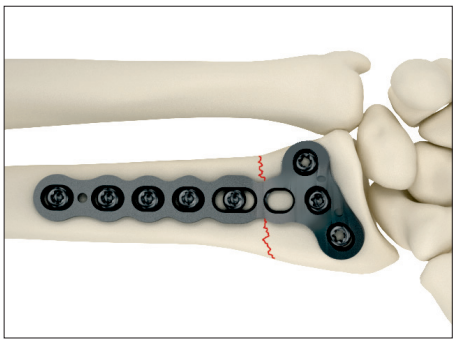


Fig. 10

Cloverleaf plate

Using Ø1.6mm or Ø2.0mm K-wires this plate can be applied temporarily to the bone. Depending on the anatomy and fracture pattern, plate contouring might be necessary. Non-locking screw insertion in a compression or neutral position concludes the fracture stabilization (fig. 11).

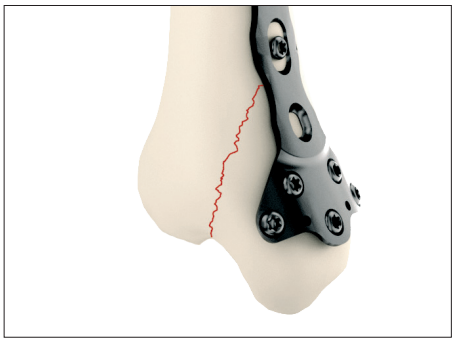


Fig. 11

One-third tubular plate

This plate is primarily a neutralisation implant. However, eccentric placement of screws will result in limited axial compression. The plate hole collars increase stability and eliminate the possible penetration of the screwhead into the near cortex thus preserving the screws' fixation. The equal hole spacing in this plate allows its application to a variety of fracture patterns without assuming the fracture location in relation to a 'gap' in the plate (fig. 12).

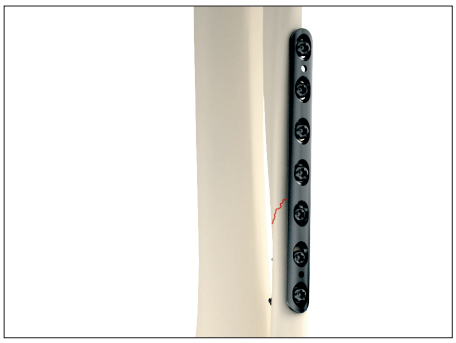


Fig. 12

4.0mm instrumentation guidelines

Bending

Should bending of the plate be required, the bending irons type 1 and 2 (ref 705006 and ref 705007) or the table plate bender (ref 702900) should be used. The bending irons are designed to be used as a pair. The holes allow the iron to be slid over the shaft of the plate for ease of bending (fig. 13).

Fig. 13

⚠ CAUTION

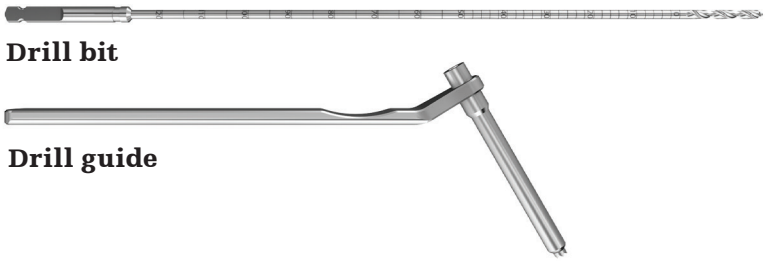
Bending of the plate in the region of the universal holes may affect the ability to correctly seat the locking screws into the plate and is therefore not permitted. Do not overbend the plate and do not bend it back and forth as this may weaken the plate.

3.5mm cortex / 4.0mm cancellous screw instrumentation

The appropriate screw length can be determined as follows:

1. Directly read off the Ø2.5mm drill bit with the drill guide for non-locking screws or the double drill guide for cortical opening (fig. 14).
2. Use the depth gauge (ref 705012, fig. 15).

Appropriately sized non-locking screws can be inserted into the plate using the T15 screwdriver (ref 705016). If inserting non-locking screws under power using the T15 screwdriver bit (ref 705015), make sure to use a low speed drill setting to avoid potential thermal necrosis. In hard bone, it is advised to use the cortical tap Ø3.5mm (ref 702804) for cortex screws or the cancellous tap Ø4.0mm (ref 702805) for cancellous screws before screw insertion.



Drill bit

Drill guide

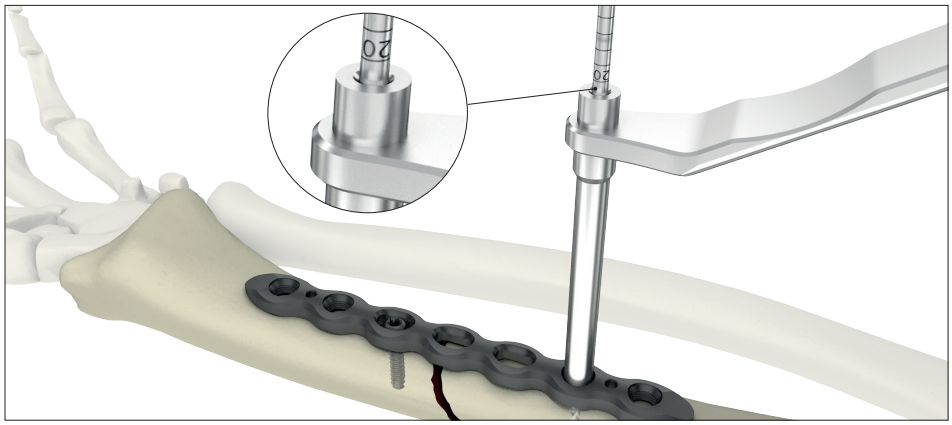


Fig. 14

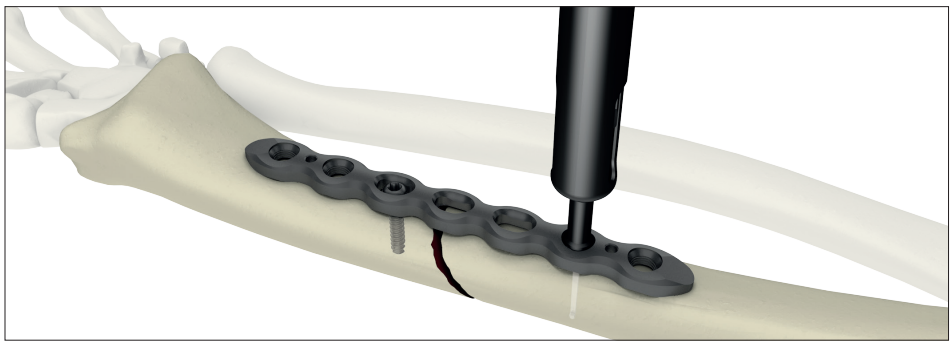


Fig. 15

4.0mm instrumentation guidelines

3.5mm lag screw instruments

To seat the Ø3.5mm non-locking cortex screw or a Ø3.5mm shaft screw in a lag function, use the dedicated double drill guide (ref 705023) for cortical opening:

1. Over-drill the first cortex using the Ø3.5mm cortical opener (ref 700353, fig. 16) through the corresponding Ø3.5mm end of the double drill guide (ref 705023).
2. Then insert the opposite Ø2.5mm end of the double drill guide (ref 705023) into the pre-drilled hole until the drill guide comes to a stop.
3. Drill through the second cortex using the Ø2.5mm drill bit (ref 705025, fig. 17). Remove the drill bit and drill guide.
4. Measure for the appropriate length cortical screw or shaft screw. As the threads will engage only in the far cortex, compression (lag) will be applied as soon as the screw head reaches the bone.

NOTICE

Do not over-tighten as this might cause stripping of the threads in the bone into the near cortex thus preserving the screws' fixation.

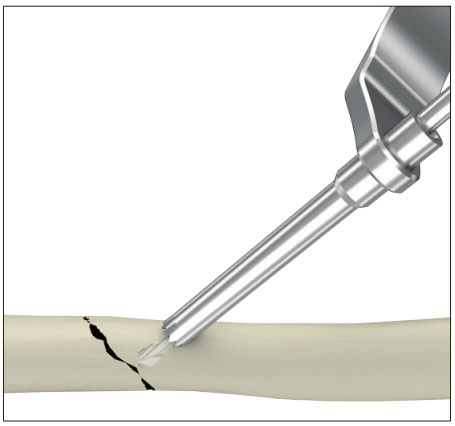


Fig. 16

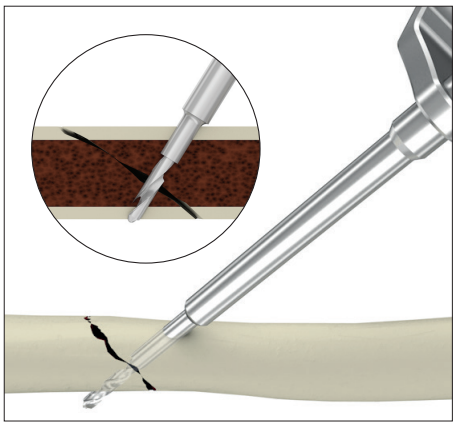


Fig. 17

Ø3.5mm overdrill

Ø2.5mm pilot drill

Double drill guide

Short drill sleeve with Ø3.1mm short drill bit

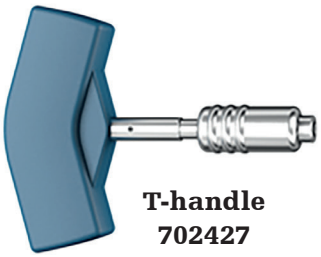
Medium drill sleeve with Ø3.1mm medium drill bit

4.0mm locking screw instrumentation

To insert a locking screw, always use a drill sleeve fully inserted into a universal hole. A Ø3.1mm drill bit (ref 705031 short or ref 705077 medium, depending on the short or medium sleeve chosen) is used to drill for Ø4.0mm locking screws. Medium size sleeves and drill bits show two orange color lines, short sleeves and drill bits show one orange line. The orange color represents the color code for the 4.0mm locking system.

4.0mm instrumentation guidelines

Final locking with torque limiting attachment



T-handle
702427

2.5Nm torque limiter
702760

T15 screwdriver bit
705015

Locking screws of appropriate length are inserted into the plate using the T15 screwdriver (ref 705016). If inserting locking screws under power using the T15 screwdriver bit (ref 705015), make sure to use a low speed drill setting to avoid damage to the screw plate interface and potential thermal necrosis. In hard bone, it is advised to use the locking tap Ø4.0mm (ref 702772) before screw insertion.

Always perform final tightening of the locking screws by hand using the 2.5Nm torque limiter (ref 702760) together with the screwdriver bit T15 and T-handle. This prevents over-tightening of locking screws and also helps ensure that these screws are properly tightened with a torque of 2.5Nm. The device will click when the torque reaches 2.5Nm. This procedure is repeated for all locking screws.

NOTICE

Ensure that the screwdriver tip is fully seated in the screw head, but do not apply axial force during final tightening. In the extreme event of broken or stripped screws, the Stryker implant extraction set (Content ID IES-ST-1) includes a variety of broken screw removal instruments.

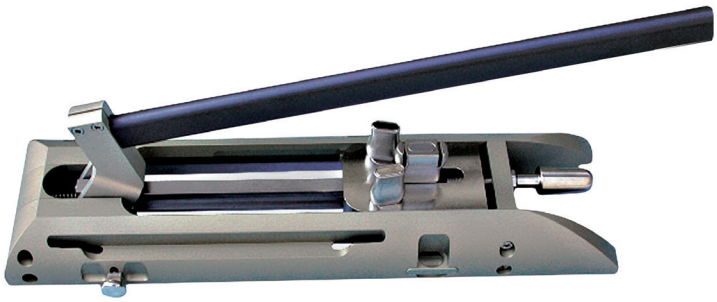
⚠ CAUTION

The torque limiters require routine maintenance. Refer to the instructions for maintenance of torque limiters (V15020).

5.0mm instrumentation guidelines

Bending

In most cases, anatomically precontoured plates will fit without the need for further bending. However, should additional bending of the plate be required the table plate bender (ref 702900) should be used.



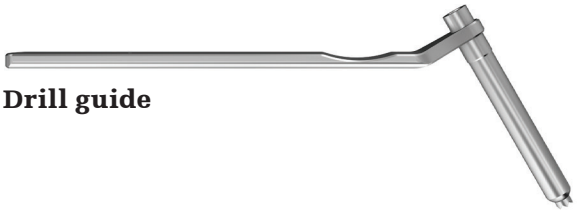
⚠ CAUTION

Bending of the plate in the region of the universal holes may affect the ability to correctly seat the locking screws into the plate and is therefore not permitted. Do not over-bend the plate or bend it back and forth as this may weaken the plate.

4.5mm cortical or 6.0mm cancellous threaded screw instrumentation

To seat a 4.5mm non-locking screw or 6.0mm threaded cancellous screw, use the drill guide for non-locking screws (ref 705036) together with the Ø3.2mm drill bit (ref 705032).

Drill bit



Drill guide

Screw measurement instruments

The correct screw length can be determined by using the depth gauge (ref 705014, fig. 18) or by reading off of the scaled drill (fig. 19).

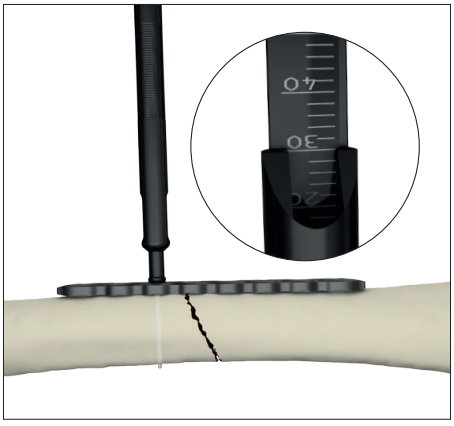


Fig. 18

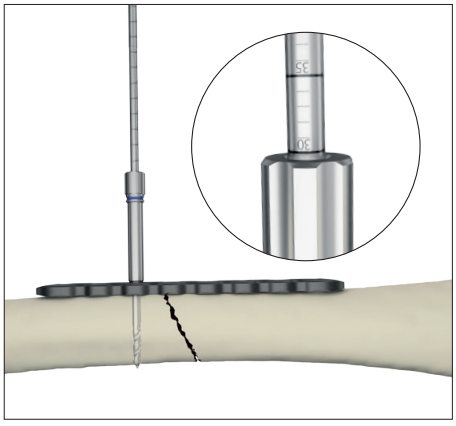


Fig. 19

5.0mm instrumentation guidelines

Lag screw instrumentation

To seat the Ø4.5mm cortical screw or Ø6.0mm partially threaded cancellous screw in a lag function, over-drill the first cortex using the cortical opener Ø4.5mm (ref 700354) and the Ø4.5mm corresponding end of the double drill guide (ref 705037, fig. 20). Then insert the opposite Ø3.2mm end of the double drill guide into the pre-drilled hole. Drill through the second cortex using the Ø3.2mm drill bit (ref 705032, fig. 21).

The appropriate screw is inserted using the T20 screwdriver (ref 705021) or the screwdriver bit (ref 705020).

When inserting a Ø4.5mm cortex screw in hard cortical bone, it is advised to use the cortical tap Ø4.5mm (ref 702806) before screw insertion.

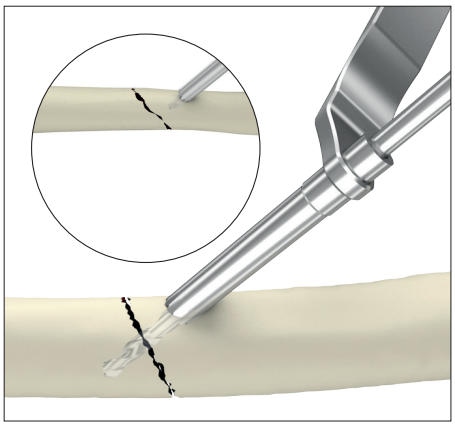


Fig. 20

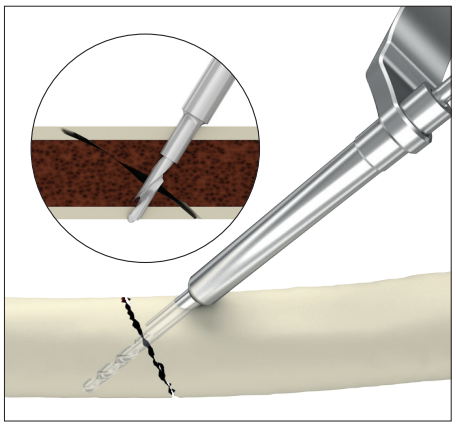


Fig. 21

4.5mm overdrill

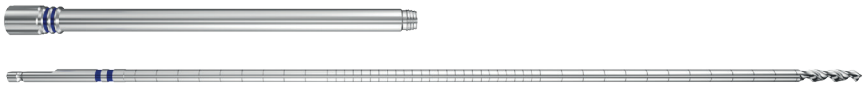
3.2mm pilot drill

5.0mm locking screw instrumentation

Use the drill sleeve (ref 705042 short, ref 705076 medium) together with a Ø4.3mm drill bit (ref 705043 short, ref 705078 medium) to pre-drill the core hole for subsequent locking screw placement. Medium size sleeves and drill bits show two blue color lines, short sleeves and drill bits show one line. Blue color represents the color code for the 5.0mm locking system.

Double drill guide

Short drill sleeve with 4.3mm short drill bit

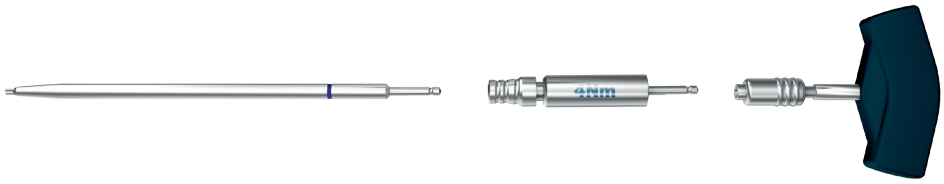


Medium drill sleeve with 4.3mm medium drill bit

5.0mm instrumentation guidelines

Final locking with torque limiting attachment

The appropriately sized locking screw is then inserted using either the screwdriver T20 (ref 705021) (fig. 15) or the screwdriver bit T20 (ref 705020) with a selected handle (teardrop handle small (ref 702429) or the T-handle (ref 702430)).



⚠ CAUTION

If inserting locking screws under power, make sure to use a low speed drill setting to avoid potential thermal necrosis.

Always perform final tightening by hand using the torque limiter (ref 702750) in combination with a screwdriver bit T20 (ref 705020) and T-handle (ref 702430).

This helps to prevent over-tightening of locking screws, and also helps ensure that these screws are tightened to a torque of 4Nm. The device will click when the torque reaches 4Nm. Ensure that the screwdriver tip is fully seated in the screw head, and do not angulate the screwdriver. In the extreme event of broken or stripped screws, the Stryker implant extraction set (Content ID IES-ST-1) includes a variety of broken screw removal instruments.

⚠ CAUTION

The torque limiters require routine maintenance. Refer to the instructions for maintenance of torque limiters (V15020).

5.0mm Variable Angle Extension Arm*

The 5.0mm variable angle extension arm* (ref 991088S, referred to as exension arm), made out of Titanium/CoCr, can be inserted into 5.0mm universal holes of the broad or narrow AxSOS 3 Titanium Compression plates or in the universal holes of the diaphyseal area of the AxSOS 3 Titanium Distal Lateral Femur Plates. The extension arm allows the variable angle placement of 4.0mm AxSOS 3 Titanium Locking Screws next to the plates, thus enabling the surgeon to go around an implant blocking the medullary canal. To insert an extension arm follow the next steps. The extension arm can be placed manually or optionally with the orange 4.0mm drill sleeve as placement aid. In this case fix and tighten the orange 4.0mm drill sleeve by hand in the polyaxial mechanism (fig. 22).

Fig. 22

NOTICE

Hole number 17 in long AxSOS 3 Distal Lateral Femur Plates is designed slightly in an oblique way to avoid conflicting protection sleeves with the optional targeting instrumentation. Hole number 17 cannot be used together with the extension arm – see picture on the right. The universal holes in the metaphyseal part of AxSOS 3 Distal Lateral Femur Plates and hole number one (oblong, non-locking) can't be used together with an extension arm.

Fig. 23

T15 screwdriver bit 705015 | **2.5Nm torque limiter 702760** | **T-handle 702427**

Insert the 4.0mm blind screw (packaged together with the extension arm) using the T15 screwdriver from the 4.0mm AxSOS 3 Titanium System (fig. 23).

* This product is not CE marked in accordance with applicable EU regulations and directives. Stryker is not marketing or distributing this product in the EU. Any reference to this product is for presentation purposes only.

5.0mm Variable Angle Extension Arm

While tightening the 4.0mm blind screw adjust the rotation of the extension arm and hold it in place if necessary. Final tighten with the 2.5Nm torque limiter. At least one click shall be emitted (fig. 24).

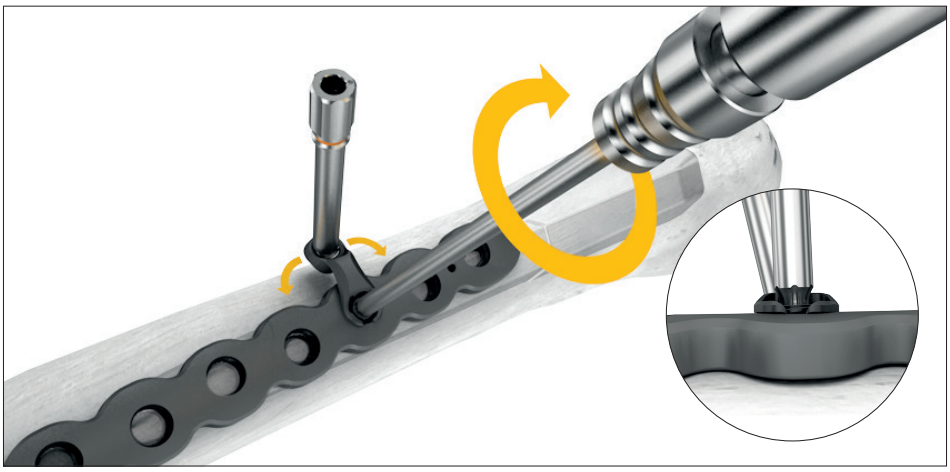


Fig. 24

Use the drill sleeve in the polyaxial hole and choose the desired angle for the screw placement. The cone allows for a +/- 15 degree cone of angulation (fig. 25).

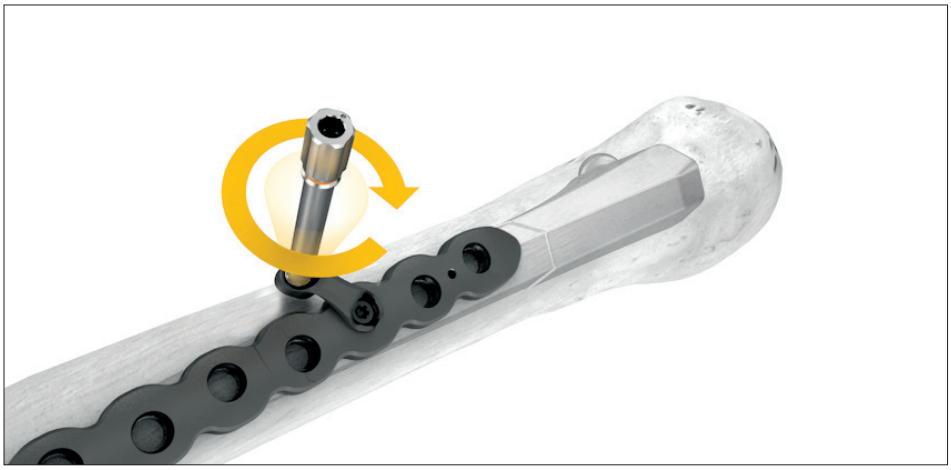


Fig. 25

In the event of placing a K-wire use it together with the K-wire sleeve (fig. 26). Tighten the drill sleeve by hand.

NOTICE

Be aware of the different diameter and flexibility between K-wire, drill bit and 4.0mm locking screws.

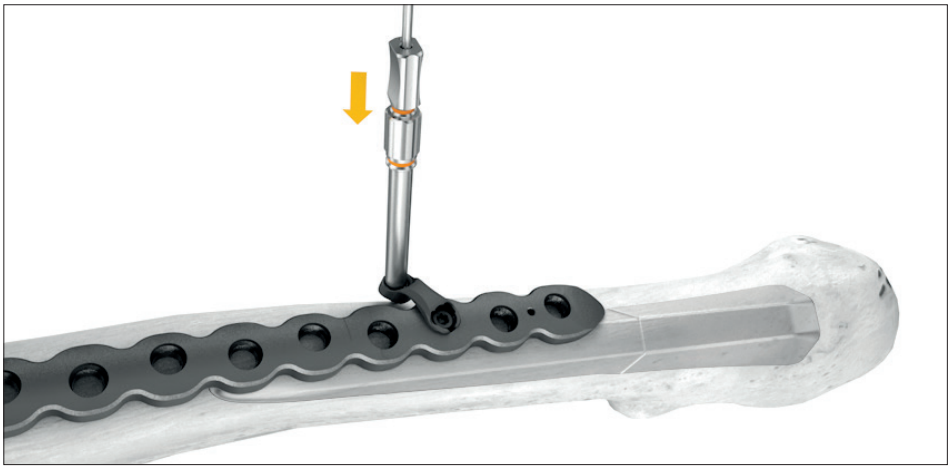


Fig. 26

5.0mm Variable Angle Extension Arm

Remove the K-wire and the K-wire sleeve and drill with the 3.1mm drill bit (fig. 27). Measure by reading off the drill bit. Alternatively remove the drill sleeve and measure with the depth gauge. Place an appropriate 4mm locking screw.

Fig. 27

Insert and final tighten the 4mm locking screw with the 2.5Nm torque limiter. At least one click shall be emitted (fig. 28).

⚠ CAUTION

In case of mixing non-locking and locking screws always follow the principle of "lag before lock".

Fig. 28

⚠ CAUTION

When using the variable angle extension arm consider bending the femur plate or compression plate for appropriate bone support.

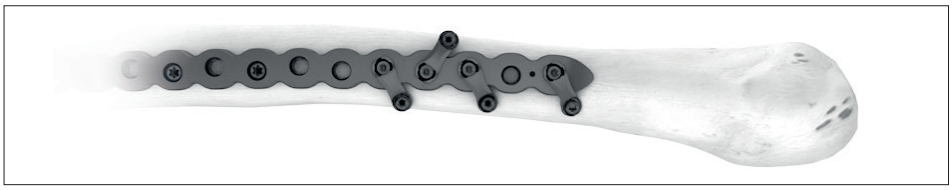


Fig. 29

⚠ CAUTION

To limit the risk of weakening the bone avoid too many screws in a concentrated area (fig. 28). Bi-cortical purchase offers better stability and limits the risk of weakening the bone (fig. 29 and 30).

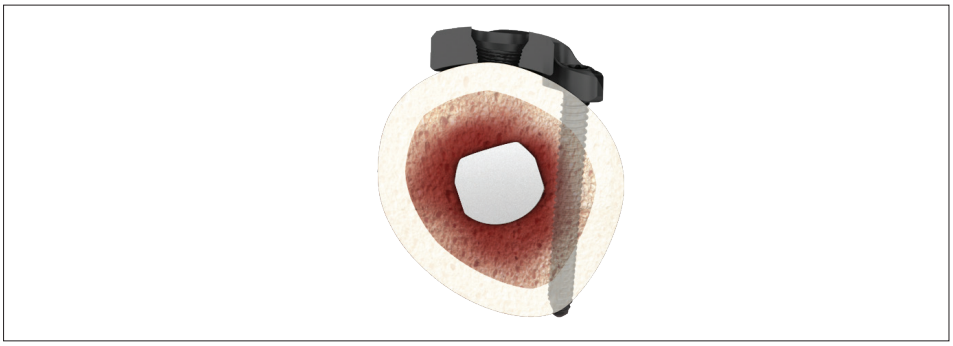


Fig. 30

5.0mm Variable Angle Extension Arm

Extension arm removal

Toggle the extension arm for disassembling by hand or use standard pliers.

⚠ CAUTION

The variable angle extension arm is a single-use, single application device. If the device has been previously used intraoperatively, discard the device and use a new extension arm.

5.0mm Cable Plug

The 5.0mm cable plug (ref 661002S) is designed to be used in combination with the 5.0mm AxSOS 3 Titanium System. It is used in combination with cobalt chrome cables of 2mm diameter.

The 5.0mm cable plug helps ensure a stable positioning of a cerclage cable on the plate and prevents slipping in oblique cable applications.

Hole allows for 2mm diameter cables

The lip clicks and turns into the thread of the 5mm universal hole

NOTICE

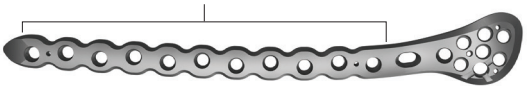
When used with AxSOS 3 Titanium Distal Femur Plates, only use the cable plug in the universal holes in the shaft of the plate.

Hole number 17 in long AxSOS 3 Titanium Distal Femur Plates is designed slightly in an oblique way to avoid conflicting protection sleeves with the targeting instrumentation. Despite the slightly oblique orientation of hole number 17 one can place a cable plug.

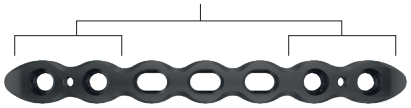
When used with the broad or narrow 5.0mm AxSOS 3 Titanium Waisted Compression Plates, only use the cable plug in the universal holes and not in the oblong compression holes of the plates.

Do not mix stainless steel cables or wires with AxSOS 3 Titanium Plates. Only use cobalt chrome wires or cables. Tests have been performed with the Vitallium (cobalt chrome) cables of the Dall–Miles Cable System from Stryker.

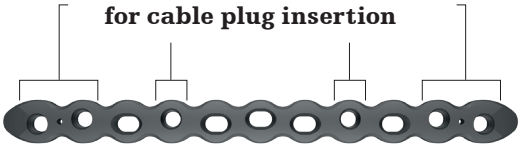
Universal holes suitable for cable plug insertion



Universal holes suitable for cable plug insertion



Universal holes suitable for cable plug insertion



⚠ CAUTION

In case of mixing non-locking and locking in the overall plate construct always follow the principle of "lag before lock".

5.0mm Cable Plug

Cable plug insertion and cable application

Insert an AxSOS 3 Titanium Cable Plug by clicking it into the appropriate universal hole. At least one "click" shall be emitted to allow for engagement of the cable plug and the threads of the universal hole. Alternatively the AxSOS 3 Titanium Cable Plug can be screwed in by turning at least half a turn clockwise (fig. 31).

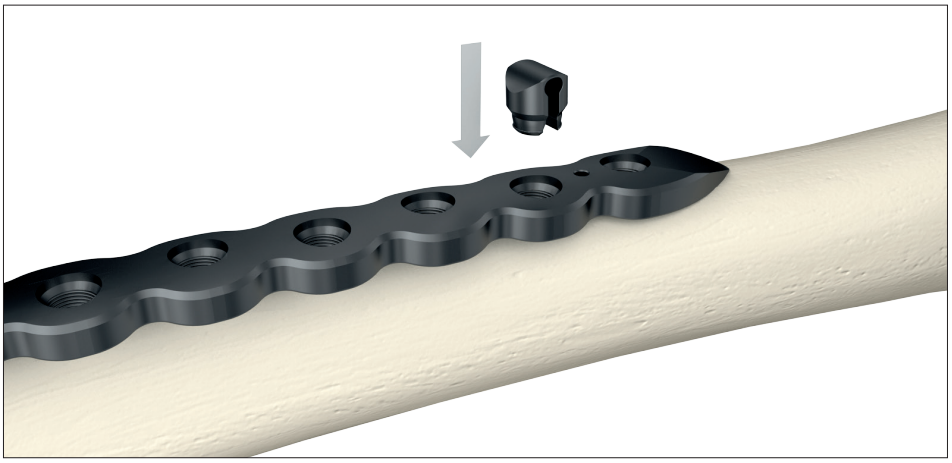


Fig. 31

Insert a cable through the eyelet of the cable plug. In case one uses a beaded cable, slide the sleeve onto the cable before sliding through the cable plug (fig. 32).

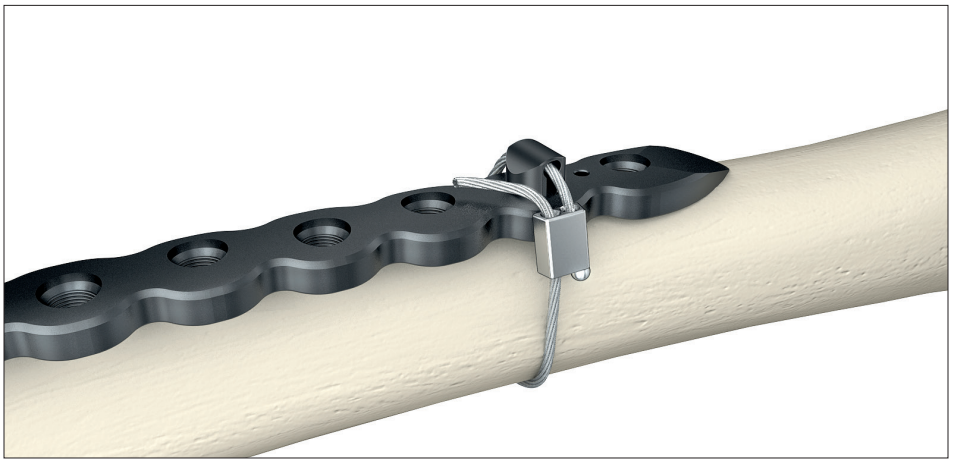


Fig. 32

Proceed as described in the respective instructions for use of the cabling system.

Then, tighten the cable and crimp the sleeve which usually sits aside the plate. As a last step, cut the cable near the crimped sleeve (fig. 33).

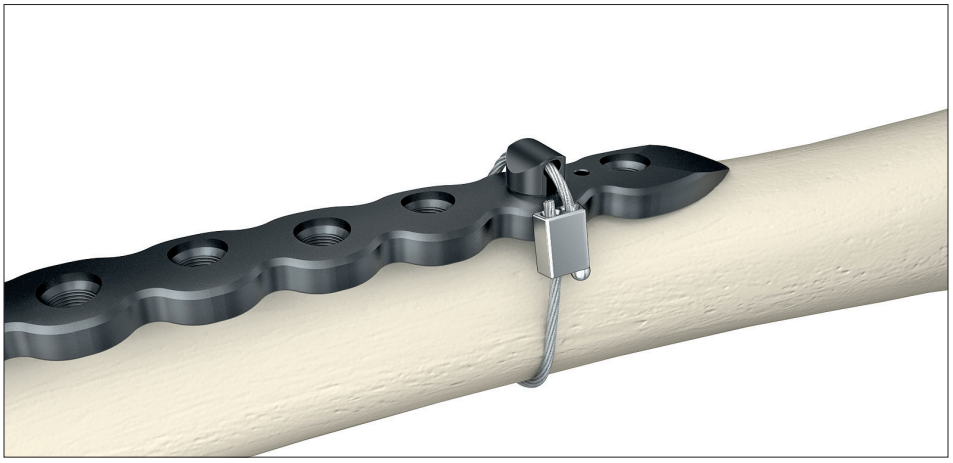


Fig. 33

5.0mm Cable Plug

Cable Plug removal

If a cable plug has to be removed simply cut or remove the cable and then unscrew the cable plug counterclockwise (fig. 34). The cable plug can be re-seated up to 3 times intraoperatively. As any implant, cable plugs are for single patient use only.

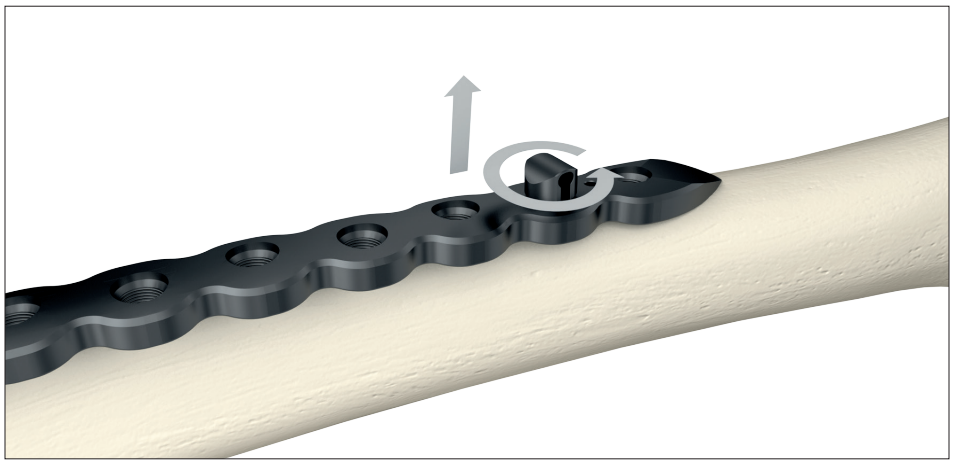
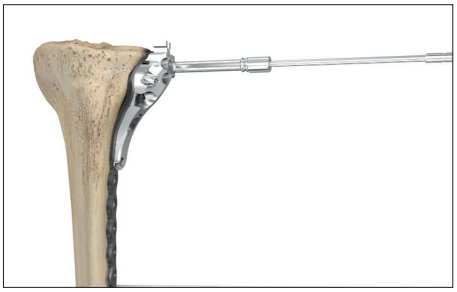


Fig. 34

Additional tips

⚠ CAUTION

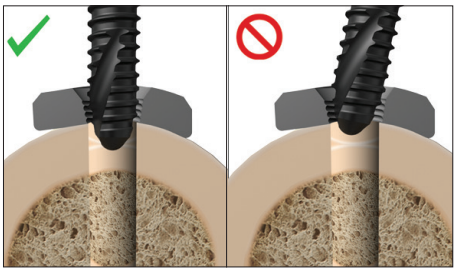
1. Always use the locking drill sleeve when drilling for locking screws.



Freehand drilling can lead to a misalignment of the screw and may result in screws cross-threading during final insertion. It is essential to drill the core hole in the correct trajectory to facilitate accurate insertion of the locking screws.

---

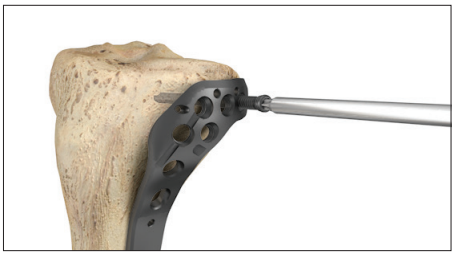
2. It is best to insert the screw manually to ensure proper alignment in the core hole which aligns the screw so it locks properly after being fully advanced. It is recommended to start inserting the screw using **"the three finger technique"** on the teardrop handle.



Locking screws should be aligned perpendicular to the plate / hole. If the locking screw head does not immediately engage the plate thread, reverse the screw and re-insert the screw once it is properly aligned.

⚠ CAUTION

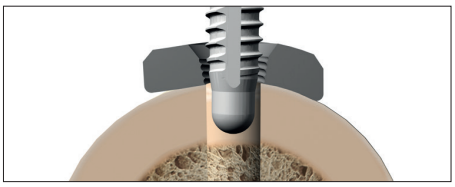
3. Use low speed only and **do not apply axial pressure** if power screw insertion is selected. Stop power insertion approximately 1cm before engaging the screw head in the plate.



Power can negatively affect final screw insertion, and if used improperly, could damage the screw / plate interface (screw jamming). This can lead to the screw head breaking or being stripped.

---

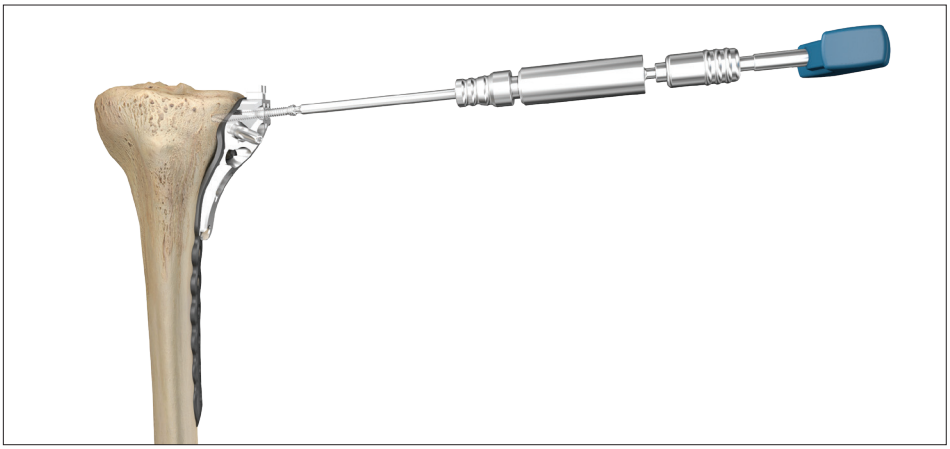
4. It is advisable to **tap hard** (dense) **cortical bone** before inserting a locking screw. Use the 4.0mm locking tap (Ref 702772).



The spherical tip of the tap is designed to precisely align with the instrument in the pre-drilled core hole during thread cutting. This will facilitate subsequent screw placement.

⚠ CAUTION

5. Do not use power for final insertion of locking screws. It is imperative to engage the screw head into the plate using the torque limiter. Ensure that the screwdriver tip is fully seated in the screw head, but do not apply axial force during final tightening. If the screw stops short of final position, back up a few turns and advance the screw again (with torque limiter on).



SPS Titanium – AxSOS 3 Titanium compatibility chart

The chart shows the compatibility of SPS Small and Basic Fragment Titanium screws with AxSOS 3 Titanium Plates and vice-versa.

Screws

			AxSOS 3 Ti 4.0mm						AxSOS 3 Ti 5.0mm										SPS 3.5mm			SPS 4.5mm				SPS 2.7mm
			661014/-095	661410/-520	607310/-400	607410/-500	661612/-640	661004	661114/-195	661714/-850	608230/-350	608020/-150	608445/-550	661922/-975	661308/-320	661005	991088S	661002S	603010/-090	604010/-060	604210/-260	601014/-150	602030/-150	602245/-400	602420/-550	605008/-060
			4.0mm locking Ti screw	3.5mm cortex Ti screw	4.0mm cancellous Ti screw - full thread	4.0mm cancellous Ti screw - partial thread	3.5mm cortex shaft Ti screw	4.0mm blind screw	5.0mm locking screw	4.5mm cortex Ti screw	6.0mm cancellous Ti screw - TL-16	6.0mm cancellous Ti screw - full thread	6.0mm cancellous Ti screw - TL-32	4.5mm cortex shaft Ti screw	5.0mm periprosthetic locking screw	5.0mm blind screw	5.0mm variable angle extension arm*	5.0mm cable plug	SPS 3.5mm Ti cortical screw	SPS 4.0mm Ti cancellous full	SPS 4.0mm Ti cancellous partial	SPS 4.5mm Ti cortical screw	SPS 6.5mm Ti cancellous 16.0mm	SPS 6.5mm Ti cancellous 32.0mm	SPS 6.5mm Ti cancellous full thread	SPS 2.7mm Ti cortical screw
Plates																										
AxSOS 3 Ti 4mm	627302/-352	Proximal lateral tibia plate	X	X	X	X	X	X											X	X	X					
	627404/-452	Distal medial tibia plate	X	X	X	X	X	X											X	X	X					
	627454/-500	Distal anterolateral tibia plate	X	X	X	X	X	X											X	X	X					X
	627704/-752	Proximal medial tibia plate	X	X	X	X	X	X											X	X	X					
	627203/-250	Proximal lateral humerus plate	X	X	X	X	X	X											X	X	X					
	627502/-520	4mm compression plate	X	X	X	X	X	X											X	X	X					
AxSOS 3 Ti 5mm	627604/-650	Distal lateral femur plate							X	X	X	X	X	X	X	X	X	X				X				
	627532/-552	5mm compression plate narrow							X	X	X	X	X	X	X	X	X	X				X				
	627566/-582	5mm compression plate broad							X	X	X	X	X	X	X	X	X	X				X				
SPS Small Fragment	621423/-436	T-plate		X	X	X	X												X	X	X					
	621463/-468	Oblique T-plate		X	X	X	X												X	X	X					
	621443/-450	Cloverleaf plate		X	X	X	X												X	X	X					
	621122/-134	One third tubular plate		X	X	X	X												X	X	X					
SPS Basic Fragment	620413/-413	T-plate																				X	X	X	X	
	620454/-458	T-buttress plate																				X	X	X	X	
	620704/-706	L-buttress plate, left																				X	X	X	X	
	620754/-758	L-buttress plate, right																				X	X	X	X	

* This product is not CE marked in accordance with applicable EU regulations and directives. Stryker is not marketing or distributing this product in the EU. Any reference to this product is for presentation purposes only.

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

If not indicated differently in this operative technique the products listed above are CE marked.

Content ID: AxSOS-ST-40 Rev 6, 10 2019

Manufacturer:

Stryker GmbH
Bohnackerweg 1
2545 Selzach
Switzerland

stryker.com