austofix

austofix S2
SUPRACONDYLAR NAIL

Surgical Technique

Australian Made • Australian Owned

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Contents

Disclaimer

This document is intended to be read by experienced orthopaedic trauma surgeons familiar with I.M. Nailing of the long bones.

This publication is intended as the recommended procedure for using the Austofix nailing system. It offers guidance only. Each surgeon should consider the particular needs of the patient and make appropriate adjustments where necessary.

For further advice please contact your local Austofix representative.

700304 S2 ST Rev 5

Introduction

Austofix is an Australian medical device manufacturer and distributor specialising in orthopaedic trauma. Since 1993, Austofix has designed, manufactured and marketed its range of implants throughout the world.

In collaboration with Australian surgeons, Austofix has introduced innovative, cost-effective implant systems that improve patient outcomes whilst supporting safe and efficient operating procedures. Austofix continues to develop its range of products through collaboration with new expertise, technologies and partnerships with surgeons and scientific institutions.

Austofix products are distributed globally from our offices based in Thebarton, Australia. Our well-trained product specialists and customer service staff are available for all customer enquiries and product support and understand the needs of the orthopaedic market.

Austofix is dedicated to excellence in every aspect of medical device design, manufacture and product service.

austofix S2

A variety of implants have been developed for the treatment of supracondylar fractures and have met with varying success.

Plating systems have been used for many years but they cause soft tissue disruption and risk blood supply to the fracture site. While minimally invasive, locked plates have recently emerged, they still fail to offer the stability of an intramedullary device.

The Austofix S2 Supracondylar Nail aims to provide anatomically stable fixation of the most distal supracondylar and intercondylar femoral fractures, even in the presence of osteoporosis. The use of crossed interlocking oblique screws enables both screws to be within 20mm of the end of the implants with each screw engaging the posterior condyles where bone quality is better.

A closed minimally invasive technique is possible if there is no intercondylar extension of the fracture. As with other fractures intramedullary nailing is mechanically superior to plating for fixation of supracondylar fractures.

For comminuted intercondylar fractures, the unique distal screw geometry of the S2 provides stable fixation of the condyles and virtually no fracture is too distal for this device.

Design Details

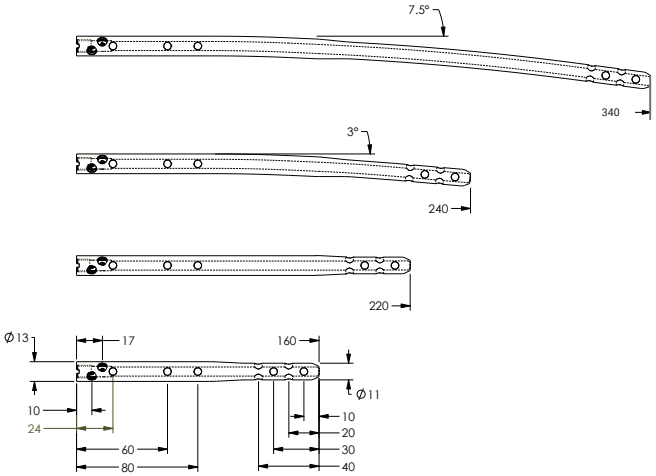
Nails

The nail diameter is 13mm in the distal end extending 90mm then 11, 12 or continuing at 13mm diameter.

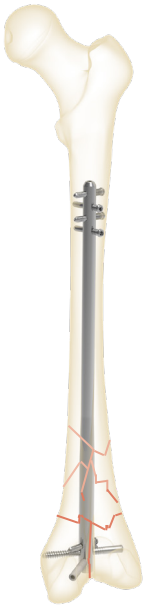
Nails 240mm and over have an anteroposterior bow to conform to the femur. The bend angle increases with length of nail, from 3° at 240mm to 7.5° at 340mm, while bend radius remains constant at 1.3m to simulate normal anatomy.

The 160, 180, 200 & 220mm nails are straight, as the femoral bow over this length is not enough to be significant.

Anteroposterior holes are provided in the proximal ends of all nails. For short nails they are useful in the presence of previous lateral plates, and for longer nails they are more accessible for freehand targeting than mediolateral holes.
Proximal locking with pre-set jigs is possible for fractures up to 180mm from the distal end of the femur.



Additional transverse cross-locking holes 24, 60 and 80mm from the distal end are available. The hole at 24mm facilitates fixation when knee replacements have a wide patellar flange, obstructing one of the oblique screws. The other holes are for retrograde nailing of femoral shaft fractures.



Intercondylar fractures are openly reduced and clamped via a standard anteromedial arthrotomy, which also provides easy access to the entry hole for the nail and the oblique screws. The condyles are then securely fixed with the crossed distal screws. 6.5mm washers may be added for interfragmentary compression.

The short nails are useful in the presence of proximal implants.

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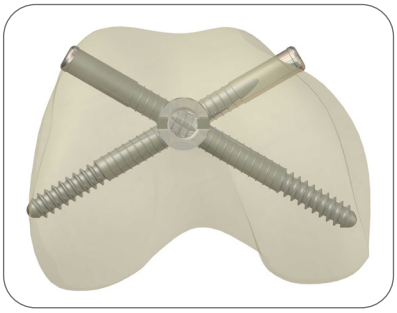
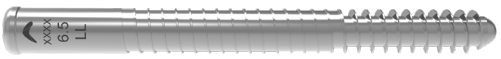
Screws

Two different types of screw are used:

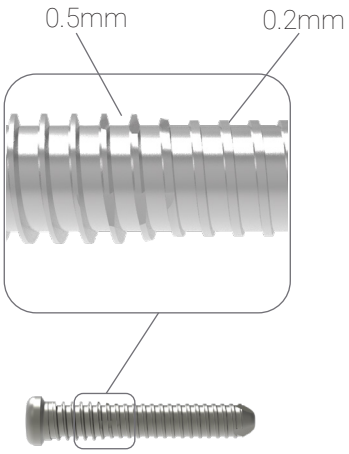
6.5mm S2 Condylar Screws. The condylar 120º oblique screws incorporate the unique Austofix locking system - preventing screw back-out and maximising fixation (see Right).

4.8mm Locking Screws are used proximally with the S2. These screws are fully threaded for ease of insertion, but with minimal loss of bending strength. The first 3/4 of the thread is shallow (0.2mm), being just enough to draw the screw in as it is turned. The last 1/4 expands (0.5mm) to grip the lateral cortex and resist back-out. This part is larger than the hole in the nail. The core of the thread (minor diameter) matches in both parts, so that the screws are inserted and extracted smoothly.



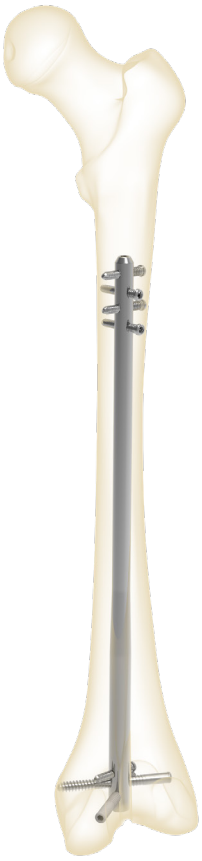


6.5 S2 Condylar Screw



Austofix Locking Screw

Indications & Pre-Operative Planning

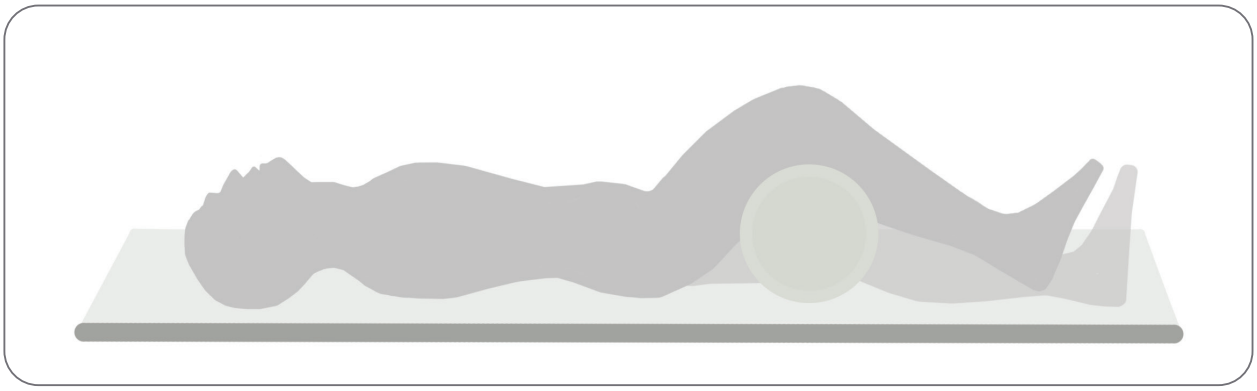


Indications for the Austofix S2 Nail include fractures which are too distal to fix with antegrade nails, fractures below hip implants, and femoral shaft fractures where antegrade nails are contraindicated by obesity, unstable pelvic fractures, or proximal deformities. Associated ipsilateral tibial fractures are a relative indication, as both fractures can be nailed with the same incision.

The length of the nail should be estimated pre-operatively, and the medullary canal should be measured (allowing 10% to 15% for X-ray magnification). This indicates whether medullary reamers will need to be available. One or two proximal screws are used, according to stability of the nail in the proximal fragment. Where possible in osteoporotic bone, avoid having the tip of the nail in the isthmus region to minimise the risk of stress-riser fractures. Distally, both oblique screws should always be used for supracondylar fractures, and one or two mediolateral screws for shaft fractures.

Patient Positioning

The patient is placed supine on a radiolucent operating table. The knee is flexed 60° over a radiolucent support. An empty plastic bucket, with its lid, is usually readily available and provides excellent support and X-ray imaging. Alternatively, a folded pillow or foam block can be used. Check that access is free for the Image Intensifier C-arm and check fracture reduction on anteroposterior and lateral X-ray views. Increased knee flexion or changes to the position of the knee support may be necessary for fracture reduction. Flexion should not be reduced to less than 45° as access to the entry point for the nail is compromised.



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Incision & Bone Preparation

Incision

The incision is 3-4 cm long, in the line of the medullary canal, which is usually in the medial third of the patellar tendon. Correct alignment of the incision in the tendon will facilitate varus/valgus alignment of supracondylar fractures.

Note: For openly reduced intercondylar fractures, use the distal end of the main incision.

Entry Point

On the A-P X-ray view, align the tip of a 2.5x250mm K-Wire (512525) in the line of the medullary canal (Right Top). Before drilling, check alignment also in the lateral view. The correct entry point is at the junction of the intercondylar notch (a dense oblique line on X-ray) and the patellar groove (Right Middle).

Use the Cannulated Awl (600040C) to make the initial entry, using image intensification to check positioning and alignment.

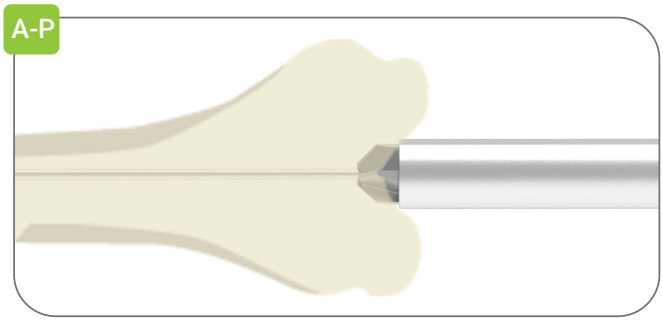
Note: In patients with knee replacements, aim for the level of the pegs in the femoral prosthesis. This usually means passing the K-Wire and 14.5mm Tissue Guard (600066) close to the tibial prosthesis, and aiming more posteriorly than one would expect. Once the tip of the K-Wire has engaged the bone, aim it more anteriorly, toward the medullary canal. Usually as the Tissue Guard levers against the tibia, the femoral fragment tilts and aligns itself correctly.

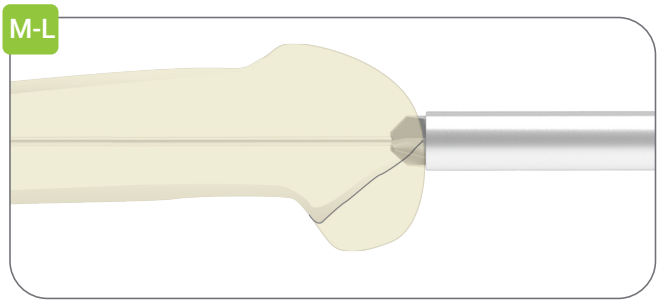
Drilling & Reaming Entry Hole

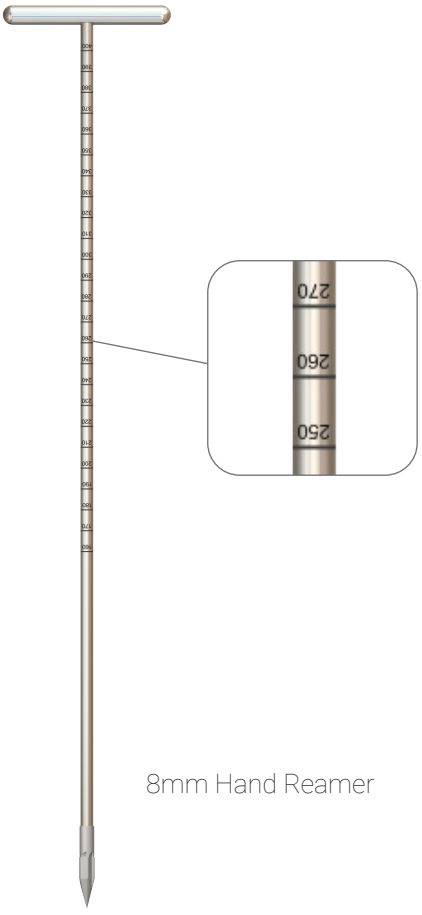
Use the 14mm Cannulated Drill Reamer (521421) and the Tissue Guard to drill to a depth of 5-6 cm. With intercondylar fractures, reduce and securely clamp the condyles first, followed by slow drilling to avoid spreading the condyles apart.

Medullary Canal Reaming (By Hand)

Pass the 8mm Hand Reamer (600008 - Right) to the desired position of the nail, and use the depth markings on it to determine the required nail length.







8mm Hand Reamer

Medullary Canal Reaming (Power)

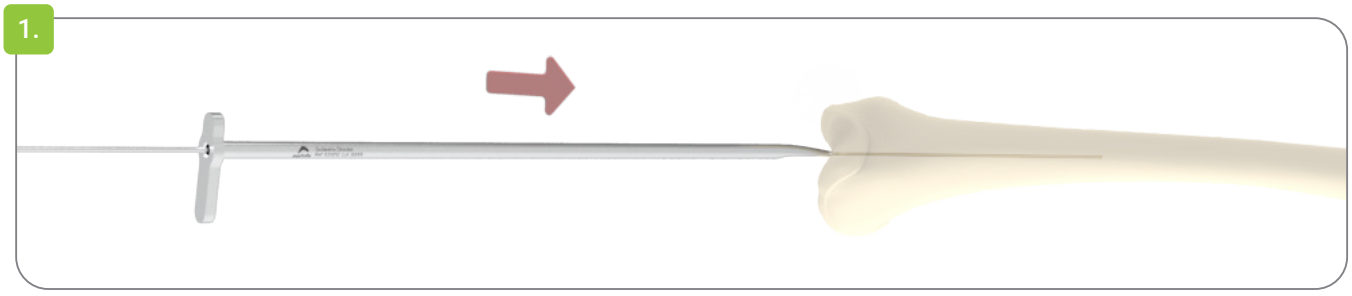
If medullary reaming with power is required, pass a 3.0x900mm Ball-tip Guidewire (533900) to the depth intended for the nail and use a Flexible Reamer* to ream a diameter 1-1.5mm more than the chosen nail diameter. The Nail Length Guidewire Gauge (600069) can then be used to determine the required nail length (see below).

Note: Use the Guidewire Pusher (531000) to stop the Guidewire from coming out while removing the Reamer. The large end is pressed against the Guidewire until it is flush with the Drill, then the Guidewire Pusher is turned around so it can pass inside the Drill and Reamer shaft.

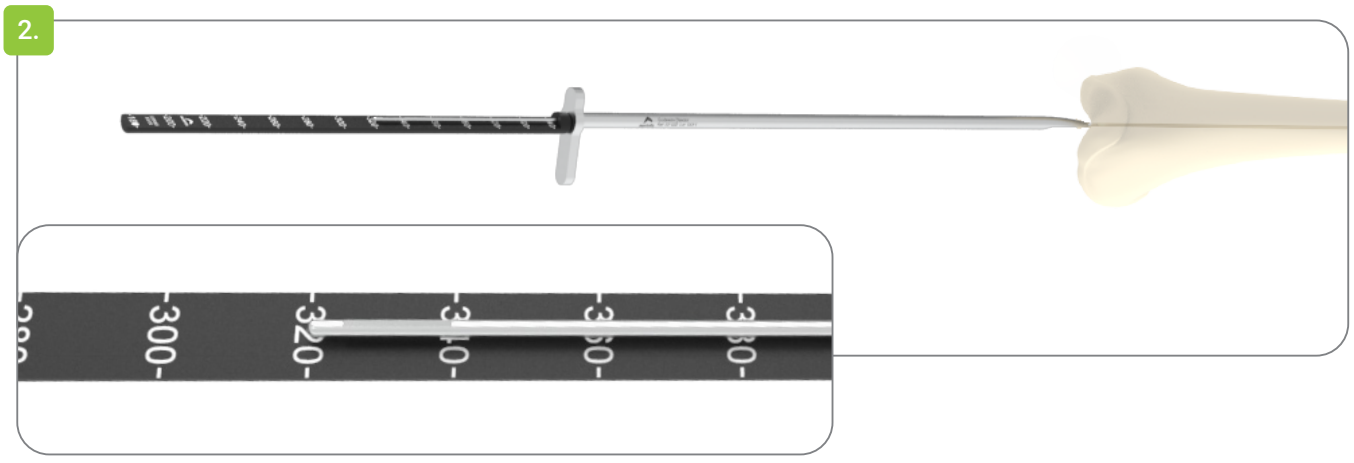
*Flexible Reamer Instrument Set (SET-INS-REAM) supplied on request.

Using the Nail Length Guidewire Gauge

1. With the Ball-tip Guidewire inserted to the intended position of the nail, pass the Guidewire Director (531002) over the guidewire.



2. Then use the Nail Length Guidewire Gauge (600069) as shown to determine the appropriate length of nail.



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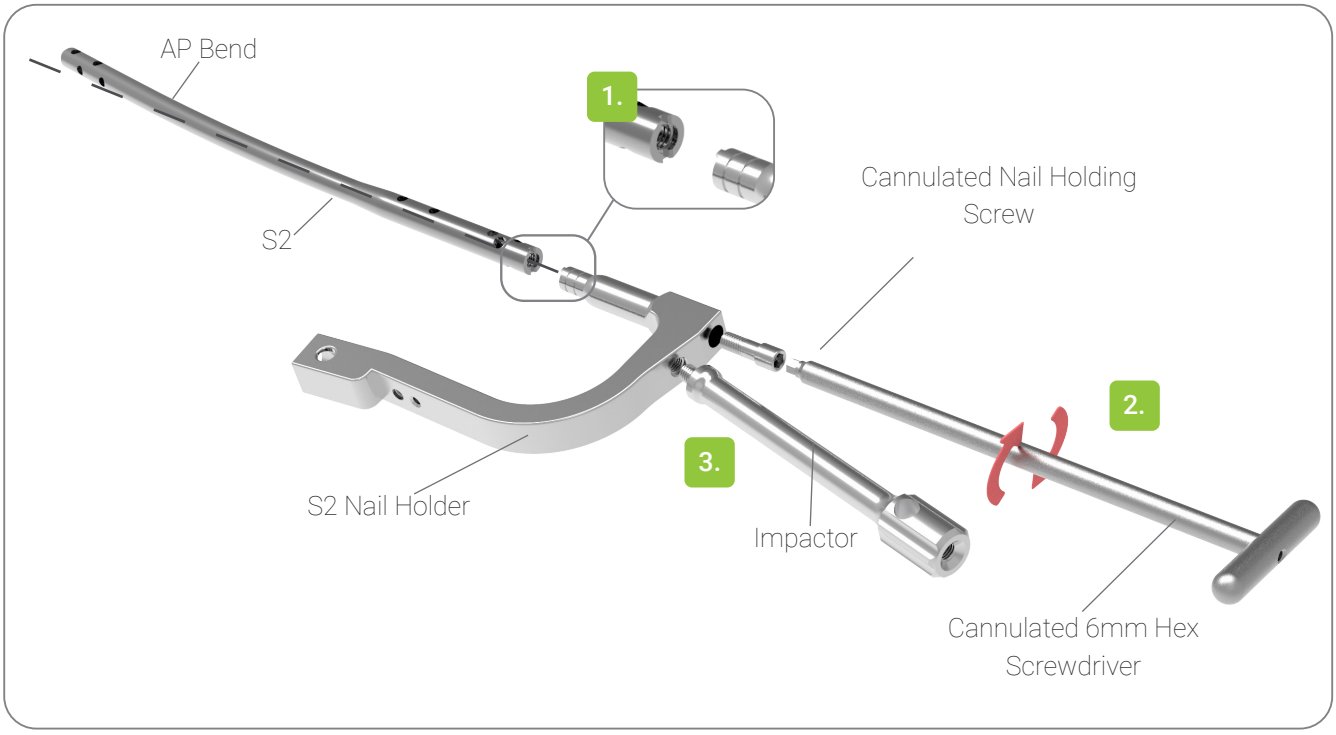
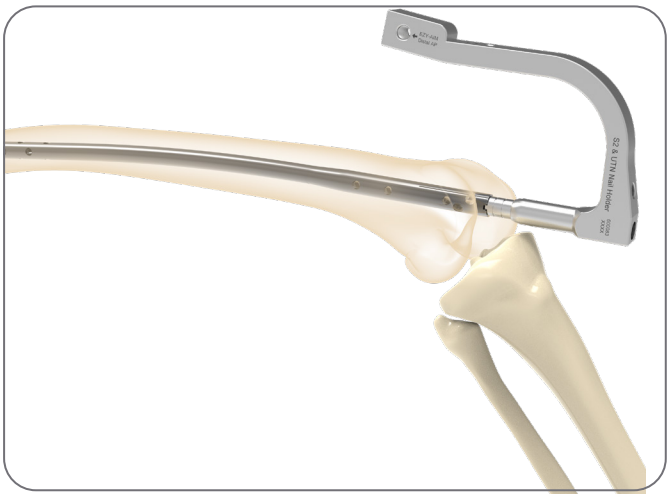
Instrument Assembly

1. Engage the slots so that the bow of the nail faces the Nail Holder, with the nail bending away from the Nail Holder.
2. Use the Cannulated 6mm Hex Ball Driver (600045) and the Cannulated Nail Holding Screw (600029) to attach the UTN & S2 Nail Holder (600083) to the nail. Regularly check the Cannulated Fixing Screw for tightness throughout the operation. If this loosens, screw targeting will not be accurate.
3. Screw the Impactor (600028) into the UTN & S2 Nail Holder. This is finally tightened by using the Hex Ball Driver as a lever through the hole in the Impactor.



Nail Insertion

Insert the nail, using a mallet or the Slide Hammer (600097) as necessary. Check instruments for loosening and maintain tightness. Check progress on the Image Intensifier and manipulate the nail across the fracture site. If this causes difficulty, the nail can be withdrawn and advanced by attaching the Slide Hammer shaft to the Impactor.
The nail must be inserted until it is a few millimetres deep to the bone surface, and this is best seen on the lateral X-ray view. For radiological orientation the end of the instrument is tapered and the tip diameter is 2mm smaller than the nail diameter. Palpate the patella and rotate the nail so that the drill guides for the condylar screws are symmetrically placed around the patella.
The method for inserting screws in all holes is described below, but the ones that are used will depend on the fracture configuration and surgeon preference.



Note: Avoid inserting the nail with the Screw Guide attached, as vibration from hammering can produce wear on the dowel holes and loss of accuracy.

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Ezy-Aim Targeting

Ezy-Aim

If using Ezy-Aim system, 4.8mm Nail Locking Screws at the proximal end of the femur must be inserted before any screws at the distal (knee) end are inserted.

Refer to the Ezy-Aim Surgical Technique (700402) for proper procedure, then switch back to page 12 for screw insertion at the knee end. Note that with these instruments, the length markings for ‘Tib’ are used instead of ‘Fem’.

Note: For short nails, up to 220mm, the nails are straight and the S2 Straight Nail Distal Screw Guide (600110A) is used. For longer nails, if they are loose in the bone, the Ezy-Aim can also be pre-set and used as a fixed jig.

Important: Freehand targeting is possible for the 4.8mm Nail Locking Screws at the proximal end of the femur and can be done after insertion of screws at the knee end. It is assumed the surgeon is proficient in freehand targeting. The A-P holes of the S2 Nail are used in freehand targeting (the Ezy-Aim uses the M-L holes). If preferred, a shorter 4.5x155mm Drill (514514) is available to avoid flexing and Drill breakages.

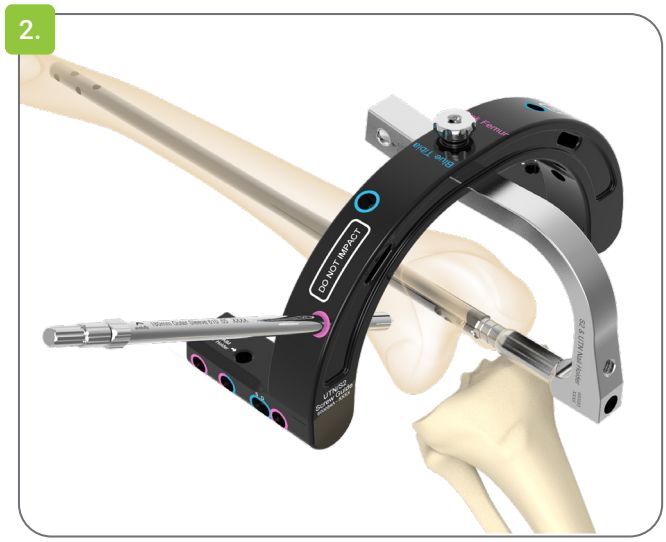
Insertion of Screws

Condylar Screws

1. Slide the S2 & UTN Screw Guide (600084A) into the top of the Nail Holder. Attach the S2 & UTN Screw Guide using the locking knob and 6mm Hex Ball Screwdriver (600045) .

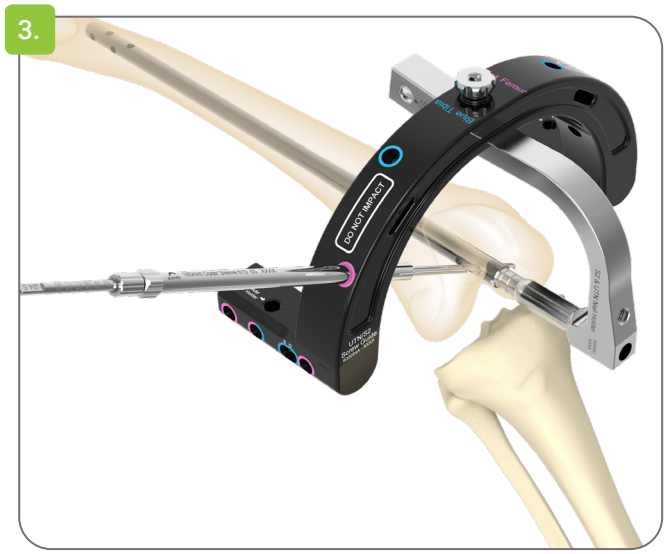
2. Pass the assembled Outer Sleeve (610065), Drill Sleeve (610064) and Trocar (610063) through the S2 & UTN Screw Guide and then through a 1cm stab wound.

   Note: It is important that the quadriceps aponeurosis is incised sufficiently to allow free passage of the Outer Sleeve, or the screw may be too prominent and the aponeurosis will later become tethered and restrict knee flexion. When the Drill Sleeve is against bone, the Trocar will not pass in the last 2-3mm.



3. Remove the Trocar and drill through with the 4.5x340mm Drill (514534).

   Note: With knee replacements, check that both holes clear the patellar flange before drilling through. If necessary rotate the nail and/or insert it further, or use only one Condylar Screw and add a 4.8mm Screw in the transverse hole which is just above the oblique holes.



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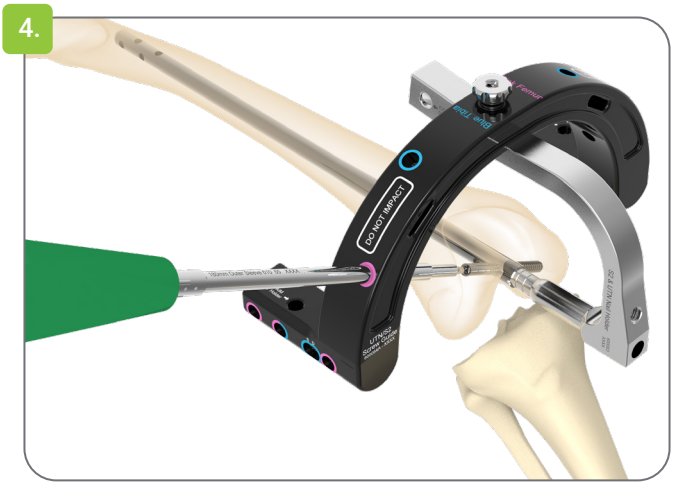
4. Remove the Drill Sleeve then drill the first cortex with the 6.5x210mm Drill (526521). Measure the depth with the Universal Depth Gauge Inner (610069B) through the Universal Depth Gauge outer (610069A).



5. Insert a 6.5mm S2 Condylar Screw of the length indicated. If using the 3.5mm Power Screwdriver (610068), stop before the last 2-3mm and screw by hand with the 3.5mm Hex Screwdriver (610067). Use the second line furthest from the driver tip as a guide to screw depth. To compress intercondylar fractures, include the 6.5mm Titanium Washer (498020).

6. Repeat steps 1-5 for the other Oblique Screw.

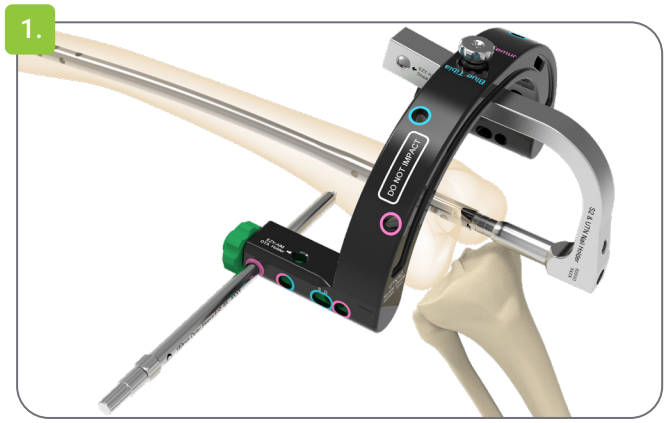
Finally check with a probe or on an appropriate oblique X-ray view that the screw is fully seated.

Mediolateral Screws (Nails 240mm and Over)

1. Insert the S2 & UTN Screw Guide Locking Sleeve (600084B) in the S2 & UTN Screw Guide(600084A).

   Recheck the tightness of the Cannulated Nail Holding Screw. Make a 1cm stab wound then pass the assembled Outer Sleeve (610065), Drill Sleeve (610064) and Trocar (610063) through the Screw Guide and secure in place with Locking Sleeve Nut. Use locking sleeve to secure sleeves in place.

   Note: The more proximal oval hole is for use with the Static/Dynamic Insert (600084C). This is rotated 180 degrees to select static or dynamic locking.

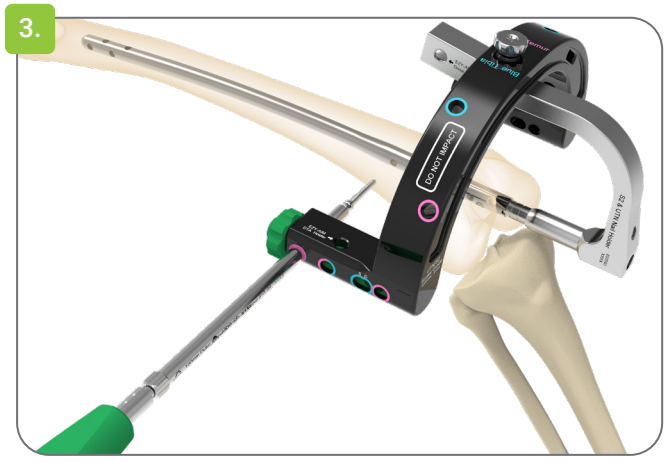


2. Remove the Trocar and drill through with the 4.5x340mm Drill (514534). When the Drill strikes the far cortex, note the length indicated on the depth scale marked on the Drill. Add 5mm to determine the length of screw required, then drill through.

   Note: Alternatively use the Universal Depth Gauge Inner (610069B) in the Universal Depth Gauge Outer (610069A) or check on X-ray.

   Warning: Drill carefully in this region as the femoral artery is at risk on the medial side.

3. Remove the Drill Sleeve and insert a 4.8mm Nail Locking Screw of the appropriate length. If using the 3.5mm Power Screwdriver (610068), stop before the last 2-3mm and screw by hand with the 3.5mm Hex Screwdriver (610067). Use the second line furthest from the driver tip as a guide to screw depth. Finally check on A-P X-ray view that the screw is fully seated.



4. Repeat steps 1-3 for the other screws.

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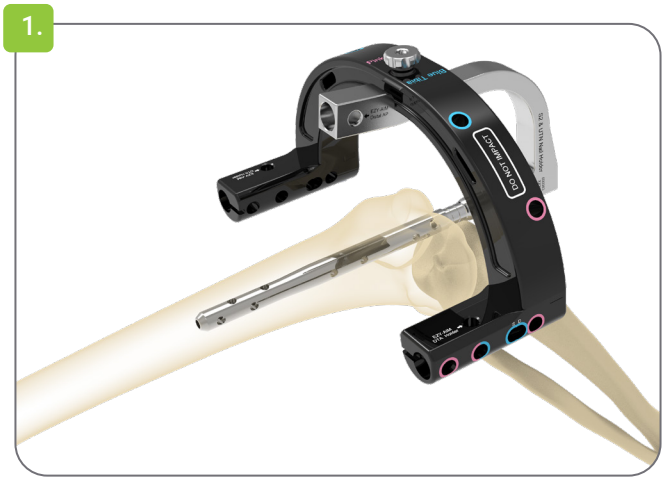
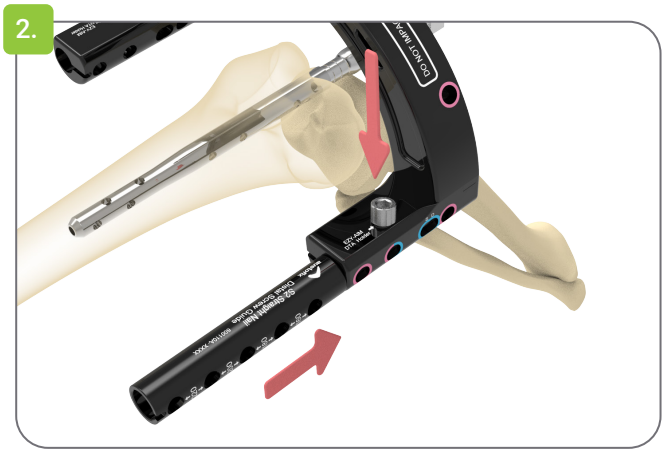
Straight Nail Distal Screws (Nails 160mm to 220mm)

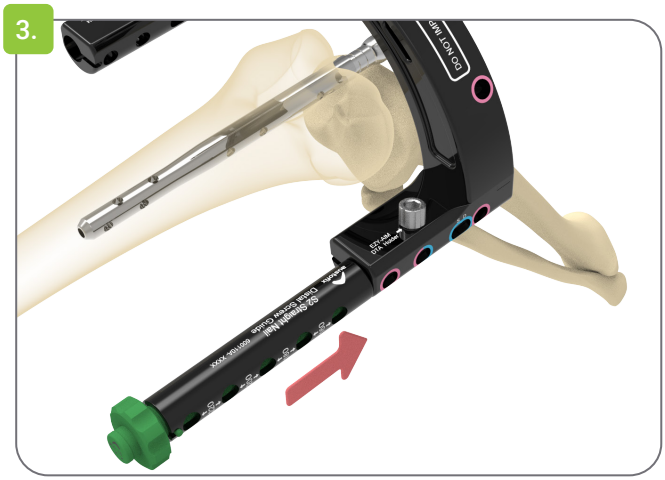
1. Assemble the straight nail of desired length onto the S2/UTN Nail Holder and S2 & UTN Screw Guide as shown in instrument assembly.



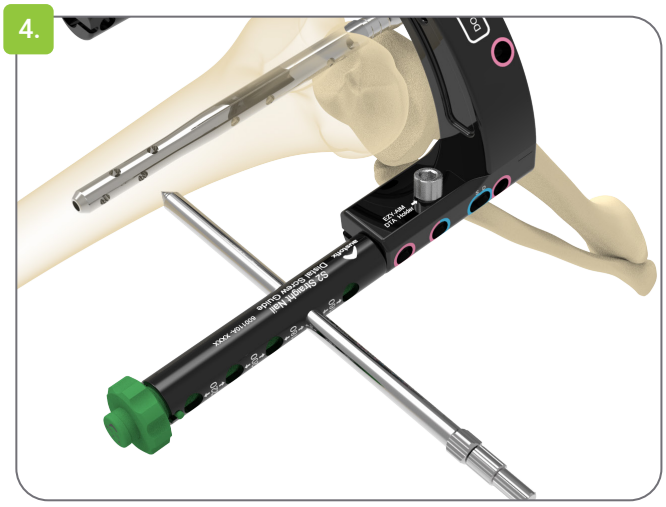
2. Slide S2 Straight Distal Screw Guide (600110A) into the S2 & UTN Screw Guide. Ensure that the pin on the Distal Screw Guide is aligned with the slot in the S2 & UTN Screw Guide. Insert M8 Mounting Screw (632007) into the Screw Guide to secure the Distal Guide. Tighten with the Cannulated 6mm Hex Ball Driver (600045).



3. Attach S2 Straight Guide Locking Sleeve (600110B) into S2 Straight Distal Screw Guide ensuring pin is aligned in the slot.

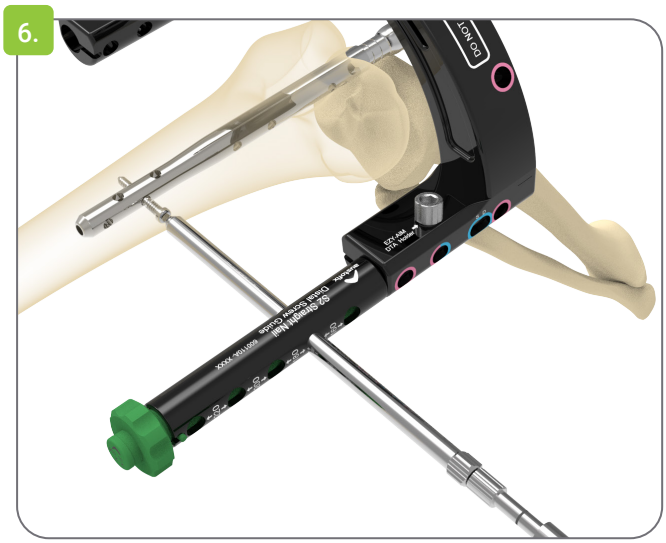


4. Pass the assembled Outer Sleeve (610065), Drill Sleeve (610064) and Trocar (610063) through the S2 Straight Distal Screw Guide and then through a 1cm stab wound. Use the Locking Sleeve Nut to secure sleeves in place. Refer to the laser marking on the S2 Straight Distal Screw Guide to choose the hole corresponding to the desired length.



5. Remove the Trocar and drill through with the 4.5 Drill. When the drill strikes the far cortex, note the length indicated on the depth scale marked on the drill. Add 5mm to determine the length of screw required, then drill through. (Alternatively use the Depth Gauge Inner(610069B) in Depth Gauge Outer (610069A) or check on X-ray).
Caution: drill carefully in this region as the femoral artery is at risk on the medial side.

6. Remove the Drill Sleeve and insert a 4.8mm Nail Locking Screw of the appropriate length. If using the 3.5mm Power Screwdriver (610068), stop before the last 2-3mm and screw by hand with the 3.5mm Hex Screwdriver (610067). Use the second line furthest from the driver tip as a guide to screw depth.



7. Repeat steps 1-6 for the other screws.

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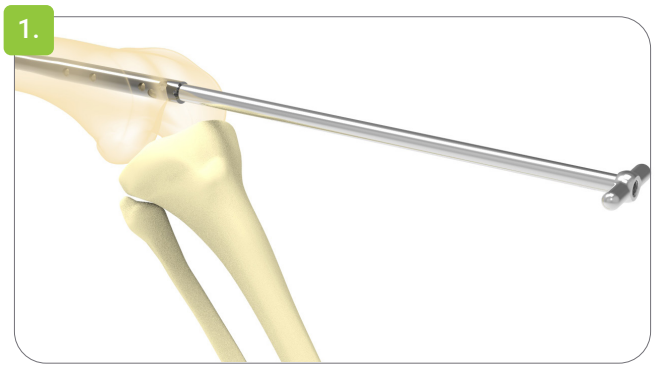
Aftercare

Postoperatively, no orthosis is normally necessary and elderly patients should be encouraged to gently take full weight on the leg. In young patients, weight-bearing should be restricted for the first six weeks, especially in the presence of intercondylar fractures.

Nail Extraction

Screw Removal

Austofix screws are fitted with a conventional 3.5mm hexagon. They can be removed either with a conventional AO large fragment screwdriver or with the Austofix 3.5x250mm Screwdriver (Hex) (610067).



Nail Removal

1. The M8 Nail Extractor (600005) is screwed into the nail.

2. Once firm in the nail, attach the slide hammer assembly onto the nail extractor and withdraw the nail.

   Note: The Nail Extractor should be screwed into the nail before the last screw is removed, to avoid the problem of unwanted nail rotation or proximal migration. The screw is then removed and the Slide Hammer assembly is attached.

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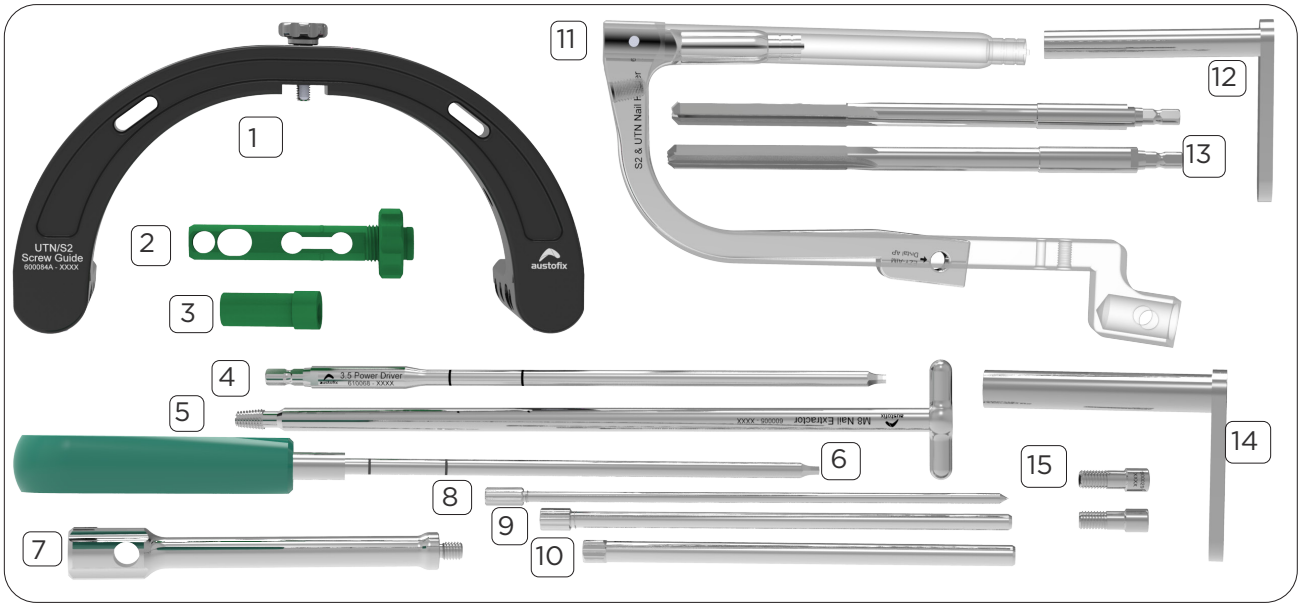
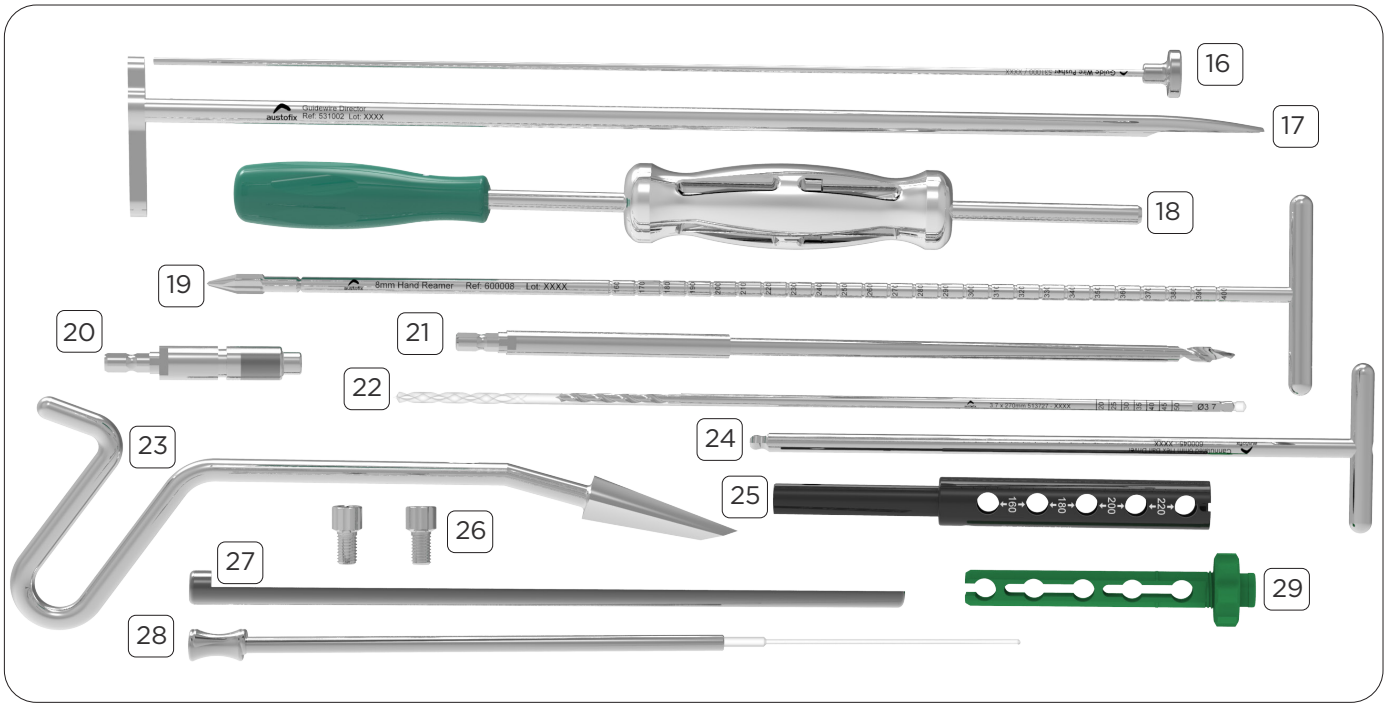
Instruments

Outercase assembly



Instruments		
#	**Code**	**Description**
1	600084A	S2 & UTN Screw Guide
2	600084B	S2 & UTN Locking Sleeve
3	600084C	S2 & UTN Static-Dynamic Insert
4	610068	Power Screwdriver 3.5 x 270mm (Hex)
5.	600005	M8 Nail Extractor
6	610067	Screwdriver 3.5 x 250mm (Hex)
7	600028	Impactor
8	610063	Trocar 180mm
9	610064	180mm Drill Sleeve
10	610065	180mm Outer Sleeve
11	600083 600083S	UTN & S2 Universal Nail Holder Suprapatellar Nail Holder (UTN Only)
12	600073	Tissue Guard 11mm (UTN Only)
13	521121 521421	Cannulated Reamer 11mm (UTN Only) Cannulated Reamer 14mm (S2 Only)
14	600066	Tissue Guard 14.5mm (S2 Only)
15	600029	Cannulated Nail Holding Screw

Instruments



Instruments		
#	**Code**	**Description**
16	531000	Guidewire Pusher
17	531002	Guidewire Director
18	600097	Slide Hammer
19	600008	Hand Reamer 8mm
20	600042	Long AO/ZH Adaptor
21	526521	Drill 6.5 x 210mm (S2 Only)
22	514534	Drill 4.5 x 340mm
	514514	Drill 4.5 x 155mm (Optional)
	513727	Drill 3.7 x 270mm (UTN only)
23	600040C	Cannulated Awl
24	600045	Cannulated Hex Ball Driver 6mm
25	600110A	S2 Straight Distal Screw Guide (S2 Only)
26	632007	M8 Mounting Screw
27	600069	Nail Length Guidewire Gauge
28	610069A	Universal Depth Gauge Outer 3.7 - 4.5mm
	610069B	Universal Depth Gauge Inner 3.7 - 4.5mm
29	600110B	S2 Straight Guide Locking Sleeve (S2 Only)

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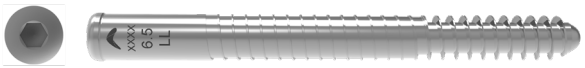
Titanium Implants

S2 Supracondylar Nail				
Nominal Length	AP Bend Angle (°)	Ø11	Ø12	Ø13
		Product Code		
160	0	391116	-	-
180	0	391118	-	-
200	0	391120	-	-
220	0	391122	-	-
240	3	391124	391224	391324
260	4	391126	391226	391326
280	4.5	391128	391228	391328
300	5.5	391130	391230	391330
320	6.5	391132	391232	391332
340	7.5	391134	391234	391334
360	7.5	391136	391236	391336
380	7.5	391138	391238	391338

End Cap M8	
Product Code	Length
368000	00
368001	01
368005	05
368010	10
368015	15
368020	20

6.5mm S2 Condylar Screw	
Product Code	Screw Length
396550	50
396555	55
396560	60
396565	65
396570	70
396575	75
396580	80
396585	85
396590	90



6.5mm Washer
Product Code
T498020

4.8mm Nail Locking Screw	
Product Code	Screw Length
364820	20
364825	25
364830	30
364832	32.5
364835	35
364837	37.5
364840	40
364845	45
364850	50
364855	55
364860	60
364865	65
364870	70
364875	75
364880	80
364885	85
364890	90

Single Use Items

Guidewire	
Product Code	Description
512525	2.5x250mm K-Wire (Twin Packed)
533900	3.0x900mm Ball-tip Guidewire

Drill	
Product Code	Description
514534	4.5x340mm Drill
514514	4.5x155mm Drill

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MRI Safety

Austofix has not evaluated its devices for safety and compatibility in a Magnetic Resonance (MR) environment. However, the materials used in their manufacture are known to have minimal ferromagnetism, with minimal risk to patients in strong magnetic fields.
Austofix has performed a review of published, peer-reviewed data, which confirms that only minor rises in MRI-related heating are observed from devices manufactured from the same titanium and stainless-steel materials. Trauma devices are considered unlikely to produce injury to patients, including in the worst-case 3.0T systems.
The devices and materials observed in the literature experience forces too weak to cause significant displacement; the risk being further mitigated by their implantation in bone. Risks of imaging artifacts are known to MRI operators, and can be reduced by choosing appropriate pulse sequences and optimizing scanning parameters by using a large bandwidth, small field-of-view and appropriate echo train length.
Average temperature changes have been observed in studies at 0.48°C in titanium and 0.74°C in stainless-steel. Rises in temperature in clinical situations may depend on individual patient factors. It should be recommended that patients be thoroughly monitored when undergoing MR scanning, and that impaired patient thermoregulation be considered a contraindication for MRI procedures.

Sources:
Chen CA, Chen W, Goodman SB, et al. New MR Imaging Methods for Metallic Implants in the Knee: Artifact Correction and Clinical Impact. 2011, 1121-1127.
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Zou Y, Chu B, Wang C, Hu Z. Evaluation of MR issues for the latest standard brands of orthopedic metal implants, Plates and screws. Eur J Radiol. 2015, 84(3):450-457.

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