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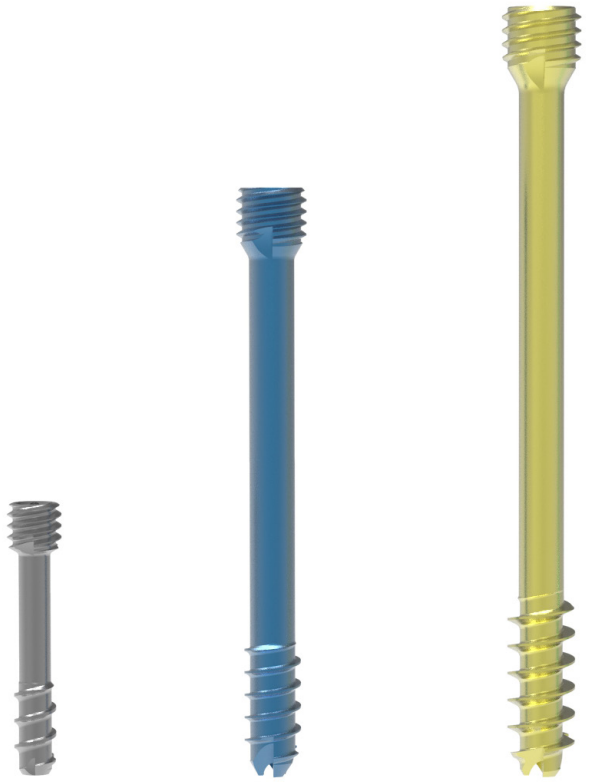
HEADLESS CANNULATED SCREWS

Surgical Technique



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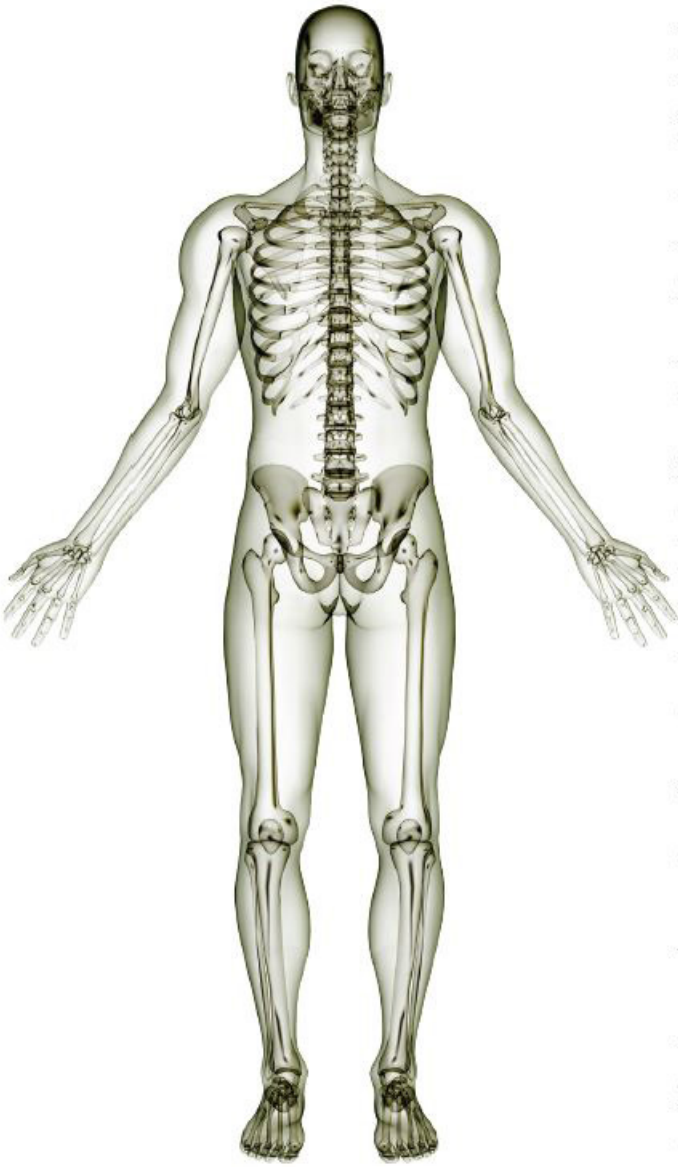


Austofix is a leading manufacturer and designer of orthopaedic trauma medical devices with a particular focus on innovation, excellence and patient safety. Austofix has the expertise and experience in developing a new device from concept to a fully Commercialised product with regulatory approval for world-wide distribution.

Throughout its 20+ years Austofix has gathered a team of world-class research and development specialists. Together with orthopaedic surgeons, our specialists identify emerging techniques and innovations in the field of orthopaedic trauma and develop world-class solutions.

Austofix is now one of Australia's key contributors to the world-wide medical technology industry. By focusing on specific market needs we can leverage our staff expertise to develop effective solutions and successfully compete on the world stage.

We understand that accidents don't wait to happen, so we ensure that our equipment and devices are ready when needed. With a dedicated 24 hour, seven day a week customer service and sales team, Austofix products are ready when you are.

With our focus on trauma we understand the specific needs of trauma surgeons. Our product specialists actively support the surgeon by being on call to support procedures and offer advice.

Austofix products and innovations assist the surgeon in performing accurate, efficient and safe procedures that result in better health outcomes for the patient.

The measurement of our success is seen through our excellent clinical results and positive surgeon feedback. We understand the need for efficiency during operations and that this is key in improving patient outcomes. Our products and tools are designed to minimise time spent in theatre. Furthermore, all clinical feedback of our products is promptly addressed to ensure product refinements reflect all surgical concerns.

For further information, updates and contact details visit austofix.com.au and follow us on LinkedIn.

Disclaimer

This document is intended to be read by experienced orthopaedic surgeons familiar with Headless Cannulated Screws.

This document is intended as the recommended procedure for using the Headless Cannulated Screw. It offers guidance only. Each surgeon should consider the particular needs of the patient and make appropriate adjustments where necessary.

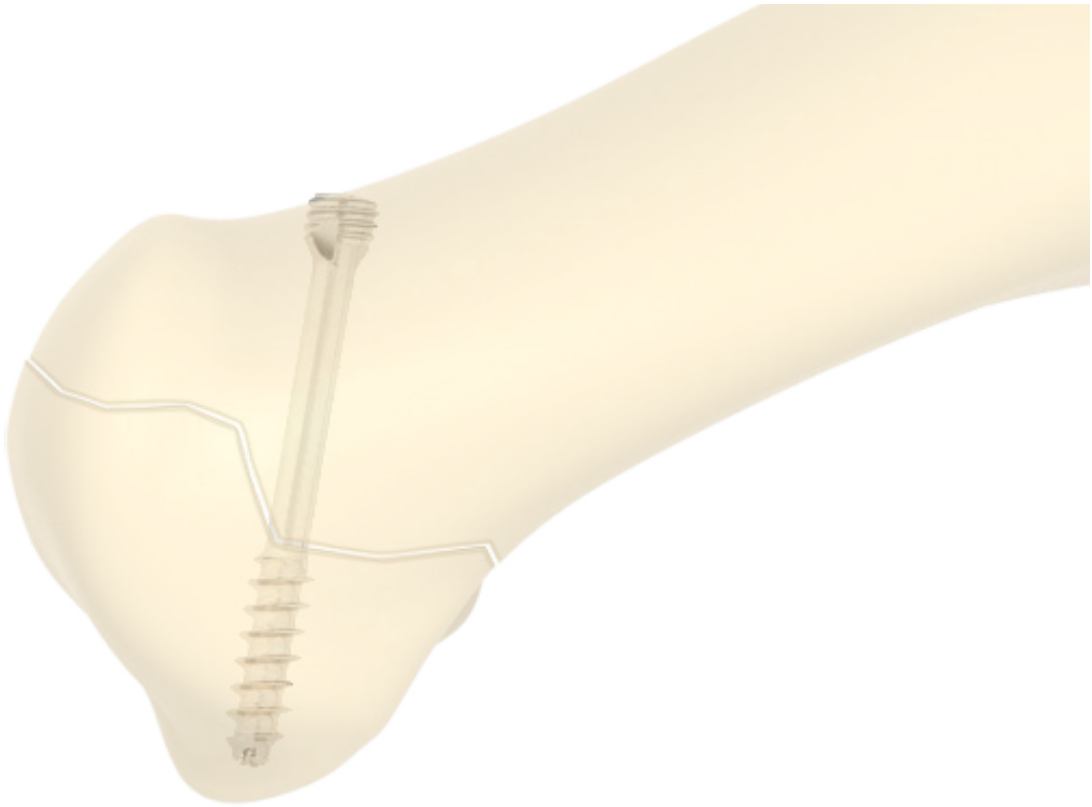
For further advice please contact your local Austofix representative.

HEADLESS CANNULATED SCREWS

The Austofix Headless Cannulated Screws are designed for the fixation of the many fracture patterns found in small bones, especially for intra and extra articular fractures.

The titanium screws incorporate significant design advantages, facilitating surgical accuracy and efficiency and delivering better patient outcomes.

Austofix understands the importance of proven, high quality medical devices and instruments. The Headless Cannulated Screws adhere to these principles and will provide the surgeon with a comprehensive fixation solution.



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Screw Range

This surgical technique applies to the following Headless Cannulated Screws. Each screw is available in a variety of lengths, see listings in back of this surgical technique. Screw selection is determined by the surgeon.

Each screw is designed to be used for but not limited to the following indications:

1.7mm Cannulated Screw

Hand	Foot
Fractures	
» Metacarpal Base » Metacarpal Head » Phalangeal Base » Phalangeal Head » Bicondylar » Condylar	» Metatarsal
Other	
» Proximal interphalangeal arthrodeses » Distal interphalangeal arthrodeses	» Hammertoe Correction » Mallet Toe Correction » Weil Osteotomy » IPJ Fusion

2.4mm Cannulated Screw

Hand	Foot
Fractures	
» Metacarpal Base » Ulnar Styloid » Scaphoid	» Metatarsal
Other	
» Scaphoid non-union	» Akin Osteotomy » Austin/Chevron Osteotomy

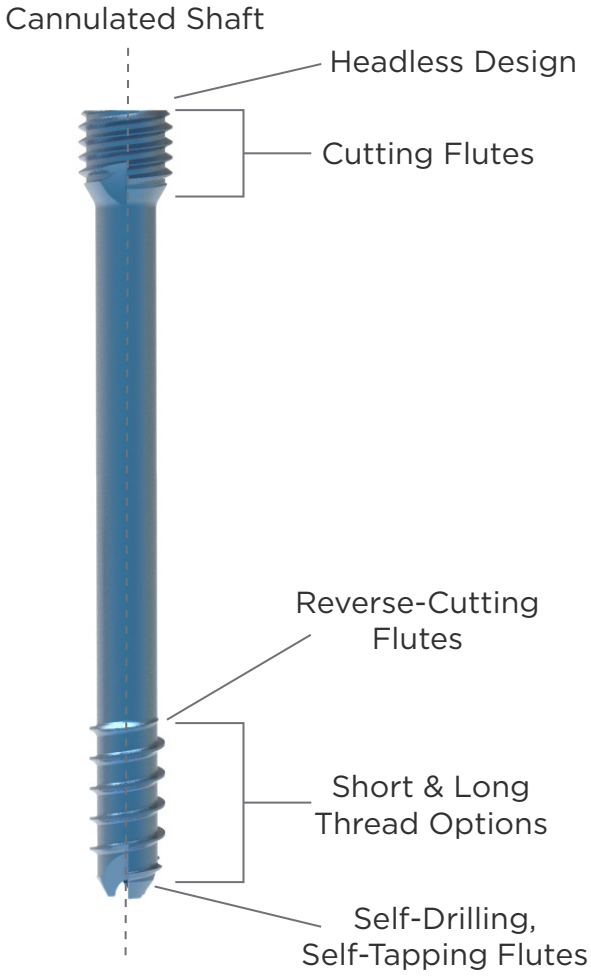
3.0mm Cannulated Screws

Hand	Foot
Fractures	
» Radial Styloid » Scaphoid	» Metatarsal » Tarsal
Other	
» Scaphoid non-union	» Hallux Valgus Correction » Bunionette » MTP Fusion » Closing Wedge Osteotomy » Scarf Osteotomy » Austin/Chevron Osteotomy

Screw Features

Screw Design

- Implant grade Titanium Screws incorporate significant benefits including lightweight, high strength properties and improved biocompatibility
- Cannulated shaft allows precise percutaneous insertion with the use of K-Wires
- Screw head cutting flutes reduces irritation of soft tissue and facilitates countersinking of Screw head
- Reverse-cutting flutes help with Screw removal
- Unique thread profile reduces probability of backout
- Large thread pitch assists with Screw insertion and removal
- Self-drilling, self-tapping flutes reduce the need for pre-drilling and pre-tapping

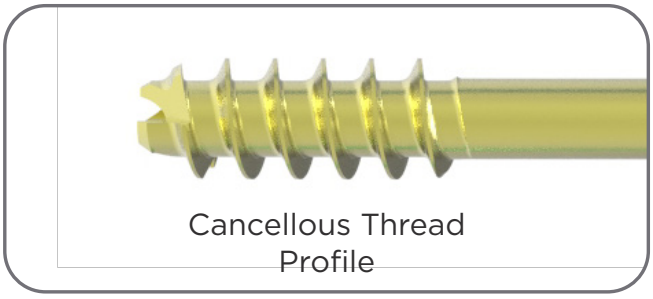


Additional Features

- Ø1.7, 2.4 and 3.0mm Screw diameter with options allow for a diverse portfolio of fracture fixation options
- Varying thread lengths allows optimal fit to far bone fragment, for interfragmentary compression

Ø3.0mm Headless Compression Screws

- Cancellous thread profile uses deep cutting threads with a large pitch to reduce probability of backout
- Achieves optimal interfragmentary compression for the larger bones of the hands and feet



Pre-Drilling

Use the table below for reference regarding required instrumentation for Headless Cannulated Compression Screw insertion. Follow the steps in the surgical technique found on page 8 to insert Ø1.7, Ø2.4, or Ø3.0mm Headless Cannulated Compression Screws correctly.

	Screw Diameter		
	Ø1.7mm	Ø2.4mm	Ø3.0mm
Instrument Set	Full 1.7 Headless Instrument Set (SET-INS-HLCANN1.7)	Full 2.4 Headless Instrument Set (SET-INS-HLCANN2.4)	Full 3.0 Headless Instrument Set (SET-INS-HLCANN3.0)
Guide Wire	Ø0.8 x 100mm (081.010)	Ø0.8 x 100mm (610.810)	Ø1.1 x 120mm (611.112)
Drill Guide	Double Head 0.8 / 0.8mm (081.099)	Double Head 0.8 / 1.9mm (028.411)	Double Head 1.1 / 2.4mm (028.413)
Drill	-	Ø1.9mm Cannulated (Ø0.8mm) (511.911)	Ø2.1mm Cannulated (Ø1.1mm) (512.111)
Handle	Quick Coupling (088.012)	Quick Coupling (110.206)	Quick Coupling (110.206)
Compression Handle	Compression (088.013) Compression Sleeve (081.020)	Compression (232.021) Compression Sleeve (232.011)	Compression (232.021) Compression Sleeve (232.012)
Depth Gauge	For Ø0.8 Guide Wire (081.016)	For Ø0.8 Guide Wire (030.940)	For Ø1.1 Guide Wire (030.941)
Driver	Ø1.8mm Torx (Star) (082.061) Ø1.8mm Cannulated (Ø0.8mm) Torx (Star) (082.051)	Ø1.9mm Torx (Star) (362.068) Ø1.9mm Cannulated (Ø0.8mm) Torx (Star) (579.069)	Ø2.24mm Torx (Star) (362.074) Ø2.24mm Cannulated (Ø1.1mm) Torx (Star) (579.075)
Countersink	For Ø1.7mm Screw, Cannulated (082.047)	For Ø2.4mm Screw, Cannulated (532.601)	For Ø3.0mm Screw, Cannulated (533.002)

Preparation

Precautions

Austofix Headless Cannulated Compression Screws are designed as a single-use implant. Headless Cannulated Compression Screws must not be re-implanted under any circumstances.

It is important to consider adverse affects which can occur as a result of damaged or loosened implants. Implant integrity can be affected by patient weight, level of activity, and adherence to weight-bearing recommendations.

Post-operative considerations must be made regarding patient condition and recovery process. Patients who present with physiological and anatomical abnormalities such as severe osteoporosis, immunological responses, hypersensitivity to foreign materials, poor physical health, or further systemic or metabolic disorders are at a greater risk of post-operative complications.

The Austofix Headless Cannulated Compression Screw system must not be used with dissimilar materials. Pre-operative assessments must be made to determine whether the Titanium implants will be suitably accepted by the patient.

Screw selection should be made with considerations to patient height, weight, morbidity, occupation and degree of mobility. The patient should be made aware of the advantages and disadvantages of orthopaedic implants, as well as post-operative limitations including but not limited to weight/load-bearing and other implant limitations.

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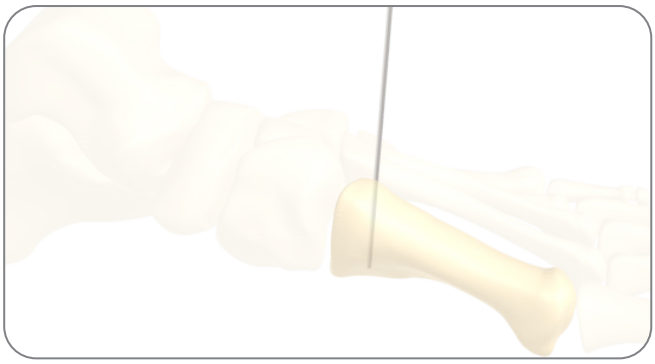
Surgical Technique

Note: Use the table on page 7 for appropriate instrumentation selection.

Guide Wire Insertion

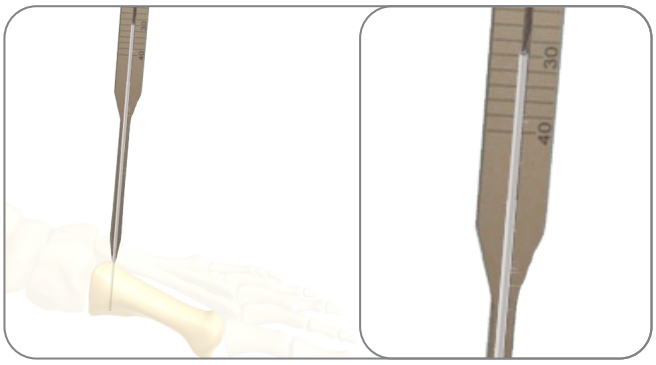
1. Make an appropriate incision allowing a clear approach to the desired region of the bone.
2. Use the appropriate Guide Wire to reduce the bone fragments intended to be repaired with the Headless Compression Screw.
3. Align the selected Drill Sleeve to the Guide Wire and advance the Guide Wire through the Sleeve in the direction of Screw insertion. Using image intensification, ensure that the Guide Wire is aligned correctly and has been inserted to the desired depth and position.



Determine Screw Length

1. Slide the narrow end of the Depth Gauge over the Guide Wire. Ensure the Depth Gauge is pressed up to bone.
2. Use the laser-marked flat side of the Depth Gauge to determine Headless Compression Screw length.

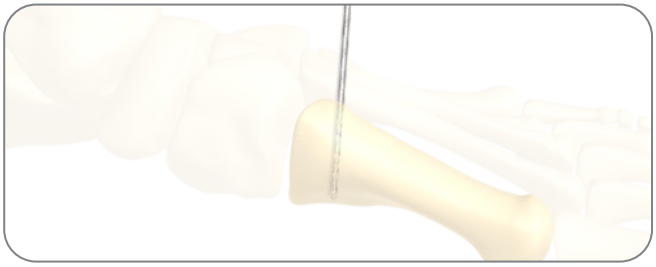
Note: A shorter length Headless Compression Screw may be selected where the Screw is being countersunk below the surface of the bone or where a large fracture gap is being reduced.



Drilling

Note: Austofix Headless Cannulated Compression Screws are self-tapping and self-drilling. The following drilling procedure is optional however recommended as Screw insertion into dense bone is made easier. The 1.7mm Headless Cannulated Screw Set does not contain a Drill Bit.

1. Following selection of the appropriate Drill, align and advance the drilling end of the Cannulated Drill over the Guide Wire.
2. Drill to the desired depth as measured using the Depth Gauge.
3. Image intensification should be used to ensure correct drilling depth and alignment.
4. Once the desired depth has been reached, remove the Drill without removing the Guide Wire.



Countersink

Note: Austofix Headless Cannulated Compression Screws contain self-tapping and self-drilling flutes on the head portion of the Screws. The following procedure is optional however recommended when inserting into dense bone.

1. Select the appropriate Countersink and advance the Countersink over the Guide Wire.
2. Use the Countersink tip to drill into the bone by rotating the Countersink clockwise while constantly applying pressure. The step of the Countersink indicates the length of the threaded Screw head.

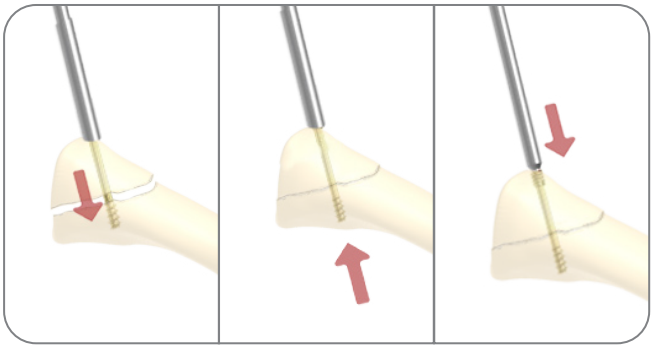
Insert Screw

1. Assemble the appropriate Compression Handle with Compression Sleeve and engage the Screw for insertion using the Compression Sleeve.
2. Insert the Screw over the Guide Wire with the Compression Sleeve still engaged over the thread. Advance the Screw into the bone to compress fracture as necessary.
3. Separate the Compression Handle from the Compression Sleeve, leaving the Compression Sleeve engaged with the head of the Screw.

   Note: The Compression Sleeve may need to be supported by hand.
4. Attach the appropriate Cannulated Driver to the Quick-Coupling T-Handle and advance through the Compression Sleeve to engage with the Stardrive (Torx) recess of the Screw.
5. While supporting the Compression Sleeve, rotate and advance the Screw until it sits flush or sub-flush below the surface of the bone.

   Note: The Cannulated Screwdrivers for Ø2.4mm and Ø3.0mm Screws are laser marked to indicate the threads of the Screw head lies within the bone.
6. Remove the Guide Wire.

Warning: Ensure that the tip of Screw does not pierce the distal cortex.



Screw Removal

1. Assemble the relevant Quick-Coupling T-Handle with the appropriate solid Screwdriver.
2. Clear any tissue overgrowth from within the Stardrive (Torx) recess and insert Driver tip.
3. Remove the Screw with anti-clockwise rotation.

Note: An appropriately selected Cannulated Screwdriver may be used in conjunction with the correct Guide Wire if it is difficult to align the Driver tip to the Screw head recess.

Ø1.7mm
Implants

1.7mm Headless Cannulated Screws		
Product Code	Length (mm)	Thread Length (mm)
1017-01-17006	6	3.5
1017-01-17007	7	3.5
1017-01-17008	8	3.5
1017-01-17009	9	3.5
1017-01-17010	10	4
1017-01-17011	11	4
1017-01-17012	12	4
1017-01-17013	13	4
1017-01-17014	14	4

Instruments

Instruments			
#	Code	Description	Qty
1	081.120	Cleaning Pin 0.8 x 120mm	1
2.	088.012	Quick Coupling Handle	1
3	088.013	Compression Handle	1
4	081.016	Depth Gauge for Guide Wire	1
5	081.010	Guide Wire 0.8 x 100mm	5
6	081.099	Drill Guide - Double Head 0.8 / 0.8mm	1
7	181.030	Screw Holder Forceps	1
8	082.061	Screwdriver 100mm (Star)	1
9	082.051	Screwdriver, Cannulated 120mm (Star)	1
10	082.047	Countersink, Cannulated 100mm	1
11	081.020	Compression Sleeve 131.5mm	1

Screw Caddy		
Code	Description	Qty in Set
0682.00116-02	1.7 Headless Screw Caddy	1

Instrument Tray		
Code	Description	Qty in Set
0682.00116-00	1.7 Headless Instrument Tray (Empty)	1
0682.00116-01	1.7 Headless Tray Lid	1

Instrument Set		
Code	Description	Qty in Set
SET-INS-HLCANN1.7	Full 1.7 Headless Instrument Set	-

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Ø2.4mm

Implants

2.4mm Headless Cannulated Compression Screws		
Product Code	Length (mm)	Thread Length (mm)
1019-02-24008	8	4
1019-02-24009	9	4
1019-02-24010	10	4
1019-02-24011	11	4
1019-02-24012	12	4
1019-02-24013	13	4
1019-02-24014	14	4
1019-02-24016	16	4
1019-02-24018	18	4
1019-02-24020	20	4
1019-02-24022	22	6
1019-02-24024	24	6
1019-02-24026	26	6
1019-02-24028	28	6
1019-02-24030	30	6

Instruments

Instruments			
#	Code	Description	Qty
1	610.881	Cleaning Pin 0.8 x 120mm	1
2.	110.206	Quick Coupling Handle	1
3	232.021	Compression Handle	1
4	030.940	Depth Gauge for Guide Wire	1
5	610.810	Guide Wire 0.8 x 100mm	5
6	028.411	Drill Guide - Double Head 0.8 / 1.9mm	1
7	225.001	Screw Holder Forceps	1
8	511.911	Drill Bit, Cannulated 100mm	1
9	532.601	Countersink, Cannulated 100mm	1
10	579.069	Screwdriver, Cannulated 120mm (Star)	1
11	362.068	Screwdriver 100mm (Star)	1
12	232.011	Compression Sleeve 131.5mm	1

Screw Caddy		
Code	Description	Qty in Set
461.031	2.4 Headless Screw Caddy	1

Instrument Tray		
Code	Description	Qty in Set
461.032	2.4 Headless Instrument Tray (Empty)	1
461.033	2.4 Headless Tray Lid	1

Instrument Set		
Code	Description	Qty in Set
SET-INS-HLCANN2.4	Full 2.4 Headless Instrument Set	-

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Ø3.0mm
Implants

3.0mm Headless Cannulated Compression Screws		
Product Code	Length (mm)	Thread Length (mm)
1019-02-30010	10	4
1019-02-30011	11	4
1019-02-30012	12	4
1019-02-30013	13	4
1019-02-30014	14	4
1019-02-30016	16	4
1019-02-30018	18	4
1019-02-30020	20	5
1019-02-30022	22	6
1019-02-30024	24	6
1019-02-30026	26	7
1019-02-30028	28	7
1019-02-30030	30	7

Instruments

Instruments			
#	Code	Description	Qty
1	611.181	Cleaning Pin 1.1 x 120mm	1
2.	110.206	Quick Coupling Handle	1
3	232.021	Compression Handle	1
4	030.941	Depth Gauge for Guidewire	1
5	611.112	Guidewire 1.1 x 120mm	5
6	028.413	Drill Guide - Double Head 1.1 / 2.4mm	1
7	225.001	Screw Holder Forceps	1
8	512.111	Drill Bit, Cannulated 120mm	1
9	533.002	Countersink, Cannulated 120mm	1
10	579.075	Screwdriver, Cannulated 120mm (Star)	1
11	362.074	Screwdriver 100mm (Star)	1
12	232.012	Compression Sleeve	1

Screw Caddy		
Code	Description	Qty in Set
461.034	Box Body	1

Instrument Tray		
Code	Description	Qty in Set
461.035	3.0 Headless Instrument Tray (Empty)	1
461.036	3.0 Headless Tray Lid	1

Instrument Set		
Code	Description	Qty in Set
SET-INS-HLCANN3.0	Full 3.0 Headless Instrument Set	-

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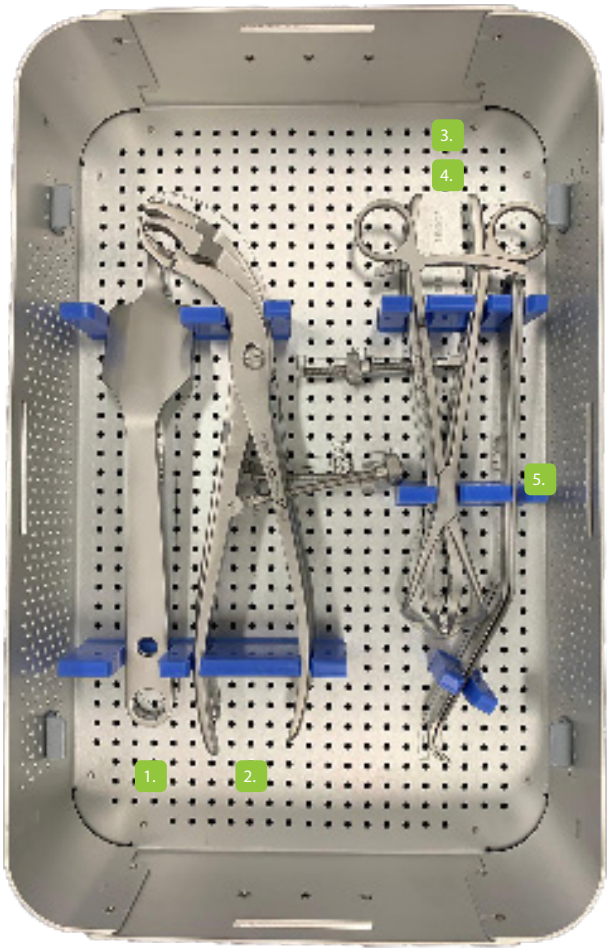
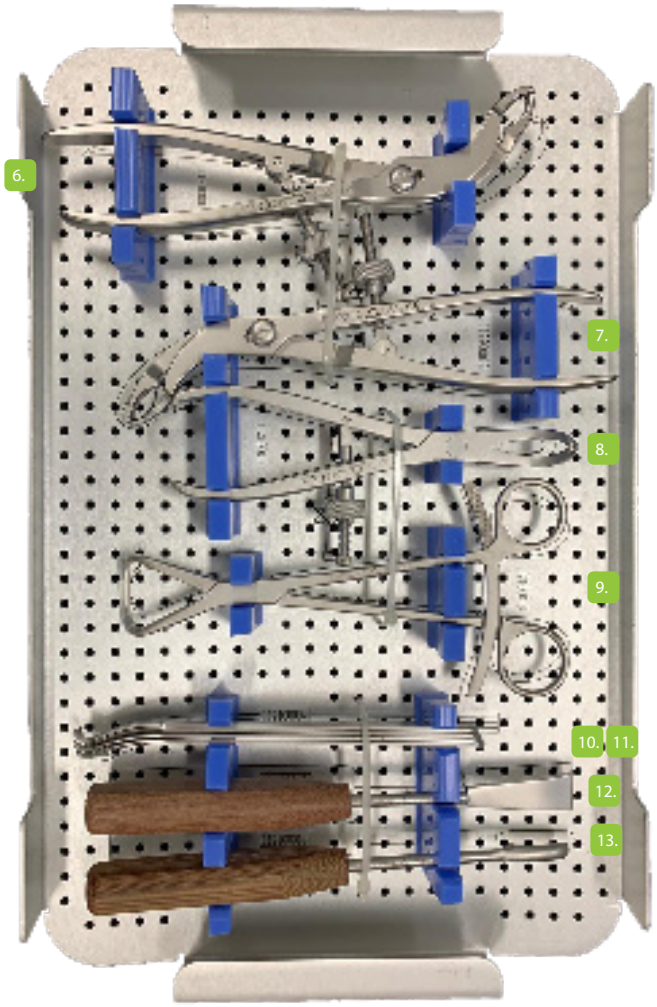
Optional Sets

Universal Trauma Set





Instruments			
#	Code	Description	Qty
1	113100017	Hohmann Retractor (Large) 43.5 x 267mm	2
2	113100019	Self-Centering Bone Holding Forceps (Speed Lock) 266mm	1
3	113100021	Reduction Forceps (Serrated Jaws) 220mm	2
4	113100022	Reduction Forceps (Point) 207mm	1
5.	113100018	Hohmann Retractor (Small) 16 x 267mm	1
6	112100010	Self-Centering Bone Holding Forceps (Speed Lock) 191.8mm	2
7	112200012	Self-Centering Bone Holding Forceps (Compression)	1
8	112100011	Reduction Forceps (Serrated Jaws) 158mm	1
9	112100013	Reduction Forceps (Points) 182mm	1
10	112100006	Hohmann Retractor (Large) 15.5 x 159mm	2
11	112100007	Hohmann Retractor (Small) 10.5 x 170mm	2
12	113100016	Periosteal Elevator (Large)191mm	1
13	112100012	Periosteal Elevator (Small) 190mm	1

Instrument Set	
Code	Description
SET-INS-UTRA	Full Universal Trauma Instrument Set

Instrument Tray	
Code	Description
1132122000	Universal Trauma Instrument Tray (Empty)

Single Use Items

K-Wires		
Code	**Description**	**Qty**
610.810	Guide Wire 0.8 x 100mm	2
611.112	Guidewire 1.1 x 120mm	2

Drills		
Code	**Description**	**Qty**
511.911	Drill Bit, Cannulated 100mm	1
512.111	Drill Bit, Cannulated 120mm	1

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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.

Gill A, Shellock FG. Assessment of MRI issues at 3-Tesla for metallic surgical implants: findings applied to 61 additional skin closure staples and vessel ligation clips. J Cardiovasc Magn Reson. 2012, 14(1):3.

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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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