

2.0 mm Quick Insertion Screws

Surgical Technique



 Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

<http://emea.depuyshes.com/hcp/reprocessing-care-maintenance>

For general information about reprocessing, care and maintenance of DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

<http://emea.depuyshes.com/hcp/reprocessing-care-maintenance>

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2.0 mm Quick Insertion Screws

Overview

The 2.0 mm Quick Insertion Screw (QIS) System includes self-drilling and self-tapping Twist-Off-Style Screws offered in lengths ranging from 11 mm –18 mm, as well as a self-retaining Quick Insertion Easy Loader Screwdriver and a self-retaining Manual Screwdriver.

The Quick Insertion Screw Loader Device (Easy Loader Screwdriver) reduces premature post-breakages of the screw.

Quick Insertion Screw facilitates low profile screw seating and recessed break-off point.



Quick Insertion Screw engaged in Easy Loader Screwdriver

Screw Material and Sizes

- Available in Titanium Alloy (TAN)
- Ø 2.0 mm with 11–18 mm lengths (1mm increments)
- Screw can be stored in provided screw rack or be purchased sterile packed in sterile tubes.



Sterile Tube Packing

The sterile packed 2.0 mm Quick Insertion Screws are available in ready-to-use sterile tubes. For usage instructions on how to open the sterile tube packaging, refer to Sterile Tube Usage Guide.

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effect and Residual Risks. Instructions for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu

The AO Principles of Fracture Management

Mission

The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

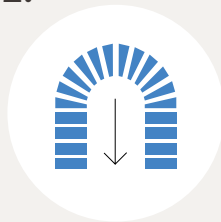
AO Principles^{1,2}

1.



Fracture reduction and fixation to restore anatomical relationships.

2.



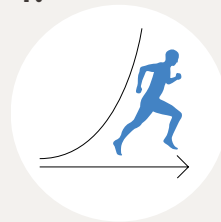
Fracture fixation providing absolute or relative stability, as required by the “personality” of the fracture, the patient, and the injury.

3.



Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling.

4.



Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

¹ Müller ME, M Allgöwer, R Schneider, H Willenegger. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg, New York: Springer. 1991

² Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

Surgical Technique

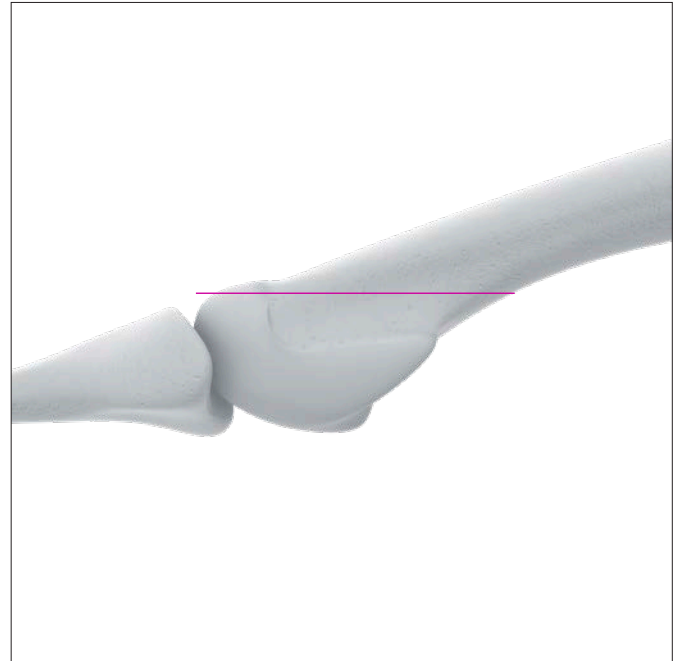
1. Approach/Osteotomy

This surgical technique describes the steps taken for a Weil osteotomy of the second metatarsal.

The Weil osteotomy is a metatarsal shortening osteotomy and is performed to decrease pressure on a prominent lesser metatarsal head in the forefoot without affecting the dorsal/plantar rotation of the metatarsal head.

Site Preparation

Prepare the osteotomy site using the preferred technique and instruments.



2. Temporary Fixation

Instruments

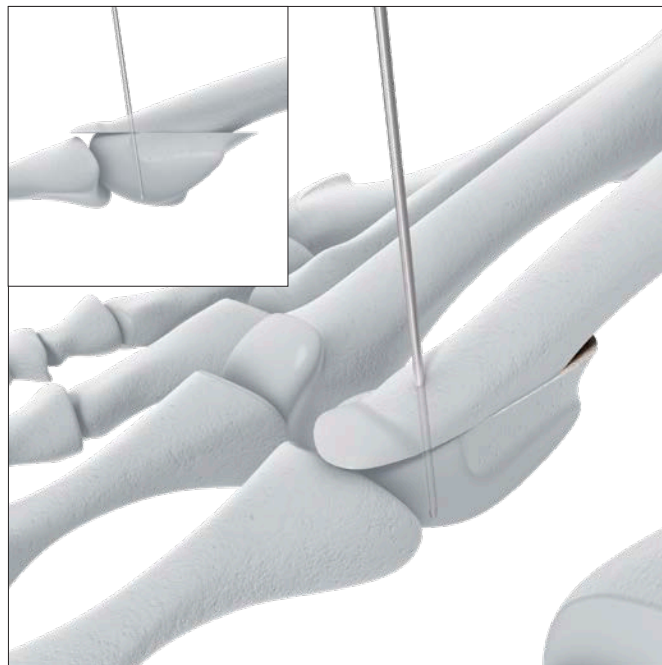
03.333.000* Guide Wire Ø 0.8 mm, length 100 mm, with trocar tip

Provisionally fix bone fragments using a Guide Wire.

- ⌚ Confirm position of fragmentes under fluoroscopy.

■ Note:

The use of general surgical equipment is recommended to protect soft tissue.



*Instrument also available sterile packed. Add suffix "S" to Part Number.

3. Screw Length Determination

Instruments

03.333.000*	Guide Wire Ø 0.8 mm, length 100 mm, with trocar tip
03.333.500	Direct Measuring Device for L 100 mm

Screw length can be estimated by using the temporary Guide Wire or inserting a second Guide Wire at the required angulation and position for the screw.

- 1 Confirm Guide Wire depth and positioning under fluoroscopy.

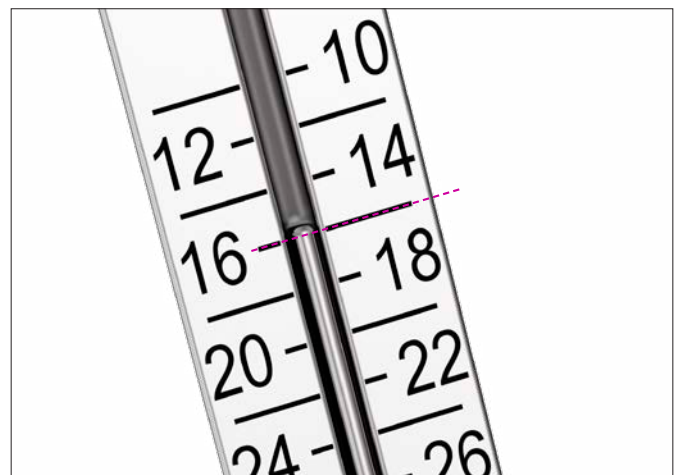
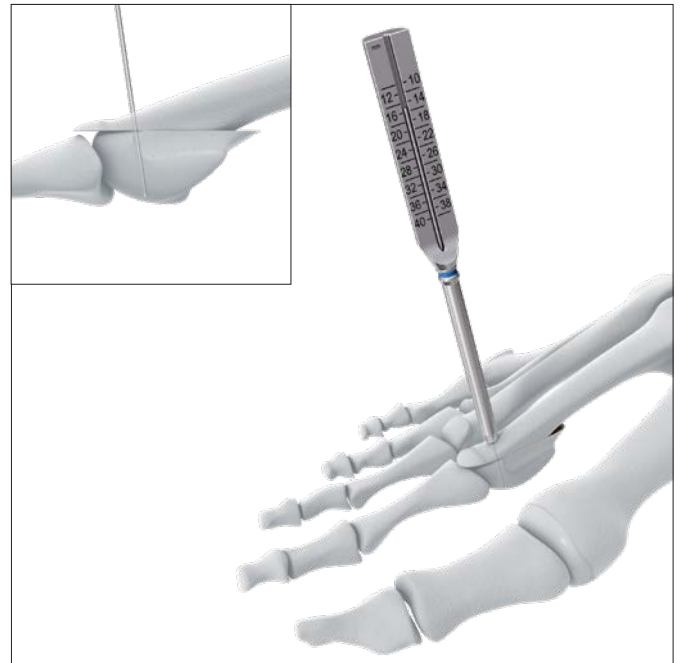
Slide the narrow end of the Direct Measuring Device over the Guide Wire and lower until surface of the bone is touched. The measurement shows the depth of the Guide Wire in the bone.

▲ Precaution:

In the event that the Guide Wire tip has penetrated past the far cortex, subtract the corresponding length. If the screw needs to be countersunk below the surface of the bone, subtract the appropriate length.

■ Note:

In situations where the reduction cannot be controlled with one wire or instruments, use a second stabilization wire to main reduction and alignment.



*Instrument also available sterile packed. Add suffix "S" to Part Number.

4. Load Screw and Insert

Choose Insertion Technique

The Quick Insertion Screw can be inserted using any of the following techniques:

- a. Insertion using the Easy Loader (Screw Loader Device; 03.028.011) under power or manual insertion
- b. Insertion using the Wire Quick Coupling (532.022) of the Power Tool
- c. Insertion using the Manual Screwdriver (03.028.012)

Each screw insertion method is described in the following sections. If the temporary Guide Wire has to be removed from the bone because it is in the position required for the screw, then ensure that alignment of the fragments is maintained.

▲ **Precaution:**

In very hard bone, it is recommended to predrill a hole for the screw using the Guide Wire, in order to reduce the likelihood of premature post separation.

■ **Note:**

Avoid bending or torsion on instruments prior to screw is fully seated.

4a. Insertion using the Easy Loader (Screw Loader Device)

Instruments

03.028.011	Q Insertion Screw Loader Device, for AO Quick Coupling
03.333.600	Handle Small, with Jeweler Cap, with QC, cannulated

To insert the Quick Insertion Screw, first connect the Screw Loader Device to the AO Quick Coupling of the Handle or the power tool. Pick up the desired Quick Insertion Screw, check the correct length and then press the screw firmly into the Screw Loader Device until it is fully seated.

Remove the second Guide Wire from bone if used. Position the screw tip at the predetermined point or in the hole remaining after removal of the second Guide Wire. Angle the screw as required and slowly advance it into the bone while holding the metatarsal head in the correct orientation. Allow the Screw Loader Device to come in contact with the cortical bone. Continue to insert the screw until the screw is fully seated.

The screw head location relative to the bone can be visualized using the laser markings on the Screw Loader Device.

For instructions on reading the laser marking, refer to section below, **Marking on Screw Loader Device**.

Apply a bending force using the Easy Loader Screwdriver to break the post from the screw.

If the screw is not fully seated, use the Manual Screwdriver to complete insertion (see section 4c, **Insertion with Manual Screwdriver**).



After the post has separated from the screw, remove the post from the Screw Loader Device prior to loading another screw or prior to instrument cleaning.

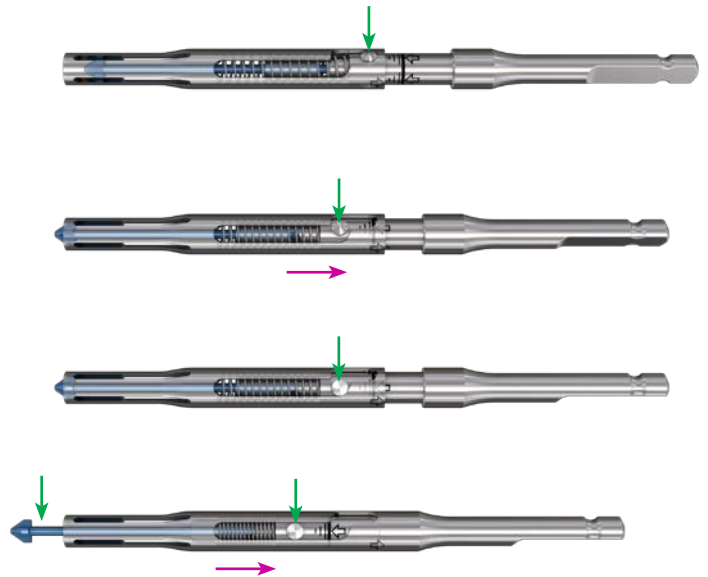
To remove the post, retract the Screw Loader Device sleeve proximally, rotate the sleeve counter clockwise and further retract until the screw post can be removed.

▲ Precaution:

In case of compromised/poor bone quality, stop insertion with power before the head of the screw reaches the cortical bone. Perform final tightening by hand.

■ Note:

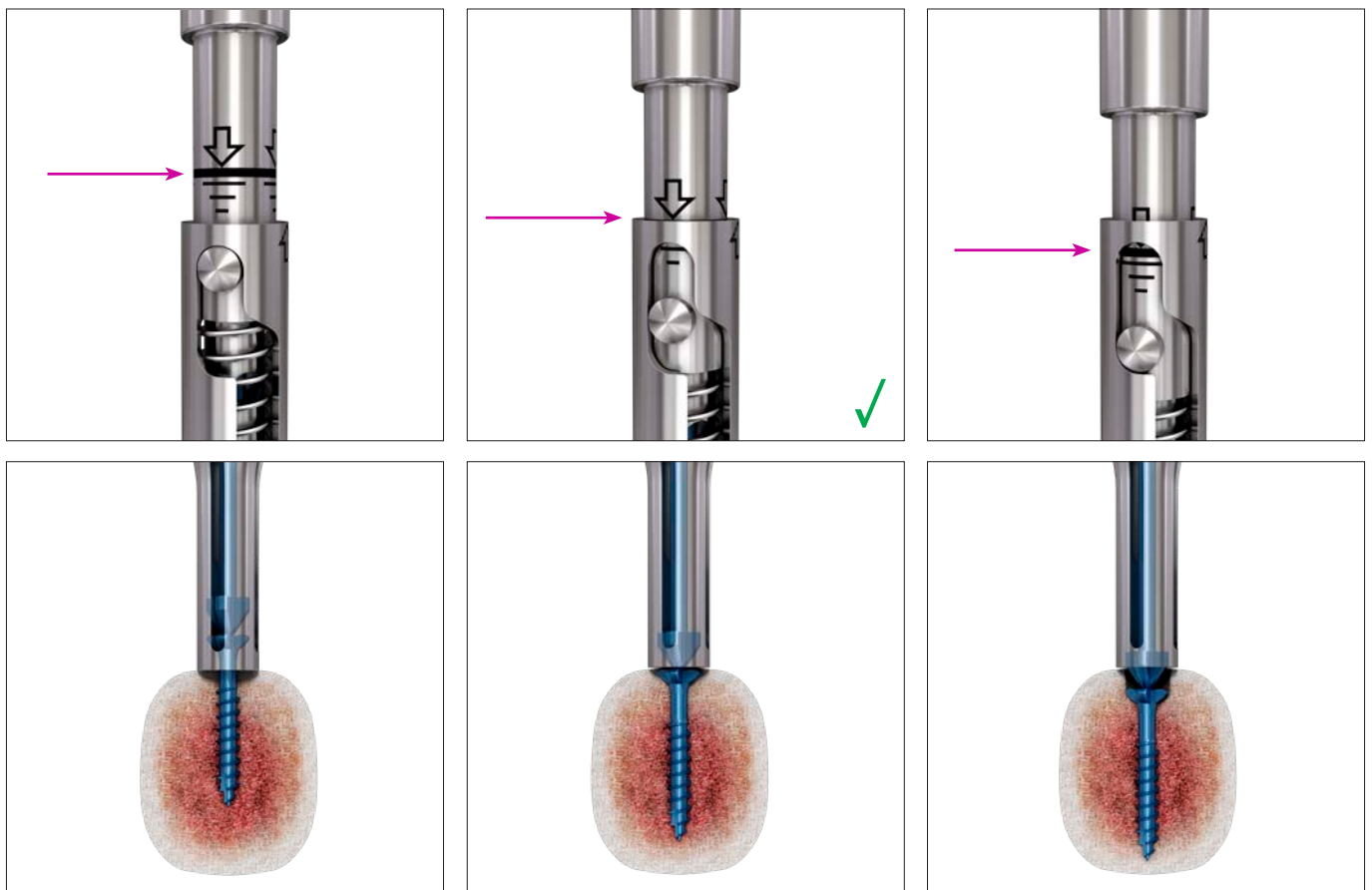
Under power, advance screw slowly in order to avoid over-insertion of the screw.



Marking On Screw Loader Device

The laser etched markings on the Screw Loader Device allow visualization of the screw's advancement into the bone. When the arrows on the sleeve of the Screw Loader Device reach the thick black line, the screw head is at the end of the Screw Loader Device. Please refer to Diagram 1, below.

Diagram 1: Visualization of Screw Advancement into Bone



Screw Proud

Screw Seated Flush

Screw Countersunk

■ Note:

When using the marking on the Screw Loader Device, an axial load must be applied to the driver in order to indicate the screw's advancement into the bone.

Screw depth shown above is only applicable when the Easy Loader Screwdriver is perpendicular to the top surface of the bone.

4b. Insertion with Quick Coupling Under Power

Instrument

532.022 Quick Coupling for Kirschner Wires
Ø 0.6 to 3.2 mm

The Quick Insertion Screw can be inserted using the Quick Coupling on the power tool. Pick up the desired Quick Insertion Screw, check the correct length and engage the Quick Insertion Screw directly into the Quick Coupling for Kirschner Wires.

Remove the second Guide Wire from bone if used. Position the screw tip at the predetermined point or in the hole remaining after removal of the second Guide Wire. Angle the screw as required and slowly advance it into the bone while holding the metatarsal head in its correct orientation. Continue to insert the screw until the screw is fully seated. Apply a bending force using the Quick Coupling to break the post from the screw.

If the post breaks prematurely, use the Manual Screwdriver to complete insertion (see section 4c **Insertion with Manual Screwdriver**).

▲ Precaution:

In case of compromised/poor bone quality, stop insertion with power before the head of the screw reaches the cortical bone. Perform final tightening by hand.

■ Note:

Under power, advance screw slowly in order to avoid over-insertion of the screw.



4c. Insertion with Manual Screwdriver

Instruments

03.028.012	Q Insertion Screw Screwdriver Shaft, for AO Quick Coupling
03.333.600	Handle Small, with Jeweler Cap, with QC, cannulated

The Manual Screwdriver, which is self-retaining, can be used to fully insert a Quick Insertion Screw or to complete fixation once the post has detached from the screw head.

To insert the Quick Insertion Screw, first connect the Manual Screwdriver to the AO Quick Coupling of the Handle or the power tool. Pick up the desired Quick Insertion Screw, check the correct length and then press the screw firmly into the Manual Screwdriver until it is fully engaged.

Remove the second Guide Wire from bone if used. Position the screw tip at the required point and angulation and slowly advance it into the bone while holding the metatarsal head in the correct orientation. Continue to insert the screw until the screw is fully seated. Apply a bending force using the Manual Screwdriver to break the post from the screw.

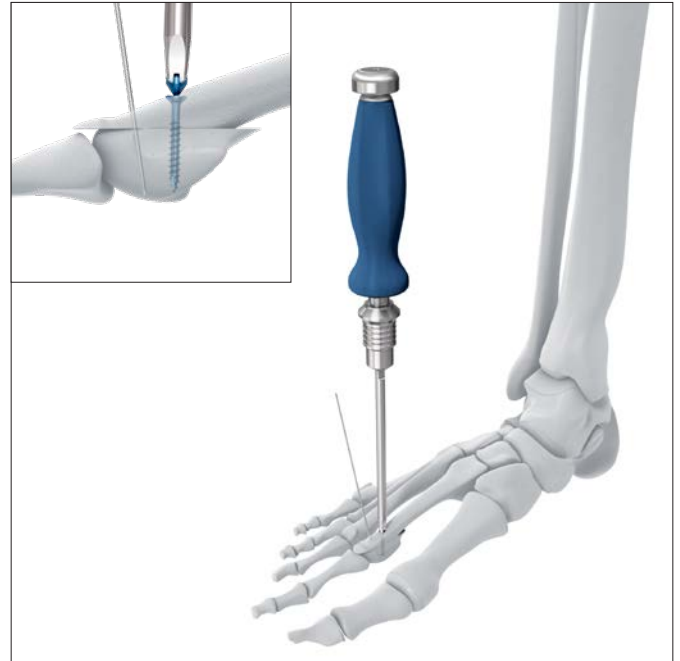
If the screw post breaks away from the screw head prior to being fully seated, reattach the Manual Screwdriver directly to the screw head and complete insertion.

▲ Precaution:

In case of compromised/poor bone quality, stop insertion with power before the head of the screw reaches the cortical bone. Perform final tightening by hand.

■ Note:

If the Manual Screwdriver is used under power, advance screw slowly in order to avoid over-insertion of the screw.



5. Final fixation

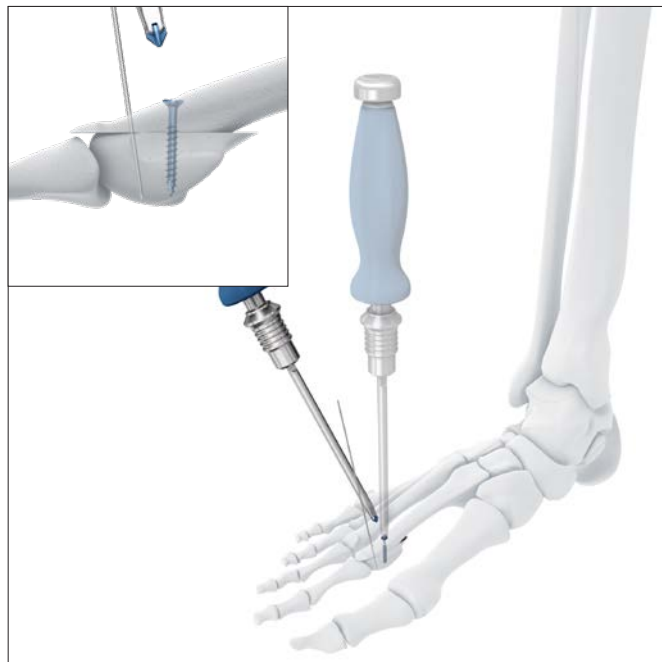
Instruments

03.028.012 Q Insertion Screw Screwdriver Shaft, for AO Quick Coupling

03.333.600 Handle Small, with Jeweler Cap, with QC, cannulated

After achieving fixation, if the screw post is still attached to the screw head, remove the screw post with the Manual Screwdriver attached to the Handle by applying a bending force on the post.

With the screw fully seated and the post detached, remove excess dorsal bone of metatarsal as appropriate and remove the Guide Wire.



Screw Removal (Optional)

Instruments

03.333.600	Handle Small, with Jeweler Cap, with QC, cannulated
03.028.012	Q Insertion Screw Screwdriver Shaft, for AO Quick Coupling
319.390	Sharp Hook, length 155 mm

The Sharp Hook can be used to remove bone fragments and attached tissue from the screw head to allow for engagement of the tip of the Manual Screwdriver to the screw head. For this attach the Manual Screwdriver to the AO Quick Coupling of the Handle and remove screw.

■ Note:

In case of difficult removal circumstances, a Screw Extraction Set – Handling technique is available with corresponding instructions.



Implants and Instruments

Implants

2.0 mm Quick Insertion Screw

The screws are made of Titanium Alloy (TAN).

Part No.	Part No. (sterile)*	Screw length (mm)
04.228.511	04.228.511TS	11
04.228.512	04.228.512TS	12
04.228.513	04.228.513TS	13
04.228.514	04.228.514TS	14
04.228.515	04.228.515TS	15
04.228.516	04.228.516TS	16
04.228.517	04.228.517TS	17
04.228.518	04.228.518TS	18



*Availability might be different depending on the market.

Instruments

03.333.500* Direct Measuring Device for L 100 mm



03.333.000*# Guide Wire Ø 0.8 mm, length 100 mm, with trocar tip



03.333.600* Handle Small, with Jeweler Cap, with QC, cannulated



03.028.011 Q Insertion Screw Loader Device, for AO Quick Coupling



03.028.012 Q Insertion Screw Screwdriver Shaft, for AO Quick Coupling



*Legal manufacturer: Tyber Medical. For Instruction for Use please refer to <https://cchs.info>

#Instrument also available sterile packed. Add suffix "S" to Part Number.

Optional

319.390 Sharp Hook, length 155 mm



532.022 Quick Coupling for Kirschner Wires
Ø 0.6 to 3.2 mm



MRI Information

Torque, Displacement and Image Artifacts according to ASTM F 2213, ASTM F 2052 and ASTM F 2119

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F 2182

Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]).

▲ Precautions:

The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.
- Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effect and Residual Risks. Instructions for Use are available at www.e-ifu.com and/or www.depuyorthosynthes.com/ifu

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