2.0 mm Quick Insertion Screws

Surgical Technique

Instruments and implants approved by the AO Foundation.

DePuy Synthes
PART OF THE JOHNSON & JOHNSON FAMILY OF COMPANIES
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.depuysynthes.com/hcp/reprocessing-care-maintenance

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

Product Description

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 unique Easy Loader Screwdriver is designed to reduce the risk of premature post-breakages of the screw.

In order to minimize the risk of soft-tissue irritation, the Quick Insertion Screw is designed for low profile screw seating and recessed break-off point.

Screw Material and Sizes

• Available in Titanium Alloy (TAN)
• Ø 2.0 mm with 11–18 mm lengths (1 mm 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 (106926-190205 DSEM).
Intended Use and Indications

**Intended use**
The DePuy Synthes 2.0 mm Quick Insertion Screws are intended for bone fractures, repair and reconstructive surgery in forefoot, midfoot and hand.

**Indications**
The DePuy Synthes 2.0 mm Quick Insertion Screws are intended for fixation of fractures, fusions, osteotomies, nonunions, and malunions of the bones of the forefoot, midfoot and hand.
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation\textsuperscript{1,2}.

\begin{itemize}
\item **Anatomic reduction**
Fracture reduction and fixation to restore anatomical relationships.

\item **Early, active mobilization**
Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

\item **Stable fixation**
Fracture fixation providing absolute or relative stability, as required by the patient, the injury, and the personality of the fracture.

\item **Preservation of blood supply**
Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.
\end{itemize}

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 3, 4.

Site Preparation
Prepare the osteotomy site using the preferred technique and instruments.

2. Temporary Fixation

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.333.000</td>
<td>Guide Wire $\odot$ 0.8 mm, length 100 mm, with trocar tip</td>
</tr>
<tr>
<td>03.333.000S</td>
<td>Guide Wire $\odot$ 0.8 mm, length 100 mm, with trocar tip</td>
</tr>
</tbody>
</table>

Provisionally fix bone fragments using a Guide Wire.

Confirm position of fragments under fluoroscopy.

**Note:** The use of general surgical equipment is recommended to protect soft tissue.
3. Screw Length Determination

Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.333.000</td>
<td>Guide Wire Ø 0.8 mm, length 100 mm,</td>
</tr>
<tr>
<td></td>
<td>with trocar tip</td>
</tr>
<tr>
<td>03.333.000S</td>
<td>Guide Wire Ø 0.8 mm, length 100 mm,</td>
</tr>
<tr>
<td>(Sterile)</td>
<td>with trocar tip</td>
</tr>
<tr>
<td>03.333.500</td>
<td>Direct Measuring Device for L100 mm</td>
</tr>
</tbody>
</table>

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.

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.
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**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.028.011</td>
<td>Q Insertion Screw Loader Device, for AO Quick Coupling</td>
</tr>
<tr>
<td>03.333.600</td>
<td>Handle Small, with Jeweler Cap, with QC, cannulated</td>
</tr>
</tbody>
</table>

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 flush with the bone and the post breaks away from the screw.

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** (see page 12).

If the post does not break once the screw head is flush to the bone surface, stop insertion and use Manual Screwdriver to remove post (see Step 5 on page 15, **Final Fixation**).

If the screw is not flush with the bone, use the Manual Screwdriver to complete insertion (see section 4c on page 14, **Insertion using the 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**

![Diagram showing screw advancement](image)

- **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.
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 flush with the bone and the post breaks away from the screw.

If the post breaks prematurely, use the Manual Screwdriver to complete insertion (see section 4c on page 14, *Insertion using Manual Screwdriver*).

If the post does not break once the screw head is flush to the bone surface, stop insertion and use Manual Screwdriver to remove post (see Step 5 on page 15, *Final Fixation*).

**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**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>003.028.012</td>
<td>Q Insertion Screw Screwdriver Shaft, for AO Quick Coupling</td>
</tr>
<tr>
<td>03.333.600</td>
<td>Handle Small, with Jeweler Cap, with QC, cannulated</td>
</tr>
</tbody>
</table>

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 flush with the bone and the post breaks away 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.

If the post does not break once the screw head is flush to the bone surface, stop insertion and use Manual Screwdriver to remove post (see Step 5 on page 15, Final Fixation).

**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**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>003.028.012</td>
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</tr>
<tr>
<td>03.333.600</td>
<td>Handle Small, with Jeweler Cap, with QC, cannulated</td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
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<th>Description</th>
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<tbody>
<tr>
<td>03.333.600</td>
<td>Handle Small, with Jeweler Cap, with QC, cannulated</td>
</tr>
<tr>
<td>03.028.012</td>
<td>Q Insertion Screw Screwdriver Shaft, for AO Quick Coupling</td>
</tr>
<tr>
<td>319.390</td>
<td>Sharp Hook, length 155 mm</td>
</tr>
</tbody>
</table>

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 (DSEM/TRM/0614/0104) is available with corresponding instructions.
Implants and Instruments

Implants

2.0 mm Quick Insertion Screw
The screws are made of Titanium Alloy (TAN).

<table>
<thead>
<tr>
<th>Part No.</th>
<th>Part No. (sterile)*</th>
<th>Screw length (mm)</th>
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<tbody>
<tr>
<td>04.228.511</td>
<td>04.228.511TS</td>
<td>11</td>
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<tr>
<td>04.228.512</td>
<td>04.228.512TS</td>
<td>12</td>
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<td>04.228.513</td>
<td>04.228.513TS</td>
<td>13</td>
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<td>04.228.515TS</td>
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<td>04.228.516</td>
<td>04.228.516TS</td>
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<td>04.228.517</td>
<td>04.228.517TS</td>
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<tr>
<td>04.228.518</td>
<td>04.228.518TS</td>
<td>18</td>
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</tbody>
</table>

* Availability might be different depending on the market.
<table>
<thead>
<tr>
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</tr>
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<tbody>
<tr>
<td>03.333.500*</td>
<td>Direct Measuring Device for L100 mm</td>
</tr>
<tr>
<td>03.333.000*</td>
<td>Guide Wire Ø 0.8 mm, length 100 mm, with trocar tip (Non-Sterile)</td>
</tr>
<tr>
<td>03.333.000S*</td>
<td>Guide Wire Ø 0.8 mm, length 100 mm, with trocar tip (Sterile)</td>
</tr>
<tr>
<td>03.333.600*</td>
<td>Handle Small, with Jeweler Cap, with QC, cannulated</td>
</tr>
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* Legal manufacturer: Tyber Medical. For Instruction for Use please refer to https://cchs.info
<table>
<thead>
<tr>
<th>Optional</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>319.390</td>
<td>Sharp Hook, length 155 mm</td>
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</tr>
<tr>
<td></td>
<td>Ø 0.6 to 3.2 mm</td>
</tr>
</tbody>
</table>
Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-14 and ASTM F 2119-07
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 2182-11a
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.