Instructions for Use
2.0 mm Quick Insertion Screws

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

2.0 mm Quick Insertion Screws:

Art. Nr.	
04.228.511	Quick Insertion Screw ∅ 2.0 mm, length 11 mm, Titanium
04.228.512	Quick Insertion Screw ∅ 2.0 mm, length 12 mm, Titanium
04.228.513	Quick Insertion Screw ∅ 2.0 mm, length 13 mm, Titanium
04.228.514	Quick Insertion Screw ∅ 2.0 mm, length 14 mm, Titanium
04.228.515	Quick Insertion Screw ∅ 2.0 mm, length 15 mm, Titanium
04.228.516	Quick Insertion Screw ∅ 2.0 mm, length 16 mm, Titanium
04.228.517	Quick Insertion Screw ∅ 2.0 mm, length 17 mm, Titanium
04.228.518	Quick Insertion Screw ∅ 2.0 mm, length 18 mm, Titanium
03.028.011	Quick Insertion Screw Loader Device, for AO Quick Coupling
03.028.012	Quick Insertion Screw Screwdriver Shaft, for AO Quick Coupling

Screw Implants are available non-sterile and/or in sterile tube packaging (corresponding article number with suffix "TS")

The Synthes 2.0 mm Quick Insertion Screw System includes self-drilling and self-tapping orthopedic bone screws made from Titanium Alloy (TAN). The screws are 2.0 mm in diameter and range in length from 11 mm to 18 mm in 1 mm increments. The screws are for single patient use only.

The system also includes a self-retaining Quick Insertion Screw Loader Device and Quick Insertion Screw Screwdriver Shaft designed to insert the Quick Insertion Screws.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Device(s)	Material(s)	Standard(s)
Quick Insertion Screws	Ti-6Al-7Nb (TAN) Titanium Alloy	ISO 5832-11

Intended Use
The Synthes 2.0 mm Quick Insertion Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of the bones of the forefoot, midfoot, and hand.

Indications
The Synthes 2.0 mm Quick Insertion Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of the bones of the forefoot, midfoot, and hand.

Contraindications
There are no specific contraindications for the Synthes 2.0 mm Quick Insertion Screws.

Patient Target Group
The product is to be used in respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User
This IFU alone does not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU, the surgical procedures, if applicable, and/or the Synthes "Important Information" brochure as appropriate.
Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly.

Expected Clinical Benefits
Expected clinical benefits of internal fixation devices such as 2.0 mm Quick Insertion Screws when used according to instructions for use and recommended technique are:
– Stabilize bone segment and facilitate healing.
– Restore anatomical relationship which, after bony healing, will restore function.

Performance Characteristics of the Device
Synthes has established the performance and safety of the Quick Insertion Screws and that they represent state of the art medical devices for bone fractures, repair and reconstructive surgery in forefoot, midfoot and hand, when used as intended according to the instructions for use and labeling.

Potential adverse Events, undesirable Side Effects and residual Risks
– Neuro-vascular Damage
– Damage to Surrounding Structures
– Soft Tissue Damage (including Compartment Syndrome)
– Poor Joint Mechanics
– Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage
– Malunion/Non-union
– Bone Damage including Intra-and Post-Operative Bone Fracture, Osteolysis, or Bone Necrosis
– Injury to User
– Adverse Tissue Reaction, Allergy/Hypersensitivity Reaction
– Pain, or Discomfort
– Infection

Sterile Device

Sterilized using irradiation

Store sterile implants in their original protective packaging, and do not remove them from the packaging until immediately before use.


Do not use when packaging is damaged

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged or date of expiration has passed.

Single-Use Device


Do not reuse

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.

Furthermore, re-use or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Warnings and Precautions
– When inserting the Guide Wire: 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.
– When inserting the screw: 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.
– When inserting the screw using a power tool: 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.

Combination of Medical Devices
Quick Insertion Screws can be applied using associated instrumentation, including the following:

03.028.011	Quick Insertion Screw Loader Device, for AO Quick Coupling
03.028.012	Quick Insertion Screw Screwdriver Shaft, for AO Quick Coupling
03.333.000 (S)	Guide Wire ∅ 0.8mm, length 100mm, w/trocar tip
03.333.500	Direct Measuring Device f/L100 mm
03.333.600	Handle Small, w/Jeweler Cap, w/QC, cannulated
319.390	Sharp Hook, length 155 mm
532.022	Quick Coupling f/Kirschner Wires ∅ 0.6 to 3.2 mm

Synthes has not assessed compatibility with devices provided by other manufacturers not listed above and assumes no liability in such instances.

Magnetic Resonance Environment

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.

Treatment before Device is used
Non-Sterile Device: Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information" (SE_023827).

Implant Removal
The Quick Insertion Screws can be removed using the Manual Screwdriver (03.028.012). The sharp hook (319.390) can be used to remove bone fragments and attached tissue from the screw head to allow for proper screwdriver engagement.

In case of difficult removal circumstances, the Screw Extraction Set (036.000.917) may be used.

Troubleshooting
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Clinical Processing of the Device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information" (SE_023827).

Additional Device-Specific Information

Reference Number

Lot or batch number


Manufacturer


Expiration date

Devices provided non-sterile¨


Consult instruction for Use

Disposal
Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Not all products are currently available in all markets.

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