
Instructions for Use Drill bits for Metal

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

Instructions for Use

Drill bits for Metal

Devices in scope:

309.503S
309.504S
309.004S
309.506S
309.006S

Synthes Drill bits for metal, HSS or carbide, are designed for drilling standard and locking screws that are blocked in the plate and are available in various sizes in sterile package configuration.

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.

Intended Use

High speed and carbide drill bits are intended to drill into metal for the removal of locking screws.

Indications

Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The indications/contraindications are based upon the implant devices rather than the instruments. Specific indications/contraindications for the implants can be found in the respective Synthes implant instructions for use.

Contraindications

Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The indications/contraindications are based upon the implant devices rather than the instruments. Specific indications/contraindications for the implants can be found in the respective Synthes implant instructions for use.

Patient Target Group

Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The patient target group is based upon the implant devices rather than the instruments. Specific patient target group for the implants can be found in the respective Synthes implant instructions for use.

Intended User

This instruction for use 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

Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The clinical benefits for the instruments are based upon the implant devices rather than the instruments. Specific clinical benefits for the implants can be found in the respective Synthes implant instructions for use.

Performance Characteristics of the Device

Synthes has established the performance and safety of drill bits for metal and that it represents a state of the art medical device and performs as intended for drilling into non-removable standard and locking screws when used according to the instructions for use and labeling.


Potential Adverse Events, Undesirable Side Effects and Residual Risks

Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The adverse events/side effects are based upon the implant devices rather than the instruments. Specific adverse events/side effects for the implants can be found in the respective Synthes implant instructions for use.


Sterile Device

STERILE R Sterilized using irradiation

Store sterile devices 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.

 Do not resterilize

Re-sterilization of the drill bits can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Single-use Device

 Do not re-use

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.

Warnings and Precautions

- The Drill bits listed here may not be reprocessed or re-sterilized. They are designed for single use only.
- HSS drill bits are hard and brittle. To prevent breakage start drilling with the drill bit already revolving and maintain the chosen drill axis throughout the entire drilling process.
- When drilling, cool with the drill suction device and aspirate the drill chips.
- Do not interrupt the water supply. Ensure that the supply and waste hose is not bent.
- Select the HSS drill bit to drill out screws from steel implants. Drill out titanium screws with carbide drill bits. To remove broken instruments from the screw recess (e.g. tips of screwdrivers, extraction screws), only use the carbide drill bits.

Combination of Medical Devices

Screw/Drill bit chart

Recommended applications

++ good drilling ability
+ sufficient drilling ability
– not recommended

Screw size	Drill bit			Drill bit suitable for		
	Art.No.	∅	Type	TiCP, TAN TAV	Stainless steel	Instrument steel
3.5, 4.0	309.503S	2.5 mm	HSS	+	++	–
3.5,4.0, 4.5, 5.0	309.504S	3.5 mm	HSS	+	++	–
3.5,4.0, 4.5, 5.0	309.004S	4.0 mm	Carbide	++	–	+
5.0, 6.5, 7.0, 7.3	309.506S	4.8 mm	HSS	+	++	–
5.0, 6.5, 7.0, 7.3	309.006S	6.0 mm	Carbide	++	–	+

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

Treatment before Device is Used

The devices are provided sterile. Remove products from the package in an aseptic manner.


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


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


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.

Additional Device-Specific Information

 Reference Number

 Lot or batch number

 Legal Manufacturer

 Expiration date

 Consult instructions 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.

Special Operating Instructions

Removal of screws

Before using the drill bit, attempt to remove the screw with the conical extraction screw. Do not use excessive force to avoid breaking the extraction screw. If this fails, two approaches may be attempted:

- a. Screw without broken instrument: step one and three are not required for removal.
- b. Screw with broken instrument in the screw recess: for complete screw removal all the steps described are necessary.

1. Attempt to remove the broken-off part of the instrument using a sharp hook and/or forceps. If this is unsuccessful, proceed to the next step.

2. Check table "Instruments required for complete screw removal". Prepare the instruments. It is recommended to cover the area around the screw removal site with sterile adhesive film to protect the surrounding soft tissue. Prepare the suction device and the irrigation system.

3. Start drilling with revolving Carbide Drill Bit with the irrigation system and suction device in operation. The direction of drilling should be perpendicular to the fractured surface. Smooth the rough surface. The suction device should be placed close to the tip of the drill bit.

4. Drill continuously without stopping. Axial force is required for efficient drilling. It is recommended to align the axis of the drill bit with the axis of the screw. If axial alignment cannot be achieved, a larger diameter drill bit may be required to separate the plate completely from the screw. The 6.0 mm Carbide Drill Bit can only be used after predrilling with the 4.0 mm Carbide Drill Bit.

5. Drill into the head of the screw until there is no longer a physical connection between the screw and the plate. Then remove the plate.

6. Removing the screw shaft from the patient

a Screw protrudes from the bone

Use the Pliers for Screw Removal. Grip the screw and turn counter-clockwise. Do not pull.

b Screw does not protrude from the bone

Use the Hollow Reamer and the Extraction Bolt. Align the axis of the Hollow Reamer with the axis of the screw. Ream to a depth of 5 mm.

Place the Extraction Bolt over the screw. Whilst pushing, turn counter-clockwise. This will create a tight connection between the conical shape of the thread of the Extraction Bolt and the screw shaft. Turn counter-clockwise until the screw shaft is completely removed.


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