
Instructions for Use

387.013S

Drill Bit \varnothing 2.5 mm, w/Stop, length 270/70 mm, 3-flute

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

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Safety precautions

Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Material

Material: Stainless Steel (SSt) Standard: ASTM F 899, ASTM A 276, ISO 7153-1

The Drill Bit 387.013S is intended for single-use only.

The drill bit has to be used with the help of an image intensifier.

The drill bit may only be used in conjunction with a power tool with the option of a slow start and continuously adjustable increase of speed. Synthes recommends the Electric Pen Drive 60.000 rpm (05.001.010) or the Air Pen Drive (05.001.080). Optional, the Colibri II Battery Power Tool (532.101) or the Compact Air Drive II (511.701) can be used.

The drill bit has to be used with the Guiding Sleeve (387.014), which guides the cutting part of the drill bit. The strengthened shaft and guide sleeve give the drill bit added bending stability, thus meeting the needs for greater precision.

Since the instruments for C1/C2 screw fixation are intended for percutaneous use, they need to be long and are therefore subjected to greater mechanical stresses than short instruments.

Therefore please note the following when using the drill bit:

If the drill bit is not held in a straight line along its axis, the weight of the power tool can exert considerable leverage on the 270 mm drill bit. This will lead to bending, and corresponding stresses, at the weakest part of the drill bit i.e. in the 2.5 mm diameter cutting section. The drill bit can break if

- the drill bit is bent excessively or repeatedly
- and/or

- the drill bit is bent and, simultaneously, a high twisting force is applied to the drill bit via the power tool.

Consequently, the drill bit should be held in a straight line along its axis and the power tool should be operated with minimal twisting force and a low rotational speed.

To avoid the risk of uncontrolled repeated bending stresses, the drill bit is indicated for single surgical use only.

Before starting to drill, check that the drill bit runs concentrically. If this is not the case, overstressing will result, potentially leading to fracture and inaccurate drilling.

If the drill bit is used in conjunction with instruments for computer navigation, please refer to their specific safety and operating instructions.

Do not place heavy objects on top of the drill bit during storage.


Sterile device

STERILE R Sterilized using irradiation

Store medical 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.

Single-use device

 Do not re-use

Products intended for single-use must not be re-used.

Re-use or 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.


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