
Instructions for Use 90° Screwdriver

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



Authorised Representative

DePuy Ireland UC
Loughbeg
Ringaskiddy
Co. Cork Ireland

Instructions for Use

Please read these instructions for use, the DePuy Synthes brochure "Important Information" and the corresponding surgical techniques 90° Screw Driver DSEM/CMF/1115/0098 carefully before use. Ensure that you are familiar with the appropriate surgical technique.

The 90° Screwdriver consists of a screwdriver handle, turning handle, shaft, a screw holder with screw holder inserts and a variety of attachments such as drill bits and screwdriver blades for manual and powered right-angled pre-drilling and insertion of screws. The 90° Screwdriver handle has an ISO 3964/EN 23 964 standard intra-coupling for connecting to an appropriate power source. The 90° Screwdriver may only be used in combination with power sources which are compliant with the guidelines for medical devices.

Instrument Material(s)

Material(s):

Stainless Steel

Aluminum Magnesium Silicon

Polyetheretherketone (PEEK)

Standard(s):

ISO 7153-1

DIN EN 10088-1

DIN EN 10028-7

ASTM F899

ASTM A564

DIN EN 573

ASTM F2026

Intended use

The 90° Screwdriver is intended to enable an intraoral and/or a less invasive approach for drilling and screw insertion into bone within applications such as mandible trauma, orthognathic surgeries, and chest wall trauma and reconstruction.

General Adverse Events

As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:

Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, neurological impairments, etc.), thrombosis, embolism, infection or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hyperreactions, side effects associated with hardware prominence, loosening, bending, or breakage of the device, mal-union, non-union or delayed union which may lead to breakage of the implant, reoperation.

For Sterile Device Components Only

STERILE R Sterilized using irradiation

Store implants 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.

Precautions

The 90° Screwdriver may only be used in combination with power sources which are compliant with the guidelines for medical devices.

For thoracic application only: Use the 2.2 mm MatrixRIB Drill guide for 90° Screwdriver to ensure perpendicular drilling for proper engagement of the locking screw in the plate.

- Do not use force or bend the drill bit when drilling. This may damage the instrument and cause injury to the patient or user.
- Drill speed rate should never exceed 1,800 rpm, particularly in dense, hard bone. This corresponds to a maximum input speed of 3,600 rpm (gear ratio of 2:1). Higher drill speed rates can result in:
 - thermal necrosis of the bone,
 - soft tissue burns,
 - an oversized hole, which can lead to reduced pullout force, increased ease of the screws stripping in bone, suboptimal fixation, and/or the need for emergency screws.

Avoid damaging the plate threads with the drill.

Always irrigate during drilling to avoid thermal damage to the bone.

Irrigate and apply suction for removal of debris potentially generated during implantation or removal.

Screw Insertion:

- Do not use a power source for screw insertion because the high torque may result in screw stripping.

For maxillofacial screw application:

- After partial insertion of the screw, the screw holder needs to be pulled back before fully tightening the screw to allow the screw to fully insert.
- When the screw holder insert is not in use, it can be retracted and positioned behind the screwdriver head for better visibility of the operative site.

When removing the drill bit using the removal instrument, it is recommended to keep one hand over the drill bit as it "pops" up and may fall on the floor.

When removing the screwdriver blade using the removal instrument, it is recommended to keep one hand over the blade as it "pops" up and may fall on the floor.

Allow the device to cool for 2 minutes after drilling or before changing attachments. Improper use may cause the system to overheat and injure the patient or user.

Warnings

To prevent injuries, ensure that the 90° screwdriver is not attached to power when inserting attachments.

These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part should be removed.

Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.

For Disassembly and/or cleaning:

Warning

Universal precautions for handling contaminated/biohazardous materials should be observed.

Combination of medical devices

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

Treatment before device is used

DePuy 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 DePuy Synthes brochure "Important Information".

Device intended to be used by a trained physician

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 of the device

Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the DePuy Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Disassembling multipart instruments" can be downloaded from <http://emea.depuySynthes.com/hcp/reprocessing-care-maintenance>

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Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
Fax: +41 61 965 66 00
www.depuyssynthes.com