Instructions for Use
90° Screw Driver

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

DePuy Synthes
CMF
COMPANIES OF Johnson&Johnson

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Instructions for Use

Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques 90° Screw Driver (036.001.596) carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The Synthes 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

Material(s)

Material(s):	Standard(s):
Stainless Steel	ISO 7153-1
Aluminium	ISO 16061
Nivaflex	ISO 5832-8

Intended use
The 90° Screwdriver is intended for intraoral screw insertion and drilling as well as drilling and placement of MatrixRIB screws via a less invasive approach.

Indications
Mandible trauma, orthognatic sugery and thoracic surgery

Side effects
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, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, nerve and/or tooth root damage 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 hypersensitivity reactions, 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.

Sterile device

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.
Always irrigate during drilling to avoid thermal bone necrosis.
Do not use force or bend the drill bit when drilling. This may damage the instrument and cause injury to the patient or user.
Drilling speed should never exceed 1800 rpm. This corresponds to an input speed of 3600 rpm (gear ratio 1:2).Higher speeds can result in thermal necrosis of the bone and increased hole diameter and may lead to unstable fixation. This clinical relevant drill speed is lower than the theoretical value for instrument protection.
Clinical relevant Drill Speed:

Input Speed (set at power source)	Drill Speed
3600 RPM	1800 RPM

Theoretical maximum Input speed to avoid the mechanical destruction of the screwdriver.

Input Speed (set at power source)	Drill Speed
15 000 RPM	7500 RPM

Screw Insertion
Do not use a power source for screw insertion. The too high torque of the power source may result in screw stripping.
For maxillofacial screw application:
After partially insertion of the screw the screw holder needs to be pulled back before fully tightening of the screw.
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

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

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

Magnetic Resonance environment
CAUTION:
Unless stated otherwise, devices have not been evaluated for safety and compatibility within the MR environment. Please note that there are potential hazards which include but are not limited to:
– Heating or migration of the device
– Artifacts on MR images

Treatment before device is used
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".

Reprocessing of the device
Detailed instructions for reprocessing reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" can be downloaded from http://www.synthes.com/reprocessing

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