

90° SCREWDRIIVER

Minimally invasive drilling and
screw insertion



This publication is not intended for distribution in the USA.

SURGICAL TECHNIQUE

This description alone does not provide sufficient background for direct use of the product. Instruction by a surgeon experienced in handling this product is 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 "Dismantling multipart instruments" can be downloaded from <http://emea.depuyshes.com/hcp/reprocessing-care-maintenance>

TABLE OF CONTENTS

INTRODUCTION	90° Screwdriver	2
	Intended use, Warnings, and General Adverse Events	4
<hr/>		
SURGICAL TECHNIQUE	Assembly	5
	Drilling	7
	Screw Insertion	10
	Disassembly	12

90° SCREWDRIVER

MINIMALLY INVASIVE DRILLING AND SCREW INSERTION

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 drilling and insertion of screws.

Low-profile head

- Minimal overall weight
- Optimized drive design

Reliable force transmission

- Drive shaft designed to transmit the torque required for screw insertion

Drilling

- Suitable for right-angled drilling
- ISO standard intracoupling for connecting to an appropriate power source
- Easy exchange of drill bits and screwdriver blades



Broad range of applications

Minimally invasive predrilling and screw insertion

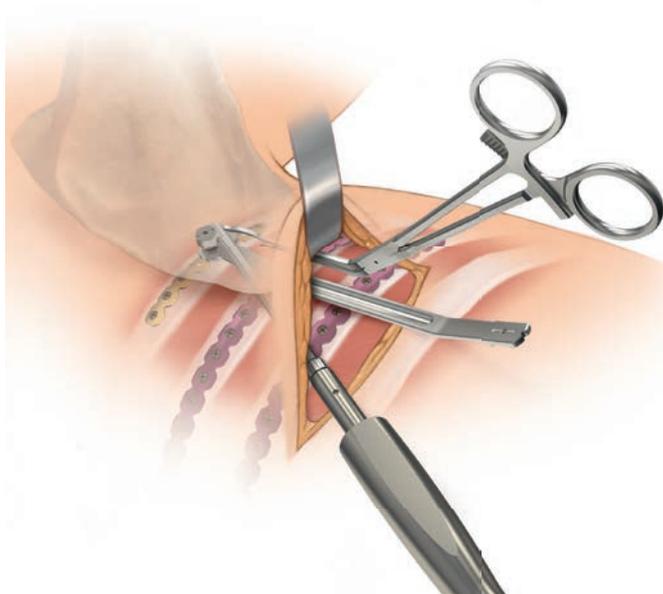
Examples – maxillofacial surgery

- Plate fixation of bilateral sagittal split osteotomies
- Endoscopically supported plate fixation of subcondylar fractures



Example – thoracic surgery

- Subscapula plate fixation for rib fracture treatment



INTENDED USE, WARNINGS, AND GENERAL ADVERSE EVENTS

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.

Warnings

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.

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 musculo-skeletal 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.

ASSEMBLY

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

1 Insert gear

Insert the gear into the head of the shaft.



2 Assemble gear cover to the head of the shaft

Use the pins located on the turning handle to tighten the gear cover in place (must be done before the turning handle is assembled).



3

Insert the axle into the shaft

Note: The shaft 03.505.003 comes preassembled (housing with gear, gear cover and axle).



4

Attach the screw holder

Attach the screw holder to the shaft end of the handle.
Optional: for maxillofacial surgery only.



5

Attach the shaft

Attach the shaft to the threaded end of the handle, press it down in the aligned position and screw the nut on the handle.



6

Attach the turning handle

Attach the turning handle or a power source to the handle.



DRILLING

The 90° screwdriver handle has an ISO 3964/EN 23 964 standard intracoupling for connecting to an appropriate power source.

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



1

Load a drillbit

Load a drill bit by pressing the head of the screwdriver onto the coupling end of the 90° screwdriver drill bit, with the drill bit held in place in the mini module. A distinctive click should be heard and/or felt in order to safely engage the drillbit to the shaft.

2

Remove the turning handle

Remove the turning handle from the screwdriver handle. Insert an appropriate powered drive unit with an intracoupling into the screwdriver handle. The powered drive unit must have an intracoupling in order to connect to the screwdriver handle.



3

Drill hole

Precaution (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.

Precautions: Drill speed rate should never exceed 1,800 rpm, particularly in dense, hard bone. This corresponds to a maximum input speed of 3600 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 pull-out 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.

Do not use force or bend the drill bit when drilling. This may damage the instrument and cause injury to the patient or user.

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.

Clinically 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
15000 RPM	7500 RPM



4

Remove the drillbit

To remove the drill bit, use the insert removal pin located on the module (or use the instrument for removal of inserts) by pressing the pin firmly through the hole in the gear cover.

Precaution: 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.



SCREW INSERTION

1

Load a screwdriver blade

Press the head of the screwdriver onto the coupling of the 90° screwdriver blade, with the blade held in place in a mini module.



2

Insert the screw

Manually turn the turning handle clockwise to insert the screw. To remove the screw, turn the turning handle counterclockwise. Gently rock the screwdriver head from side to side to release the screwdriver blade from the screw head.

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

Note: For mandible trauma and orthognathic surgery emergency screws are available in case of screws not engaging properly into the bone. Refer to MatrixMandible technique guide 03.000.971 and MatrixOrthognathic technique guide 036.000.413.

3

Remove the screwdriver blade

To remove the 90° screwdriver blade, use the insert removal pin located on each module (or use the instrument for removal of inserts) by pressing the pin firmly through the hole in the gear cover.

Precaution: 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.



Option: Screw holder for maxillofacial screw application

1

Attach screw holder insert

Attach the appropriate screw holder insert to the coupling on the screw holder.



2

Secure the screw

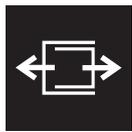
Slide the screw holder forward so that the screw is held securely to the blade by the screw holder insert.

Precautions:

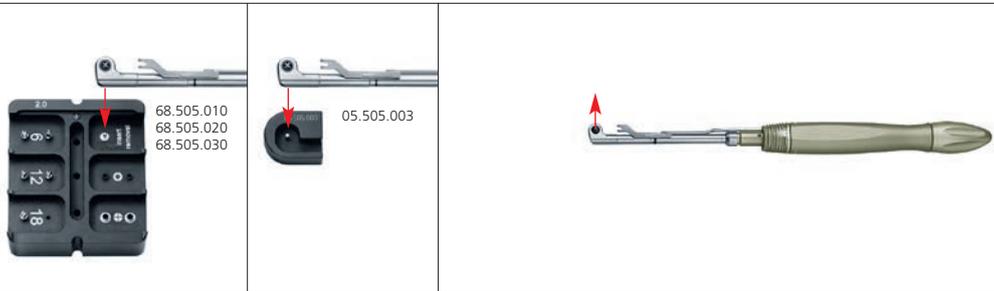
- After partial insertion of the screw, the screw holder needs to be pulled back before fully tightening the screw to allow the screw to be fully inserted.
- When the screw holder insert is not in use, it can be retracted and positioned behind the screwdriver head for better visibility of the operative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



DISASSEMBLY



1



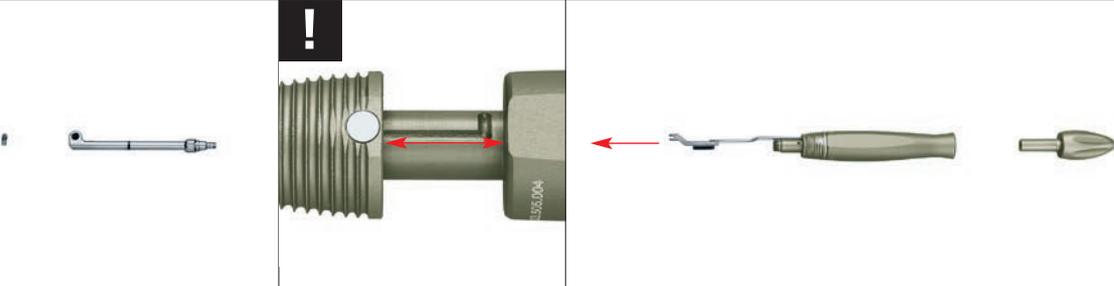
2



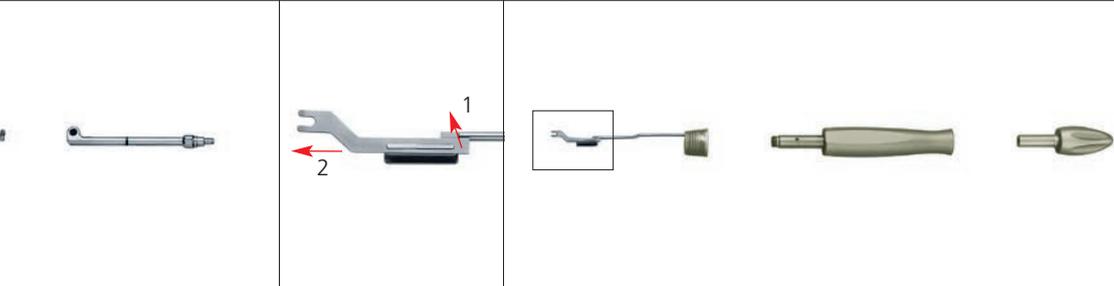
3



4

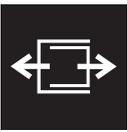


5



6

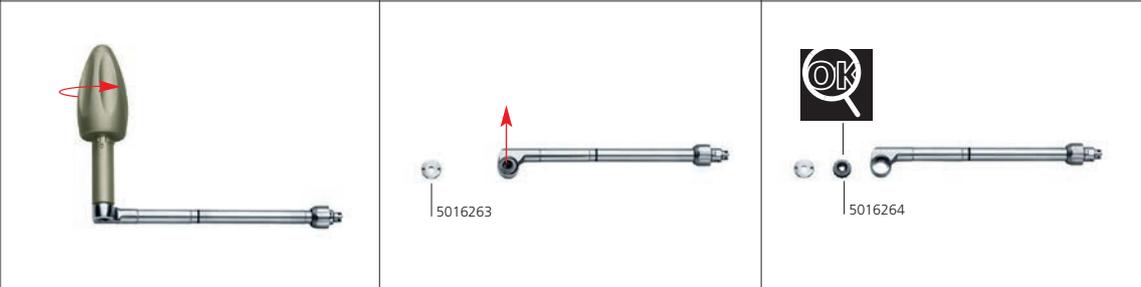




7



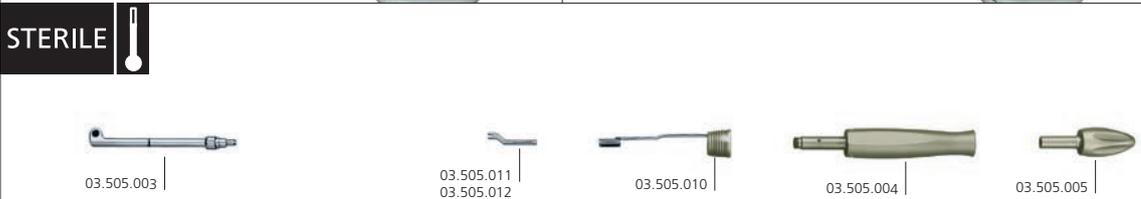
8



9



10



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

