

# 90° Screwdriver. Instructions for disassembly, cleaning and maintenance.

User's Manual



# 90° Screwdriver

The Synthes 90° Screwdriver consists of a screwdriver handle, shaft, screw holder, screw holder insert and a variety of attachments such as drill bits and screwdriver blades for manual and powered right-angled predrilling and insertion of screws.

## Low-profile head

- Minimal overall height
- Optimized drive design
- Easy to clean
- Facilitates intraoral treatment of subcondylar fractures.

## Reliable transmission of force

- Drive shaft designed to transmit the torque required for screw insertion
- Optimized bearings minimize mechanical wear and prolong instrument life

## Broad range of applications

Minimally invasive predrilling and insertion of screws in the mandible, without a transbuccal approach.

Examples:

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

## Screwholder

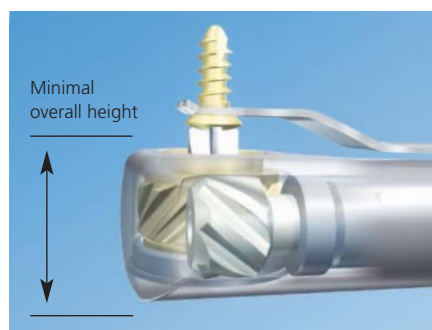
The Screwholder can be turned at an angle behind the head.

- Easier visibility
- Simple handling
- Minimally invasive

## Predrilling

Suitable for right-angled predrilling.

- Can be attached to a power source by removing the Turning Handle: maximum input speed 15,000 rpm
- Adaptor for Intra-Coupling (05.001.103.98) allows the 90° Screwdriver to connect to the Synthes Electric Pen Drive for drilling under power
- Easy exchange of drill bits and screwdriver blades



# Indications and Warnings

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## Indications

The Synthes 90° Screwdriver is indicated for the manual and powered predrilling and insertion of bone fixation screws in oral and maxillofacial surgery.

## Warnings

To prevent injuries, ensure that the 90° Screwdriver is not connected to power when inserting or removing drill bits.

Always use irrigation when drilling under power to minimize the risk of necrosis.

Allow the device to cool for 2 minutes after drilling or before changing attachments.

To minimize the risk of overheating and to ensure optimal function of the instrument and attachments, Synthes recommends the use of the Synthes Maintenance Spray after each use of the 90° Screwdriver. Improper use may cause the system to overheat and injure the patient or user. Refer to the Maintenance section for the manual for more details.

To avoid risk of damage to the instrument or patient, do not exceed the 15,000 rpm maximum input speed for the 90° Screwdriver.

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

# Assembly

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## Instruments

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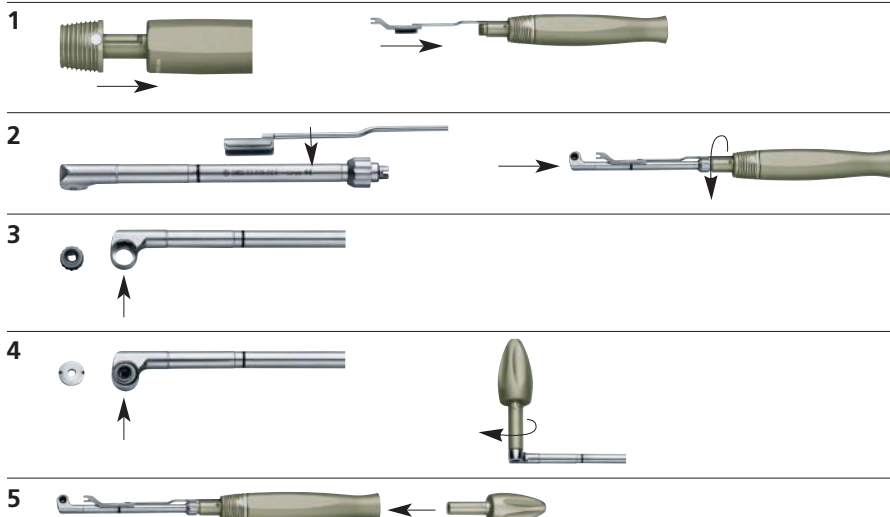
03.505.003	Shaft for 90° Screwdriver
03.505.004	Handle for 90° Screwdriver
03.505.005	Turning Handle for 90° Screwdriver
03.505.007	Gear Cover for 90° Screwdriver
03.505.008	Gear for 90° Screwdriver
03.505.010	Screwholder for 90° Screwdriver, without Insert

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

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- 1 Attach the Screwholder to the shaft end of the Handle.
- 2 Attach the Shaft to the threaded end of the Handle.
- 3 Insert the Gear into the head of the Shaft.
- 4 Assemble the 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.)
- 5 Attach the Turning Handle to the Handle.
- 6 To remove attachments, repeat Steps 1–5 in reverse order.



# Drilling

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## Instruments

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- |               |   |
|---------------|---|
| 05.001.010.98 | Electric Pen Drive, 60,000 rpm                            |
| 05.001.103.98 | Adaptor for Intra-Coupling for Pen Drive                  |
| 05.505.003    | Instrument for Removal of Inserts,<br>for 90° Screwdriver |
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**Note:** The Adaptor for Intra-Coupling, for attachment to the Synthes Electric Pen Drive, meets ISO 3964/EN 23 964 standard.

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**Warning:** Do not exceed 15,000 rpm maximum input speed for 90° Screwdriver. The 90° Screwdriver has a gear ratio of 2:1.

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The 90° Screwdriver Handle has an ISO standard\* intra-coupling for connecting to an appropriate dental power source (Figure 1). The screwdriver can also be connected to the Electric Pen Drive using the Adaptor for Intra-Coupling for Pen Drive.

Remove the Turning Handle from the proximal end of the screwdriver Handle to access the intra-coupling for drilling under power.

To drill with the 90° Screwdriver:

- 1 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.
  - 2 Remove the Turning Handle from the screwdriver Handle, and insert an appropriate powered drive unit with an intra-coupling into the screwdriver Handle. The powered drive unit must have an intra-coupling in order to connect to the screwdriver Handle.
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**Note:** Use the Adaptor for Intra-Coupling with the Electric Pen Drive.

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- 3 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.



05.001.010.98



05.001.103.98



Figure 1



05.505.003

\* ISO 3964/EN 23 964

# Inserting Screws

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## Instruments

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	Screwholder Inserts for Screws,
03.505.011	1.5 mm and 2.0 mm
03.505.012	2.4 mm

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05.505.003	Instrument for Removal of Inserts
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The Screwholder Insert can be used for improved blade retention of screws. When not in use, it can be retracted and positioned behind the screwdriver head for better visibility of the operative site.

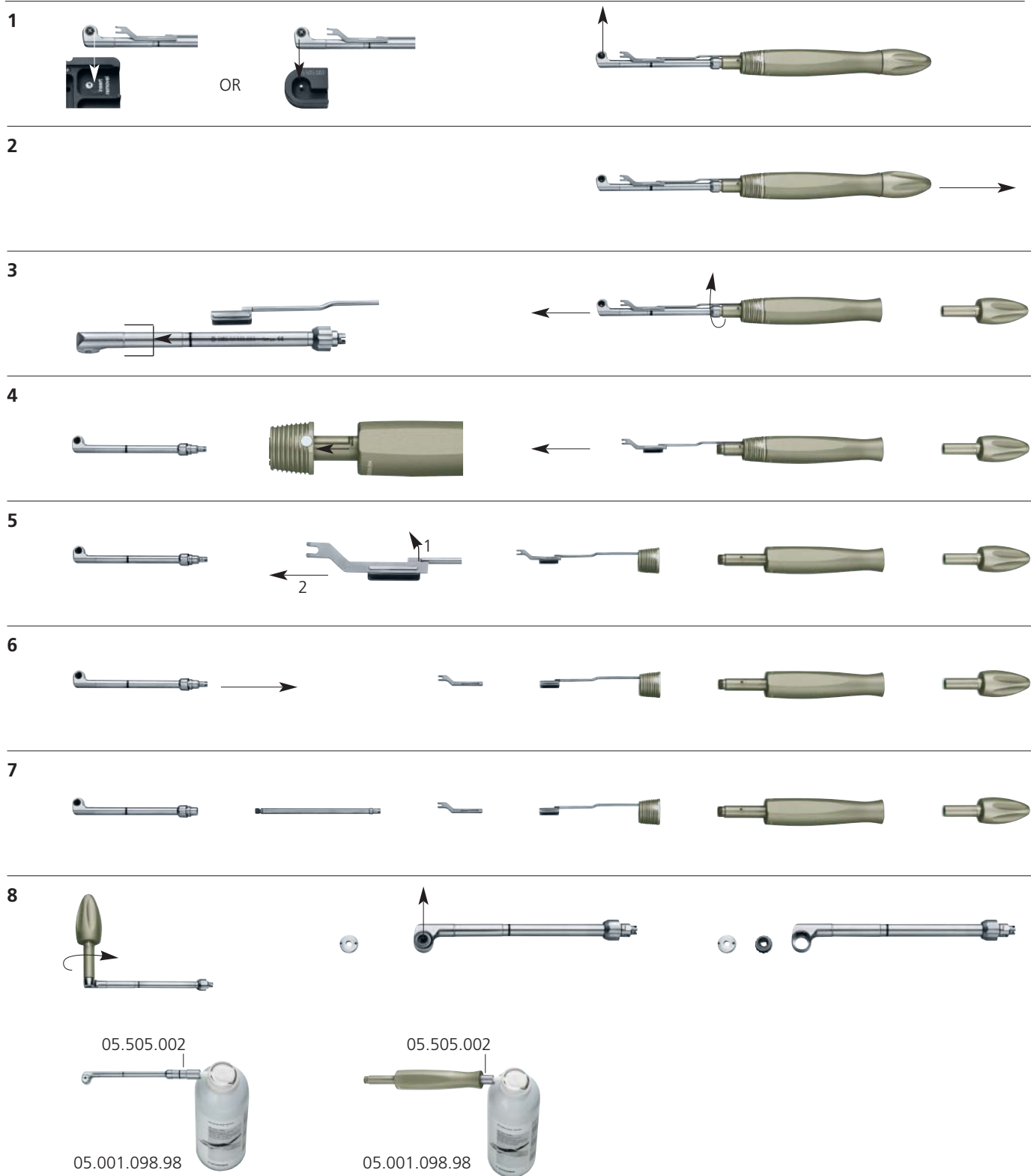
- 1 Attach the appropriate Screwholder Insert to the coupling on the Screwholder.
- 2 Press the head of the screwdriver onto the coupling of the 90° screwdriver blade, with the blade held in place in a mini module.
- 3 Using the holes located on the edge of each module to hold screws, press the screwdriver blade securely into the screwhead.
- 4 Slide the Screwholder forward so that the screw is held securely to the blade by the Screwholder Insert.
- 5 After partially inserting the screw into a predrilled hole, slide the Screwholder back toward the Handle. Turn the Screwholder so that the Screwholder Insert is positioned behind the screwdriver head to provide better visibility of the operative site.
- 6 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 screwhead.
- 7 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.

### Mini module

Easy to pick up and remove screwdriver shafts and drill bits.



# Disassembly



# Cleaning

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## Cleaning

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

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### Preparation for Decontamination

1. The 90° Screwdriver should be reprocessed as soon as is reasonably practical following use.
2. Disassemble the device according to the instructions on page 5 before cleaning.
3. Remove sharp parts for manual cleaning or place into a separate tray.
4. Lumens and cannulas should be manually processed before cleaning.
5. Soak and/or rinse heavily soiled parts or cannulated parts before cleaning, to loosen any dried soil or debris. Use a neutral pH enzymatic soak or detergent to soak parts. Follow the enzymatic cleaner or detergent manufacturer's instructions for use, for correct exposure time, temperature and concentration. Use cool tap water to rinse all parts.
6. Synthes parts must be cleaned separately from Synthes instrument trays and Synthes graphic cases unless otherwise noted. Lids should be removed from the graphic case and modules for the cleaning process, if applicable.
7. It is the responsibility of the end user to ensure that all equipment used to reprocess Synthes devices is properly installed, validated, maintained and calibrated.



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## Mechanical method

### Precleaning

1. Disassemble the 90° Screwdriver according to the instructions on page 5 before cleaning.
2. Rinse soiled parts under running cold tap water for a minimum of two minutes. Remove gross soil using a soft bristled brush or soft, lint-free cloth.
3. Manually clean the device for a minimum of two-and-a-half minutes in a freshly prepared neutral pH enzymatic or detergent solution. Follow the enzymatic cleaner or detergent manufacturer's instructions for the correct dilution, temperature and exposure time. Use a soft-bristled brush to remove soil and debris. Actuate movable device features to expose areas to detergent solution. Clean device under water to prevent aerosolization of contaminants.  
Note: fresh solution is a newly made, clean solution.
4. Rinse the parts using cool to lukewarm running tap water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate moveable device features in order to rinse thoroughly under running water.
5. Visually inspect parts. Repeat steps 2 through 4 until no visible soil remains on device.
6. Assemble components into case and load into an automated washer.

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**Mechanical method**

Equipment: Washer- disinfectant, neutral enzymatic cleaner and/or detergent with a pH  $\leq$  8.5.

Use the following cycle parameters:

<b>Cycle</b>	<b>Time (minutes)</b>	<b>Temperature/Water</b>	<b>Type of Detergent</b>
Prewash	2	Cold tap water	N/A
Enzymatic wash	5	Cool to warm tap water	Neutral pH $\leq$ 8.5
Wash 1	2	Warm tap water ( $>40^{\circ}\text{C}$ )	Detergent with pH $\leq$ 8.5
Rinse	5	Warm to hot DI or PURW ( $>40^{\circ}\text{C}$ )	N/A
Dry	20	$< 120^{\circ}\text{C}$	N/A

**Drying**

If a dry cycle is not included in a mechanical washer or if the device is not processed in a mechanical washer:

- Dry each part thoroughly inside and out to prevent rusting and malfunction.
- Use a soft, lint free cloth to avoid damage to the surfaces.
- Pay special attention to threads, ratchets, and hinges or areas where fluid can accumulate.
- Open and close parts so that all areas are reached.

Dry hollow parts using the air jet with clean compressed air.

# Maintenance

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## Instruments

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05.001.098.98 Maintenance Spray, for Electric Pen Drive

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05.505.002 Spray Adaptor for 90° Screwdriver

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

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Before sterilization, the screwdriver Shaft and the Handle must be oiled. Use the Synthes Maintenance Spray for Electric Pen Drive, as in Step 8 of the disassembly chart, and follow the steps below.

- 1** Reassemble the screwdriver Shaft, as in Step 6 of the disassembly chart.
  - 2** Click the Spray Adaptor onto the Maintenance Spray.
  - 3** Press the assembled screwdriver Shaft tightly onto the Spray Adaptor.
  - 4** Wrap the other end of the Shaft with a cloth to catch excess oil or hold over a wash basin.
  - 5** Apply spray once briefly (approximately 1 sec.). Always spray away from the body.
  - 6** Remove excess oil with a cloth after spraying.
  - 7** Repeat the same procedure (Steps 3–6) for the screwdriver Handle.
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**Attention:** Only use the Synthes Maintenance Spray for Electric Pen Drive. Its composition is compatible with requirements in the operating room. Lubricants with other compositions may compromise the mechanism and void the warranty.

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# Sterilization

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## Sterilization

- Synthes nonsterile devices should be sterilized before use.
- The following are the recommendations for the sterilization of Synthes devices:

Cycle Type	Minimum Sterilization Exposure Time	Minimum Sterilization Exposure Temperature	Minimum Dry Time
Prevacuum	4 minutes	132°C (270°F)	20 minutes

## Notes

- Dry times may be highly variable due to differences in packaging materials (e.g. nonwoven wraps), environmental conditions, steam quality, device materials, total mass, sterilizer performance, and varying cool down time. The user should employ verifiable methods (e.g. visual inspection) for achieving adequate drying, where the manufacturer's recommendations and the user's results differ.
- These parameters are only valid for devices that are adequately cleaned.
- These parameters are only valid for a properly installed, maintained, and calibrated AAMI compliant healthcare sterilizer.

The instructions provided above have been validated by the medical device manufacturer as being capable of preparing a nonsterile Synthes medical device. It remains the responsibility of the processor to ensure that the processing is actually performed, using equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires verification and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

# 90° Screwdriver Set (01.505.002)

## Instrument Tray and Modules

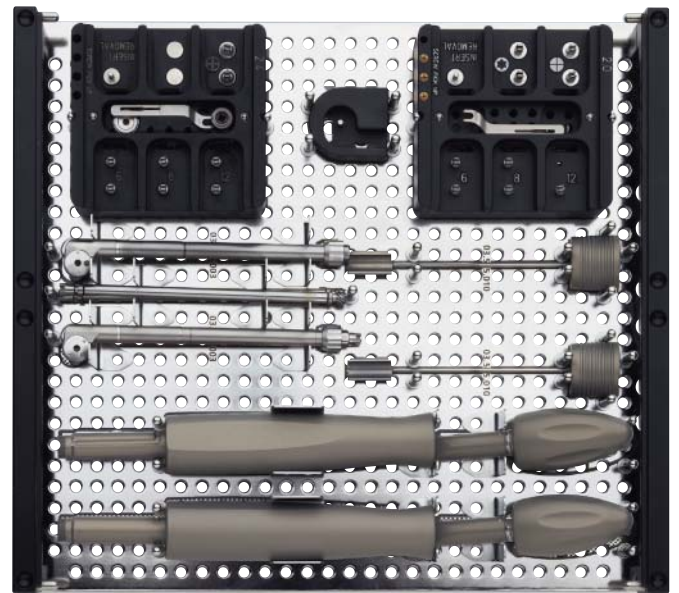
- 60.505.003 Instrument Tray for 90° Screwdriver
- 60.505.004 Mini Module 1.5 mm for Instrument Tray, for 90° Screwdriver
- 60.505.005 Mini Module 2.0 mm for Instrument Tray, for 90° Screwdriver
- 60.505.006 Mini Module 2.4 mm for Instrument Tray, for 90° Screwdriver
- 68.505.009 Lid for Instrument Tray, for 90° Screwdriver

## Instruments

- 03.505.003 Shaft for 90° Screwdriver, 2 ea.
- 03.505.004 Handle for 90° Screwdriver, 2 ea.
- 03.505.005 Turning Handle for 90° Screwdriver, 2 ea.
- 03.505.006 Drivershaft for 90° Screwdriver, 2 ea.
- 03.505.007 Gear Cover for 90° Screwdriver, 4 ea.
- 03.505.008 Gear for 90° Screwdriver, 4 ea.
- 03.505.010 Screwholder for 90° Screwdriver, without Insert, 2 ea.

Screwholder Inserts for Screws, for 90° Screwdriver

- 03.505.011 1.5 mm and 2.0 mm
- 03.505.012 2.4 mm
- 1.0 mm Drill Bits, for 90° Screwdriver
  - 03.505.020 11 mm length, 4 mm stop
  - 03.505.022 15 mm length, 8 mm stop
  - 03.505.024 19 mm length, 12 mm stop
- 1.1 mm Drill Bits, for 90° Screwdriver
  - 03.505.030 11 mm length, 4 mm stop
  - 03.505.032 15 mm length, 8 mm stop
  - 03.505.034 19 mm length, 12 mm stop
- 1.5 mm Drill Bits, for 90° Screwdriver
  - 03.505.041 13 mm length, 6 mm stop
  - 03.505.044 15 mm length, 8 mm stop
  - 03.505.047 19 mm length, 12 mm stop
  - 03.505.065 21 mm length, 14 mm stop
  - 03.505.066 23 mm length, 16 mm stop
  - 03.505.067 25 mm length, 18 mm stop
- 1.8 mm Drill Bits, for 90° Screwdriver
  - 03.505.051 13 mm length, 6 mm stop
  - 03.505.054 15 mm length, 8 mm stop
  - 03.505.057 19 mm length, 12 mm stop



- Cruciform Screwdriver Shafts, self-retaining, for 90° Screwdriver, 2 ea.
  - 03.505.101 1.5 mm/2.0 mm
  - 03.505.103 2.4 mm
- StarDrive Screwdriver Shafts, self-retaining, for 90° Screwdriver, 2 ea.
  - 03.505.110 1.3 mm
  - 03.505.111 1.5 mm
  - 03.505.112 2.0 mm
- PlusDrive Screwdriver Shafts, self-retaining, for 90° Screwdriver, 2 ea.
  - 03.505.120 1.3 mm
  - 03.505.121 1.5 mm/2.0 mm
- 05.505.002 Spray Adaptor for 90° Screwdriver
- 05.505.003 Instrument for Removal of Inserts, for 90° Screwdriver

Note: For additional information, please refer to package insert.

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**Matrix Instrument Tray and Modules**

68.505.042	Instrument Tray for Mini Module for 90° Screwdriver
68.505.043	Lid for 68.505.042
68.505.040	MatrixMANDIBLE Mini Module Tray for 90° Screwdriver
68.505.050	MatrixMIDFACE Mini Module Tray for 90° Screwdriver

03.503.081	MatrixMANDIBLE Screwdriver Blade, self-retaining, for 90° Screwdriver
03.503.083	MatrixMIDFACE Screwdriver Blade, self-retaining, for 90° Screwdriver

**Also Available**

05.001.098.98	Maintenance Spray, for Electric Pen Drive
05.001.103.98	Adaptor for Intra-Coupling for Pen Drive

**MatrixMIDFACE Drill Bits**

	1.1 mm Drill Bits, for 90° Screwdriver
03.505.035	11 mm length, 4 mm stop
03.505.036	13 mm length, 6 mm stop
03.505.037	15 mm length, 8 mm stop
	1.25 mm Drill Bits, for 90° Screwdriver
03.505.026	17 mm length, 10 mm stop
03.505.027	19 mm length, 12 mm stop

**MatrixMANDIBLE Drill Bits**

	1.5 mm Drill Bits, for 90° Screwdriver
03.505.075	13 mm length, 6 mm stop
03.505.076	15 mm length, 8 mm stop
03.505.078	19 mm length, 12 mm stop
	1.8 mm Drill Bits, for 90° Screwdriver
03.505.081	13 mm length, 6 mm stop
03.505.082	15 mm length, 8 mm stop
03.505.084	19 mm length, 12 mm stop
03.505.085	21 mm length, 14 mm stop
03.505.086	23 mm length, 16 mm stop
03.505.087	25 mm length, 18 mm stop
	2.4 mm Drill Bits, for 90° Screwdriver
03.505.091	13 mm length, 6 mm stop
03.505.092	15 mm length, 8 mm stop
03.505.094	19 mm length, 12 mm stop





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