Instructions for Use
Instruments for Universal Small Fragment System

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

EC REP

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DePuy Synthes
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Instructions for Use

Instruments for Universal Small Fragment System

Drill Guides:	**Drill Bits (non-sterile):**	**Drill Bits (sterile):**
03.133.001	03.133.100	03.133.100S
03.133.002	03.133.101	03.133.101S
03.133.003	03.133.102	03.133.102S
03.133.004	03.133.103	03.133.103S
03.133.005	03.133.104	03.133.104S
03.133.006	03.133.105	03.133.105S
03.133.007	03.133.106	03.133.106S
03.133.008	03.133.107	03.133.107S
	03.133.108	03.133.108S
Depth Gauges:	03.133.109	03.133.109S
03.133.080	03.133.110	03.133.110S
03.133.081		
General Instruments:		
Screwdriver Handle	03.133.371	03.133.420
and Shaft:	03.133.374	03.133.421
03.133.150	03.133.375	03.133.424
03.133.175	03.133.376	03.133.425
	03.133.379	03.133.432
Bending Irons:	03.133.380	03.133.434
03.133.200	03.133.384	03.133.435
03.133.201	03.133.385	03.133.436
	03.133.386	03.133.437
Periosteal Elevator:	03.133.387	03.133.438
03.133.202	03.133.388	03.133.439
	03.133.389	03.133.441
3D Templates:	03.133.390	03.133.442
03.133.350	03.133.391	03.133.445
03.133.351	03.133.392	03.133.446
03.133.352	03.133.393	03.133.447
03.133.353	03.133.394	03.133.448
03.133.354	03.133.395	03.133.450
03.133.355	03.133.396	03.133.453
03.133.356	03.133.397	03.133.454
03.133.357	03.133.398	03.133.455
03.133.358	03.133.399	03.133.456
03.133.360	03.133.400	03.133.457
03.133.361	03.133.406	03.133.458
03.133.362	03.133.407	03.133.463
03.133.363	03.133.410	03.133.464
03.133.366	03.133.411	03.133.465
03.133.367	03.133.412	03.133.466
03.133.368	03.133.413	03.133.467
03.133.369	03.133.416	
03.133.370	03.133.417	

The Universal Small Fragment System consists of two components: 1) A core set of instruments, screws, and standard implants; and 2) modular anatomic implant trays for the supported small fragment anatomy. In addition, the core set can support all 2.7 mm/3.5 mm DePuy Synthes non-locking, LCP®, and VA LCP® plating technologies.

The present Instructions for Use apply to the listed devices.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read this instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Device(s)	**Material(s)**	**Standard(s)**
Drill Guides	17-4 PH Stainless Steel	ASTM F899
	PAEK	ASTM D6262
	Custom 465 Stainless Steel	ASTM F899
Depth Gauges	304 Stainless Steel	ASTM F899
	17-4 PH Stainless Steel	ASTM F899
	304 Stainless Steel	ASTM F899
	PAEK	ASTM D6262
Drill Bits	440A Stainless Steel	ASTM F899
Screwdriver Handle	17-4 PH Stainless Steel	ASTM F899
	304 Stainless Steel	ASTM F899
	302 Stainless Steel	ASTM F899
	420A Stainless Steel	ASTM F899
	420B Stainless Steel	ASTM F899
	Santoprene	ASTM F2042 / F2038
	Polypropylene	None
Screwdriver Shaft	Custom 465 Stainless Steel	ASTM F899
Bending Iron	Custom 465 Stainless Steel	ASTM F899
Periosteal Elevator	Santoprene	ASTM F2042/2038
	Polypropylene	None
	420A Stainless Steel	ASTM F899
3D Templates	17-4 PH Stainless Steel	ASTM F899

Intended use
The Universal Small Fragment System is used by the surgeon in the fixation of implants for small fragment fractures where 2.7 mm/3.5 mm non-locking, LCP and VA LCP plating technology is utilized. It is not intended for use in craniomaxillofacial and spine.

Indications
For specific indications related to 2.7 mm/3.5 mm Plate Systems refer to the corresponding labelling of the system being used.

Contraindications
For specific contraindications related to 2.7 mm/3.5 mm Plate Systems refer to the corresponding labelling of the system being used.

Patient Target Group
For specific patient target groups related to 2.7 mm/3.5 mm Plate Systems refer to the corresponding labelling of the system being used.

Intended User
This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU, the surgical procedures, if applicable, and/or the Synthes "Important Information" brochure as appropriate. Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly.

Expected Clinical Benefits
Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The clinical benefits for the instruments are based upon the implant devices rather than the instruments. Specific clinical benefits for the implants can be found in the respective Synthes implant instructions for use.

Performance Characteristics of the Device
Synthes has established the performance and safety of the Universal Small Fragment System, and that they represent state of the art medical devices for surgical treatment and stabilization of fractures in various anatomical regions when used according to their instructions for use and labeling.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The adverse events/side effects are based upon the implant devices rather than the instruments. Specific adverse events/side effects for the Implants can be found in the respective Synthes implant instructions for use.

Sterile device

STERILE R Sterilized using irradiation

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.

Do not use when packaging is damaged

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged or date of expiration has passed.

Single-use device

Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical 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.

Measuring Device
Purpose of Measuring Device: Depth Gauges below are intended to measure quantitatively an anatomical parameter of the human body:

Parts

03.133.080	Depth Gauge 2.7/3.5 mm, 0 to 60 mm Measuring Range: 0 to 60 mm, maximum measurement: 66 mm
03.133.081	Depth Gauge 2.7/3.5 mm, 40 to 100 mm Limit of Accuracy: +/- 0.5 mm Measuring Range: 40 to 100 mm, maximum measurement: 106 mm Limit of Accuracy: +/- 0.5 mm

Warnings and Precautions
- Instruments may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Handle devices with care and dispose of worn bone cutting instruments in an approved sharps container.
- When using sterile packed instruments, use proper operating room aseptic technique.
- Do not strike the back of the Periosteal Elevator.
- Use of incorrect instrumentation for bending may weaken the plate and lead to premature plate failure (e.g. breakage).
- Do not bend the plate using the threaded drill guide. Damage may occur to the plate hole threads.
- Do not measure with the calibration on drill bits when using lag screw technique.
- Non-Locking Drill Guides should not be used for screw insertion in locking and variable angle locking screw holes.
- Neutral (i.e., centered) sleeve adaptors are not designed for use with LCP Locking holes or variable angle locking holes. They should be used only with non-threaded holes or the non-threaded portion of Combi holes.
- Avoid excessive angulation when using the Neutral Sleeve Adapter in the non-threaded holes and stay nominal to the central axis of the hole.
- Ensure the drill bits do not contact the side of the plate holes.
- Avoid applying excessive force on drill guides.
- Avoid overtorquing when threading the drill guide into locking and variable angle locking screw holes.
- Overtorquing can give a false impression of guide seating. Overtorquing and cross threading may cause screw hole damage.
- Improper placement of threaded drill guide can lead to locking screws not locking into the locking plate hole.
- Use care in carefully pushing in depth gauge measuring insert hook tip. Hook tip may be sharp and may pinch or tear user's glove or skin.
- Use the Holding Sleeve (314.060) along with the 2.5 mm hex shaft if the self-retaining hex driver shaft does not retain screw during removal from the screw rack.
- Speed of drilling and speed of screw insertion directly correlate to temperature at the bone interface. High temperatures could impact screw to bone interface and may impact clinical outcome.
- Do not implant template.
- Ensure proper plates selection by verifying the L(left) and R(right) etching on the trial implant.
- Do not contour or bend template.
- Template use with drill bit is not permitted.
- Aseptic technique should be followed.

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
Refer to the corresponding plate labeling for additional instructions or information essential to safe use in the MR environment.

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 in this Instructions for Use.

For Synthes products provided in a sterile condition: Remove products from the package in an aseptic manner. Store them 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.

Implant Removal
For specific implant removal instruction, refer to the labelling of the implant being removed.

Troubleshooting
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the state in which the user and/or patient is established.

Clinical Processing of the Device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Reprocessing of the devices in corresponding trays specific to the Universal Small Fragment System can be found in SE_736845 which is also available online. Assembly and disassembly instructions of instruments "Dismantling multipart instruments" can be downloaded from the website.

Assembly and Disassembly Depth Gauges
The 2.7/3.5 mm Depth Gauge is available in two length measurements ranging from 0 to 60 mm (03.133.080) and from 40 to 100 mm (03.133.081). The depth gauge consists of two parts: a metal sleeve and the measuring insert with hook tip.

Depth Gauge Assembly
The depth gauge 0 to 60 mm appears in the Insertion Tray disassembled into two pieces: the metal sleeve and the measuring insert with hook tip. To assemble, insert the measuring insert through the sleeve. Match the depth gauge key to the top of the depth gauge sleeve D-shape and gently advance towards the measuring insert handle until it stops (1). Rotate 180 degrees in one direction while gently advancing toward the handle until a stop is felt (2).Turn another 180 degrees in the opposite direction with gentle pressure applied on the sleeve towards the handle (3). Advance the remainder of the insert down the depth gauge sleeve until the sleeve meets the depth gauge handle (4).

Depth Gauge Disassembly
To disassemble, advance the sleeve away from the handle until it stops at the hook tip. Push in hook tip to slide sleeve over the hook. The sleeve will stop at the key feature. Reverse steps for assembly described above to complete disassembly. (1 and 2).

Disposal
Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Special Operating Instructions

3D Template Steps
1. Prior to using a template, complete the preoperative radiographic assessment and prepare the preoperative plan.
2. Use template to determine implant selection.
   a. Select the appropriate template according to anatomy and fracture type being considered.
   b. Optional step: Use a ruler in conjunction with template to ascertain correct implant length.
   c. Select corresponding implant needed for surgery.
3. Optional step if using template intraoperatively: Temporarily secure template to patient anatomy using 1.25 mm, 1.6 mm, or 2.0 mm K-wire(s).

Not all products are currently available in all markets.

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