Instructions for Use
Instruments for Universal Small Fragment System

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Printed on: Mai 20, 2019

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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 SE_737400 AA 02/2019

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:
03.133.150
03.133.175
03.133.200
03.133.201
03.133.202

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 OR 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 carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Device(s)	**Material(s)**	**Standard(s)**
Drill Guides	17-4 PH Stainless Steel	ASTM F 899/A 564
	PAEK	ASTM D6262
Depth Gauges	440A Stainless Steel	ISO 7153-1
	PAEK	ASTM D6262
Drill Bits	440A Stainless Steel	ISO 7153-1
Screwdriver Handle	17-4 Stainless Steel	ASTM F899/A564
	304 Stainless Steel	ASTM F899/A276
	302 Stainless Steel	ASTM F899/A313
	420A Stainless Steel	ISO 7153-1
	420B Stainless Steel	ISO 7153-1
	Santoprene	ASTM F2052 / F2038
	Polypropylene	–
Screwdriver Shaft	465 Stainless Steel	ASTM F899/A564
Bending Iron	465 Stainless Steel	ASTM F899/A564
Periosteal Elevator	Santoprene	ASTM F2052/2038
	Polypropylene	–
	420A Stainless Steel	ISO 7153-1

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, radiologists, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU and the surgical technique. Implantation is to take place according to the instructions for use following the recommended surgical technique. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly. The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating.

Clinical Benefits
Based on the clinical evaluation, all residual risks are deemed acceptable when weighed against the benefits to the patient based on current knowledge/the state of the art.

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 in conjunction with plates implants and according to their instructions for use and labeling.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
- Surgical Delay
- Damage to surrounding structures
- Injury to User
- Infection
- Adverse Tissue Reaction
- User Dissatisfaction
- Device loosening
- Malunion/non-union
- Bone Damage
- Poor Joint Mechanics
- Device Breakage

Sterile device

Sterilized using irradiation

Store sterile implants 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

For the limits of accuracy of the Depth Gauges, see eIFU for Measuring Instruments.

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.

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.

Not all products are currently available in all markets.

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