
Instructions for Use

Instruments for Universal Small Fragment System

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



Authorised Representative

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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 re-sterilization) 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 overtightening when threading the drill guide into locking and variable angle locking screw holes.
- Overtightening can give a false impression of guide seating. Overtightening 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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