Instructions for Use
Cases and Trays for the Universal Small Fragment System

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

Cases and Trays for the Universal Small Fragment System

Cases and Trays:
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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)
Trays	AL 5052 Aluminum Alloy	ASTM B209M, B221M, B221M
	AL 6061 Aluminum Alloy	ASTM B209M, B221M, B221M
	304 Stainless Steel	ASTM F899
	305 Stainless Steel	ASTM A276
	Silicone	ASTM F2042/F2038
	Radel PPSU*	ISO16061
Lid for Trays	AL 5052 Aluminum Alloy	ASTM B209M, B221M, B221M
	301 Stainless Steel	ASTM F899
	304 Stainless Steel	ASTM F899
	305 Stainless Steel	ASTM A276
Outer Case	AL 5052 Aluminum Alloy	ASTM B209M, B221M, B221M
	304 Stainless Steel	ASTM F899
	305 Stainless Steel	ASTM A276
	Silicone	ASTM F2042/F2038
	Santoprene	ASTM F2042/F2038
Outer Case Lid	AL 5052 Aluminum Alloy	ASTM B209M, B221M, B221M
	AL 6061 Aluminum Alloy	ASTM B209M, B221M, B221M
Screw Rack	AL 5052 Aluminum Alloy	ASTM B209M, B221M, B221M
	AL 6061 Aluminum Alloy	ASTM B209M, B221M, B221M
	301 Stainless Steel	ASTM F899
	304 Stainless Steel	ASTM F899
	305 Stainless Steel	ASTM A276
	Silicone	ASTM F2042/F2038
	Santoprene	ASTM F2042/F2038
	Viton 75 Fluorocarbon	None

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 and the surgical procedures. 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 cases and trays intended to prepare the site and aid in implantation of Synthes implants. The clinical benefits for the cases and trays are based upon the implant devices rather than the cases and trays. 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.

Combination of Medical Devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances

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.

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

Cleaning – Automated Method

1. Prepare a neutral enzymatic or mild alkaline cleaning solution (pH 7 to 9) in accordance to the detergent manufacturer's instructions. The temperature of the solution should be ≤40 °C (104 °F) for manual cleaning.
   NOTE: The cleaning solution may contain enzymes. Aluminum-safe alkaline cleaners can be used but can vary in material compatibility overtime based on their formulation. Material compatibility should be confirmed with the detergent manufacturer.
2. Fully immerse tray with devices (in the designated locations) in the detergent solution, and soak for a minimum of 5 minutes. The tray lid should not be attached to the tray during processing.
3. While immersed, use a soft non-metallic bristle brush (plastic bristles, like nylon) to thoroughly scrub all traces of blood and debris from all device surfaces for at least one minute. Remove device from tray and manually brush under the detergent solution.
4. Ensure all lumens are thoroughly brushed. Push the brush through the entire length of the lumen using a twisting motion to remove debris from both ends for at least one minute.
5. During cleaning, actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable.
6. Place device into tray and repeat for each device within the tray.
7. Load tray with devices into the washer-disinfector in accordance with manufacturer's instructions, ensuring that the devices and lumens can drain freely.

Automated washing shall be conducted in a validated washer-disinfector in compliance to ISO 15883-1 and-2, or to an equivalent standard. Automated washing can be included as part of a validated washing, disinfection, and/or drying cycle in accordance to manufacturer's instructions. An example of a validated cycle used for cleaning validation included:

Phase	Recirculation Time (mins)	Water Temp	Detergent/ Water Type
Pre-Wash	2	Cold Tap Water	N/A
Enzyme wash	1	<40 °C (104 °F)	Neutral, Enzymatic Cleaner
Wash	5	66 °C (151 °F)	Neutral, pH Detergent
Rinse	2	>40 °C (104 °F)	Tap water
Rinse	0.25	Warm Water	Critical water (RO, deionized or distilled water)

Thermal Disinfection

Thermal disinfection is recommended to render devices safe for handling prior to steam sterilization. Thermal disinfection should be conducted in a washer-disinfector compliant to ISO 15883-1 and-2, or to an equivalent standard. Thermal disinfection in the washer-disinfector shall be validated to provide an A0 of at least 600 (e.g., 90 °C (194 °F) for 1 min). Higher levels of A0 can be achieved by increasing the exposure time and temperature (e.g., A0 of 3000 at >90 °C (194 °F) for 5 min, in accordance with local requirements). Load the device components in the washer-disinfector in accordance with manufacturer's instructions, ensuring that the devices and lumens can drain freely. Lumened devices should be placed in a vertical position. If this is not possible due to space limitations within the washer-disinfector, use an irrigating rack /load carrier with connections designed to ensure an adequate flow of process fluids to the lumen or cannulation of the device if provided.

The following automated cycle is an example of a validated cycle:

Phase	Recirculation Time (mins)	Water Temp	Water Type
Thermal Disinfection	5	>90 °C (194 °F)	Critical water (RO, deionized or distilled water)

Drying

It is recommended that drying is conducted in a washer-disinfector compliant to ISO 15883-1 and -2, or to an equivalent standard. Drying efficiency in washer-disinfectors can range considerably based on the automated system design and load configuration.

The following automated cycle is an example of a validated cycle:

Phase	Recirculation Time (mins)	Air Temp	Air Type
Dry	7	115 °C (239 °F)	Medical grade

Following automated drying, inspect the device for residual moisture. Any residual moisture identified should be dried manually (as described below).

For manual drying

- Ensure each device is dried and inspected thoroughly.
- For external surfaces, use a clean, soft, lint-free cloth to avoid damage to the surface.
- Open and close or actuate any applicable devices with moving parts during drying. Pay special attention to any device threads, ratchets and hinges or areas where fluid can accumulate. Clean, compressed air (e.g., medical grade) may be used to facilitate surface drying.
- Dry all lumen/cannulated parts using clean compressed air (e.g., medical grade)

Inspection

Instruments should be visually inspected under ambient lighting, to verify that the devices do not have visible soil, damage or moisture.

Inspect devices for:

- Lack of moisture. Carefully inspect device lumens and moving parts. If moisture is detected, manually drying should be performed.
- Cleanliness. If any residual soil is discovered during inspection, repeat the cleaning steps on those devices until all visible soil is removed from the device.
- Damage, including but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks and wear.
- Proper function, including but not limited to, sharpness of cutting tools, bending of flexible devices, movement of hinges/joints/box locks and moveable features such as handles, ratcheting and couplings and missing or removed part numbers.

Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and worn devices should be discarded.

Disassembled devices should be reassembled prior to sterilization when specified.

Lubricate any moving parts with a water-soluble surgical instrument lubricant. The lubricant should be approved for use on medical devices and provided with data to ensure biocompatibility and compatibility with steam sterilization.

Packaging

Place cleaned, dry devices into the specified locations within the cases provided, if applicable. Only legally marketed, and locally approved sterilization barriers (e.g. wraps, pouches or containers) should be used for packaging terminally sterilized devices, in compliance to the manufacturer's instructions.

Sterilization

Steam (moist heat) sterilization shall be performed in a locally approved, prevacuum (forced air removal) cycle. The steam sterilizer should be validated to the requirements of any local standards and guidance such as EN 285 or AAMI/ ANSI ST8. The steam sterilizer should be installed and maintained in compliance to manufacturer's instructions and local requirements. Ensure that the steam sterilizer cycle is chosen that is designed to remove air from porous or lumened device loads in accordance to manufacturer's instructions and does not exceed the criteria for sterilizer load.
The following steam sterilization cycles are examples of validated cycles:

Conditioning Phase	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Dry Time
Prevacuum	4	132 °C (270 °F)	20–50 minutes
Prevacuum	3	134 °C (274 °F)	20–50 minutes

Extended steam exposure cycle can be used to meet local requirements such as 134 °C (274 °F) for 18 minutes.

The efficiency of steam sterilizer drying can range considerable depending on the sterilizer design, loading, packaging and steam supply during the sterilization process. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying. Extended drying within the sterilizer or in an externval drying cabinet in accordance with manufacturer's instructions may be necessary. Do not exceed 140 °C (284 °F) during drying. Immediate-use steam sterilization is only intended for individual instruments and should only be considered under emergency situations and when approved by local policies. DePuy Synthes does not support immediate-use steam sterilization of instrument sets, cases or implants using this method. The following steam sterilization cycle is an example of a validated cycle for individual instruments only:

- Unwrapped instrument 132 °C (270 °F) for 4 (four) minutes

Storage
Sterilized products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity. Refer to sterilization wrap or rigid container manufacturers IFU for limits on sterile product storage time and storage requirements for temperature and humidity.

Additional Information
Cleaning agent information: Examples of detergents that have been used during cleaning validations include Prolystica™ 2X Concentrate Enzymatic Cleaner, Prolystica™ 2X Neutral Detergent, Enzol™, Endozime™, Neodisher Medizym™, Terg-A-Zyme™, and NpH-Klenz™. Further information regarding the use of specific cleaning agents, ultrasonic washers, washer-disinfector, packaging materials or sterilizers during validation studies are available on request. The chemical quality of the water used during reprocessing can impact device safety. Facilities should use the recommended water quality requirements for device reprocessing in accordance with local guidance (such as AAMI TIR 34, Water for the reprocessing of medical devices) and these instructions for use. These instructions for use have been validated in accordance with ISO 17664. It remains the responsibility of the facility to ensure that the processing is performed using equipment, materials and personnel at a designated area, and achieves the desired requirements. This includes verification and/or validation and routine monitoring of the process. Likewise, any deviation by the processor from these recommendations should be evaluated for effectiveness and any potential adverse consequences. All personnel using these instructions should be qualified with documented expertise, competency and training. Users should be trained on healthcare facility policies and procedures along with current applicable guidelines and standards.

Manufacturer Contact
For further information, contact your local Synthes sales representative.

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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