Universal Small Fragment System

System Tutorial

This document is intended for use as an in-service training on the Universal Small Fragment System and assumes that a demo system is present simultaneously and teams are familiar with basic instrumentation and implants used in other 2.7mm / 3.5mm DePuy Synthes Plating Systems.
FOR USE WITH OPERATING ROOM STAFF
Introduction

The Universal Small Fragment System is intended to be used for small bone trauma, including anatomy such as Shoulder, Clavicle, Elbow, Tibia and Fibula.

The core set can support any DePuy Synthes 2.7mm or 3.5mm non-locking, LCP® or VA LCP® Implant System¹

Training topics for USF
• System Trays
• Instruments

¹. Universal Small Fragment Surgical Technique Guide
Universal Small Fragment (USF) System

System Trays

✓ Core Set
✓ Anatomic Implant Trays

Instruments

✓ Drill Guides
✓ Drill Bits
✓ Depth Gauge
✓ Handle and Driver Shafts
✓ Bending Irons
✓ Periosteal Elevator
Core Set

Auxiliary Tray  Graphic Case  Standard Plate Tray  Screw Rack  Insertion Instruments Tray  Reduction Instruments Tray

Key Points
- No new implants introduced with this product release.
- The Association for the Advancement of Medical Instrumentation’s (AAMI) guidelines state that no loaded tray should be heavier than 25 pounds, including the weight of the tray itself. With all instruments, implants, trays, graphic case and lid, the Core Set weight is 22 pounds (10 kilograms).
- Auxiliary Tray may be used to hold additional instruments not configured in tray.

Core Set supports USF Anatomic Implant Trays

Note: The USF Core Set can also be used with any DePuy Synthes 2.7mm or 3.5mm non-locking, LCP® or VA LCP® Implant System.

Note for OR Staff: Surgeon preference cards may need to be changed based on what hospital used prior to Universal Small Fragment System.

Note for OR Staff: Not all lengths and plate families offered are available in tray. Sterile packaged implants and screws may be needed in addition to the Core Set and Implant Tray.
USF Handle, Drivers, Bending Irons and Periosteal Elevator

- Bending Irons: Combine function of F and Recon benders. Open and closed benders help secure the place while bending

- Handle – fully cannulated. Ensure Cannulation is clean before using. Shaft snaps into collar automatically. Disassemble shaft from handle by pulling collar back

- Driver Shafts: All drivers in system are self retaining. 2.5mm Hex driver will not retain low profile screws; use holding sleeve for low-profile cortex screws. Shaft must be disassembled from handle prior to cleaning and sterilization

- Elevator: Do not strike the back of the elevator

- Use cleaning styllet to ensure cannulation on devices are clear of debris before use
Drill Guides

Non-Locking Drill Guide

Variable Angle Drill Guide

Threaded Drill Guide

Notes
- Spring loaded feature on Universal Drill guide removed in favor of using Neutral Sleeve adapter
- Longer sleeve for soft tissue protection
- Threaded drill guides may be used in VA LCP® or LCP® Screw Holes
- VA Drill guides have freehand (tactile feedback) and VA Cone side
- Color coordination with drill bits; single band for lagging, double band for gliding
- Black = 3.5mm; Orange = 2.7mm
- Direct measuring with calibrated drill bits; USF Drill bits calibrate with USF drill guides only. Cannot calibrate off of VA Cone

Precautions
- 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
- Use cleaning stylet to ensure cannulation on devices are clear of debris before use

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## Drill Bits

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Diameter</th>
<th>No. of Bands</th>
<th>Color Band</th>
<th>Function (Drill / Gliding)</th>
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<tbody>
<tr>
<td>03.133.100</td>
<td>2.0</td>
<td>1</td>
<td>Orange</td>
<td>Drill</td>
</tr>
<tr>
<td>03.133.101</td>
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<td>Orange</td>
<td>Drill</td>
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<td>2.7</td>
<td>2</td>
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<td>Gliding</td>
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<td>03.133.106</td>
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</tr>
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<td>03.133.107</td>
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<tr>
<td>03.133.108</td>
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<td>03.133.110</td>
<td>3.5</td>
<td>2</td>
<td>Black</td>
<td>Gliding</td>
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</table>

Note: Non-USF drill bits may be used with USF Drill Guides, but cannot calibrate with USF Drill guides
Please practice assembly and disassembly prior to use in OR.

During assembly and disassembly, 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.

Maximum measurement for the 2.7/3.5 mm Depth Gauge 0 to 60 mm (03.133.080) is 66 mm; Maximum measurement for the 2.7/3.5 mm Depth Gauge 40 to 100 mm (03.133.081) is 106 mm.

When measuring for 2.7 mm locking or variable angle locking screws, **subtract 2 mm from the reading from the Depth Gauge.** No subtraction is required for 3.5 mm screws and 2.7 mm non-locking screws.

Use cleaning stylet to ensure cannulation on devices are clear of debris before use.

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**Assembly**

1) 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.

2) Rotate 180 degrees in one direction while gently advancing toward the handle until a stop is felt.

3) Turn another 180 degrees in the opposite direction with gentle pressure applied on the sleeve towards the handle.

4) Advance the remainder of the insert down the depth gauge sleeve until the sleeve meets the depth gauge handle.

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**Disassembly**

1) 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.

2) Navigate around key feature as described in assembly to complete disassembly.
Why do I have to subtract 2mm for measuring 2.7mm Locking and VA Locking Screws?

- 2.7mm LCP® and VA LCP® Holes have a smaller hole and more narrow geometry than the 2.7mm cortex or any of the 3.5mm screw holes.
- The geometry of the Depth Gauge tip allows the device to sit closer to the top of the 2.7mm Locking and VA Locking holes, while the tip can be inserted farther into the plate for the other screw holes.
- Consequently, the depth gauge wire measures from a slightly higher place on the plate for 2.7mm Locking and VA Locking holes.
- Subtracting 2mm for 2.7mm Locking and VA Locking is required to correct the longer measurement to ensure accurate screw selection.
### Screw Reference Chart printed on Screw Rack

- **Appears on side of Screw Rack**
- **Use to help identify drill bit, torque limiter and driver shaft needed for each screw diameter**

**Screw Reference Chart**

- **Use for 2.7mm screws**
- **Use for 3.5mm screws**
- **Use for 4.0mm screws**

#### Screw Reference Chart

<table>
<thead>
<tr>
<th>Screw Size (mm)</th>
<th>Screw Type</th>
<th>Drill Bit (mm)</th>
<th>Torque Limit (Nm)</th>
<th>Drivers</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
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<td>1.2</td>
<td>T8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Locking</td>
<td>0.8</td>
<td>T8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cortex</td>
<td>1.2</td>
<td>T8</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Screw Size (mm)</th>
<th>Screw Type</th>
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<th>Torque Limit (Nm)</th>
<th>Drivers</th>
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<td>2.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Locking</td>
<td>2.5</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cortex</td>
<td>2.5</td>
<td>Do Not Use</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Screw Size (mm)</th>
<th>Screw Type</th>
<th>Drill Bit (mm)</th>
<th>Torque Limit (Nm)</th>
<th>Drivers</th>
</tr>
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<tbody>
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<td>4.0</td>
<td>VA</td>
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<td></td>
<td>Lag Technique Cortex</td>
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<td>2.5</td>
<td></td>
</tr>
</tbody>
</table>

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Push Pins for “Locking, VA Locking, Cortex, Metaphyseal”

Look for Screw Type on Push Pins above screws in Screw Rack

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2.5mm Hex Driver – when to use Holding Sleeve

2.5mm Hex Driver does NOT retain Low Profile Cortex Screws

Use Holding Sleeve (314.06) to secure screw to driver shaft

- 2.5mm Hex Driver retains Standard Cortex Screws
  - e.g., 2.7mm Cortex, 3.5mm Low Profile Cortex Screws
  - 3.5mm Cortex Screws, 4.0mm Cancellous

314.06 Holding Sleeve
Measuring screw length using gauge on Screw Rack

- Measuring gauge appears on side of Screw Rack as a pop out feature.
- While measuring screw length – either with an individual screw or a screw retained on a driver, ensure that the tip of the screw is flat against the wall of the measuring gauge on the screw Rack.
- Measure length from flat surface (top) of screw head.

Lie screw flat on measuring gauge, with tip of screw against wall surface (screw is 50mm length).

If screw retained on driver, ensure screw tip flat against wall surface (screw is 50mm length).
Additional Resources

Surgical Technique Guide
(www.DePuysynthes.com/hcp/trauma)

System Catalog
(www.DePuysynthes.com/hcp/trauma)

System Brochure and Evidence Infographic if useful in the discussion about system benefits:
https://www.depuysynthes.com/hcp/trauma/products/qs/universal-small-fragment-system

US Regulatory Memo is available upon request (internal access only). All new instruments have been determined by DePuy Synthes to be Class 1 devices and are exempt from the FDA pre-market submission process. Regulatory Memo indicates such and provides all product codes released for the first time with the Universal Small Fragment System.

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Introduction

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• Instruments
Universal Small Fragment (USF) System

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✓ Drill Guides
✓ Depth Gauge
✓ Handle and Driver Shafts
✓ Bending Irons
✓ Periosteal Elevator

DePuy Synthes

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US Guidelines: The Association for the Advancement of Medical Instrumentation’s (AAMI) guidelines state that no loaded tray should be heavier than 25 pounds, including the weight of the tray itself.²

With all instruments, implants, trays, graphic case and lid, the Core Set weight is 22 pounds (10 kilograms)

Upper Limb Anatomic Implant Trays are available in Stainless Steel or Titanium

LCP® Lower Limb Anatomic Implant Trays are available in Stainless Steel or Titanium

VA LCP® Lower Limb Anatomic Implant Trays are available in Stainless Steel only
What is “In-Tray Washing”?

• Instructions for Use (IFU) include handling instructions for Sterile Processing Departments to correctly wash and sterilize our reusable medical devices and include these process steps:

  - Pre-Cleaning
  - Cleaning
  - Thermal Disinfection
  - Drying
  - Inspection
  - Packaging
  - Sterilization

• **Universal Small Fragment System** Trays have been tested and verified to allow all instruments and implants to be manually precleaned during the Pre-Cleaning phase, then placed back in tray to continue the Cleaning step.

• Within the Cleaning process step, current DePuy Synthes systems use eIFU GP0030, which requires all medical devices (instruments and implants) be cleaned and disinfected outside of tray in a separate container.

• Test Protocol used to validate In-Tray washing defined within the IFU.

• US IFU for In-Tray Washing: GP3030 ([e-ifu.com](http://e-ifu.com)) – Instructions for Processing Medical Devices using In-Tray Cleaning
What does in-tray washing look like?

### Out-of-Tray Washing
- Instruments taken out of tray to be washed in separate bin per IFU
- Multiple trays to wash
- Tray reassembly required after washing

### In-Tray Washing
- Instruments manually pre-cleaned, then placed back in tray prior to washing
- 1 tray to wash
- Tray already assembled after washing

Universal Small Fragment System eIFU recommends **In-Tray Washing**.

All existing DePuy Synthes systems eIFUs recommend **Out-Of-Tray Washing**.
Interpreting the “X” in Part Number for Restocking Trays

To restock with stainless steel implant, use part number beginning with 2
To restock with titanium implant, use the part number beginning with 4
Finding device part number to reassemble trays

Insertion Instrument Tray (60.133.100)

Match the part number on the device with the part number in tray (e.g., 03.133.004).

Standard Plate Tray (60.133.102)

Match the part number on the device with the part number in tray (e.g., 223.591 for Stainless Steel).
USF Non-Locking Drill Guide does not use a spring as is present in comparable device (e.g., 323.26 or 323.36). Neutral Sleeve adapter must be disassembled from Non-Locking Drill Guide prior to cleaning (unscrew from device, slide off).

Ensure that cannula are cleaned according to washing instructions.
Depth Gauge must be disassembled prior to cleaning; follow instructions as shown for disassembly.

During assembly and disassembly, 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.

Disassembled instrument has 2 pieces instead of 4 in comparable device (e.g., 319.19).

Ensure that cannula are cleaned according to washing instructions.

Assembly
1) 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.
2) Rotate 180 degrees in one direction while gently advancing toward the handle until a stop is felt.
3) Turn another 180 degrees in the opposite direction with gentle pressure applied on the sleeve towards the handle.
4) Advance the remainder of the insert down the depth gauge sleeve until the sleeve meets the depth gauge handle.

Disassembly
1) 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.
2) Navigate around key feature as described in assemble to complete disassembly.
USF Handle, Drivers, Bending Irons and Periosteal Elevator

- Handle – shaft snaps into collar automatically. Disassemble by pulling collar back.
- Driver Shafts: Shaft must be disassembled from handle prior to cleaning and sterilization.
- Ensure that cannula on universal handle is cleaned according to washing instructions.
Additional Resources

Surgical Technique Guide
(www.DePuysynthes.com/hcp/trauma)

System Catalog
(www.DePuysynthes.com/hcp/trauma)

Cleaning, Disinfecting, and Sterilization Information
https://www.e-ifu.com. eIFU# GP3030

Instrument Durability Testing
(Please ask Sales Team for copy)

Note: GP3030 is new and provides supporting information for in-tray washing

Tray Images and excel file, instrument images and instrument durability testing paper available from Sales Consultant (access via Huddle) to use for installing USF at the account into the Central Processing Systems.

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