

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.



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FOR USE WITH OPERATING ROOM STAFF



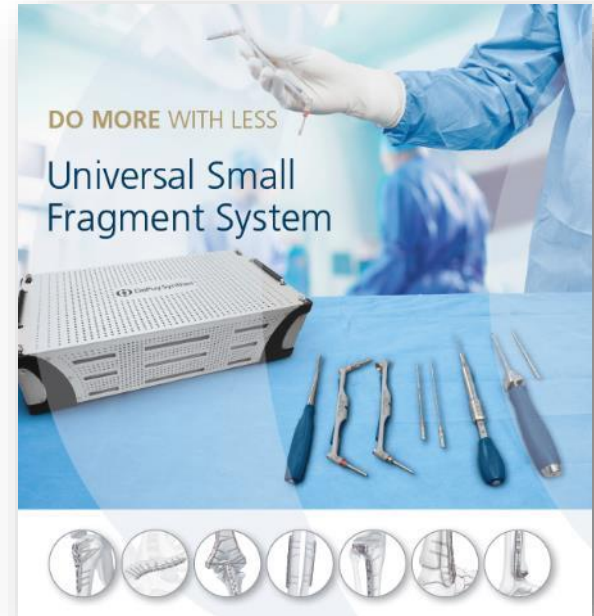
Introduction

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



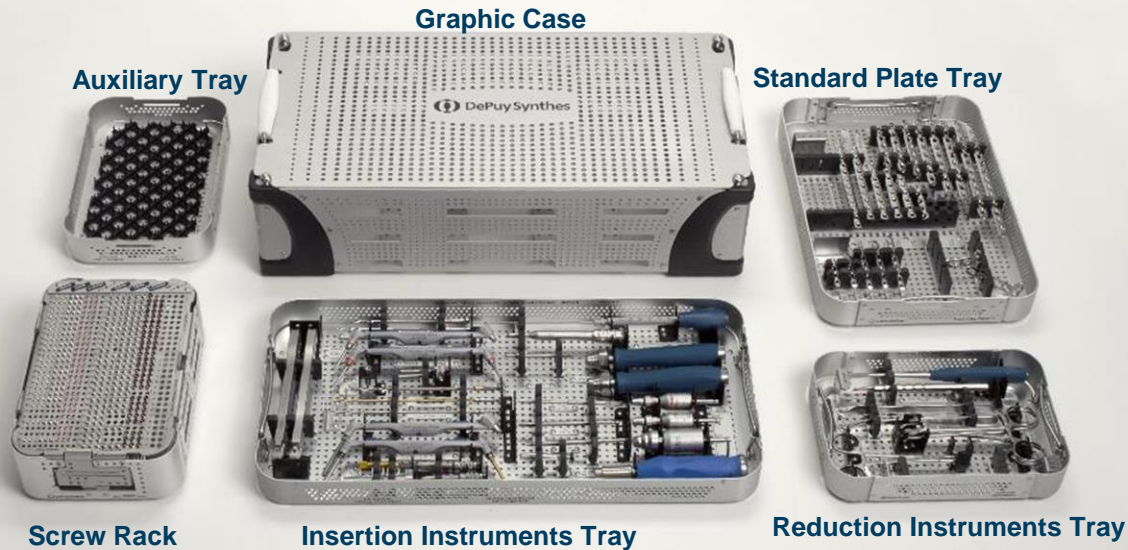
- ✓ Core Set
- ✓ Anatomic Implant Trays

Instruments



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

Core Set

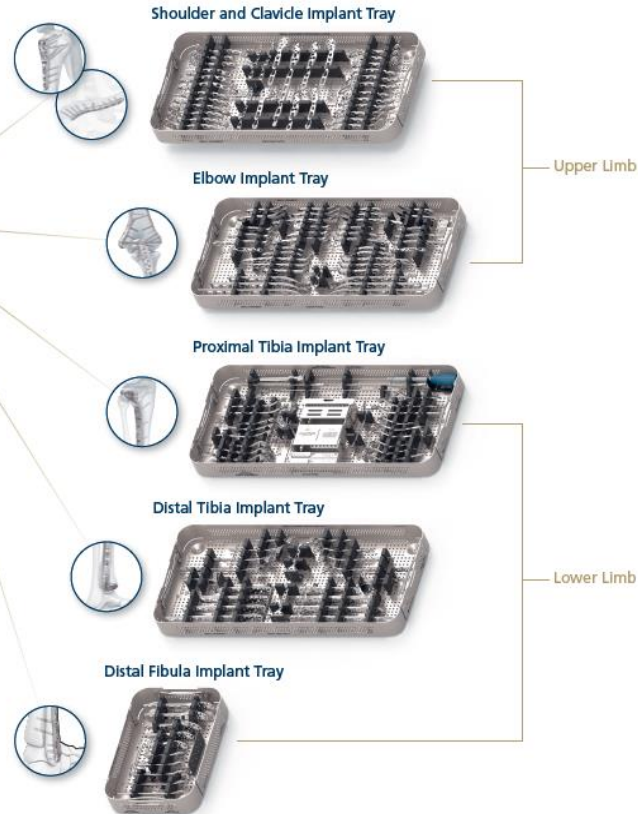
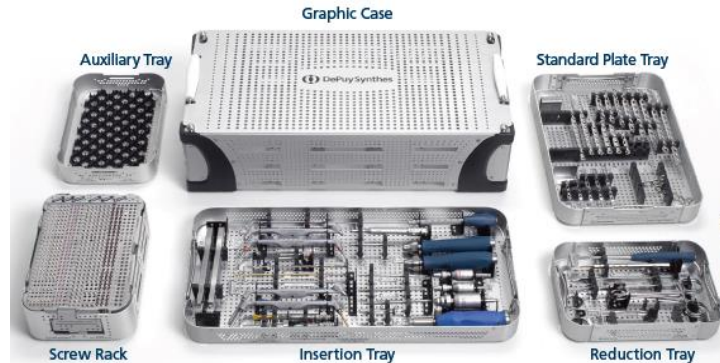


Key Points

- 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.² 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.

2. "Heavy Instrument Sets Shed Pounds," OR Manager. February 2008. Accessed at <https://www.ormanager.com/wp-content/uploads/pdfx/ORMVol24No2instrumentSetsShedPounds.pdf>.

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



03.133.200



03.133.201



03.133.150



03.133.175

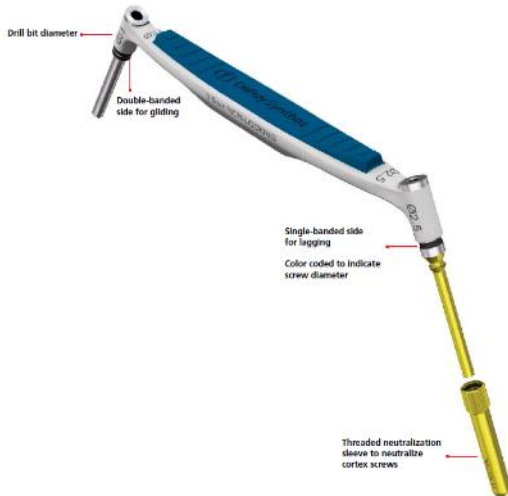


03.133.202

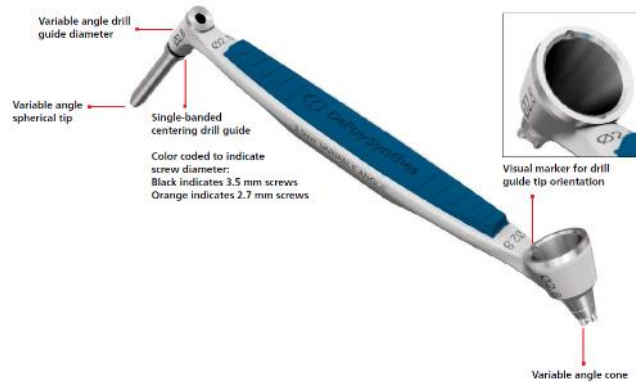
- Bending Irons: Combine function of F and Recon benders. Open and closed benders help secure the plate while bending
- Handle – fully cannulated. Ensure Cannulation is clean before using. Shaft snaps into collar automatically. Disassemble shaft from handle by pulling collar back
- Driver Shafts: All 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 stylet to ensure cannulation on devices are clear of debris before use

Drill Guides

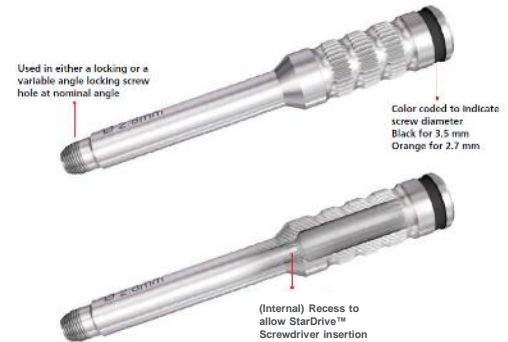
Non-Locking Drill Guide



Variable Angle Drill Guide



Threaded Drill Guide



Notes

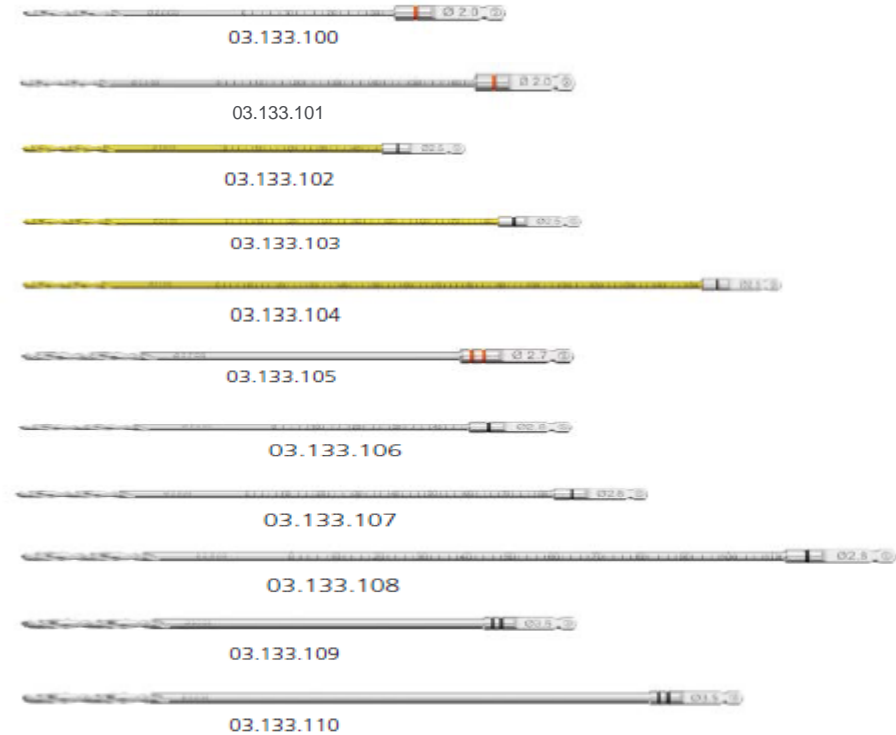
- Spring loaded feature on Universal Drill guide removed in favor of using Neutral Sleeve adapter
- Longer sleeve for soft tissue protection
- Threaded drill guides may be used in VA LCP® or LCP® Screw Holes
- VA Drill guides have freehand (tactile feedback) and VA Cone side
- Color coordination with 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 adapters 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

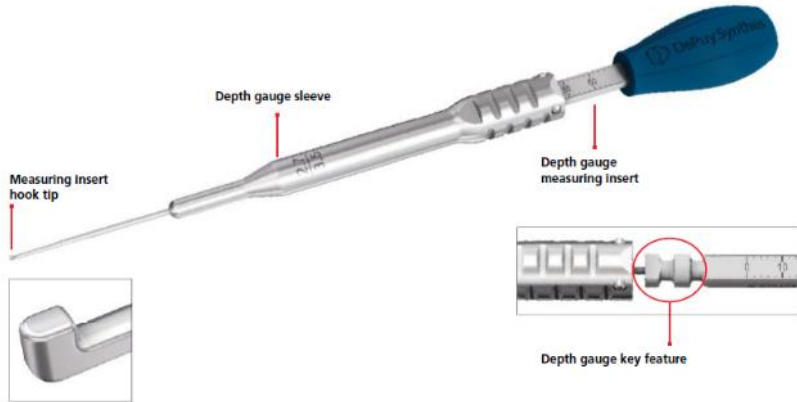
Drill Bits

Part Number	Diameter	No. of Bands	Color Band	Function (Drill / Gliding)
03.133.100	2.0	1	Orange	Drill
03.133.101	2.0	1	Orange	Drill
03.133.102	2.5	1	Black	Drill
03.133.103	2.5	1	Black	Drill
03.133.104	2.5	1	Black	Drill
03.133.105	2.7	2	Orange	Gliding
03.133.106	2.8	1	Black	Drill
03.133.107	2.8	1	Black	Drill
03.133.108	2.8	1	Black	Drill
03.133.109	3.5	2	Black	Gliding
03.133.110	3.5	2	Black	Gliding



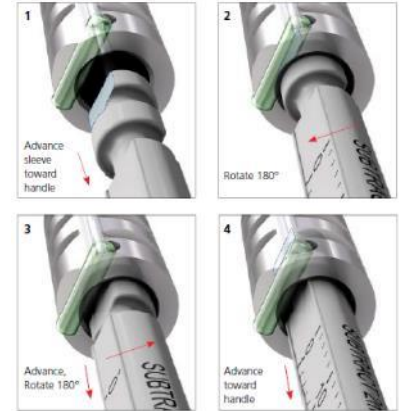
Note: Non-USF drill bits may be used with USF Drill Guides, but cannot calibrate with USF Drill guides

Depth Gauge



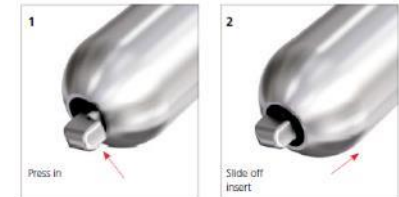
Assembly

- 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.



Please practice assembly and disassembly prior to use in OR.

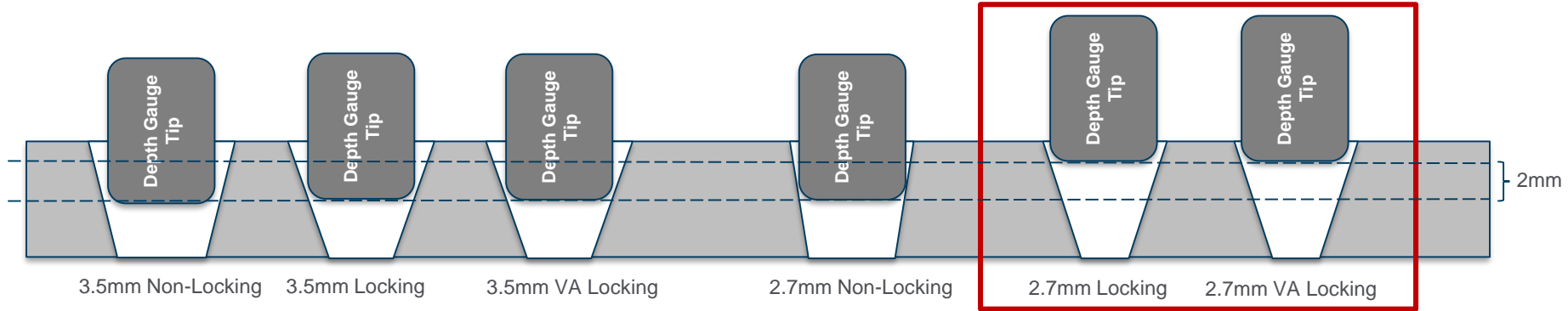
During assembly and disassembly, use care in carefully pushing in depth gauge measuring insert hook tip. Hook tip may be sharp and may pinch or tear user's glove or skin.

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.

Why do I have to subtract 2mm for measuring 2.7mm Locking and VA Locking Screws?



Simulation showing depth gauge tip resting into screw holes. Tip rests closer to middle of plate for all screw holes except 2.7mm Locking and VA LCP Locking. Tip rests approximately 2mm higher for these screw holes. Note: For illustration purposes only; not drawn to scale

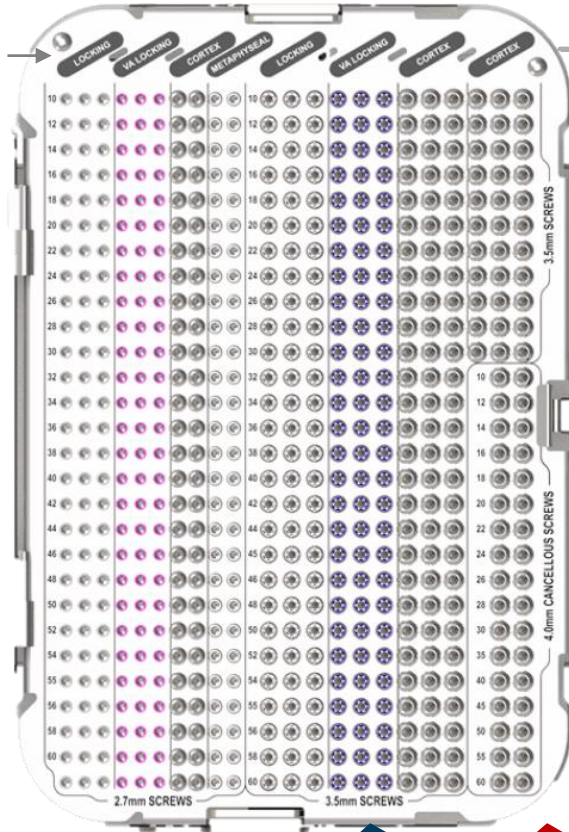
- 2.7mm LCP® and VA LCP® Holes have a smaller hole and more narrow geometry than the 2.7mm cortex or any of the 3.5mm screw holes.
- The geometry of the Depth Gauge tip allows the device to sit closer to the top of the 2.7mm Locking and VA Locking holes, while the tip can be inserted farther into the 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

Push Pins for
"Locking, VA
Locking,
Cortex,
Metaphyseal"

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



Screw Reference Chart

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

Screw Size (mm)	Screw Type	Drill Bit (mm)	Torque Limit (Nm)	Drivers	
2.7	VA	2.0	1.2	★ T8	
	Locking		0.8	★ T8	
	Metaphyseal		1.2	★ T8	
	Cortex		Do Not Use	★ T8 ● 2.5mm	
	Lag Technique Cortex		① 2.7 ② 2.0	Do Not Use	★ T8 ● 2.5mm

Screw Size (mm)	Screw Type	Drill Bit (mm)	Torque Limit (Nm)	Drivers
3.5	VA	2.8	2.5	★ T15
	Locking		1.5	★ T15
	Cortex	2.5	Do Not Use	★ T15 ● 2.5mm
	Lag Technique Cortex	① 3.5 ② 2.5	Do Not Use	★ T15 ● 2.5mm
4.0	Cancellous	2.5	Do Not Use	● 2.5mm

Use for 2.7mm screws

Use for 3.5mm screws

Use for 4.0mm screws



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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



314.06

Holding Sleeve



e.g., 2.7mm Cortex,
3.5mm Low Profile
Cortex Screws



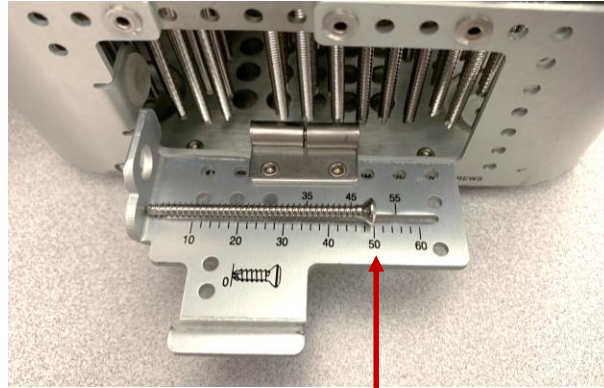
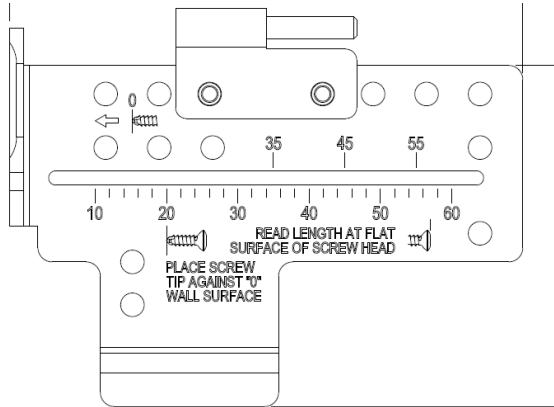
3.5mm Cortex
Screws, 4.0mm
Cancellous

2.5mm Hex Driver retains
Standard Cortex Screws

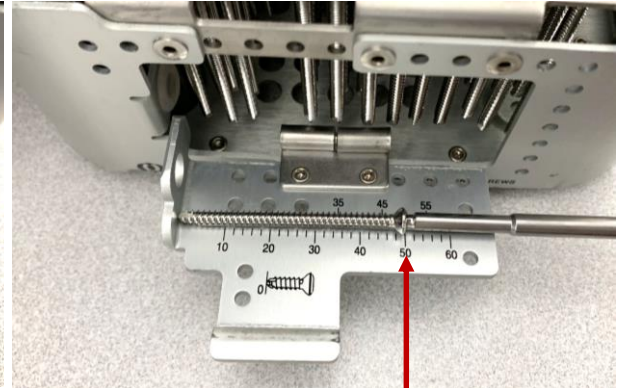


Measuring screw length using gauge on Screw Rack

- 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



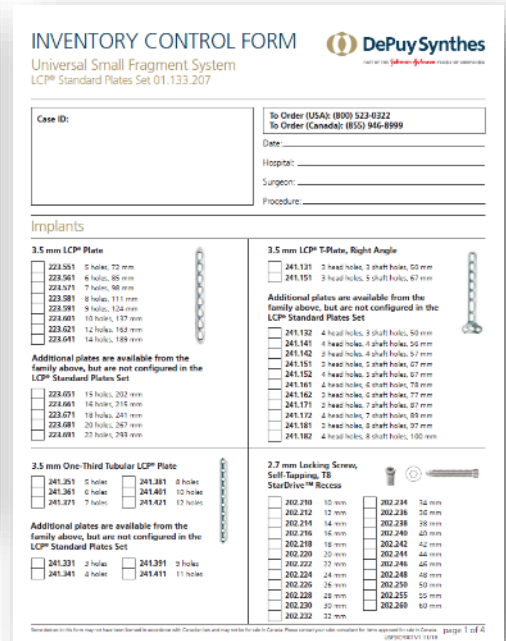
Surgical Technique Guide
www.DePuysynthes.com/hcp/trauma



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.



Inventory Control Forms
www.DePuysynthes.com/hcp/trauma

FOR USE WITH STERILIZATION PROCESSING STAFF



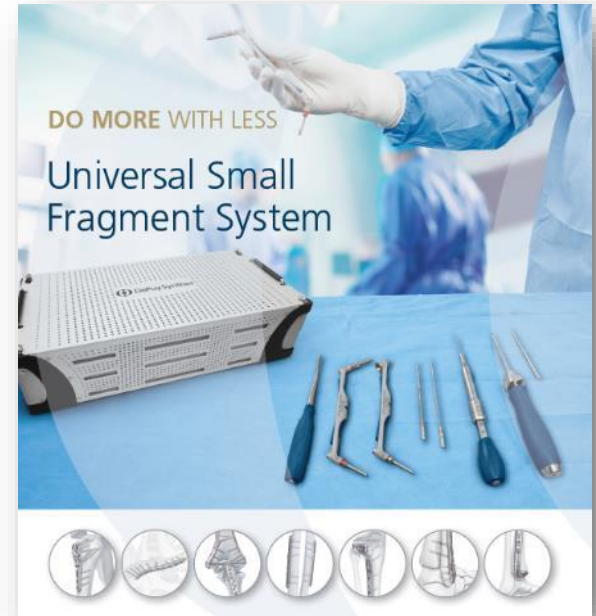
Introduction

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

Training topics for USF

- System Trays
- Instruments



Universal Small Fragment (USF) System

System Trays



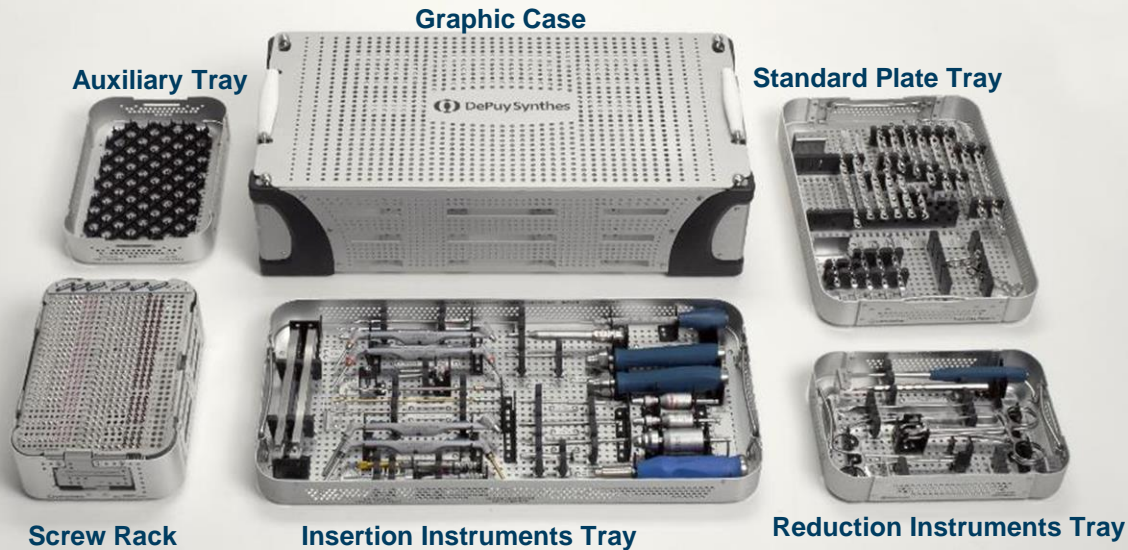
- ✓ Core Set
- ✓ Anatomic Implant Trays

Instruments



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

Core Set

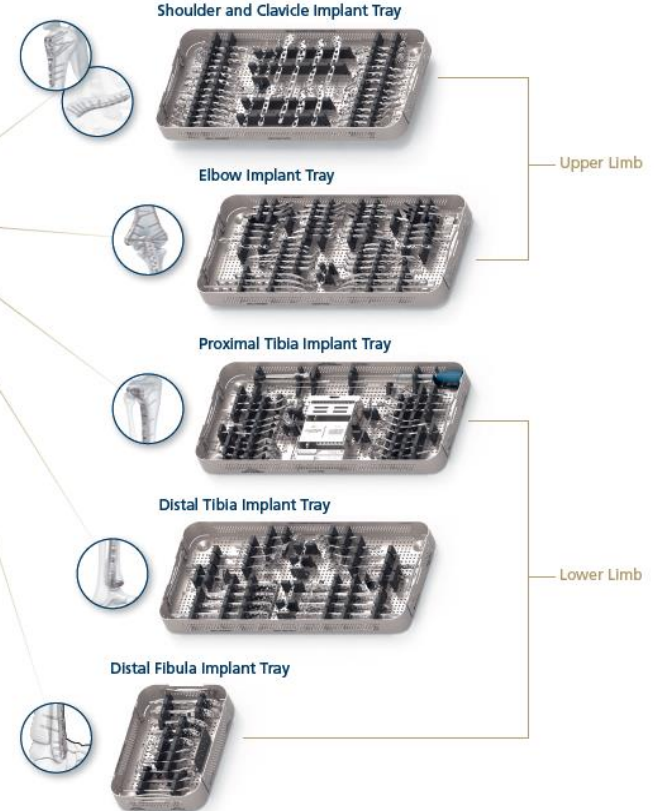
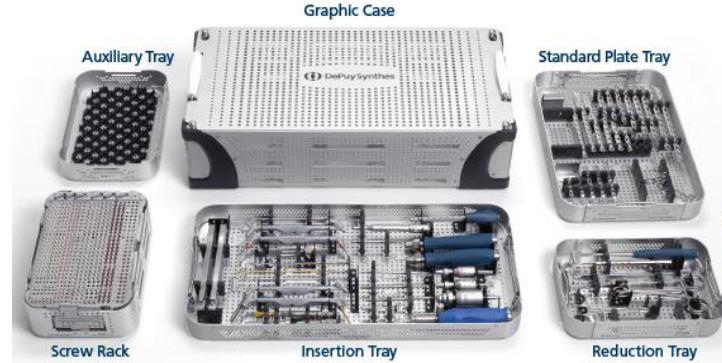


US Guidelines: The Association for the Advancement of Medical Instrumentation's (AAMI) guidelines state that no loaded tray should be heavier than **25 pounds**, including the weight of the tray itself.²

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

2. "Heavy Instrument Sets Shed Pounds," OR Manager. February 2008. Accessed at <https://www.ormanager.com/wp-content/uploads/pdfx/ORMVol24No2instrumentSetsShedPounds.pdf>.

Core Set + USF Anatomic Implant Trays



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:

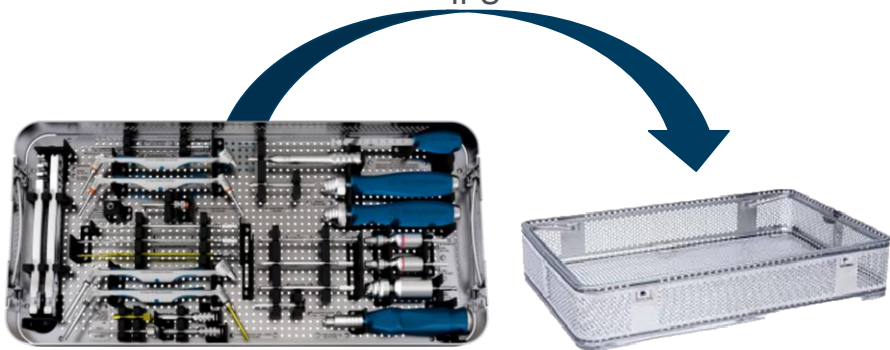


- **Universal Small Fragment System** Trays have been tested and verified to allow all instruments and implants to be manually precleaned during the Pre-Cleaning phase, then placed back in tray to continue the Cleaning step.
- Within the Cleaning process step, current DePuy Synthes systems use eIFU GP0030, 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) – Instructions for Processing Medical Devices using In-Tray Cleaning

What does in-tray washing look like?

Out-of-Tray Washing

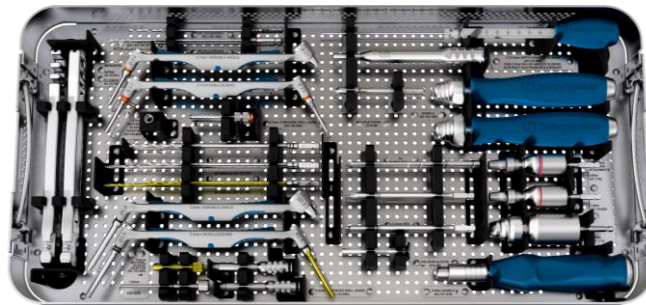
Instruments taken out of tray to be washed in separate bin per IFU



- ⊗ Multiple trays to wash
- ⊗ Tray reassembly required after washing

In-Tray Washing

Instruments manually pre-cleaned, then placed back in tray prior to washing

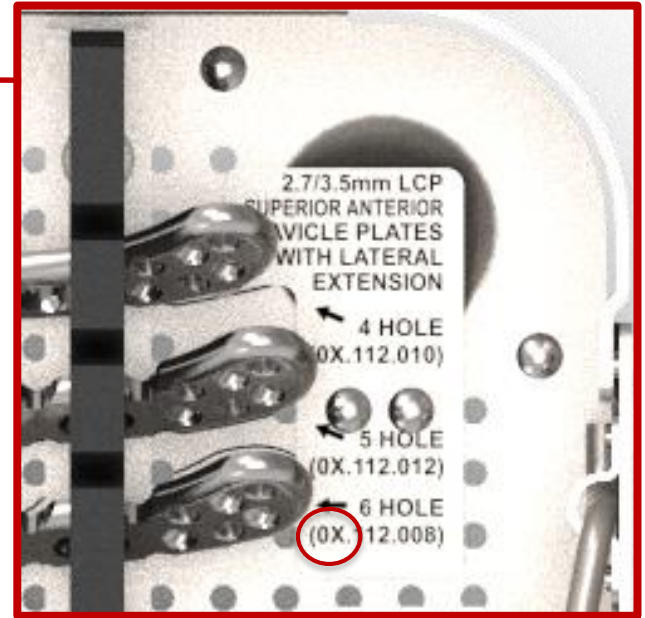
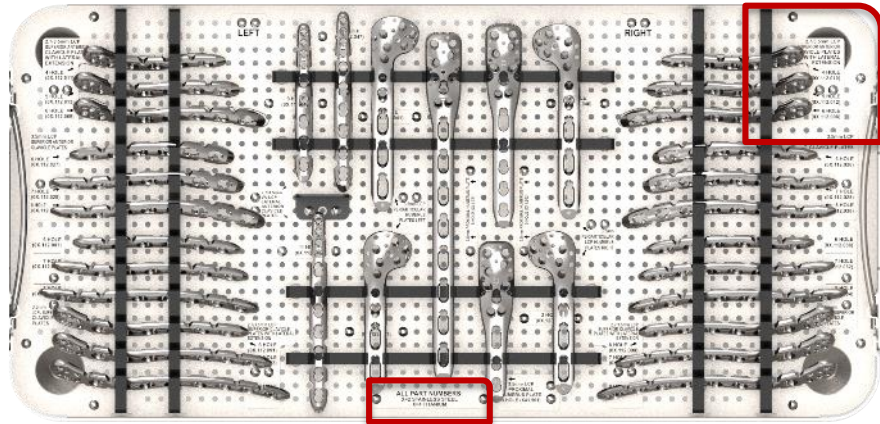


- ✓ 1 tray to wash
- ✓ Tray already assembled after washing

Universal Small Fragment System eIFU recommends In-Tray Washing.

All existing DePuy Synthes systems eIFUs recommend Out-Of-Tray Washing.

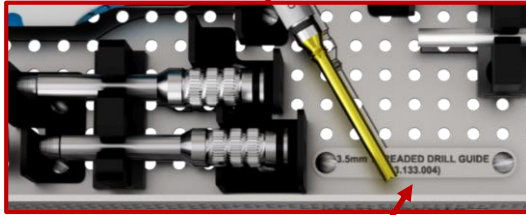
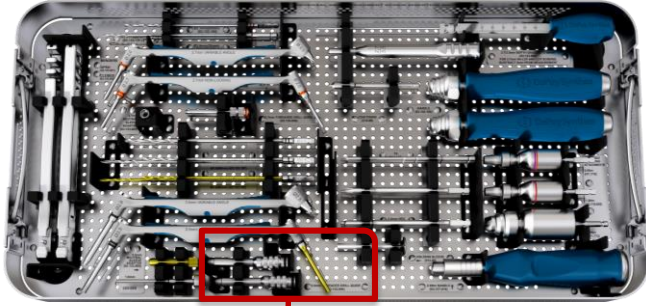
Interpreting the “X” in Part Number for Restocking Trays



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

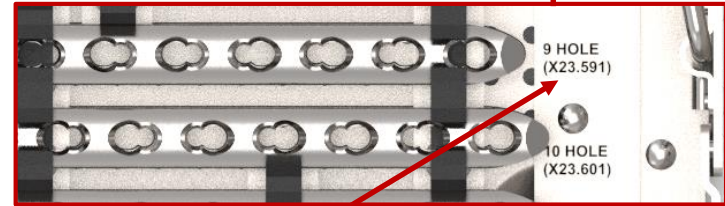
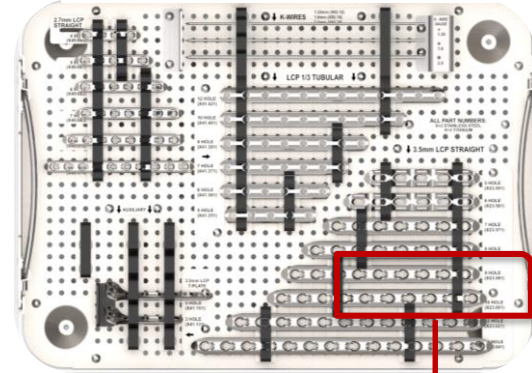
Insertion Instrument Tray (60.133.100)



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



Standard Plate Tray (60.133.102)

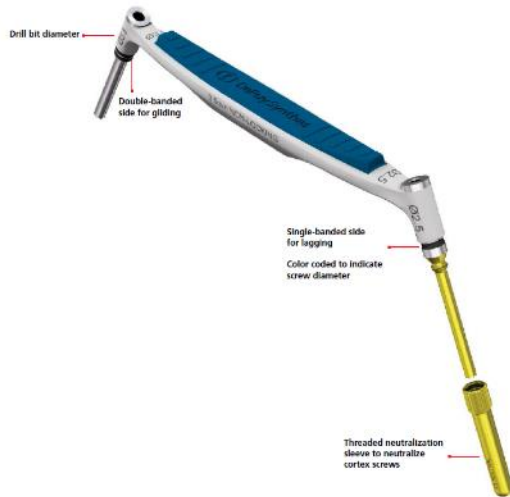


Match the part number on the device with the part number in tray (e.g., 223.591 for Stainless Steel).

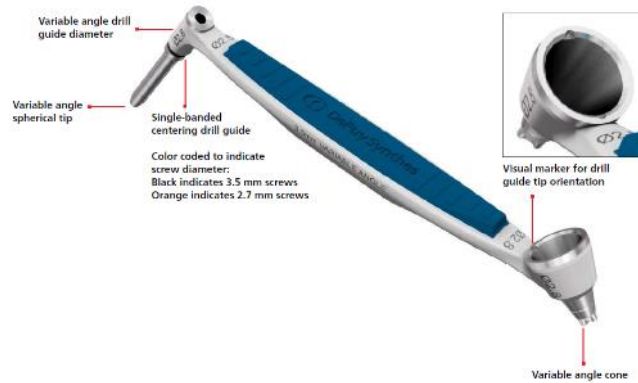


Drill Guides

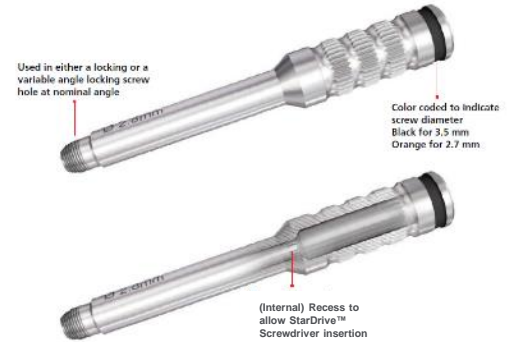
Non-Locking Drill Guide



Variable Angle Drill Guide

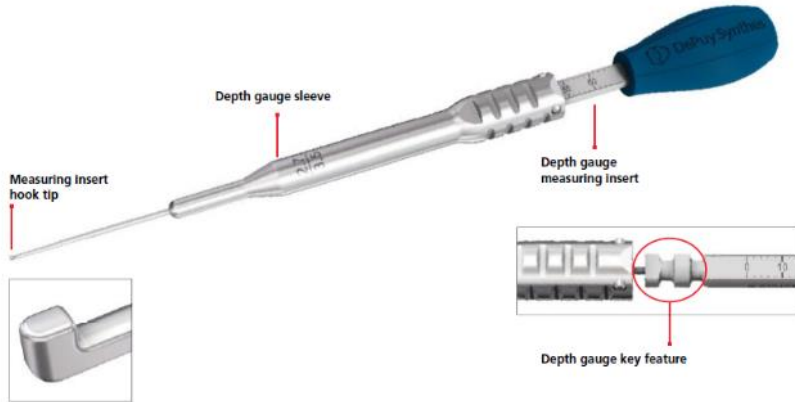


Threaded Drill Guide



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



Depth Gauge must be disassembled prior to cleaning; follow instructions as shown for disassembly.

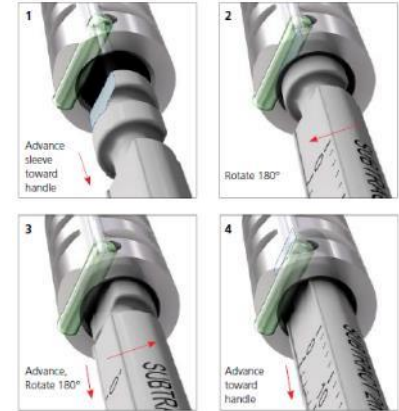
During assembly and disassembly, use care in carefully pushing in depth gauge measuring insert hook tip. Hook tip may be sharp and may pinch or tear user's glove or skin.

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

Ensure that cannula are cleaned according to washing instructions.

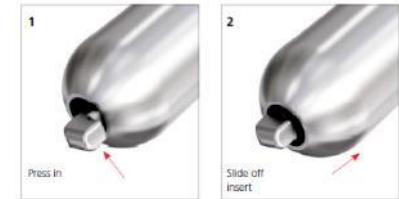
Assembly

- 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 toward 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



03.133.200



03.133.201



03.133.150



03.133.175



03.133.202

- 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.

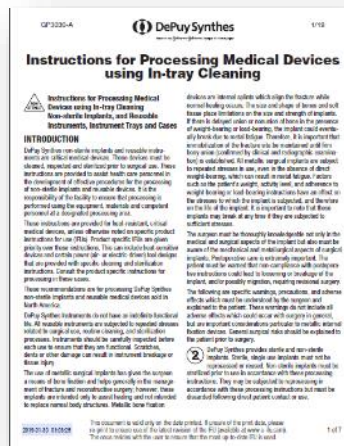
Additional Resources



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)