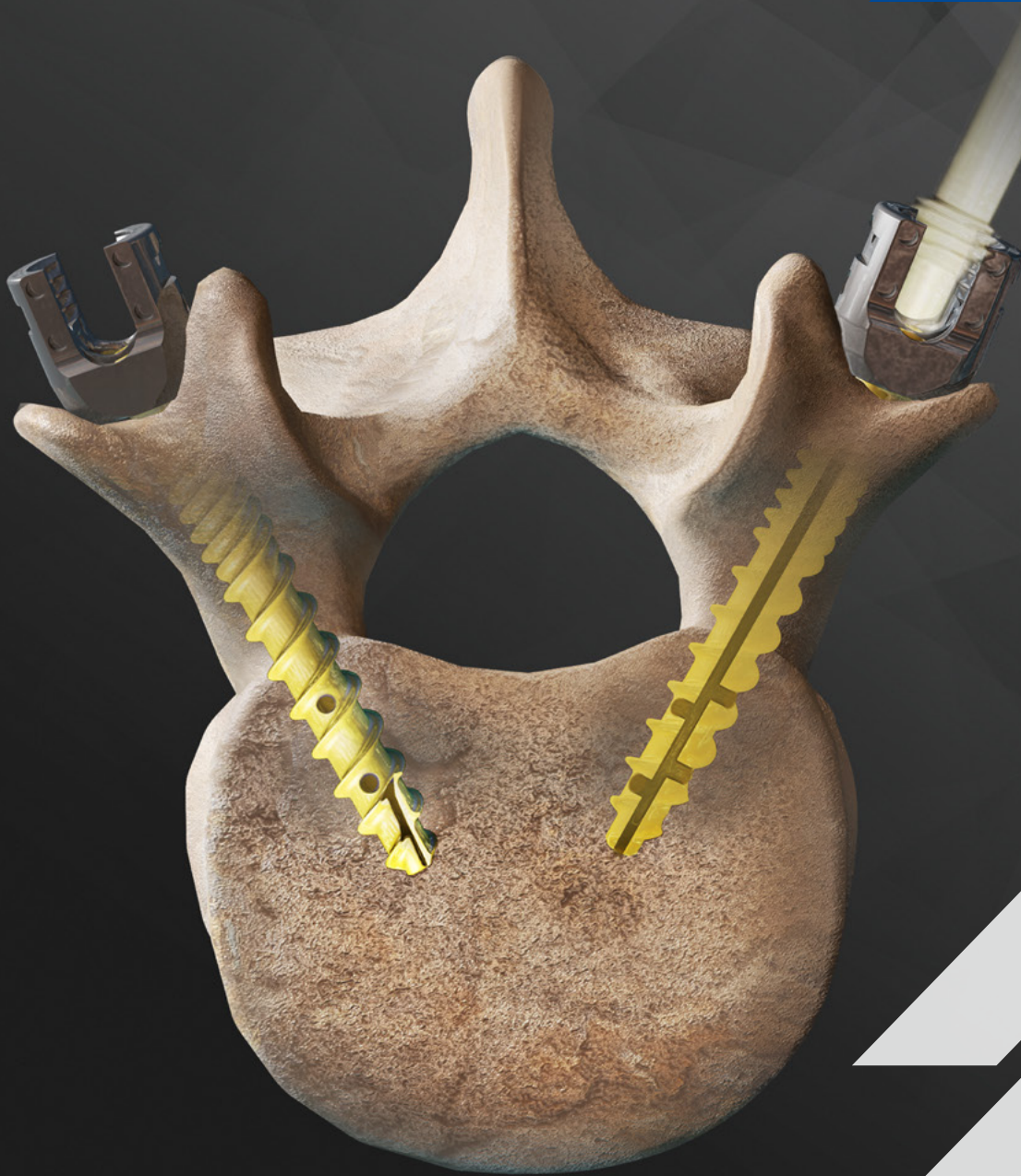




Operative Technique



For U.S. Use Only

 **ORTHOFIX**® | **SPINE**

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the Instructions For Use for the complete list of indications, warnings, precautions, and other important medical information.



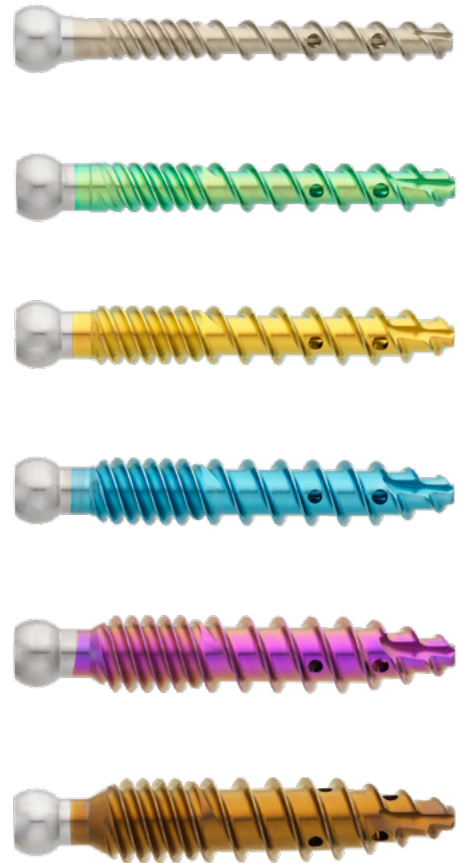
INTRODUCTION

The JANUS® Fenestrated Screw is designed to achieve more cortical bone purchase while allowing delivery of saline and radiopaque dye in patients who may require spinal column integrity restoration.

The JANUS Fenestrated Bone Screws are a family of modular, cannulated bone screws manufactured from Ti-6AL-4V ELI Coating and feature procedures specific to delivering saline and radiopaque dye into the vertebral body through the JANUS Fenestrated Screw. There are two delivery methods outlined: an open delivery method used for open, mini-open or midline spinal procedure and a minimally invasive delivery method used in minimally invasive spinal procedure.

When using the JANUS Fenestrated Screw, consult the respective Firebird® System, Firebird Deformity System, Firebird® NXG Spinal Fixation System, Phoenix® Minimally Invasive Spinal Fixation System, Phoenix® CDX™ Minimally Invasive Spinal Fixation System, or JANUS® Midline Fixation Screw operative technique for comprehensive procedure and system information.

Warning: The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.



OPEN PROCEDURE

1. SCREW INSERTION

Consult the respective Firebird® Spinal Fixation System operative technique for targeting, site preparation and bone screw placement.

The bone screws are inserted using the same technique as the multi-axial procedures in the respective Firebird Spinal Fixation System operative techniques.

2. SALINE AND RADIOPAQUE DYE ADAPTER ASSEMBLY

Attach the **Adapter Inserter (36-1603)** to the **Short Adapter (36-1604)**. Use the **Multi-Axial Body Inserter (54-0007)** to lift and stabilize the Firebird or Firebird NXG body to prevent rotation during adapter insertion. Insert the Short Adapter assembly until fully seated in the Firebird (44-2XXX) or Firebird NXG (36-2XXX) body. **Fig. 2**

Remove the Adapter Inserter (36-1603) leaving the Short Adapter (36-1604) in-situ. Utilizing the **Adapter Wrench (36-1606)**, tighten the Short Adapter (36-1604) ensuring a secure connection. Refer to step 3 Saline and Radiopaque Dye Delivery. If needed, the **Cannula (36-1601)** may be used to extend the length of the Short Adapter (36-1604) for surgery. **Fig. 2b**

Note: Avoid overtightening the Short Adapter (36-1604) to body connection. It could result in damaging the Short Adapter threads.

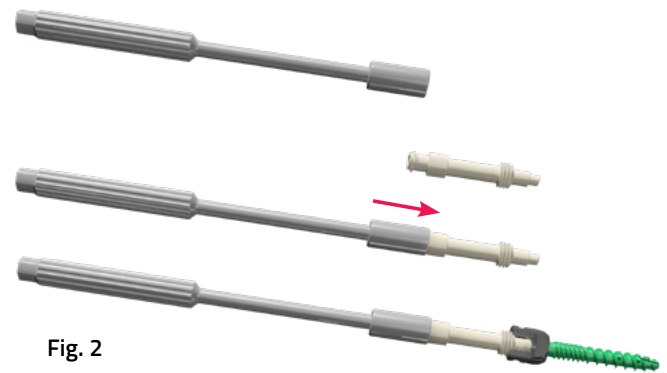


Fig. 2

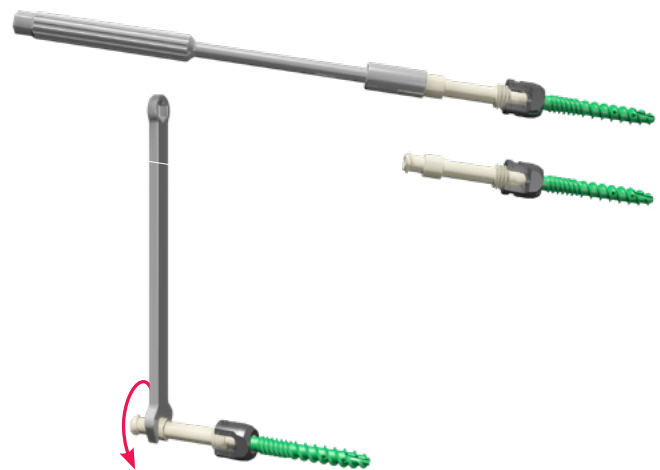


Fig. 2b

3. SALINE AND RADIOPAQUE DYE DELIVERY

When delivering saline and radiopaque dye through the Short Adapter (36-1604) and/or with the Cannula (36-1601), attach the respective saline and radiopaque dye delivery instruments to the Short Adapter (36-1604) through a standard luer connector to inject saline and radiopaque dye into the vertebral body.

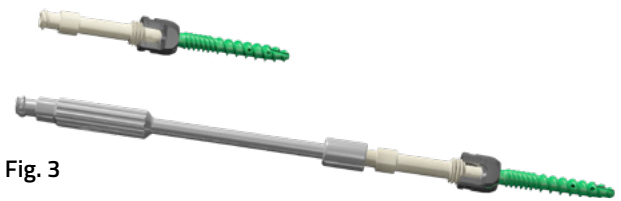


Fig. 3

4. ADJACENT LEVELS

Repeat steps 2 and 3 for each desired vertebral level.

5. Adapter Removal

After saline and radiopaque dye introduction is complete, the Short Adapter (36-1604) and/or with the Cannula (36-1601) may be removed by unthreading from the body. The Adapter Wrench (36-1606) may be used to assist in loosening the Short Adapter (36-1604). **Fig. 5**

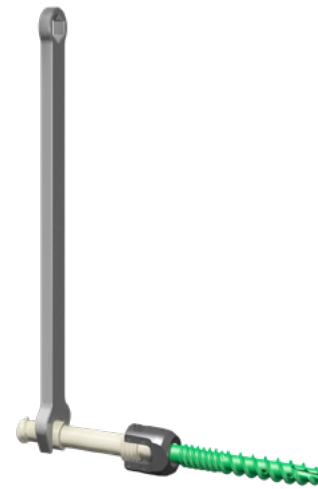


Fig. 5

6. ROD INSERTION AND FINAL TIGHTENING

Consult the respective Firebird Spinal Fixation System operative technique for rod insertion and final tightening.

7. INSTRUMENT CLEANING USING THE PLUNGER

The **Plunger (36-1602)** is provided in the instrument set and may be used to clear the instruments in case a blockage occurs during surgery. **Fig.7**

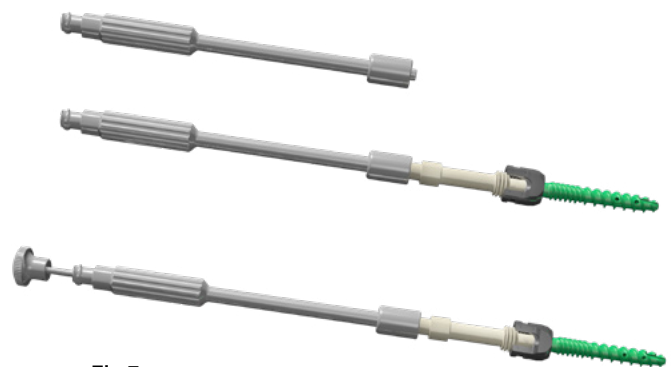


Fig.7

MINIMALLY INVASIVE PROCEDURE (MIS)

1. SCREW INSERTION

Consult the respective Phoenix® Spinal Fixation System operative technique for targeting, site preparation and bone screw placement.

The bone screws are inserted using the same technique as the multi-axial procedures in the respective Phoenix Spinal Fixation System operative techniques.

For minimally invasive screw insertion, do not remove the small or large tabs on the Phoenix body. The tabs must remain in place throughout saline and radiopaque dye delivery.

2. SALINE AND RADIOPAQUE DYE ADAPTER ASSEMBLY

Attach the **Tall Adapter (36-1605)** until fully seated in the Phoenix Open (20-8XXX) or Closed (20-3XXX) body.

Use the Adapter Wrench (36-1606) to tighten the Tall Adapter (36-1605) ensuring a secure connection. Refer to step 3 Saline and Radiopaque Dye Delivery. **Fig. 2**

Note: Avoid overtightening the adapter to body connection. It could result in damaging the Phoenix body threads.

3. SALINE AND RADIOPAQUE DYE DELIVERY

When delivering saline and radiopaque dye through the Tall Adapter (36-1605), attach the respective saline and radiopaque dye delivery instruments to the Tall Adapter (36-1605) through a standard Luer connector to inject saline and radiopaque dye into the vertebral body.

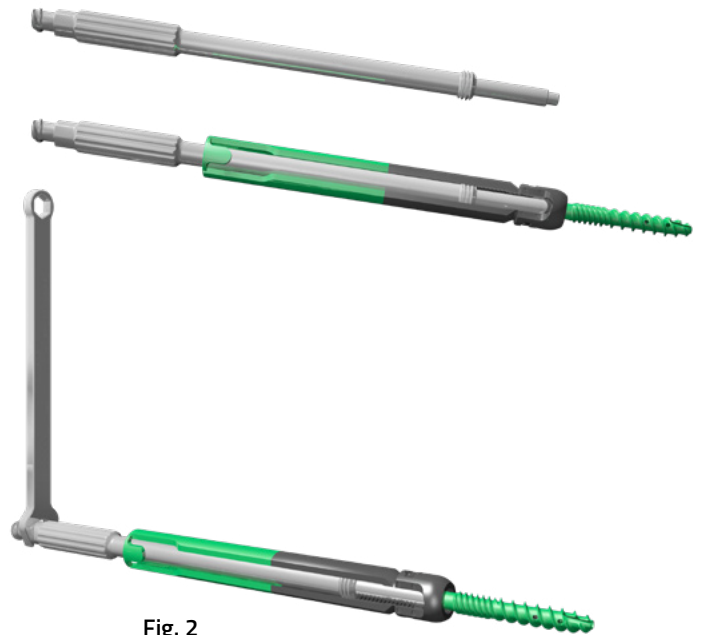


Fig. 2



Fig. 3

4. ADJACENT LEVELS

Repeat steps 2 and 3 for each desired vertebral level.

5. ADAPTER REMOVAL

After saline and radiopaque dye introduction is complete, the Tall Adapter (36-1605) may be removed by unthreading from the body. The Adapter Wrench (36-1606) may be used to assist in loosening the Tall Adapter (36-1605).

6. ROD INSERTION AND FINAL TIGHTENING

Consult the Phoenix® Minimally Invasive Spinal Fixation System operative technique for rod insertion and final tightening.

7. INSTRUMENT CLEANING USING THE PLUNGER

The **Plunger (36-1602)** is provided in the instrument set and may be used to clear the instruments in case a blockage occurs during surgery.

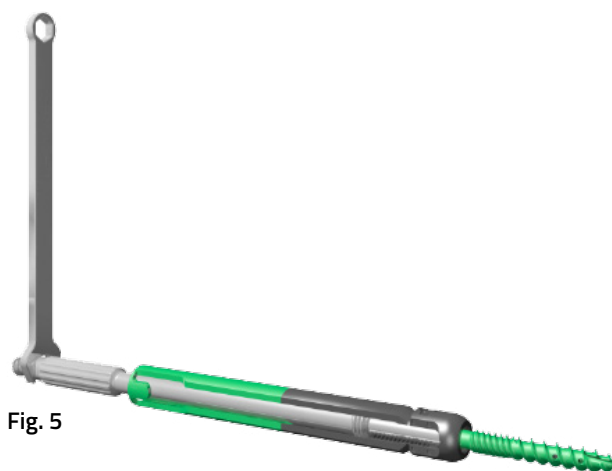


Fig. 5



Fig. 7

Implants

Part #	Description	Qty	Part #	Description	Qty
36-4535	5.5mm x 35mm Fenestrated Screw	4	36-4650	6.5mm x 50mm Fenestrated Screw	8
36-4540	5.5mm x 40mm Fenestrated Screw	8	36-4655	6.5mm x 55mm Fenestrated Screw	4
36-4545	5.5mm x 45mm Fenestrated Screw	8	36-4740	7.5mm x 40mm Fenestrated Screw	4
36-4550	5.5mm x 50mm Fenestrated Screw	2	36-4745	7.5mm x 45mm Fenestrated Screw	4
36-4635	6.5mm x 35mm Fenestrated Screw	4	36-4750	7.5mm x 50mm Fenestrated Screw	4
36-4640	6.5mm x 40mm Fenestrated Screw	8	36-4755	7.5mm x 55mm Fenestrated Screw	4
36-4645	6.5mm x 45mm Fenestrated Screw	10			

Optional Implants

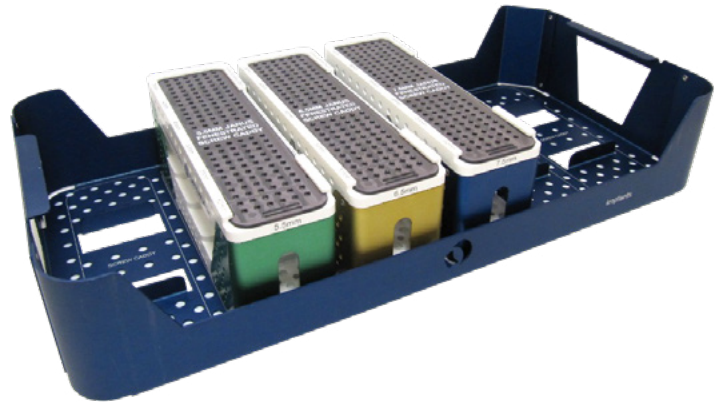
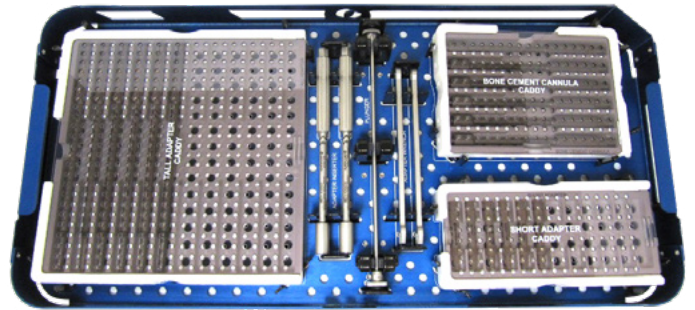
Part #	Description	Qty	Part #	Description	Qty
36-4430	4.5mm x 30mm Fenestrated Screw	By Request	36-4765	7.5mm x 65mm Fenestrated Screw	By Request
36-4435	4.5mm x 35mm Fenestrated Screw	By Request	36-4770	7.5mm x 70mm Fenestrated Screw	By Request
36-4440	4.5mm x 40mm Fenestrated Screw	By Request	36-4775	7.5mm x 75mm Fenestrated Screw	By Request
36-4445	4.5mm x 45mm Fenestrated Screw	By Request	36-4780	7.5mm x 80mm Fenestrated Screw	By Request
36-4450	4.5mm x 50mm Fenestrated Screw	By Request	36-4830	8.5mm x 30mm Fenestrated Screw	By Request
36-4455	4.5mm x 55mm Fenestrated Screw	By Request	36-4835	8.5mm x 35mm Fenestrated Screw	By Request
36-4460	4.5mm x 60mm Fenestrated Screw	By Request	36-4840	8.5mm x 40mm Fenestrated Screw	By Request
36-4465	4.5mm x 65mm Fenestrated Screw	By Request	36-4845	8.5mm x 45mm Fenestrated Screw	By Request
36-4470	4.5mm x 70mm Fenestrated Screw	By Request	36-4850	8.5mm x 50mm Fenestrated Screw	By Request
36-4475	4.5mm x 75mm Fenestrated Screw	By Request	36-4855	8.5mm x 55mm Fenestrated Screw	By Request
36-4480	4.5mm x 80mm Fenestrated Screw	By Request	36-4860	8.5mm x 60mm Fenestrated Screw	By Request
36-4530	5.5mm x 30mm Fenestrated Screw	By Request	36-4865	8.5mm x 65mm Fenestrated Screw	By Request
36-4555	5.5mm x 55mm Fenestrated Screw	By Request	36-4870	8.5mm x 70mm Fenestrated Screw	By Request
36-4560	5.5mm x 60mm Fenestrated Screw	By Request	36-4875	8.5mm x 75mm Fenestrated Screw	By Request
36-4565	5.5mm x 65mm Fenestrated Screw	By Request	36-4880	8.5mm x 80mm Fenestrated Screw	By Request
36-4570	5.5mm x 70mm Fenestrated Screw	By Request	36-4930	9.5mm x 30mm Fenestrated Screw	By Request
36-4575	5.5mm x 75mm Fenestrated Screw	By Request	36-4935	9.5mm x 35mm Fenestrated Screw	By Request
36-4580	5.5mm x 80mm Fenestrated Screw	By Request	36-4940	9.5mm x 40mm Fenestrated Screw	By Request
36-4630	6.5mm x 30mm Fenestrated Screw	By Request	36-4945	9.5mm x 45mm Fenestrated Screw	By Request
36-4660	6.5mm x 60mm Fenestrated Screw	By Request	36-4950	9.5mm x 50mm Fenestrated Screw	By Request
36-4665	6.5mm x 65mm Fenestrated Screw	By Request	36-4955	9.5mm x 55mm Fenestrated Screw	By Request
36-4670	6.5mm x 70mm Fenestrated Screw	By Request	36-4960	9.5mm x 60mm Fenestrated Screw	By Request
36-4675	6.5mm x 75mm Fenestrated Screw	By Request	36-4965	9.5mm x 65mm Fenestrated Screw	By Request
36-4680	6.5mm x 80mm Fenestrated Screw	By Request	36-4970	9.5mm x 70mm Fenestrated Screw	By Request
36-4730	7.5mm x 30mm Fenestrated Screw	By Request	36-4975	9.5mm x 75mm Fenestrated Screw	By Request
36-4735	7.5mm x 35mm Fenestrated Screw	By Request	36-4980	9.5mm x 80mm Fenestrated Screw	By Request
36-4760	7.5mm x 60mm Fenestrated Screw	By Request			

36-9110 Implants and Instruments







Part #	Description	Qty
36-6300	JANUS Fenestrated Implant and Instrument Case	1
36-6310	Top Level Tray	1
36-6312	5.5mm JANUS Fenestrated Screw Caddy	1
36-6313	6.5mm JANUS Fenestrated Screw Caddy	1
36-6314	7.5mm JANUS Fenestrated Screw Caddy	1
36-6320	Bottom Level Tray	1
36-6321	Cannula Caddy	1
36-6333	Tall Adapter Caddy	1
36-6322	Short Adapter Caddy	1

Optional Caddies

Part #	Description	Qty
36-6311	4.5mm JANUS Fenestrated Screw Caddy	By Request
36-6315	8.5mm JANUS Fenestrated Screw Caddy	By Request
36-6316	9.5mm JANUS Fenestrated Screw Caddy	By Request



Instruments

	Part #	Description	Qty Set
	36-1604	Short Adapter*	12
	36-1605	Tall Adapter*	12
	36-1601	Cannula*	6
	36-1603	Adapter Insert	2
	36-1606	Adapter Wrench	2
	36-1602	Plunger*	2

*Single Use Only Instruments

Notes

Please visit [Orthofix.com/IFU](https://www.orthofix.com/IFU) for full information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.



Orthofix
3451 Plano Parkway
Lewisville, Texas 75056-9453 USA
1.214.937.3199
1.888.298.5700
www.orthofix.com



Medical Device Safety Services (MDSS):
Schiffgraben 41
30175, Hannover
Germany
+49 511 6262 8630
www.mdss.com

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