



FIREBIRD[®] SI
SI FUSION SYSTEM

Operative Technique

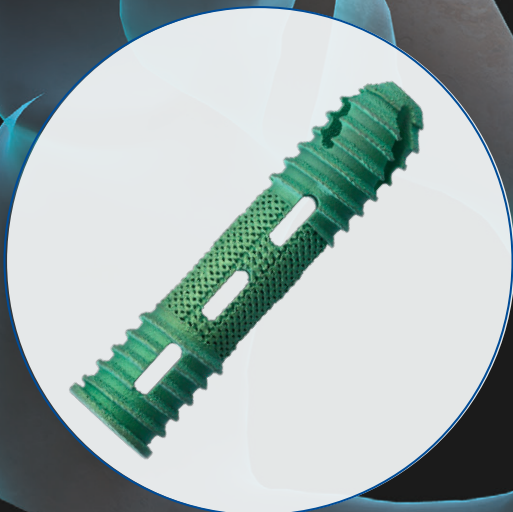


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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each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



INTRODUCTION

The FIREBIRD™ SI Fusion System is a temporary, multiple component system consisting of non-sterile instruments and sterile, cannulated screws of various lengths and diameters with multiple fenestrations on their shafts. The FIREBIRD SI screws are constructed from medical-grade titanium alloy (Ti-6Al-4V ELI). The 11mm and 12mm FIREBIRD SI screws are 3D printed with a mid-shaft porous region. The porous titanium region has open macroscopic 3D pores with a microscopic roughened surface. FIREBIRD SI screws allow for packing of autograft and allograft materials.

FIREBIRD SI Fusion System consists of cannulated, fenestrated, 9mm, 11mm, and 12mm diameter implants in lengths ranging from 25mm to 70mm. The 11mm diameter implant features a tapered proximal end and dual-pitch threads. The 12mm diameter implant maintains a single pitch thread form on the proximal and distal ends.

The Steinmann Pins, Drills, and Packing Tubes are single use devices and should be discarded after use.



Implant Specifications

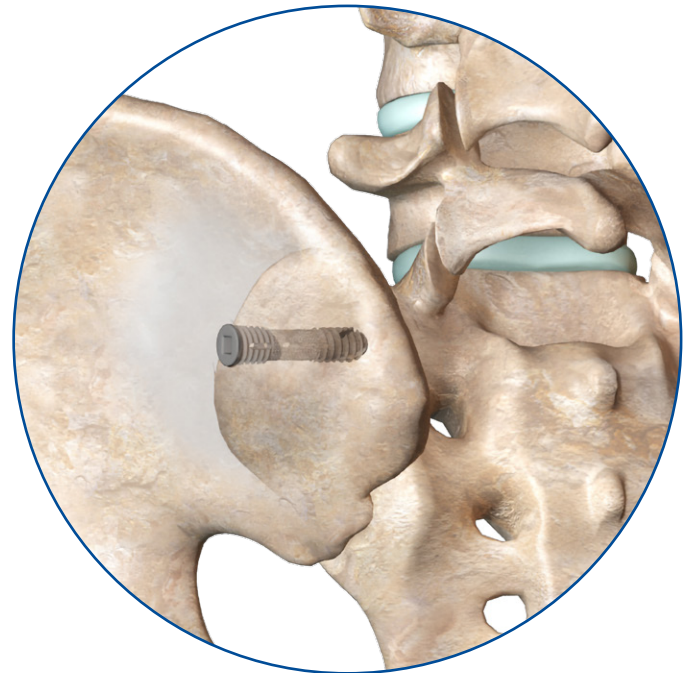
The FIREBIRD SI Fusion System is intended for fixation of sacroiliac joint disruptions. This fixation device is to only be used in skeletally mature patients.

The FIREBIRD SI Fusion System is intended for fixation of sacroiliac joint disruptions, and intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

This operative technique describes the minimally invasive lateral approach to deliver the FIREBIRD SI Fusion System implants. There are two methods outlined: Single Steinmann Pin and the Three Steinmann Pin technique.

The 11mm screw also possesses:

- The proprietary manufacturing process creates macroscopic 3D pores with microscopic roughened surface and nano-scale features on the mid shaft porous region.
- The nano-scale features have been shown to increase proliferation and alkaline phosphatase activity (an early osteogenic differentiation marker) in human stem cells in vitro. In vitro performance may not be representative of clinical performance.
- The mid shaft porous region with 400 micron pores and 50% porosity is designed to help facilitate bone ingrowth as suggested in an in-vivo ovine lumbar spinal fusion model.



Three Steinmann Pin Technique

1. PATIENT SETUP

Position the patient prone on the operative table (**Fig. 1**). Use imaging to obtain lateral, inlet and outlet views. EMG and somatosensory evoked potentials may be utilized during the procedure. If using EMGs, monitor the following muscles during surgery:

- L5 Nerve Root, Anterior Tibialis
- S1 Nerve Root, Gastrocnemius
- S2 Nerve Root, Rectal Sphincter

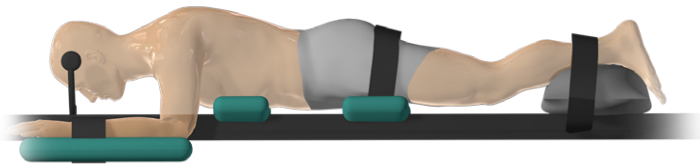


Fig. 1

2. INCISION LOCATION

Mark the skin utilizing lateral imaging. Use the **Long Blunt Steinmann Pin, (11-1109-FD21)** to locate and mark the skin along the:

- Superimposed Alar Slope
- Anterior Sacral Wall
- Posterior Sacral Wall

The three markings will create a triangular working space. The incision should bisect this area and measure approximately 7.5cm / 3.0in in length. In an obese patient, the incision should be slightly more posterior.

NOTE: Use a single Long Blunt Steinmann Pin prior to draping surgical site. The **Fluoroscopic Targeting Crosshair (71-5010)** may be used in place of the Long Blunt Steinmann Pin. The Fluoroscopic Targeting Crosshair is available by request only.

3. PLACEMENT OF 3 STEINMANN PINS

First Steinmann Pin

Advance the **Sharp, Short Steinmann Pin (18-3105)** through the incision to the ilium (**Fig. 2**). Utilizing imaging, check the position of the entry point to ensure proper trajectory of the pin. Initial pin starting position, which is 1cm from the anterior sacral wall and 1 cm caudal from the alar slope/line, is completed utilizing the lateral view only. The sharp end of the Steinmann Pin will appear smaller than the blunt end and will sit caudal or below the superimposed ala and midline of the sacrum. On the inlet view, the Steinmann Pin will point toward the middle of the sacrum. On the outlet view, the Steinmann Pin will point between the S1 endplate and S1 neuroforamen. Under imaging, advance the Steinmann Pin using a mallet (not provided) through the ilium and across the sacroiliac joint. The final position of the Steinmann Pin is approximately 1cm from the anterior sacral wall and 1cm caudal from the alar slope/line, and is approximately mid-S1. This pin position ensures starting point location.

The **Radiolucent Pin Holder (18-3015)** may be used to retain the Steinmann Pin and distance hands from imaging exposure.

NOTE: Neuromonitoring may be used at the level of the S1 foramen.

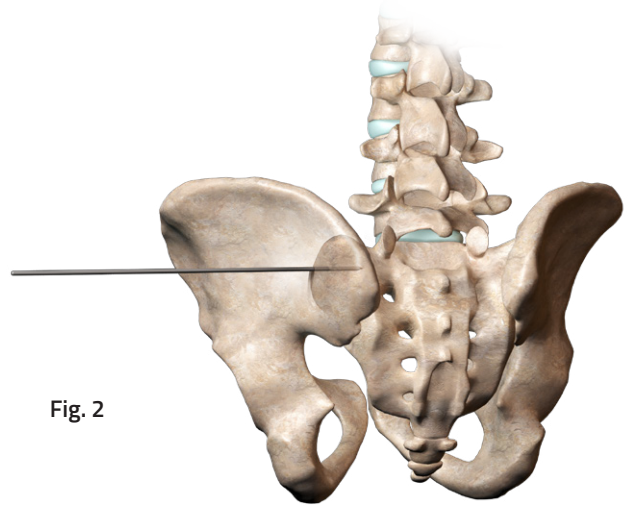


Fig. 2

Second Steinmann Pin

Insert and thread the **Large Radiolucent Tube (18-3014)** or the **Large Radiolucent Tube, Short (18-3020)** into the **3 Pin Parallel Guide Plate (18-3016)**. Select the desired distance of 16mm, 18mm, 20mm, or 22mm between the first and second FIREBIRD SI screw (**Fig. 3**). The distance will vary depending on the patient's anatomy. Insert and secure the **Small Radiolucent Tube (18-3013)** or the **Small Radiolucent Tube, Short (18-3019)** into the first set of holes on the 3 Pin Parallel Guide Plate corresponding to the desired distance between the first and second implant. Insert and secure another Small Radiolucent Tube into the second set of holes on the 3 Pin Parallel Guide Plate corresponding to the desired distance between the second and third implant. Insert the Large Radiolucent Tube of the Radiolucent Parallel Guide assembly over the first Sharp, Short Steinmann Pin.

The second FIREBIRD SI screw entry point should follow the same trajectory keeping within the center of the triangular markings of the posterior and anterior sacral walls. Ensure the Large and Small Radiolucent Tubes are tightly threaded into the 3 Pin Parallel Guide Plate. Insert the Sharp, Short Steinmann Pin into the Small Radiolucent Tube. Using a mallet, advance the Sharp, Short Steinmann Pin across the sacroiliac joint, stopping short of the S1 neuroforamen.

Third Steinmann Pin

Insert the Sharp, Short Steinmann Pin into the Small Radiolucent Tube furthest from the Large Radiolucent Tube. Using a mallet, advance the Sharp, Short Steinmann Pin across the sacroiliac joint. The third FIREBIRD SI screw should be located between the S1 and S2 neuroforamen. Carefully remove the 3 Pin Parallel Guide Plate assembly while maintaining the position of all 3 Steinmann Pins.

Fourth Steinmann Pin

To place the fourth Steinmann Pin, carefully remove the 3 Pin Parallel Guide Plate assembly while maintaining the position of all 3 Steinmann Pins. Remove the second (most caudal) Small Radiolucent Tube from the 3 Pin Parallel Guide Plate. Select the desired distance of 16mm, 18mm, 20mm, or 22mm between the third and fourth FIREBIRD SI screw. Insert and secure a Small Radiolucent Tube into the first set of the small holes on the 3 Pin Parallel Guide Plate corresponding to the desired distance between the third and fourth implant. Insert the Large Radiolucent Tube of the assembled 3 Pin Parallel Guide Plate over the third Steinmann Pin.

Insert the Sharp, Short Steinmann Pin into the Small Radiolucent Tube. Using a mallet, advance the Sharp, Short Steinmann Pin across the sacroiliac joint. The fourth implant should be located at the level of the S2 neuroforamen.

The **Radiolucent Pin Holder (18-3015)** may be used to retain the Steinmann Pin and distance hands from imaging exposure.

For adequate fixation and/or fusion, it is recommended that three FIREBIRD SI screw implants be placed. As an option, two or four implants may be used due to variations in anatomy.

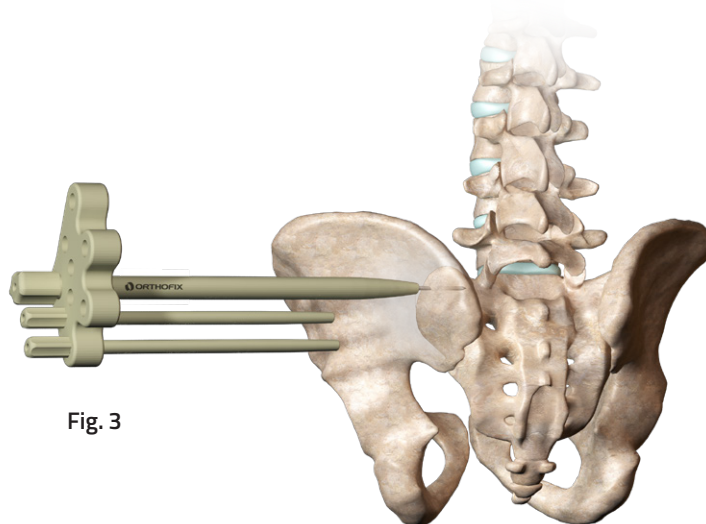


Fig. 3

4. TISSUE DISSECTION

Dissect the soft tissue down to the ilium prior to inserting the Drill Guide. Connect the **Ratcheting Straight Handle (18-3007)** or **Ratcheting T-Handle (18-3006)** to the **Tissue Dissector (18-3008)** and insert over the Steinmann Pin until the tip of the Tissue Dissector is firmly against the ilium (**Fig. 4**). Rotate the Tissue Dissector to release any remaining soft tissue surrounding the Steinmann Pin. Repeat tissue dissection for all Steinmann Pins.

NOTE: Ensure the handle is in Neutral position for ease of dissection.

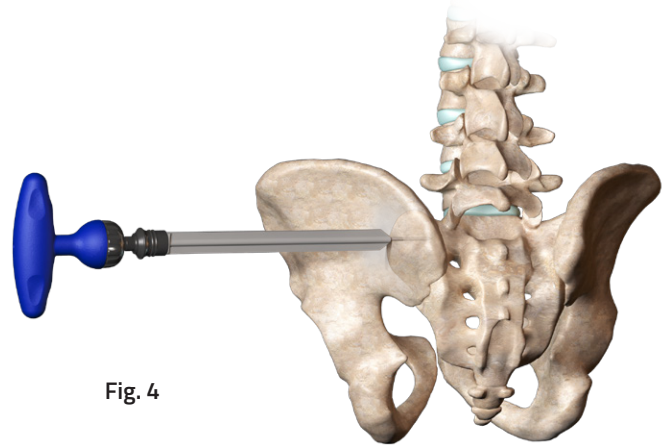


Fig. 4

5. DRILL GUIDE ASSEMBLY AND INSERTION

Assemble the **Pin Sleeve (18-3003)** and **Drill Guide (18-3002)** by inserting and threading the Pin Sleeve into the Drill Guide and tighten (**Fig. 5**). Once assembled, the Pin Sleeve's tapered tip will protrude beyond the distal spiked end of the Drill Guide. Insert the Drill Guide-Pin Sleeve Assembly, with the handle pointing downward, over the Steinmann Pin until the distal tip of the Pin Sleeve is firmly against the ilium. While maintaining forward pressure on the Drill Guide, unthread the Pin Sleeve from the Drill Guide to expose the spikes on the distal end, but do not remove the Pin Sleeve from the Drill Guide (**Fig. 6**). Install the **Striker Tube (18-3004)** by pulling backward on the spring-loaded tabs. Slide the Striker Tube down onto the proximal end of the Drill Guide, so that the flange on the Striker Tube sits in the groove of the Drill Guide. Release the spring loaded tabs of the Striker Tube (**Fig. 7**).

Use a mallet and tap the Striker Tube until the distal spiked end of the Drill Guide is secured to the ilium. Once the Drill Guide is secured, remove the Striker Tube and Pin Sleeve from the Drill Guide (**Fig. 8**).

NOTE: Do not overtighten the Pin Sleeve into the Drill Guide.

NOTE: Maintain control by keeping hand on the Drill Guide to reduce the risk of dislodgement from the ilium.



Fig. 5

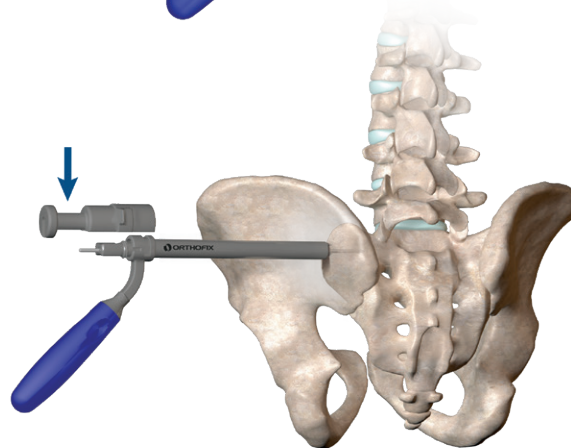


Fig. 6

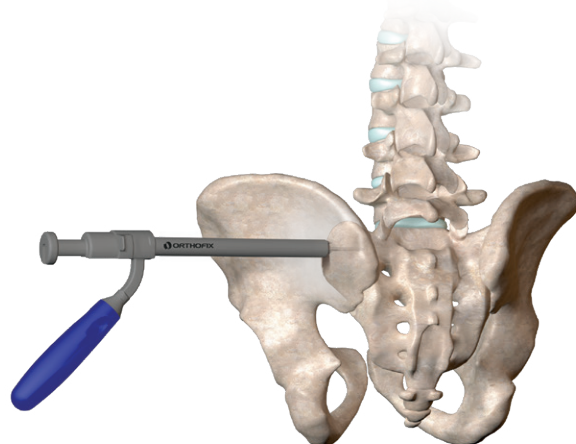


Fig. 7

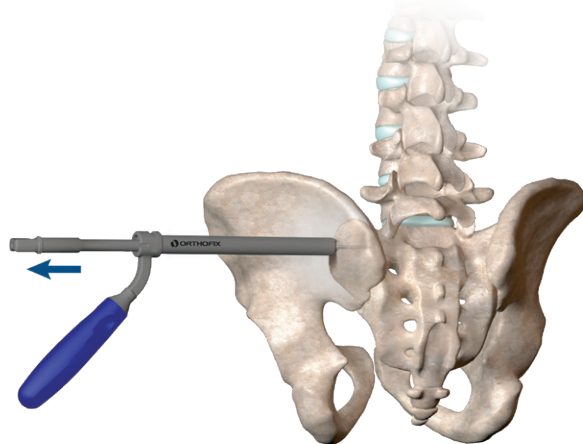


Fig. 8

6. FIREBIRD SI SCREW LENGTH AND DIAMETER SELECTION

Ensure the Drill Guide teeth are seated into the ilium (**Fig. 9**). Slide the **Screw Sizing Template (18-3005)** over the Steinmann Pin until it rests flush against the Drill Guide. Read the Screw Sizing Template according to where the proximal end of the Steinmann Pin is located (**Fig. 10**). The measurement represents the length of FIREBIRD SI screw to select. Remove the Screw Sizing Template. Select the size of the implant based on patient anatomy.

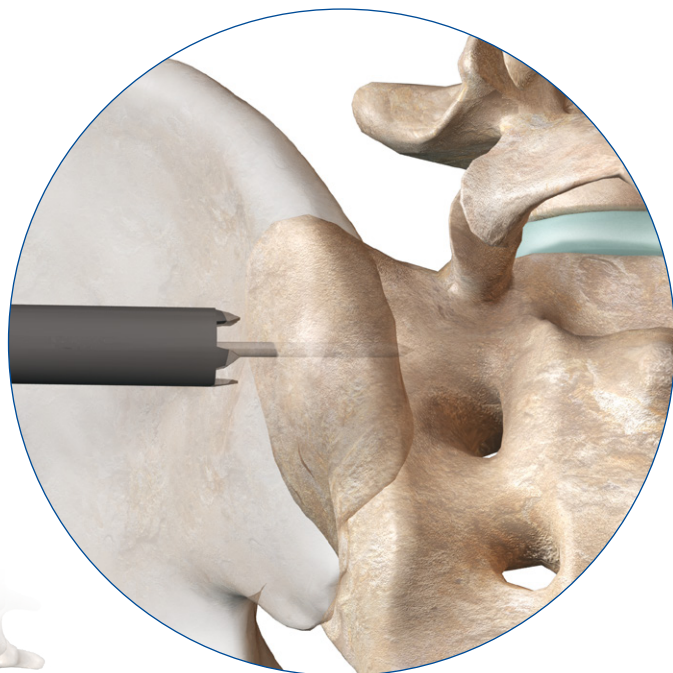


Fig. 9

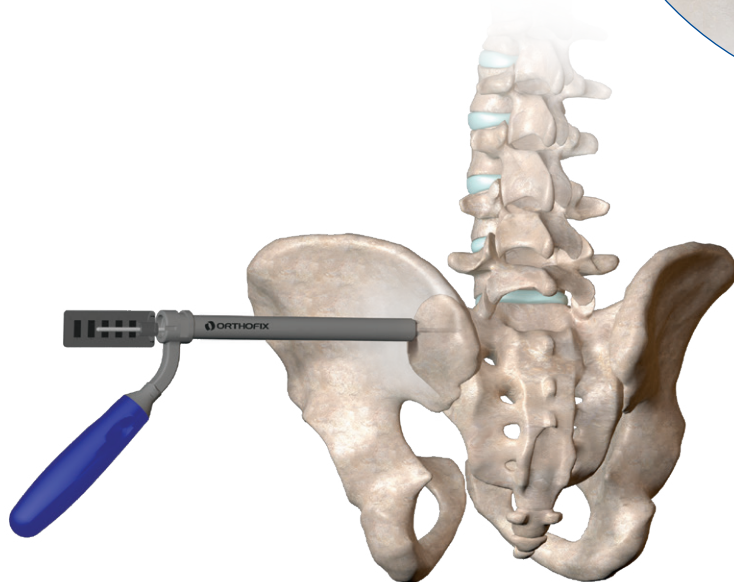


Fig. 10

7. DRILLING

Once the FIREBIRD SI screw length and diameter has been determined, select the appropriate diameter Drill, **9mm (18-3100)**, **11mm (18-3101)**, or **12mm (18-3102)**. Slide the **Adjustable Collar (18-3011)** onto the appropriate Drill from the proximal end with the arrow pointing toward the operative site. Press the button and slide the Adjustable Collar to select the depth (5mm to 10mm shorter than desired screw length). The depth is read by noting the number marking on the Drill showing through either one of two windows at the distal end of the Adjustable Collar (**Fig. 11**). Connect the Ratcheting Straight Handle or Ratcheting T-Handle to the Drill. Utilizing the outlet view, create the pilot hole by advancing the Drill until the Adjustable Collar stops against the proximal end of the Drill Guide. Ensure to drill across the SI Joint. Once the desired depth is reached, remove the Drill (**Fig. 12**).

NOTE: The Steinmann Pin may be inadvertently withdrawn while removing the Drill. Use the Long Blunt Steinmann Pin to retain the Sharp, Short Steinmann Pin by placing the Long Blunt Steinmann Pin through the cannula of the Handle and Drill while removing the Drill.

NOTE: Observe the Steinmann Pins to ensure no further advancement occurs. If the Drill appears to be advancing the Sharp, Short Steinmann Pin while drilling the pilot hole, the Sharp, Short Steinmann Pin should be removed and replaced by the Blunt, Short Steinmann Pin, or Long Blunt Steinmann Pin.

NOTE: To maximize the amount of autograft harvested, rotate Drill clockwise when removing Drill. Autograft will remain in Drill flutes.



Fig. 11

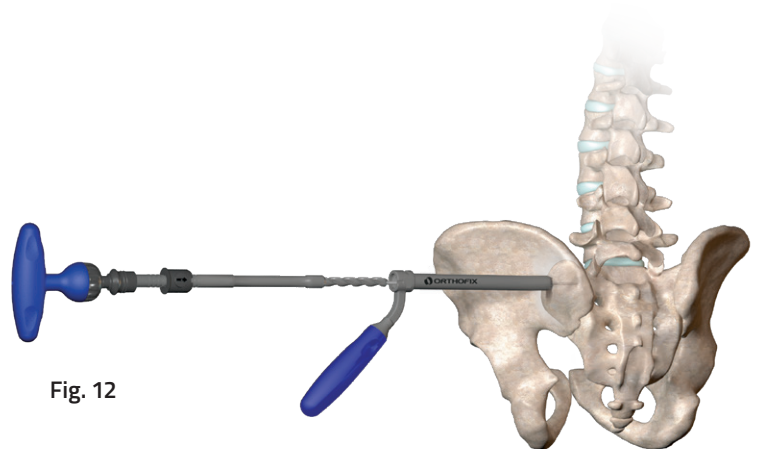


Fig. 12

8. FIREBIRD SI SCREW PLACEMENT

Option A: With Steinmann Pin Removed.

Prior to insertion, fill the FIREBIRD SI screw with allograft or autograft. Connect the Ratcheting Straight Handle or Ratcheting T-Handle to the **Screw Driver (18-3001)** and load the appropriately sized FIREBIRD SI screw onto the Screw Driver. Insert the Screw Driver with implant attached into the Drill Guide (**Fig. 13**). Under imaging guidance, advance the FIREBIRD SI screw clockwise into the prepared hole to the desired depth. The laser markings on the Screw Driver indicate two depths. When the distal laser mark is aligned with the proximal end of the Drill Guide, the FIREBIRD SI screw head is 5mm proud of the ilium. The proximal laser mark denotes when the FIREBIRD SI screw head is contacting the ilium. Remove the Screw Driver once insertion is complete. If additional biologic delivery is desired, proceed to step 9.

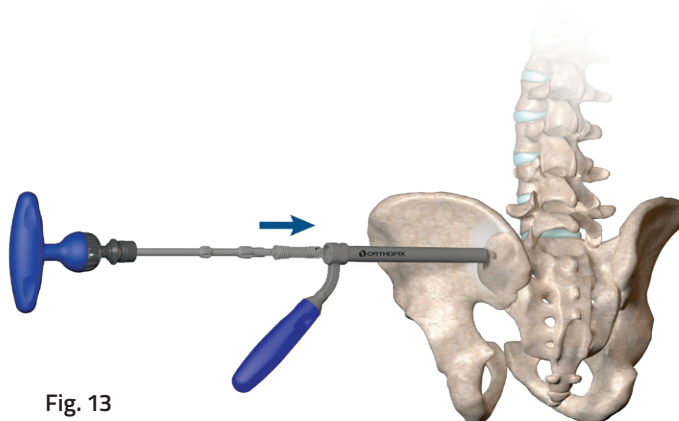


Fig. 13

Option B: With the Steinmann Pin in Place.

Insert an additional Steinman Pin through selected FIREBIRD SI screw. Fill FIREBIRD SI screw with allograft or autograft prior to insertion around an additional Steinmann Pin. Connect the Ratcheting Straight Handle or Ratcheting T-Handle to the Screw Driver (18-3001) and load the appropriately sized FIREBIRD SI screw onto the Screw Driver. Under imaging guidance, advance the FIREBIRD SI screw clockwise into the prepared hole to the desired depth. The laser markings on the Screw Driver indicate two depths. When the distal laser mark is aligned with the proximal end of the drill guide, the FIREBIRD SI screw head is 5mm proud of the ilium. The proximal laser mark denotes when the FIREBIRD SI screw head is contacting the ilium. Remove the Screw Driver once insertion is complete. Proceed to step 9 for additional biologic delivery.

If the FIREBIRD SI screw depth needs to be adjusted after the Screw Driver is removed, proceed to step 10.

NOTE: Observe the Steinmann Pins to ensure no further advancement is observed. If the implant appears to be advancing the Sharp, Short Steinmann Pin during insertion, the Sharp, Short Steinmann Pin should be removed and replaced by the Blunt, Short Steinmann Pin, or Long Blunt Steinmann Pin.

9. ADDITIONAL BIOLOGIC DELIVERY

(Required for Option B in Step 8)

If the Steinmann Pin is still in place, remove the Steinmann Pin while leaving the Drill Guide in place. Determine the desired amount of biologic material, and load the **Packing Tube (18-3009)**. Next, insert the Packing Tube into the Drill Guide and engage the distal tip of the Packing Tube with the square drive feature on the FIREBIRD SI screw (**Fig. 14**). Use the **Packing Plunger (18-3010)** to inject the biologic material into the FIREBIRD SI screw, ilium, sacrum, and the sacroiliac joint. Allograft or autograft may be used.

The Packing Tube (18-3009) and **Packing Plunger (18-3010)** are available by request only.

NOTE: Do not over pack as implant will obtain patient autograft during implantation.

Repeat steps 5-9 of the "Three Steinmann Pin Technique" for each of the remaining FIREBIRD SI screw placements.

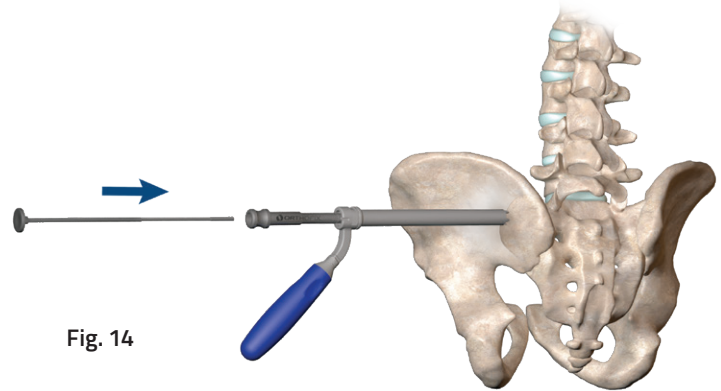


Fig. 14

10. IMPLANT REMOVAL AND ADJUSTMENT

Prior to wound closure, visualize all implants in the lateral, inlet, and outlet views to assure proper positioning across the sacroiliac joint without violating the spinal canal, the neuroforamen(s), the anterior sacral wall, and the sacral ala.

If the FIREBIRD SI screw depth needs to be adjusted after the Screw Driver is removed, the **Adjustment Driver (18-3017)** may be used to advance or withdraw the FIREBIRD SI screw.

Using palpation and fluoroscopy, locate the proximal end of the FIREBIRD SI screw.

Use imaging to confirm that the Adjustment Driver is fully seated in the FIREBIRD SI screw. If the Adjustment Driver is not fully seated, clearing the FIREBIRD SI screw cannula may be necessary.

Thread the **Adjustment Driver Insert (18-3018)** into the Adjustment Driver down to the laser mark. The Adjustment Driver Insert will not sit flush (**Fig. 15**).

Rotate the Adjustment Driver counterclockwise to withdraw or fully remove the FIREBIRD SI screw.

If the healthcare professional desires to replace the FIREBIRD SI screw, a Steinmann Pin should be used to locate the original placement site after removal. Use standard protocol for wound closure and postoperative care.

WARNING: If the FIREBIRD SI screw has been in place for a sufficient amount of time for bone to have grown in to the FIREBIRD SI screw, removal may not be feasible.

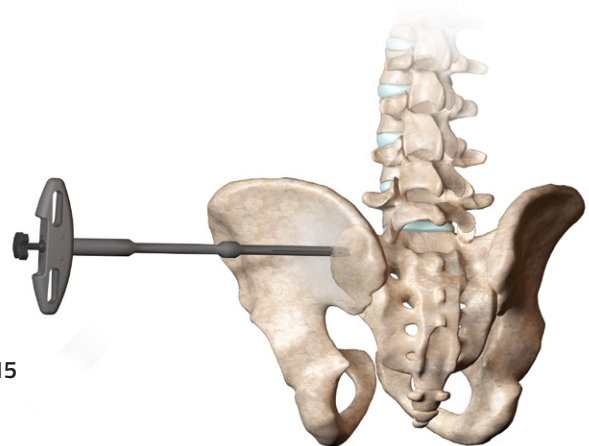


Fig. 15

Single Steinmann Pin Technique

1. PATIENT SETUP

Position the patient prone on the operative table (**Fig. 16**). Use imaging to obtain lateral, inlet and outlet views. EMG and somatosensory evoked potentials may be utilized during the procedure. If using EMGs, monitor the following muscles during surgery:

- L5 Nerve Root, Anterior Tibialis
- S1 Nerve Root, Gastrocnemius
- S2 Nerve Root, Rectal Sphincter

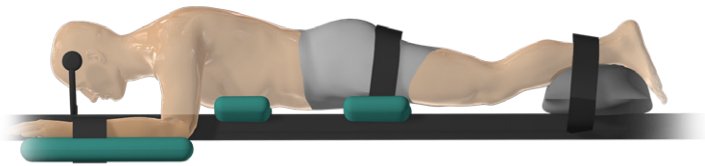


Fig. 16

2. INCISION LOCATION

Mark the skin utilizing lateral imaging. Use the **Long Blunt Steinmann Pin, (11-1109-FD21)** to locate and mark the skin along the:

- Superimposed Alar Slope
- Anterior Sacral Wall
- Posterior Sacral Wall

The three markings will create a triangular working space. The incision should bisect this area and measure approximately 7.5cm / 3.0in in length. In an obese patient, the incision should be slightly more posterior.

NOTE: Use a single Long Blunt Steinmann Pin prior to draping surgical site. The **Fluoroscopic Targeting Crosshair (71-5010)** may be used in place of the Long Blunt Steinmann Pin. The Fluoroscopic Targeting Crosshair is available by request only.

3. PLACEMENT OF STEINMANN PIN

Advance the **Sharp, Short Steinmann Pin (18-3105)** through the incision to the ilium (**Fig. 17**). Utilizing imaging, check the position of the entry point to ensure proper trajectory of the pin. Initial pin starting position, which is 1cm from the anterior sacral wall and 1cm caudal from the alar slope/line, is completed utilizing the lateral view only. The sharp end of the Steinmann Pin will appear smaller than the blunt end and will sit caudal or below the superimposed ala and midline of the sacrum. On the inlet view, the Steinmann Pin will point toward the middle of the sacrum. On the outlet view, the Steinmann Pin will point between the S1 endplate and S1 neuroforamen. Under imaging, advance the Steinmann Pin using a mallet (not provided) through the ilium and across the sacroiliac joint. The final position of the Steinmann Pin is approximately 1cm from the anterior sacral wall and 1cm caudal from the alar slope/line, and is approximately mid-S1. This pin position ensures starting point location.

The **Radiolucent Pin Holder (18-3015)** may be used to retain the Steinmann Pin in position and distance hands from imaging exposure.

NOTE: Neuromonitoring may be used at the level of the S1 foramen.

4. TISSUE DISSECTION

Dissect the soft tissue down to the ilium prior to inserting the Drill Guide. Connect the **Ratcheting Straight Handle (18-3007)** or **Ratcheting T-Handle (18-3006)** to the **Tissue Dissector (18-3008)** and insert over the Steinmann Pin until the tip of the Tissue Dissector is firmly against the ilium (**Fig. 18**). Rotate the Tissue Dissector to release any remaining soft tissue surrounding the Steinmann Pin.

NOTE: Ensure the Handle is in Neutral position for ease of dissection.

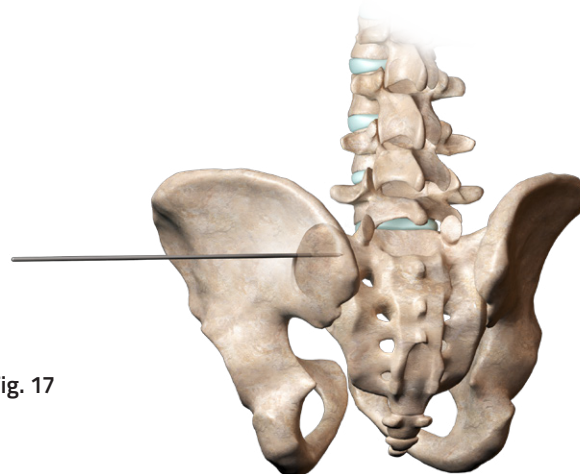


Fig. 17

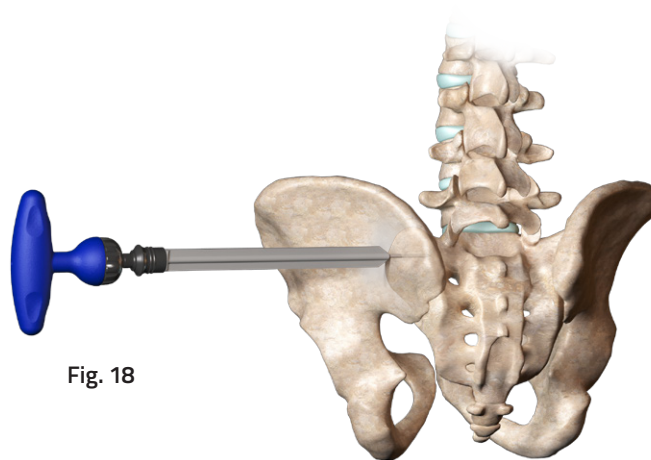


Fig. 18

5. DRILL GUIDE ASSEMBLY AND INSERTION

Assemble the **Pin Sleeve (18-3003)** and **Drill Guide (18-3002)** by inserting and threading the Pin Sleeve into the Drill Guide and tighten (**Fig. 19**). Once assembled, the Pin Sleeve's tapered tip will protrude beyond the distal spiked end of the Drill Guide. Insert the Drill Guide-Pin Sleeve Assembly with the handle pointing downward, over the Steinmann Pin until the distal tip of the Pin Sleeve is firmly against the ilium. While maintaining forward pressure on the Drill Guide against the ilium, unthread the Pin Sleeve from the Drill Guide to expose the spikes on the distal end, but do not remove the Pin Sleeve from the Drill Guide (**Fig. 20**). Install the **Striker Tube (18-3004)** by pulling backward on the spring loaded tabs. Slide the Striker Tube down onto the proximal end of the Drill Guide, so that the flange on the Striker Tube sits in the groove of the Drill Guide. Release the spring loaded tabs of the Striker Tube (**Fig. 21**).

Use a mallet and tap the Striker Tube until the distal spiked end of the Drill Guide is secured to the ilium. Once the Drill Guide is secured, remove the Striker Tube and Pin Sleeve from the Drill Guide (**Fig. 22**).

NOTE: Do not overtighten the Pin Sleeve into the Drill Guide.

NOTE: Maintain control by keeping one hand on the Drill Guide to reduce the risk of dislodgement from the ilium.



Fig. 19

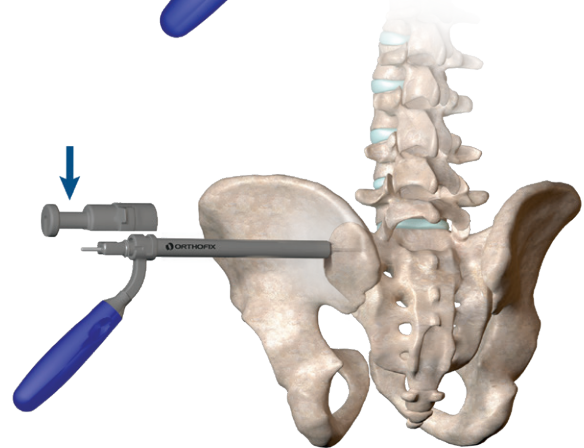


Fig. 20

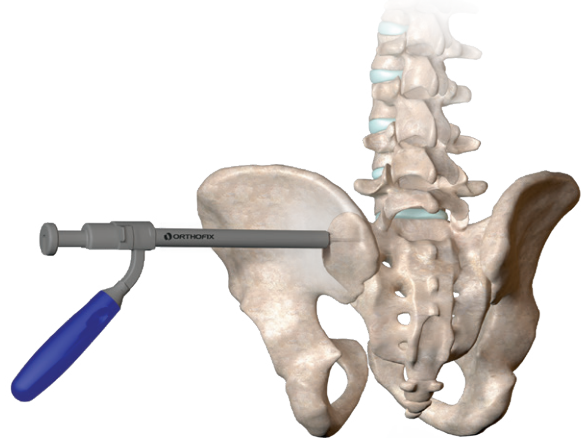


Fig. 21

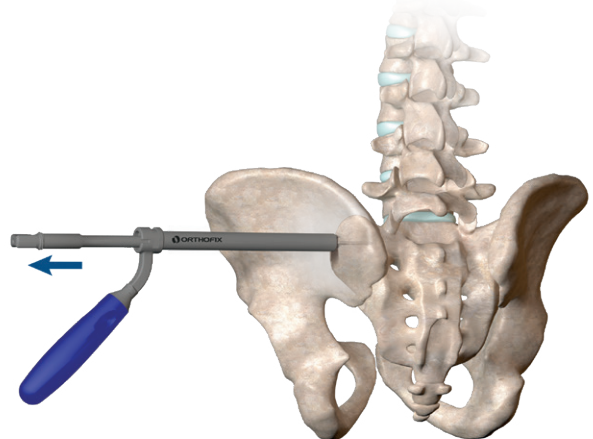


Fig. 22

6. FIREBIRD SI SCREW LENGTH AND DIAMETER SELECTION

Ensure the Drill Guide teeth are seated into the ilium (**Fig. 23**). Slide the **Screw Sizing Template (18-3005)** over the Steinmann Pin until it rests flush against the Drill Guide. Read the Screw Sizing Template according to where the proximal end of the Steinmann Pin is located. (**Fig. 24**) The measurement represents the length of FIREBIRD SI screw to select. Remove the Screw Sizing Template. Select the size of the implant based on patient anatomy.

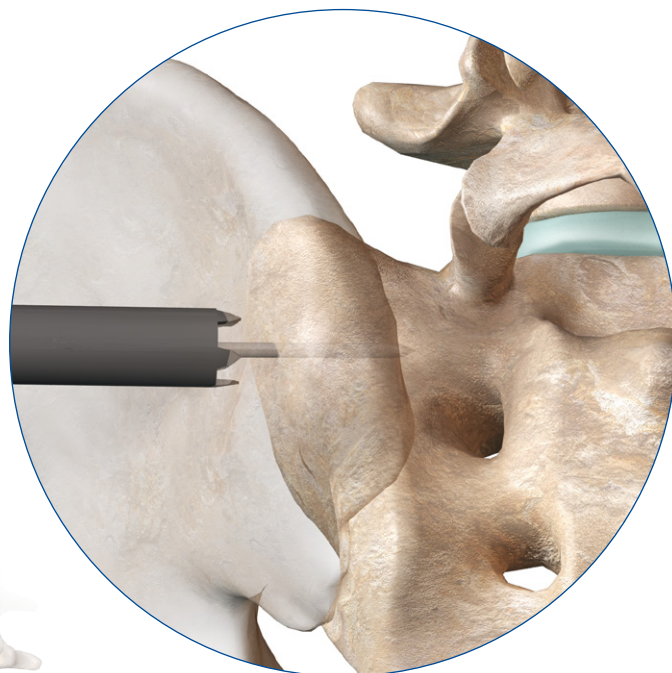


Fig. 23

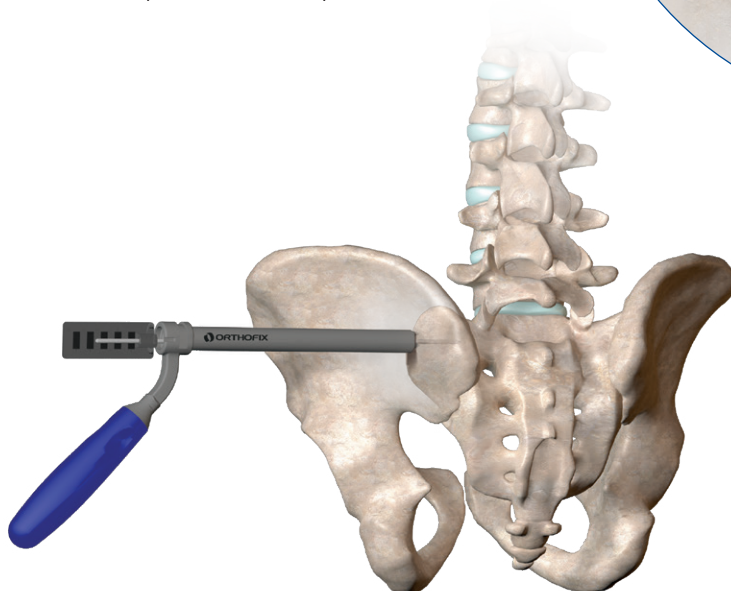


Fig. 24

7. DRILLING

Once the FIREBIRD SI screw length and diameter has been determined, select the appropriate diameter Drill, **9mm (18-3100)**, **11mm (18-3101)**, or **12mm (18-3102)**. Slide the **Adjustable Collar (18-3011)** onto the appropriate Drill from the proximal end with the arrow pointing toward the operative site. Press the button and slide the Adjustable Collar to select the depth (5mm to 10mm shorter than the desired screw length). The depth is read by noting the number marking on the Drill showing through either one of two windows at the distal end of the Adjustable Collar (**Fig. 25**). Connect the Ratcheting Straight Handle or Ratcheting T-Handle to the Drill. Utilizing the outlet view, create the pilot hole by advancing the Drill until the Adjustable Collar stops against the proximal end of the Drill Guide. Ensure to drill across the SI Joint. Once the desired depth is reached, remove the Drill (**Fig. 26**).

NOTE: The Steinmann Pin may be inadvertently withdrawn while removing the Drill. Use the Long Blunt Steinmann Pin to retain the Sharp, Short Steinmann Pin by placing the Long Blunt Steinmann Pin through the cannula of the Handle and Drill while removing the Drill.

NOTE: Observe the Steinmann Pins to ensure no further advancement occurs. If the Drill appears to be advancing the Sharp, Short Steinmann Pin while drilling the pilot hole, the Sharp, Short Steinmann Pin should be removed and replaced by the Blunt, Short Steinmann Pin, or Long Blunt Steinmann Pin.

NOTE: To maximize the amount of autograft harvested, rotate Drill clockwise when removing Drill. Autograft will remain in Drill flutes.



Fig. 25

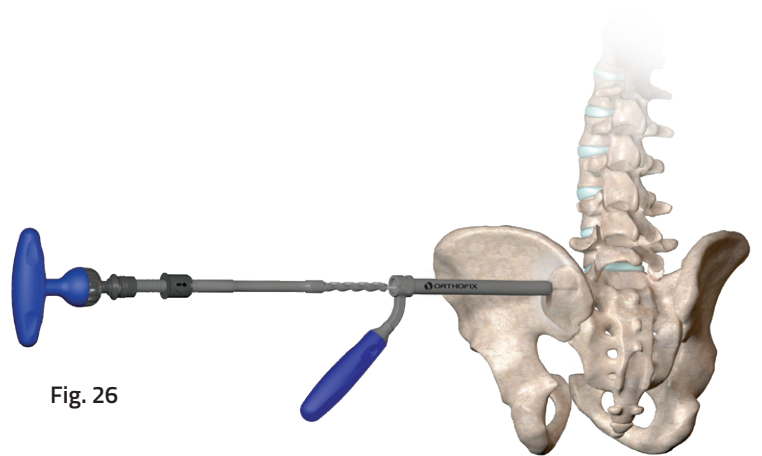


Fig. 26

8. FIREBIRD SI SCREW PLACEMENT

Option A: With Steinmann Pin Removed.

Prior to insertion, fill the FIREBIRD SI screw with allograft or autograft. Connect the Ratcheting Straight Handle or Ratcheting T-Handle to the **Screw Driver (18-3001)** and load the appropriately sized FIREBIRD SI screw onto the Screw Driver. Insert the Screw Driver with implant attached into the Drill Guide (**Fig. 27**). Under imaging guidance, advance the FIREBIRD SI screw clockwise into the prepared hole to the desired depth. The laser markings on the Screw Driver indicate two depths. When the distal laser mark is aligned with the proximal end of the Drill Guide, the FIREBIRD SI screw head is 5mm proud of the ilium (**Fig. 27**). The proximal laser mark denotes when the FIREBIRD SI screw head is contacting the ilium. Remove the Screw Driver once insertion is complete. If additional biologic delivery is desired, proceed to step 9.

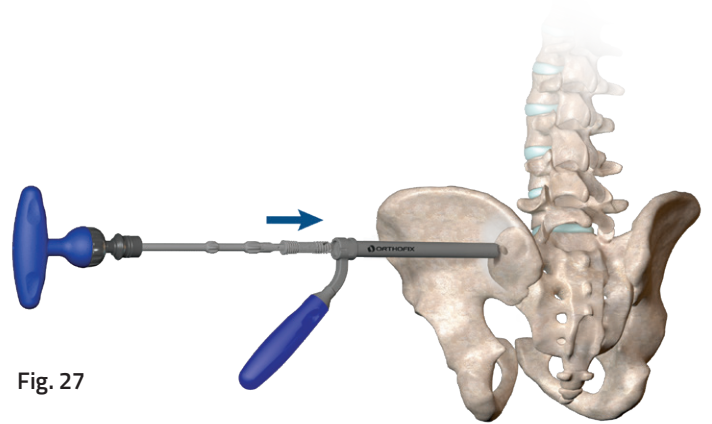


Fig. 27

Option B: With the Steinmann Pin in Place.

Prior to insertion, place an additional Steinmann Pin through the FIREBIRD SI screw. Fill the FIREBIRD SI screw with allograft or autograft and remove the additional Steinmann Pin. Connect the Ratcheting Straight Handle or Ratcheting T-Handle to the **Screw Driver (18-3001)** and load the appropriately sized FIREBIRD SI screw onto the Screw Driver. Insert the FIREBIRD SI screw and Screw Driver over the Steinmann Pin and into the Drill Guide. Under imaging guidance, advance the FIREBIRD SI screw clockwise into the prepared hole to the desired depth. The laser markings on the Screw Driver indicate two depths. When the distal laser mark is aligned with the proximal end of the Drill Guide, the FIREBIRD SI screw head is 5mm proud of the ilium. The proximal laser mark denotes when the FIREBIRD SI screw head is contacting the ilium. Remove the Screw Driver once insertion is complete. Proceed to step 9 for additional biologic delivery.

NOTE: Observe the Steinmann Pins to ensure no further advancement occurs. If the implant appears to be advancing the Sharp, Short Steinmann Pin during insertion, the Sharp, Short Steinmann Pin should be removed and replaced by the Blunt, Short Steinmann Pin, Long Blunt Steinmann Pin or advanced without Steinmann Pin guidance.

9. ADDITIONAL BIOLOGIC DELIVERY

(Required for Option B in Step 8)

If the Steinmann Pin is still in place, remove the Steinmann Pin while leaving the Drill Guide in place. Determine the desired amount of biologic material, and load the **Packing Tube (18-3009)**. Next, insert the Packing Tube into the Drill Guide and engage the distal tip of the Packing Tube with the square drive feature on the FIREBIRD SI screw (**Fig. 28**). Use the **Packing Plunger (18-3010)** to inject the biologic material into the FIREBIRD SI screw, ilium, sacrum, and the sacroiliac joint. Allograft or autograft may be used.

The Packing Tube (18-3009) and Packing Plunger (18-3010) are available by request only.

NOTE: Do not over pack as implant will obtain patient autograft during implantation.

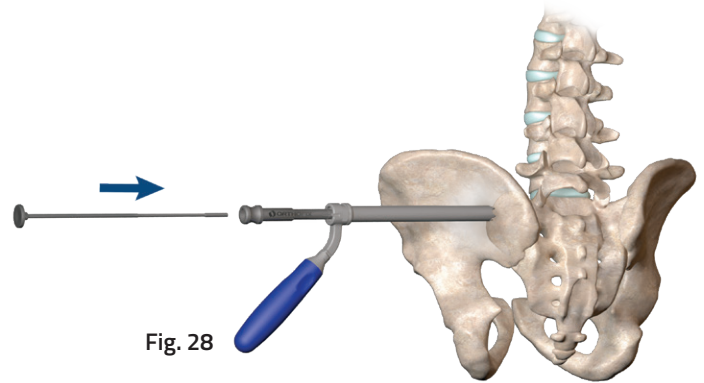


Fig. 28

10. PLACEMENT OF MULTIPLE FIREBIRD SI SCREW IMPLANTS

For adequate fixation and/or fusion, it is recommended that three FIREBIRD SI screw devices be implanted. As an option, two or four implants may be used due to variations in anatomy.

Insert and thread the **Large Radiolucent Tube (18-3014)** or the **Large Radiolucent Tube, Short (18-3020)** into the **2 Pin Parallel Guide Plate (18-3012)**. Select the desired distance of 16mm, 18mm, 20mm, or 22mm between each FIREBIRD SI screw, so that the location of the second FIREBIRD SI screw is at the S1 neuroforamen. The distance may vary depending on the patient's anatomy. Insert and thread the **Small Radiolucent Tube (18-3013)** or the **Small Radiolucent Tube, Short (18-3019)** into the correct hole for the selected distance on the 2 Pin Parallel Guide Plate. Insert the Large Radiolucent Tube of the Radiolucent Parallel Guide Assembly into the Drill Guide and over the Steinmann Pin, if present. The second FIREBIRD SI screw entry point should follow the same trajectory keeping within the center of the triangular markings of the posterior and anterior sacral walls. Ensure the Large and Small Radiolucent Tubes are tightly threaded into the 2 Pin Parallel Guide Plate (**Fig. 29**).

Place the second Sharp, Short Steinmann Pin into the Small Radiolucent Tube. Using a mallet, advance the Sharp, Short Steinmann Pin across the sacroiliac joint, stopping short of the S1 neuroforamen.

NOTE: Use imaging guidance in the outlet view while advancing the Sharp, Short Steinmann Pin at the level of the S1 neuroforamen to avoid injury to the nerve root.

NOTE: Once the second Steinmann Pin is in the desired position, the Radiolucent Parallel Pin Guide Assembly, Drill Guide, and first Steinmann Pin, if present, may be removed. Repeat Steps 4-10 of the "Single Steinmann Pin Technique" for the subsequent implants. A third and fourth FIREBIRD SI screw may be implanted using the same technique. The third FIREBIRD SI screw should be located between the S1 and S2 neuroforamen. The fourth FIREBIRD SI screw, if present, should be located at the level of the S2 neuroforamen.

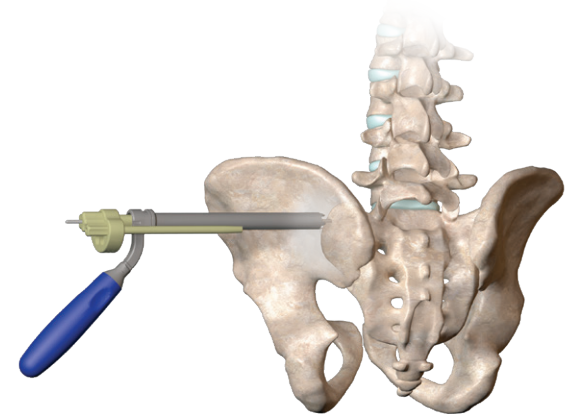


Fig. 29

11. IMPLANT REMOVAL AND/OR ADJUSTMENT

Prior to wound closure, visualize all implants in the lateral, inlet, and outlet views to assure proper positioning across the sacroiliac joint without violating the spinal canal, the neuroforamen(s), the anterior sacral wall, and the sacral ala.

If the FIREBIRD SI screw depth needs to be adjusted after the Screw Driver is removed, the **Adjustment Driver (18-3017)** may be used to advance or withdraw the FIREBIRD SI screw.

Using palpation and fluoroscopy, locate the proximal end of the FIREBIRD SI screw.

Use imaging to confirm Adjustment Driver is fully seated in the FIREBIRD SI screw. If Adjustment Driver is not fully seated, clearing the FIREBIRD SI screw cannula may be necessary.

Thread the **Adjustment Driver Insert (18-3018)** into the Adjustment Driver down to the laser mark. The Adjustment Driver Insert will not sit flush (**Fig. 30**).

Rotate the Adjustment Driver counterclockwise to withdraw or fully remove the FIREBIRD SI screw.

If the healthcare professional desires to replace the FIREBIRD SI screw, a Steinmann Pin should be used to locate the original placement site after removal. Use standard protocol for wound closure and postoperative care.

WARNING: If the FIREBIRD SI screw has been in place for a sufficient amount of time for bone to have grown in to the FIREBIRD SI screw, removal may not be feasible.

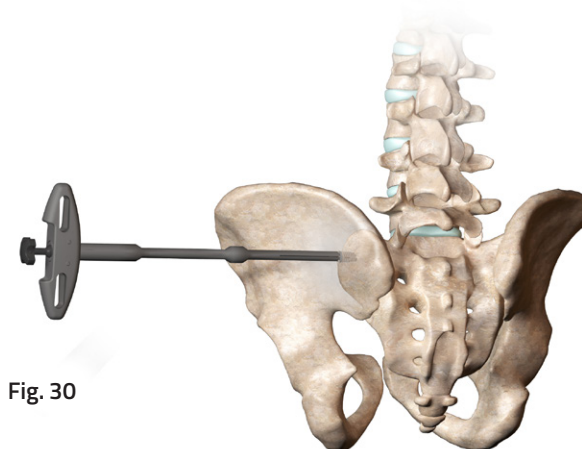
















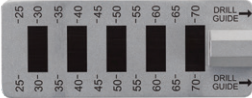

Fig. 30

Implants and Instruments

	Part #	Description	Qty
	18-09XXSP	9mm FIREBIRD SI Screw, Sterile	
	18-10XXSP	11mm FIREBIRD SI Screw, Sterile	
	18-20XXSP	12mm FIREBIRD SI Screw, Sterile	
	11-1109-FD21*	Long Blunt Steinmann Pin	3
			
	18-3104*	Blunt, Short Steinmann Pin	2
			
	18-3105*	Sharp, Short Steinmann Pin	4
			
	18-3008	Tissue Dissector	1
	18-3002	Drill Guide	1

*Single Use Only

Instruments





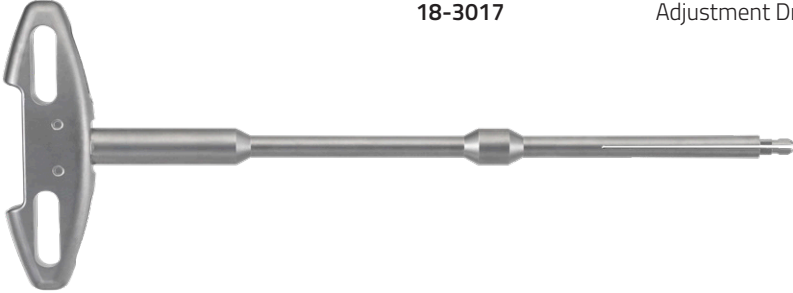

	Part #	Description	Qty
	18-3003	Pin Sleeve	1
	18-3004	Striker Tube	1
	18-3100*	9mm Drill	2
	18-3101*	11mm Drill	2
	18-3102*	12mm Drill	2
	18-3011	Adjustable Collar	1
	18-3005	Screw Sizing Template	1
	18-3001	Screw Driver	2

*Single Use Only

Instruments

	Part #	Description	Qty
	18-3012	2 Pin Parallel Guide Plate	1
	18-3016	3 Pin Parallel Guide Plate	1
	18-3013	Small Radiolucent Tube	2
	18-3014	Large Radiolucent Tube	1
	18-3019	Small Radiolucent Tube, Short	2
	18-3020	Large Radiolucent Tube, Short	1
	18-3006	Ratcheting T-Handle	1
	18-3007	Ratcheting Straight Handle	1

Instruments

Part #	Description	Qty
18-3009*	Packing Tube	Optional
		
18-3010	Packing Plunger	Optional
		
18-3015	Radiolucent Pin Holder	1
		
71-5010	Fluoroscopic Targeting Crosshair	Optional
		
18-3017	Adjustment Driver	1
		
18-3018	Adjustment Driver Insert	1
		

*Single Use Only

11mm & 12mm Implant Tote (18-1001)

Part #	Description	Qty
18-1025SP	11mm x 25mm FIREBIRD SI Screw Sterile	4
18-1030SP	11mm x 30mm FIREBIRD SI Screw Sterile	4
18-1035SP	11mm x 35mm FIREBIRD SI Screw Sterile	4
18-1040SP	11mm x 40mm FIREBIRD SI Screw Sterile	4
18-1045SP	11mm x 45mm FIREBIRD SI Screw Sterile	4
18-1050SP	11mm x 50mm FIREBIRD SI Screw Sterile	4
18-1055SP	11mm x 55mm FIREBIRD SI Screw Sterile	4
18-1060SP	11mm x 60mm FIREBIRD SI Screw Sterile	4
18-1065SP	11mm x 65mm FIREBIRD SI Screw Sterile	4
18-1070SP	11mm x 70mm FIREBIRD SI Screw Sterile	4
18-2025SP	12mm x 25mm FIREBIRD SI Screw Sterile	2
18-2030SP	12mm x 30mm FIREBIRD SI Screw Sterile	2
18-2035SP	12mm x 35mm FIREBIRD SI Screw Sterile	2
18-2040SP	12mm x 40mm FIREBIRD SI Screw Sterile	2
18-2045SP	12mm x 45mm FIREBIRD SI Screw Sterile	2
18-2050SP	12mm x 50mm FIREBIRD SI Screw Sterile	2
18-2055SP	12mm x 55mm FIREBIRD SI Screw Sterile	2
18-2060SP	12mm x 60mm FIREBIRD SI Screw Sterile	2
18-2065SP	12mm x 65mm FIREBIRD SI Screw Sterile	2
18-2070SP	12mm x 70mm FIREBIRD SI Screw Sterile	2

Optional 9mm Implant Tote (18-1002)

Part #	Description	Qty
18-0925SP	9mm x 25mm FIREBIRD SI Screw Sterile	3
18-0930SP	9mm x 30mm FIREBIRD SI Screw Sterile	3
18-0935SP	9mm x 35mm FIREBIRD SI Screw Sterile	3
18-0940SP	9mm x 40mm FIREBIRD SI Screw Sterile	3
18-0945SP	9mm x 45mm FIREBIRD SI Screw Sterile	3
18-0950SP	9mm x 50mm FIREBIRD SI Screw Sterile	3

Optional Implants

Part #	Description
18-0955SP	9mm x 55mm FIREBIRD SI Screw Sterile
18-0960SP	9mm x 60mm FIREBIRD SI Screw Sterile
18-0965SP	9mm x 65mm FIREBIRD SI Screw Sterile
18-0970SP	9mm x 70mm FIREBIRD SI Screw Sterile

Instrument Case 18-9093

Part #	Description	Qty
11-1109-FD21*	Long Blunt Steinmann Pin, 457mm	3
18-3105*	Sharp, Short Steinmann Pin	4
18-3104*	Blunt, Short Steinmann Pin	2
18-3008	Tissue Dissector	1
18-3002	Drill Guide	1
18-3003	Pin Sleeve	1
18-3004	Striker Tube	1
18-3100*	9mm Drill	2
18-3101*	11mm Drill	2
18-3102*	12mm Drill	2
18-3011	Adjustable Collar	1
18-3005	Screw Sizing Template	1
18-3001	Screw Driver	2
18-3012	2 Pin Parallel Guide Plate	1
18-3016	3 Pin Parallel Guide Plate	1
18-3013	Small Radiolucent Tube	2
18-3019	Small Radiolucent Tube, Short	2
18-3014	Large Radiolucent Tube	1
18-3020	Large Radiolucent Tube, Short	1
18-3006	Ratcheting T-Handle	1
18-3007	Ratcheting Straight Handle	1
18-3015	Radiolucent Pin Holder	1
18-3017	Adjustment Driver	1
18-3018	Adjustment Driver Insert	1

Optional Instruments

Part #	Description
18-3009*	Packing Tube
18-3010	Packing Plunger
71-5010	Fluoroscopic Targeting Crosshair

*Single Use Only

Items in blue available upon request only.

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