Mighty Oak Medical

FIREFLY® PEDICLE SCREW NAVIGATION GUIDE

SURGICAL TECHNIQUE

FF-PSG-407 Rev. AH

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The FIREFLY® Pedicle Screw Navigation Guide features patented FIREFLY® Technology. For information about Mighty Oak Medical's patents, visit: mightyoakmedical.com/patents

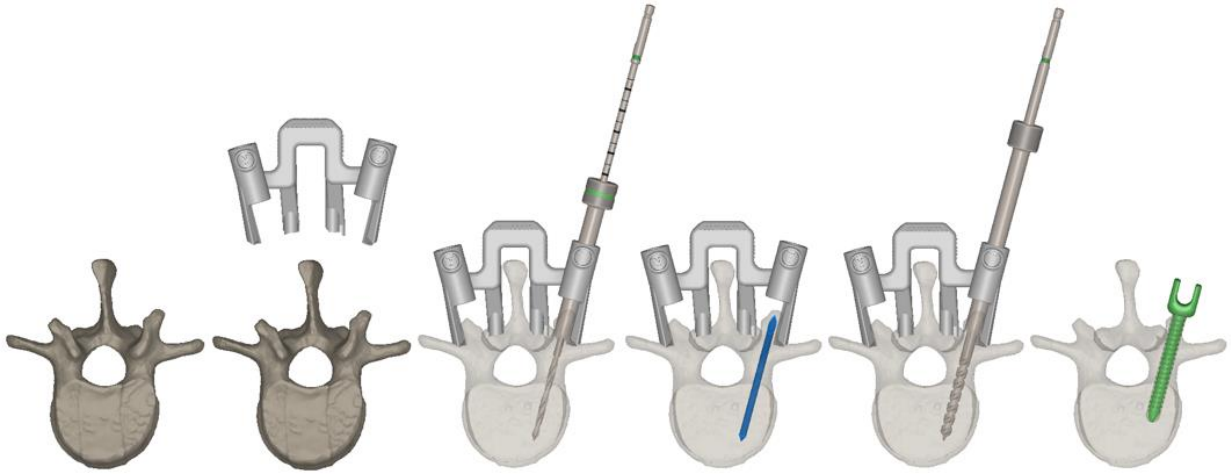
COMPARISON FIREFLY® AND FREEHAND (STANDARD) SURGICAL TECHNIQUES

FIREFLY® Pedicle Screw Navigation Guide

The guide is placed on the matching spinal level (images 1-2 below) and temporary fixation screws are inserted through the Guide to affix it to the bone. Metallic instrument sleeves are inserted in the Guide, through which instruments (e.g. drill bits) are advanced to the surgeon's desired depths, creating pilot holes (3-4).

Compatible OEM taps may be guided to the surgeon's desired depth within each pilot hole (5) or the Guide may be removed from the bone.

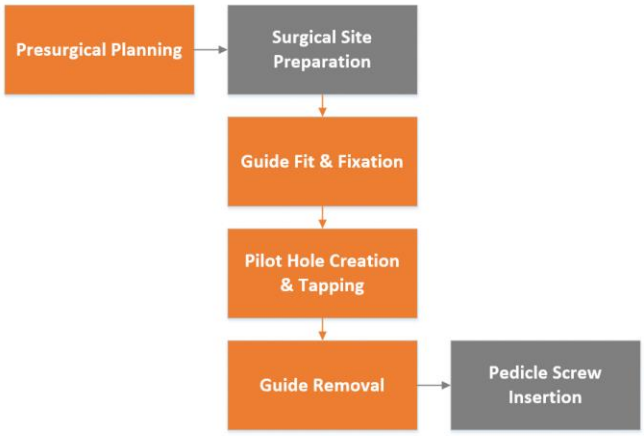
After the Guide is removed, any remaining necessary steps of the OEM pedicle screw system's surgical technique may be followed for implanting pedicle screws (6).



Similarities and Differences

1. FIREFLY® guides instruments to make pilot holes instead of the surgeon manually orienting these instruments.
2. The Guide may be used to direct compatible OEM taps along the planned trajectories (or this may be done manually, as in freehand surgery).
3. After the Guide is removed, the surgeon is left with pilot holes through the pedicles, just as they would have using freehand techniques. Freehand techniques are followed for any remaining steps of implanting pedicle screws, such as inserting guide wires, freehand tapping, pedicle sounding, or measuring pilot hole depths.
4. Intraoperative imaging aids (e.g. fluoroscopy) are not required, but may be used at the surgeon's discretion, just as in freehand surgery.

PROCESS FLOW



PRESURGICAL PLANNING

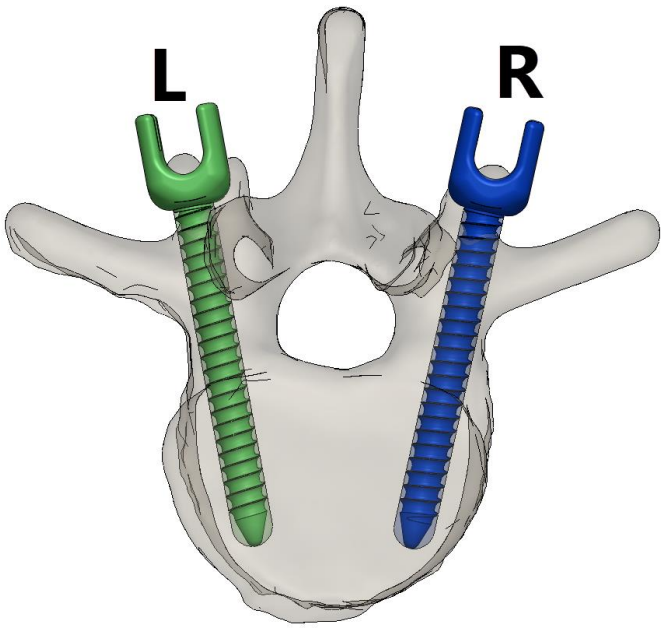
FIREFLY® Patient-Specific Pedicle Screw Guides assist in placing pedicle screws following a surgeon-approved presurgical plan. Presurgical planning starts from a CT scan of the patient's spine for creating virtual models of the spine. The FIREFLY® CT Scan Protocol provides instructions for acquiring a high-resolution CT scan for surgical planning. In addition to the CT scan, order information (patient's name, patient's DOB, anatomical levels to be guided, OEM pedicle screw system to be used) is requested before beginning the planning process. If Patient-Specific Bone Models are desired, they may be ordered at any point before approving the presurgical plan.

Mighty Oak Medical creates a Proposed Patient-Specific Surgical Plan consisting of virtual models of the patient's spine and planned pedicle screw sizes & trajectories based on the patient's anatomy. The Proposed Plan is presented to the surgeon for review and if any changes are requested, Mighty Oak Medical will return a revised plan.

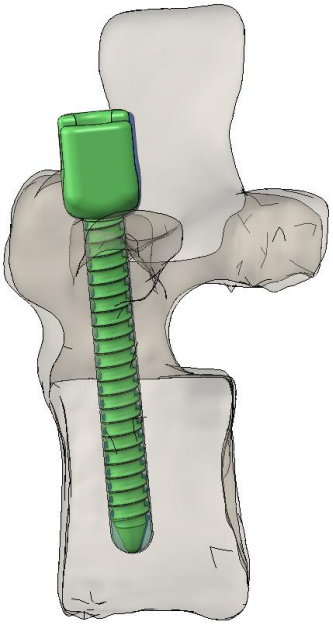
If the surgeon has any special considerations that need to be accounted for (e.g. due to unusual anatomy or to accommodate a preferred surgical workflow), they will be incorporated into planning and Guide design processes. For example: a special request for Guides to avoid contacting certain anatomical regions because of facetectomies to be done prior to screw implantation.

The Proposed Patient-Specific Surgical Plan includes images of the patient's vertebrae and simulated pedicle screw placements that match the diameters & lengths of planned pedicle screw sizes. Representative pedicle screw features (e.g. thread form, tip, & tulip) are also shown, but the simulated screw placements encompass these features to accommodate a variety of pedicle screw designs, ensuring safe outcomes no matter which compatible pedicle screw system is used.

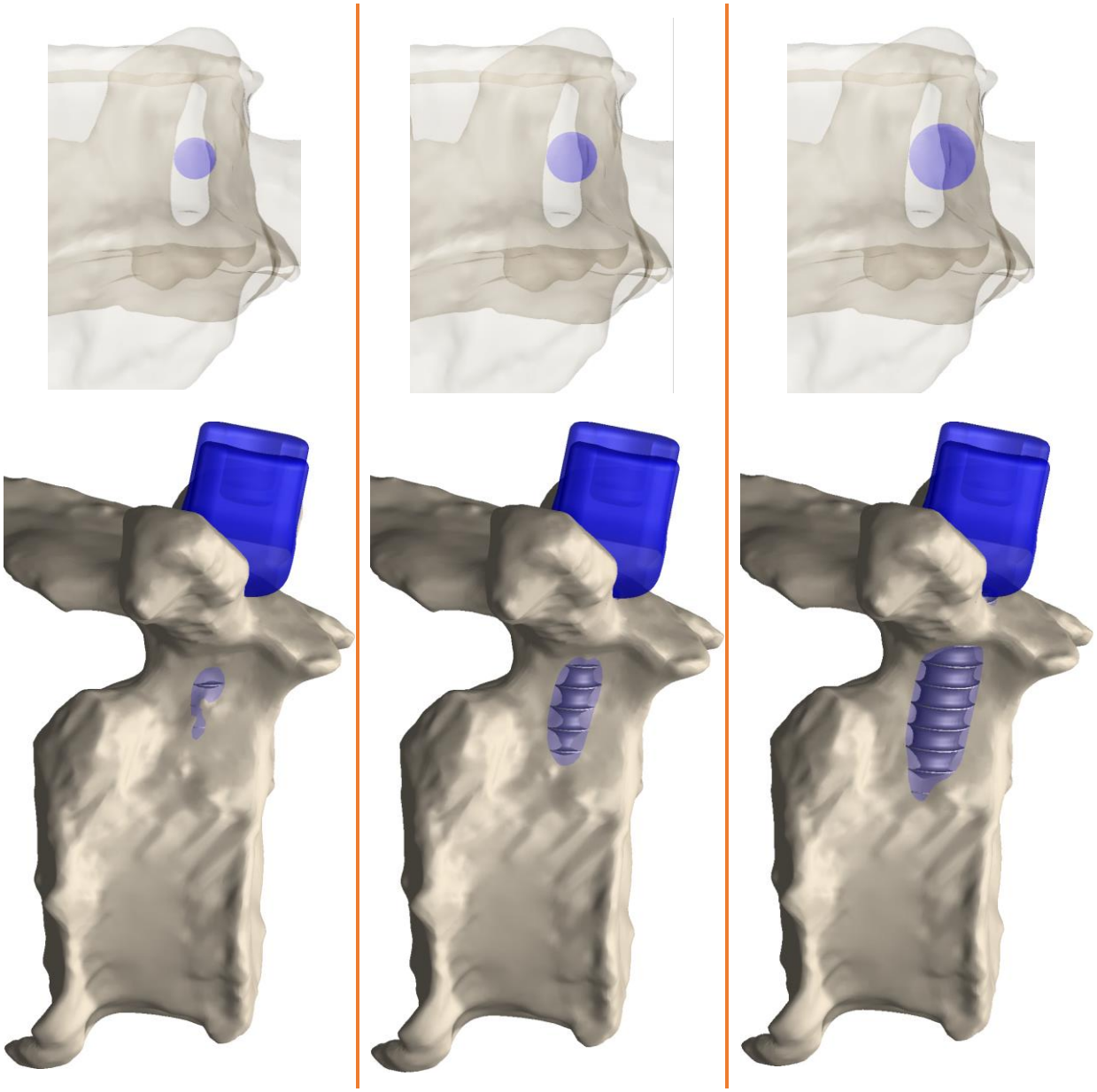
Example Transverse View



Example Lateral View



FIREFLY® planning protects the spinal cord and nerve roots, avoiding the medial and inferior pedicle walls. Where necessary, planned lateral pedicle breaches may be presented, for example due to small anatomy or to accommodate the surgeon's request for larger screw diameters. To ensure that the surgeon has adequate information to determine their ideal pedicle screw sizing & trajectories, planned lateral pedicle breaches are depicted conservatively, ignoring any possible pedicle expansion or soft tissue that may surround the bone (e.g. periosteum or cartilage). This conservative depiction ensures safe and effective screw placement according to the Plan. Examples of various types of controlled lateral pedicle breaches are shown below.



When the surgeon approves that the Proposed Plan matches their intended treatment plan, Patient-Specific Pedicle Screw Guides are designed to fit the patient's unique anatomy and guide instruments following the presurgical plan. After Guides are designed, manufactured, and quality inspected, they are packaged with other FIREFLY® Pedicle Screw Navigation Guide instruments and delivered for surgery. Details about the approved presurgical plan are documented in the Approved Patient-Specific Surgical Plan and delivered to the surgeon with each order.

SURGICAL SITE PREPARATION

Preparation for Use

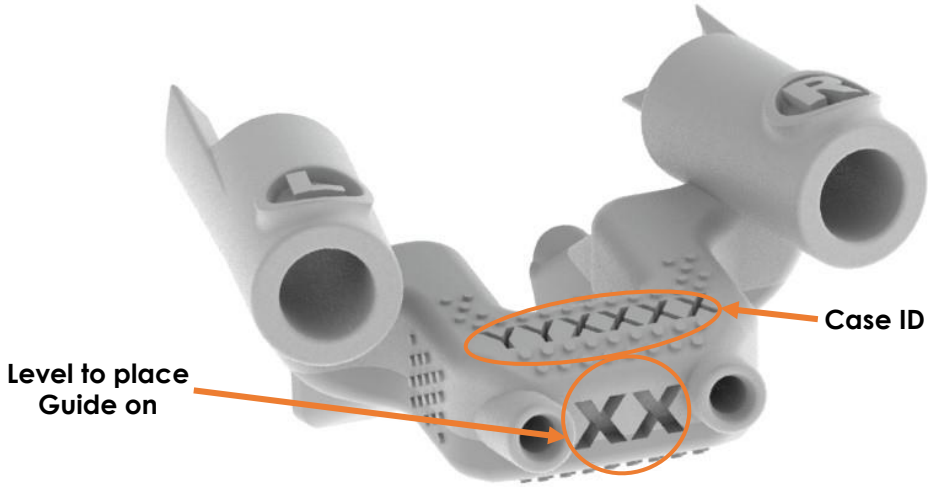
Components from the FIREFLY® Pedicle Screw Navigation Guide must be cleaned and sterilized prior to use. Refer to the IFU for cleaning and sterilization instructions.

Patient Verification

Before beginning the procedure, confirm that the patient's name and DOB listed in the Approved Patient-Specific Surgical Plan match the patient who is having surgery.

Confirm that the Case ID listed in the Approved Patient-Specific Surgical Plan matches the Case ID marked on each Patient-Specific Pedicle Screw Guide (FF-101-XX or FF-102-XX) and Patient-Specific Bone Model (FF-103-XX).

Confirm that all Patient-Specific Pedicle Screw Guides and Patient-Specific Bone Models listed in the Approved Patient-Specific Surgical Plan are present. Each Guide is marked according to the anatomical level it fits on and each Instrument Sleeve Cannula is marked according to its planned trajectory.

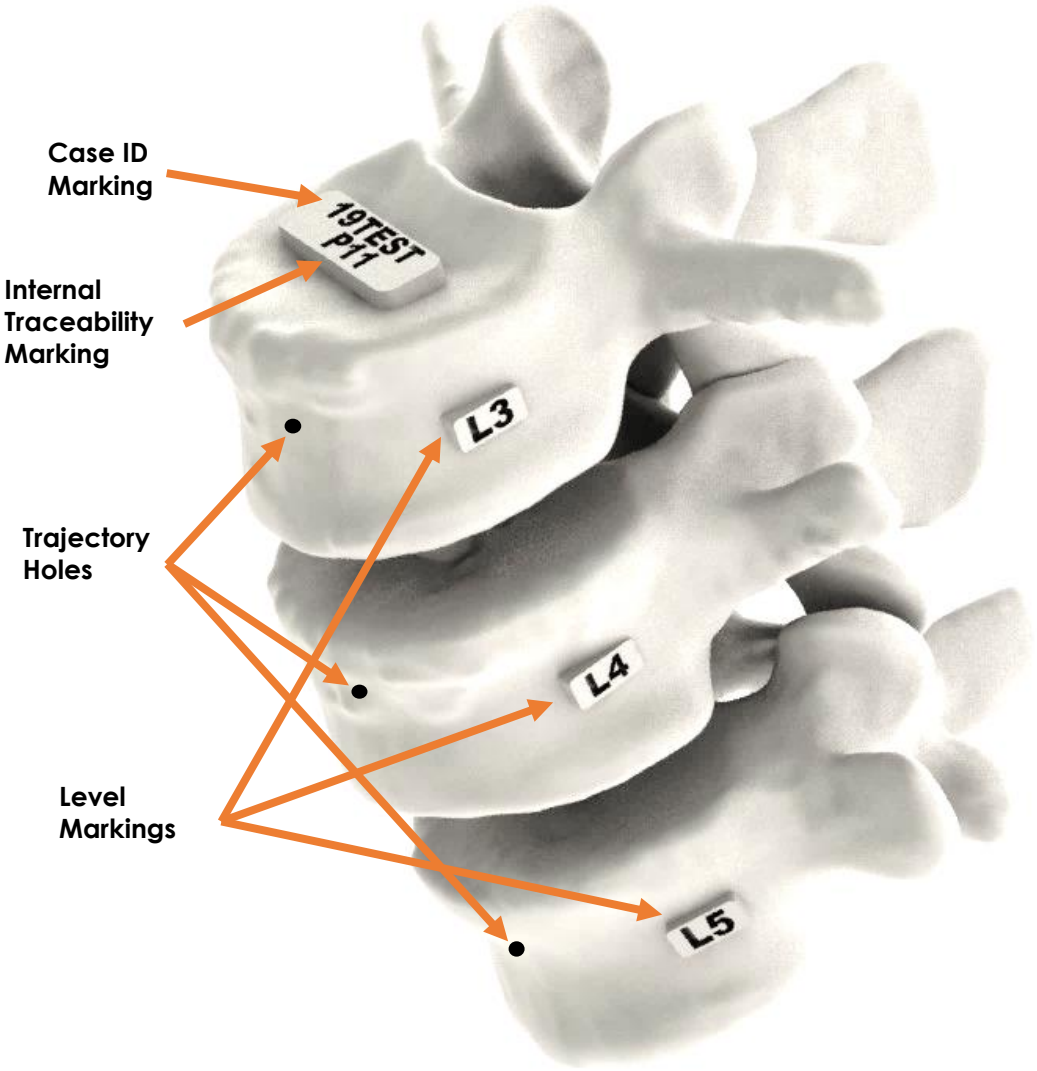


Note: An additional marking may be present on the bottom if each Instrument Sleeve Cannula of the Guide, opposite the L/R marking. This is used by Mighty Oak Medical for internal traceability purposes and may be ignored.

Tip: After the Guides or Bone Models have been sterilized, readability can be improved by coloring over the tops of markings with a nontoxic marker safe for surgical use.

If a Bone Model was provided, at least the top and bottom levels of the Bone Model are marked with their representative anatomical levels, except for the sacrum or ilium (if included). The markings identify which levels are contained in the Bone Model.

Note: An additional marking may be present on the Bone Model, usually below the Case ID marking. This is used by Mighty Oak Medical for internal traceability purposes and may be ignored.



The Bone Model may also include trajectory holes for visual reference of each planned screw trajectory.

Refer to the Approved Patient-Specific Surgical Plan to determine anatomical levels on which to place the Patient-Specific Surgical Guides. Ensure level identification completed intraoperatively on the patient matches that on the Level Identification page(s) of the Approved Patient-Specific Surgical Plan. Expose these levels using an open posterior approach to the spine. Position the patient prone, with legs flat or slightly bent (e.g. via anatomical surgical table or propped on a pillow). This operative positioning prevents movement in the SI joint relative to the preoperative CT scan.

Guide Test-Fit (optional)

Test-fit the Patient-Specific Pedicle Screw Guide on its respective level of the Patient-Specific Bone Model prior to placing the Guide onto the patient's anatomy. Test-fitting the Guide gives tactile feedback for an appropriately placed Guide. Similar tactile feedback should be felt when placing the Guide on the exposed patient's anatomy.

Note: Bone Models may depict small portions of bony anatomy to be removed, when necessary to achieve proper Guide fit; this will be discussed in the Approved Patient-Specific Surgical Plan.

During surgery, do not attempt to drill into the Bone Model or modify it in any way. Do not insert non-FIREFLY instrumentation into trajectory holes.

Soft Tissue Preparation

Remove soft tissue to expose the bony surfaces for each Patient-Specific Pedicle Screw Guide to be placed on its respective anatomical level. Care should be taken to leave the bony surface intact.

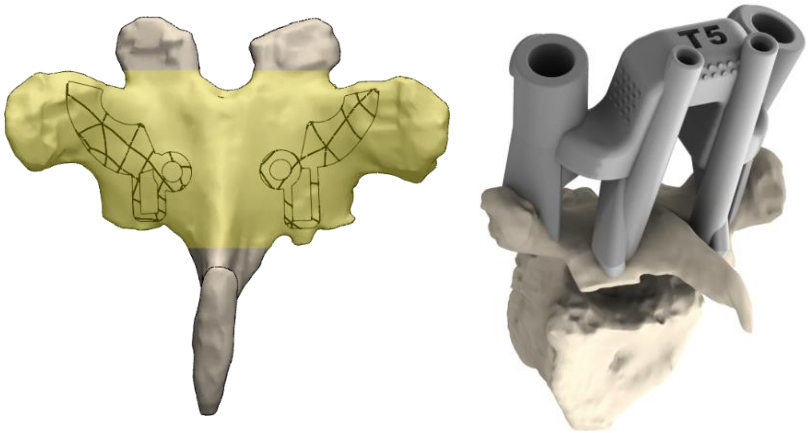
FIREFLY® Guides are designed to avoid facet capsules. Soft tissue may require removal around the articular processes, however the facet capsule can remain intact.

The bony-contacting regions where a Guide can contact the vertebra are:

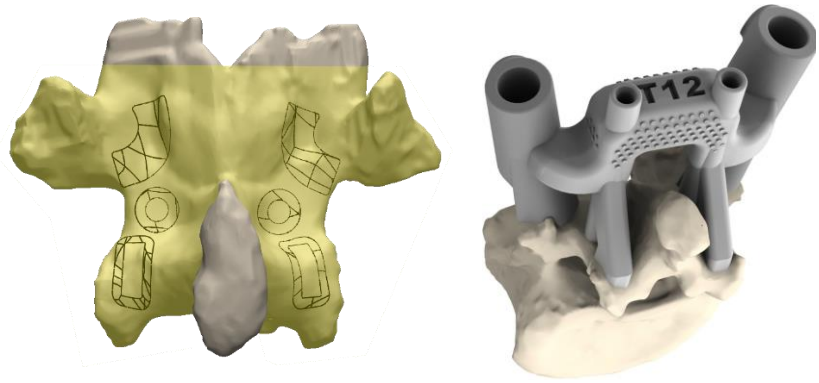
- Transverse Processes
- Lamina/Pars
- Inferior Articular Processes

Due to variations between each patient's spinal morphology, small portions of bony anatomy (e.g. parts of superior articular processes, spinous processes, or the median sacral crest) may interfere with proper Guide placement. If so, this will be denoted in the Approved Patient-Specific Surgical Plan and must be removed in order to adequately fit the Guide on the Bone.

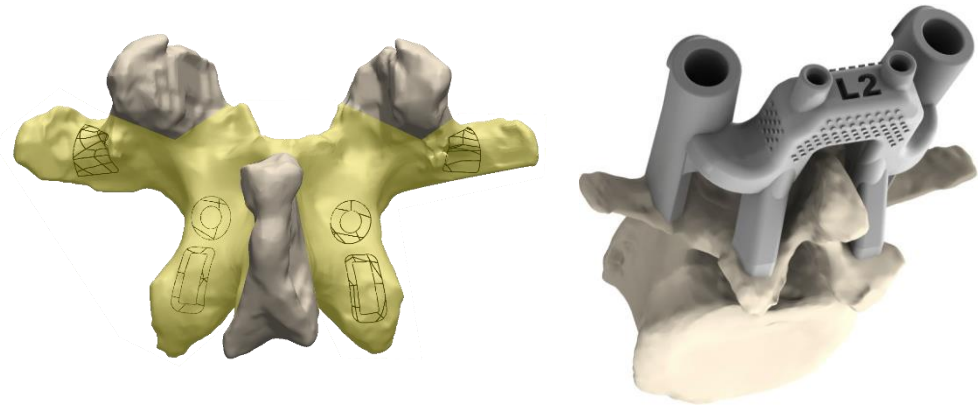
The following images illustrate potential patient-contacting regions (yellow) and typical Guide contact locations (blue lines) for each indicated spinal region. Example images of Guides fitting on those spinal regions are also included below.



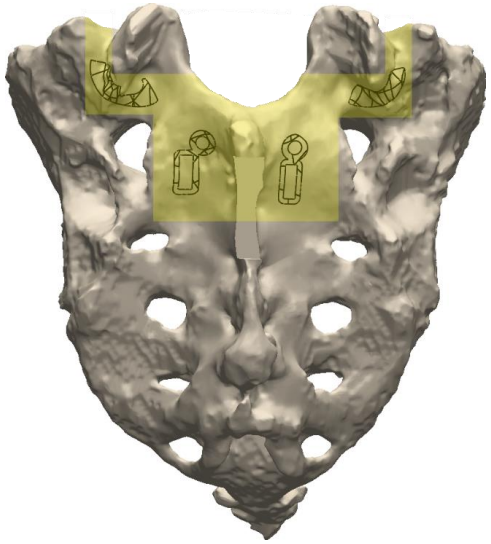
Thoracic

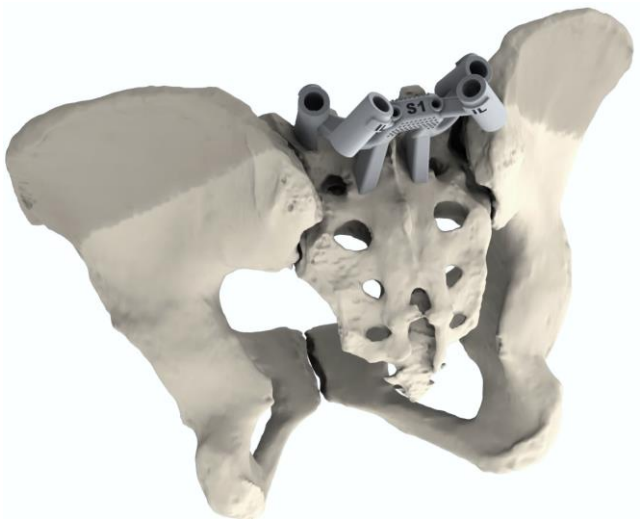


Transitional

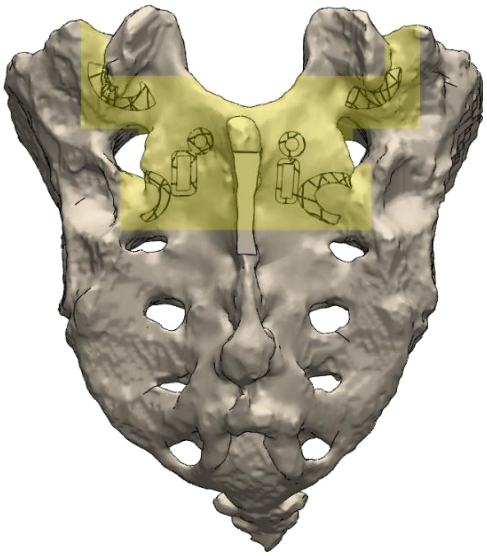


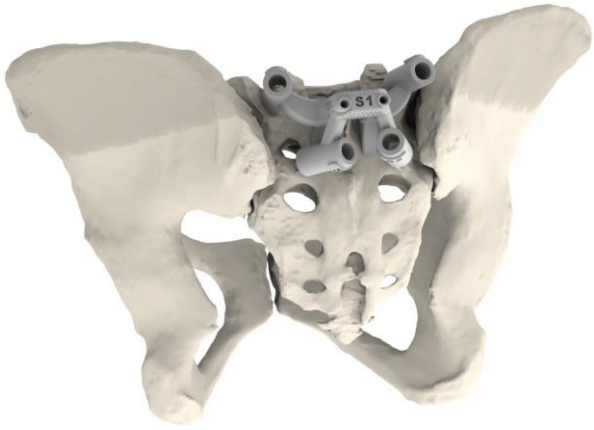
Lumbar





Sacroiliac





S2AI (S2-Alar-Iliac)

GUIDE FIT

Sequence of Use

It is recommended to begin at the most rostral vertebral level and work caudally.

Guides may be used in the reverse sequence (beginning at caudal levels and continuing rostrally), but pedicle screws implanted below the Guides could interfere with proper Guide placement. If desired, fit the Guides on the Bone Model and compare their positions to the planned positions of caudal pedicle screws to determine whether or not the reverse sequence may be used.

Patient-Specific Pedicle Screw Guides are intended to be used sequentially, one Guide at a time. Placing multiple Guides simultaneously may prevent proper positioning of the Guides.

Guide Placement

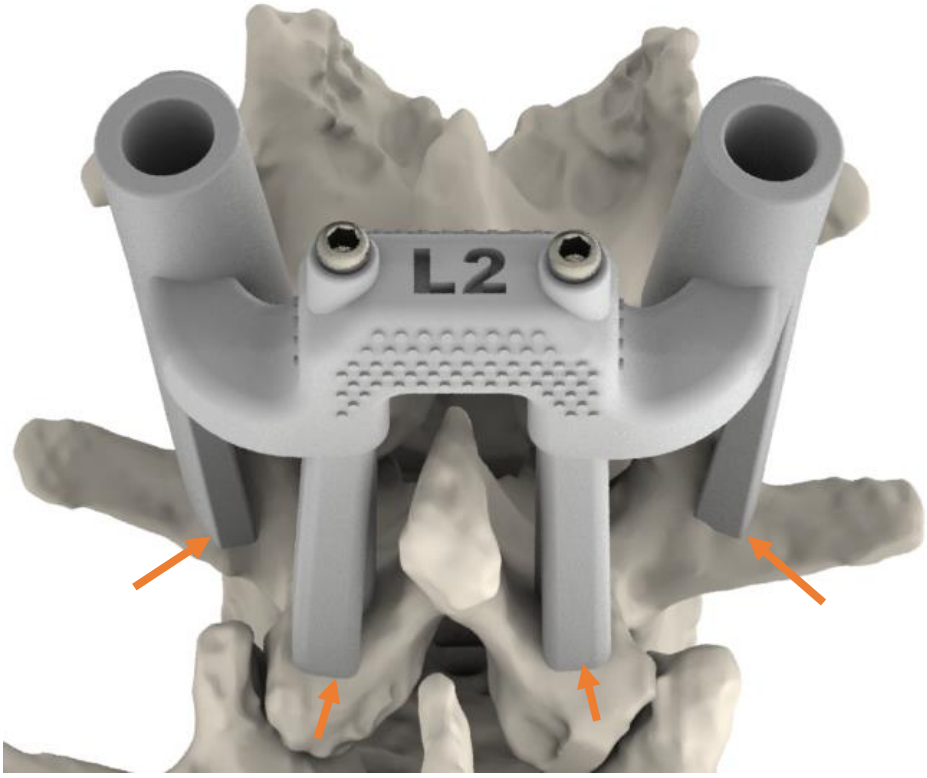
Each Instrument Sleeve Cannula is marked with "L" or "R" to identify the proper orientation on the bone with respect to the patient's left and right sides.

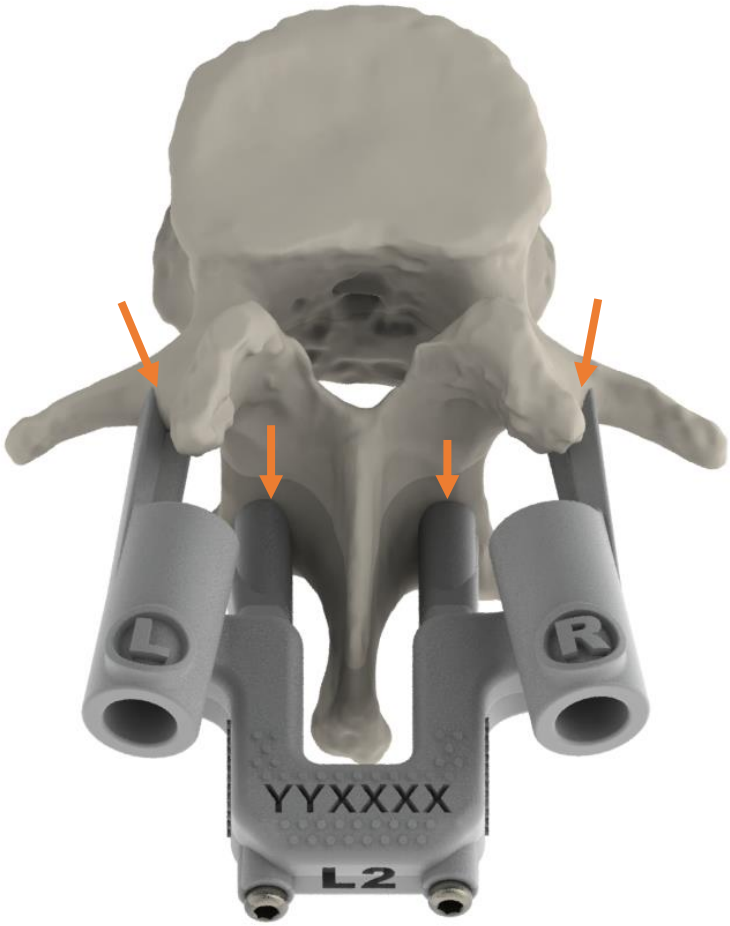
Place the Guide on its respective anatomical level.

Before using each Guide, ensure that:

- Soft tissue has been removed from patient-contacting regions
- Bony anatomy in patient-contacting regions remains intact
- Guide fits in the proper position when pressed against the vertebra
  - There should be no free-motion of the Guide
- All patient-contacting portions of the Guide must be firmly seated on the bone

If there are gaps present between the Guide and bone, check that the Guide is seated properly on the bone and adjust as necessary until no gaps can be seen and the Guide is properly seated. Remove soft tissue, as necessary, to allow the Guide to fit properly. If noted in the Approved Patient-Specific Surgical Plan, remove small portions of bony anatomy as necessary for proper Guide fit.





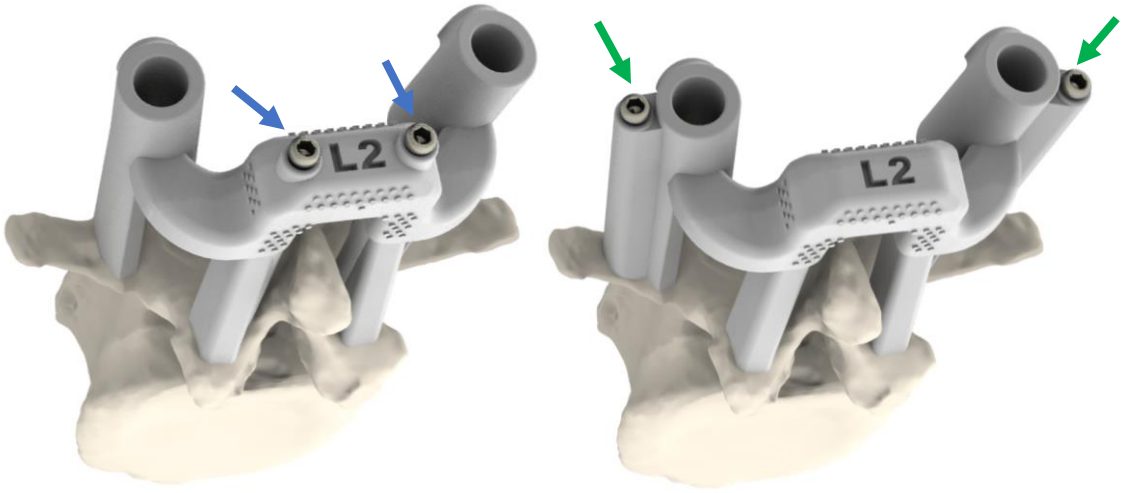
GUIDE FIXATION (OPTIONAL)

Fixation Screws may be used to keep the Guide in place without needing to be constantly held by hand, but their use is optional. The Guides function equivalently with or without Fixation Screws.

Fixation Screw Placement Locations

Guides may be provided with medial and/or lateral cannulae for placing Fixation Screws through:

- **Medial Fixation Screws** are typically directed towards the lamina or pars
- **Lateral Fixation Screws** are typically directed towards the transverse processes

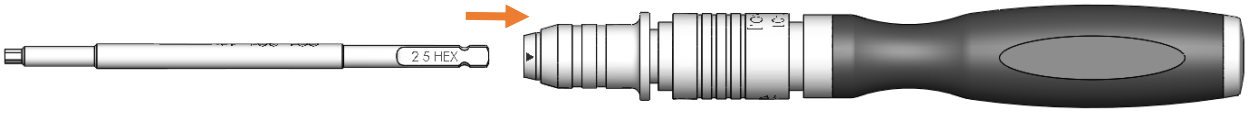


⚠ Fixation screws are available in two lengths, short (24 mm) and long (50 mm). Guides are designed to use long Fixation Screws by default. If unusual circumstances require using short Fixation Screws, they will be denoted in the Approved Patient-Specific Surgical Plan at the level(s) to be used.

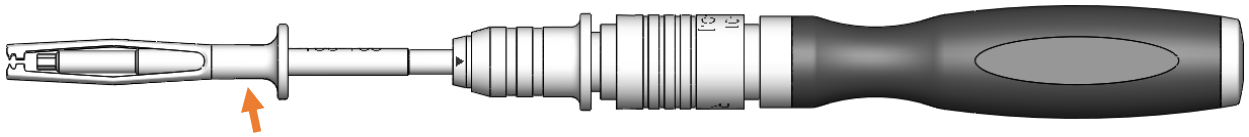
Description	Short Fixation Screw	Long Fixation Screw
Part No.	FF-105-24	FF-105-50
Length	24 mm	50 mm

Screwdriver Assembly

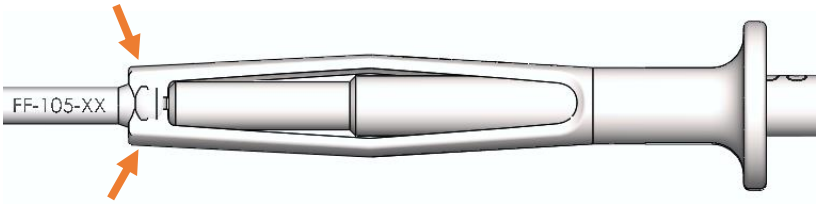
Connect the Screwdriver Bit (FF-106-100) to the ratcheting Handle (FF-111-01), making sure that the connection is secure. The arrow at the tip of the Handle's connector aligns with the flat spot of the Screwdriver Bit's connector. Pull the connector's release on the Handle while inserting the Screwdriver Bit to connect them.



Slide the Screw Holding Sleeve (FF-107-01) over the shaft of the Screwdriver Bit. Retract the Screw Holding Sleeve.



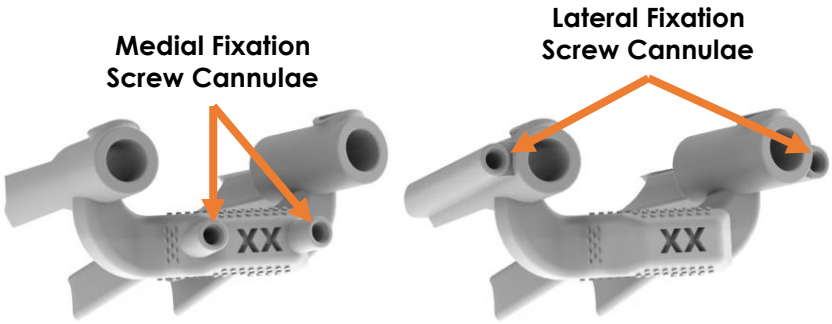
Connect the appropriately sized Fixation Screw to the Screwdriver Bit, then slide the Screw Holding Sleeve forwards to secure it around the head of the Fixation Screw.



Fixation Screw Insertion

Insert the Fixation Screw through a Fixation Screw Cannula and then retract the Screw Holding Sleeve to avoid interference between the Screw Holding Sleeve and Guide.

⚠ Two Fixation Screws are required to rigidly secure each Guide onto the bone.



While applying downward pressure on the Guide to keep it secured in the proper position, use the Screwdriver Bit to drive the Fixation Screw into the bone. All Fixation Screws are designed with the following safety criteria to ensure safe placement: depth controlled and a minimum of 2 mm of surrounding bone. Tighten the screw until resistance can be felt from the Fixation Screw's head pressing against the Guide. Do not over-tighten or use excessive force to place the Fixation Screws.

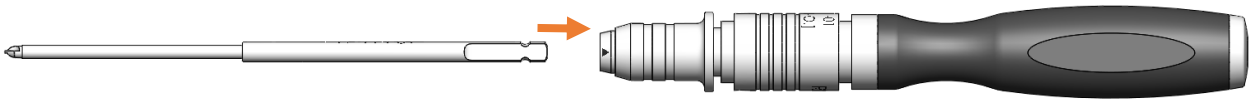
⚠ Never use powered instruments to install Fixation Screws. Fixation Screws are intended to be installed using the Screwdriver Bit and Handle.

Reaming Cortical Bone

If the Fixation Screw is having difficulty biting into hard cortical bone, a Reamer (FF-114-01) can be used to abrade the bone to facilitate Fixation Screw insertion.

Remove the Fixation Screw, taking care not to drop it. The Screw Holding Sleeve can be used to secure the Fixation Screw to the Screwdriver Bit again.

Assemble the Reamer and Handle in the same manner as the Screwdriver Bit was attached.



Insert the Reamer into the Fixation Screw Cannula and twist the Reamer in a clockwise direction to abrade the cortical bone surface. Use this step sparingly to maximize the amount of bone remaining for the Fixation Screw to bite into.

Remove the Reamer and re-attempt to install the Fixation Screw.

Remaining Fixation Screws

Repeat this process to install additional Fixation Screws, as necessary.

PREVIEW TRAJECTORY (OPTIONAL)

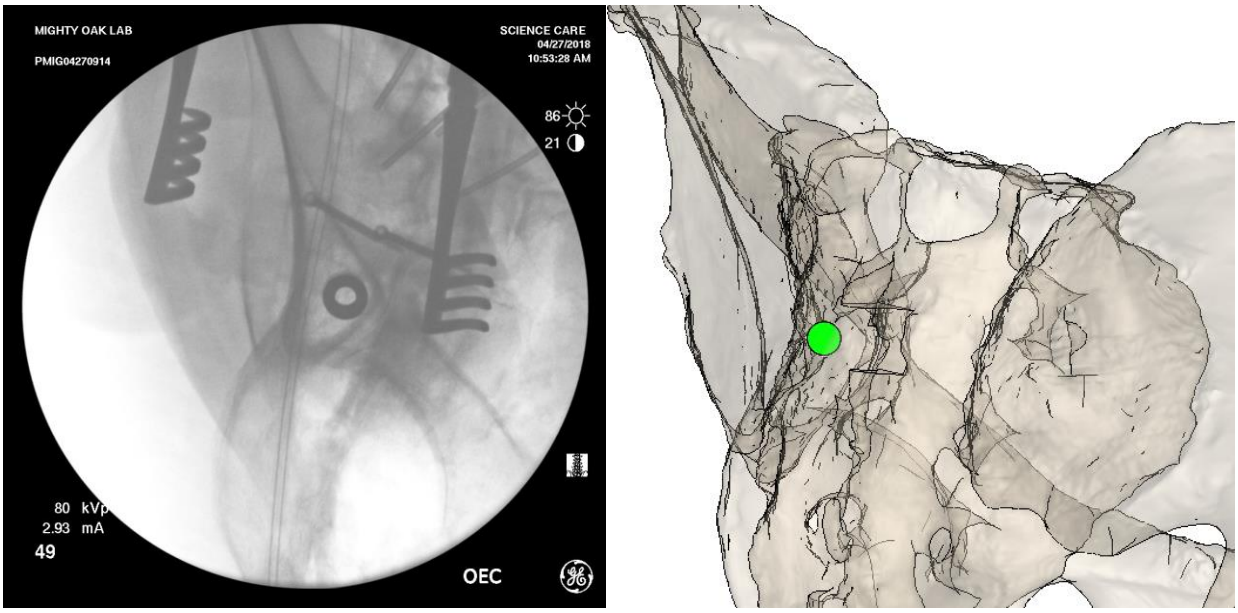
Prior to creating pilot holes, optional fluoroscopy may be used to preview trajectories.

With the Guide placed on anatomy, insert a Tap Instrument Sleeve in the Guide cannula and obtain a fluoroscopic image down the axis of the cannula.

Note: Guides are radiopaque so a Tap Instrument Sleeve is used to make trajectories visible.

Compare the fluoroscopic image obtained to the Patient-Specific Presurgical Plan to verify correct Guide placement, trajectory orientation, and anatomical alignment.

Note: Previewing a trajectory is especially useful for visualizing a "tear-drop" image for S2AI trajectories.



CREATING PILOT HOLES

Due to limitations in available bony purchase, Fixation Screws are not intended to withstand all the possible eccentric forces which could be applied during drilling or tapping the pedicle. Care should be taken to maintain the instrument alignment along the axis of the guided trajectory.

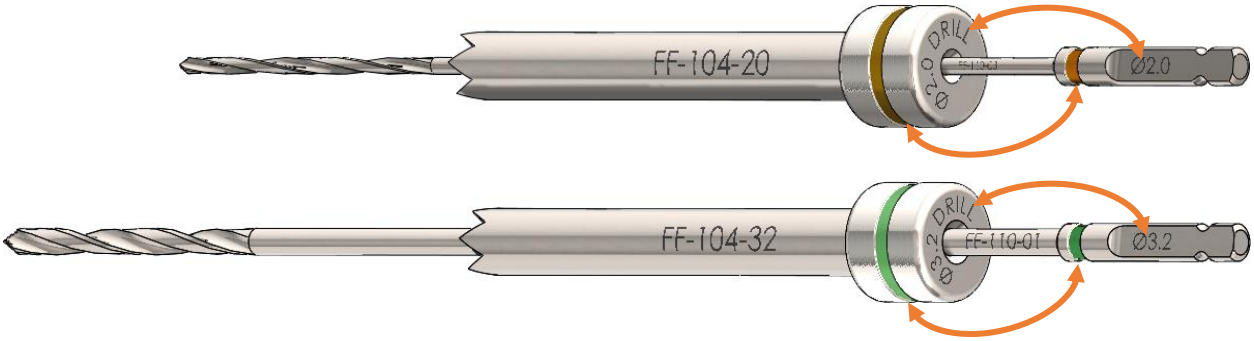
Two drill bit sizes are available for use with FIREFLY®.

Ø3.2 mm Drill Bits and their mating Drill Sleeves are provided for each surgery.

Ø2.0 mm Drill Bits and Drill Sleeves are available per special request.

When drilling across the SI joint, use a Ø3.2 mm Drill Bit. The Ø2.0 mm Drill Bits are not intended to cross the SI joint.

The Drill Bit and Drill Sleeve sizes can be identified by their text markings or matching color-coded bands.



The Drill Bit features a tip to minimize its potential to walk or deflect. When drilling, it is recommended to advance the drill incrementally using a bumping/oscillating motion.

After selecting a size, place the corresponding Drill Sleeve (FF-104-20 or FF-104-32) through the Instrument Sleeve Cannula on the Guide.

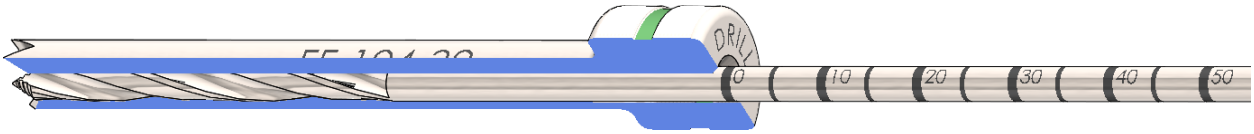
Each Drill Sleeve has a trephined cutting end. Gently twist the Drill Sleeve as necessary to advance the Drill Sleeve through soft tissue until it contacts the bone surface.

Connect the Drill Bit to the powered drill (not included).

Place the Drill Bit through the Drill Sleeve until it contacts the bone surface.

Note: Drill Bits with AO connectors are provided, but versions for connecting to Jacobs chucks may be available per special request.

Depth markings are etched on each FIREFLY® Drill Bit. These markings are calibrated to their mating Drill Sleeves, where 0 mm indicates the Drill Bit's tip is located at the distal end of the Drill Sleeve (see cross-section view below).



The Drill Bit does not include a physical depth-controlled stop. Depth markings are provided to determine the depth of drilling.

Drill to the desired depth using the markings on the Drill Bit as a gauge.

Tip: When drilling an S2AI trajectory, bony resistance should be felt at all times, except while the Drill Bit is within the SI joint. Feel for increased resistance again as the Drill Bit exits the SI joint, drilling through the iliac cortex.

Remove the Drill Bit from the Drill Sleeve.

Repeat as necessary for all pedicle screws to be placed using this Guide.

FURTHER PREPARATION OF PILOT HOLES

Pedicle Sounding

If desired, a pedicle sounding probe (not included) may be used to confirm bony borders within the pilot holes prior to tapping or removal of the Guide.

Tapping Pilot Holes with FIREFLY® Guide

⚠ Taps are not included as part of the FIREFLY® Pedicle Screw Navigation Guide. Only compatible taps as listed on the Approved Patient Specific Surgical Plan can be guided by the FIREFLY® Pedicle Screw Navigation Guide.

Refer to the Approved Patient-Specific Surgical Plan to determine the planned pedicle screw sizes and compatible taps for the planned pedicle screw system. Use taps in accordance with the OEM Pedicle Screw system's instructions for use.

Taps not listed in the Approved Patient Specific Surgical Plan must only be used after the Guide has been removed from the bone (see next section: Removal of Guide).

⚠ Due to limitations in available bony purchase, Fixation Screws are not intended to withstand all the possible eccentric forces which could be applied during drilling or tapping the pedicle. Care should be taken to maintain the instrument alignment along the axis of the guided trajectory.

Remove the Drill Sleeve from the Guide and replace it with the Tap Sleeve (FF-112-01).

The Tap Sleeve has a trephined cutting end. Gently twist the Tap Sleeve as necessary to advance the Tap Sleeve through soft tissue until it contacts the bone surface.

Assemble the compatible tap as necessary for use (e.g. connect to a handle), per the tap manufacturer's instructions.

Place the compatible tap through the Tap Sleeve until it contacts the bone surface.

Compatible taps include depth markings, where 0 mm represents the tap's tip located at the distal end of the Tap Sleeve.

⚠ Compatible taps do not include a physical depth-controlled stop. Depth markings are provided to determine the depth of tapping.

Advance the compatible tap to the desired depth, following the OEM technique, using the markings on the compatible tap as a gauge.

Remove the compatible tap and Tap Sleeve from the Guide.

PEDICLE SCREW INSERTION

Removal of Guide

After all pilot holes have been made using the Guide, remove Fixation Screws and the Patient-Specific Pedicle Screw Guide from the anatomy.

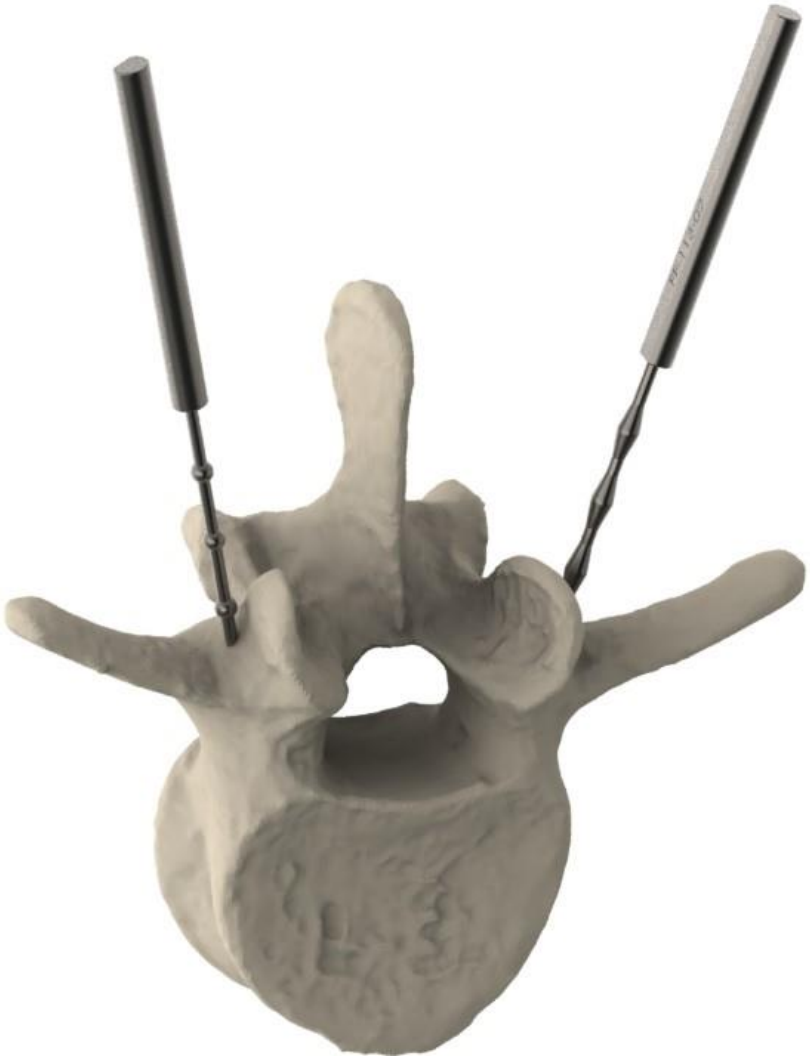
Note: After the Guide is removed, the anatomy (i.e. vertebra with pilot holes through pedicles) is equivalent to the result of a freehand procedure. Any remaining steps necessary for pedicle screw implantation may be followed per freehand surgical techniques.

Confirmation and Visualization of Pilot Hole for Freehand Tapping

OEM pedicle sounding probes may be used to check bone borders and OEM taps may be used (freehand) following the pilot hole.

Pedicle Markers (FF-113-01 or FF-113-02) are provided and may be inserted into the pilot holes to visualize the trajectories prior to freehand tapping. Pedicle Markers are Ø3.0 mm and will not fit in pilot holes drilled with the Ø2.0 mm Drill Bits.

Note: Fluoroscopy may be used to confirm the trajectory. Pedicle Markers with two differently shaped indicators are provided to differentiate between left and right sides.



OEM Pedicle Screw Insertion Technique

The Approved Patient-Specific Surgical Plan lists the compatible pedicle screw system and planned pedicle screw sizes. Follow the OEM pedicle screw system's surgical technique for implanting pedicle screws.

Pedicle Markers (FF-113-01 or FF-113-02) are provided and may be inserted into the pilot holes to visualize the trajectories prior to implanting OEM pedicle screws. Pedicle Markers are Ø3.0 mm and will not fit in untapped pilot holes drilled with the Ø2.0 mm Drill Bits.

Insertion of Additional Pedicle Screws

If multiple Patient-Specific Pedicle Screw Guides are provided, repeat these steps, as necessary, to place the remaining planned pedicle screws.

⚠ Always begin at the most rostral vertebral level in order to avoid interference from implanted pedicle screws.

Guides may not always fit in their correct positions on the anatomy if pedicle screws are implanted caudal to the vertebral level being used.

Patient-Specific Pedicle Screw Guides are intended to be used sequentially, one Guide at a time. Placing multiple Guides simultaneously may prevent proper positioning of the Guides.

Completion of Surgery with Patient-Specific Pedicle Screw Guides

⚠ After all Patient-Specific Pedicle Screw Guides have been used, be sure to remove any Guides, surgical instruments, or temporary Fixation Screws from the patient. The FIREFLY® Pedicle Screw Navigation Guide's components are not intended to be used as permanent implants.

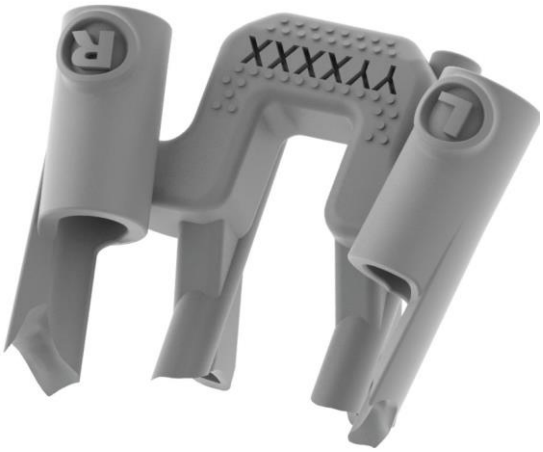
Patient-Specific Pedicle Screw Guides and Bone Models must be scrapped after use on the intended patient to prevent reuse. Other instruments are reusable and should be returned to Mighty Oak Medical. Please refer to the IFU for further instructions.

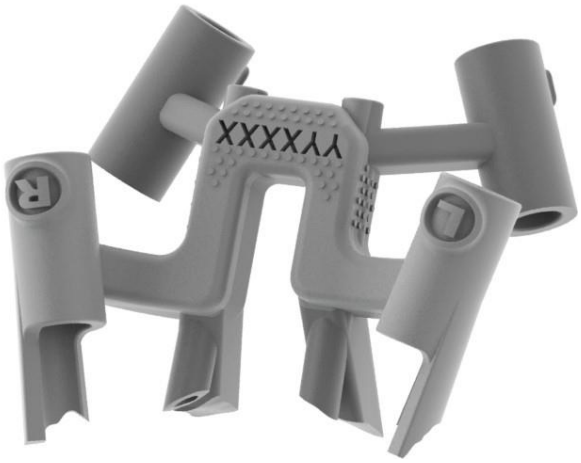
MATERIALS

Patient contacting materials used have been tested and shown to be biocompatible in accordance with ISO 10993-1. The material used to manufacture patient-specific components is an epoxy resin for use in stereolithography systems. Patient contacting materials used for non-patient-specific components are manufactured in accordance with ASTM F899 or F136.

FIREFLY® GUIDES AND COMPONENTS

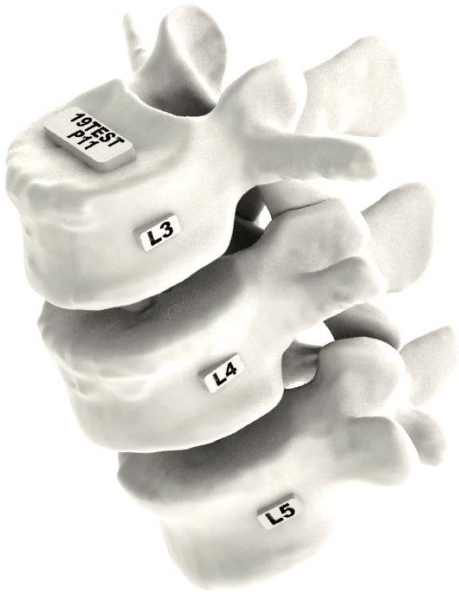
Patient-Specific Pedicle Screw Guide (FF-101-XX)
Guides that fit on a single spinal level





Patient-Specific Pedicle Screw Guide (FF-102-XX)
Guides that fit on multiple fused or immobile spinal levels (Multi-Level)

Patient-Specific Bone Model (FF-103-XX)



Instrument Sleeve, Ø2.0 Drill (FF-104-20)
Drill Sleeve for use with FIREFLY® Ø2.0 mm Drill Bits (FF-110-03 or FF-110-04).

Instrument Sleeve, Ø3.2 Drill (FF-104-32)
Drill Sleeve for use with FIREFLY® Ø3.2 mm Drill Bits (FF-110-01 or FF-110-02).

Instrument Sleeve, Tap (FF-112-01)
Tap Sleeve for use with compatible taps, as listed on the Approved Patient-Specific Surgical Plan.

Drill Bit, Ø3.2 AO (FF-110-01)
Ø3.2 mm. Intended for use with AO drill chucks. Depth markings are accurate within 1 mm.

Drill Bit, Ø3.2 Jacobs (FF-110-02)**
Ø3.2 mm. Intended for use with Jacobs drill chucks. Depth markings are accurate within 1 mm.
**Available per special request.

Drill Bit, Ø2.0 AO (FF-110-03)**
Ø2.0 mm. Intended for use with AO drill chucks. Depth markings are accurate within 1 mm.
**Available per special request

Drill Bit, Ø2.0 Jacobs (FF-110-04)**
Ø2.0 mm. Intended for use with Jacobs drill chucks. Depth markings are accurate within 1 mm.
**Available per special request.

OEM Taps (Not Provided)
Taps are not included as part of the FIREFLY® Pedicle Screw Navigation Guide.

⚠ Only compatible taps as listed on the Approved Patient Specific Surgical Plan can be guided by the FIREFLY® Pedicle Screw Navigation Guide.

Use compatible OEM taps as consistent with their surgical techniques.

OEM Pedicle Screw System (Not Provided)
Pedicle screws and other OEM Instruments are not included as part of the FIREFLY® Pedicle Screw Navigation Guide.

⚠ Use the compatible OEM pedicle screw system as consistent with its surgical technique.

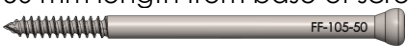
Fixation Screw (FF-105-24)*

24 mm length from base of screw head to tip.

*This size is only provided when necessary.

Fixation Screw (FF-105-50)

50 mm length from base of screw head to tip.



Screwdriver Bit (FF-106-100)

Screw Holding Sleeve (FF-107-01)

Handle (FF-111-01)

Ratcheting.

Pedicle Marker (FF-113-01)

Ball shaped markers.

Pedicle Marker (FF-113-02)

Diamond shaped markers.

Reamer (FF-114-01)

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

DESCRIPTION

The FIREFLY® Pedicle Screw Navigation Guide is intended to assist in the accurate placement of pedicle screws. It consists of single-use components designed for treatment of a specific patient as well as reusable non-patient-specific components.

The FIREFLY® Pedicle Screw Navigation Guide uses Patient-Specific Pedicle Screw Guides that fit on the patient's anatomy to guide surgical instruments in line with trajectories chosen presurgically, by the surgeon, based on the patient's CT imaging data. Navigation guides are intended to guide instruments to create pilot holes in the pedicles for placing pedicle screws following the Approved Patient-Specific Surgical Plan.

Patient-Specific Bone Models may also be provided.

INDICATIONS FOR USE

The FIREFLY® Pedicle Screw Navigation Guide can be used with any 510(k) cleared, legally marketed, pedicle screw spinal system (for its cleared indications for use) and its respective compatible components for non-cervical open, posterior spinal fixation procedures (T1-S2/S2AI and ilium) intended for fusion, with the additional conditions listed below:

- Pedicle screw's shank is straight along its longitudinal axis (i.e. not curved)
- Pedicle screw's major and minor thread diameters are centered about the longitudinal axis
- Pedicle screw's longitudinal axis matches the direction of insertion
- Pedicle screw is intended to be inserted into a pilot hole
- Pedicle screw's diameter is larger than the pilot hole created with FIREFLY®
- Patient's pedicle must be dimensionally adequate to accommodate a pedicle screw, as determined on preoperative scan
- Compatible pedicle screw spinal system instruments may be used with the FIREFLY® Pedicle Screw Navigation Guide
    - Pedicle sounding probes (a.k.a. feeler/ball-tip probes) may be used to confirm pedicle integrity
    - Only OEM pedicle screw spinal system taps specified in the Approved Patient-Specific Surgical Plan may be guided to tap pilot holes
    - All other pedicle screw spinal system components and accessories (including non-guided taps) are to be used, after removal of the FIREFLY® Pedicle Screw Navigation Guide, as directed by the pedicle screw spinal system's instructions for use

This device is intended for single use only.

PRECAUTIONS

1. The user must review this instruction for use and all other labeling provided with these devices. ⚠
2. The FIREFLY® Pedicle Screw Navigation Guide is not to be construed as supplying a medical diagnosis. This product merely reprocesses existing data to facilitate preoperative planning that is reviewed and approved by the surgeon.
3. Patient-Specific Pedicle Screw Guide and Bone Model identifiers are to be checked for readability and confirmed by the user.
4. Use the compatible OEM pedicle screw system as consistent with its surgical technique.
5. CT imaging data for S2AI is to be obtained with the patient in a non-weight bearing position (e.g. supine or prone position with legs flat or slightly bent)
6. FIREFLY® should not be used if significant changes to the patient's anatomy have occurred since the CT radiological images used for product definition were obtained.
7. Especially for pediatric patients, confirm that the CT imaging data accurately represents the patient's anatomy before using the product.
8. For pediatric patients, it is recommended that surgery occurs less than 6 months after the CT scan acquisition.
9. Patient-Specific Pedicle Screw Guides and Bone Models should be handled cautiously to avoid damage.
10. Do not use excessive force as this may damage the Guide. Excessive force is not required to attach or use these components.
11. Do not use the FIREFLY® Pedicle Screw Navigation Guide if components are broken, cracked, corroded, or damaged in any way.
12. Do not attempt to modify the Guide to be used in any other orientation, on any other level, or for any other patient. Patient-Specific Pedicle Screw Guides are intended only to be used, as marked, in a specific orientation on an anatomical level of the patient identified in the Approved Patient-Specific Surgical Plan.
13. Do not use the Ø2.0 mm drill bit to create pilot holes that cross the sacroiliac joint.
14. The Patient-Specific Pedicle Screw Guides must fit on bony anatomy. Remove soft tissue from patient-contacting locations to ensure proper fit.
15. Sharp edges may exist. Use caution when handling the FIREFLY® Pedicle Screw Navigation Guide.
16. Multi-level Patient-Specific Pedicle Screw Guides, which contact multiple anatomical levels, are only to be used on fused spinal regions.
17. The smallest pilot hole diameter made by FIREFLY® instruments is Ø2.0 mm. Do not attempt to implant pedicle screws smaller than Ø2.0 mm.
18. Check the expiration date prior to use.
19. The FIREFLY® Pedicle Screw Navigation Guide should be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.
20. The FIREFLY® Pedicle Screw Navigation Guide is not provided sterile. Clean and sterilize the FIREFLY® Pedicle Screw Navigation Guide immediately prior to surgery.
21. Automated cleaning methods are not recommended.
22. Patient-Specific Pedicle Screw Guides and Bone Models are single use only. Do not attempt to reuse them. ②
23. Patient-Specific Pedicle Screw Guides and Bone Models may be cleaned and sterilized up to a total of 3 times.

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