

3D Printed Patient-Specific Guides: A Cost Effective Navigation Solution for Spinal Fusions



Mighty Oak Medical



The Navigation Dilemma for Surgery Centers

■ **PROBLEM:**

- Your spine surgeons do not feel comfortable moving their smaller fusion surgeries out of the hospital.
- They use navigation in the hospital and need something with comparable accuracy in the surgery center.
- The surgery center investors are reluctant to incur debt and a long-term commitment.

■ **SOLUTION:** FIREFLY Patient-Specific Guides: single-use and disposable!



VS






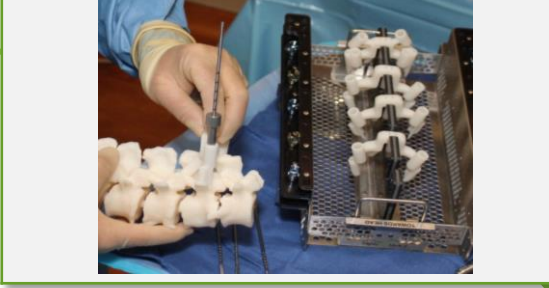
Platform Overview and Components

The complete FIREFLY® solution

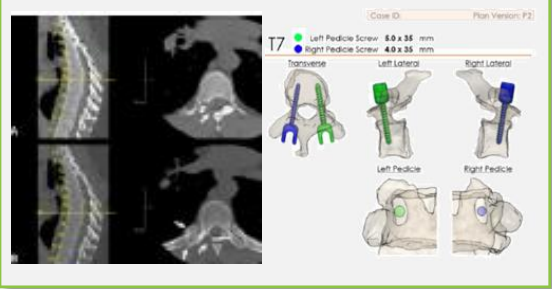
B Patient-Specific 3D-Printed Guides and Bone Model



C Instrumentation Set




A Concierge Presurgical Planning Services




D Predetermined Screws

Guided Level(s)	Left (mm)	Right (mm)
T4	4.0 X 35	4.0 X 35
T5	4.0 X 35	4.0 X 35
T6	4.0 X 35	4.0 X 35
T7	5.0 X 35	4.0 X 35
T8	5.0 X 35	4.0 X 35
T9	5.0 X 40	4.0 X 40
T10	5.0 X 40	5.0 X 40
T12	6.0 X 45	5.0 X 45
L1	6.0 X 45	5.0 X 45
L2	6.0 X 50	6.0 X 50
L3	6.0 X 50	6.0 X 50
L4	6.0 X 40	6.0 X 40
L5	6.0 X 40	6.0 X 40
S1	6.0 X 50	6.0 X 50
S2	8.0 X 35	8.0 X 35

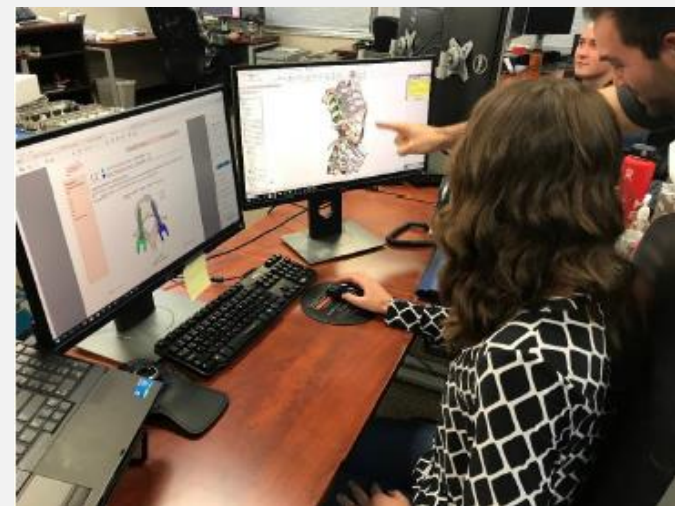
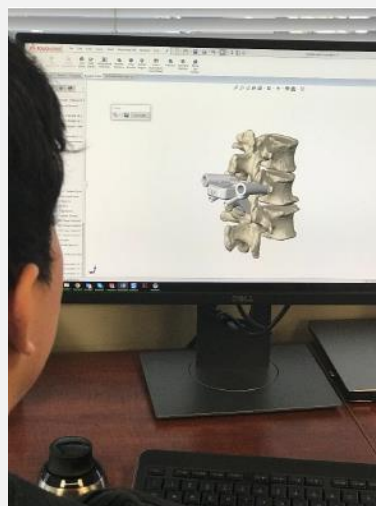




Concierge Presurgical Planning Services

A highly differentiated, FDA-cleared concierge presurgical planning service offering for spine

- The FIREFLY® concierge presurgical planning provides proprietary technology and development of patient-specific surgical plans
- Presurgical planning process cleared by FDA with rigorous operating protocol
- Skilled team performs presurgical planning for the surgeon
- Final surgical plan is signed off on by surgeon and includes screw trajectories and sizes



Case ID: _____ Plan Version: P2

Navigation

Case Information

T4

T6

T7

T8

T9

T10

T12

L1

L2

L3

L4

L5

S1

S2

Screw System

T7

● Left Pedicle Screw 5.0 x 35 mm

● Right Pedicle Screw 4.0 x 35 mm

Transverse

Left Lateral

Right Lateral

Left Pedicle

Right Pedicle

PATIENT-SPECIFIC SURGICAL PLAN APPROVED

Case ID _____

Patient _____

Date of Birth _____

Surgeon _____

Guided Levels

Level	Left (mm)	Right (mm)
T4	4.0 x 35	4.0 x 35
T5	4.0 x 35	4.0 x 35
T6	4.0 x 35	4.0 x 35
T7	5.0 x 35	4.0 x 35
T8	5.0 x 35	4.0 x 35
T9	5.0 x 40	4.0 x 40
T10	5.0 x 40	5.0 x 40
T12	6.0 x 45	5.0 x 45
L1	6.0 x 45	5.0 x 45
L2	6.0 x 50	6.0 x 50
L3	6.0 x 50	6.0 x 50
L4	6.0 x 40	6.0 x 40
L5	6.0 x 40	6.0 x 40
S1	6.0 x 50	6.0 x 50
S2	8.0 x 35	8.0 x 35

Note: Please refer to the pedicle system spiral system (pedicle) for required indications for use and surgical techniques. If applicable, consult the guidelines for the pedicle screw system.



Patient Specific Surgical Plan: A Prescription for Every Level



Case ID: 18BOMA
Plan Version: P1

Case Information									
T10	T11	T12	L1	L2	L3	L4	L5	S1	S2

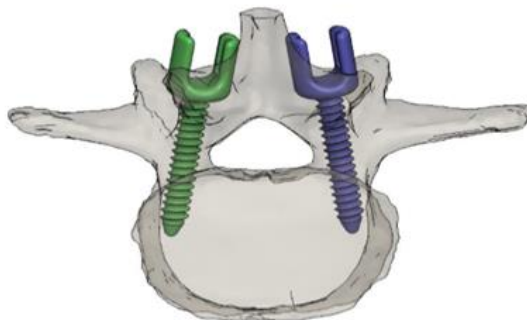
L3

- Left Pedicle Screw **5.5 x 35** mm
- Right Pedicle Screw **5.5 x 35** mm

Posterior



Transverse



Lateral

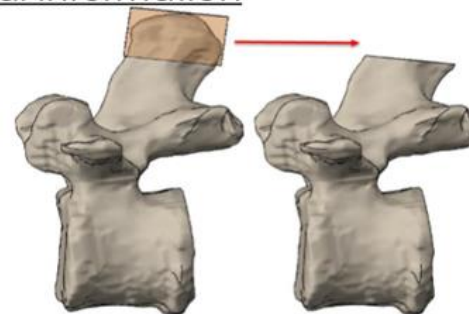


Guide Fit/Entry Point



Supplemental Information

Guide cannulae interfere with spinous process. Removal of spinous process required for Guide to fit. Reference Bone Model for simulation of removal.

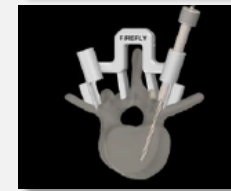




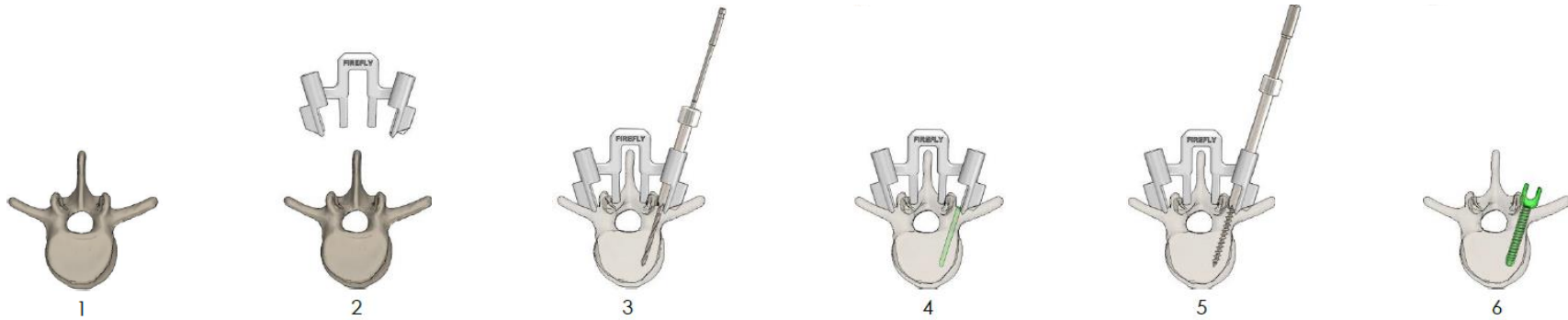
Patient-Specific 3D-Printed Guides

Surgeon-friendly, customized solution

- 3D-printed, patient-specific template that provides accurate guidance at every level
- Intuitive FIREFLY® guides enable short learning curve and faster screw implantation time; ability to use in conjunction with surgical power drill
- **Unlike traditional navigation systems, intersegmental motion is solved, as each guide is designed for each specific vertebrae**
- Autoclavable bone model yields unsurpassed vision of the patient spinal anatomy
 - Provides “ideal fit” for presurgical validation in OR
 - Planned trajectories built into bone model
 - Enables advanced patient education



FIREFLY® Pedicle Screw Navigation Technique



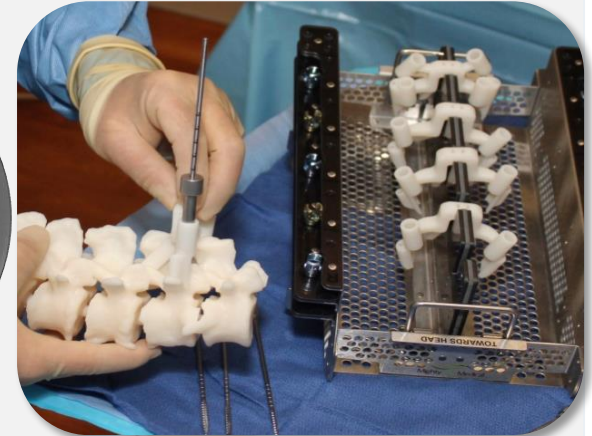
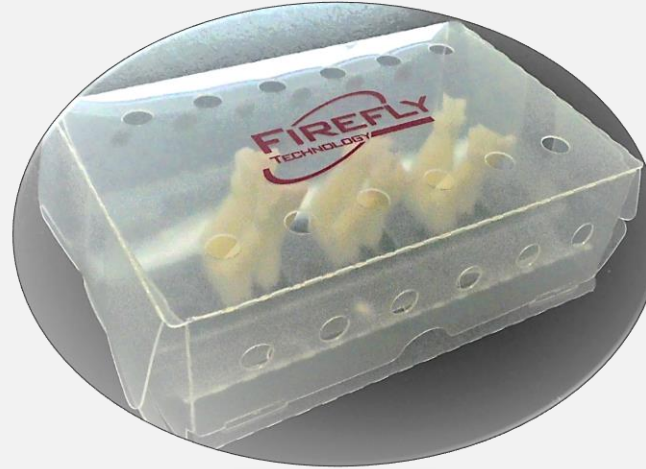


Instrumentation Set and Predetermined Screws

Future gold standard in operating room efficiency

FIREFLY® Solution

- FIREFLY® greatly reduces OR inventory levels and efficiently provides exactly what the surgeon needs
- All screw sizes are selected preoperatively
- This synchronization can significantly reduce screw placement time



Benefits of FIREFLY® vs Traditional Solutions

- FIREFLY® reduces inventory burden due to presurgical planning component
- Shipping, autoclaving and excess implants not utilized in OR are wasteful and can be eliminated
- Improved efficiency for hospitals and surgery centers





FIREFLY Guides are cleared by the FDA for use with ALL qualified screw systems





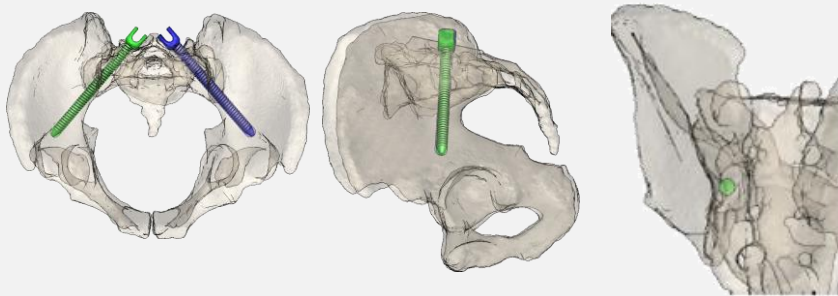
FDA Cleared Sacral Alar-Iliac (S2AI) Guides

FIREFLY® S2AI Guides offer advantages over existing navigational platforms

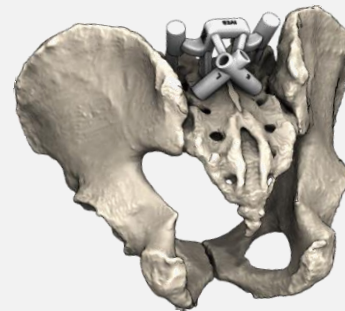
S2AI Guides

- S2AI trajectory is becoming the standard of care for bottom of construct fixation
- However, S2AI trajectory is one of the most (if not the most) difficult trajectories to achieve in spine surgery
- FIREFLY® makes S2AI simple, safe, and accurate by reducing or eliminating many complications associated with this trajectory:
 - Trajectories are placed with extreme accuracy while avoiding critical pelvic elements such as the sciatic notch or acetabulum
 - Reduces the amount of radiation exposure by enabling the trajectory to be instrumented without the use of fluoroscopy

Presurgical Planning



FIREFLY® S2AI Guide in Place on Ilium



Probing of S2AI Trajectory



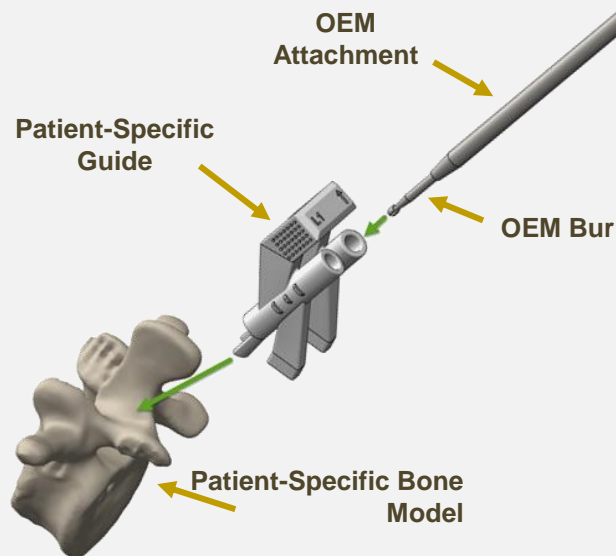


FDA Cleared Midline Navigation Guides

Midline solution helps surgeons move fusion cases into the surgery center

Midline Navigation System

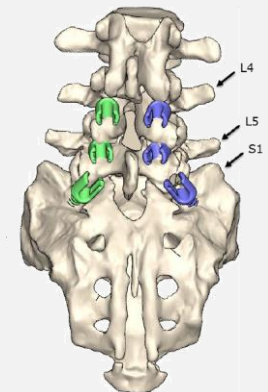
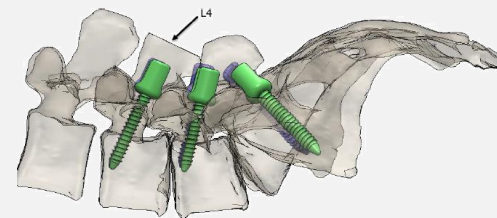
- Designed for cortical trajectory and is indicated for use from T10 to S2
- Offers the same advantages: improved trajectory, less dissection, less inventory, no intraoperative radiation, etc.
- Ideal for both hospitals and surgery centers



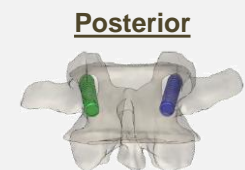
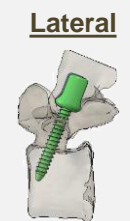
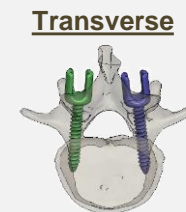
1st Case Review

Presurgical Planning

Guided Levels	Presurgically Planned Screws	
	Left Screw (mm)	Right Screw (mm)
L4	5.5 x 35	5.5 x 35
L5	5.5 x 30	5.5 x 30
S1	6.5 x 40	6.5 x 40



Surgery and Screw Placement (L4)





FIREFLY®: Three Simple Steps

From initial surgeon consultation to successful outcome

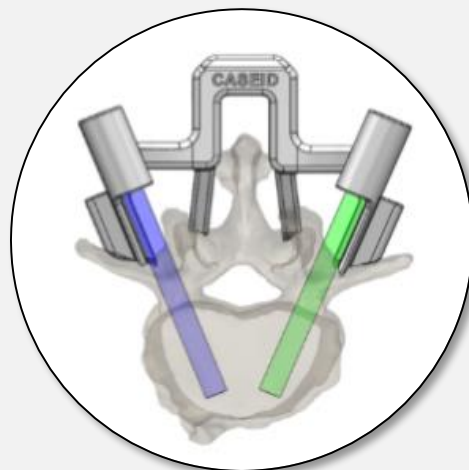
Customer Experience

ORDER CT SCAN



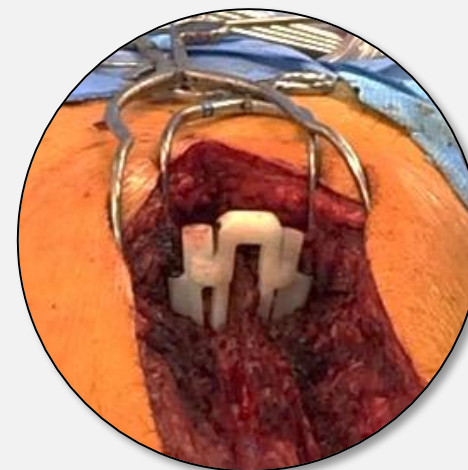
High quality CT scan is ordered and data set is put through segmentation process for 3D modeling

REVIEW & APPROVE PLAN



Information is uploaded and a presurgical plan is developed with direction from the surgeon

PERFORM SURGERY



3D-printed guides are manufactured; surgical plan, instrumentation and bone model displayed in OR



Surgeon Enabling Technology Moved Upstream

Outside OR
Before Surgery

Inside OR
Day of Surgery

Current
Enabling
Technology

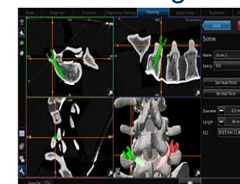
Setup



Imaging



Planning

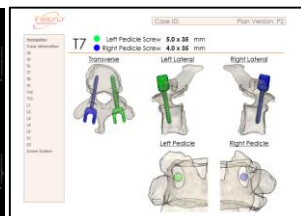
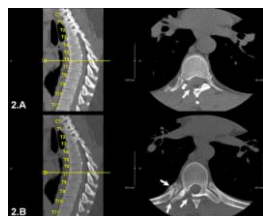


Navigation

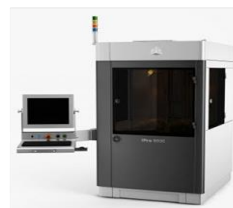


Planning
(concierge)

Imaging



3D printing



Navigation





Operating Room Simplicity and Reliability

Designed with surgery centers in mind

FIREFLY® Operating Room Footprint

- ✓ Zero footprint
- ✓ Zero power
- ✓ Zero software
- ✓ Zero setup
- ✓ Zero technology risk





Navigation Reimbursement Breakthrough

Effective July 1, 2019, AMA Category III CPT codes exist for both 3D-printed guides and bone models

FIREFLY® Reimbursed Navigation is PER LEVEL

BONE MODEL	0559T	Anatomic model 3D printed from image data set(s); individually prepared and processed component of an anatomic structure
	+0560T	Each additionally prepared and processed component of an anatomic structure (List separately in addition to code for primary procedure) (Use 0560T in conjunction with 0559T)
GUIDE	0561T	Anatomic guide 3D printed and designed from image data set(s); first anatomic guide
	+0562T	Each additional anatomic guide (List separately in addition to code for primary procedure) (Use 0562T in conjunction with 0561T)

FIREFLY® reimbursement resource guide currently under development



FIREFLY® Capitalizes on Strong Industry Trends

