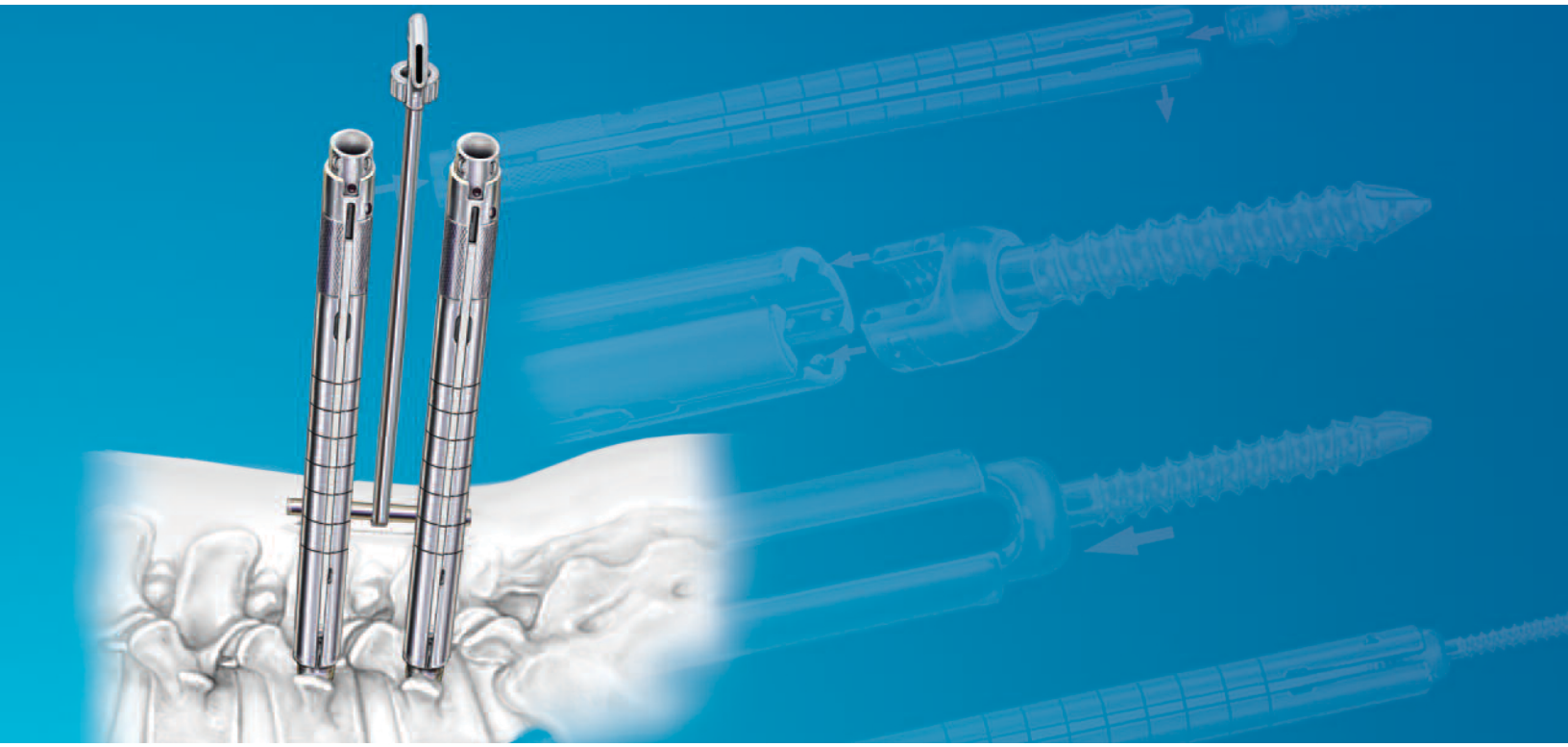
OPERATIVE TECHNIQUE

ProView™

MINIMAL ACCESS PORTAL (MAP) SYSTEM



Percutaneous Screw Delivery System

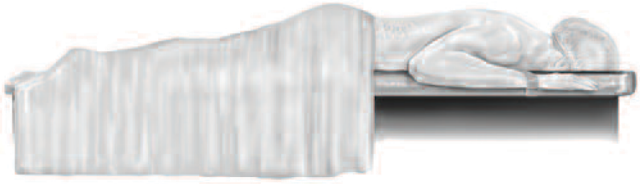
U.S. EDITION

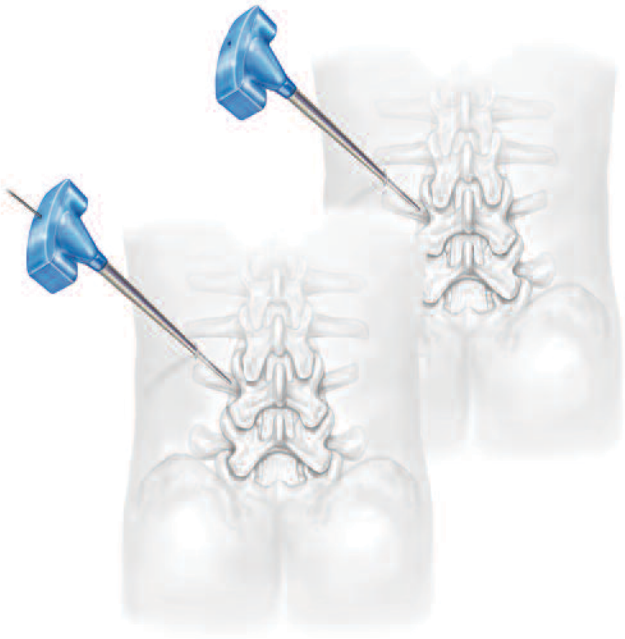
ORTHOFIX®
Spinal Implants

1 OPERATIVE TECHNIQUE

7 PART NUMBERS

8 INSTRUCTIONS FOR USE





1. POSITIONING

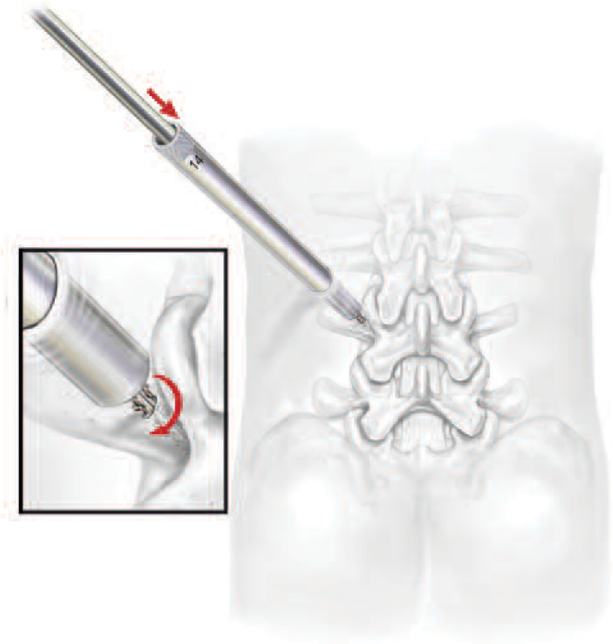
Position the patient in the prone position. A/P and lateral fluoroscopy should be used to provide proper imaging.

2. INITIAL INCISION

Create a longitudinal incision slightly larger than the #21 non-conductive dilator.

Insert the jamshidi needle at the origin of the pedicle. Ensure that the jamshidi needle is not medial to the medial border of the pedicle prior to the entrance into the vertebral body.

Remove the inner stylet of the jamshidi needle. Insert the guidewire through the jamshidi needle and place the guidewire into the mid portion of the vertebral body on the lateral view.



3. DILATION AND PEDICLE PREPARATION

Insert the #6 dilator over the guidewire. Place the #10 and #14 dilators over previous dilators.

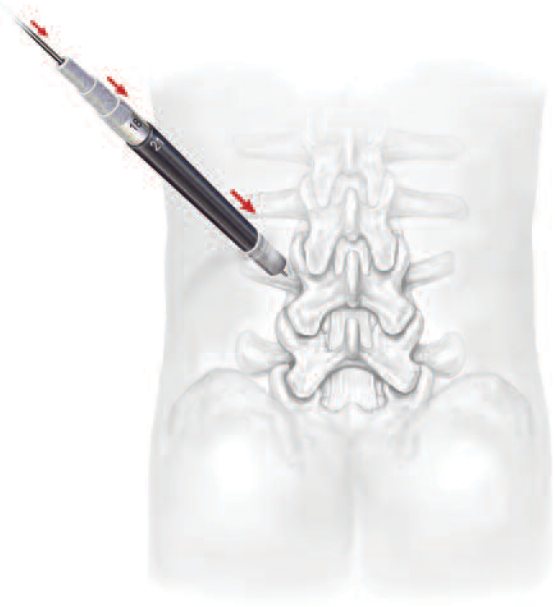
Bone Awl

Slide the bone awl over the guidewire to create a pilot hole at the pedicle entry point.

Tap

Tap through the #14 dilator and identify the length of the screw by marking on the tap.

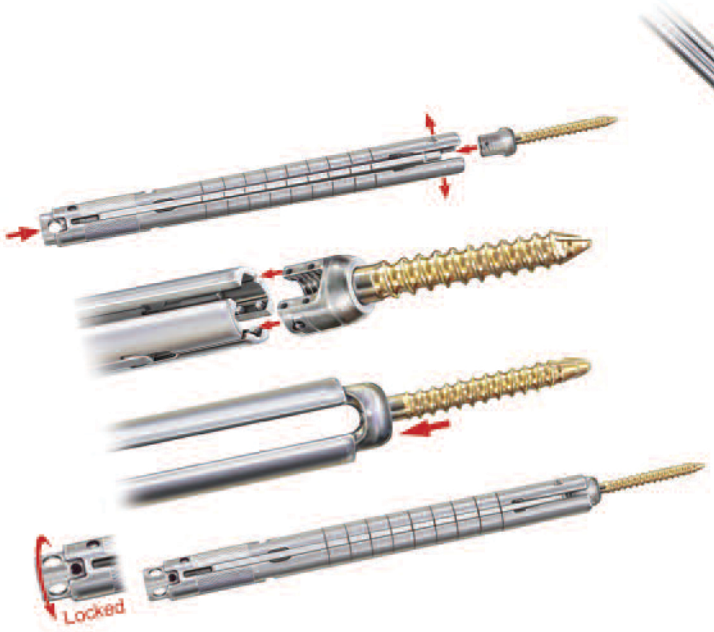
Utilizing fluoroscopy, remove the tap and ensure the guidewire does not advance.

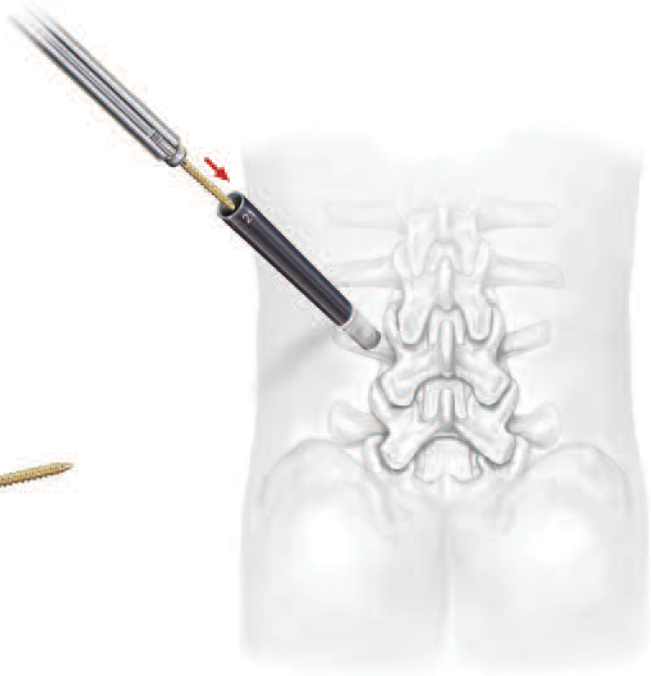


4. INSERTER HANDLE ATTACHMENT

After tapping continue to place the #18 and #21 non-conductive dilator over previous dilators.

Remove all dilators except the non-conductive dilator #21 and guidewire.





5. MULTI-AXIAL SCREW ATTACHMENT

Turn the knob on the head holder to unlock and depress the button located at the proximal aspect of the head holder to expand the distal screw head attachment site.

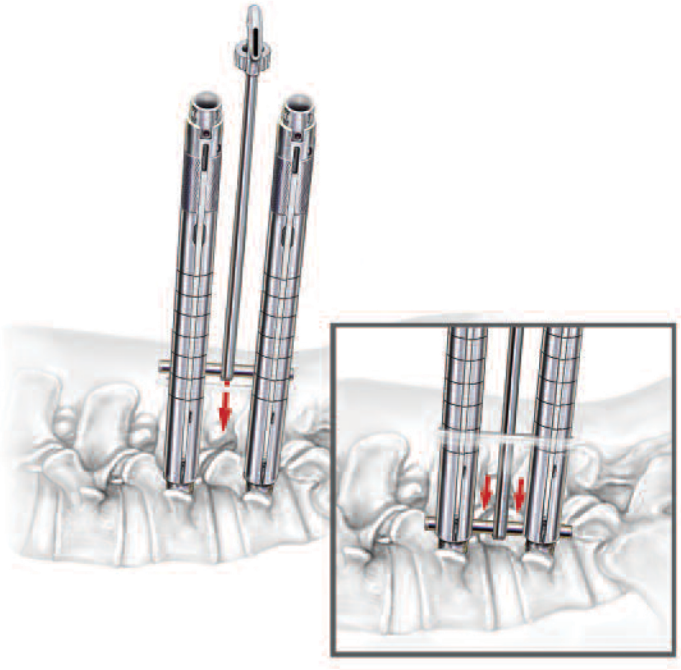
While depressing the button down, secure the multi-axial screw to the head holder. Ensure that the screw head saddle aligns with the slots in the head holder.

Rotate the proximal aspect of the head holder to lock the screw head into position.

6. MULTI-AXIAL SCREW PLACEMENT

Using the multi-axial screw driver, drive the multi-axial screw of appropriate length into the prepared pedicle. Remove the k-wire.

Place remaining screws using the same technique.



7. ROD INSERTION

Connect incisions to allow for passing of the rod. Create a trough between the two head holders using the blunt dissector.

Place calipers into head holders ensuring they seat completely into the multi-axial screw. Measure the rod length required for the construct. Add 15mm – 20mm to length measurement for final rod length.

Using the rod inserter, deliver the rod through the slots of the head holder. Seat the rod securely in the multi-axial screw heads.

For identification and ease of removal, the black line on the "T" handle identifies the open end on the distal portion of the rod inserter.

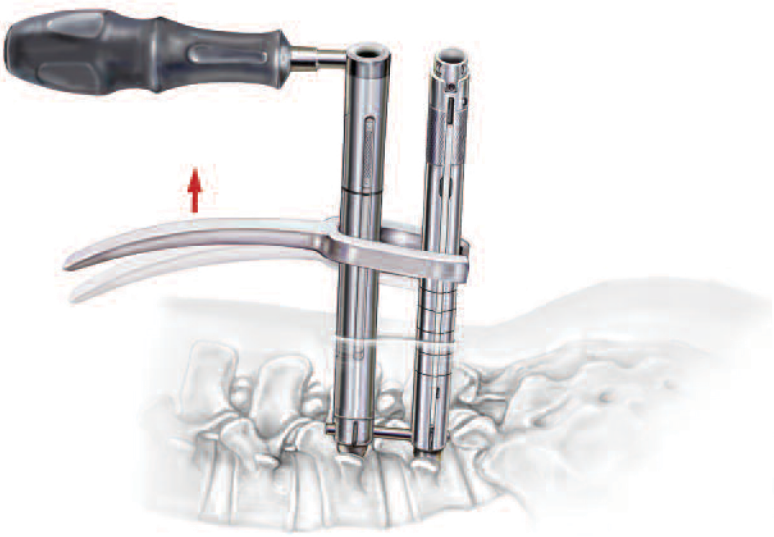
8. SET SCREW PLACEMENT AND FINAL TIGHTENING

Insert the set screw to secure rod in place. Ensure the rod is in the proper position with both A/P and lateral views. Place remaining set screws using the same technique.

Slide the cannulated counter torque wrench over the head holder. Ensure the black line on the counter torque wrench aligns to the top of the slot on the head holder. This visual marking along with tactile feedback confirms that the counter torque wrench is positioned correctly.

Insert the set screw driver through the head holder and engage the set screw. Apply clockwise torque to tighten the set screw. An audible click and tactile feedback will indicate that the required torque has been applied. Perform final tightening on all set screws using the same technique.

Rotate the knob on the head holder to unlock and depress the button to release the head holder from the screw.

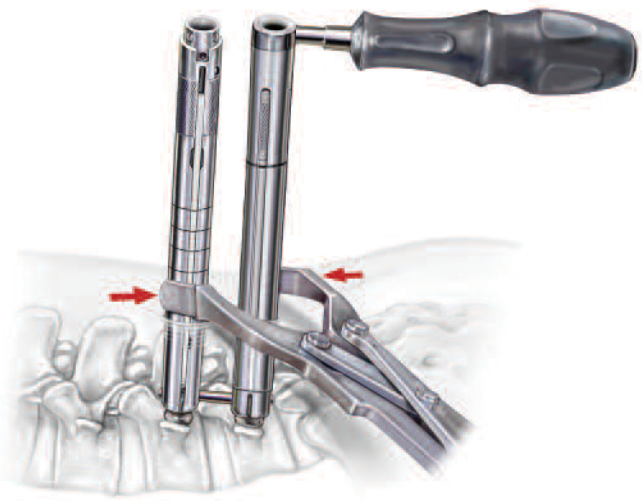


9. COMPRESSION

Alignment Tool

Place the counter torque wrench on the remaining screw construct. Slide the alignment tool under the handle of the counter torque wrench and over the head holder.

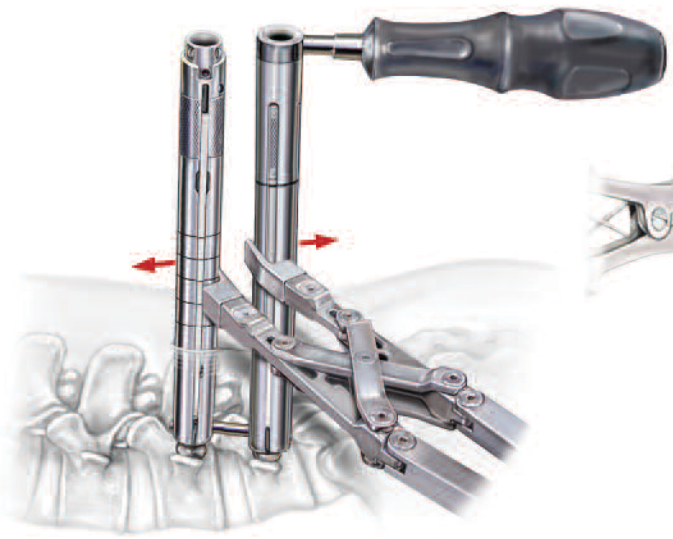
Position the alignment tool as close to the skin level as possible. Pull the alignment tool handle towards the counter torque wrench handle. Perform final tightening once desired compression is achieved.

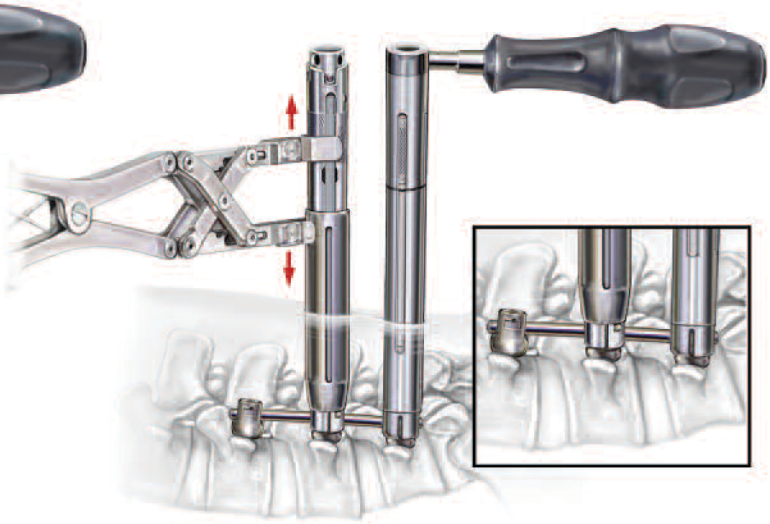


10. COMPRESSION (cont.)

Compressor

Slide the counter torque wrench over one of the head holders. Place the compressor into the slots of the head holders and counter torque wrench. Position the compressor as close to the skin level as possible. Press the compressor until desired compression is achieved. Perform final tightening on the construct prior to removing the compressor.





11. DISTRACTION

Slide the counter torque wrench over one of the head holders. Place the distractor in between the head holder and counter torque wrench.

Position the disctractor as close to the skin level as possible. Press the distractor until desired distraction is achieved. Perform final tightening on the construct prior to removing the distractor.

12. REDUCTION

Slide the cannula over the head holder of the construct requiring reduction.

Attach one each of the reduction tips, cannula and head holder, to the distractor.

Position the distractor on the head holder with the reduction tip (cannula) connecting to the hook on the cannula and the reduction tip (head holder) to the indentations on the head holder.

Press the distractor until the rod meets the screw head. Insert the set screw to secure the rod in place and perform final tightening utilizing the set screw driver.

PERCUTANEOUS SCREW DELIVERY SYSTEM

Firebird Case 1, 77-9020

PART #	DESCRIPTION	QTY
70-2001	K-Wire Blunt Percutaneous MIS	10
70-2002	K-Wire Sharp Percutaneous MIS	10
70-2006	Dilator #6, .230 OD, .100 ID MIS	2
70-2010	Dilator #10, .375 OD, .250 ID MIS	2
70-2014	Dilator #14, .545 OD, .397 ID MIS	2
70-2018	Dilator #18 .688 OD, .563 ID MIS	2
70-2121	Dilator #21 .813 OD .703 ID MIS	3
70-3000	Percutaneous Head Holder Assy	6
70-3100	K-wire Holder Assembly Percutaneous MIS	1
70-3201	Softgrip Handle, Quick Connect w/Ratchet, Black	2
70-3205	Dissector Percutaneous MIS	1
70-3207	Rod Inserter, Articulating Percutaneous MIS	1
70-3208	Rod Inserter Percutaneous MIS	1
70-3211	Rod Pusher Percutaneous MIS	1
70-3212	Hex Driver Assy MIS	2
70-3213	Inner SHaft Assy MIS	2
70-3216	Assy, Counter Torque Wrench Percutaneous MIS	1
77-3155	5.5mm Cannulated Tap, Quick Connect, MIS	1
77-3165	6.5mm Cannulated Tap, Quick Connect, MIS	1
77-3175	7.5mm Cannulated Tap, Quick Connect, MIS	1
77-3202	Multi-Axial Screw Driver	2

Firebird Case 2, 77-9030

PART #	DESCRIPTION	QTY
54-1050	Screw Sizing Template Screw Sizing Template	1
55-1042	Rod Bender	1
70-3206	Caliper Percutaneous	1
70-3217	Grip Instrument Percutaneous MIS	1
70-3218	Parallel Compressor Percutaneous	1
70-3219	Distractor Body Percutaneous MIS	2
70-3220	Distractor Tip Left Percutaneous MIS	1
70-3221	Alignment Tool Percutaneous	1
70-3222	Distractor Tip Right Percutaneous MIS	1
70-3223	Reduction Tip Cannula Percutaneous MIS	2
70-3224	Reduction Tip Head Holder Percutaneous MIS	2
70-3225	Reduction Cannula Percutaneous MIS	2

DEVICE SYSTEM NAME

ProView™ Minimal Access Portal (MAP) System
Percutaneous Screw Delivery System for Firebird™ Spinal Fixation System

Intended Use:
The ProView Minimal Access Portal (MAP) System, Percutaneous Screw Delivery System, is used to deliver the Firebird Spinal Fixation System multi-axial pedicle screws and rods in a minimally invasive manner. The system is intended to reduce muscle trauma compared to the traditional open surgical procedure.

The system consists of instrumentation to attach to the existing Firebird Spinal Fixation System implants and deliver the implants through a dilated incision. Once the multi-axial pedicle screws are placed, the rod is delivered through a connected incision with a rod inserter that allows delivery of the rod through a narrow incision and split in the muscle fascia.

The system consists of instrumentation only and does not include any implants, although it is designed to be used with components of the existing Firebird Spinal Fixation System implants.

Refer to the instructions for use supplied with the Firebird Spinal Fixation System implants for specific information on indications for use, contraindications, warnings, precautions, adverse reaction information, and sterilization information for the implant components.

Contraindications include, but are not limited to:
1) Morbid obesity
2) Mental illness
3) Alcoholism or drug abuse
4) Pregnancy
5) Metal sensitivity/allergies
6) Severe osteopenia
7) Patients unwilling or unable to follow post-operative care instructions
8) Any circumstances not listed under the heading Indications

Potential Adverse Events:
All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:
1) Device component fracture
2) Neurological injury
3) Vascular or visceral injury
4) Foreign body (allergic) reaction to instruments, debris, corrosion products, including metallosis, straining, tumor formation, and/or auto-immune disease
5) Infection
6) Hemorrhage
7) Cessation of any potential growth of the operated portion of the spine
8) Death

Note: Potential risks identified with the use of the device system may require additional surgery.

Warnings and Precautions:
1) The ProView MAP System is sold nonsterile and therefore must be sterilized before use.
2) Care should be exercised in the handling and storage of instruments. Instruments should not be scratched, notched, or otherwise damaged since such actions may reduce functional performance. Store away from corrosive environments.
3) An adequate inventory should be available at surgery other than those expected to be used.
4) All components and instruments should be cleaned and sterilized prior to use. Additional sterile components should be available in case of anunexpected need.
5) If used around the spinal cord and nerve roots, extreme caution should be taken.
6) Reuse of devices labeled as single-use could result in injury or re-operation due to breakage or infection. Do not attempt to re-sterilize single-use implants that come in contact with body fluids.

Cleaning:
All instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning can include the use of neutral cleaners followed by a deionized water rinse. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Sterilization:
The ProView MAP System should be sterilized by the hospital using one of the following recommended cycles:

Method: Steam Cycle: Gravity Temperature: 250° F (121° C) Exposure time: 30 minutes	Or:	Method: Steam Cycle: Prevac Temperature: 270° F (132° C) Exposure time: 8 minutes

Product Complaints:
Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the company, Blackstone Medical, Inc., 1720 Bray Central Dr., McKinney, TX 75069 USA, Phone: 1-888-298-5700, Email: complaints@orthofix.com.

Authorized European Representative:
Medical Device Safety Service (MDSS)
Schiffgraben 41, D-30175 Hannover, Germany

Please visit Orthofix.com/IFU for full information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

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

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