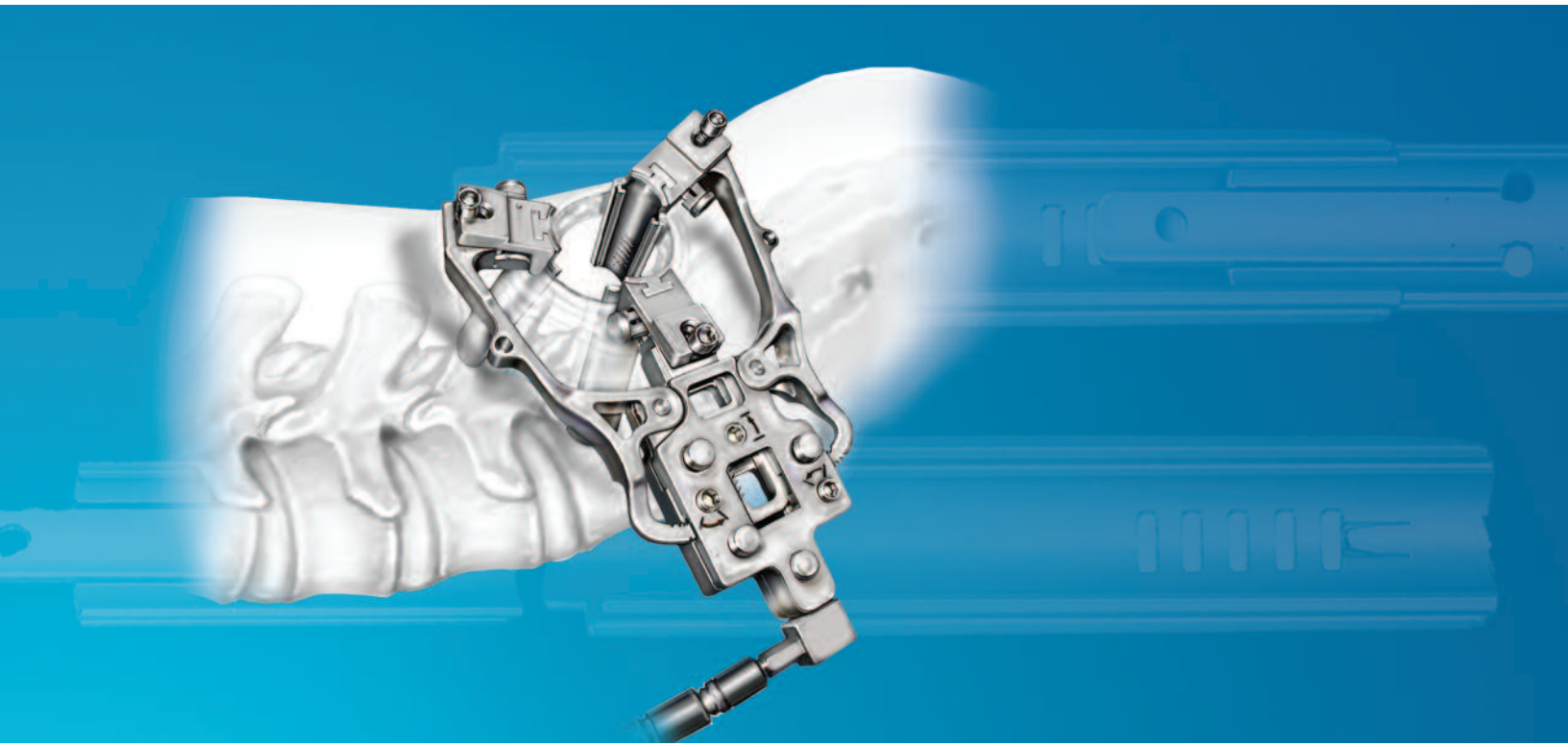
OPERATIVE TECHNIQUE

ProView™

MINIMAL ACCESS PORTAL (MAP) SYSTEM



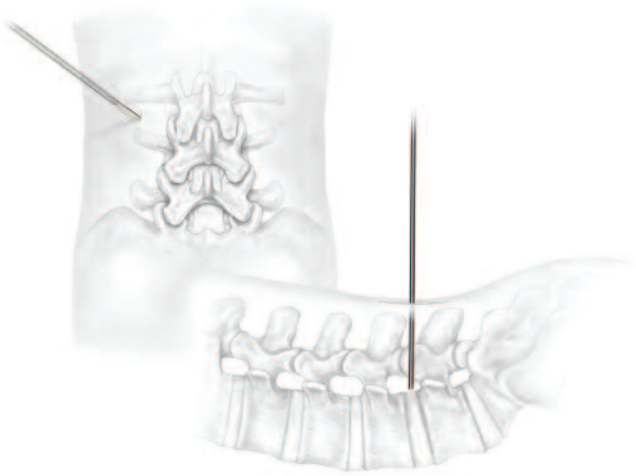
Expandable Retractor System

U.S. EDITION

ORTHOFIX®
Spinal Implants

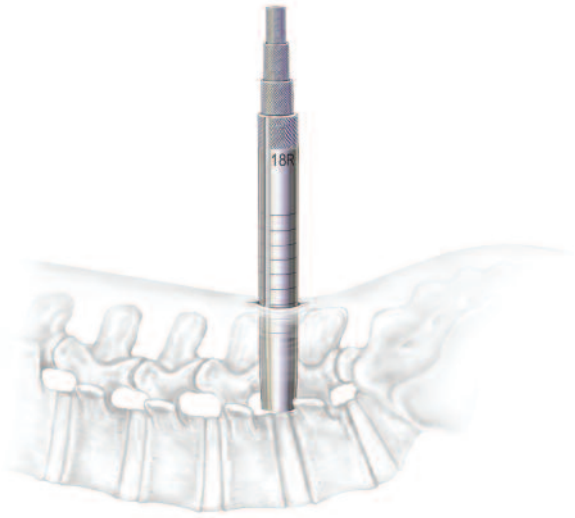
POSITIONING

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



1. ACCESS/INITIAL INCISION

Place k-wire on the desired vertebral level. Insert the k-wire through the fascia. A longitudinal incision is made slightly larger than the maximum working diameter. Confirm position fluoroscopically.



2. DILATION

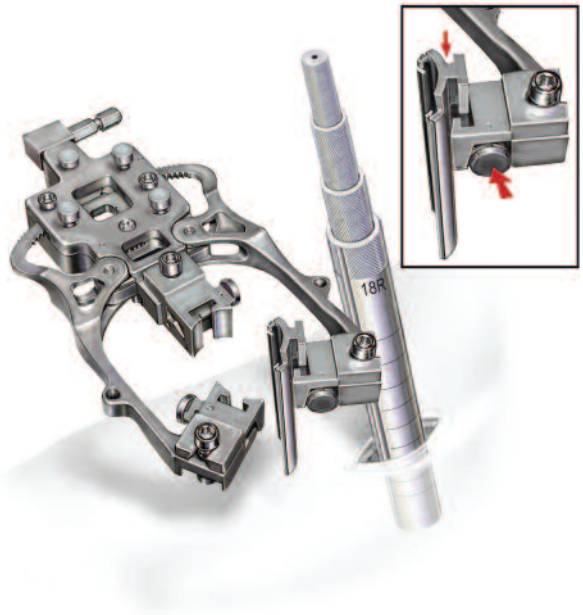
Insert the 1st blunt dilator over the k-wire and dock onto the bone.

For a diskectomy/decompression, position the dilator on the lamina.

For a transforaminal lumbar interbody fusion, position the dilator on the facet/joint/pars region.

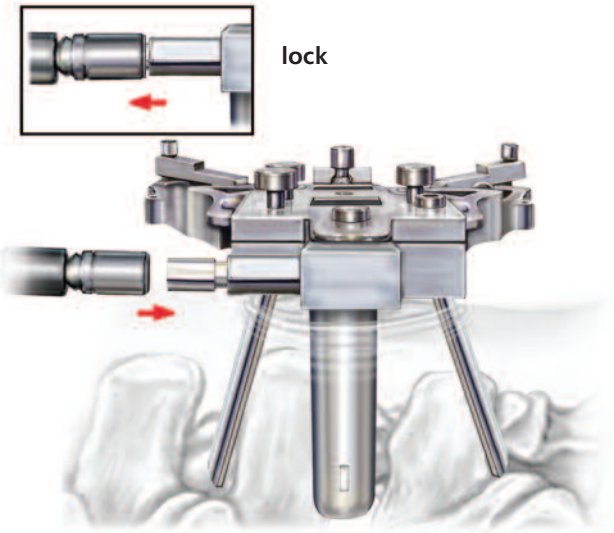
Place sequential dilators over previous dilators. Remove the k-wire. Careful wanding of dilators will clear soft tissue from the lamina, spinous process, and facet joints and ensure that dilators are flush against bone.

Position dilators flush to the bone. Measure the depth at the point where skin contacts the dilator. Select retractor blades according to the dilator depth measurements. If skin edge falls between two depths, select the longer length retractor blades.



3. BLADE ATTACHMENT

Depress the blade lock button and insert the blade into the blade holder.

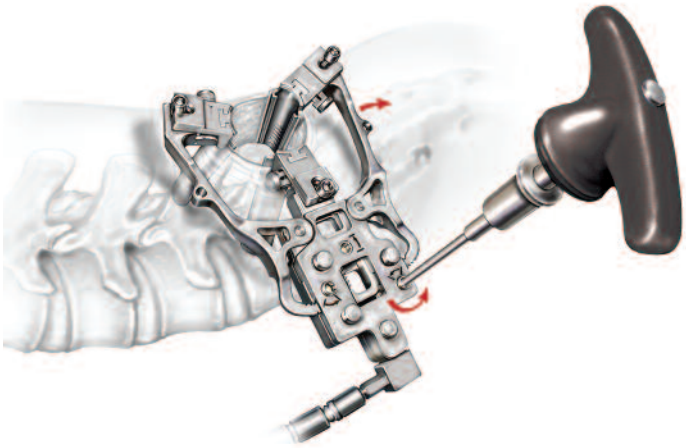


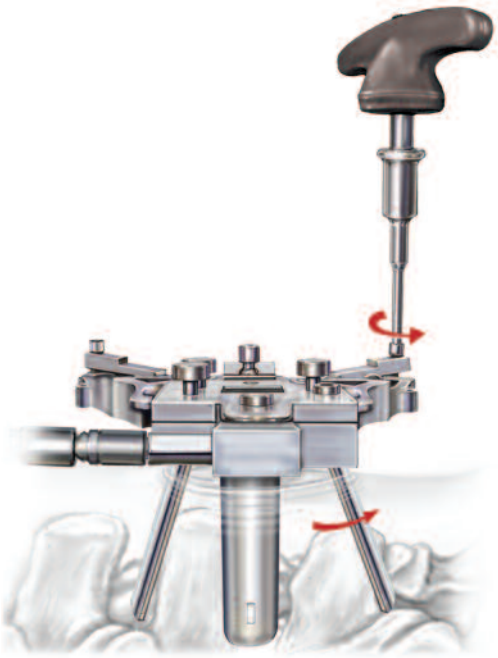
4. POSITIONING

Be sure that the expandable retractor is in the closed position, prior to insertion, with the retractor blades perpendicular to the retractor body when placing over the dilators. Position the expandable retractor body over the dilators until flush with bone.

5. FLEXIBLE ARM ATTACHMENT

Push the knob into the unlocked position to attach the flexible arm to the expandable retractor pull the knob to lock the flexible arm. Confirm secure attachment and tighten the flexible arm to the desired rigidity. Remove the inner dilators.



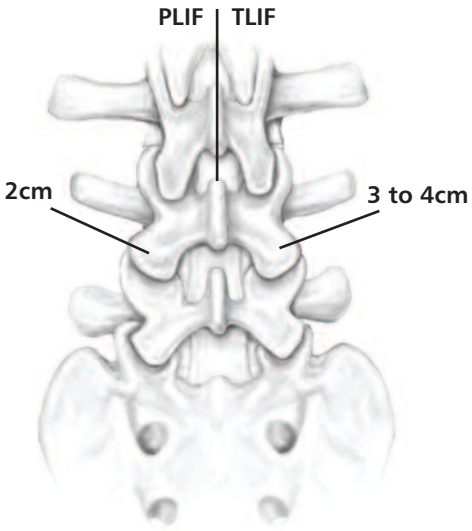


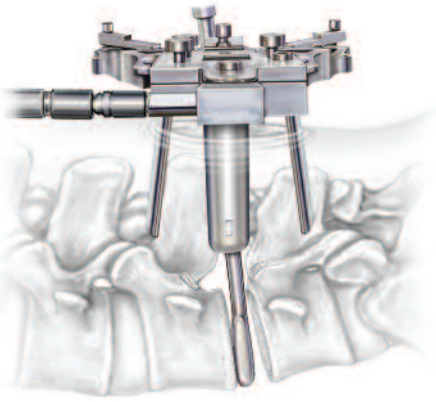
6. RETRACTOR EXPANSION

To expand the retractor, insert and rotate the universal driver counter clockwise in one of the three holes to open the retractor blade.

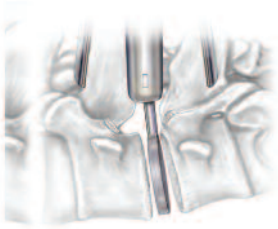
7. RETRACTOR ANGULATION

To increase blade angulation, insert the universal driver into the screw holes located above each retractor blade and turn counter clockwise. Maximum angulation is 15° per blade.

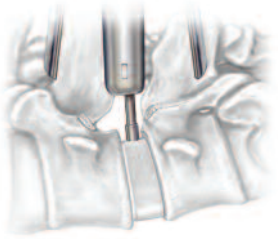




Distraction



Implant trial



Implant insertion

8A. POSTERIOR LUMBAR INTERBODY FUSION

For a posterior lumbar interbody fusion, position the retractor 2cm lateral off the midline at the appropriate level.

8B. TRANSFORAMINAL LUMBAR INTERBODY FUSION

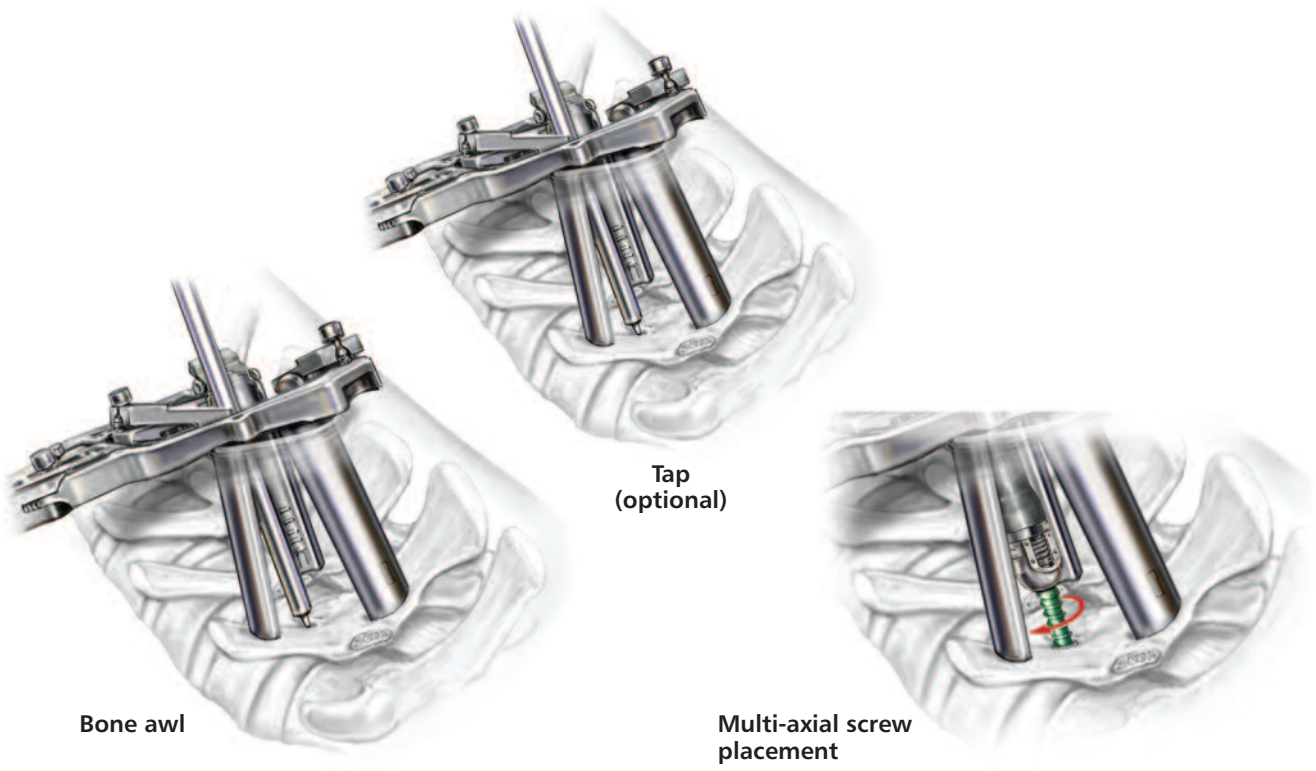
For a transforaminal lumbar interbody fusion, position the retractor 3 to 4cm lateral off the midline at the appropriate level.

Positioning will depend on varying patient anatomies. Confirm position using A/P and lateral fluoroscopy.

9. PREPARATION AND IMPLANT INSERTION

Perform a complete discectomy and prepare the vertebral endplates. Distract the disc space to the proper height either via intradiscal distractor or via pedicle screws in preparation for the placement of the implant.

Determine the width, height, and length of the implant using the trial. Once the sizing is determined, select the corresponding implant. Insert the implant into position using the inserter. An impactor may be used for final positioning of the implant.



Bone awl

Tap
(optional)

Multi-axial screw
placement

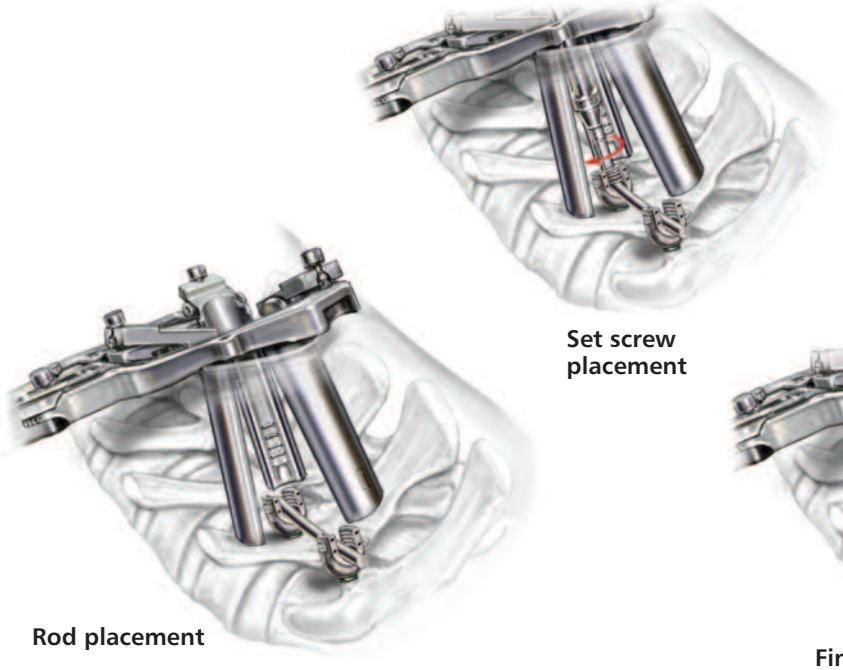
10. PEDICLE SCREW FIXATION WITH FIREBIRD™ SPINAL FIXATION SYSTEM

Pedicle Screw Placement

Using the bone awl, create a pilot hole at the pedicle entry point. Tap the pedicle to facilitate screw insertion. (optional)

Using the multi-axial driver, drive the multi-axial screw assembly into the prepared pedicle. Place remaining screws into position.

If posterior lateral fusion is desired, decorticate the facets and place biologic material of choice.



Rod placement

Set screw placement

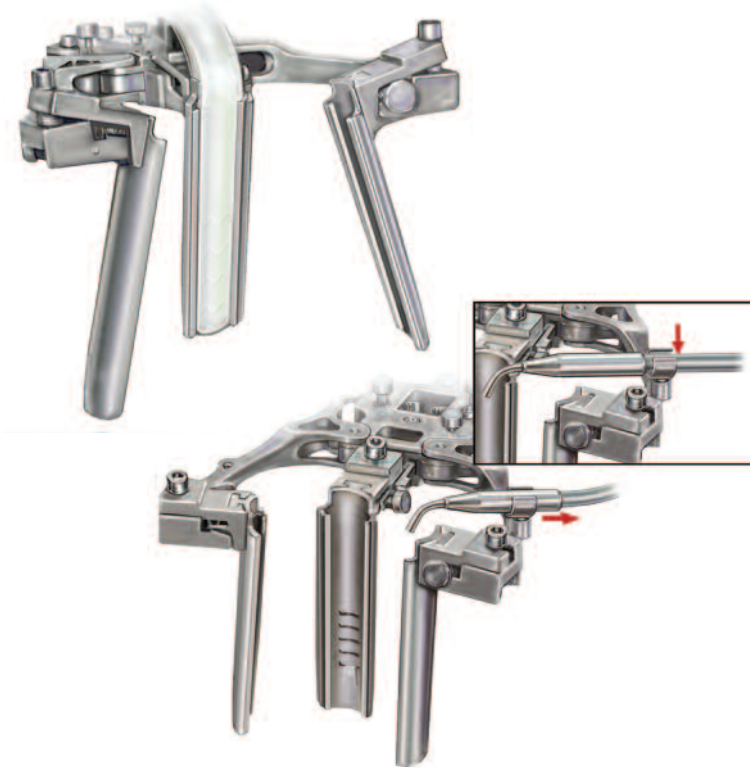
Final tightening

11. ROD PLACEMENT, SET SCREW PLACEMENT, AND FINAL TIGHTENING

Secure the appropriate length rod in the multi-axial screws. Use the set screw holder to insert the set screw.

Slide the cannulated counter torque wrench over the multi-axial head. Insert the set screw driver through the counter torque wrench 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. Continue with the remaining set screws in the same manner.



ACCESSORIES

Shim Blades

Shim blades can be attached to increase the blade length without removing the retractor. Each additional slot will increase the overall length by 5mm for a total of 20mm increase in length.

Right, left and double shims are available to help prevent muscle and tissue creep.

Disposable Fiberoptic Light Cables

Disposable fiberoptic light cables are provided for illumination of the operative sight. Insert the disposable light cable into the retractor blades by sliding down the center blade groove.

Reusable Fiberoptic Light Cables

Single and bifurcated reusable fiberoptic light cables are provided for illumination of the operative site.

Place the light posts into the retractor arm.

Insert the gray portion of the cable into the post and then pull to position securely.

PROVIEW™ MINIMAL ACCESS PORTAL (MAP) SYSTEM

EXPANDABLE RETRACTOR SYSTEM 70-0004

IInstrument Case	
70-2001	K-Wire, Blunt
70-2002	K-Wire, Sharp
70-2006	Dilator # 6
70-2010	Dilator # 10
70-2014	Dilator # 14
70-2018	Dilator # 18
70-2118	Dilator # 18R
70-2300	ACMI Adapter Cable 7ft.
70-2301	Fiber Optic Light Cable, Post
70-2302	Single Fiber Optic Light Cable, Reusable
70-2303	Bifurcated Fiber Optic Light Cable, Reusable
70-2304	Disposable Light Cable
70-4001	Expandable Retractor
70-4090	System Case
70-4100	Retractor Quick Connect
70-4103	Driver Handle
70-4102	Driver Shaft
70-4104	Blade, 4 cm
70-4105	Blade, 5 cm
70-4106	Blade, 6 cm
70-4107	Blade, 7 cm
70-4108	Blade, 8 cm
70-4109	Blade, 9 cm
70-4110	Blade, 10 cm
70-4200	Shim Inserter
70-4201	Shim Blade, Center
70-4202	Shim Blade, Left
70-4203	Shim Blade, Right
70-4204	Shim Blade, Double
70-4210	Shim Inserter, Depth Stop

ONYX™ INSTRUMENTATION SET

70-0010	**ONYX Instrumentation Set, Case 1**
70-1090	System Case 1
70-1202	Curved Kerrison, 2mm
70-1204	Curved Kerrison, 4mm
70-1220	Kerrison, 40°, 2mm
70-1221	Kerrison, 90°, 2mm
70-1230	Kerrison, 40°, 3mm
70-1231	Kerrison, 90°, 3mm
70-1240	Kerrison, 40°, 4mm
70-1241	Kerrison, 90°, 4mm
70-1311	Curette, Straight, 1
70-1312	Curette, Up, 1
70-1314	Curette, 90°, Reverse, 1
70-1321	Curette, Straight, 00
70-1322	Curette, Up, 00
70-1324	Curette, 90°, Reverse, 00
70-1341	Curette, Straight, 0000
70-1342	Curette, Up, 0000
70-1344	Curette, 90°, Reverse, 0000
70-0020	**ONYX Instrumentation Set, Case 2**
70-1021	Micro Pituitary, Straight, 2mm
70-1022	Micro Pituitary, Up, 2mm
70-1091	ONYX Instrumentation Set - Case 2
70-1121	Pituitary, Straight, 2mm
70-1122	Pituitary, Up, 2mm
70-1123	Pituitary, Down, 2mm
70-1141	Pituitary, Straight, 4mm
70-1142	Pituitary, Up, 4mm
70-1401	Ball Probe, 5mm
70-1402	Ball Probe, 10mm
70-1403	Woodson Probe
70-1404	Penfield #2
70-1405	Penfield #4
70-1406	Nerve Hook
70-1408	Stylet
70-1409	Suction Tube, 9Fr

PROVIEW™ MINIMAL ACCESS PORTAL (MAP) SYSTEM

ONYX™ INSTRUMENTATION SET (cont.)

70-1411	Suction Tube, 11Fr
70-1413	Dura Retractor
70-1414	Suction Nerve Retractor
70-1416	Scalpel Handle
70-1417	Penfield Push, #3
70-1418	Nerve Root Retractor

TABLE ATTACHMENTS - 70-0005

70-5001	Rail Clamp Assembly
70-5002	Flexible Arm
70-5003	Rail Adapter
70-5004	Side Rail
70-5090	System Case

DEVICE SYSTEM NAME

ProView™ Minimal Access Portal (MAP) System

Description
The ProView MAP System (Tubular Retractors System, Expandable Retractor System) consists of surgical instruments intended to aid the surgeon's visualization of the surgical area and allow for performance of spinal procedures.

The tubular retractor system includes stainless steel tubular retractors in multiple lengths and diameters, a handle for insertion to operative site, fiber optic lighting, and table attachments to connect to the side rail of the operating room table. The expandable retractor system includes stainless steel detachable blades in multiple lengths, fiber optic lighting, and table attachments to connect to the side rail of the operating room table.

Indications
The ProView MAP System consists of surgical instruments intended to aid the surgeon's visualization of the surgical area and allow for performance of spinal procedures such as herniated disc repair, visualization of the circumferential decompression of the nerve roots, aiding in the search and removal of nucleus material, spinal fusion, or insertion of spinal implants.

Contraindications
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) The retractors should be assembled prior to surgery. 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 an unexpected need.
5) If used around the spinal cord and nerve roots, extreme caution should be taken.
6) The reusable fiber optic light cables are designed for use with 300 watt xenon illuminators using the provided ACMI adapter cable. Do not use light sources rated higher than 300 watts or any cables other than the provided ACMI adapter cable. Use of higher watt sources or cables other than the provided ACMI adapter cable could result in overheating; causing product failure and patient injury.

7) Do not operate the light source and adapter cable without the reusable fiber optic light cables attached. Without the reusable fiber optic light cable, the output from the adapter cable is extremely bright, hot, and may cause burns, ignite drapes/gowns, or temporarily blind vision.
8) Reuse of devices labeled as single-use could result in injury or re-operation due to breakage or infection. Do not 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	Or:	Method: Steam
Cycle: Gravity		Cycle: Prevac
Temperature: 250° F (121° C)		Temperature: 270° F (132° C)
Exposure time: 30 minutes		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, Orthofix Spinal Implants, 1720 Bray Central Drive, McKinney, TX 75069, USA, Telephone: 1.888-298-5700, Email: complaints@orthofix.com

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

Orthofix Spinal Implants
1720 Bray Central Drive
McKinney, TX 75069

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
⚠ Refer to the instructions for use supplied with product for specific information on indications for use, contraindications, warnings, precautions, adverse reaction information, and sterilization.

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. Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.

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Fusion | Biologics | MIS | Bone Growth Stimulation | Bracing

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