OPERATIVE TECHNIQUE

ProView™

MINIMAL ACCESS PORTAL (MAP) SYSTEM

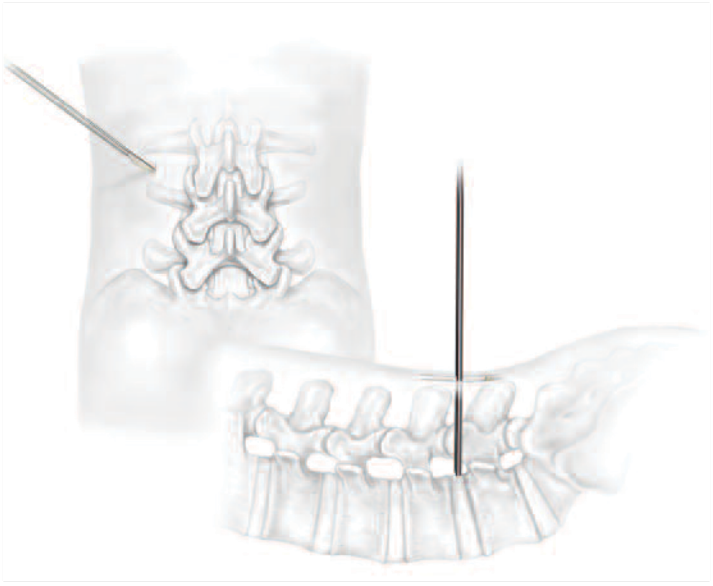
Tubular Retractors System

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. INITIAL INCISION

Insert guidewire 1 to 1.5 cm off the midline over the disc space. A longitudinal incision is made slightly larger than the maximum tubular diameter. Confirm position fluoroscopically.

2. DILATION

Insert the #6 dilator over the guidewire and advance to the inferior aspect of the superior lamina. Place sequential dilators over previous dilators. Careful wanding of dilators will clear soft tissue from the lamina, spinous process, and facet joints and ensure that dilators are flush against bone.

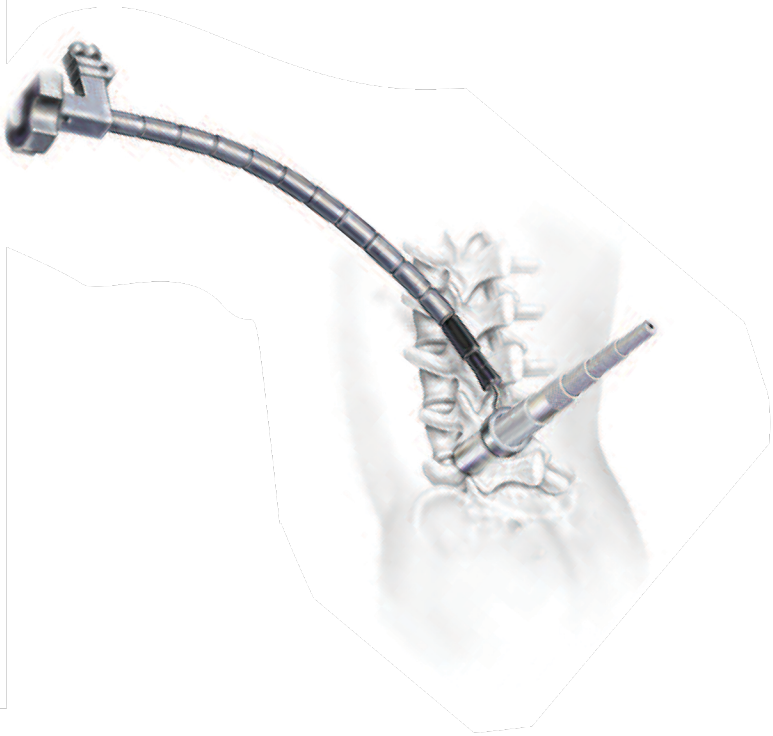
Position dilators flush to the bone. Measure the depth at the point where skin contacts the dilator. Select tubular retractor according to the dilator depth measurements. If the skin edge falls between two depths, select the longer length tubular retractor.

3. INSERTER HANDLE ATTACHMENT

Push the knob into the unlocked position to attach the inserter handle to the tubular retractor and pull the knob to lock. Place the tubular retractor over the dilators. Remove the inserter handle.

4. FLEXIBLE ARM ATTACHMENT

Remove the inserter handle and push the knob into the unlocked position to attach the flexible arm to the tubular retractor and pull the knob to lock the flexible arm. Confirm secure attachment and tighten the flexible arm to the desired rigidity. Remove the inner dilators.



5. DECOMPRESSION

Decompression may now be accomplished with the instruments provided in the ONYX™ Instrumentation Set:

1) Bayoneted Kerrisons
2) Bayoneted Pituitary Rongeurs
3) Bayoneted Curettes
4) Bayoneted Penfields
5) Bayoneted Nerve Hooks

MINIMAL ACCESS PORTAL (MAP) SYSTEM

TUBULAR RETRACTORS SYSTEM - 70-0002

Instrument 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
70-2021	Dilator # 21
70-2024	Dilator # 24
70-2090	Instrument Case
70-2100	Inserter Handle
70-2180	Tubular Retractor 18mm x 10cm
70-2184	Tubular Retractor 18mm x 4cm
70-2185	Tubular Retractor 18mm x 5cm
70-2186	Tubular Retractor 18mm x 6cm
70-2187	Tubular Retractor 18mm x 7cm
70-2188	Tubular Retractor 18mm x 8cm
70-2189	Tubular Retractor 18mm x 9cm
70-2210	Tubular Retractor 21mm x 10cm
70-2214	Tubular Retractor 21mm x 4cm
70-2215	Tubular Retractor 21mm x 5cm
70-2216	Tubular Retractor 21mm x 6cm
70-2217	Tubular Retractor 21mm x 7cm
70-2218	Tubular Retractor 21mm x 8cm
70-2219	Tubular Retractor 21mm x 9cm
70-2240	Tubular Retractor 24mm x 10cm Beveled End
70-2244	Tubular Retractor 24mm x 4cm Beveled End
70-2245	Tubular Retractor 24mm x 5cm Beveled End
70-2246	Tubular Retractor 24mm x 6cm Beveled End
70-2247	Tubular Retractor 24mm x 7cm Beveled End
70-2248	Tubular Retractor 24mm x 8cm Beveled End
70-2249	Tubular Retractor 24mm x 9cm Beveled End
70-2300	ACMI Adapter Cable 7ft.
70-2302	Single Fiber Optic Light Cable, Reusable
70-2303	Bifurcated Fiber Optic Light Cable, Reusable

ONYX INSTRUMENTATION SET

70-0010	**ONYX Instrumentation Set, Case 1**
70-1090	Instrument 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	Instrument 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

MINIMAL ACCESS PORTAL (MAP) SYSTEM

ONYX INSTRUMENTATION SET (cont.)

70-1409	Suction Tube, 9Fr
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

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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