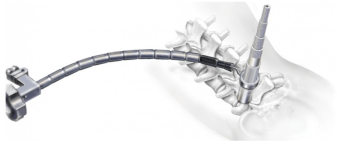

ORTHOFIX AW-70-9906 ProView Minimal Access Portal System Instruction Manual

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ORTHOFIX®

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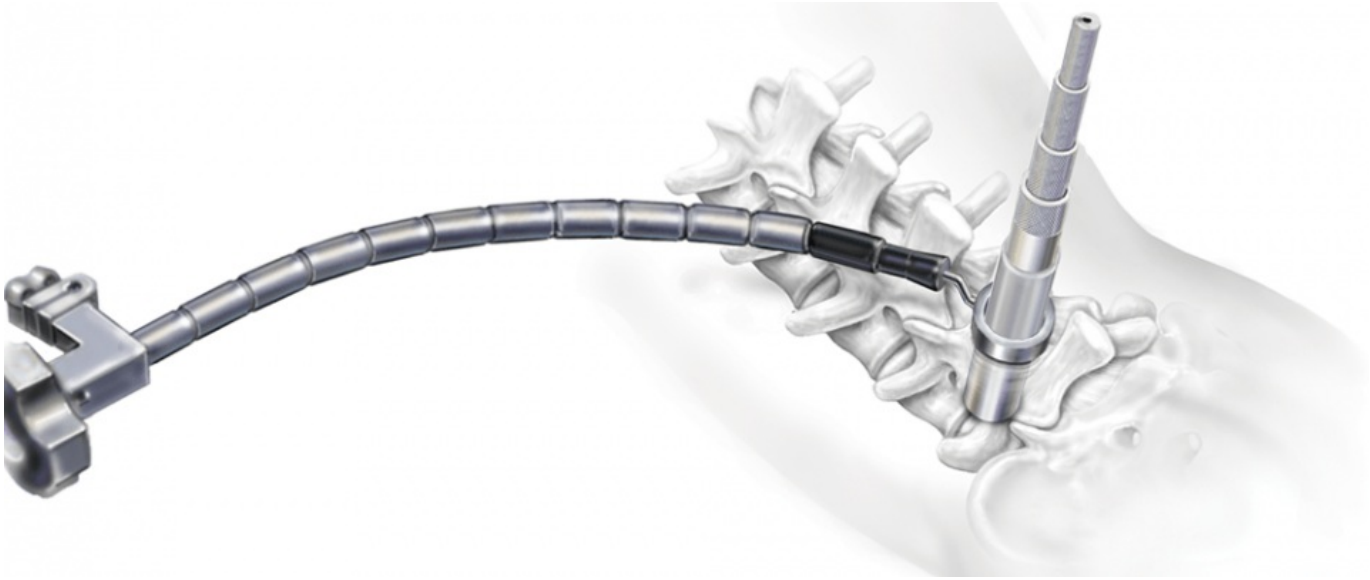


Description

The ProView MAP Systems consist of surgical instruments intended to aid surgeons in visualization of surgical sites for spinal procedures. The ProView Tubular Retractor System includes stainless steel tubular retractors in multiple lengths and diameters, a handle for insertion into the operative site, fiber optic lighting, and table attachments to connect to the side rail of the operating room table. The ProView Expandable Retractor System includes detachable blades in multiple lengths, fiber optic lighting, and table attachments to connect to the side rail of the operating room table. The ProView Percutaneous Screw Delivery System consists of instrumentation designed to deliver multi-axial pedicle screws and rods in a minimally invasive manner. The system is designed to reduce muscle trauma compared to the traditional open surgical procedure. The ProView ONYX System features a comprehensive set of black-coated kerrisons, curettes, pituitaries, stylets, hand held retractors, probes and scalpel handles. The instruments are designed to perform specific functions such as cutting, grasping, dissecting, probing, retracting and draining.

Indications for Use

The ProView Tubular and Expandable Retractor System are 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. The ProView Percutaneous Screw Delivery System is used to deliver multi-axial pedicle screws and rods in a minimally invasive manner. The ProView ONYX System is intended to aid in cutting and removal of soft tissue during a surgical procedure.

Contraindications

The ProView MAP System is contraindicated for use in patients with:

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 for Use.

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 notn limited to:

1. Neurological injury.
2. Vascular or visceral injury.
3. Foreign body (allergic) reaction to instruments, debris, etc.
4. Infection.
5. Hemorrhage.
6. 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 thoroughly cleaned and sterilized before each 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.
4. If used around the spinal cord and nerve roots, extreme caution should be taken.
5. 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.
6. 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.
7. Single Use Only. Reuse of devices labeled as single-use (e.g. guidewires) could result in injury or reoperation due to breakage or infection.

Cleaning

ProView MAP System instruments are provided clean but not sterile. All instruments must be thoroughly cleaned after each use. Cleaning may be done using validated hospital methods or following the validated cleaning processes described below. None of the instruments in the system require disassembly prior to cleaning.

From Point of Use

Whenever possible, do not allow blood, debris or body fluids to dry on instruments. For best results and to prolong the life of the surgical instrument reprocess immediately after use.

1. Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place instruments in a basin of purified water or in a tray covered with damp towels. Do not allow saline, blood, body

fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.
2. For optimal results, instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning.
3. Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

Note: Soaking in proteolytic enzymatic detergents or other pre-cleaning solutions facilitates cleaning, especially in instruments with complex features and hard-to-reach areas (e.g. cannulated and tubular designs, etc.). These enzymatic detergents as well as enzymatic foamsprays break down protein matter and prevent blood and protein based materials from drying on instruments. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed.

Preparation for Cleaning

1. All instruments with moving parts (e.g., knobs, triggers, hinges) should be placed in the open position to allow access of the cleaning fluid to areas that are difficult to clean.
2. Soak the instruments for a minimum of 10 minutes in purified water prior to the manual or automated cleaning process.
3. Use a soft cloth or a soft plastic bristle brush to remove any visible soil from the instruments prior to manual or automated cleaning. Use a soft plastic bristle brush or a pipe cleaner to remove soil from any inner lumens. You can also use a syringe (if appropriate) for hard-to-reach areas.
4. Enzymatic detergent should be used for manual and automated cleaning. All enzymatic detergents should be prepared at the use dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare the enzymatic detergents. The use of recommended temperatures is important for the optimal performance of the enzymatic detergent.

Manual Cleaning

1. Completely submerge instruments in an enzymatic detergent and allow to soak for 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors, and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
2. Remove the instruments from the enzymatic detergent and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
3. Place prepared cleaning solution in a sonication unit. Completely submerge the device in the cleaning solution and sonicate for 10 minutes.
4. Rinse the instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
5. Repeat the sonication and rinse the steps above.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.
7. Inspect the instruments for visible soil.
8. If visible soil is noted, repeat the steps listed above.

Automated Cleaning

1. Completely submerge the instruments in an enzymatic detergent and allow to soak and sonicate for 10 minutes each. Use a soft nylon-bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon-bristled brush (i.e. pipe cleaner). Use of a syringe or water jet will improve flushing of difficult-to-reach areas and closely mated surfaces.
2. Remove instruments from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas.
3. Place instruments in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle.
4. Orient instruments into the automated washer's carriers as recommended by the washer manufacturer.
5. The following minimum parameters are essential for thorough cleaning.
    1. 2-minute prewash with cold tap water
    2. 1 minute prewash with hot tap water
    3. 2-minute detergent wash with hot tap water (64-66°C/146-150°F)
    4. 1-minute hot tap water rinse
    5. 2-minute thermal rinse with purified water (80-93°C/176-200°F)
    6. 1 minute purified water rinse (64-66°C/146-150°F)
    7. 7 to 30 minutes hot-air dry (116°C/240°F)
6. Inspect the instruments for visible soil.
7. If visible soil is noted, repeat the above-listed steps until no visible soil is noted.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach, and/or other alkaline cleaners may damage instruments. These solutions should not be used.

Torque Limiting Instrument Maintenance

- If a torque-limiting handle has been dropped, impacted or used incorrectly, return to Orthofix.
- Torque-limiting handles require maintenance at a minimum, every three years or per your service agreement. Please return your torque limiting handles to Orthofix for required maintenance

Instrument End of Life Determination

Do not reuse Single Use instruments. Visually inspect the reusable instruments to determine if the instrument has reached end of life. Orthofix reusable instruments have reached End of Life when:

1. Instruments show signs of damage such as binding, bending, breakage, overt signs of wear and/or any other conditions which may impact the devices safe and effective use.
2. Instruments intended for cutting bone and/or tissue (e.g. tap, rasp, curette, rongeur) – when any of the cutting surfaces show signs of wear such as nicks, abrasions or otherwise dulled cutting surfaces.
3. Instruments that interface with other devices (e.g. implants, instruments, handles) – when the mating feature binds, fails to attach or fails to hold the device securely. The instrument function should be verified prior to each use.
4. Do not use instruments that reached End of Life. Discard End of Life instruments per your hospital procedure or return to Orthofix for disposal.

Sterilization

The ProView MAP System is supplied NON-STERILE. Prior to use, all instruments should be placed in the instrument case which will be wrapped in an FDA cleared sterilization wrap and placed in the autoclave for sterilization by the hospital using one of the following recommended cycles:

- Method: Steam
- Cycle: Gravity
- Temperature: 250°F (121°C)
- Exposure time: 30 minutes

Packaging

Packages for each of the components should be intact upon receipt. If a consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for damage prior to use. Damaged packages or products should not be used and should be returned to Orthofix.The ProView MAP System instruments are provided in modular cases specifically intended tocontain and organize the system's components. The system's instruments are organized intotrays within each modular case for easy retrieval during surgery. These trays also provideprotection to the system components during shipping. Additionally, individual instruments are provided in sealed poly bags with individual product labels.

Product Complaints

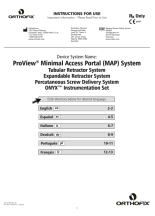
Any Health Care Professional (e.g., customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction with the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Orthofix Inc., 3451 Plano Parkway, Lewisville, TX 75056, USA, by telephone at 1-214-937-3199 or 1-888-298-5700 or by e-mail at **complaints@orthofix.com.**

Latex Information

The instruments and/or packaging material for the ProView MAP System are not formulated with and do not contain natural rubber. The term "natural rubber" includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Documents / Resources

	ORTHOFIX AW-70-9906 ProView Minimal Access Portal System [pdf] Instruction Manual AW-70-9906 ProView Minimal Access Portal System, AW-70-9906, ProView Minimal Access P ortal System

References

- EU Authorized Representative Services For Medical Devices
- Medical Devices & Solutions - Orthofix