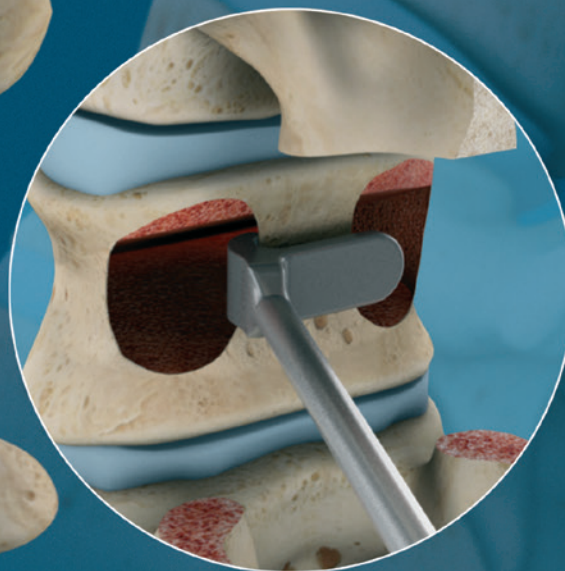


PSO Instrument Set



PSO Instrument Set

Specialized Instrumentation to Aid Surgeons

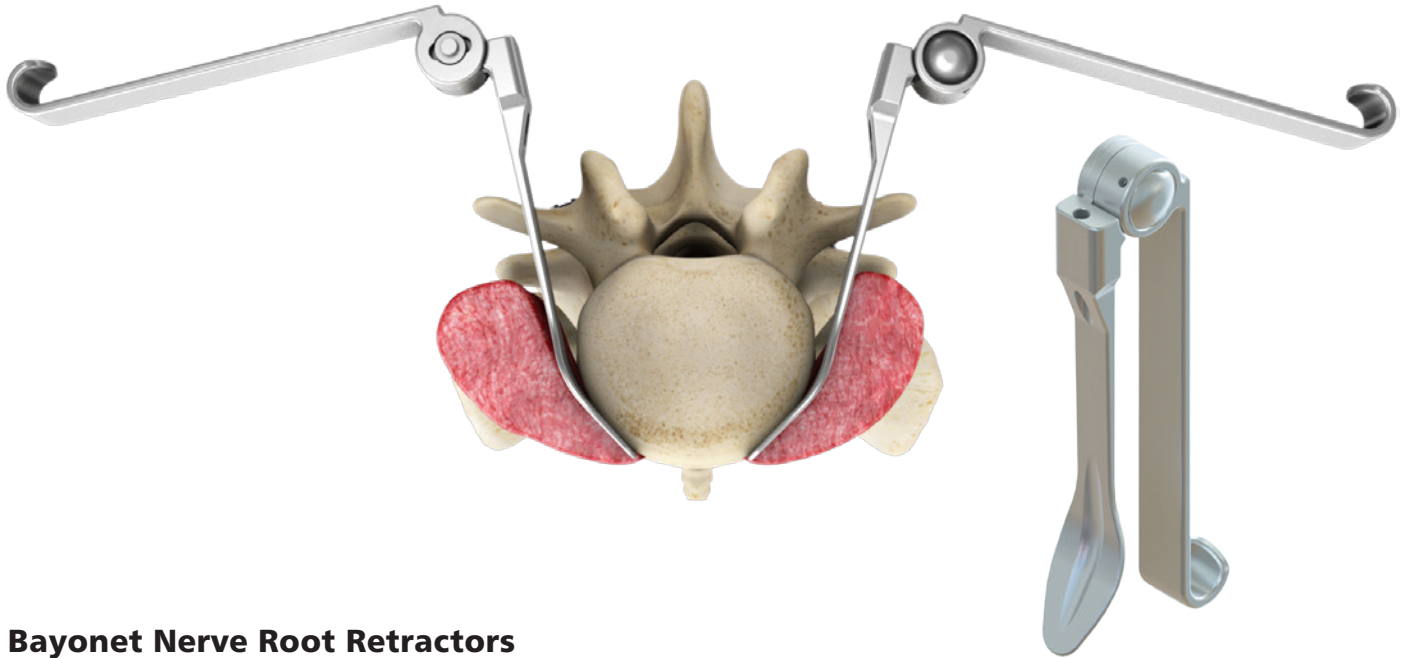
Procedures such as a Pedicle Subtraction Osteotomy (PSO) and a Vertebral Column Resection (VCR) provide surgeons with techniques to correct sagittal deformity. The Orthofix PSO Instrument Set has specialized instruments designed to aid surgeons in these types of challenging procedures.



Soft Tissue Retraction and Protection

Adjustable Vertebral Body Retractors

- Push Button Articulation
- Suction holder built-in
- 3 Different sized spoon tips



Bayonet Nerve Root Retractors

- Small lip on tip designed to inhibit movement of retracted soft tissue
- Bayonet handle for visualization



Pre-planning

Angular Templates

- Available in 25°, 30°, and 35° angles
- Flat end for planning of posterior elements



Vertebral Body Resection

L-Shaped Vertebral Body Osteotomes

- L-shaped or right angle osteotomes allows for a simultaneous cut parallel to the nerve root and dura



Straight Osteotomes

- Available in a variety of widths to meet clinical needs



Cancellous Bone Removal

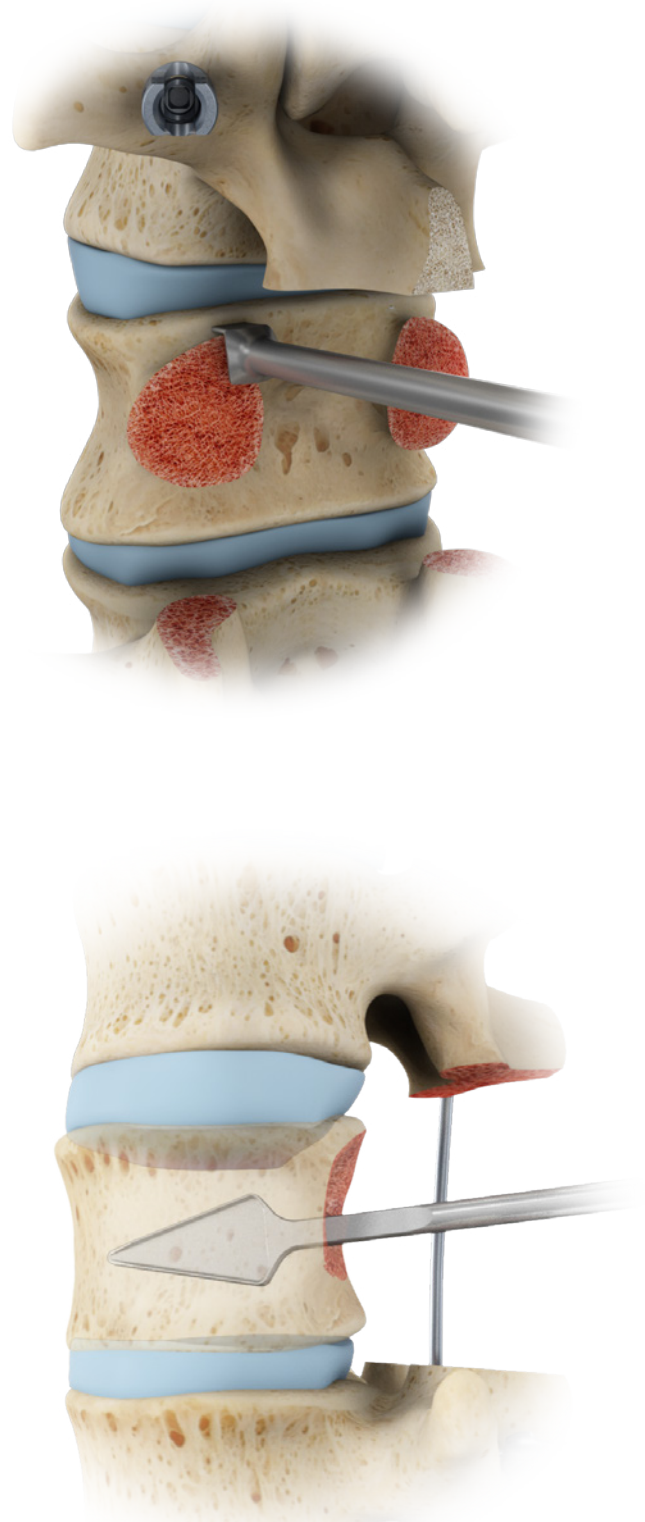
Triangle Shavers

- Available in 25°, 30°, and 35° angles
- Assist in the removal of the wedge shape of cancellous bone



Curettes

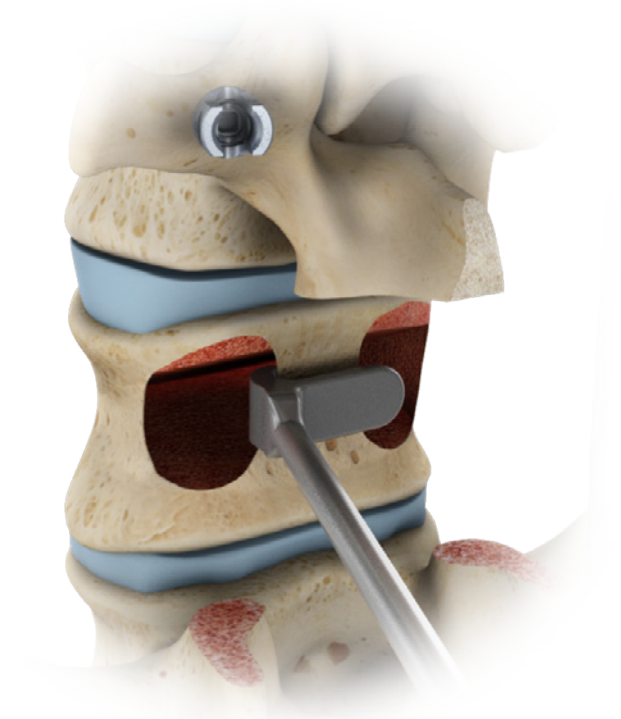
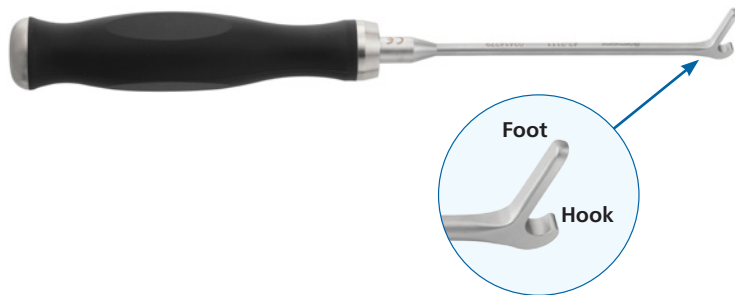
- Available in both large and small versions of straight and 45° down



Fracturing the Posterior Wall

Posterior Vertebral Body Punches

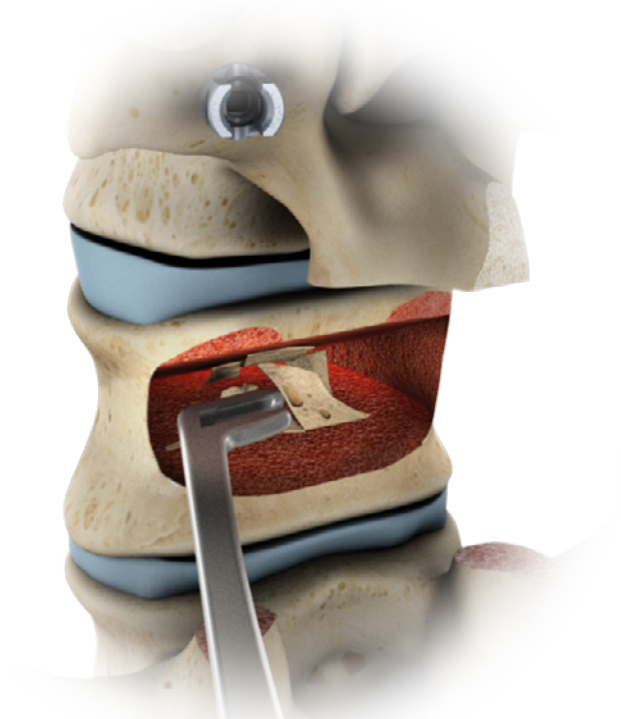
- Hook designed to grip bony posterior edge to prevent instrument from sliding
- Available in different widths and lengths to match patient anatomy



Removing Bone Fragments

Posterior Wall Removal Kerrison

- Extended up-biting design for removal of posterior bone fragments



42-2100, PSO Instrument Set

Part #	Description	Qty
Top Tray		
42-2102	Adjustable Vertebral Body Retractor, 15mm	2
42-2103	Adjustable Vertebral Body Retractor, 20mm	2
42-2104	Adjustable Vertebral Body Retractor, 30mm	2
42-2115	Vertebral Body Osteotome, 6mm x 8mm, 10°	1
42-2116	Vertebral Body Osteotome, 6mm x 8mm, 10°	1
42-2117	Straight Osteotome, 6mm	1
42-2118	Straight Osteotome, 10mm	1
42-2119	Straight Osteotome, 13mm	1
42-2120	Straight Osteotome, 25mm	1
Bottom Tray		
42-2105	Bayonet Nerve Root Retractor, 10mm	1
42-2106	Bayonet Nerve Root Retractor, 12mm	1
42-2107	Bayonet Nerve Root Retractor, 14mm	1
42-2108	Angular Template, 25°	1
42-2109	Angular Template, 30°	1
42-2110	Angular Template, 35°	1
42-2111	Posterior Vertebral Body Punch, 20mm	1
42-2112	Posterior Vertebral Body Punch, 20mm Wide	1
42-2113	Posterior Vertebral Body Punch, 25mm	1
42-2114	Posterior Vertebral Body Punch, 25mm Wide	1
42-2121	Posterior Wall Removal Kerrison, 20mm	1



Top Tray



Bottom Tray

42-2200, PSO Auxiliary Set

Part #	Description	Qty
42-2202	Curette, Straight, Size #1	1
42-2203	Curette, Straight, Size #3	1
42-2204	Curette, 45° Down, Size #1	1
42-2205	Curette, 45° Down, Size #3	1
42-2206	Curved Elevator, 6mm	1
42-2207	Curved Elevator, 10mm	1
42-2208	Curved Elevator, 13mm	1
42-2209	Triangle Shaver, 25°	1
42-2210	Triangle Shaver, 30°	1
42-2211	Triangle Shaver, 35°	1



Auxiliary Set



INDICATIONS FOR USE

Description / Material Composition:

Surgical instruments within the PSO Set are manual medical tools designed solely for use in surgical procedures outlined by the Orthofix PSO Set Surgical Technique. Instruments are made from different materials including stainless steels and medical grade silicone that comply with the standards applicable to them. These materials are not implantable. PSO Set instruments do not contain any Latex components.

Use:

Instruments contained within the PSO Set must be used in the manner prescribed in the Orthofix PSO Set Surgical Technique provided by Orthofix. Prior to using the instruments, the surgeon shall give full consideration to all aspects of the surgical intervention as well as to the limits of the instrumentation. Recommendations for use are provided in the Orthofix PSO Set Surgical Technique provided by Orthofix.

Potential Adverse Effects:

Incorrect maintenance, cleaning, or handling may render the instruments unsuitable for their intended use, cause corrosion, dismantling, distortion and/or breakage or cause injury to the patient or operating staff. As a result of the mechanical features required, the instruments contained in the PSO Set are made from NON-IMPLANTABLE materials. In the event an instrument breaks, no fragment must remain in the patient as this could cause post-operative complications and require further intervention.

Below is a list, albeit not exhaustive, of potential complications:

- Neurological lesion, paralysis, pain, lesion of the soft tissues, the visceral organs or the joints, in the event of incorrect use or breakage of the instruments.
- Infection, if the instruments are not properly cleaned and sterilized.
- Dural leaks, compression of vessels, damage to nerves or nearby organs as a result of slippage or poor positioning of a faulty instrument.
- Damage caused by the involuntary releasing of the springs of certain instruments.
- Damage caused by the instruments used to bend or cut in-situ due to excessive forces occurring when they are used.
- Cutting the gloves or the skin of surgical staff.
- Tissue lesions on the patient or surgical staff and/or an increase in operating time as a result of having to disassemble the instruments during surgery.
- Crack, fracture or involuntary perforation of the bone.

Pre-Operative Precautions:

Anyone using the PSO Set can obtain a Surgical Technique by requesting one from an Orthofix representative or distributor. Those using brochures published more than two years before the surgical intervention are advised to request an updated version from Orthofix directly. Do not use any instrument in a manner that it was not designed or intended for as described in the accompanying Surgical Technique. Misuse of instruments could have an adverse effect on the patient or staff.

The devices may only be used by doctors who are fully familiar with the surgical technique required. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by the implant manufacturer. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to cause injury to the patient.

To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments.

Extreme care must be taken when the instruments are used near vital organs, nerves or vessels.

Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization.

Any electrosurgical devices have the potential for providing an ignition source. Do not use in the presence of flammable substances.

Ensure that any product intended for reuse is properly cleaned and sterilized to avoid any detrimental effects to the patient or staff.

Caution:

Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

Packaging:

Instruments contained in the PSO Set are supplied NON-STERILE in an instrument container or individually packaged. The containers and the packaging of the instruments must be intact when received. The packaging materials must be completely removed prior to cleaning and sterilization.

Instruction Prior To Use:

The life of the instruments depends on the number of times they are used as well as precautions taken in handling, cleaning, and storage. A high level of care must be used to ensure the instruments remain in good working order.

All instruments should be examined for signs of wear damage by doctors and staff in operating centers prior to surgery. The examination shall include a visual and functional inspection of the working surfaces, articulation points, and springs. It should also include verifying all welded connections, that all components are present, and the cleanliness of the orifices and cavities, as well as the absence of any cracks, distortion, impact, corrosion or other change. For instruments with articulations, lubrication may be necessary. Instruments within the set that perform a measuring function must be inspected of wear and the clear visibility of any surface markings.

Orthofix shall not be responsible in the event of the use of instruments that are damaged, incomplete, show signs of excessive wear and tear, or that have been repaired or sharpened outside the control of Orthofix. Any faulty instruments must be replaced prior to any surgical intervention.

Complaints:

Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and / or its performance, should notify Orthofix or its representative. Moreover, if a device has malfunctioned, or is suspected of having malfunctioned, Orthofix or its representative must be advised immediately. If a Orthofix PSO Set product has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or Orthofix must be informed as soon as possible by telephone, fax or in writing. For all complaints, please give the name and reference along with the batch number of the component(s), your name and address and a detailed description of the event to help Orthofix understand the causes of the complaint.

For further information or complaints, please contact:

ORTHOFIX
3451 Plano Parkway
Lewisville, TX 75056
(214) 937-2000



Instrumed International
626 Cooper Court
Schaumburg, Illinois 60173
847.908.0292

Instrumed GmbH
Unter Buchsteig 3
78532 Tuttlingen, Germany
+49 7462 200490

Distributed by:
Orthofix
3451 Plano Parkway
Lewisville, Texas 75056 U.S.A.

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

1.888.298.5700
orthofix.com

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