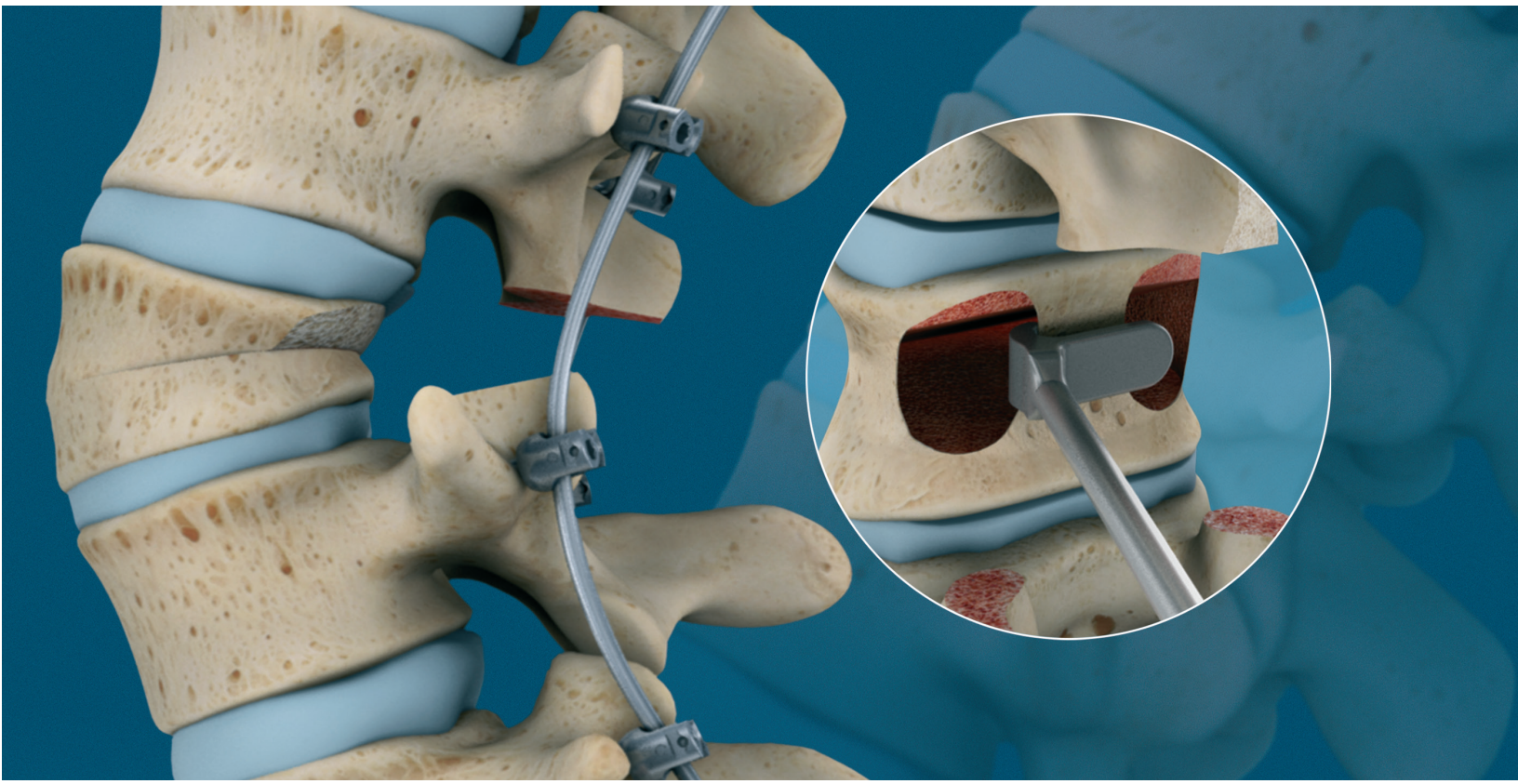
PSO INSTRUMENT SET



Osteotomy Set

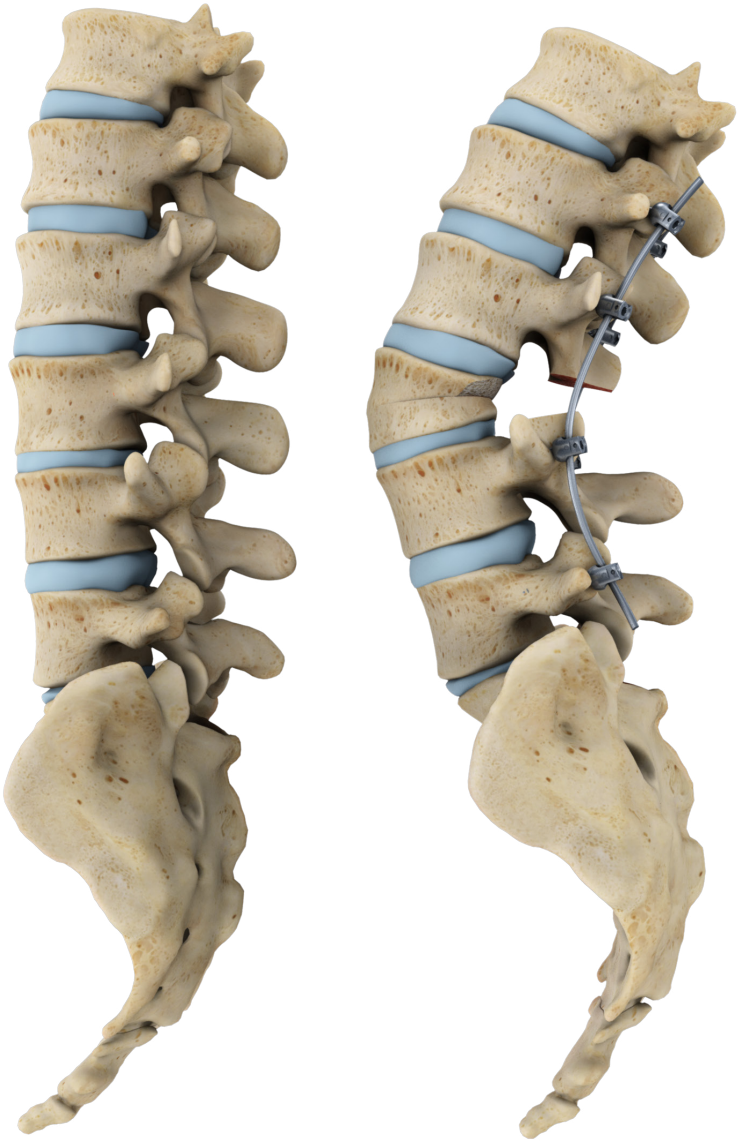
OPERATIVE TECHNIQUE

ORTHOFIX®

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see Instructions for Use for the complete list of indications, warnings, precautions, and other important medical information.

INTRODUCTION / DEVICE DESCRIPTION

Pedicle Subtraction Osteotomy (PSO) and Vertebral Column Resection (VCR) procedures provide surgeons with techniques to correct sagittal deformity. The Orthofix PSO Instrument Set described by this surgical technique is designed to aid surgeons in these procedures.



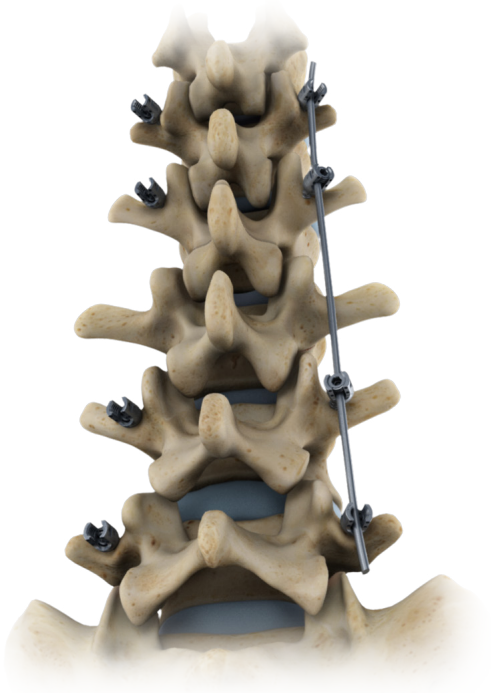


Fig. 1

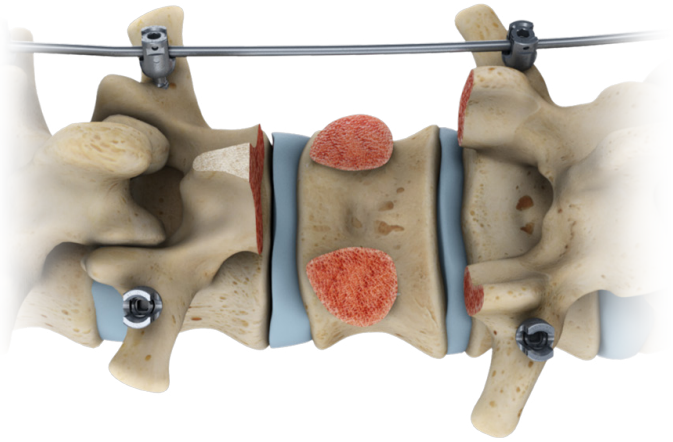


Fig. 2

1. PREPARATION AND PLANNING

Spinal fixation hardware must be in place prior to the osteotomy procedure. Refer to the manufacturer's instructions for use and operative technique for information on placing the fixation hardware (e.g. FIREBIRD® Spine Fixation System). **(Fig. 1)**

Resection measurement is based on preoperative measurements. **Angular Templates** are available in 25˚, 30˚, and 35˚ **(42-2108, 42-2109,** and **42-2110** respectively**)** to assist in the planning process.

2. REMOVAL OF TRANSVERSE PROCESS

The posterior elements in the resection can be removed with rongeurs or curettes.

The transverse process can also be removed or disconnected from the pedicle. It is recommended to remove the transverse process in a way as to leave it as a vascularized bone graft bed. **(Fig. 2)**

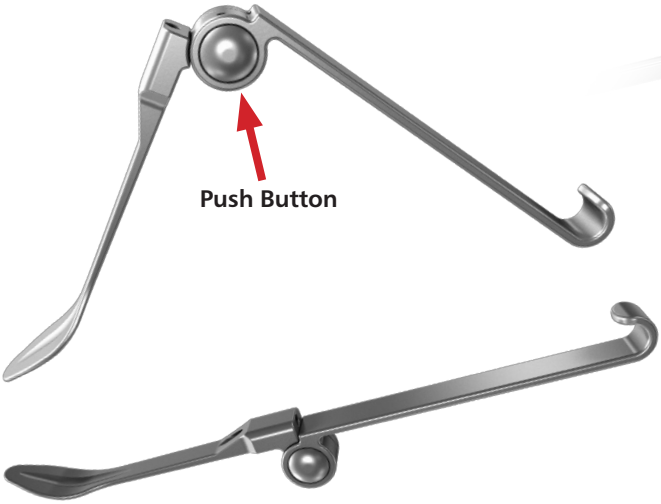


Fig. 3

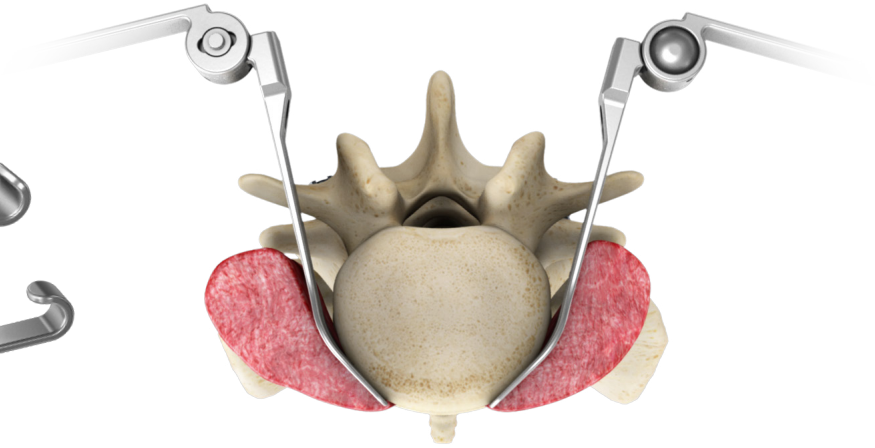


Fig. 4

3. SOFT TISSUE RETRACTION

The **Adjustable Vertebral Body Retractors** are designed to fit along the vertebral body where the front edge tapers to a rounded narrow point. This is designed for a final subperiostial dissection anteriorly along the vertebral body. The **Adjustable Vertebral Body Retractors** are offered with three different width spoon tips: 15, 20, and 30mm **(42-2102, 42-2103,** and **42-2104** respectively**)** to allow the surgeon to choose the retractor that is most appropriate for varying patient anatomies.

Inserting the smallest retractor may help get around the anterior aspect of the vertebral body and then sequentially increase in size.

Press the side button to retract the instrument into its final position. **(Fig. 3)** The tip is located around the vertebral body at its anterior aspect. This anchors the retractor along the soft tissue and allows maximum exposure of the vertebral body to facilitate the performance of the osteotomy. Retractors can be placed unilaterally or bilaterally. **(Fig. 4)**

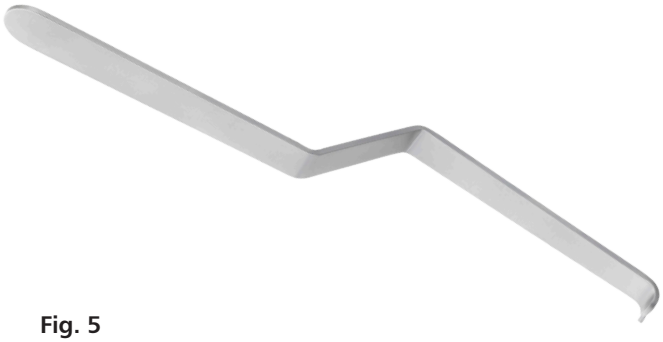


Fig. 5

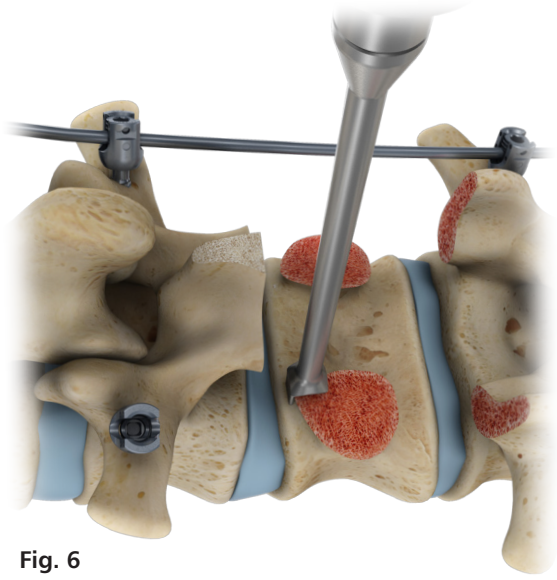


Fig. 6

4. SOFT TISSUE PROTECTION

The **Bayonet Nerve Root Retractors** are available in 10, 12, and 14mm widths **(42-2105, 42-2106,** and **42-2107** respectively**)**. They can be used to protect soft tissues during use of the bone removal instruments. The small lip on the tip is designed to inhibit movement of retracted tissues while in use. **(Fig. 5)**

5. VERTEBRAL BODY RESECTION

Vertebral body osteotomes are available as L-shaped and straight. The **Straight Osteotomes** come in varying widths of 6, 10, 13, and 25mm **(42-2117, 42-2118, 42-2119,** and **42-2120** respectively**)**. The L-shaped **Vertebral Body Osteotomes (42-115** and **42-116)** have slightly angled tips with 3mm increment depth markings on the tip.

Remove the wall of the pedicles, creating larger openings for instrumentation. The cephalad aspect of the cut can be made by placing one edge of the L-shaped **Vertebral Body Osteotome** parallel to the nerve root and the other edge parallel to the dura. **(Fig. 6)**

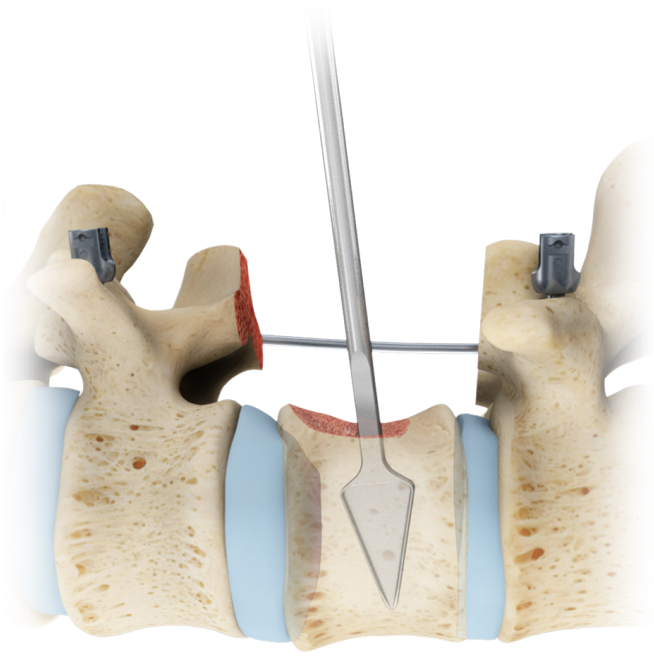


Fig. 7

6. REMOVING THE CANCELLOUS BONE

Remove the cancellous bone of the vertebral body with curettes and/or rongeurs. **Straight Curettes** size #1 and #3 (**42-2202** and **42-2203**) and **45˚ Down Currettes** size #1 and #3 **(42-2204** and **42-2205)** are available in the set. **Triangle Shavers**, available in 25°, 30°, and 35° **(42-2209, 42-2210,** and **42-2211)**, can be used to assist in removing the desired wedge shape of cancellous bone by inserting and rotating through a transpedicular approach on each side.

Remove as much cancellous bone from the desired region as possible while being sure to leave a thin layer of cortical bone intact on the anterior wall to act as a pivot point. **(Fig. 7)**

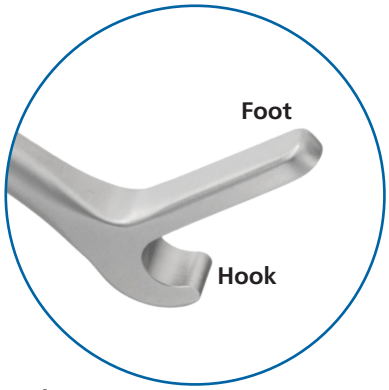


Fig. 8

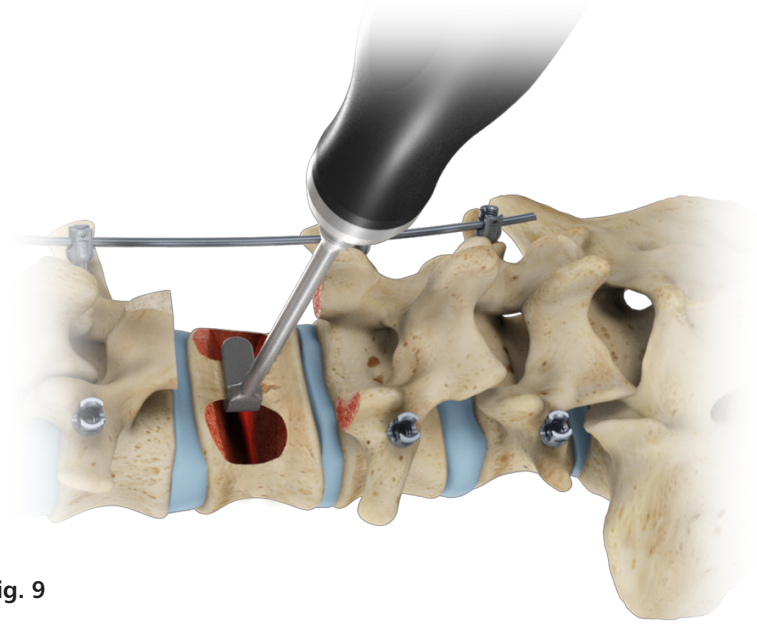


Fig. 9

7. FRACTURING THE POSTERIOR WALL

Posterior Vertebral Body Punches (42-2111, 42-2112, 42-2113, and **42-2114)** are designed with a foot that fits over the posterior wall and a hook that grips the bony edge. **(Fig. 8)** These design features help prevent sliding of the instrument and help direct forces anterior and medial to the bony elements. They are available in varying lengths of 20 and 25mm and widths of 5 and 10mm. It is recommended to choose a **Posterior Vertebral Body Punch** that provides maximum surface area contact with the vertebral body wall.

Care should be taken when advancing the instrument to incur the least amount, if any, dural retraction. The instrument should be advanced until the tip of the foot is visible at least slightly past the contralateral aspect of the dura. **(Fig. 9)**

NOTE: If a temporary rod has been placed, the instrument should be placed on the side opposite the rod. If two temporary rods have been placed, the instrument should be gently and carefully rotated into position.

A mallet is used to strike the top of the **Posterior Vertebral Body Punch** and as a result the posterior vertebral body wall is fractured. If required, the **Posterior Vertebral Body Punch** is then placed at the opposite end of the resection and the impaction is repeated. The site should be reviewed to ensure there are no bony fragments remaining.

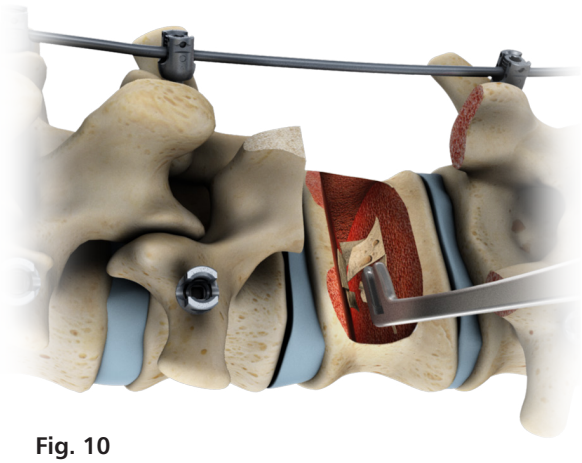


Fig. 10

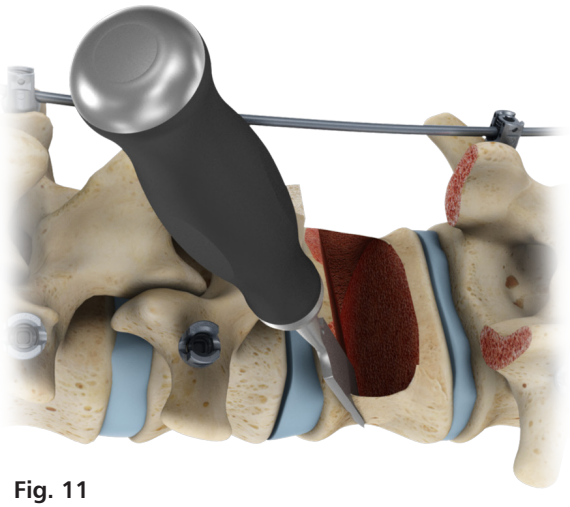


Fig. 11

8. REMOVING BONE FRAGMENTS

The **Posterior Wall Removal Kerrison** can be used to extract the posterior wall of the vertebral body. **(Fig. 10)** Ensure there are no bony fragments remaining during this step and the following bone removal step.

NOTE: The Vertebral body can be saved for grafting.

9. BONE REMOVAL

Vertebral body osteotomes are available as L-shaped and straight. The **Straight Osteotomes** come in varying widths of 6, 10, 13, and 25mm **(42-2117, 42-2118, 42-2119,** and **42-2120** respectively**)**. The L-shaped **Vertebral Body Osteotomes (42-115** and **42-116)** have slightly angled tips with 3mm increment depth markings on the tip.

The osteotomes can be utilized to removed the desired wedge of bone from the lateral aspect of the vertebral body. **(Fig. 11)**

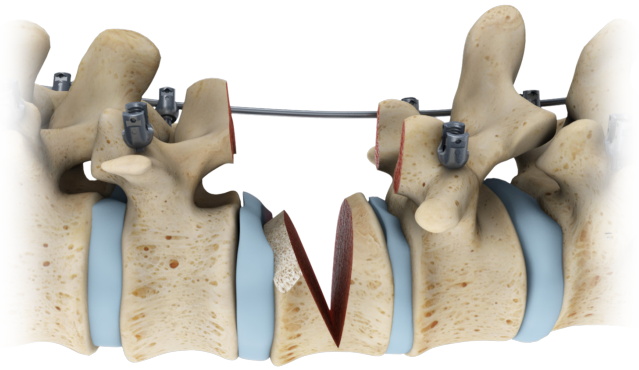


Fig. 12

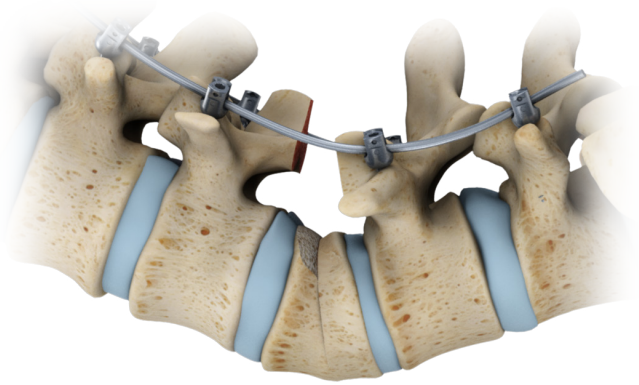


Fig. 13

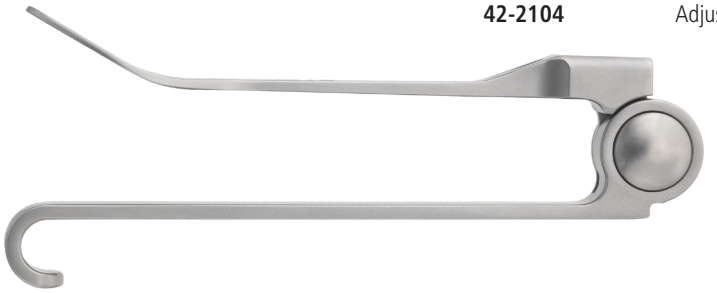
10. OSTEOTOMY CLOSURE

If not previously placed, a second temporary rod can be placed to help close the osteotomy. The boney elements should naturally relax and compression of the screws and or a table which can break will help achieve closure. If satisfactory, final rods can be used to replace the temporary rods.

NOTE: Care should be taken to confirm the dura and nerve roots are not compressed. **(Figs. 12, 13)**

Instruments

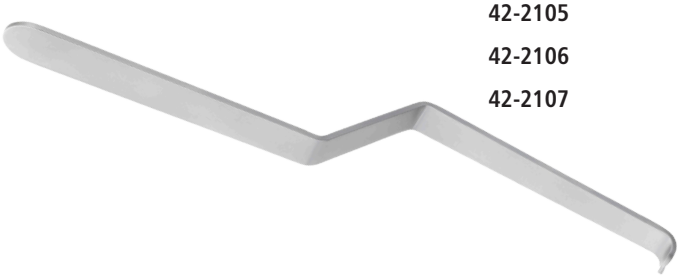
Part #	Description	Qty Set
42-2102	Adjustable Vertebral Body Retractor, 15mm	2
42-2103	Adjustable Vertebral Body Retractor, 20mm	2
42-2104	Adjustable Vertebral Body Retractor, 30mm	2



42-2115	Vertebral Body Osteotome, 6mm X 8mm, 10°	1
42-2116	Vertebral Body Osteotome, 8mm X 6mm, 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

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

Instruments

Part #	Description	Qty Set
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

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

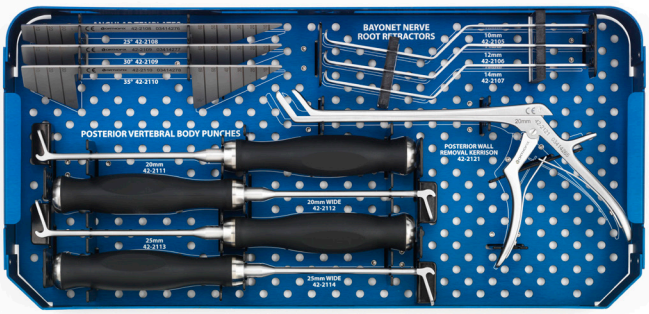
42-2206	Curved Elevator, 6mm	1
42-2207	Curved Elevator, 10mm	1
42-2208	Curved Elevator, 13mm	1

42-2209	Triangle Shaver, 25°	1
42-2210	Triangle Shaver, 30°	1
42-2211	Triangle Shaver, 35°	1

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 Boby Punch, 20mm	1
42-2112	Posterior Vertebral Boby Punch, 20mm Wide	1
42-2113	Posterior Vertebral Boby Punch, 25mm	1
42-2114	Posterior Vertebral Boby Punch, 25mm Wide	1
42-2121	Posterior Wall Removal Kerrison, 20mm	1

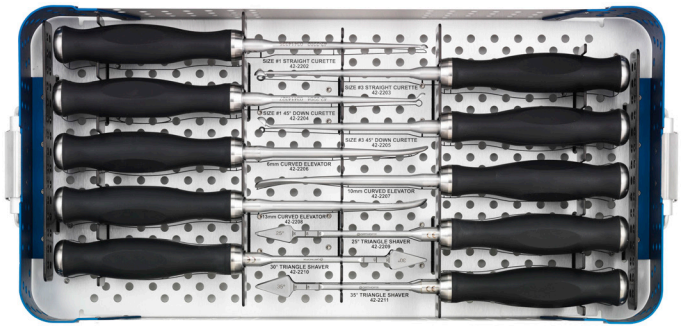
Top Tray



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

ORTHOFIX PSO SET
INSTRUMENTATION INSTRUCTIONS

Manufactured by INSTRUMED INTERNATIONAL – Distributed by ORTHOFIX

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 dissemble 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 causes 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.

Information For Cleaning And Sterilization Of Surgical Instruments:
Instruments are provided NON-STERILE.

For safety reasons, non-sterile devices must be pre-cleaned, cleaned and sterilized prior to use. Furthermore, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps outlined in the following sections.

Cleaning:
Refer to the table below for specific pre-cleaning and cleaning cycle information for manual and automatic cleaning methods. Prepare an enzymatic cleaning solution per the manufacturer's instructions. Soak soiled instrument in the cleaning solution. Use a soft bristle brush to remove all traces of blood and debris, paying close attention to threads, crevices, seams, and any hard to reach areas. If the instrument has sliding mechanisms, hinged joints or flexible areas, actuate the area to free any trapped blood and debris. Rinse the instrument(s) thoroughly with warm tap water. Rinse all lumens, internal areas, sliding mechanisms, and hinged joints, actuating sliding mechanisms and crevices while rinsing. Ultrasonically clean instrument using an enzymatic solution, prepared in accordance with the manufacturer's instructions. Rinse the instrument thoroughly with warm water. Rinse all lumens, internal areas, sliding mechanisms, and hinged joints. Actuate sliding mechanisms and hinged joints while rinsing. Dry immediately after final rinse. Dry any internal areas with filtered, compressed air if available. Check for visible soil, if any soil is present, repeat the cleaning procedure. For instruments with moving parts, lubrication with a medical grade water-soluble lubricant may be necessary where applicable.

	Manual Cycle Information	Automatic Cycle Information
Precleaning	• Alcohol wipe • Soak in cleaning solution • 15 minutes, 40°C (104°F) • Use non-metallic brush • Rinse thoroughly in running water	• Soak in Ultrasonic bath • 15 minutes • Use non-metallic brush • Rinse thoroughly in running water
Cleaning	• Soak in Ultrasonic bath • 15 minutes, 40°C (104°F) • Use non-metallic brush • Rinse thoroughly in demineralized water • Dry	• Wash • 93°C (200°F) minimum • 10 minutes • Rinse • Dry

A facility may choose to use different cleaning cycles other than the cycle suggested if the facility has properly validated the cycle to ensure adequate cleaning to facilitate sterilization.

Inspect all instruments prior to sterilization or storage to ensure instruments are suitable for use. Any instruments showing signs of damage should be set aside and sent for service or repair.

Sterilization:
Sterilize with steam sterilization. The following steam sterilization cycles are suggested based upon validation of a single, wrapped, instrument case or a single instrument case enclosed by the appropriate rigid sterilization container (either Filtered Bottom or Solid Bottom, 23 1/4" long x 11 1/4" wide container), within a properly maintained autoclave. It is critical that process parameters be validated for each facility's individual type of sterilization equipment and product load configuration.

Single Wrapped Instrument Case:

Cycle Type	Temperature	Exposure Time	Drying Time
Prevacuum	132 + 3°C (270°F)	4 minutes	45 minutes + 15 minute cool down

Single Instrument Case Enclosed in Rigid Sterilization Container:

Cycle Type	Temperature	Exposure Time	Drying Time
Prevacuum	132 + 3°C (270°F)	4 minutes	30 minutes

A facility may choose to use different steam sterilization cycles other than the cycle suggested if the facility has properly validated the cycle to ensure adequate steam penetration and contact with the instrument case for sterilization. Note: rigid sterilization containers cannot be used in gravity steam cycles.

For further information related to the use of this instrument, please contact your Orthofix representative or distributor.

Storage:
The instruments are packaged in individual packages or in containers. After they are used they must be stored in a clean, dry and temperate place.

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

Warranty:
Orthofix and Instrumed do not and will not warranty any repairs made to the product by a source not approved by Orthofix and Instrumed. Orthofix and Instrumed will not be responsible for any product failure with unauthorized repairs. For instruments produced by another manufacturer, reference the manufacturer's instructions for use.

Manufactured by:
INSTRUMED INTERNATIONAL
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Schaumburg, IL 60173
(847) 908-0292

Distributed by:
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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.

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