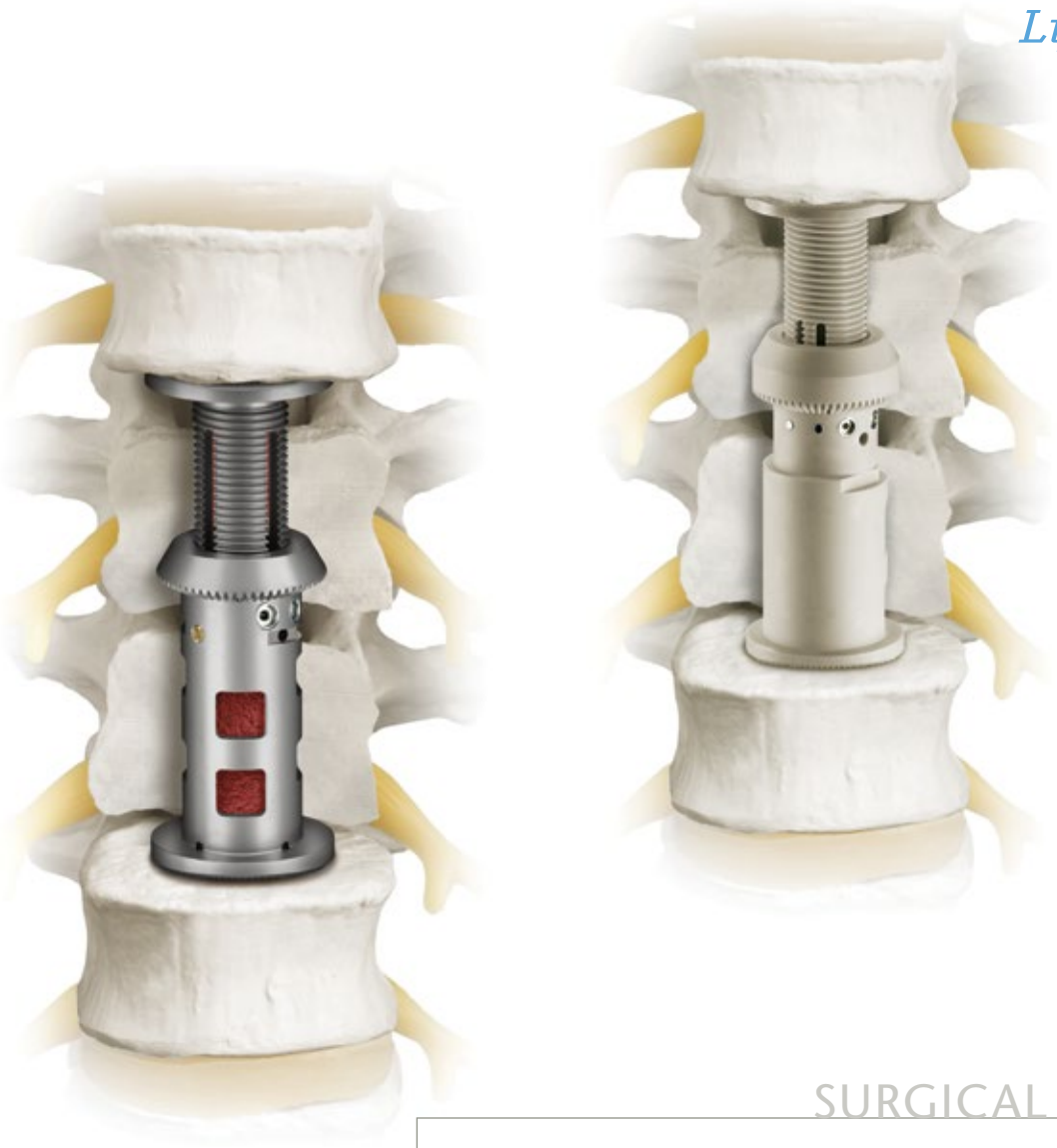
Life moves us



SURGICAL TECHNIQUE

XPand®

Corpectomy Spacer System

GLOBUS MEDICAL

Life moves us

At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.

GLOBUS
MEDICAL

www.globusmedical.com

XPand®

Corpectomy Spacer System

XPand®/XPand®-R is a unique expandable corpectomy device that offer continuous adjustable expansion through a holder that controls both insertion and expansion. In addition, it offers self-distracting capabilities and a large open canal for bone graft material. XPand®/XPand®-R is available in a wide variety of footprints, heights, lordotic/kyphotic angles, and can be placed at multiple insertion angles to accommodate various approaches.

XPand®-R is made from radiolucent polymer (PEEK), allowing visualization to assess fusion. Radiolucency offers a substantial advantage in treating tumor and trauma conditions, in terms of post-operative visualization of tumor recurrence and fusion.

XPand®
CORPECTOMY SPACER SYSTEM

- Ability to simultaneously expand and distract, simplifying technique
- Wide range of implant configurations to accommodate patient anatomy
- Available in both PEEK and Ti materials

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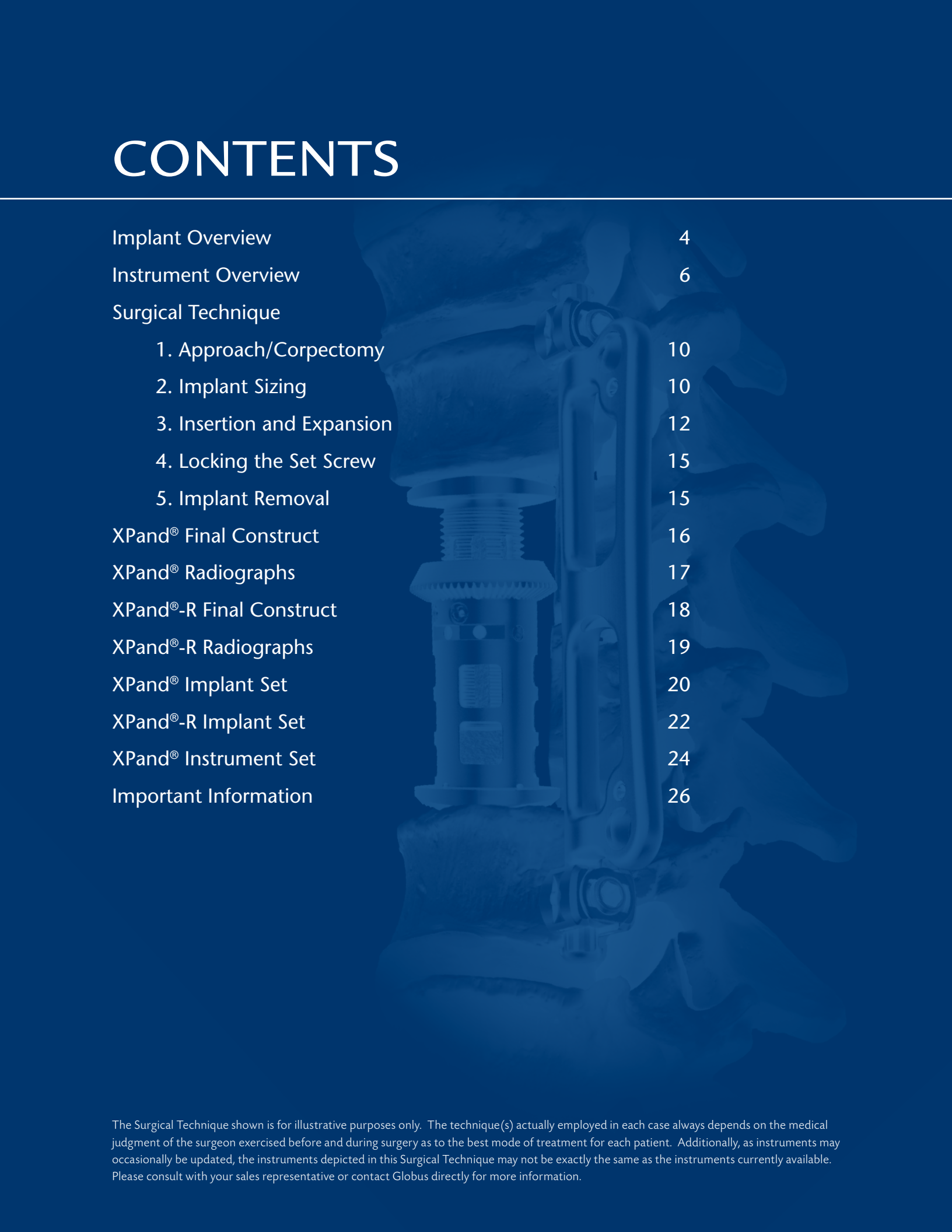
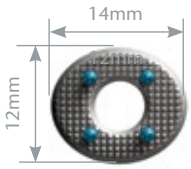
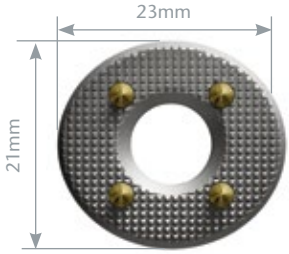
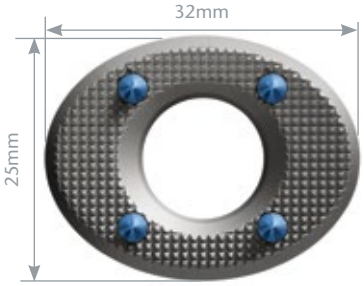


The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

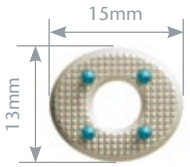
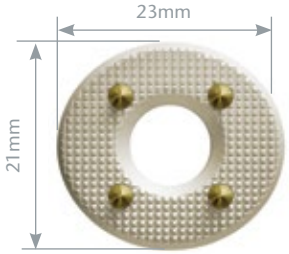
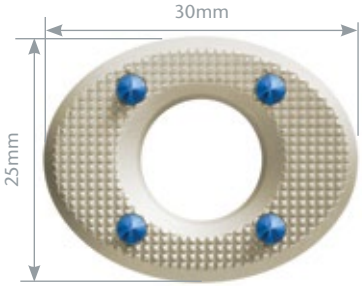
XPand® IMPLANT OVERVIEW

- Wide range of implant sizes
- Large open canal for bone graft material
- Simple surgical technique
- Multiple insertion angles to accommodate various approaches
- One step insertion and expansion
- Smooth *in situ* continuous expansion
- Self-distracting capability
- Captured locking screw
- Titanium alloy

Small	Medium	Large
		
Green spikes 	**Gold spikes** 	**Blue spikes** 
Approach: Anterior **Endplate Options:** 0° Parallel 7° Lordotic 6°/10° Lordotic **Height Range:** 15–89mm	**Approach Options:** Anterolateral Lateral **Endplate Options:** -6° Kyphotic 0° Parallel **Height Range:** 24–70mm	**Approach Options:** Anterior Anterolateral Lateral **Endplate Options:** 0° Parallel -8° Kyphotic 8° Lordotic 16° Lordotic 0°/16° Lordotic **Height Range:** 29–119mm

XPand®-R IMPLANT OVERVIEW

- Wide range of implant sizes
- Large open canal for bone graft material
- Simple surgical technique
- Multiple insertion angles to accommodate various approaches
- One step insertion and expansion
- Smooth *in situ* continuous expansion
- Self-distracting capability
- Captured locking screw
- Large windows for post-insertion bone graft packing
- PEEK radiolucent polymer material

Small	Medium	Large
		
Green spikes 	**Gold spikes** 	**Blue spikes** 
Approach: Anterior **Endplate Options:** 0° Parallel 7° Lordotic 6°/10° Lordotic **Height Range:** 20–88mm	**Approach Options:** Anterolateral Lateral **Endplate Options:** -6° Kyphotic 0° Parallel **Height Range:** 32–76mm	**Approach Options:** Anterior Anterolateral Lateral **Endplate Options:** 0° Parallel -8° Kyphotic 8° Lordotic 16° Lordotic 0°/16° Lordotic **Height Range:** 33–120mm

INSTRUMENT OVERVIEW

Implant Sizing Instruments

Caliper 610.801

Trial, Small
616.110*

Trial, Medium
616.210*

Trial, Large
616.010*

Small Trial Holder 601.024

Medium/Large Trial Holder 606.004

Assembly
601.024 and 616.110

Assembly
606.004 and 616.210

Assembly
606.004 and 616.010

**For use with both XPand® and XPand®-R implants*

Insertion/Expansion Instruments

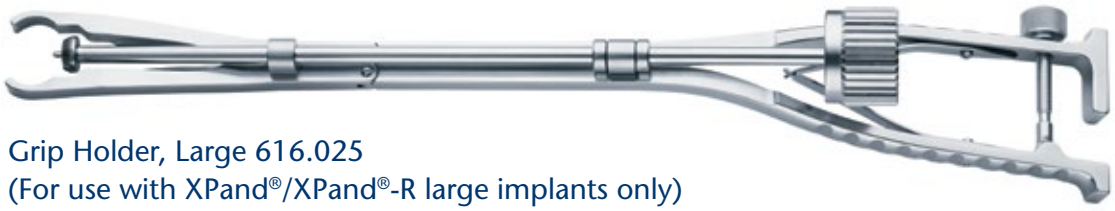
Vertebral Body Spreader, Small 616.112

Vertebral Body Spreader, Large 616.113

Grip Holder, Small 616.125
(For use with XPand® small implants only)

Grip Holder, Small, Radiolucent 616.325
(For use with XPand®-R small implants only)

Grip Holder, Medium 616.225
(For use with XPand®/XPand®-R medium implants only)



Grip Holder, Large 616.025
(For use with XPand®/XPand®-R large implants only)

Insertion/Expansion Instruments (cont'd)

Positioner, Small 616.121

Positioner, Medium/Large 616.021

Gear Driver, Small 616.131

Gear Driver, Medium 616.231

Gear Driver, Large 616.031

Screw Locking Instruments

1.3mm Hex Driver, 240mm 616.150 [Used with XPand® Small (Titanium) only]

Tapered Hex Driver, Short 616.450

Tapered Hex Driver, Long 616.550

XPand®
SURGICAL TECHNIQUE

The XPand® Corpectomy Spacer System is available in titanium and radiolucent (PEEK) implant options. For the purposes of this surgical technique guide, the titanium implant option is shown.

Step 1 Approach/Corpectomy

The XPand®/XPand®-R Corpectomy Spacer may be inserted using multiple approaches:

Small: Anterior

Medium: Lateral, Anterolateral

Large: Lateral, Anterolateral, Anterior

Remove the vertebral body(s) at the indicated level(s) to achieve a partial or complete corpectomy.

The indications for the XPand®/XPand®-R device are summarized on page 26, please refer to the product insert for a complete description, indications, warnings, precautions, and contraindications.

Step 2 Implant Sizing

Determine the approximate height of the corpectomy space using the **Caliper**. The **Vertebral Body Spreader** may be used in conjunction with the Caliper to determine the approximate height under distraction.

Determine the appropriate footprint of the corpectomy space by inserting the **Trial** and corresponding **Trial Holder**. Use fluoroscopy to determine the proper sagittal angle of the endplate. The following Trials are used to determine the appropriate spacer footprint:

Trial Footprint	 Small	 Medium	 Large
Trial Part Number	616.110	616.210	616.010
Holder Part Number	601.024	606.004	606.004
AP Depth	12mm	21mm	25mm
ML Width	14mm	23mm	32mm
Anterior Approach	✓	–	✓
Anterolateral Approach	–	✓	✓
Lateral Approach	–	✓	✓

Using the Trial to select proper footprint

Step 3 Insertion and Expansion

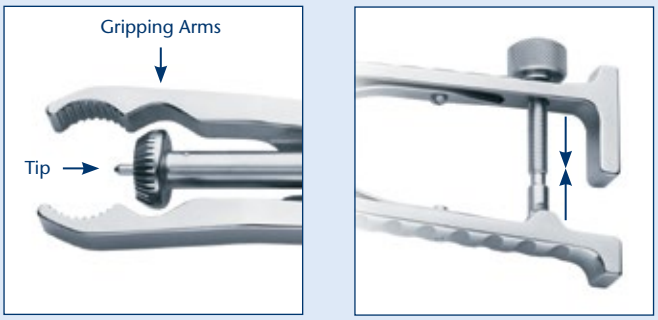
After determining the appropriate implant height and footprint, select the corresponding XPand®/XPand®-R Spacer. Since some implant expansion ranges overlap, select the implant that will best expand into the corpectomy space. For example, if a 54mm height is measured, select the 43–58mm implant.

Note: The implant range is measured from spike to spike in the contracted (smallest) position and from endplate to endplate in the expanded (largest) position. To avoid impaction, some implants with smaller expansion ranges (e.g. implant height ranges 20–26mm) are offered without spikes. These implants are measured from endplate to endplate for the contracted and expanded form. See pages 21 and 23 for further details.

Locate the desired insertion hole on the implant and carefully place the **Grip Holder** (Small, Medium or Large) tip into the selected XPand®/XPand®-R implant. Align the tip on the holder with the hole on the implant.

Implant attached to the Grip Holder

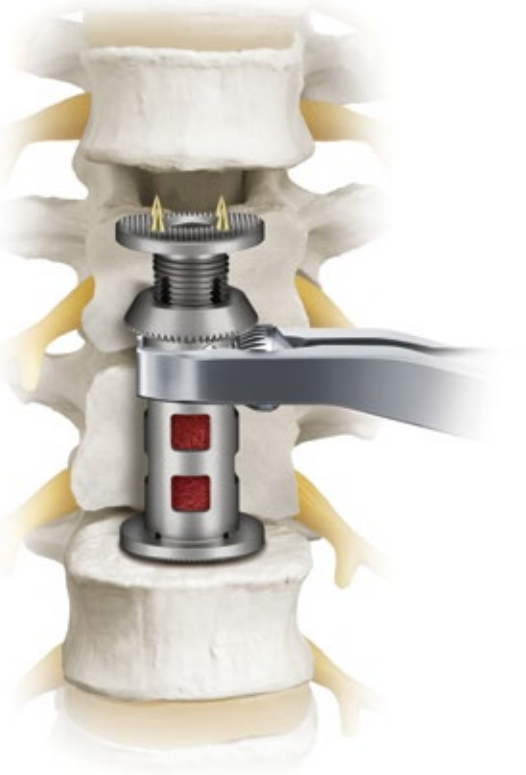
Attach the holder to the implant, engaging both the tip and the gripping arms. Grip the holder lightly to secure the implant and rotate the locking nut. When the tip is aligned and the arms are securely gripping the implant, the gears automatically align.



A Vertebral Body Spreader may be used for easier insertion

Before insertion, slightly expand the implant so the endplate is above the expanding mechanism. Fill the central canal of the implant with bone graft material.

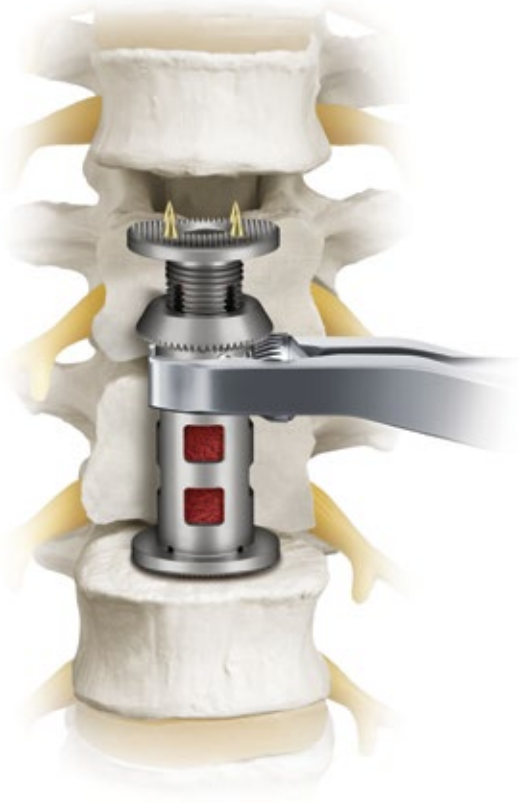
Caution: Do not attempt to contract the implant below its minimum height, as this could affect the function of the implant.



XPand® implant inserted into the corpectomy space

Using fluoroscopy to visualize the implant height, expand the implant to the desired height by rotating the gear handle clockwise. The implant height may also be contracted by rotating the gear handle counterclockwise. Take care when rotating the gear to avoid over-distraction. For final positioning, ensure that the spikes are embedded into the vertebral endplates.

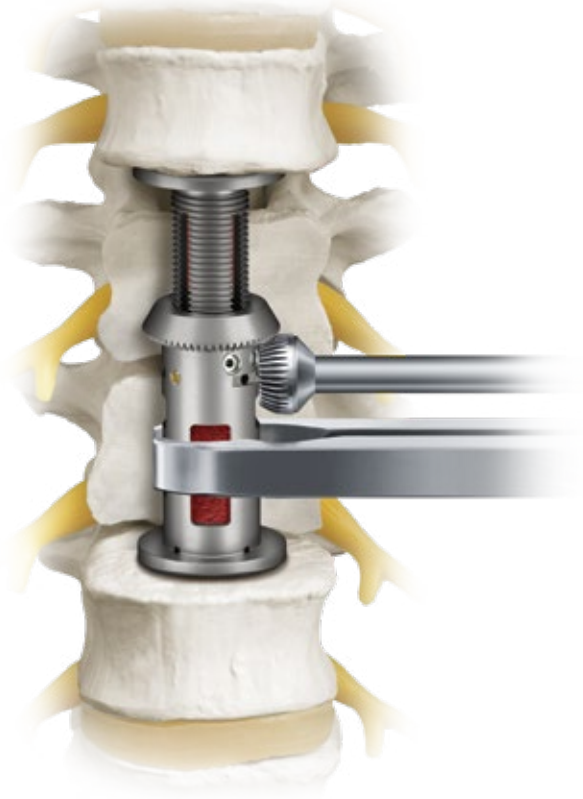
Gear Handle



XPand® implant expanding in the corpectomy space using Grip Holder

After removing the Grip Holder, the **Gear Driver** and **Positioner** may be used for adjustment of the implant height or position. Grasp the inferior portion of the implant with the Positioner. Grip the Positioner lightly and rotate the speed nut to secure. Align the pin on the driver with the insertion hole on the implant. Rotate the driver clockwise to expand the implant and counterclockwise to contract.

Caution: Do not attempt to expand the implant further when it has reached its maximum height. This may cause the gears to strip and could affect the function of the implant.



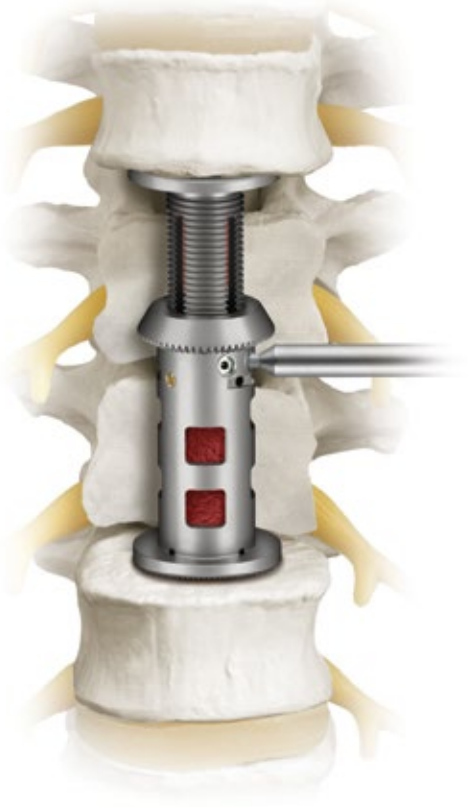
Adjusting the implant with the Gear Driver and Positioner

Step 4 Locking the Set Screw

The set screw adjacent to the holder slot must be gently tightened to prevent any motion of the gear. Use the appropriate hex driver (page 9) to tighten the set screw, which is located near the holder slot.

NOTE: Locking the set screw requires minimal effort. For a small implant, a 3/4 turn is required, and for medium and large implants approximately one turn is required.

The XPand®/XPand®-R Corpectomy Spacer is now secure within the corpectomy space. Supplemental fixation such as the PROTEX® or REVERE® Stabilization Systems, the GATEWAY® Thoracolumbar Plate, the CITADEL® Anterior Lumbar Plate, or the TRUSS® Thoracolumbar Plate is required.



Securing locking screw with hex driver

Step 5 Implant Removal

If necessary, the XPand®/XPand®-R implant may be removed. Use the appropriate hex driver to loosen the set screw. Reinsert the Grip Holder and rotate the gear handle counterclockwise to contract implant height.

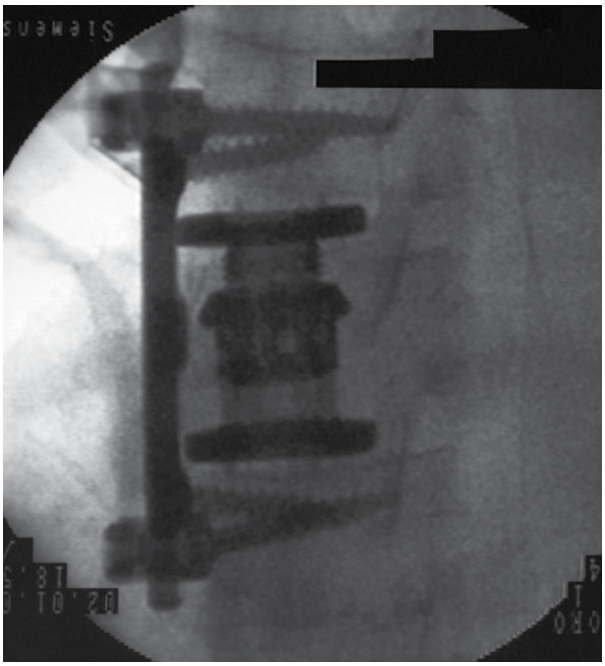
NOTE: If the set screw cannot be accessed, reinsert the Grip Holder and rotate the gear counterclockwise. The holder can overpower the locking ability of the set screw.

XPand® Final Construct

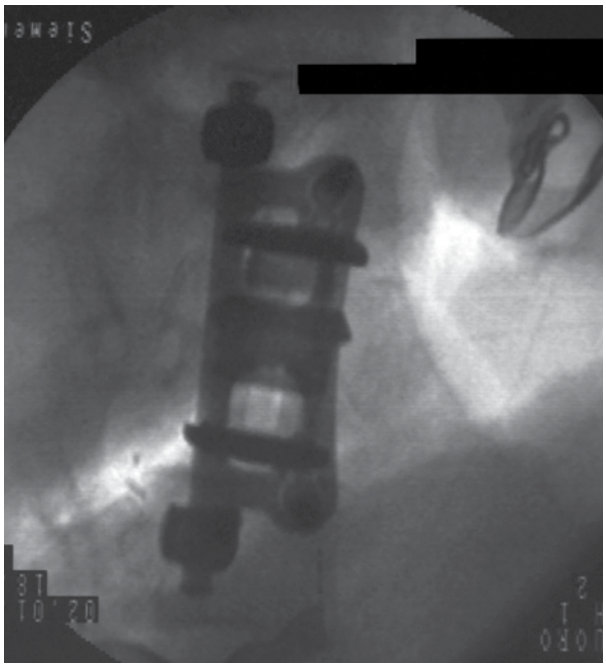
XPand® implant in final position with the GATEWAY® Thoracolumbar Plate System (Open)

XPand® implant in final position with the GATEWAY® Thoracolumbar Plate System (Closed)

XPand® Radiographs



AP image of an implanted XPand® device and the GATEWAY® Thoracolumbar Plate System



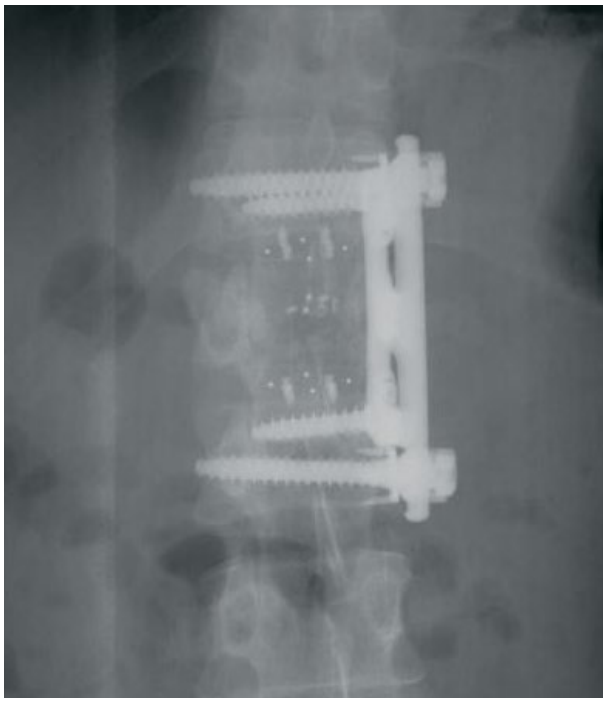
Lateral image of an implanted XPand® device and the GATEWAY® Thoracolumbar Plate System

XPand®-R Final Construct

XPand®-R implant in the final position with the GATEWAY® Thoracolumbar Plate (Open)

XPand®-R implant in the final position with the GATEWAY® Thoracolumbar Plate (Closed)

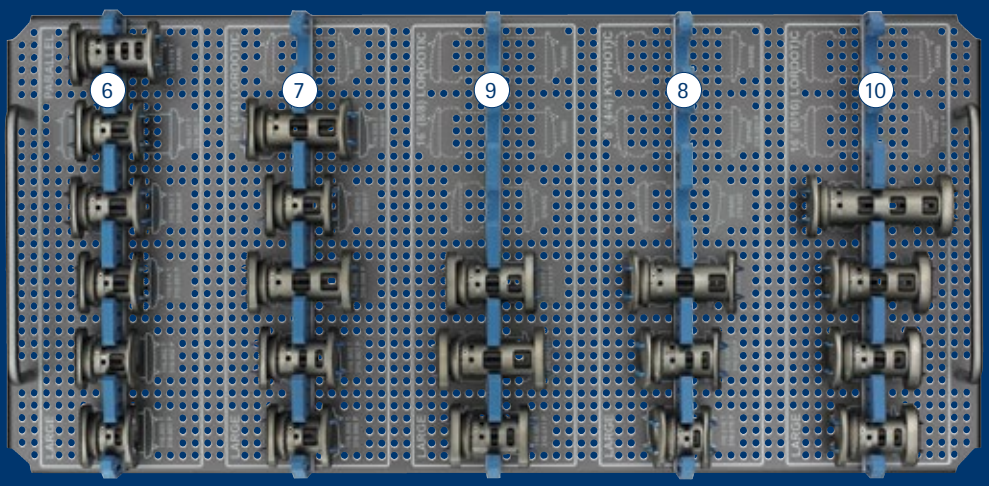
XPand®-R Radiographs

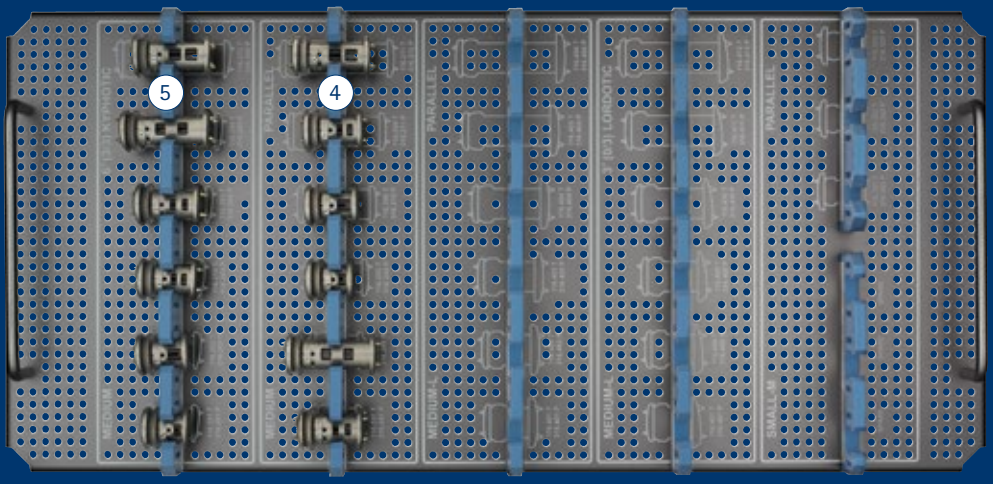


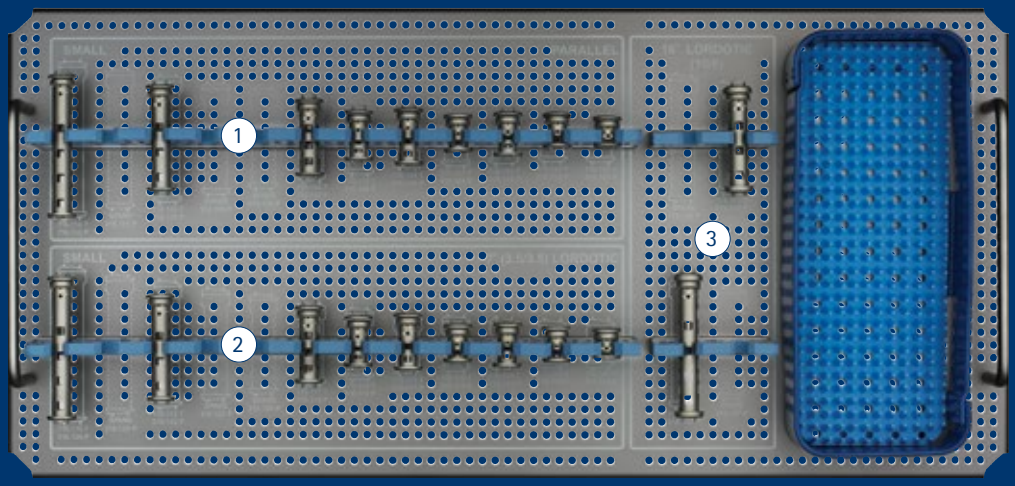
AP image of an implanted XPand®-R device and the GATEWAY® Thoracolumbar Plate System

Lateral image of an implanted XPand®-R device and the GATEWAY® Thoracolumbar Plate System

XPand® IMPLANT SET







XPand® Implant Set 916.902

Small Corpectomy Spacers

1 0° Parallel

Part No.	Range
116.101	15–18mm
116.102	18–23mm
116.103	26–30mm
116.104	32–40mm
116.105	42–57mm
116.106	56–71mm
116.114	74–89mm
116.117	19–24mm
116.119	29–36mm
116.121	15–18mmS
116.123	18–23mmS
116.125	19–24mmS

2 7° Lordotic

Part No.	Range
116.107	15–18mm
116.108	18–23mm
116.109	26–30mm
116.110	32–40mm
116.111	42–57mm
116.112	56–71mm
116.115	74–89mm
116.118	19–24mm
116.120	29–36mm
116.122	15–18mmS
116.124	18–23mmS
116.126	19–24mmS

3 6°/10° Lordotic

Part No.	Range
116.113	56–71mm
116.116	74–89mm

Small/Medium Hybrid Corpectomy Spacers*

0° Parallel

Part No.	Range
116.301	18–21mm
116.302	19–23mm
116.303	21–27mm
116.304	18–21mmS
116.305	19–23mmS
116.306	21–27mmS

Medium Corpectomy Spacers

4 0° Parallel

Part No.	Range
116.205	24–28mm
116.206	27–34mm
116.207	37–46mm
116.208	49–70mm
116.209	33–39mm
116.211	43–58mm
116.223	24–28mmS
116.224	27–34mmS

5 6° Kyphotic

Part No.	Range
116.201	24–28mm
116.202	27–34mm
116.203	37–46mm
116.204	49–70mm
116.210	33–39mm
116.212	43–58mm
116.221	24–28mmS
116.222	27–34mmS

Medium/Large Hybrid Corpectomy Spacers**

0° Parallel

Part No.	Range
116.401	24–26mm
116.402	26–30mm
116.403	29–36mm
116.404	41–50mm
116.405	51–70mm
116.411	36–40mm
116.413	26–30mmS
116.415	29–36mmS

0°/3° Lordotic

Part No.	Range
116.406	24–26mm
116.407	26–30mm
116.408	29–36mm
116.409	41–50mm
116.410	51–70mm
116.412	36–40mm
116.414	26–30mmS
116.416	29–36mmS

Large Corpectomy Spacers

6 0° Parallel

Part No.	Range
116.001	29–33mm
116.002	32–39mm
116.003	44–51mm
116.014	39–41mm
116.017	41–45mm
116.019	51–65mm
116.023	29–33mmS
116.024	32–39mmS

7 8° Lordotic

Part No.	Range
116.004	39–41mm
116.005	46–55mm
116.006	60–81mm
116.018	41–45mm
116.020	51–65mm

8 8° Kyphotic

Part No.	Range
116.009	47–57mm
116.016	29–33mm
116.010	61–85mm
116.022	29–33mmS

9 16° Lordotic

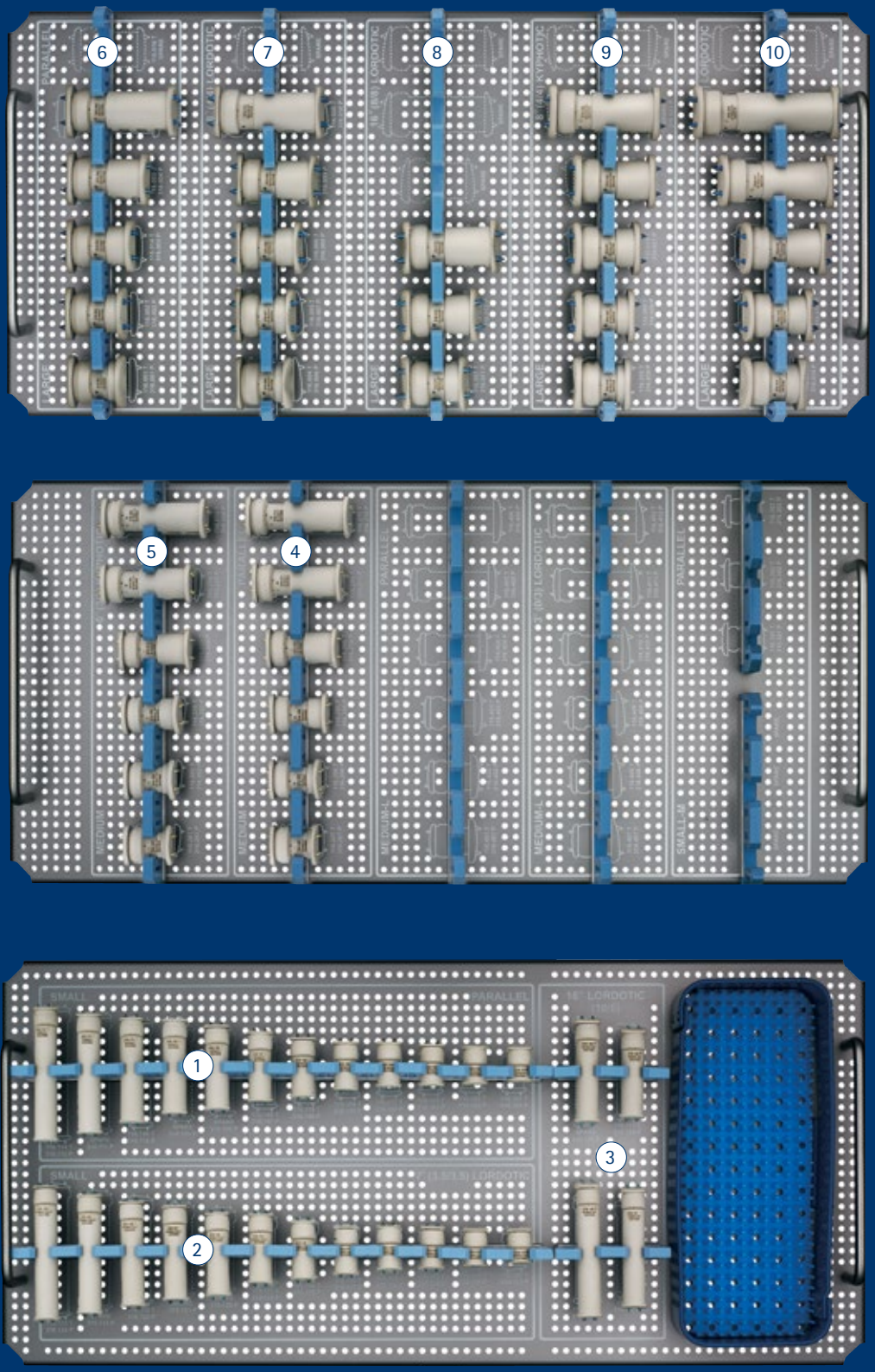
Part No.	Range
116.007	47–55mm
116.008	57–81mm
116.021	51–63mm

10 0°/16° Lordotic

Part No.	Range
116.011	47–55mm
116.012	58–77mm
116.013	79–119mm
116.015	51–63mm

Note: Implants in black lined boxes do not have spikes. Implants highlighted in gray are additionally available. Implants with a "mmS" description have spikes and cover the same height ranges as implants without spikes.
**S/M Hybrids have medium footprint and small gear*
***M/L Hybrids have medium superior endplate and large inferior endplate*

XPand®-R IMPLANT SET



XPand®-R Implant Set 916.904

Small Corpectomy Spacers

1 0° Parallel

Part No.	Range
316.101	20–22mm
316.102	22–26mm
316.103	28–30mm
316.104	30–34mm
316.105	32–38mm
316.106	38–46mm
316.107	44–52mm
316.108	52–60mm
316.109	58–66mm
316.110	64–72mm
316.111	72–80mm
316.112	80–88mm
316.129	20–22mmS
316.131	22–26mmS

2 7° Lordotic

Part No.	Range
316.113	20–22mm
316.114	22–26mm
316.115	28–30mm
316.116	30–34mm
316.117	32–38mm
316.118	38–46mm
316.119	44–52mm
316.120	52–60mm
316.121	58–66mm
316.122	64–72mm
316.123	72–80mm
316.124	80–88mm
316.130	20–22mmS
316.132	22–26mmS

3 10°/6° Lordotic

Part No.	Range
316.125	56–64mm
316.126	64–72mm
316.127	72–80mm
316.128	80–88mm

Small/Medium Hybrid Corpectomy Spacers*

0° Parallel

Part No.	Range
316.301	23–26mm
316.302	24–28mm
316.303	26–32mm
316.304	23–26mmS
316.305	24–28mmS

Medium Corpectomy Spacers

4 0° Parallel

Part No.	Range
316.207	32–34mm
316.208	34–38mm
316.209	38–46mm
316.210	46–56mm
316.211	56–66mm
316.212	64–74mm

5 6° Kyphotic

Part No.	Range
316.201	32–34mm
316.202	34–38mm
316.203	38–46mm
316.204	46–56mm
316.205	56–66mm
316.206	64–74mm

Medium/Large Hybrid Corpectomy Spacers**

0° Parallel

Part No.	Range
316.401	28–34mm
316.402	35–38mm
316.403	39–46mm
316.404	45–54mm
316.405	55–64mm
316.406	61–70mm
316.413	28–34mmS

0°/3° Lordotic

Part No.	Range
316.407	28–34mm
316.408	35–39mm
316.409	39–46mm
316.410	45–54mm
316.411	55–64mm
316.412	61–70mm
316.414	28–34mmS

Large Corpectomy Spacers

6 0° Parallel

Part No.	Range
316.001	33–39mm
316.002	41–43mm
316.003	45–51mm
316.004	53–67mm
316.005	69–91mm
316.024	33–39mmS

7 8° Lordotic

Part No.	Range
316.006	33–39mm
316.007	41–43mm
316.008	45–51mm
316.009	53–67mm
316.010	69–91mm
316.025	33–39mmS

8 8° Kyphotic

Part No.	Range
316.019	33–39mm
316.020	41–43mm
316.021	45–51mm
316.022	53–67mm
316.023	69–91mm
316.026	33–39mmS

9 16° Lordotic

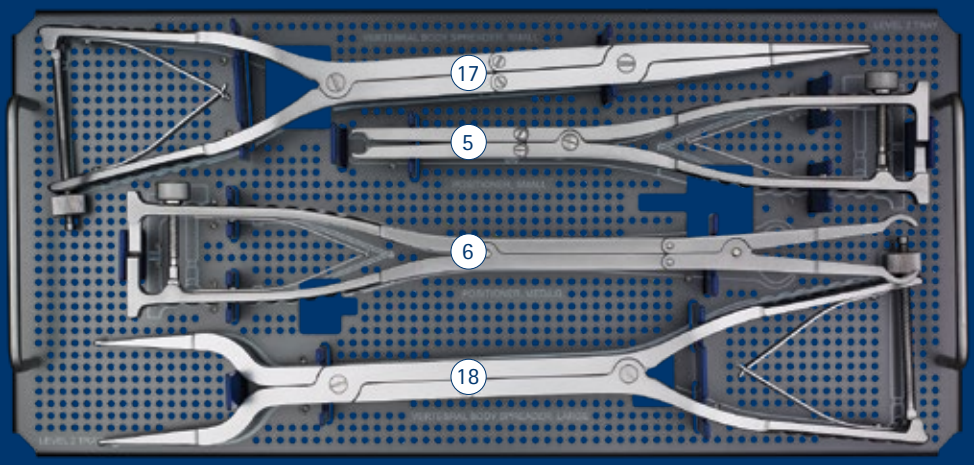
Part No.	Range
316.011	45–49mm
316.012	51–61mm
316.013	63–85mm

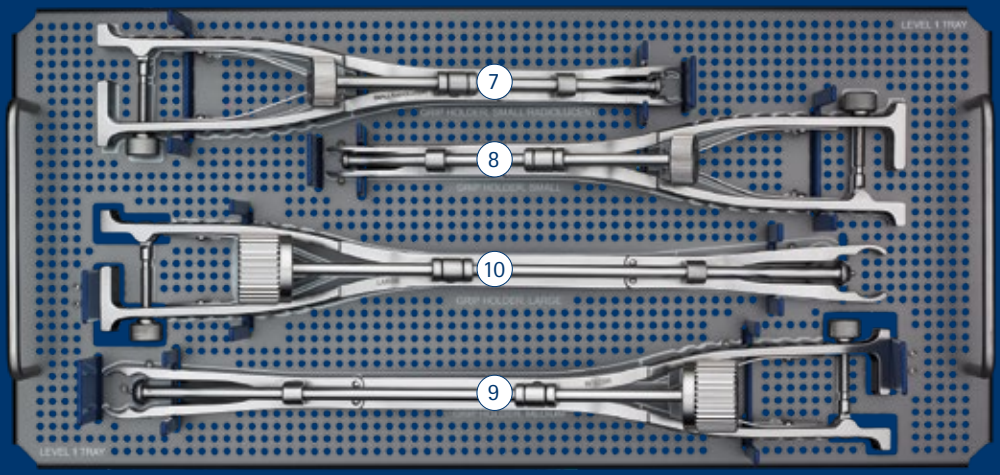
10 0°/16° Lordotic

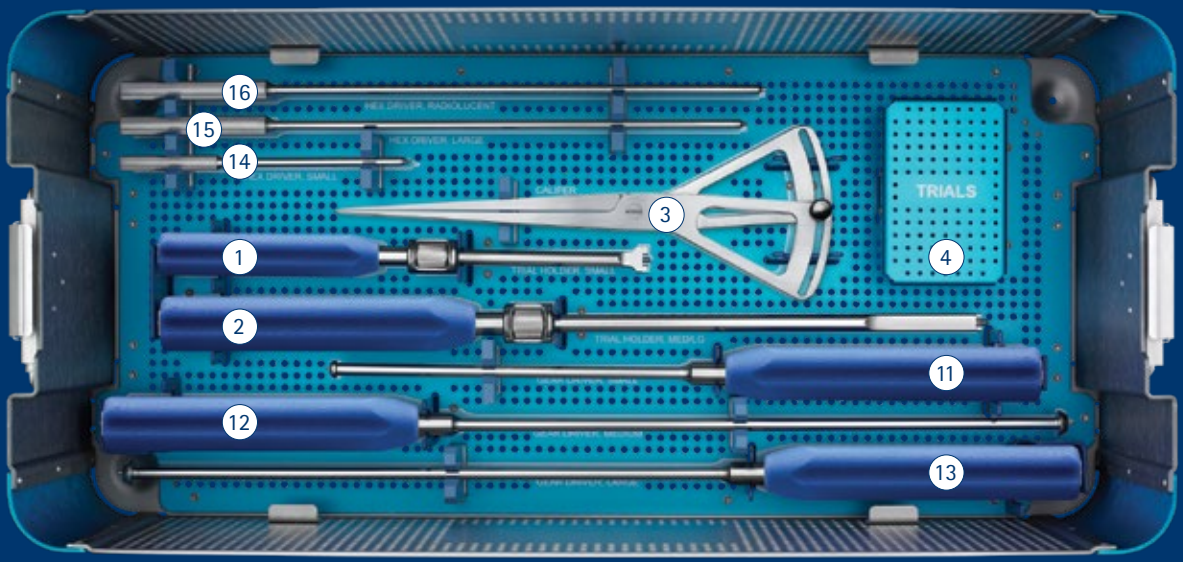
Part No.	Range
316.014	39–46mm
316.015	48–55mm
316.016	57–72mm
316.017	74–103mm
316.018	91–120mm
316.027	39–46mmS

Note: Implants in black lined boxes do not have spikes. Implants highlighted in gray are additionally available. Implants with a "mmS" description have spikes and cover the same height ranges as implants without spikes.
**S/M Hybrids have medium footprint and small gear*
***M/L Hybrids have medium superior endplate and large inferior endplate*

XPand® INSTRUMENT SET







XPand® Instrument Set 916.910

	Instruments		Qty
1	601.024	Small Trial Holder	1
2	606.004	Medium/Large Trial Holder	1
3	610.801	Caliper	1
4	616.110	Trial, Small	1
	616.210	Trial, Medium	1
	616.010	Trial, Large	1
5	616.121	Positioner, Small	1
6	616.021	Positioner, Medium/Large	1
7	616.325	Grip Holder, Radiolucent, Small	1
8	616.125	Grip Holder, Small	1
9	616.225	Grip Holder, Medium	1
10	616.025	Grip Holder, Large	1
11	616.131	Gear Driver, Small	1
12	616.231	Gear Driver, Medium	1
13	616.031	Gear Driver, Large	1
14	616.150	1.3mm Hex Driver, 150mm, Small	1
15	616.450	Tapered Hex Driver, Short	1
16	616.550	Tapered Hex Driver, Long	1
17	616.112	Vertebral Body Spreader, Small	1
18	616.113	Vertebral Body Spreader, Large	1
	916.005	XPand® Corpectomy Spacer System Instrument Graphic Case	

IMPORTANT INFORMATION ON THE XPand® CORPECTOMY SPACER SYSTEM

DESCRIPTION

The XPand® and XPand® Radiolucent Corpectomy Spacer devices are vertebral body replacement devices used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The system is comprised of spacers of various heights and footprints to fit the anatomical needs of a wide variety of patients. Each spacer has an axial hole to allow grafting material to be packed inside of the spacer. Protrusions on the superior and inferior surfaces of each device will grip the endplates of the adjacent vertebrae to resist expulsion.

The XPand® devices are made from titanium alloy as specified in F136 and F1295.

The XPand® Radiolucent Corpectomy Spacer devices are made from radiolucent polymer and titanium alloy as specified in ASTM F2026, F136 and F1295, and include markers made from titanium alloy or tantalum as specified in ASTM F136, F1295 and F560.

INDICATIONS

The XPand® and XPand® Radiolucent Corpectomy Spacers are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The XPand® and XPand® Radiolucent Corpectomy Spacers are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material. The XPand® and XPand® Radiolucent Corpectomy Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

WARNINGS

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- neurological injury, and
- vascular or visceral injury.

PRECAUTIONS

The implantation of vertebral body replacement devices should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

ATTENTION

See Warnings, Precautions and Potential Adverse Events sections of the insert entitled "Suggestions Concerning Orthopaedic Metallic Internal Fixation Devices" for a complete list of potential risks.

CONTRAINDICATIONS

1. Use of the XPand® or XPand® Radiolucent Corpectomy Spacer is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.

STERILIZATION

XPand® implants and instruments have been validated to assure a Sterility Assurance Level (SAL) of 10^{-6}. The use of an FDA cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.*

Implants:
These devices are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132°C (270°F)	10 Minutes	30 Minutes
Steam	Pre-vacuum (Wrapped)	132°C (270°F)	4 Minutes	30 Minutes

Instruments:
These devices are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132°C (270°F)	25 Minutes	45 Minutes
Steam	Pre-vacuum (Wrapped)	132°C (270°F)	15 Minutes	30 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal Law (U.S.A) Restricts this Device to Sale by or on the order of a Physician.

REV D

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Audubon, PA 19403
www.globusmedical.com

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