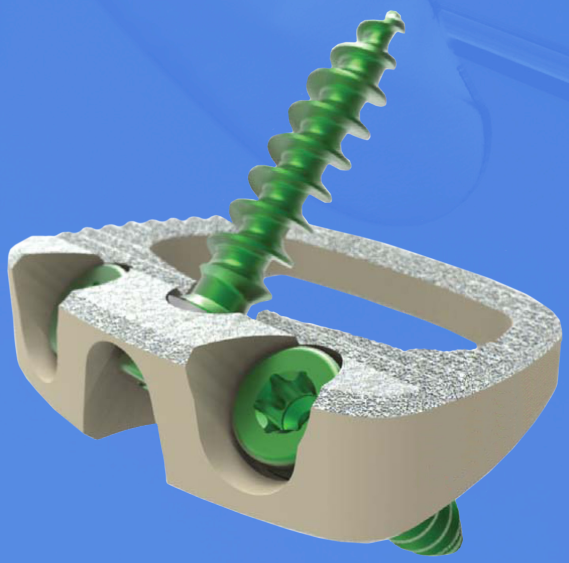
Advantage ALIF

Surgical Technique Guide



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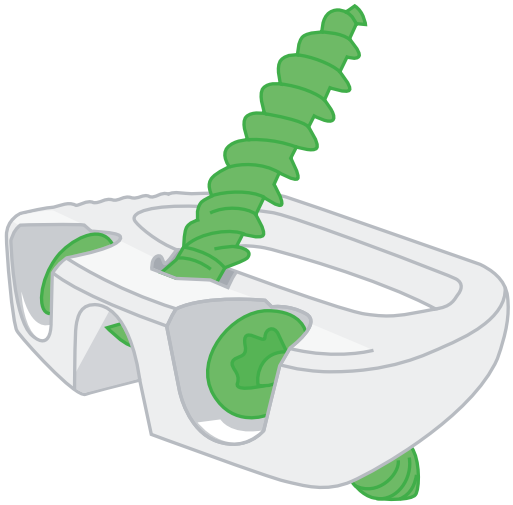
Advantage ALIF

Introduction

ADVANTAGE ALIF is an innovative, titanium-coated, PEEK device. Commercially pure titanium is applied to the PEEK cage by a plasma spray to create the **ADVANTAGE ALIF** device.

The **ADVANTAGE ALIF** device is plasma spray coated with Titanium on the superior and inferior endplate contact surfaces of the device. Analysis shows that the plasma spray process provides uniform porosity with controlled roughness and thickness. The surface roughness is twenty times greater than that of a typical PEEK device. The increased surface roughness and friction at the bony endplates enhances stability upon implantation.



The **ADVANTAGE ALIF** device blends benefits of titanium and PEEK integrated interbody devices. Our porous Titanium coating provides an osteoconductive surface with hydrophilic properties that facilitate human mesenchymal stem cell (hMSC) adhesion and proliferation. The coating results in bony on-growth to the device surface—further promoting stability and load sharing. PEEK has a modulus of elasticity that is similar to that of cortical bone. Consequently, PEEK cages have a lower subsidence rate than titanium cages whose modulus of elasticity is significantly higher.

ADVANTAGE ALIF has undergone rigorous quality testing according to TGA guidance documents and international standards. The Titanium coating was shown to withstand loading under dynamic testing conditions.

Indications for Use

The **ADVANTAGE ALIF** is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach.

The **ADVANTAGE ALIF** is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems. The **ADVANTAGE ALIF** system must be used with bone grafting material.

Contraindications

- Osteoporosis, sepsis
- Infection or inflammation at or near the operative site
- Fever of undetermined origin
- Allergy to device materials
- Patient is unable or unwilling to follow post-operative instructions
- Disease or condition which precludes the possibility of healing
- Prior fusion at the level to be treated
- Any conditions not described in the indications

Warnings & Precautions

- Patients with previous spinal surgery at the levels to be treated may not experience the same clinical outcomes as those without a previous surgery.
- Selection of an appropriately sized device for the patient is important and increases the likelihood of a satisfactory outcome.
- The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this type of device.
- Do not use if the package is damaged or opened. Contents may not be sterile.
- Do not use if current date exceeds label expiry date.
- Do not re-sterilize sterile devices.
- Instrumentation provided with the devices must be used in accordance with the approved surgical technique.
- Do not use excessive force when introducing and positioning the device within the inter- vertebral body space to avoid damaging the device.
- Re-usable surgical instruments must be re- sterilized prior to next use.
- Do not reuse the device even if the device shows no external signs of damage. Internal stresses from previous use may cause early failure.

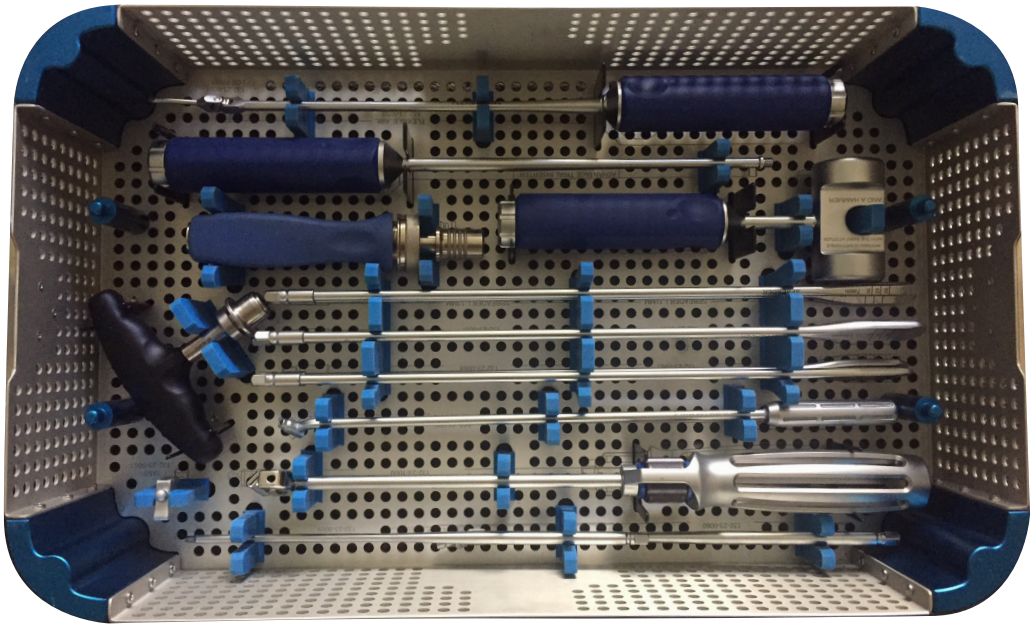
Surgical Technique

ADVANTAGE ALIF is designed for use with a standard anterior approach to the spine.

The anterior longitudinal ligament and annulus are incised as close to the bony surfaces as possible and a thorough discectomy is performed to allow the **ADVANTAGE ALIF** to be positioned on the apophyseal ring of the vertebral bodies.

The surgeon has a choice of four different device heights (11, 13, 15 and 17mm) with three lordotic angles (8°, 12° and 16°) and three medial-lateral footprints (36, 39 and 42mm). Heights vary based on footprint.

Devices and screws are supplied sterile and individually packaged.



ADVANTAGE ALIF Instrument Set

Disc Removal & Distraction

During the discectomy, particular care must be taken to fully remove the nucleus material from the posterolateral corners. The disc space can then be progressively distracted using the Paddle Distractors (Figure 1) sequentially to mobilize the soft tissue, re-tension the annulus and allow for the appropriately sized **ADVANTAGE ALIF** device to be selected.

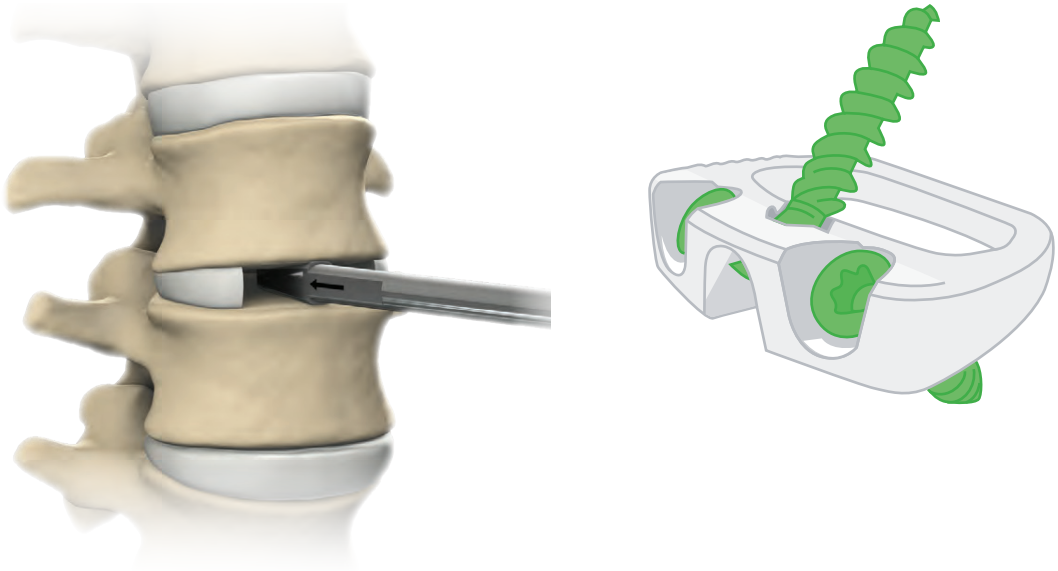


Figure 1: Demonstrating the Paddle Distractor

NOTE Take care to fully remove the nucleus material from the posterolateral corners

Device Trialing

Once the disc space has been prepared, **ADVANTAGE ALIF** trial sizers are mounted onto the threaded handles (Figure 2) and used to determine the correct device with respect to A/P depth. width, height and lordotic angle (Figure 3).

Trials should also be used to judge lateral width of the device. It is recommended to select the largest footprint that can safely be implanted to optimize the load transfer across the apophyseal ring.

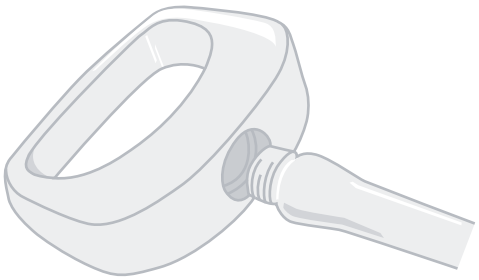


Figure 2: Straight Handle with Trial Sizer

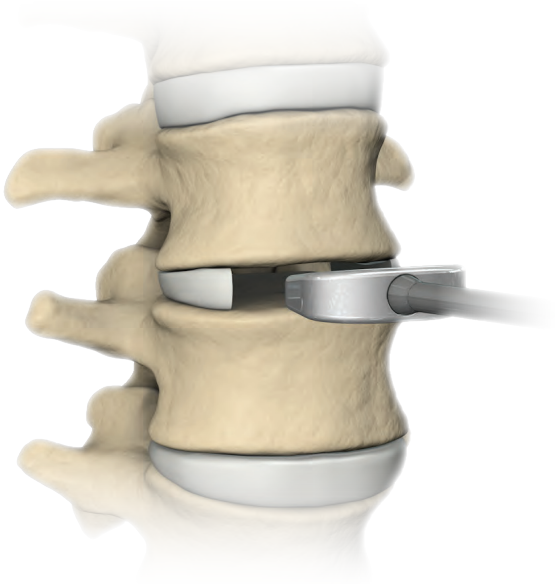


Figure 3: Trial Sizer Insertion

TECH TIP Imaging should be performed to verify proper trial sizer fit

Please select the largest device footprint that can safely be implanted to optimize the load transfer across the apophyseal ring

Device Loading

To begin, rotate the tensioning knob fully counterclockwise (Figure 4) to prepare the introducer for device attachment. The selected device is attached to the Introducer (Figure 5) and the **ADVANTAGE ALIF** is secured with clockwise rotation

of the tensioning knob (marked “Load”) (Figure 6). If repositioning is necessary, then reverse the steps to secure the device to the introducer prior to repositioning.

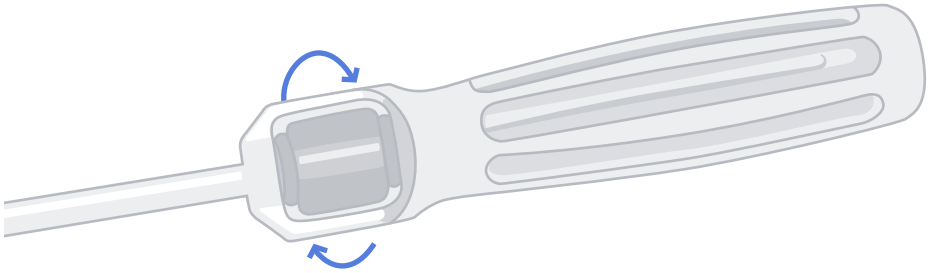


Figure 4: Tensioning Knob

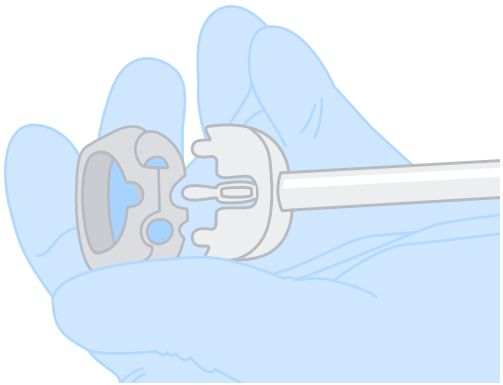


Figure 5: Securing Device

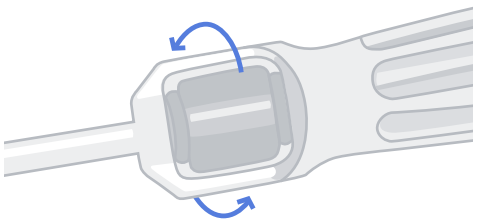


Figure 6: Tensioning Knob

TECH TIP Once the Introducer has been tightened, check to verify a snug fit between the device and Introducer

Graft Packing

Autologous bone graft material is inserted into the **ADVANTAGE ALIF** device cavity. It is recommended that the **ADVANTAGE ALIF** be packed 2mm proud both superiorly and inferiorly (Figure 7) to assure optimal graft / endplate contact.

Figure 7: Advantage ALIF with bone graft

Device Insertion

The **ADVANTAGE ALIF** device is inserted into the disc space using the Device Introducer (Figure 8). The device is positioned flush or up to 1mm anterior to the lip of the vertebral body. This is to ease insertion of screws and allow the lag effect to reduce the device to align with the apophyseal ring.

If additional positioning is required, use the tamp attached to the straight handle (Figure 9).

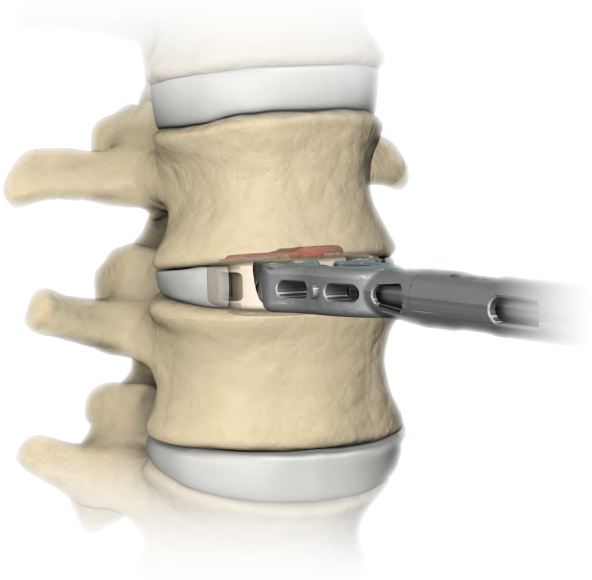


Figure 8: Device Insertion

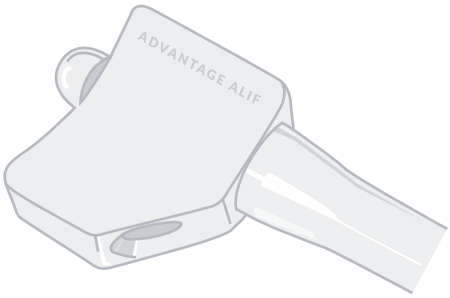


Figure 9: Device Tamp and Straight Handle

Pilot Hole Preparation

Once the **ADVANTAGE ALIF** is correctly positioned, beginning with the central aperture, the screw pilot holes are prepared with either the straight or angled awls and guides (Figure 13).

On occasion, to facilitate proper angulation to the screw holes, it may be necessary to remove a small portion of the lip of the vertebral body adjacent to the screw holes.

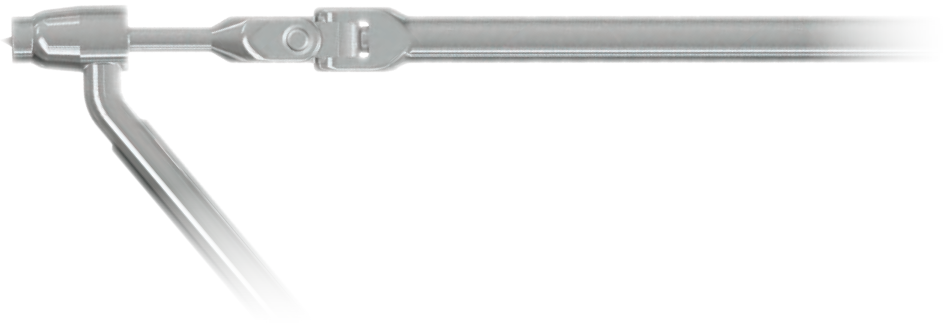


Figure 13: Universal-Joint and Angled Awl Guide

NOTE It is critical that the awl guides be used and seated correctly so that the pilot hole is concentric and the screw trajectory optimized

Screw Insertion

Screw insertion is initiated with the central screw. However, the screw should not be fully tightened to prevent rotation of the device until an opposing screw is positioned. Final tightening can then be accomplished.

The head of each of the three screws must be fully seated within the screw apertures (Figures 17a & 17b).

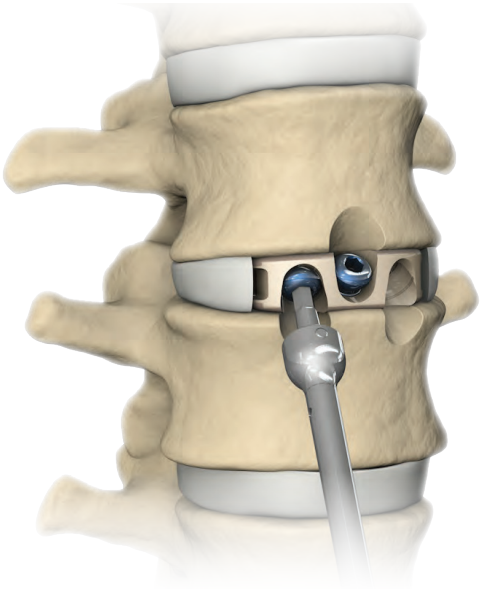


Figure 14: Screw Insertion

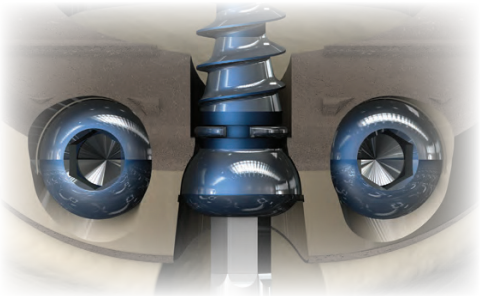


Figure 16: Cancellous Screw with ABO Titanium Split Ring Deployed

Figure 17a: Screw Heads Not Fully Seated

Figure 17b: Screw Heads Fully Seated

NOTE The titanium split ring is properly deployed when the screw head passes the screw-depthindicating groove (highlighted in Figures 17a and 17b)

X-Ray Confirmation

Intraoperative fluoroscopy should be taken during and after screw insertion, and prior to closure, to ensure proper positioning (Figures 18a & 18b).

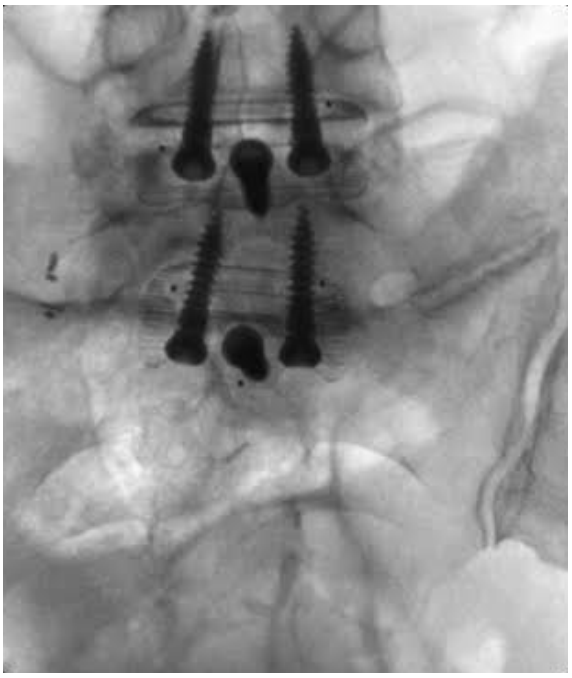


Figure 18a: A/P View

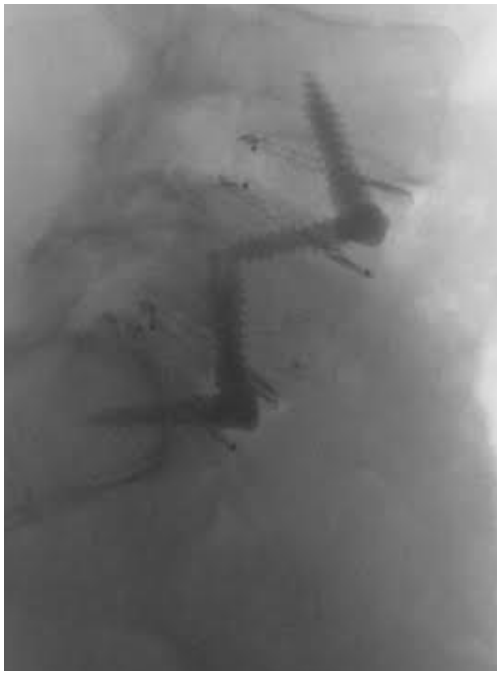


Figure 18b: Lateral View

Removal / Revision

In the unlikely event that a revision procedure is necessary, the **ADVANTAGE ALIF** system can be removed by reversing the steps in the surgical procedure.

Device Codes and Descriptions

Advantage ALIF Cage

Part Number	Size	Width	Depth	Angle
131-23-3081	Medium Wide	36	28	8°
131-23-3083	Medium Wide	36	28	8°
131-23-3085	Medium Wide	36	28	8°
131-23-3087	Medium Wide	36	28	8°
131-23-3121	Medium Wide	36	28	12°
131-23-3123	Medium Wide	36	28	12°
131-23-3125	Medium Wide	36	28	12°
131-23-3127	Medium Wide	36	28	12°
131-23-3161	Medium Wide	36	28	16°
131-23-3163	Medium Wide	36	28	16°
131-23-3165	Medium Wide	36	28	16°
131-23-3167	Medium Wide	36	28	16°
131-23-4081	Large	39	30	8°
131-23-4083	Large	39	30	8°
131-23-4085	Large	39	30	8°
131-23-4087	Large	39	30	8°
131-23-4121	Large	39	30	12°
131-23-4123	Large	39	30	12°
131-23-4125	Large	39	30	12°
131-23-4127	Large	39	30	12°
131-23-4161	Large	39	30	16°
131-23-4163	Large	39	30	16°
131-23-4165	Large	39	30	16°
131-23-4167	Large	39	30	16°
131-23-5081	Extra Large	42	31	8°
131-23-5083	Extra Large	42	31	8°
131-23-5085	Extra Large	42	31	8°
131-23-5087	Extra Large	42	31	8°
131-23-5121	Extra Large	42	31	12°
131-23-5123	Extra Large	42	31	12°
131-23-5125	Extra Large	42	31	12°
131-23-5127	Extra Large	42	31	12°
131-23-5161	Extra Large	42	31	16°
131-23-5163	Extra Large	42	31	16°
131-23-5165	Extra Large	42	31	16°
131-23-5167	Extra Large	42	31	16°

Device Codes and Descriptions

Advantage Screws

Part Number	Size	Ø	Length
131-23-6012	Standard	5.5	20
131-23-6014	Standard	5.5	25
131-23-6016	Standard	5.5	30
131-23-6017	Standard	5.5	35
131-23-6112	Rescue	6.0	25
131-23-6114	Rescue	6.0	30
131-23-6117	Rescue	6.0	35

Figure 19: Advantage ALIF Trials

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As Precision Surgical is an Australian distributor for Ulrich Medical, you may be interested in our suite of products

For more information visit **precisionsurgical.com.au**

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