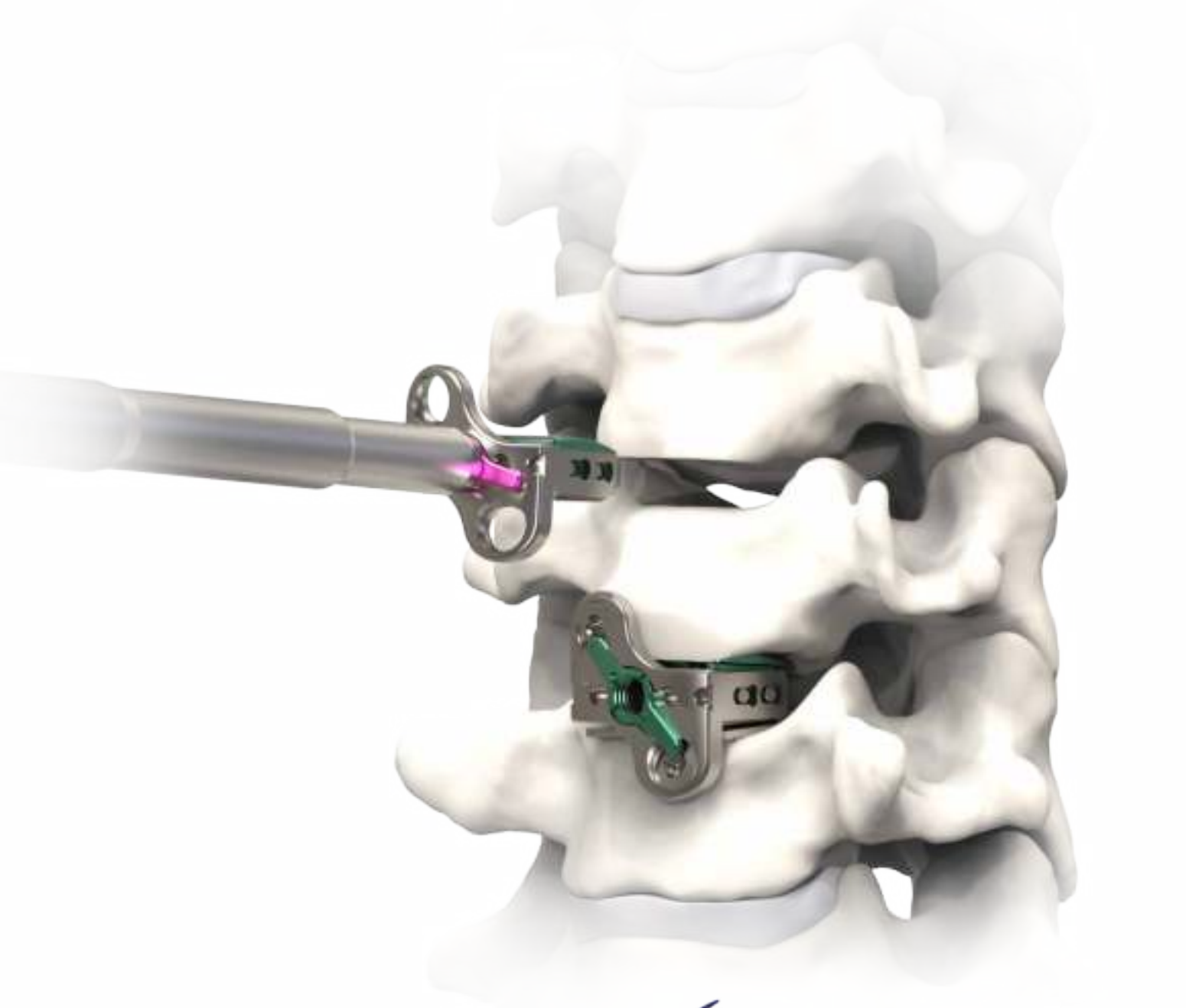
HiJAK sa

SURGICAL TECHNIQUE

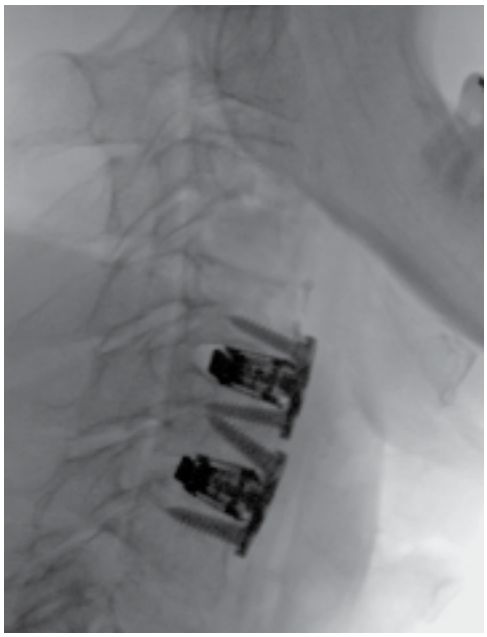


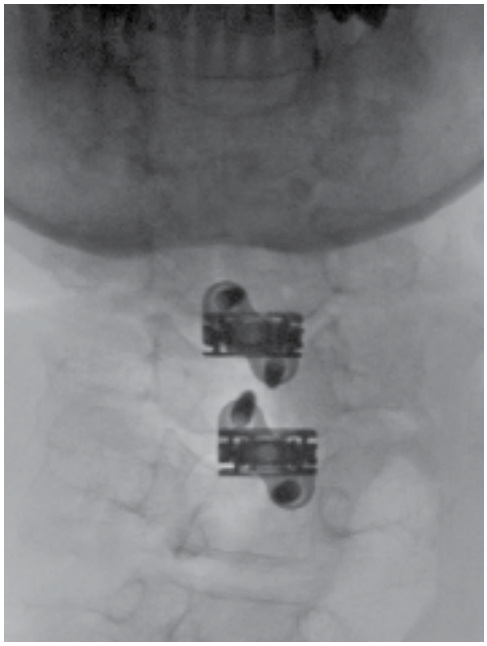
InterMed Resources
TENNESSEE

Designed for the surgeon who recognizes the importance of sagittal balance restoration, HiJAK SA is the FIRST expandable cervical stand-alone interbody to offer ADJUSTABLE HEIGHT and LORDOSIS with the added simplicity of integrated fixation. The integrated plate design allows for better screw accessibility in those difficult to reach angles providing greater screw to bone purchase vs. typical "zero profile " stand-alone devices.

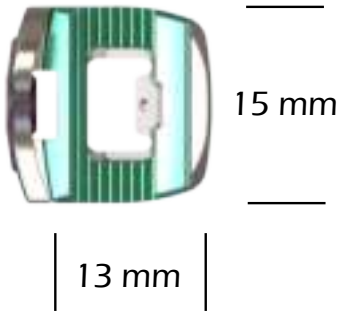
Additional benefits include:

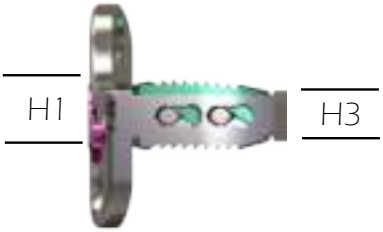
- SIMPLE, SINGLE INSTRUMENT WORK FLOW
- GREATER CONFIDENCE OF SCREW PLACEMENT
- NO IMPLANT MIGRATION DURING SCREW INSERTION
- HYPER LORDOTIC OPTIONS (UP TO 20 deg)
- PROPRIETARY ENDPLATE SURFACE TECHNOLOGY
- POST EXPANSION GRAFT- PACKING CAPABILITY
- AN UNOBSTRUCTED GRAFT CHAMBER
- POSTERIOR EXPANSION FOR FORAMINAL DECOMPRESSION
- REDUCED NEED FOR EXTERNAL DISTRACTION
- LESS IMPACTION TO PRESERVE ENDPLATE INTEGRITY
- REDUCED NEED FOR EXCESSIVE BONY RESECTION

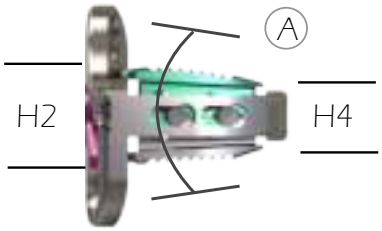




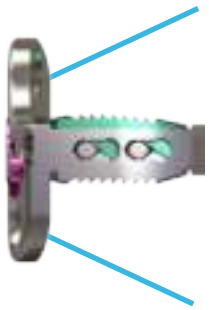
Slim 1.6 mm
Plate Thickness







SIZES	ANTERIOR HEIGHT (mm) H1	H2	POSTERIOR HEIGHT (mm) H3	H4	LORDOTIC RANGE (deg) A
7mm	4.5	7	4	5.25	0 -7
8mm	5.5	8	4	5.25	5 -12
9mm	6.5	9	5	6.25	5 -12
10mm	7.5	10	6	7.25	5 -12
8mm HL	5.5	8	4	5	12 -20
9mm HL	6.5	9	5	6	12 -20
10mm HL	7.5	10	6	7	12 -20



Up to 50° included
screw angulation
(10° convergent)

SELF-DRILLING SCREW OPTIONS IN 12, 14, AND 16MM LENGTHS

VARIABLE FIXED — 3.4 mm Ø

RESCUE — 3.9 mm Ø

INSTRUMENTATION APPLICATION

Figure 1

STEP 1: TRIALING

Static lollipop trials are provided in the set for both footprints. The trials are the initial, unexpanded, height of each implant offering (4.5, 5.5, 6.5, 7.5mm). Expandable trials are available upon special request.

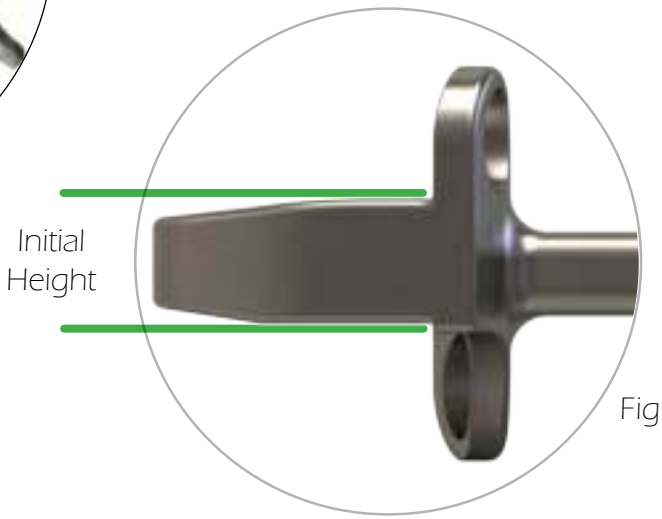


Figure 2

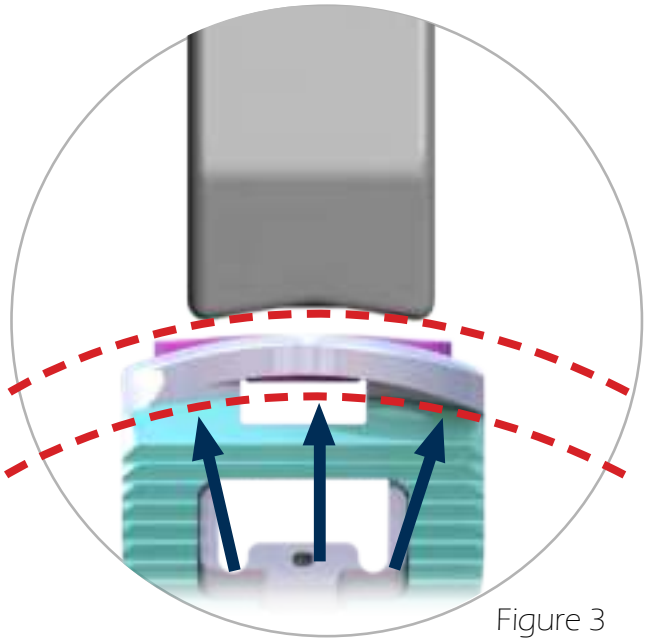


Figure 3

STEP 2: BONE PREPARATION

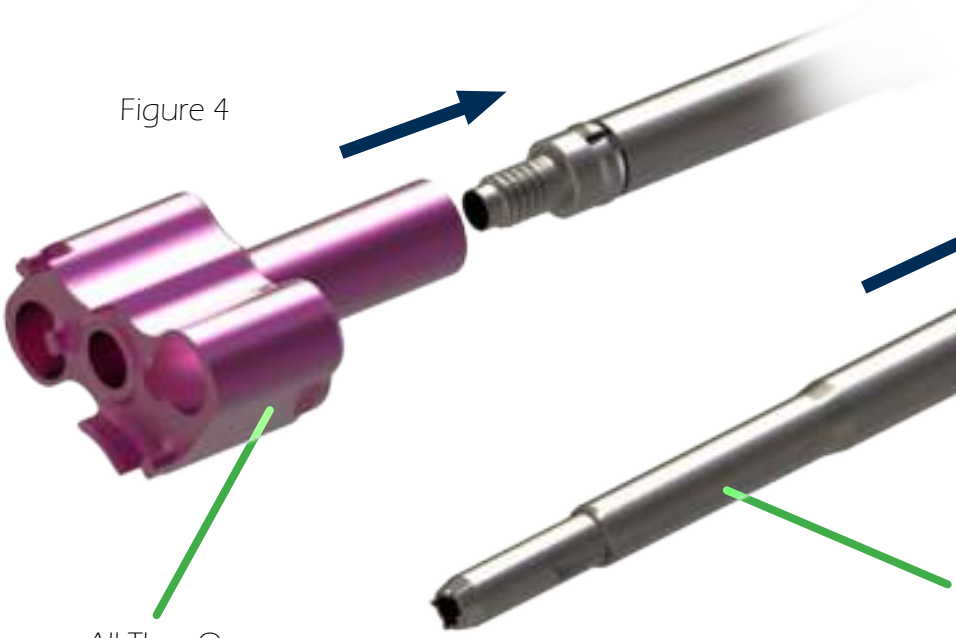
The HiJAK SA system offers the osteophyte rongeur for precise removal of osteophytes and other bony irregularities. The rongeur's cutting edge matches the axial contour of the plate to optimize the plate-to-bone interface.

Place the flat surface of the rongeur against the endplate and the contoured cutting edge against the vertebral surface and squeeze handles to groom the surface.

STEP 3: INSERTER ASSEMBLY

Once the desired implant is selected, attach the inserter body to the to the universal tip. Alternatively, choose the all-thru-one tip, which provides the opportunity for hole prep and screw insertion at a fixed trajectory (15 cephalad/caudal, 5 deg converging).

Figure 4



All-Thru-One Tip

Figure 5

Universal Tip

STEP 4: LOADING THE IMPLANT

Dock the inserter and universal tip onto the implant and ensure the castle feature engages into the locking tab. While rotating the inserter knob clockwise, hold the universal tip as a counter torque to ensure the locking tab does not rotate.

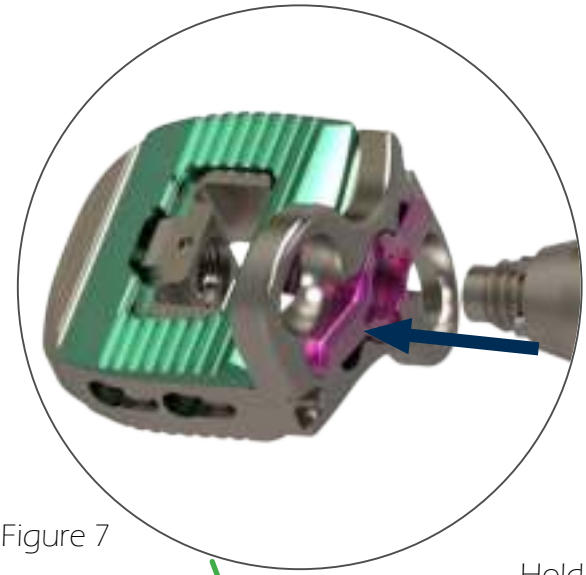


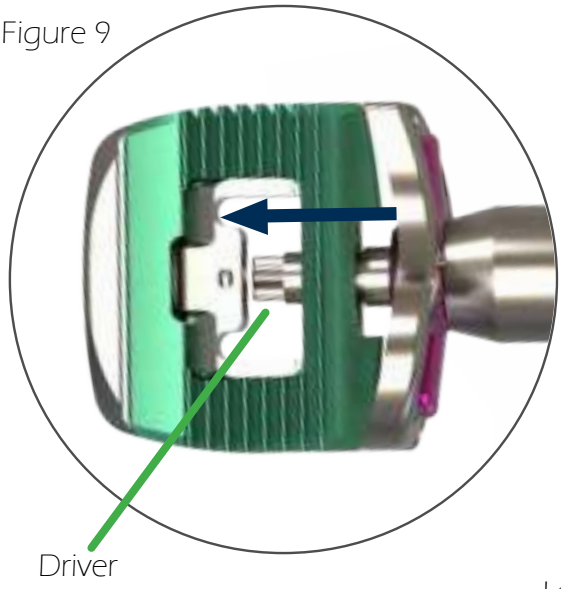
Figure 7

Figure 8

Hold Universal Tip as Counter Torque

Figure 6

Figure 9



STEP 5: LOADING THE DRIVER/PACKING GRAFT

Select the driver associated with the implant footprint chosen and attach to the torque-limiting handle. The drivers are marked small and large as shown in Figure(s) 10 and 11. Insert the driver through the implant inserter and into the implant until the T8 driver engages. When fully engaged, the tip of the T8 driver should not be visible. Pack biologic material of choice into the cage and around the shaft.

Note: Packing graft material prior to loading the driver can interfere with the operation of the implant.

Figure 10

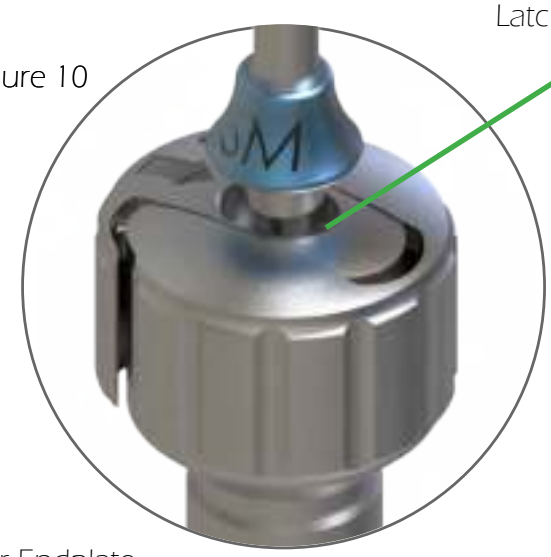
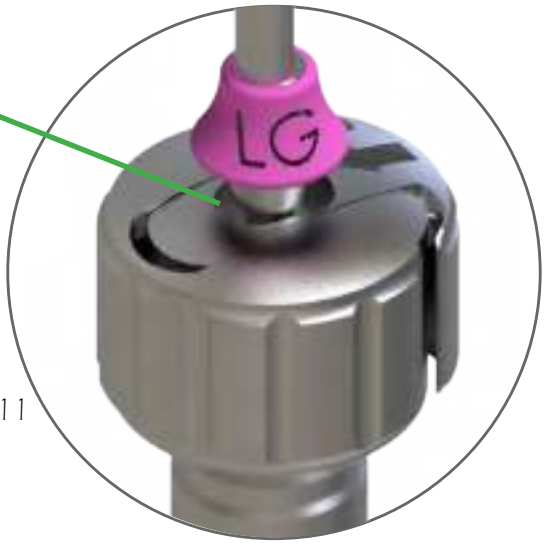


Figure 11



STEP 6: IMPLANT INSERTION AND EXPANSION

The contour on the colored endplate has been designed for an anatomic fit on the superior endplate. Insert the cage parallel to the disc space and then expand the implant by rotating the torque-limiting handle clockwise until the desired height is achieved. The implant can be left partially expanded.

The torque-limiting handle will click off at 9 in-lbs to protect against damage to the implant. If adequate expansion is not achieved at this torque, the implant should be removed and additional disc prep work conducted.

Note: HiJAK SA is a single use implant. If an implant is removed from the disc space after expansion it should be discarded. **Do not use the implants for demo.**

Superior Endplate Colored

Figure 12

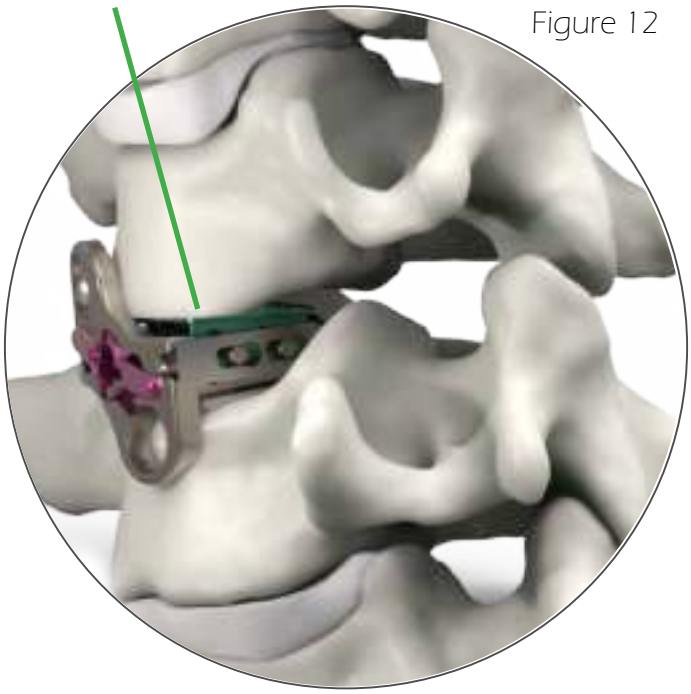


Figure 13

STEP 7: SCREW HOLE PREPARATION

The HiJAK SA system contains an awl for screw hole preparation. The tips can be changed should they become dull or damaged. Use the instrument wrenches to engage the flats on the tips and shafts.

Note: The HiJAK SA screw has a unique design. Only use the prep. instruments provided in the set for hole preparation.

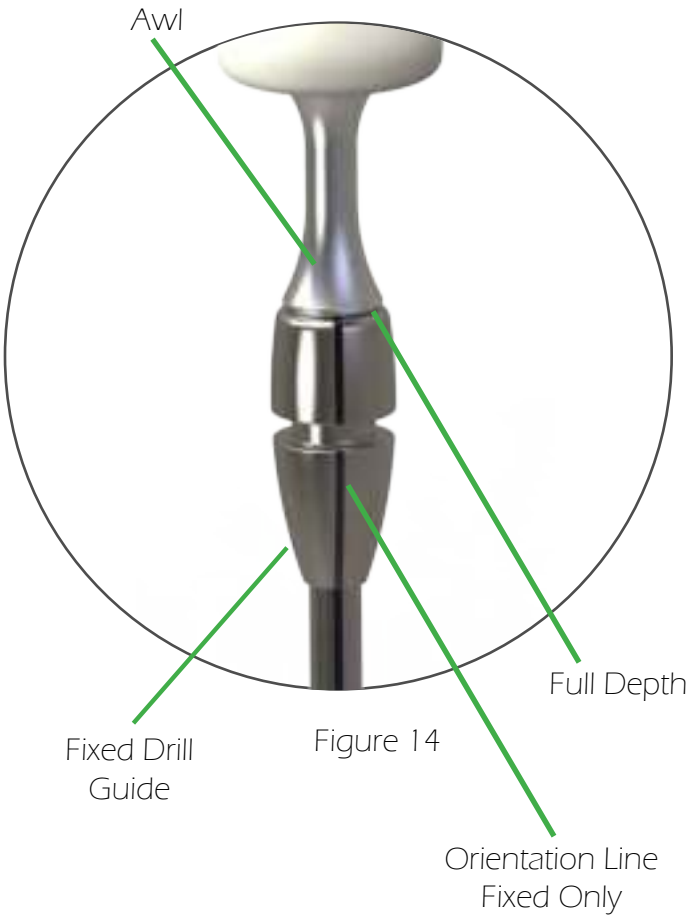


Figure 14

STEP 8: DRILL GUIDE

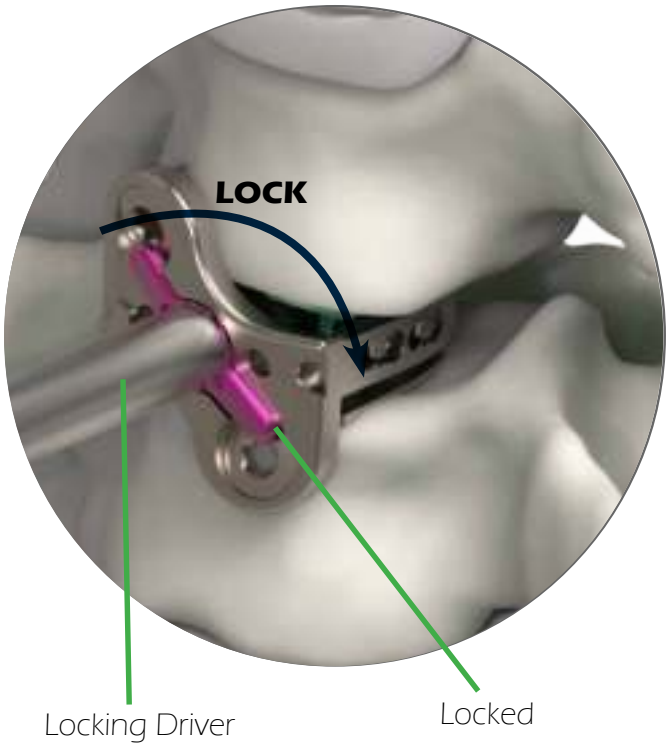
Pre-assemble the fixed or variable drill guide by placing the awl through the guide. The guides are spring loaded for soft tissue protection and can be used with the universal tip or the all-thru-one guide. Fully seat the distal tip of either guide until there is tactile feedback of engagement with the plate (Figure 14). The HiJAK SA plate has a nominal screw angle of 5° convergent in the axial plane and 15° divergent in the sagittal plane. Drill guides allow for hole preparation up to 10mm in depth. Full depth is reached when the awl assembly contacts the proximal end of the drill guide. The fixed drill guide has a marking along its shaft indicating correct orientation when docking into the plate (cephalad for superior screws, caudal for inferior screws).

Figure 15

STEP 9: SCREW SELECTION AND INSERTION

The HiJAK SA System offers a variety of screw types. Variable and fixed trajectory screws are all available in 3.4mm diameter in 12, 14, 16 mm lengths. Rescue screws at 3.9mm are available in the same lengths. The tapered pin on the tip of the screw/locking driver provides self-retention of the screw upon removal from the screw kit.

Figure 16



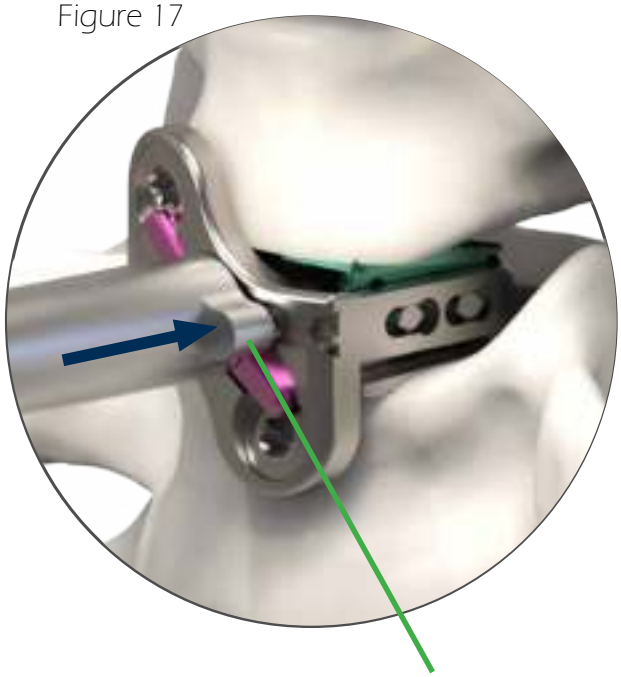
STEP 10: FINAL LOCKING

If using the universal tip, rotate the proximal portion of the inserter clockwise until the tab has covered the screw.

If using an all-thru-one guide, first remove the implant inserter by unthreading the proximal knob and removing the full assembly. Then engage the final locking driver into the tab and rotate clockwise to lock.

Note: The locking tab is single use only and should not be cycled. If resistance is felt at final lockup ensure screws are fully seated. Rotate until the screw is visually covered, the handle is not torque limiting.

Figure 17



Pins on funnel shaft dock into holes on implant

STEP 11: POST EXPANSION GRAFTING

After engagement of the locking tab the cage may be post filled with a biologic material. Prior to post packing the cage, imaging should be taken to confirm desired location and size. To remove the inserter first unthread the inserter knob and remove the driver and the inserter as one full assembly. At this point, the implant may be post packed manually or by using the bone funnel. Dock the funnel into the implant as shown in Figure 17, and insert the plunger to advance graft.

Note: Verify the ability of graft choice to flow through funnel prior to usage. Follow volume instructions to ensure cage is not overpacked.

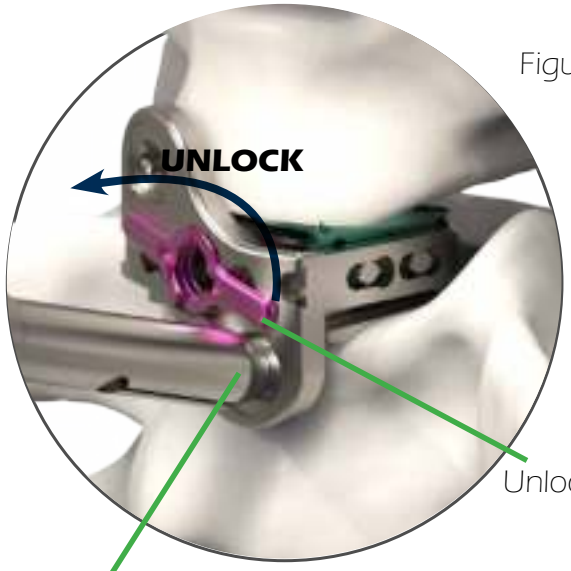
STEP 12: IMPLANT REMOVAL

To remove the implant, first rotate the locking tab counter clockwise to the open position. A removal tool is available for screw removal. Engage the screw tip and rotate the knob clockwise to self retain the screw.

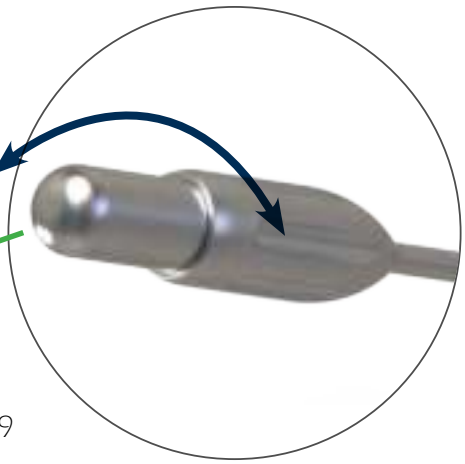
Next reattach the inserter and engage the expansion driver into the interbody portion. Collapse the implant to its initial height by rotating the driver counter clockwise and then remove from the disc space.

Note: Implants are single use only and should not be used again after any expansion within the disc space.

Figure 18



Removal Tool Tip

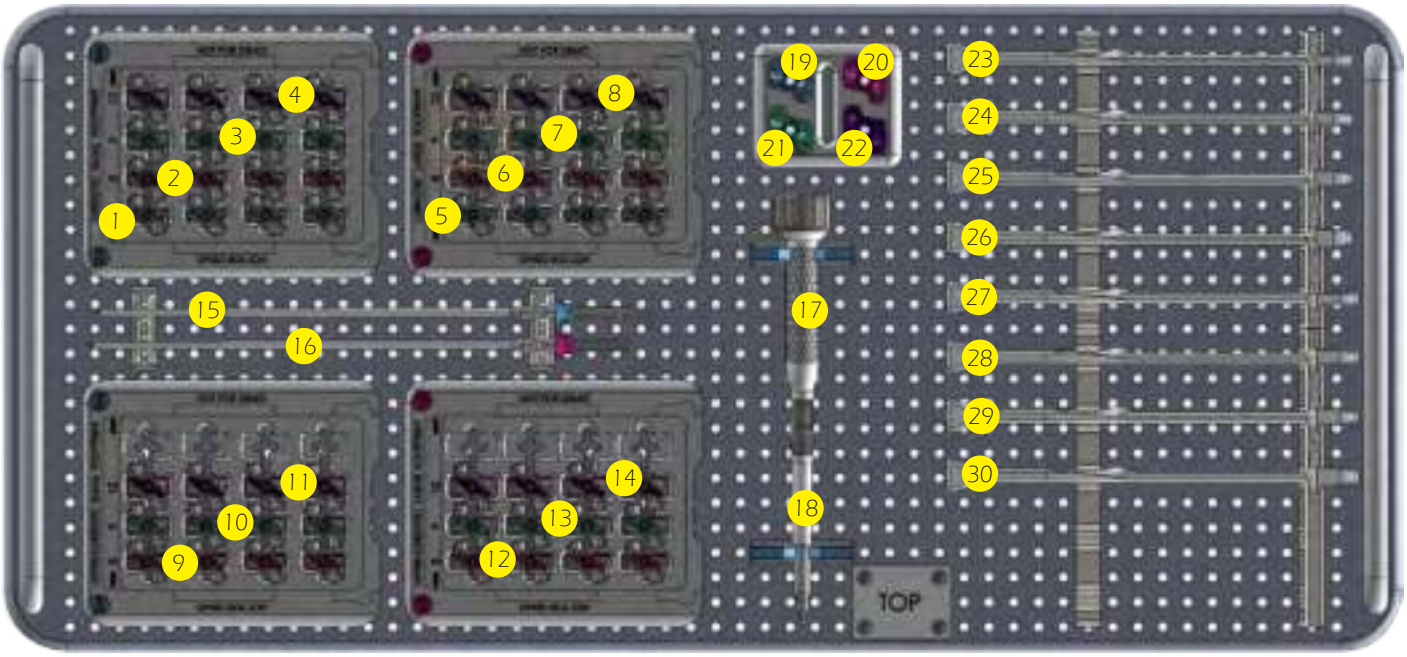


Removal Tool Knob

Figure 19

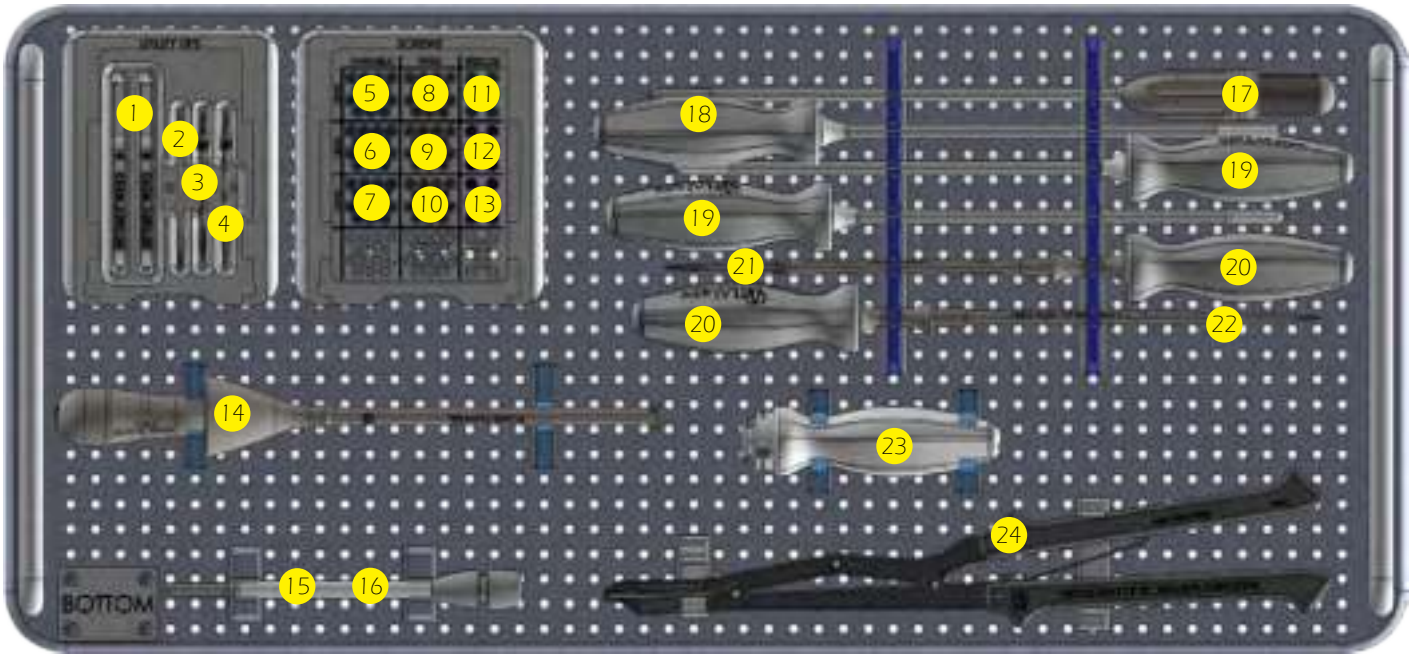
GRAFT VOLUME			
HEIGHT (mm)	PRE PACK (cc)	POST PACK (cc)	TOTAL (cc)
SMALL (13mm x 15mm)			
7	.10	.13	.23
8	.12	.14	.26
9	.15	.15	.29
10	.17	.15	.32
8 HL	.13	.13	.26
9 HL	.15	.14	.29
10 HL	.17	.15	.32
LARGE (15mm x 17mm)			
7	.18	.21	.40
8	.23	.22	.45
9	.27	.23	.50
8 HL	.24	.21	.45
9 HL	.28	.22	.50
10 HL	.32	.23	.56

TOP TRAY



1	1123-01-0007	Small Lordotic 7mm
2	1123-01-0008	Small Lordotic 8mm
3	1123-01-0009	Small Lordotic 9mm
4	1123-01-0010	Small Lordotic 10mm
5	1123-02-0007	Large Lordotic 7mm
6	1123-02-0008	Large Lordotic 8mm
7	1123-02-0009	Large Lordotic 9mm
8	1123-02-0010	Large Lordotic 10mm
9	1123-03-0008	Small Hyper-Lordotic 8mm
10	1123-03-0009	Small Hyper-Lordotic 9mm
11	1123-03-0010	Small Hyper-Lordotic 10mm
12	1123-04-0008	Large Hyper-Lordotic 8mm
13	1123-03-0009	Large Hyper-Lordotic 9mm
14	1123-03-0010	Large Hyper-Lordotic 10mm
15	2023-01-0006	T8 Driver Small
16	2023-01-0007	T8 Driver Large
17	2023-01-0000	Inserter Assembly
18	2023-01-0004	Universal Inserter Tip
19	2023-02-0007	All-Thru-One 7mm
20	2023-02-0008	All-Thru-One 8mm
21	2023-02-0009	All-Thru-One 9mm
22	2023-02-0010	All-Thru-One 10mm
23	2023-03-0007	Small Lordotic Trial 7mm
24	2023-03-0008	Small Lordotic Trial 8mm
25	2023-03-0009	Small Lordotic Trial 9mm
26	2023-03-0010	Small Lordotic Trial 10mm
27	2023-04-0007	Large Lordotic Trial 7mm
28	2023-04-0008	Large Lordotic Trial 8mm
29	2023-04-0009	Large Lordotic Trial 9mm
30	2023-04-0010	Large Lordotic Trial 10mm

BOTTOM TRAY



1	IGW-001-000	Instrument Wrench
2	2021-01-0006	Tap Bit
3	2021-01-0007	Awl Bit
4	2021-01-0008	Drill Bit
5	1121-02-0012	Variable Screw 12mm
6	1121-02-0014	Variable Screw 14mm
7	1121-02-0016	Variable Screw 16mm
8	1121-03-0012	Fixed Screw 12mm
9	1121-03-0014	Fixed Screw 14mm
10	1121-03-0016	Fixed Screw 16mm
11	1121-04-0012	Rescue Screw 12mm
12	1121-04-0014	Rescue Screw 14mm
13	1121-04-0016	Rescue Screw 16mm
14	2023-01-0001	Bone Funnel Assembly
15	2021-01-0002	Variable Drill Guide
16	2021-01-0003	Fixed Drill Guide
17	2021-01-0000	Screw Removal Tool
18	2023-01-0005	Locking Tab Driver
19	2021-01-0004	Screw Locking Tab
20	2021-02-0001	Universal Holder Assembly
21	2021-01-0008	Drill Bit
22	2021-01-0007	Awl Bit
23	2019-01-0005	Torque Limiting Handle
24	IVR-001-000	Osteophyte Rongeur

INSTRUCTIONS FOR USE

Device System Name:
Expandable Standalone Cervical Interbody System

Description:
The Expandable Cervical Standalone Interbody System is comprised of an assortment of non-sterile, single use, titanium alloy (Ti6Al4V ELI per ASTM F136) and nickel-titanium alloy (NiTi per ASTM F2063) spacers with height ex-pansion capability. The expandable standalone interbody spacer is inserted into the cervical disc space and expanded to fit the patient anatomy. Each spacer must be used with two fixation screws (cephalad/caudal) provided by the previ-ously cleared V3 Segmental Plating System (K182418).

The interbody spacers are offered in adjustable lordotic and adjustable hyper-lordotic configurations to help restore the natural curvature of the spine. The implants can be used in Anterior Cervical Discectomy and Fusion (ACDF).

The interbody spacers feature a bulleted nose for ease of insertion and anti-migration ripples on both the inferior and superior surfaces to provide increased stability and help prevent anterior/posterior movement of the device.

The Expandable Cervical Standalone Interbody System is intended to be used as a stand-alone device and no additional fixation is required. The system is provided non-sterile and requires sterilization prior to use.

Indications for Use:
The Expandable Cervical Standalone Interbody System is a stand-alone anterior cervical interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (C2-T1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). These patients should have received at least six weeks of nonoperative treat-ment prior to treatment with the device. The Expandable Cervical Standalone Interbody System is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and implanted via an open, anterior approach. The Atlas Spine Expandable Cervical Standalone Interbody System is intended to be used with the bone screw fixation provided by the V3 Segmental Plating system and requires no additional fixation.

Contraindications:
The Expandable Cervical Standalone Interbody System, as with other orthopedic implants, is contraindicated for use in patients with:
1. Active infections in which the use of an implant could preclude adequate and appropriate treatment of the infection.
2. Rapidly progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis which may prevent adequate fixation.
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity, pregnancy or degenerative diseases. The decision to use this system in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. Prior fusion at the level to be treated.
5. Any circumstances not listed under the heading indications.

Potential Adverse Events:
Potential adverse events include, but are not limited to:
1. Failure of the device to provide adequate mechanical stability.
2. Loss of fixation of the implant.
3. Device component failure.
4. Migration or bending of the device.
5. Loss of bony alignment.
6. Non-union.
7. Fracture of bony structures.
8. Resorption without incorporation of any bone graft utilized.
9. Immunogenic response to the implant materials.

Note: As with any major surgical procedure, there are risks involved in ortho-pedic surgery. Infrequent operative and postoperative complications known to occur are: early or late infection, which may result in the need for additional surgeries, damage to blood vessels, spinal cord or peripheral nerves, pulmonary emboli, loss of sensory and/or motor function, impotence, permanent pain and/or deformity. Rarely, some complications may be fatal.

Warnings and Precautions:
The surgeon should be aware of the following when using implants:
1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape, and design of the implant. No implant can be expected to withstand the unsupported stresses of full weight bearing. The size, shape and condition of human bones are also contributing factors to the success of the surgery.
2. Do not use damaged implants. The correct handling of the implant is extremely important. Implants should not be bent, notched or scratched. These operations can produce defects in surface finish and may cause internal stress concentrations which may become the focal point for eventual failure of the device.
3. Non-sterile; the Expandable Cervical Standalone Interbody System implants and instruments are provided non-sterile, and therefore, must be thoroughly cleaned and sterilized prior to each use.
4. Single use only. Expandable Cervical Standalone Interbody System implants are intended for SINGLE USE ONLY. No surgical implants should be reused. Reuse of devices labeled as single-use could result in injury or re-opera-tion due to breakage or infection. Any implant once used should be discarded. Even though the device appears undamaged, it may already have small defects and internal stress patterns that may lead to fatigue failure.
5. Do not re-sterilize single-use implants that come in contact with body fluids.
6. Postoperative care is important. The patient should be instructed in the limitations of the implant and should be cautioned regarding weight bearing and body stress on the device prior to secure bone healing.
7. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the intervertebral body fusion device.
8. The implantation of the intervertebral body fusion device should be per-formed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
9. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

MRI Safety Information:
The Expandable Cervical Standalone Interbody System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the Expandable Cervical Standalone Interbody System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Cleaning and Decontamination:

Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. The decontamination process should begin immediately after completion of the surgical procedure.

Rigid instrument cases may be washed and/or disinfected by using an automated washer-disinfection unit utilizing thermal disinfection. Temperatures, cycles, and disinfectant type used as instructed by manufacturer of washer-disinfection unit.

1. **Decontamination:** Saturate the surface completely with full strength disinfectant/cleaner* (e.g. Cavicide) and allow to remain in contact with devices for 5 minutes.

2. **Pre-Cleaning:** Remove gross contaminants by immersing the devices in room temperature neutral pH enzymatic cleaner* (e.g. Metrizyme) and disassemble instruments per instructions provided in the following pages. The majority of the surgical instruments and trial devices are simply constructed and will not require disassembly. However, some of the more complex instruments are made of several components and these should be disassembled into their individual parts prior to decontamination. Scrub with the appropriate soft bristle brush until visibly clean.

3. **Washing:** Immerse devices in the ultrasonic washer/cleaner with room temperature neutral pH enzymatic cleaner* (e.g. Metrizyme) and sonicate for 10 minutes. For ultrasonic cleaning follow the manufacturer's specifications for suggested water level and concentration. When using mechanical washers, make sure the instruments are secured in place, and do not touch or overlap.
* Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures.

4. **Rinsing:** Thoroughly rinse the devices with deionized or distilled water. For example, a minimum of 2 minutes three (3) times.

5. **Drying:** Allow devices to air dry a minimum of 30 minutes prior to inspection and sterilization preparation. Instruments must be thoroughly dried to remove residual moisture before they are stored.

Preparation and Assembly: After cleaning/disinfection, the disassembled instruments should be reassembled and visually inspected. Check for misalignment, burrs, bent, or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Place instruments into appropriate configuration within instrument case and wrap with protective sterilization wrap according to AAMI / AORN guidelines.

Note: Visually inspect instruments after cleaning and prior to each use. Discard or return to us any instruments that are broken, discolored, corroded, have cracked components, pits, gouges, or are otherwise found defective. Do not use defective instruments.

Sterilization:
The Expandable Cervical Standalone Interbody System instruments and implants are supplied NON-STERILE. Prior to use, all instruments and implants should be placed in the appropriate Atlas Spine case which will be wrapped in a FDA cleared sterilization wrap and placed in the autoclave for sterilization by the hospital using the following recommended cycle:

Method: Steam
Cycle: Pre-vac
Temperature: 270°F (132°C)
Preconditioning: Per manufacturer's settings
Exposure time: 4 minutes
Drying time: 30 minutes
Double wrapped (FDA cleared wrap)

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 Atlas Spine.

The Expandable Cervical Standalone Interbody System instruments and implants are provided in a modular case specifically intended to contain and organize the system's components. The system's instruments are organized into trays within each modular case for easy retrieval during surgery. These trays also provide protection to the system components during shipping. Additionally, individual instruments and implants 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 InterMed Resources TN by telephone at 800-224-6113.

Further Information:
A recommended operative technique for the use of this system is available upon request from Atlas Spine at the phone numbers provided above.

Latex Information:
The implants, instruments and/or packaging material for the Spine Expandable Cervical Standalone Interbody 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.

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1-800-224-6113
support@intermedtn.com
www.intermedtn.com

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

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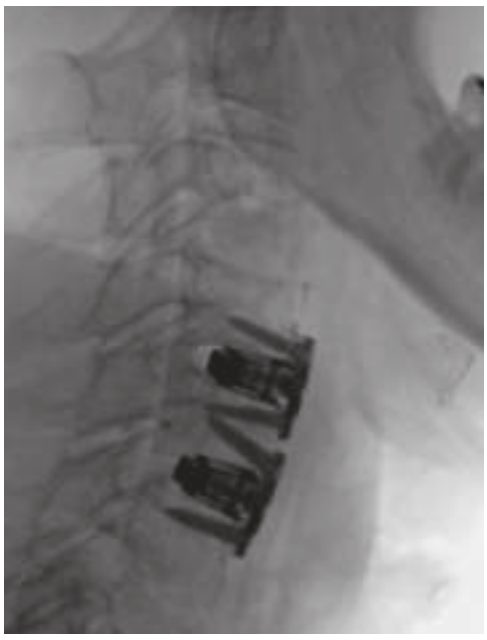
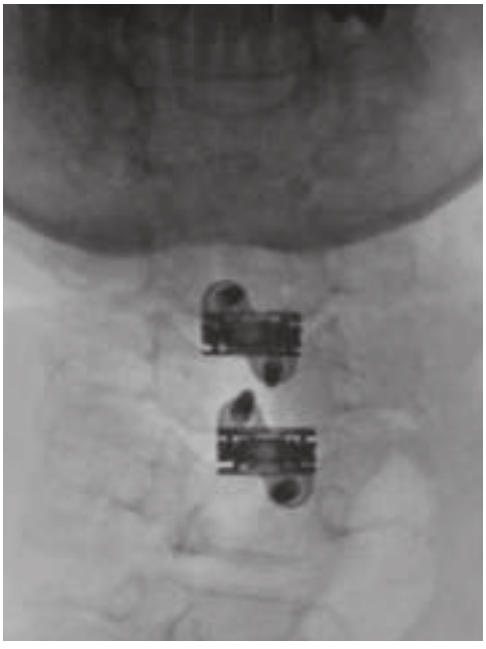
Designed for the surgeon who recognizes the importance of sagittal balance restoration, HiJAK SA is the FIRST expandable cervical stand-alone interbody to offer ADJUSTABLE HEIGHT and LORDOSIS with the added simplicity of integrated fixation. The integrated plate design allows for both better accessibility in those difficult to reach screw angles and greater screw to bone purchase vs. typical "zero profile " stand-alone devices.

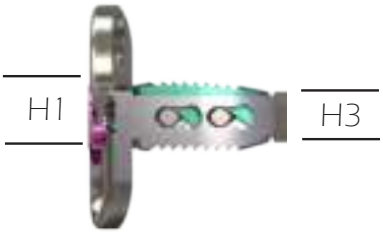
Additional benifits include:

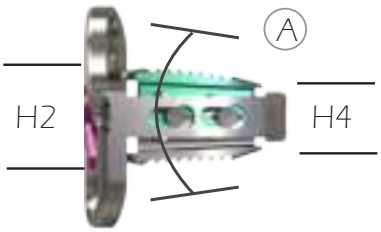
- SIMPLE, SINGLE INSTRUMENT WORK FLOW
- GREATER CONFIDENCE OF SCREW PLACEMENT
- NO IMPLANT MIGRATION DURING SCREW INSERTION
- HYPER LORDOTIC OPTIONS (UP TO 20 deg)
- PROPRIETARY ENDPLATE SURFACE TECHNOLOGY
- POST EXPANSION GRAFT- PACKING CAPABILITY
- UNOBSTRUCTED GRAFT CHAMBER
- POSTERIOR EXPANSION FOR FORAMINAL DECOMPRESSION
- REDUCED NEED FOR EXTERNAL DISTRACTION
- LESS IMPACTION TO PRESERVE ENDPLATE INTEGRITY
- REDUCED NEED FOR EXCESSIVE BONY RESECTION





Slim 1.6 mm
Plate Thickness





SIZES	ANTERIOR HEIGHT (mm) H1	H2	POSTERIOR HEIGHT (mm) H3	H4	LORDOTIC RANGE (deg) A
7mm	4.5	7	4	5.25	0 -7
8mm	5.5	8	4	5.25	5 -12
9mm	6.5	9	5	6.25	5 -12
10mm	7.5	10	6	7.25	5 -12
8mm HL	5.5	8	4	5	12 -20
9mm HL	6.5	9	5	6	12 -20
10mm HL	7.5	10	6	7	12 -20

Up to 50° included
screw angulation
(10° convergent)

SELF-DRILLING SCREW OPTIONS IN 12, 14, AND 16MM LENGTHS

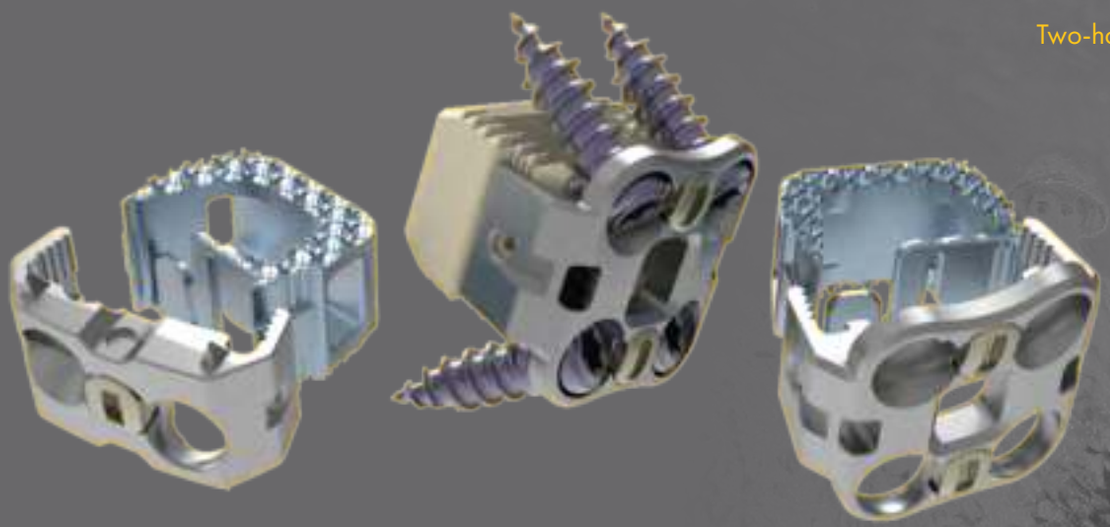
VARIABLE FIXED — 3.4 mm Ø

RESCUE — 3.9 mm Ø

MONET™

ANTERIOR CERVICAL FUSION SYSTEM

The MONET™ Anterior Cervical Fusion system is designed for intra-operative flexibility. The cage component can be implanted in conjunction with the MONET™ supplemental fixation plates, making it a truly comprehensive Anterior Cervical Fusion solution.



Two-hole and four-hole plate configurations accommodate anatomical variation

Torsional stabilizers enhance rotational stability (two-hole plate only)

Large graft window allows for maximum graft volume and greater likelihood of fusion

Efficient screw blocking mechanism

Tapered leading edge for ease of insertion

Multiple screw options

IMPLANT FOOTPRINTS AND SIZES

CAGE ONLY:	CAGE AND PLATE ASSEMBLY:
Small: W13 x L10mm	Small: W14 x L12mm
Medium: W15 x L11mm	Medium: W17 x L14mm
Large: W17 x L13mm*	Large: W20 x L16mm*

*Large footprint only available upon request

InterMed Resources
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MONET™ ACIF Cage, Small & Medium

8 Degree	Size	
Part Number	S/M	Height (mm)
113.4206	S	6
113.4207	S	7
113.4208	S	8
013.4209	S	9
113.4210	S	10
113.4406	M	6
113.4407	M	7
113.4408	M	8
113.4409	M	9
113.4410	M	10

MONET™ ACIF TiCro™ Cage, Small & Medium

8 Degree	Size	
Part Number	S/M	Height (mm)
113.5206	S	6
113.5207	S	7
113.5208	S	8
013.5209	S	9
113.5210	S	10
113.5406	M	6
113.5407	M	7
113.5408	M	8
113.5409	M	9
113.5410	M	10

* 11mm and 12mm heights available upon request

MONET™ ACIF Screw, 3.5mm Diameter

Fixed, Self Drilling	Fixed, Self Tapping	Variable, Self Drilling	Variable, Self Tapping	
Part Number	Part Number	Part Number	Part Number	Length (mm)
113.0512	113.0712	113.0112	113.0312	12
113.0514	113.0714	113.0114	113.0314	14
113.0516	113.0716	113.0116	113.0316	16
113.0518	113.0718	113.0118	113.0318	18
113.0520	113.0720	113.0120	113.0320	20

MONET™ ACIF Screw, 4.0mm Diameter

Fixed, Self Drilling	Fixed, Self Tapping	Variable, Self Drilling	Variable, Self Tapping	
Part Number	Part Number	Part Number	Part Number	Length (mm)
113.0612	113.0812	113.0212	113.0412	12
113.0614	113.0814	113.0214	113.0414	14
113.0616	113.0816	113.0216	113.0416	16
113.0618	113.0818	113.0218	113.0418	18
113.0620	113.0820	113.0220	113.0420	20

MONET™ ACIF Plate, Small & Medium

Two-Hole	Four-Hole	
Part Number	Part Number	Height (mm)
113.1106	113.1406	6
113.1107	113.1407	7
113.1108	113.1408	8
113.1109	113.1409	9
113.1110	113.1410	10
113.1206	113.1506	6
113.1207	113.1507	7
113.1208	113.1508	8
113.1209	113.1509	9
113.1210	113.1510	10

InterMed Resources
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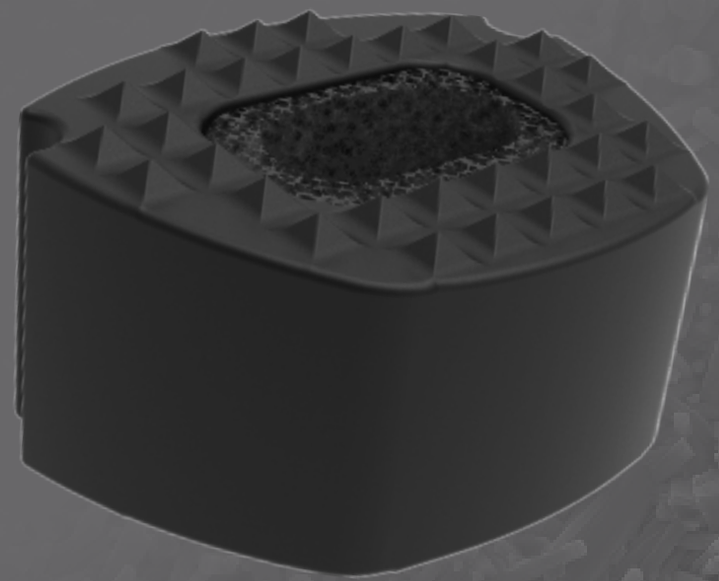
VALEO C+CSC *W/ LUMEN*

ANTERIOR CERVICAL
INTERBODY FUSION DEVICES



SILICON NITRIDE

In the race to achieve interbody fusion, material matters. And no material fosters an environment for faster fusion like silicon nitride. Featuring the ability to achieve superior new bone growth and osseointegration, along with proven bacteriostatic properties and enhanced imaging attributes, silicon nitride outperforms PEEK and titanium.

Nanotopography enhances osteoblast response, initiating faster fusion

Optimal material density enables radiotranslucent and reduced artifact imaging

Surface chemistry generates bacteriostatic properties

IMPLANT FOOTPRINTS AND SIZES

FOOTPRINTS:
16x12mm [6°]
17x14mm [6°]

HEIGHTS:
5-10mm, 1mm increments

InterMed Resources
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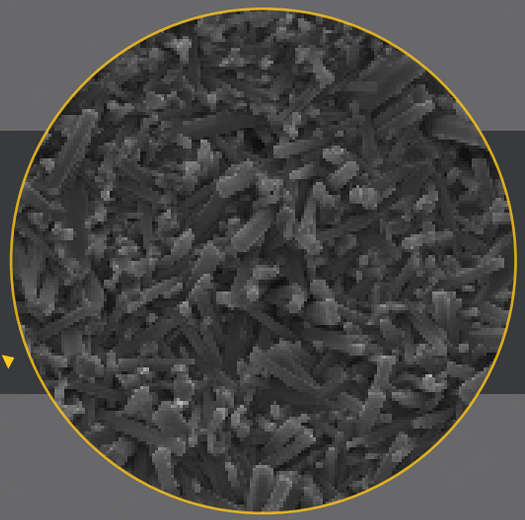
THE IDEAL BIOMATERIAL

SILICON NITRIDE

Silicon nitride has the ability to achieve superior new bone growth. Along with anti-microbial properties and enhanced imaging capabilities, silicon nitride is the ideal biomaterial.



Silicon nitride's nano-texture surface at 10 microns

Faster Fusion Rates

Compared to PEEK and titanium, silicon nitride demonstrates greater new bone formation[1] and has an innate nanotopography and surface chemistry that provides an optimal environment for bone growth. The surface chemistry initiates bone growth, while the instrinsic nanotopography increases surface area. This combination of initiating bone growh with increased surface area enhances osteoblast response, accelerating the fusion process.

Enhanced Imaging Capabilities

Silicon nitride implants are radiotranslucent with visible boundaries and produce no artifact under CT or MRI; this enables an exact view of the implant for precise intraoperative placement and post-operative fusion assessment.

Proven Bacteriostatic Properties

The negative surface charge of silicon nitride repels bacteria and prevents biofilm formation[2], reducing the chance of infection. The hydrophilic surface creates a molecular water barrier preventing the adhesion of bacteria.

REFERENCES:

1. Webster TJ, Patel AA, Rahaman MN, et al. Anti-infective and osteointegration properties of silicon nitride, poly(ether ether ketone), and titanium implants. Acta Biomater. 2012;8(12):4447-4454. doi: 10.1016/j.actbio.2012.07.038. Epub 2012 Jul 31.
2. Gorth DJ, Puckett S, Ercan B, et al. Decreased bacteria activity on Si_3N_4 surfaces compared with PEEK or titanium. Int J Nanomedicine. 2012;7:4829-4840.

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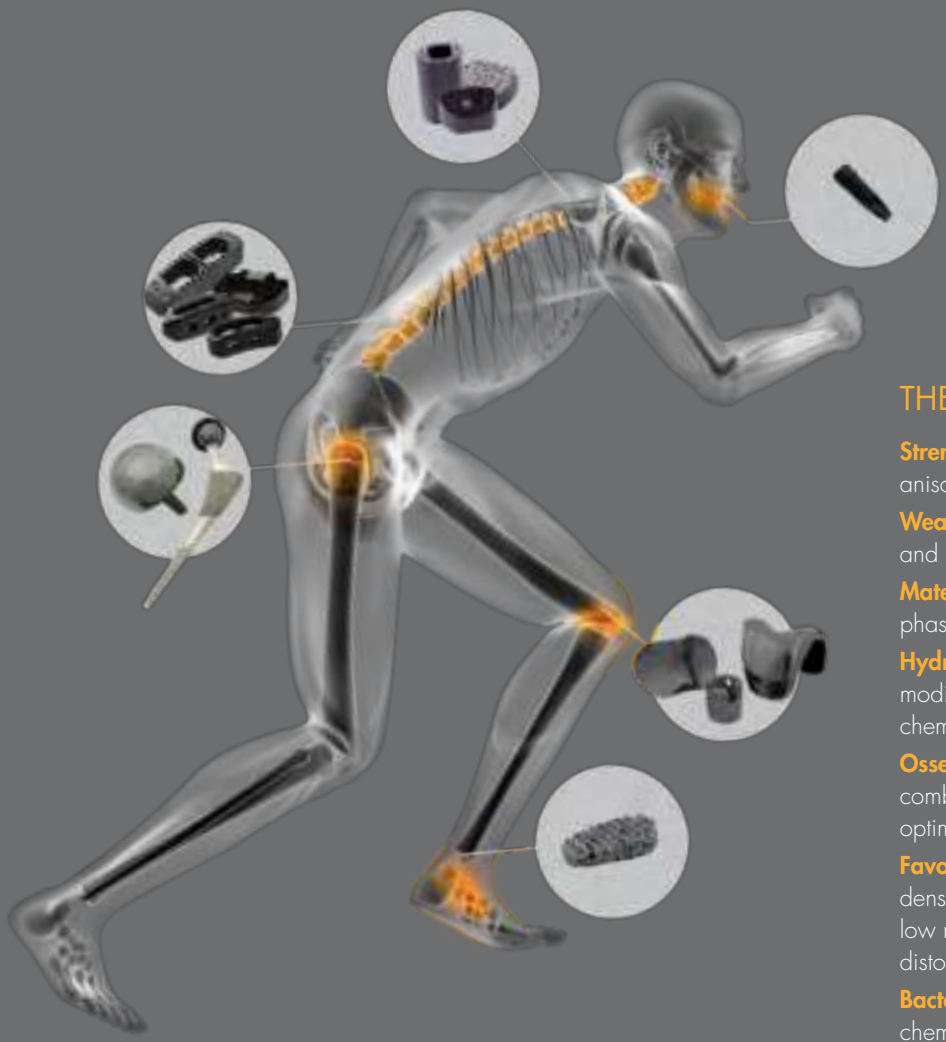
MEDICAL GRADE SILICON NITRIDE

Our proprietary composition of silicon nitride provides the right combination of strength, toughness, wear resistance, biocompatibility, bioactivity, bone integration, structural stability, corrosion resistance, and easier imaging, all of which are desirable in medical implants.



THE IDEAL BIOMATERIAL

Strength and fracture toughness: Interlocking anisotropic grains deflect and bridge cracks.

Wear resistance: High hardness, strength, and fracture toughness prevent wear.

Material phase stability: No spontaneous phase transformation or associated weakening.

Hydrophilicity: Tunable through modification of surface topography and chemistry, from <10° up to ~70°.

Osseointegration: Nanostructured topography combined with complex surface chemistry optimal for cell adhesion and bone growth.

Favorable imaging: Semi-radiolucent density appears bone-like in X-rays and low magnetic susceptibility eliminates distortion in CT and MRI scans.

Bacterial resistance: Surface chemistry, nanotexture, and charge inhibit biofilm formation.

CALL **800.224.6113** OR VISIT US AT **INTERMEDTN.COM** TO DISCOVER WHY MATERIAL MATTERS.

SILICON NITRIDE

TYPICAL PROPERTIES

Property	Units	Test Method	Typical	Specification
Density	g/cc	ASTM C 373	3.26	≥ 3.23
Grain Size	microns	BS EN 623-3	0.5 x 5.0	≤ 25
Flexural Strength	MPa	ASTM C 1161	1,000	≥ 900
Compressive Strength	MPa	*	>4,000*	-
Elastic Modulus	GPa	ASTM C 1161	296	≥ 290
Poisson's Ratio	-	*	0.27*	-
Weibull Modulus	-	ASTM C 1239	10	≥6
Fracture Toughness	MPa·m1/2	ASTM E 399	10.5	≥ 9.0
Biocompatibility	-	ISO 10993	Pass	Pass
Hardness	GPa	ASTM C 1327	15.0	≥ 14.3
Coefficient of Thermal Expansion (RT – 200°C)	1 x 10-6/°C	*	2.2*	-
Thermal Conductivity	W/m·°K	*	15-30*	-
Si3N4 Phase Composition	%	X-ray Diffraction JCPDS# 82-0697	100% ß-Si3N4	≥95% ß-Si3N4
Specific Heat	J/Kg·°K	*	170*	-
Volume Resistivity	ohm-cm	*	>1012*	-

*Reported data are typical of silicon nitride. These values have not been specifically measured for silicon nitride.

BIOCOMPATIBILITY TESTING

Test	Method
Cytotoxicity	ISO 10993-05
Sensitization	ISO 10993-10
Intracutaneous Toxicity	ISO 10993-10
Acute Systemic Toxicity	ISO 10993-11
Subchronic Toxicity	ISO 10993-11
Genotoxicity	ISO 10993-3
Muscle Implant tests	ISO 10993-6
Physicochemical Testing	USP

COMPATIBILITY WITH STERILIZATION METHODS

	Gamma Irradiation, E-Beam, X-Ray	Steam	Ethylene Oxide Gas
Silicon Nitride	Yes	Yes	Yes

ASTM OR ISO SPECIFICATIONS FOR BIOMATERIALS TABLE[1]

Property	Al_2O_3 ASTM F-603	Al_2O_3 ISO 6474-1	Mg-PSZ ASTM F-2393	Y-TZP ASTM F-1873	ZTA, AMC ISO 6474-2	Si_3N_4 ASTM F-2094[1]	Si_3N_4 ISO 266021	CoCr ASTM F799	Ti6Al4V ASTM F136	PEEK ASTM F2026
Chemical Purity (%)	≥ 99.5	≥ 99.7	≥ 99.8	≥ 99.0	≥ 99.8	≥ 97.0	NS	NA	≥ 99.3	NA
Density (g/cc and %)	≥ 3.93 ≥ 98.6	≥ 3.94 ≥ 98.8	≥ 5.80 ≥ 98.8	≥ 6.00 ≥ 98.4	≥4.31 ≥ 98.6	3.0 – 3.4 ≥ 99.8	3.0 – 3.6 NS	NA	NA	1.28 – 1.32
Grain Size (µm)	≤ 4.5	≤ 2.5	NS	≤ 0.6	Al_2O_3 ≤ 1.5 ZrO_2 ≤ 0.6	NS	NS	≤ 64	NA	NA
Flexural Strength (MPa)[1]	≥ 400	≥ 500	≥ 600	≥ 800	≥ 750	≥ 765	≥ 760	827 (YS) 1172 (TS)[2]	760 (YS) 825 (TS)	110
Weibull Modulus	≥ 8	≥ 8	≥ 10	NR	≥ 8	≥ 12	≥ 12	NA	NA	NA
Fracture Toughness (MPa·$m^{1/2}$)	NS	≥ 2.5	NS	NS	≥ 3.5	≥ 6.0	≥ 6.0	NA	NA	50[3]
Hardness (GPa)	≥ 18	≥ 18	≥ 10	≥ 12	≥ 15.5	≥ 15	≥ 14.2	≥ 3.3	NA	NA
Elastic Modulus (GPa)	≥ 380	≥ 380	≥ 180	≥ 200	≥ 320	270 – 330	270 – 330	NA	NA	3

PHYSICAL & MECHANICAL PROPERTIES AND PERFORMANCE OF BIOMATERIALS[1]

Property or Performance	Units	Alumina	Zirconia		Zirconia-Alumina Composites			Industrial Silicon Nitride	Cobalt Chromium	Ti6Al4V	PEEK	Cortical Bone	Titanium Nitride	Diamond-Like Carbon	Zirconium Nitride	Titanium Niobium Nitride	Oxidized Zirconium	Hydroxyapatite
Composition	NA	Al2O3	Mg-PSZ	Ce- or Y-TZP	m-ZTA	AMC	ATZ	Si_3N_4	ASTM F799	ASTM F136	ASTM F2026	Collagen, Proteins, HAp	TiN	DLC	ZrN	TiNbN	Ox-Zr	ASTM F1609
Density	g/cc	3.98	5.65 – 5.77	6.00 – 6.05	4.25	4.37	5.51	3.22 – 3.35	8.29 – 8.50	4.43 - 4.50	1.29	1.5 – 2.0	4.87 – 5.22	0.90 – 3.20	7.09	~5.69	5.84	2.55 – 3.21
Grain Size	µm	<1.8 Equiaxed	50 Equiaxed	0.1 – 0.6 Equiaxed	0.4 – 0.7 Equiaxed	0.54 Equiaxed	0.4 Equiaxed	0.5 x 5.0 Non-Equiaxed	~62 Equiaxed	~10 x 60 Lamellar	NA	NA	30 – 300 nm Columnar	Amorphous 2 - 25 nm	10 – 30 nm Nanocrystals	10 – 30 nm Nanocrystals	40 x 200 nm	0.4 - 100 µm splats
Flexural or Tensile Strength	MPa	400 – 580 Flexural	450 – 700 Flexural	700 – 1500 Flexural	700 – 1248 Flexural	1250 – 1400 Flexural	755 – 1163 Flex./Biaxial	800 – 1100 Flexural	827 Tensile	860 – 970 Tensile	170 Flexural	90 – 228 Flexural	10 – 60 N LC Adhesion	35 – 160 N LC Adhesion	24 – 60 N LC Adhesion	83 N LC Adhesion	35 N LC Adhesion	39 – 189 Bond 25 – 60
Compressive Strength	MPa	4100 – 5000	2000 - 3000	2000 – 2200	4000 - 4500	4300	~2600	4000	600 – 1800	800 - 970	118	150 – 260 ∥ 70 – 110 ⊥	400 – 5500	NA	NA	NA	~2000	102 – 1000
Elastic Modulus	GPa	380	200 – 250	210 – 223	340 – 390	358	240 - 250	296 – 313	197 – 210	105 – 120	4	7.5 – 25.8 ∥ 5 – 20 ⊥	402 – 550	110 – 900	175 – 395	200 – 600	200	3.2 to 122 coat vs. bulk
Poisson's Ratio	NA	0.23	0.30	0.30 – 0.33	~0.24	0.24	~0.28	0.27	0.27 – 0.32	0.31 – 0.34	0.4	0.19 – 0.48	0.21	0.17 – 0.20	0.19	~0.20	0.34	0.11 – 0.27
Weibull Modulus	NA	5 – 29	22	7 – 87	NA	10 – 15	6 – 17	8 – 53	NA	NA	NA	NA	5 – 18	6 – 12	NA	NA	NA	2 – 19
Fracture Toughness	KIC, MPa·$m^{1/2}$	3.3 – 4.2	2.9 – 16.0	4.5 – 20.0	>4.1	6.4 – 8.5	8.0 – 12.0	4.4 – 15.0	50 – 100	46.3 – 93.3	7.6 kJ/m^2 Impact Test	1.0 – 5.0 ∥ 3.0 – 20.0 ⊥	0.7 – 12.4	1.6 – 5.1	2.3 – 7.5	NA	2.2 – 2.8	0.5 – 1.2
Fatigue Resistance	K_{TH}/K_{IC}	0.52 – 0.84	0.45 – 0.90	0.37 – 0.92	NA	0.67	NA	0.50 – 0.97	0.14 – 0.36	0.10 – 0.40	0.53 – 0.62	0.30 – 0.83	NA	NA	NA	NA	NA	0.61
Biocompatibility	NA	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Marginal	Pass	Marginal	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Surface Phase Composition	%	100% α-Al_2O_3	42% - 54% t-ZrO_2	65% - 95% t-ZrO_2	83% - 93% t-ZrO_2	58% - 90% t-ZrO_2	95% - 99% t-ZrO_2	100% ß-Si_3N_4	NA	Mixture of α & ß Ti	Amorphous & Crystalline	Collagen and HAp	TiN Nanocrystals	Amorphous	ZrN Nanocrystals	TiN, NbN Nanocrystals	95% m-ZrO_2 5% t-ZrO_2	ACP, TCP, HA
LTD Susceptibility	NA	Stable	Marginal	Metastable (Y-TZP; Marginal (Ce-TZP)	Stable	Marginal	Metastable	Stable	Stable	Stable	Stable	NA	Stable	Stable	Stable	Stable	Stable	Purposely Unstable
Hardness	GPa	18.0 – 23.0	10.0 – 12.0	11.0 – 12.5	15.7 – 20.8	19	13.7 – 15.0	15.0	3.0 - 4.0	2.8 – 3.3	99 Rockwell M	0.68 – 0.78 ∥ 0.46 – 0.57 ⊥	33 – 56	14.5 – 80.0	14.0 – 31.0	14.0 - 24.5	12.0 – 14.0	3.0 – 9.0
Wear Rate PE HXLPE Hard-on-Hard	mm^3/MC	20 – 58 0.0 – 6.9 0.02 – 4.71	- 1.8 – 5.1 NA	11 – 63 5.0 – 6.0 Catastrophic	NA	1 – 20 0.1 – 4.4 0.00 – 0.45	17 - 32 5.6 – 6.1 0.02 – 0.06	17 - 25 3.7 – 6.3 0.18 – 0.98	14 – 201 0.0 – 11.7 0.18 – 25.00	NA	NA	NA	21 NA NA	28 – 67 2.8 NA	NA 3.5 NA	NA	- 0.2 – 1.7 NA	NA
Thermal Expansion Coefficient	10-6/°C	8	7 - 10	11	~8	8.1	~10	2.0 – 4.6	7.32	8.5 – 9.7	47	22.0 – 32.4	7.4 – 9.2	2.3	5.9 - 7.2	~7.4 – 9.2	7 – 10	11.6 – 14.2
Thermal Conductivity	W/m°K	30	2	2 – 3	~17	17	~6	30 - 50	12.7	6.7 - 7.0	0.29	0.41 – 0.63	11.9	0.2 – 30	20	~12 - 14	2 – 3	1.1 – 1.2
X-Ray Radiolucency	NA	Radiolucent	Opaque	Opaque	Opaque	Opaque	Opaque	Radiolucent	Opaque	Opaque	Transparent	Radiolucent	Opaque	Opaque	Opaque	Opaque	Opaque	Radiolucent
Sessile Water Contact Angle	Degree (°)	50 – 72	79	82	90	90	90	40 – 70	55 – 93	76	95	NA	31 - 69	55 – 71	89	73 - 75	71	34 – 39
Bacteriostatic Capabilities	⊕ = Excellent; + = Good; ∅ = Fair; ⊗ = Poor; × = Very Poor	∅	+	+	NA	+	NA	⊕	⊗	+	×	NA	+	+	⊕	NA	+	+
Osseointegration Ability		∅	+	+	NA	+	NA	⊕	⊗	+	×	⊕	+	+	⊕	NA	NA	⊕

[1] B.J. McEntire, B.S. Bal, M.N. Rahaman, J. Chevalier, and G. Pezzotti, "Ceramics and Ceramic Coatings in Orthopaedics," J. Eur. Ceram. Soc., **35** [16] 4327–4369 (2015).

SILICON NITRIDE FORMS

As Fired



5000x


Nano-scale topography, increased surface area
Ideal for: Bone on growth

Textured



100x

1000x


Customizable macro-scale topography
Ideal for: Grip, bone on growth

Porous

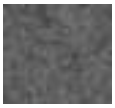


50x

1000x

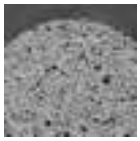

Up to 70% connective porosity with 100-700 µm pore size
Ideal for: Bone ingrowth

Polished



5000x


Ra ~ 5 nm, Hardness ~15 GPa
Ideal for: Bearing surfaces

Composite




Application-specific custom morphologies
Ideal for: Hybrid applications

SHARING OUR EXPERTISE

We have the scientific and manufacturing expertise to produce medical grade silicon nitride - a patented platform technology for use in a variety of medical applications. Silicon nitride is bioactive and compatible across all imaging modalities, offering surgeons and patients a preferable alternative to commonly used materials.

Let our leading R&D and manufacturing teams convert your existing medical devices into silicon nitride. With our unrivaled in-house capabilities, we are equipped to control complex geometries on a macro-, micro-, and nano-level, which allows for intricate designs and shapes that can be rapidly developed, prototyped, and tested in our FDA registered and ISO 13485 certified facility.

Contact us at **800.224.6113** or online at **intermedtn.com** to learn more.

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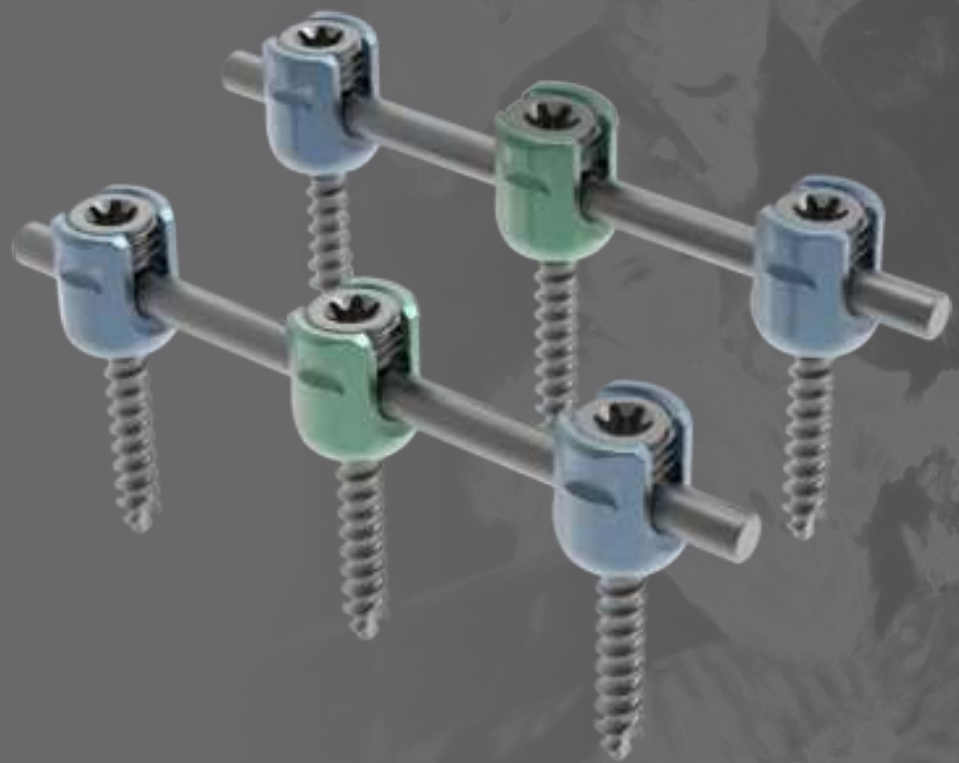
CALL **800.224.6113** OR VISIT US AT **INTERMEDTN.COM** TO DISCOVER WHY MATERIAL MATTERS.

RENOIR™

POSTERIOR CERVICO-THORACIC FIXATION PLATFORM

The RENOIR™ Posterior Cervico-Thoracic Fixation System consists of various rods, multi-application polyaxial screws and locking set screws to provide efficient and secure top-loading, rigid fixation.



Set Screw available in standard and cap with cap screw configuration to be used with crosslink

Polyaxial screw angulation ± 30°

Self-tapping screws with a pitch distance of 1.7mm

Trilobe Drive Feature for increased torque

Tulip height 10.6mm for a low profile construct

Curved rods additionally available

Lamina hooks additionally available upon request

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RENOIR™ Polyaxial Screws: 3.5mm Diameter

Part Number	Length(mm)
012.1408	8
012.1410	10
012.1412	12
012.1414	14
012.1416	16
012.1418	18
012.1420	20
012.1422	22

*longer screws available upon request

RENOIR™ Polyaxial Screws: 4.0mm Diameter

Part Number	Length(mm)
012.1510	10
012.1512	12
012.1514	14
012.1516	16
012.1518	18
012.1520	20
012.1522	22
012.1524	24

*longer screws available upon request

RENOIR™ Lamina Hooks: 3.5 Diameter

Part Number	Angle	Length(mm)
012.1816	Straight	16
012.1826	Right	17
012.1836	Left	18

RENOIR™ Cross Connectors

Size	Length(mm)
Small	30
Medium	35
Large	45

RENOIR™ Straight Rods: 3.5mm Diameter

Part Number	Length(mm)
012.1030	30
012.1040	40
012.1050	50
012.1060	60
012.1070	70
012.1080	80
012.1090	90
012.1100	100
012.1120	120
012.1200	200
012.1240	240

RENOIR™ Transition Rods: 3.5 - 5.5mm Diameter

Part Number	Length(mm)
012.0300	150mm
012.0400	200mm

RENOIR™ Set Screws

Part Number	Length(mm)
012.1404	Set Screw, Star, OD7 xL3.7mm
012.1405	Set Screw, Cap Head, Star, OD7 x L3.5mm

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VAN GOGH II™

ANTERIOR CERVICAL PLATING SYSTEM

VAN GOGH™ Anterior Cervical Plate System offers a low profile plate, robust screws, and intuitive instruments that are designed to provide a safe and streamlined procedural experience.

Available in a variety of sizes to accommodate anatomical varation

Multiple screw options and a high degree of angulation provide intraoperative flexability

Features a simple integrated screw head blocking mechanism

1.9mm thickness and 17mm width minimizes tissue disruption

Plate window for improved visualization

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VAN GOGH™ ACP System Plates: 1 Level

Part Number	Lordotic	Extra Lordotic	Length (mm)
011.1012	X		12
011.1014	X		14
011.1016	X		16
011.1018	X		18
011.1020	X		20
011.1022	X		22
011.1024	X		24
011.1026	X		26
011.1028	X		28
011.1062		X	12
011.1064		X	14

VAN GOGH™ ACP System Plates: 2 Level

Part Number	Lordotic	Extra Lordotic	Length (mm)
011.2024	X		24
011.2026	X		26
011.2028	X		28
011.2030	X		30
011.2032	X		32
011.2034	X		34
011.2036	X		36
011.2038	X		38
011.2040	X		40
011.2042	X		42
011.2044	X		44
011.2046	X		46
011.2124		X	24
011.2126		X	26

VAN GOGH™ ACP System Plates: 3 Level

Part Number	Lordotic	Extra Lordotic	Length (mm)
011.3039	X		39
011.3042	X		42
011.3045	X		45
011.3048	X		48
011.3051	X		51
011.3054	X		54
011.3057	X		57
011.3060	X		60
011.3063	X		63
011.3066	X		66
011.3069	X		69
011.3139		X	39

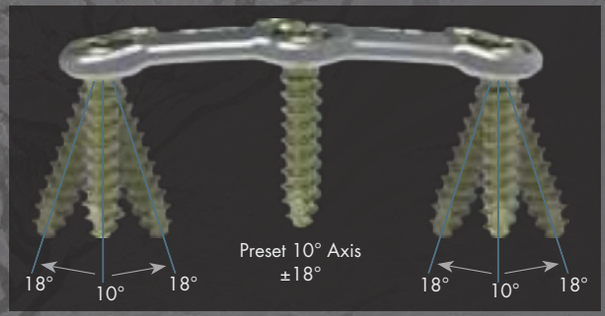
* 4 & 5 Levels available upon request

VAN GOGH™ Screws: Self-Tapping

Variable		Fixed			
Part Number	Color	Part Number	Color	Diameter (mm)	Length (mm)
011.0410	Blue	011.0810	Grey	4.0	10
011.0412	Blue	011.0812	Grey	4.0	12
011.0414	Blue	011.0814	Grey	4.0	14
011.0416	Blue	011.0816	Grey	4.0	16
011.0418	Blue	011.0818	Grey	4.0	18
011.0420	Blue	011.0820	Grey	4.0	20
011.0462	Aqua	011.0862	Bronze	4.5	12
011.0464	Aqua	011.0864	Bronze	4.5	14
011.0466	Aqua	011.0866	Bronze	4.5	16
011.0468	Aqua	011.0868	Bronze	4.5	18
011.0470	Aqua	011.0870	Bronze	4.5	20

VAN GOGH™ Screws: Self-Drilling

Variable		Fixed			
Part Number	Color	Part Number	Color	Diameter (mm)	Length (mm)
011.0210	Gold	011.0610	Green	4.0	10
011.0212	Gold	011.0612	Green	4.0	12
011.0214	Gold	011.0614	Green	4.0	14
011.0216	Gold	011.0616	Green	4.0	16
011.0262	Purple	011.0662	Magenta	4.5	12
011.0264	Purple	011.0664	Magenta	4.5	14
011.0266	Purple	011.0666	Magenta	4.5	16



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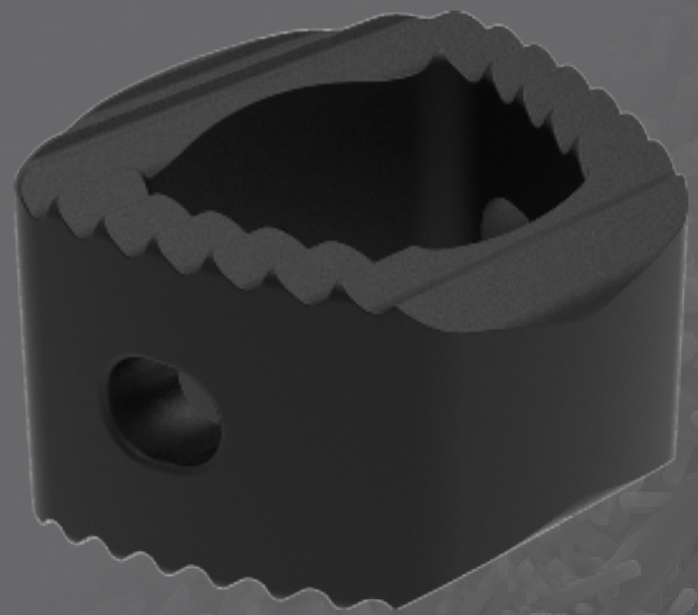
VALEO II C

SILICON NITRIDE

ANTERIOR CERVICAL
INTERBODY FUSION DEVICES

In the race to achieve interbody fusion, material matters. And no material fosters an environment for faster fusion like silicon nitride. Featuring the ability to achieve superior new bone growth and osseointegration, along with proven bacteriostatic properties and enhanced imaging attributes, silicon nitride outperforms PEEK and titanium.



Nanotopography enhances osteoblast response, initiating faster fusion

Optimal material density enables radiotranslucent and reduced artifact imaging

Surface chemistry generates bacteriostatic properties

IMPLANT FOOTPRINTS AND SIZES

FOOTPRINTS:
14x12mm [6°]
16x14mm [6°]

HEIGHTS:
5-10mm, 1mm increments

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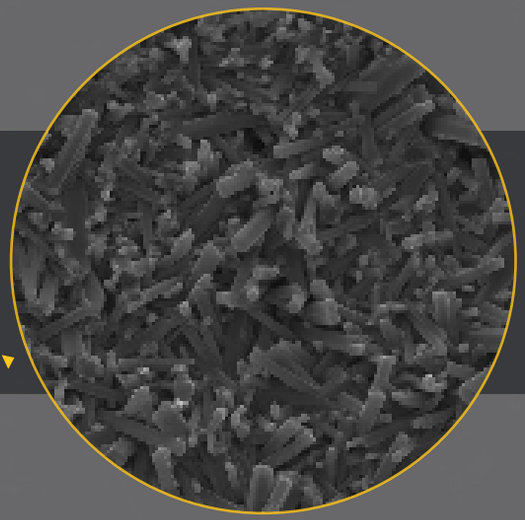
THE IDEAL BIOMATERIAL

SILICON NITRIDE

Silicon nitride has the ability to achieve superior new bone growth. Along with anti-microbial properties and enhanced imaging capabilities, silicon nitride is the ideal biomaterial.



Silicon nitride's nano-texture surface at 10 microns

Faster Fusion Rates

Compared to PEEK and titanium, silicon nitride demonstrates greater new bone formation[1] and has an innate nanotopography and surface chemistry that provides an optimal environment for bone growth. The surface chemistry initiates bone growth, while the instrinsic nanotopography increases surface area. This combination of initiating bone growh with increased surface area enhances osteoblast response, accelerating the fusion process.

Enhanced Imaging Capabilities

Silicon nitride implants are radiotranslucent with visible boundaries and produce no artifact under CT or MRI; this enables an exact view of the implant for precise intraoperative placement and post-operative fusion assessment.

Proven Bacteriostatic Properties

The negative surface charge of silicon nitride repels bacteria and prevents biofilm formation[2], reducing the chance of infection. The hydrophilic surface creates a molecular water barrier preventing the adhesion of bacteria.

REFERENCES:

1. Webster TJ, Patel AA, Rahaman MN, et al. Anti-infective and osteointegration properties of silicon nitride, poly(ether ether ketone), and titanium implants. Acta Biomater. 2012;8(12):4447-4454. doi: 10.1016/j.actbio.2012.07.038. Epub 2012 Jul 31.
2. Gorth DJ, Puckett S, Ercan B, et al. Decreased bacteria activity on Si_3N_4 surfaces compared with PEEK or titanium. Int J Nanomedicine. 2012;7:4829-4840.

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MATISSE™

ANTERIOR CERVICAL
INTERBODY FUSION DEVICES

The MATISSE™ ACIF cage platform is engineered to accommodate a wide range of patient anatomies and surgeon preferences and is available in various footprints, heights and lordotic angles.

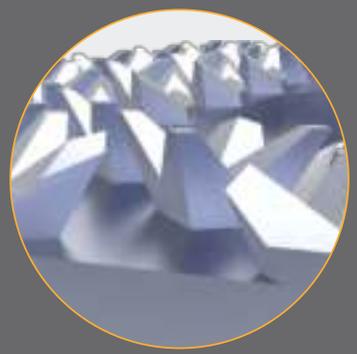
Design that accomodates various patient anatomies and resists migration

PEEK cages built with distinct radiographic markers helping to ensure proper implant placement

Large graft window allows for maximum graft volume

TiCro™-PEEK cages are manufactured with a titanium end plate shell and radioluscent PEEK bodies to promote adhesion and improved imaging

Tapered leading edge for ease of insertion



The proprietary **TiCro®** design offers significantly greater surface area, improving endplate contact.

This unique surface geometry enhances bone interlocking properties and helps to ensure cage placement.

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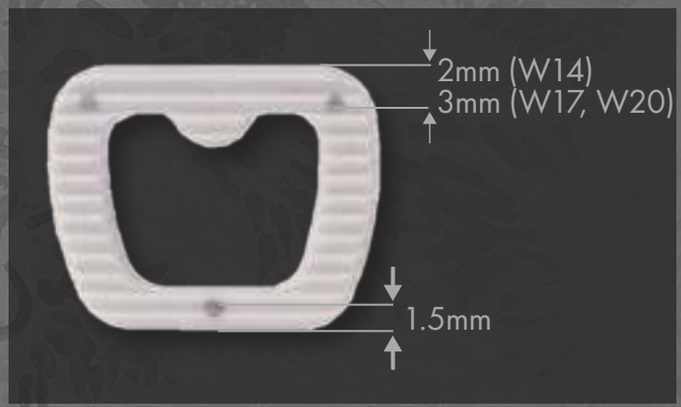
MATISSE™ W14 x L12mm Cages: 6 Degree

PEEK	TiCro™	TiCro-PEEK	
Part Number	Part Number	Part Number	Height
013.4115	013.0205		5
013.4116	013.0206	013.1406	6
013.4117	013.0207	013.1407	7
013.4118	013.0208	013.1408	8
013.4119	013.0209	013.1409	9
013.4120	013.0210	013.1410	10

* 11mm and 12mm heights additionally available

MATISSE™ W17 x L14mm Cages: 6 Degree

PEEK	TiCro™	TiCro-PEEK	
Part Number	Part Number	Part Number	Height
013.4155	013.0605		5
013.4156	013.0606	013.1806	6
013.4157	013.0607	013.1807	7
013.4158	013.0608	013.1808	8
013.4159	013.0609	013.1809	9
013.4160	013.0610	013.1810	10



* 20mm x16mm footprint additionally available upon request

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