K2M

COMPLEX SPINE INNOVATIONS™

SURGICAL TECHNIQUE

ALEUTIAN® & CAYMAN®

ALEUTIAN ANTERIOR-LUMBAR (ALIF) INTERBODY SYSTEM
CAYMAN BUTTRESS & ANTERIOR PLATE SYSTEMS

ALEUTIAN® ANTERIOR - LUMBAR

CAYMAN® BUTTRESS

CAYMAN® ANTERIOR

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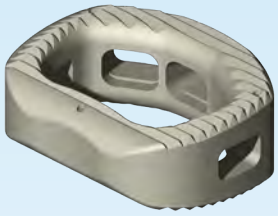
FEATURES & BENEFITS

ALEUTIAN ANTERIOR-LUMBAR (ALIF) INTERBODY SYSTEM



IMPLANTS

- 24 x 30 & 28 x 36 mm Footprints Available to Accommodate Patients' Varying Anatomies
- 5°, 10°, & 15° Lordotic Options
- Designed to Allow for a Large Grafting Space
- Provides Three Points of Insertion to Facilitate Direct Anterior, Anterolateral, & Direct Lateral Surgical Approaches
- Manufactured of Biocompatible PEEK Polymer
- Radiopaque Tantalum Markers in the Implant to Visually Confirm Placement Radiographically
- Hollow, Fenestrated Geometry to Allow for Bony Ingrowth
- Self-retaining Teeth for Gripping the Endplates & Resisting Expulsion
- Large Range of Implant Heights to Accommodate Differing Anatomy Sizes

INSTRUMENTS

- Anterior Insertion Ramp: Unique Insertion Tool That Allows for Parallel Distraction & Controlled, Threaded Insertion of the Implant
- Variety Of Curette Options: Facilitate the Removal of the Disc, Nucleus Pulposus, & Cartilaginous Endplate
- Rongeurs, Rasps, Osteotomes, & Cobbs: Available for the Preparation & Decortication of the Cartilaginous Endplates
- Disc Spreaders: Distract to Facilitate Access to the Disc Space
- Trials: Used to Select the Appropriate Implant Size Without Disrupting the Anatomy of the Vertebral Bodies

FEATURES & BENEFITS

CAYMAN BUTTRESS PLATE SYSTEM

PLATES

- 20, 22, & 24 mm Plate Lengths
- Reduces Risk of Graft Expulsion

SCREWS

- Self-Tapping Screws Available in Ø6.0 mm & 22, 26, & 30 mm Lengths

***tifix*® Locking Technology**

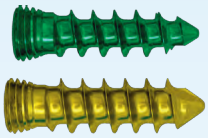
- Utilizes *tifix* Locking Technology, a One-step Locking Mechanism in Which the Screw Forms an Autogenic Lock to the Plate
- No Additional Locking Mechanism
- Screws May be Adjusted up to Three Times Without Compromising the Locking Mechanism

FEATURES & BENEFITS

CAYMAN ANTERIOR PLATE SYSTEM

PLATES

- Assortment of Plate Lengths to Address Varying Anatomy
- Pre-contoured With a Radius & Lordosis to Match the Spinal Anatomy
- Maintains Compression & Fixation Across the Interbody or Bone Graft



SCREWS

- Self-Tapping Ø6.0 & Ø7.0 mm Screw Options, Color Coded by Diameter
- Selection of Various Screw Lengths in Each Diameter

***tifix* Locking Technology**

- Utilizes *tifix* Locking Technology, a One-step Locking Mechanism in Which the Screw Forms an Autogenic Lock to the Plate
- No Additional Locking Mechanism
- Screws May be Adjusted up to Three Times Without Compromising the Locking Mechanism

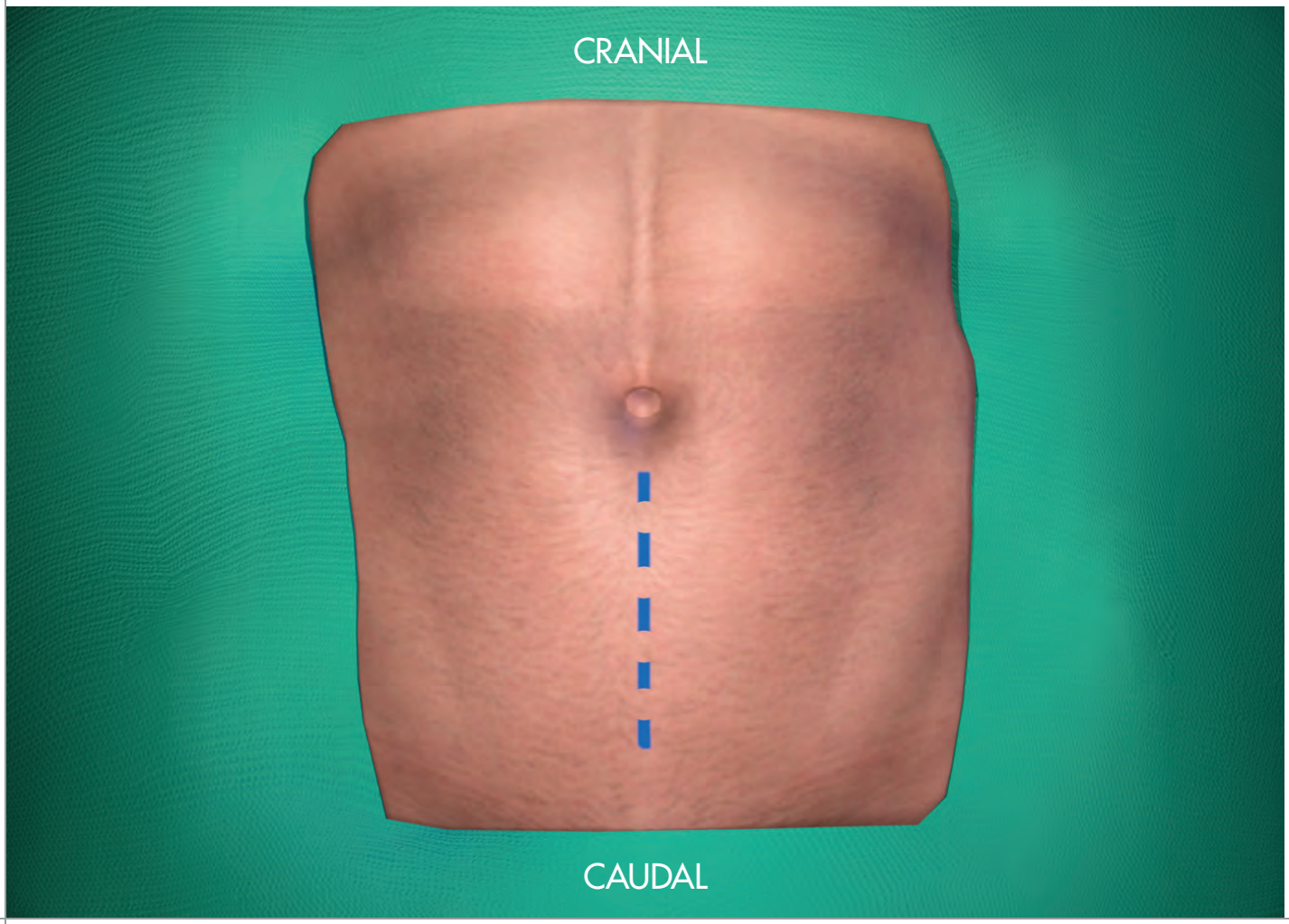
ALEUTIAN ALIF SURGICAL TECHNIQUE

STEP 1

PLANNING, APPROACH, & PATIENT POSITIONING

Pre-surgical planning defines the type of construct, the most appropriate implants, and the optimal implant location.

The ALEUTIAN ALIF set is designed to facilitate anterior, anterolateral, and direct lateral surgical approaches.

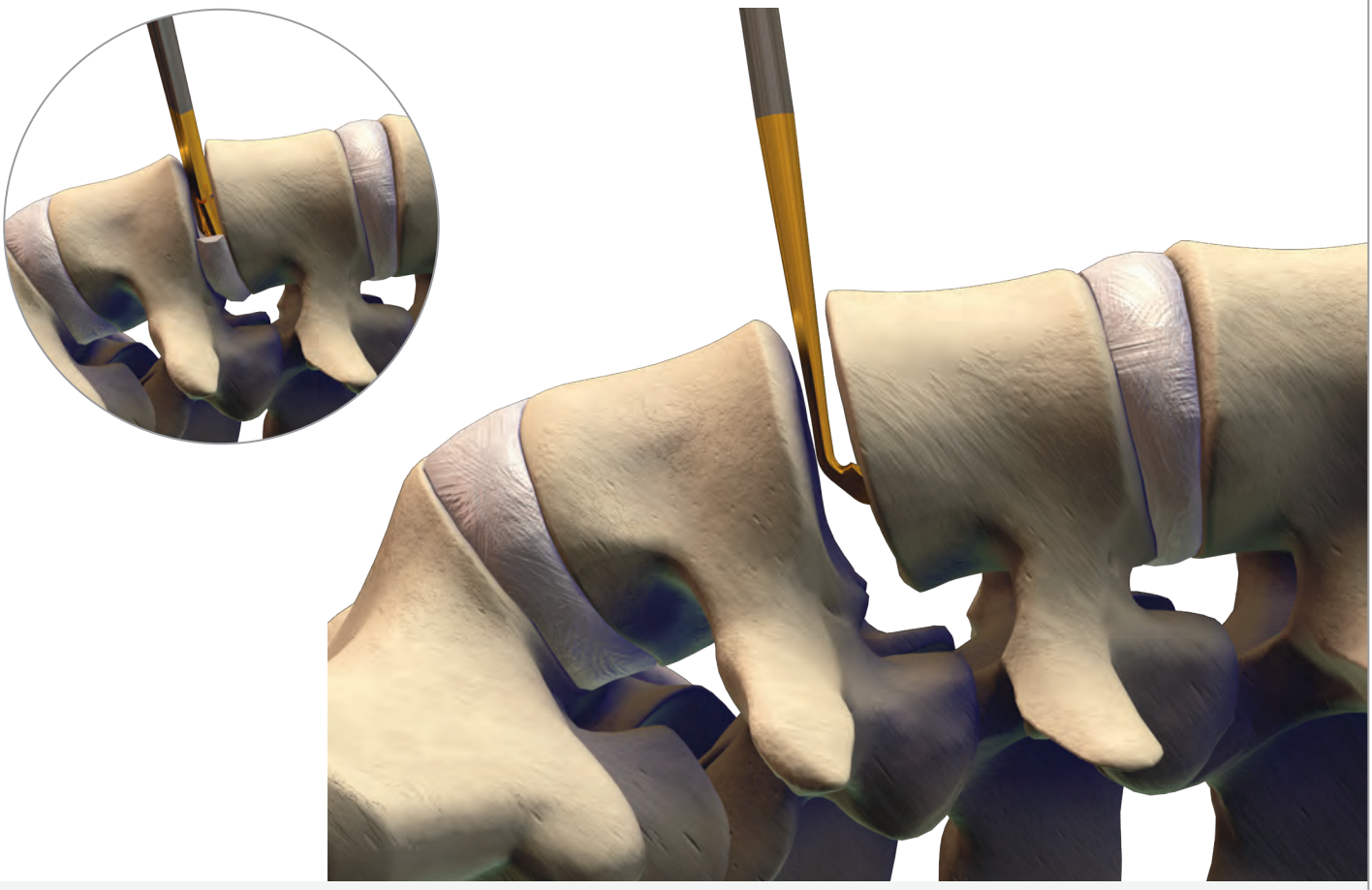


STEP 2

DISCECTOMY & ENDPLATE PREPARATION

A selection of disc preparation instruments is available to facilitate a complete discectomy and to decorticate the vertebral endplates. These instruments include a variety of cup style Curettes, Pituitary Rongeurs, Rasps, Chisels, and Cobbs.

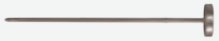
NOTE: For a complete listing of instrument options, please see the Product Catalog.



#4 FORWARD ANGLED CURETTE

4 mm ANTERIOR PITUITARY RONGEUR 45°

CURETTE CONNECTOR SHAFT



8 mm DOUBLE ACTION RONGEUR

CHISEL

CURETTE HANDLE

CONVEX RASP

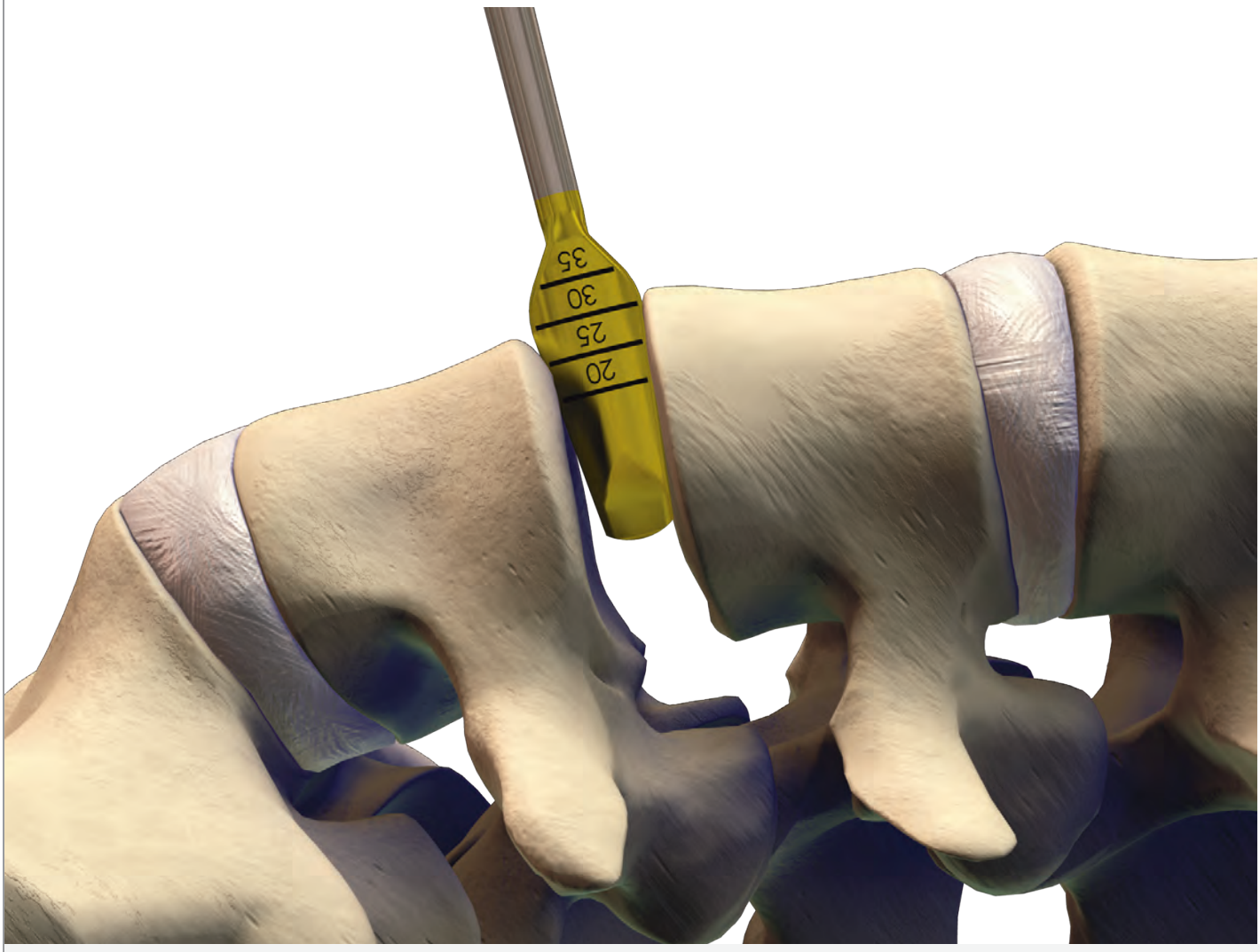
SMALL COBB

STEP 3

DISC ELEVATION

A Disc Spreader may be inserted as a temporary spacer while additional preparation is performed on the contralateral side. Modular Disc Spreaders, which connect to a Fixed T-Handle, are included in the set.

A starter size of 5 mm is available for initial distraction. Sizes increase sequentially thereafter from 7–19 mm in 2 mm increments. Distraction is performed until the appropriate height is achieved.



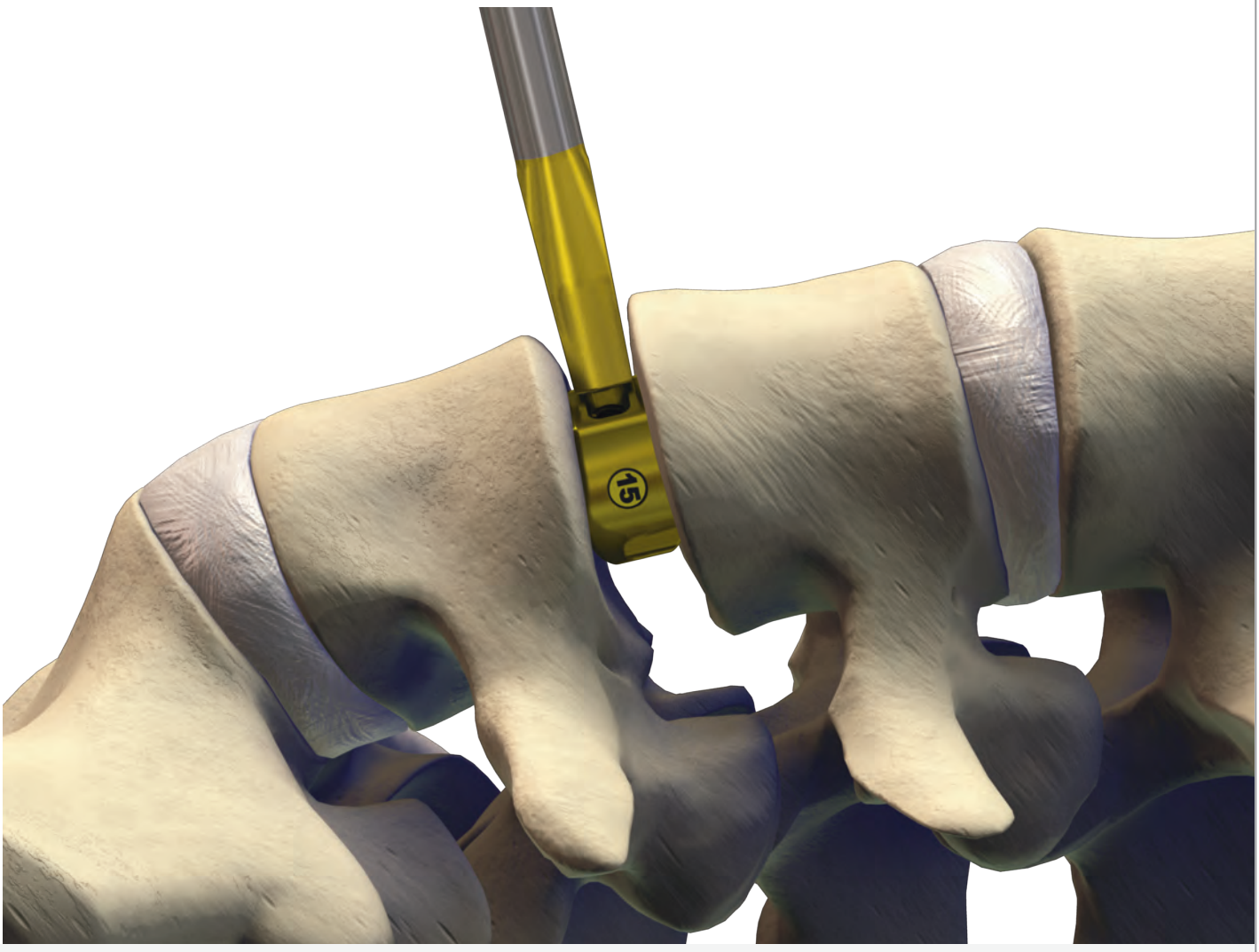
DISC SPREADER

FIXED T-HANDLE

STEP 4

DETERMINING INTERBODY SIZE

Trials are available in 5°, 10°, and 15° of lordosis to aid in initial test fitting and size confirmation of the interbody. Load the Trial onto the distal end of the Trial Inserter. The thumbwheel, located on the proximal end of the Trial Inserter, is turned in a clockwise direction to secure the Trial. Trials are 0.5 mm undersized to allow for a slight press fit of the implant. If the Trial appears to be too small, gradually increase the size until a secure fit is achieved.



15 mm 24 x 30 mm 5° TRIAL

TRIAL INSERTER

STEP 5

INTERBODY SELECTION

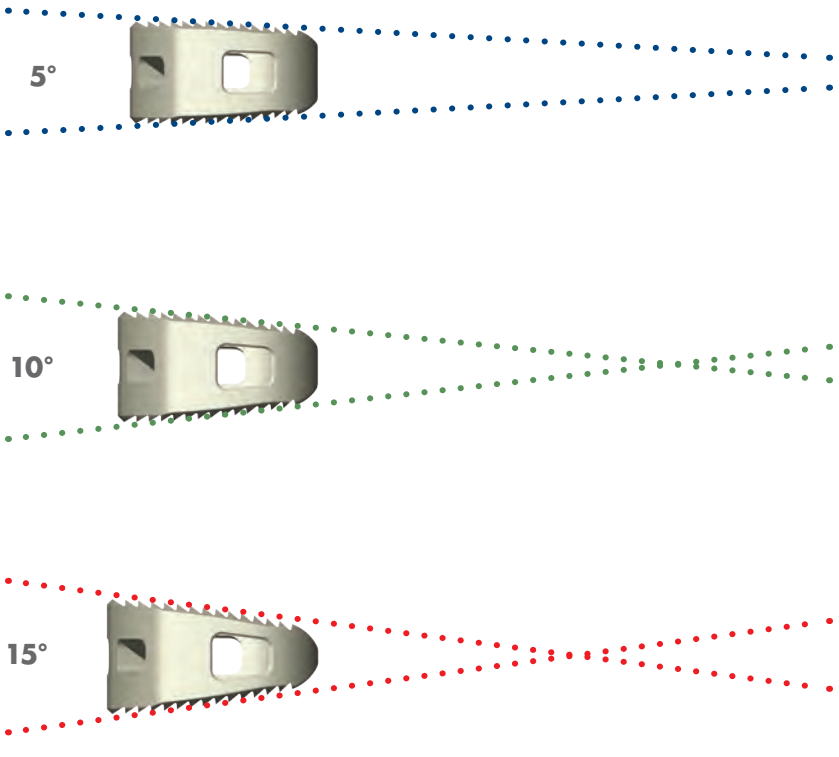
An appropriately sized interbody is chosen at the discretion of the surgeon; one which is securely seated with a tight fit between the endplates when the segment is fully distracted. Implants are sized at 24 x 30 and 28 x 36 mm footprints and are available in 5°, 10°, and 15° lordotic angles in heights ranging from 9–19 mm in 2 mm increments.*

The interbodies are included in color-coded caddies for ease of size identification. The height of the interbody is measured from tip-of-tooth to tip-of-tooth.

The implant should be packed with bone graft to facilitate the fusion process.

24 x 30 mm

28 x 36 mm



*9 mm only available in 5° & 10°, 21 mm available upon request.

STEP 6

INTERBODY INSERTION: OPTION 1 – ANTERIOR INSERTION RAMP

The Anterior Insertion Ramp utilizes a controlled threaded mechanism that provides parallel distraction, resulting in a zero-impact load on the implant.
To ensure proper use of the Anterior Insertion Ramp, complete the following steps:

1. Adjust the countersink depth by rotating the knurled countersink thumbwheel behind the countersink depth bar. Countersink may be adjusted from 0–6 mm.
2. Hold the instrument vertically to allow the distraction ramps to open.
3. Place the selected interbody onto the tip of the distal end of the instrument.
4. Finger-tighten by turning the knob at the proximal end of the inserter clockwise to engage the interbody.

NOTE: To avoid damaging the tips that hold onto the interbody, do not turn the knob at the proximal end of the Anterior Insertion Ramp without an interbody attached.

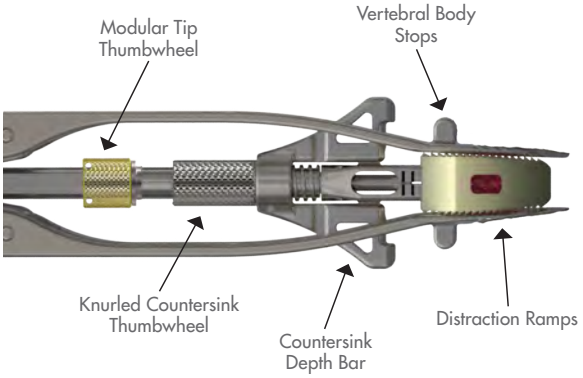
ALEUTIAN Modular Tip

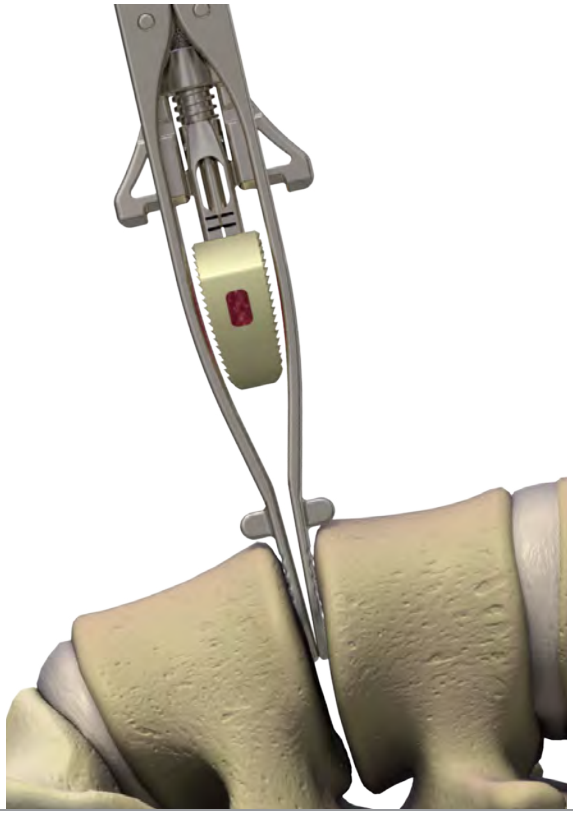
Anterior Insertion Ramp

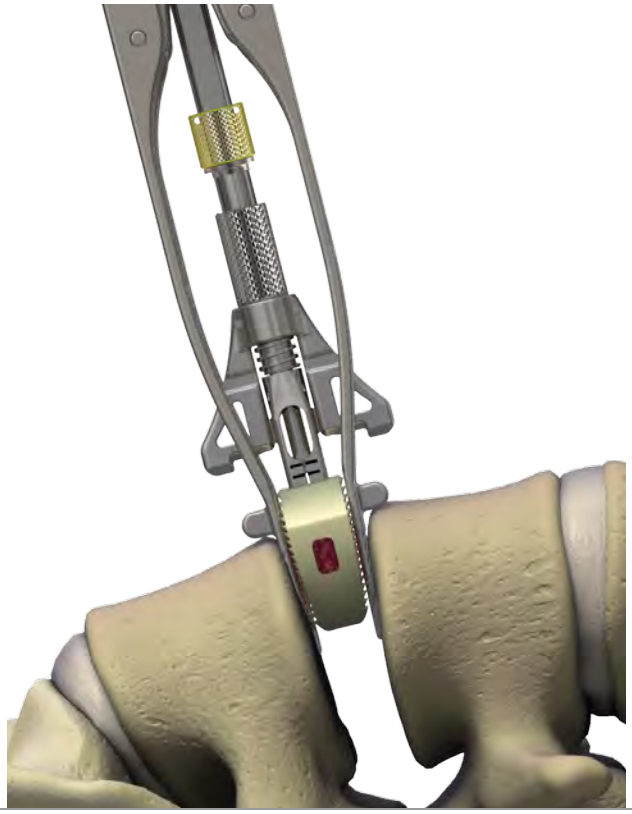
STEP 6

INTERBODY INSERTION: OPTION 1 – ANTERIOR INSERTION RAMP (CONT.)

5. Once the interbody is fully tightened, rotate the entire instrument 180° to allow gravity to close the distraction ramps.
6. Place the distal end of the distraction ramps into the disc space until the verterbral body stops make contact with the anterior portion of the vertebral body.
7. Turn the T-Handle clockwise to advance the interbody into the disc space.
8. When the countersink depth bar makes contact with the vertebral bodies, the Anterior Insertion Ramp will begin to remove itself from the disc space while placing the interbody to pre-set countersink depth.
9. Turn the knob at the proximal end of the inserter counter-clockwise to disengage the interbody.
10. Remove the Anterior Insertion Ramp from the surgical wound.





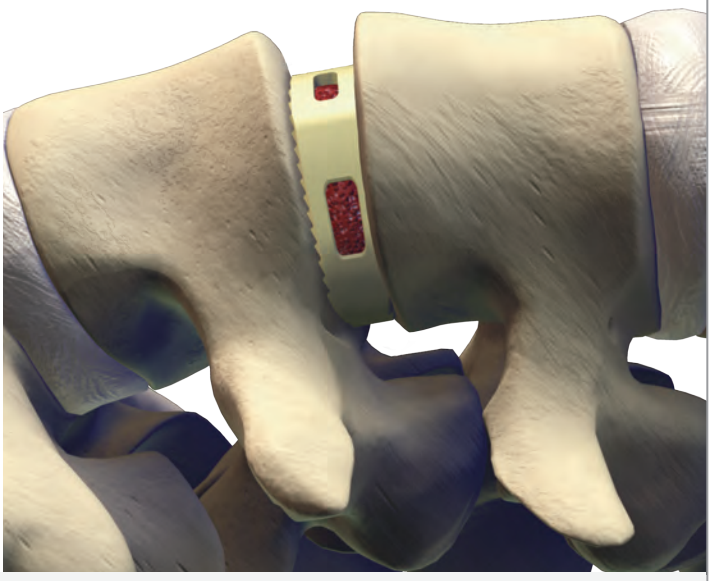


INTERBODY INSERTION: OPTION 2 – IMPLANT INSERTER

Load the interbody onto the Implant Inserter. Turn the thumbwheel on the proximal end of the Implant Inserter in a clockwise direction to secure the interbody. The Large Mallet or Slap Hammer may be used to aid in implant placement. X-ray or fluoroscopy may be used live or periodically to verify placement. The interbody is disengaged by turning the thumbwheel on the proximal end of the Implant Inserter counterclockwise.

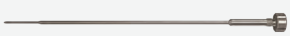
Care must be taken to protect the vascular elements before removing the Implant Inserter from the surgical site. For fine adjustments of the interbody, the In-Situ Adjuster may be utilized to move the implant posteriorily. If needed, the Removal Tool may be used to adjust or remove the implant.

NOTE: To help prevent graft expulsion or for additional anterior support, use the CAYMAN Buttress or Anterior Plate System. See the following sections for additional surgical instructions.



ALEUTIAN IMPLANT INSERTER

ALEUTIAN IMPLANT INSERTER – INNER SHAFT



SLAP HAMMER

MALLET

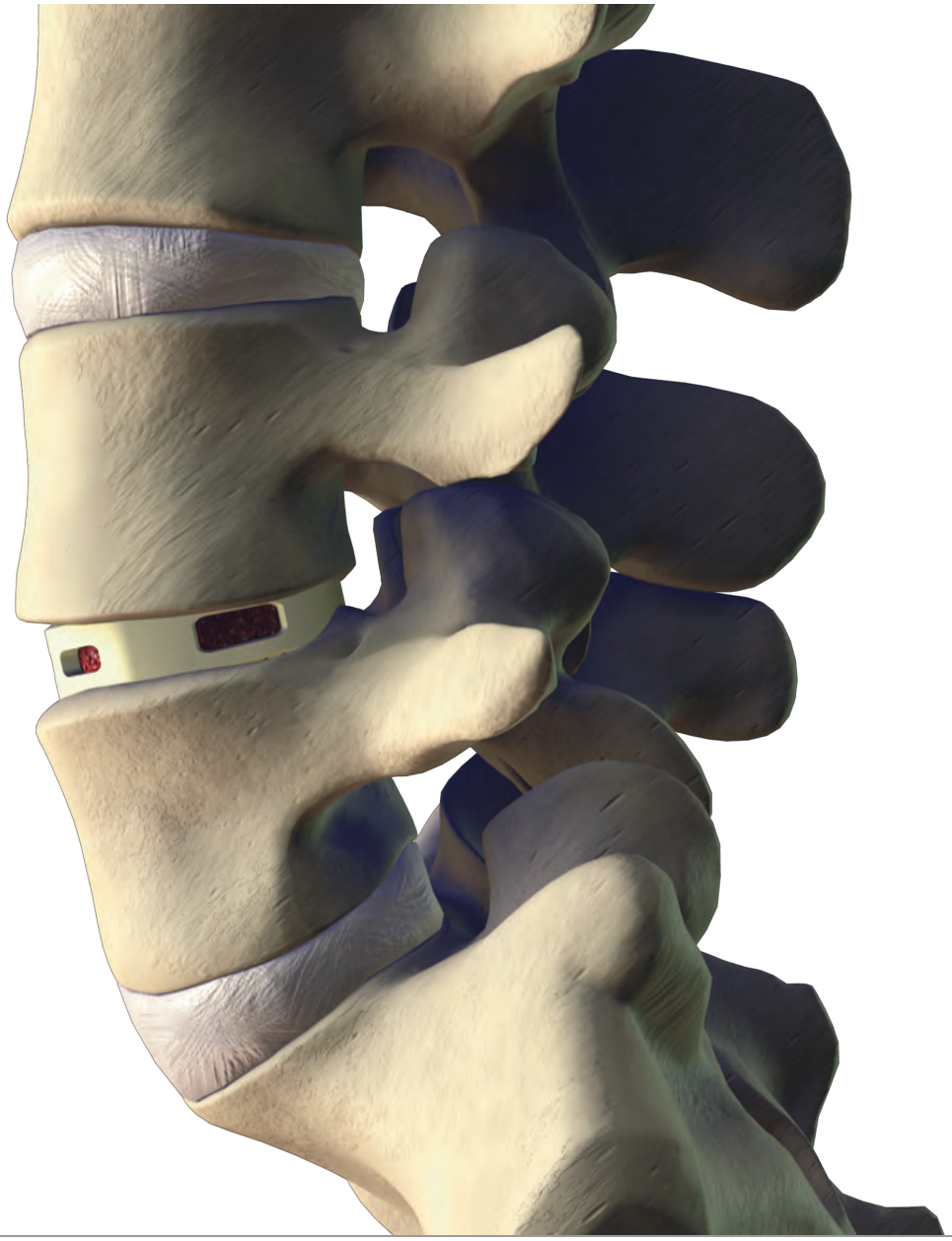
CAYMAN BUTTRESS SURGICAL TECHNIQUE

STEP 1

EXPOSURE & VERTEBRAL BODY PREPARATION

Ensure the ALEUTIAN Interbody or bone graft is properly positioned in the disc space and retraction of vessels is maintained.

Prepare the anterior surface of the vertebral body to achieve a smooth surface. This will allow the plate to sit flush against the vertebral body.



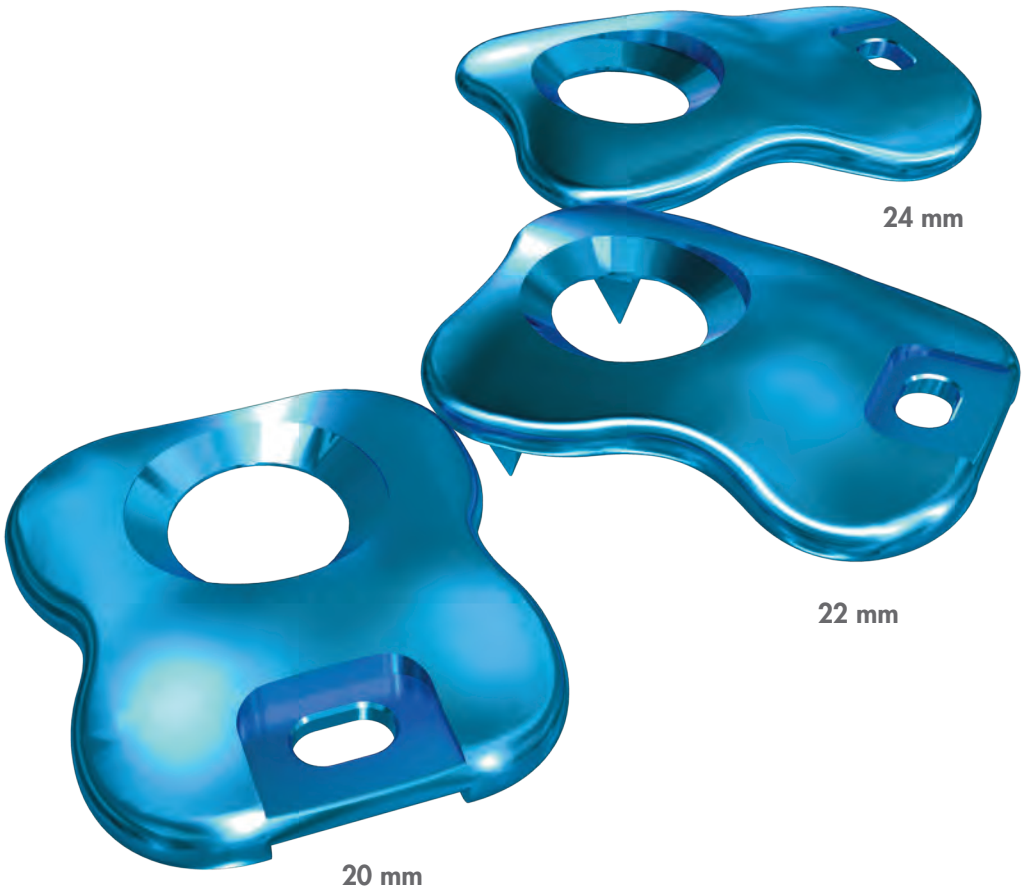
STEP 2

BUTTRESS PLATE SELECTION

Select the correct plate and screw size to best fit the application.

When considering plate length, note that the plate should be positioned so 50–75% of the disc space is covered by the plate to prevent graft expulsion.

Plate Length	20 mm
	22 mm
	24 mm
Screw Length (Ø6.0 mm)	22 mm
	26 mm
	30 mm



STEP 3

BUTTRESS PLATE INTRODUCTION

Using the Plate Holder, insert the distal tip into the slot at the base of the selected CAYMAN Buttress Plate and squeeze the handle to grip the plate tightly.

With the plate secured by the Plate Holder, press firmly onto the vertebral body so the prongs are fully seated and the plate sits flush to the bone.

NOTE: If the plate cannot be fully seated with the Plate Holder, the screw will reduce the plate to the bone during screw insertion.

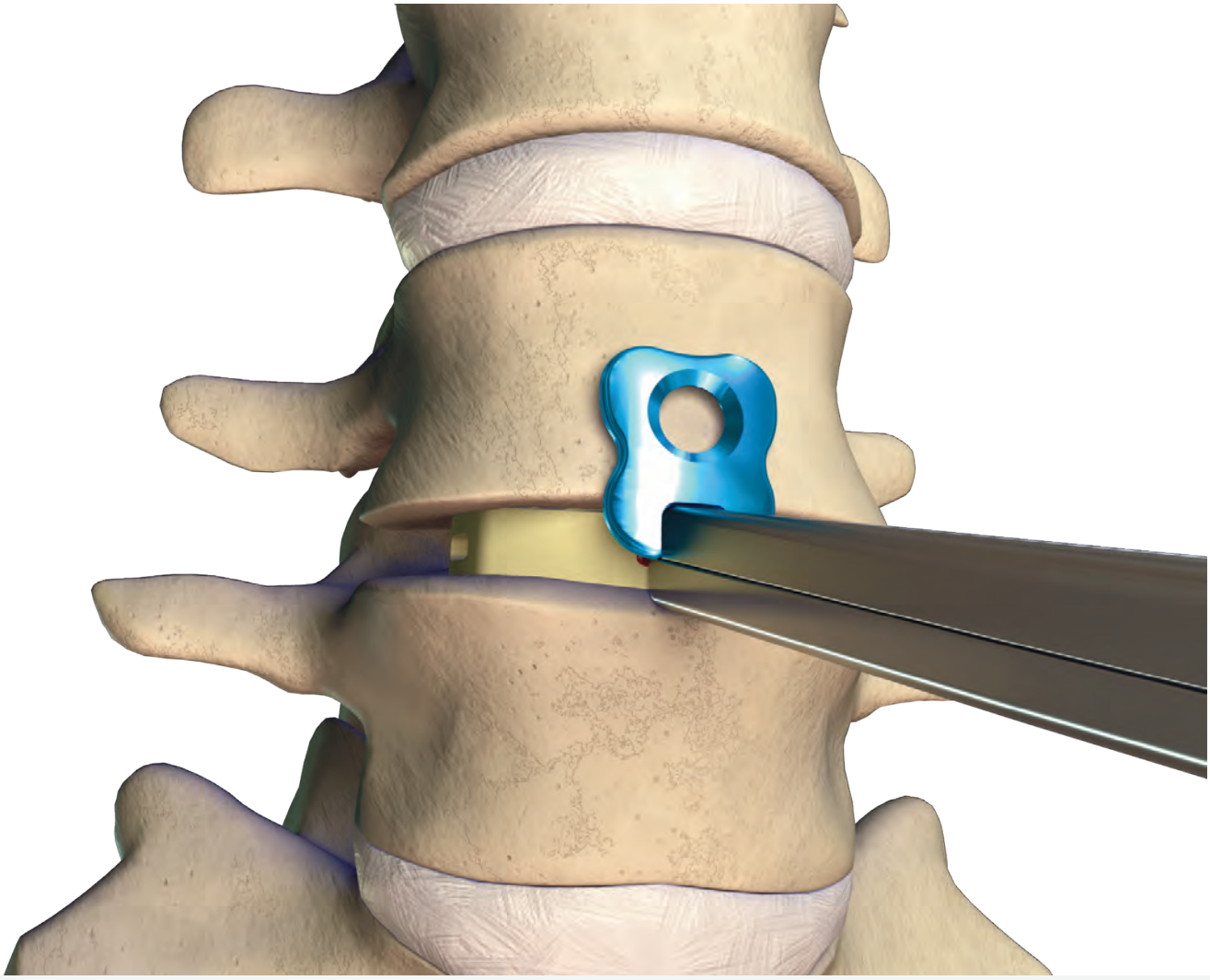
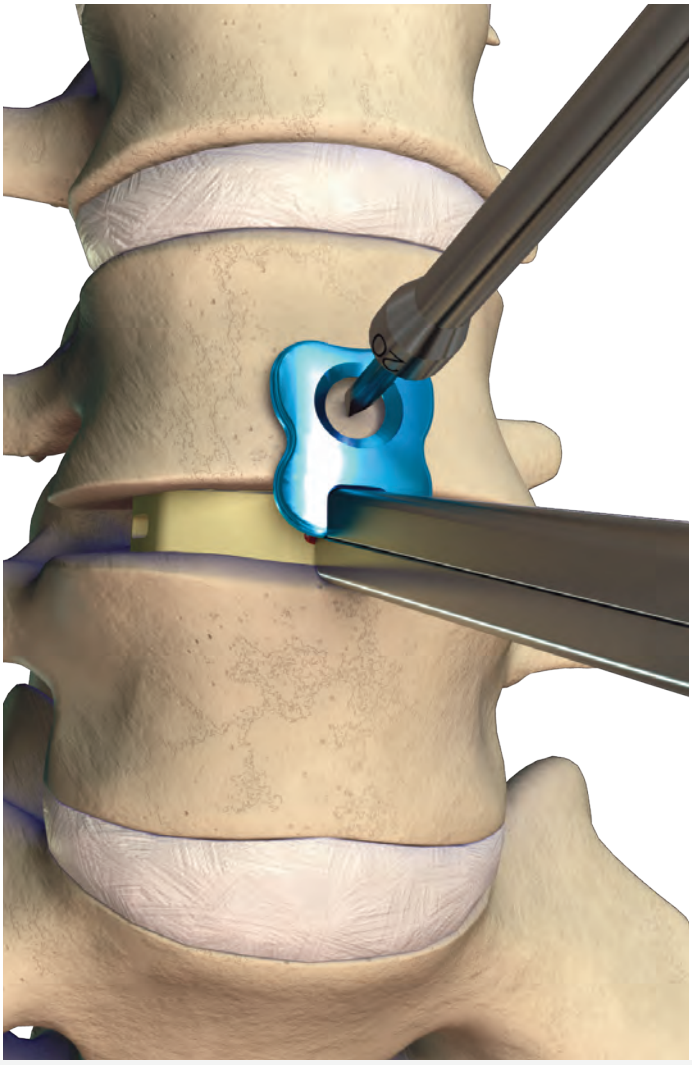


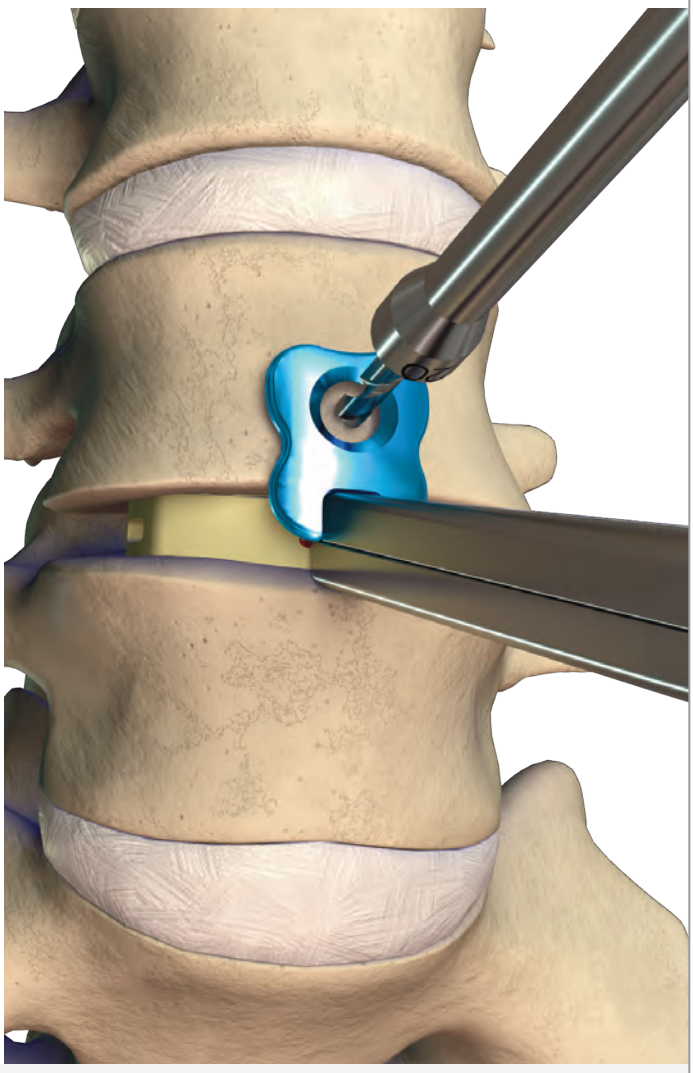
PLATE HOLDER

STEP 4

HOLE PREPARATION

Once the plate is situated, attach the 20 mm Awl to the aqua-colored Ratcheting Hudson Handle and perforate the vertebral body to create a pilot hole. If preferred, use the 20 mm Drill attached to the Ratcheting Hudson Handle to create a path for the screw.





RATCHETING HUDSON HANDLE

FREEHAND AWL

FREEHAND DRILL

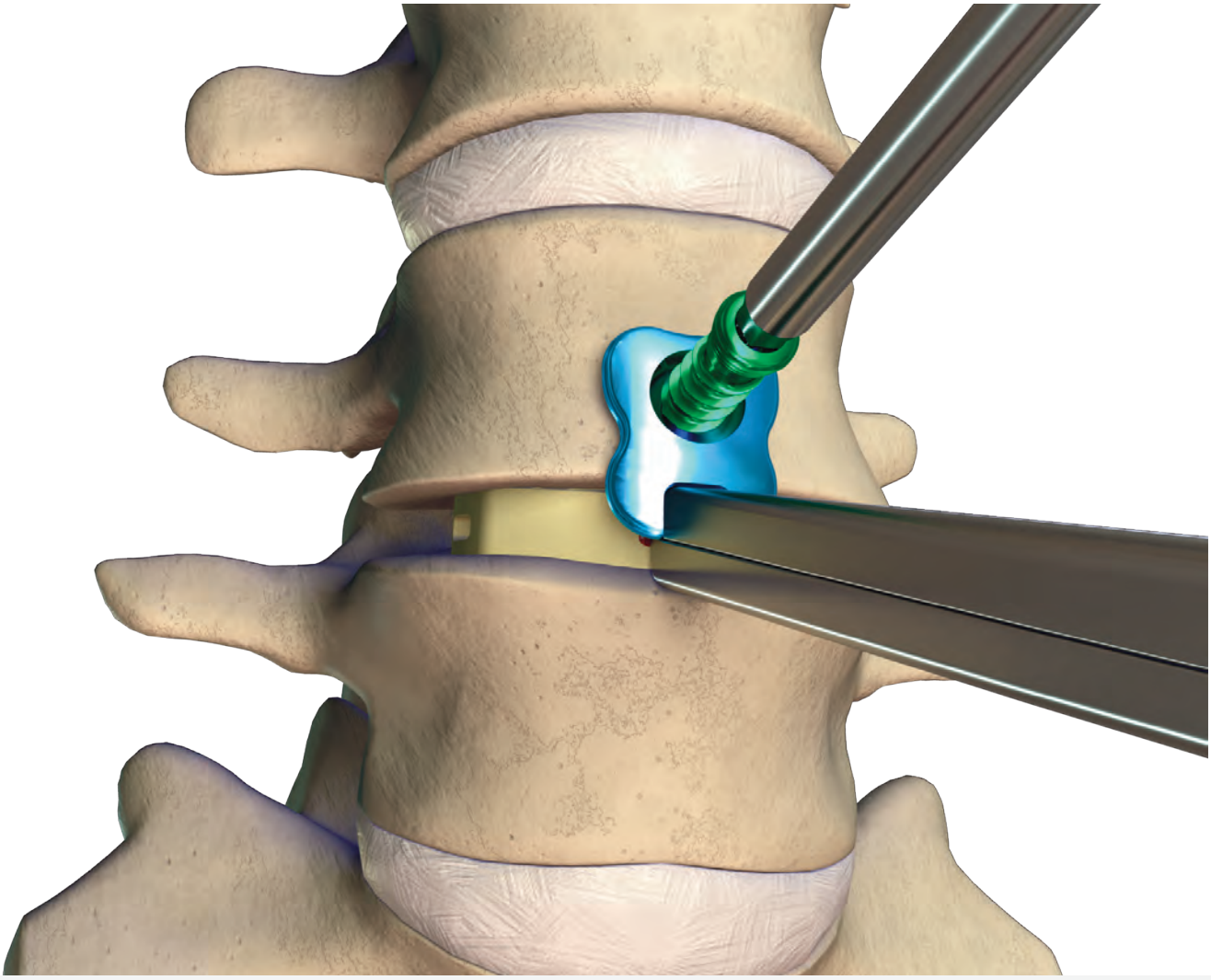
STEP 5

SCREW INSERTION

Connect the Size 25 Driver to the Ratcheting Hudson Handle. Proceed to load the CAYMAN Screw onto the tapered tip at the distal end of the Driver.

With a firm grasp on the Plate Holder, which serves as an anti-torque device, tighten the screw until it makes contact with the plate.

NOTE: The screw can be inserted at a conical angulation of 15°, or up to 7.5° in any direction, and lock to the plate.



SIZE 25 DRIVER

STEP 6

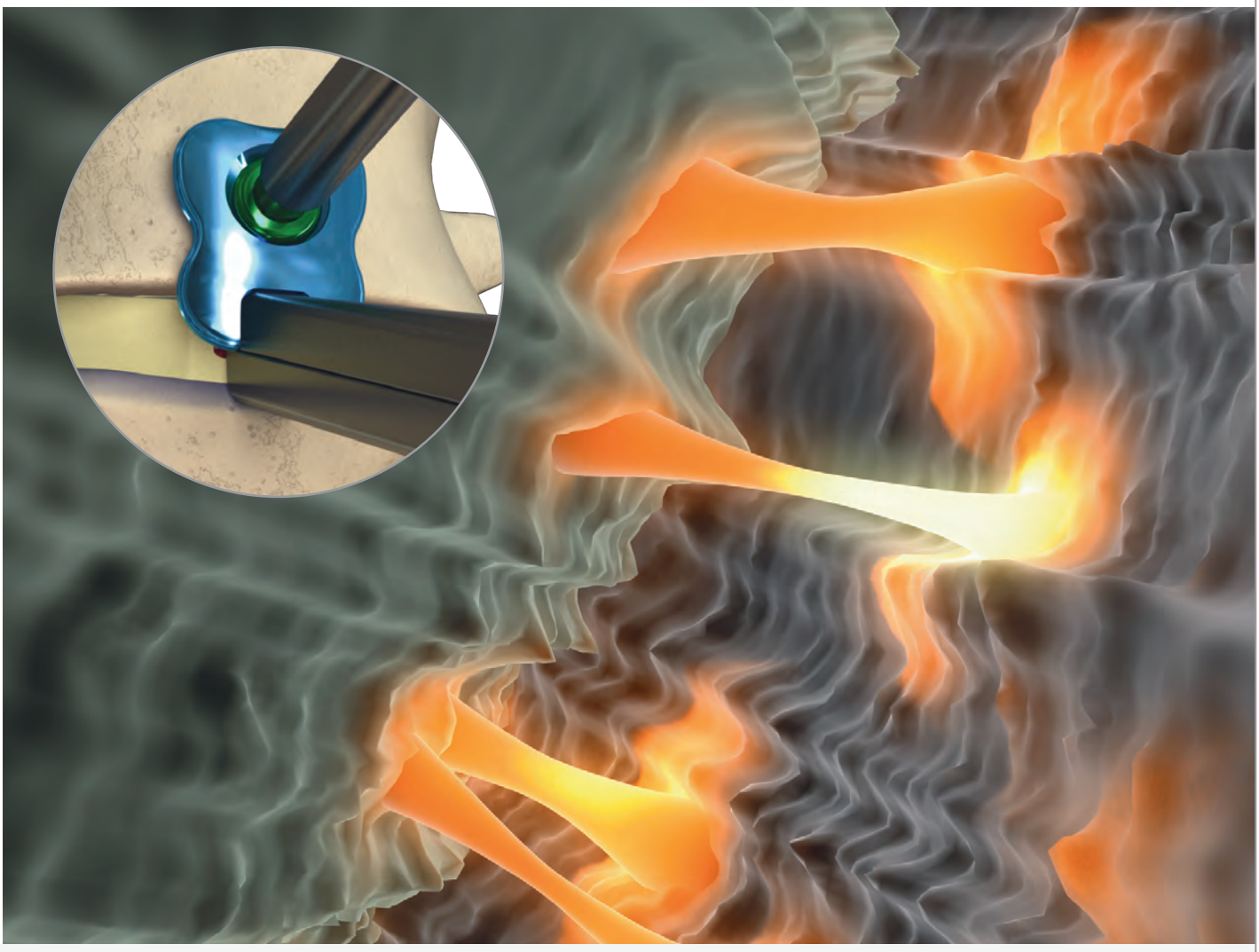
FINAL LOCKING

When the screw head engages on the locking lip of the plate, the plate will lag down to the bone and the revolutionary *tifix* Locking Technology will commence. Due to a difference in material hardness and design, the screw head begins to deform the plate through a reshaping process, and forms an autogenic lock to the plate.

To final lock the screw, use the black Torque Limiting Handle with the Size 25 Driver.

The Torque Limiting Handle emits an audible "click" at 35 in-lbs to signify the screw has formed an autogenic lock with the plate. Use of the Torque Limiting Handle further ensures the screw is not over tightened. No additional locking step is required.

NOTE: Optionally, if realignment or removal of the screw is required after final tightening, the screw may be unlocked using the Ratcheting Hudson Handle and the Size 25 Driver. The screw may be locked and unlocked up to three times without compromising the locking mechanism.

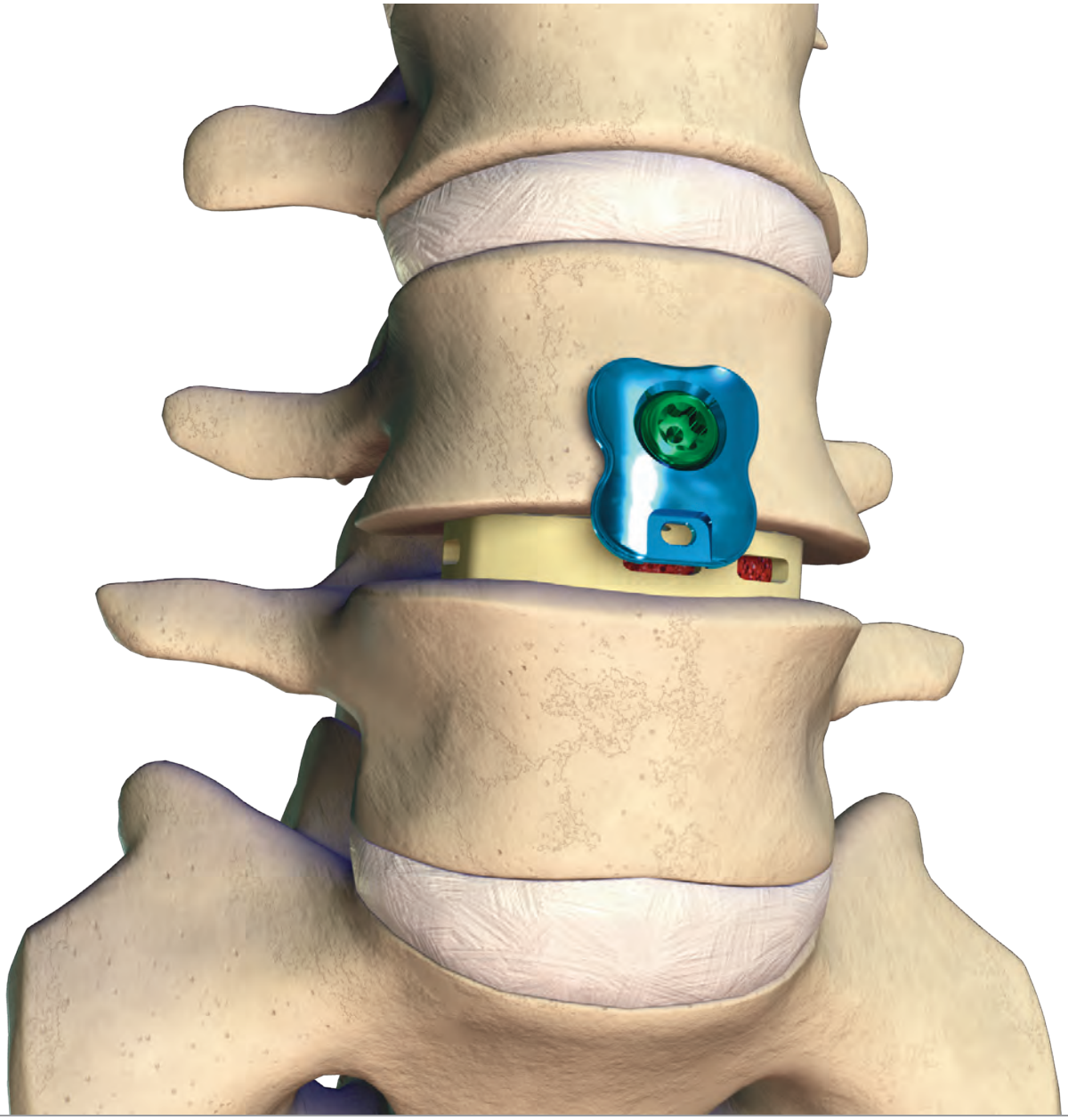


TORQUE LIMITING HANDLE

STEP 7

WOUND CLOSURE

When the construct is completed, perform a standard, multi-layer wound closure.



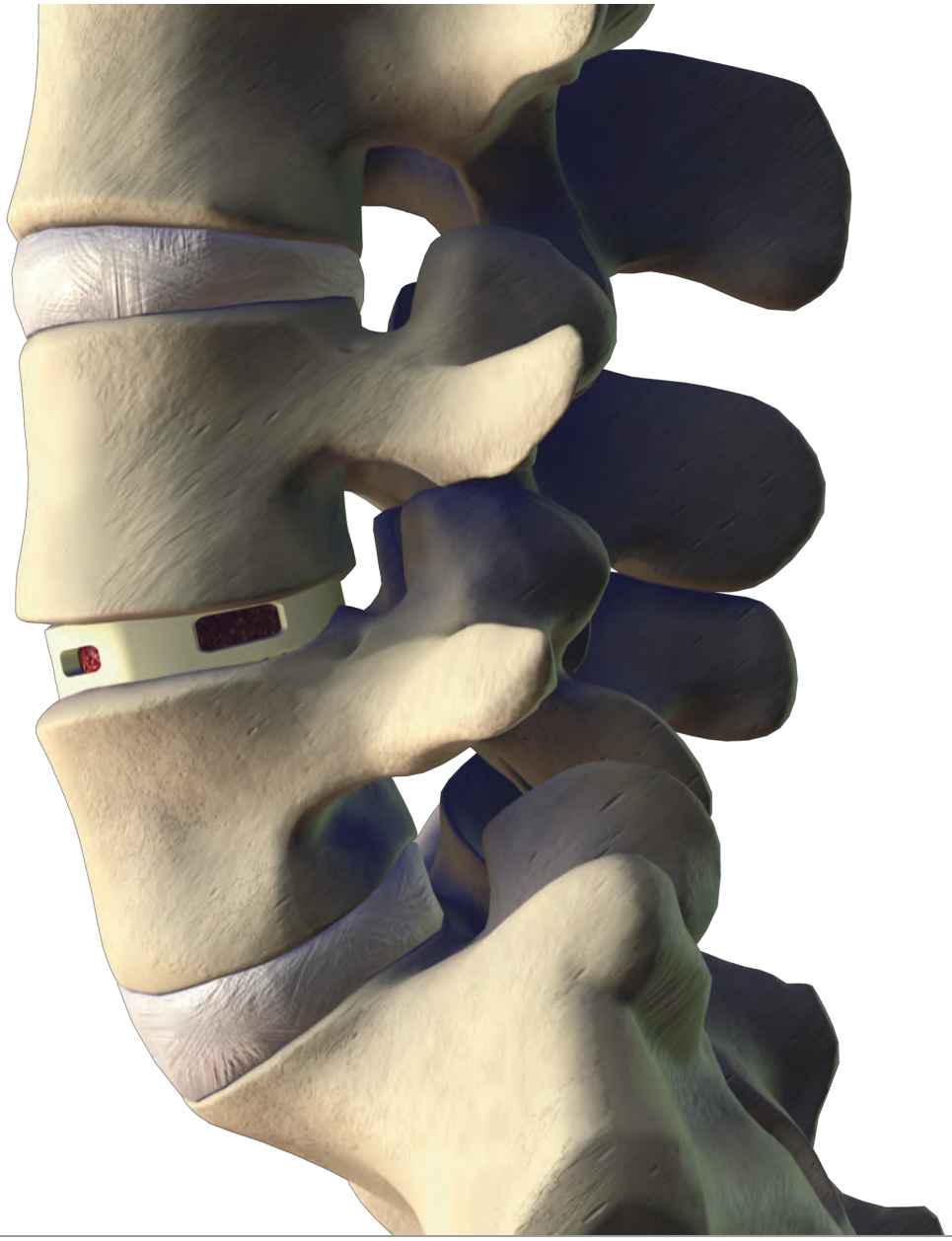
CAYMAN ANTERIOR SURGICAL TECHNIQUE

STEP 1

EXPOSURE & VERTEBRAL BODY PREPARATION

Ensure the ALEUTIAN Interbody and bone graft is properly positioned in the disc space and retraction of vessels is maintained.

Prepare the anterior surface of the vertebral body to achieve a smooth surface. This will allow the plate to sit flush against the vertebral body.



STEP 2

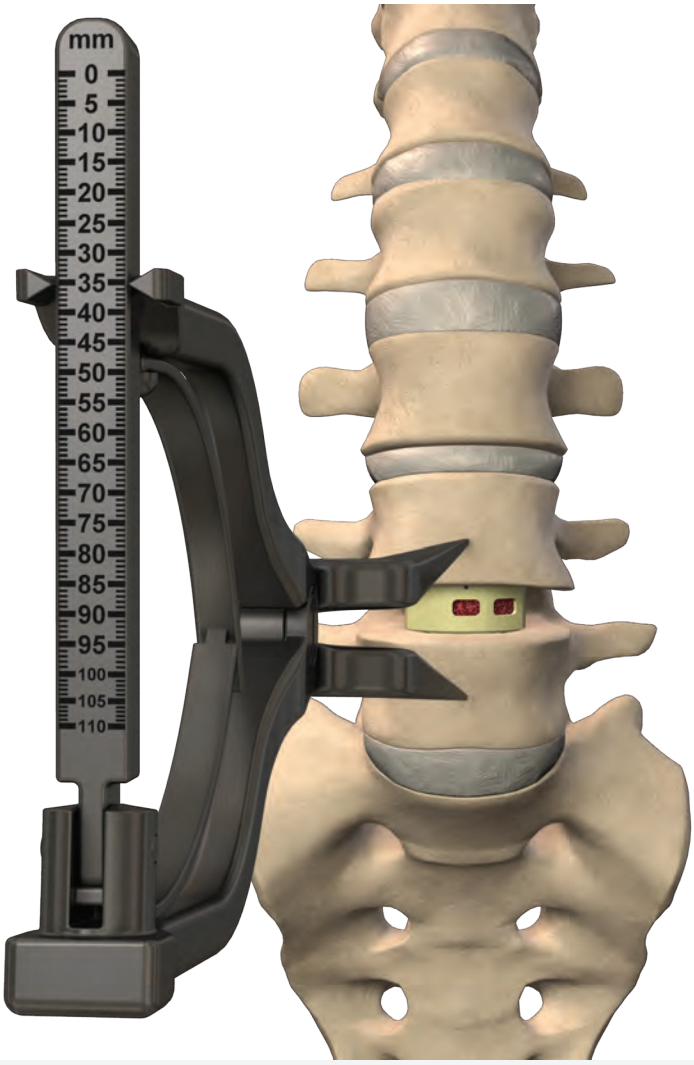
ANTERIOR PLATE SELECTION & PLACEMENT

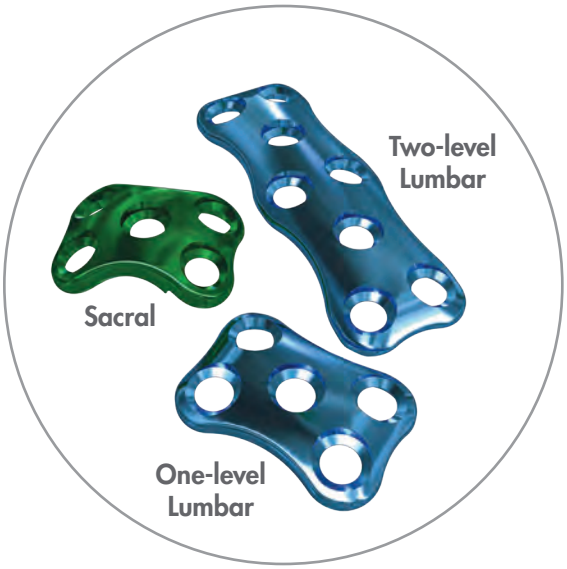
Select the correct plate and screw lengths to best fit the application. The appropriate plate length is selected by placing the tips of the 110 mm Caliper on the vertebral bodies at the anticipated plate length. The correct length should be closest to the indicated length for the number of levels being fused.

Be sure the plate does not extend over the adjacent disc spaces.

A properly sized plate will allow access to both screw holes at each end of the plate.

Plate Type	Lengths
Sacral	32–46 mm
One-level Lumbar	32–46 mm
Two-level Lumbar	74–100 mm





110 mm CALIPER

STEP 3

PLATE CONTOURING

Plates are designed with a radius and a lordotic curvature to minimize intraoperative contouring. A Plate Bender is available to contour the plate to better match the patient's anatomy. The Plate Bender may be used to add additional lordosis or kyphosis to the plate. All plates can be bent anatomically without impairing the ability of the screws to lock at any angle, eliminating bend zones.

LUMBAR PLATE BENDER

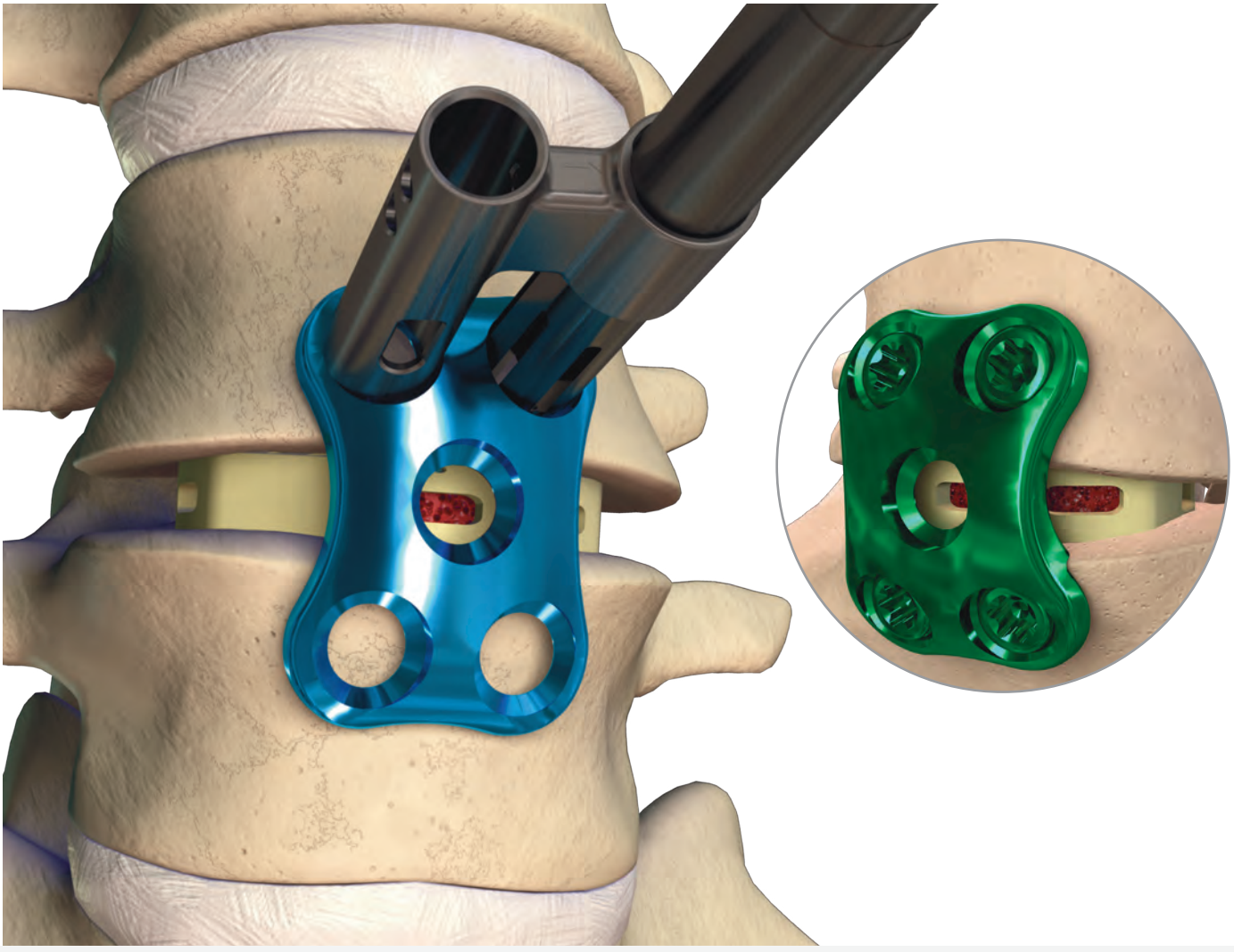
STEP 4

PLATE INTRODUCTION

Use the Plate Holder to introduce the plate into the body. To connect the Plate Holder to the plate, place the Holder in the preferred screw hole on the plate and turn the proximal thumbwheel clockwise to tighten it.

If used in conjunction with the Screw- Thru Drill Guide, position the Plate Holder and the Drill Guide in adjacent holes on the end of the plate.

NOTE: When inserting the Sacral Plate, the ridge of the plate should rest on the sacral promontory in order to reduce movement of the plate during screw insertion.



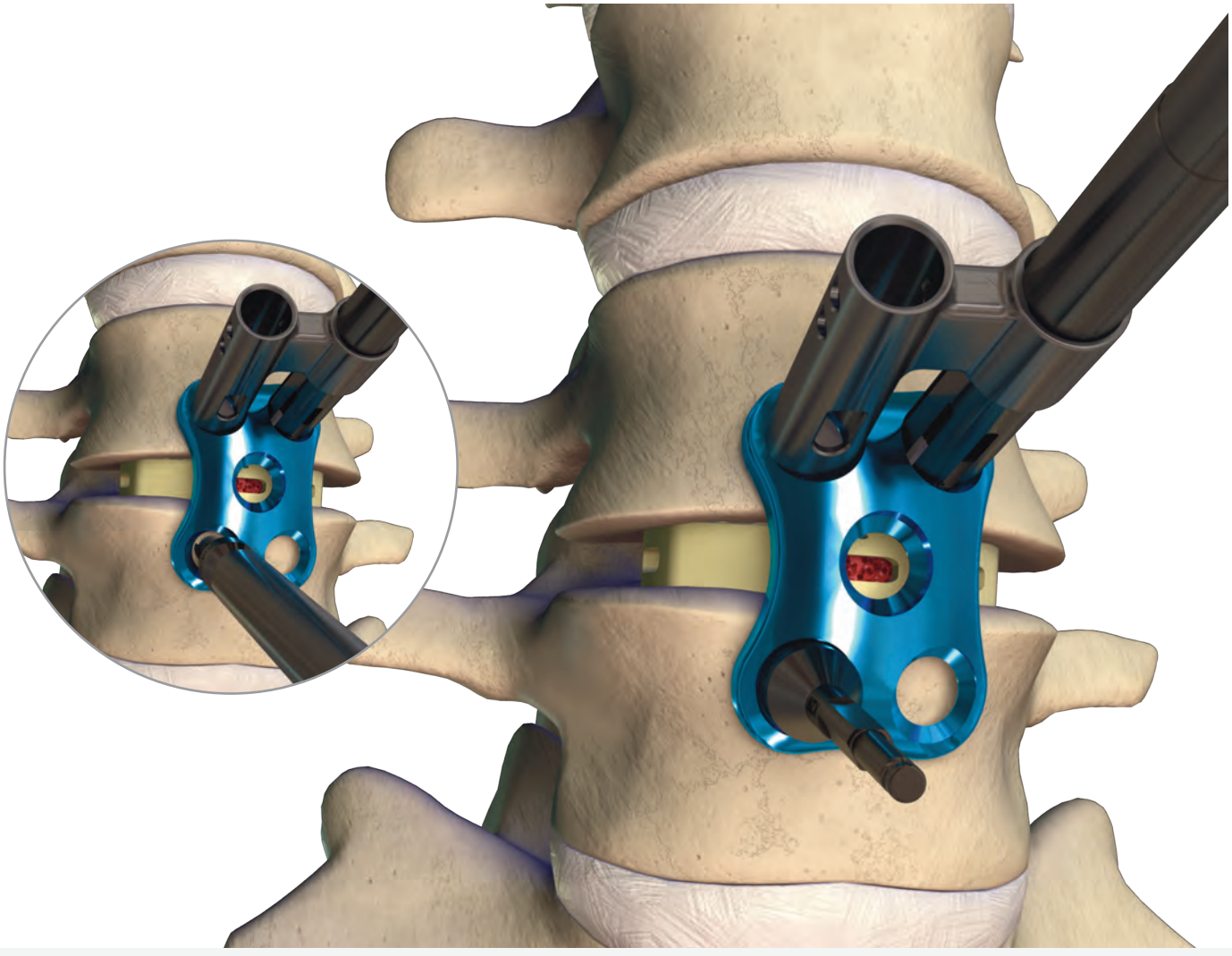
SCREW-THRU DRILL GUIDE

PLATE HOLDER

STEP 5

OPTIONAL STEP: TEMPORARY FIXATION PIN

After the plate has been properly positioned on the anterior lumbar spine, Smooth or Threaded Temporary Fixation Pins may be used to temporarily secure the plate to the vertebra. Pull back on the shaft of the Temporary Pin Inserter to engage the Pin, and once inserted, repeat to disengage the Pin.



SMOOTH TEMPORARY FIXATION PIN

THREADED TEMPORARY FIXATION

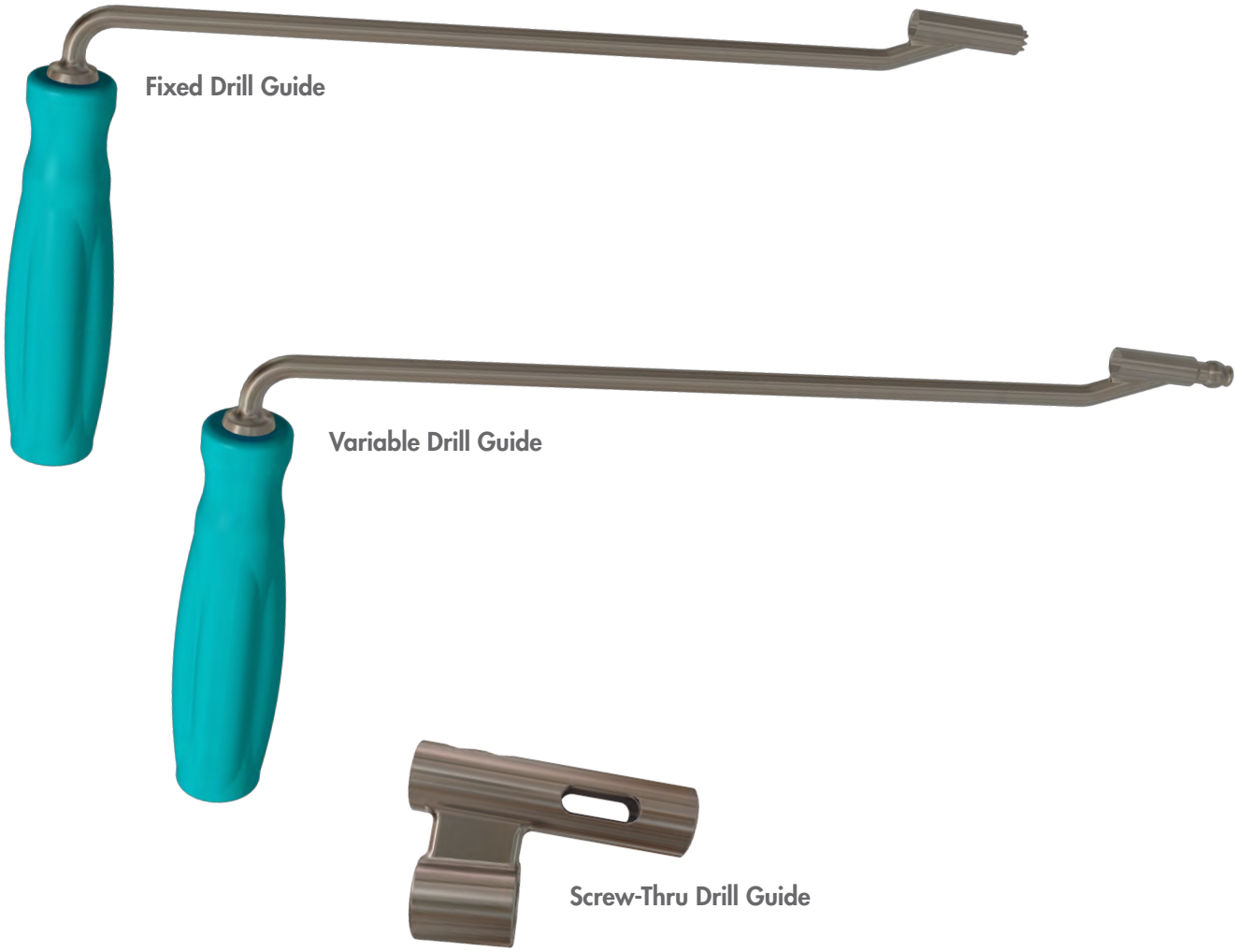
TEMPORARY PIN INSERTER

STEP 6

DRILL GUIDES

Three drill guides are available for use; a Fixed Drill Guide, a Variable Drill Guide, and a Screw-Thru Drill Guide.

The Screw-Thru and Fixed Drill Guides are used to drill at a fixed trajectory of 6° on the Lumbar Plates, and 15° on the Sacral Plate in the cephalad and caudal screw holes. The Variable Drill Guide is designed to accommodate up to 15° of conical angulation for drilling.



Fixed Drill Guide

Variable Drill Guide

Screw-Thru Drill Guide

STEP 7

CREATE PILOT HOLE & DRILL VERTEBRAL BODY

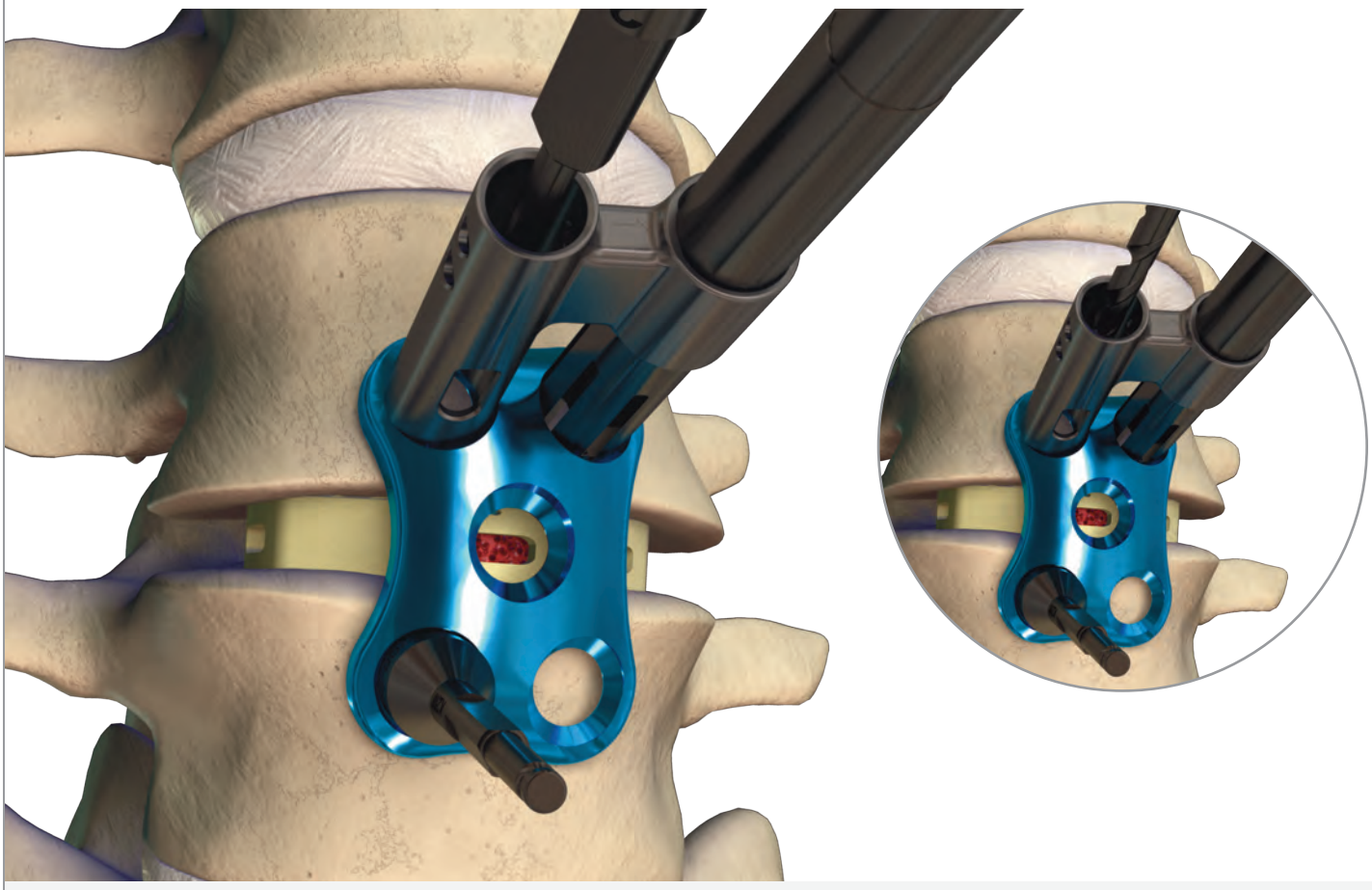
If preferred, the 20 mm Spring Loaded Awl or the 20 mm Fixed or Freehand Awl may be used to perforate the vertebral body.

Select the Ø3.5 or 4.5 mm x 20 mm Drill and attach it to the aqua-colored Ratcheting Hudson Handle. These Drills will restrict the depth to 20 mm through the Drill Guides.

If a power drill is required, the Hudson Adapter may be used to connect the drill bit to power.

Proceed to drill the screw hole through the chosen Drill Guide.*

*For a complete listing of instrument options, please see the Product Catalog.



20 mm FIXED AWL

Ø3.5 x 20 mm DRILL

20 mm SPRING LOADED AWL

RATCHETING HUDSON HANDLE

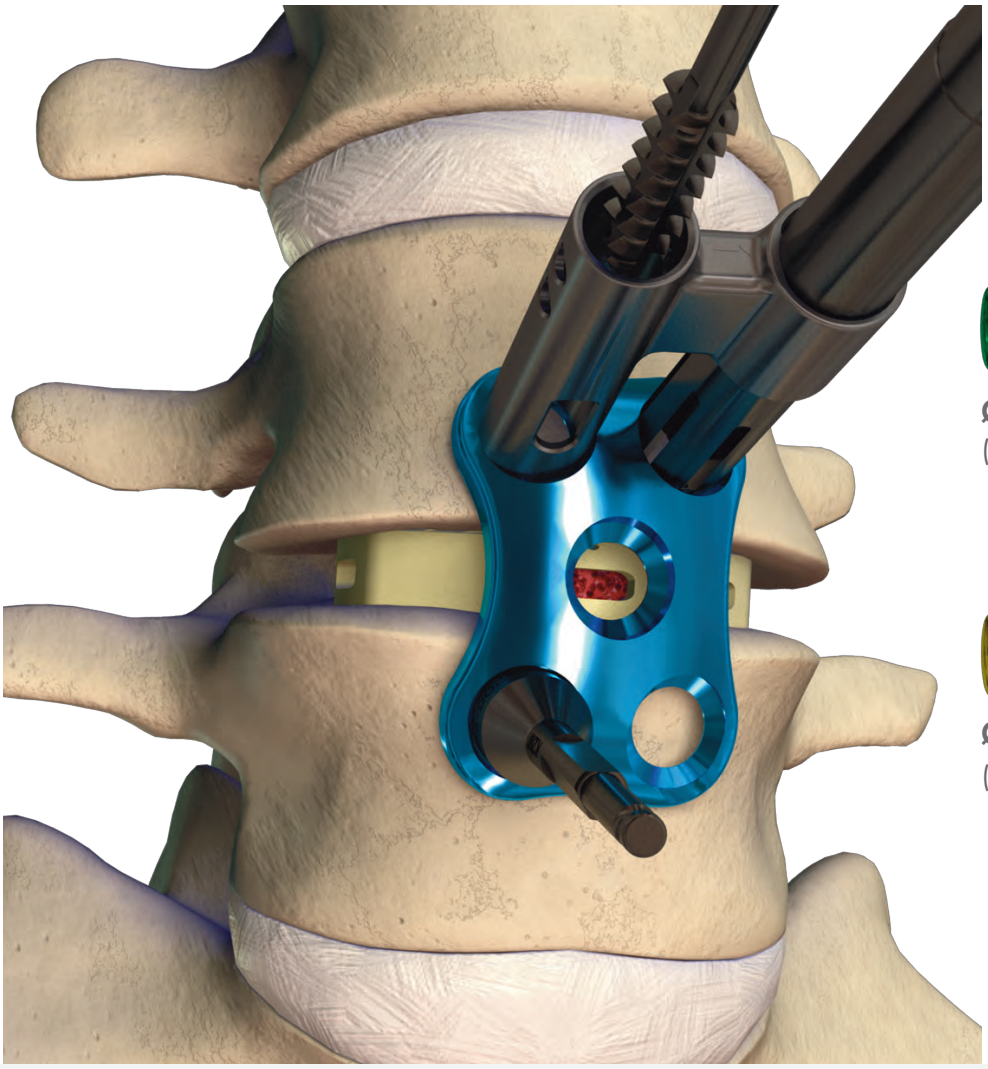
HUDSON ADAPTER

STEP 8

SCREW PREPARATION & INSERTION

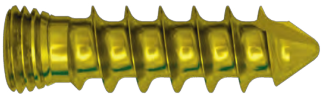
The CAYMAN screws are color-coded by diameter. Screw size may be determined by inserting the 100 mm Depth Gauge through the screw hole and into the cancellous bone.

The screws are self tapping; however, the 20 mm Tap may be inserted through the Drill Guide into the pilot hole at the same angulation that it was drilled to tap the vertebral bodies.



Ø6.0 mm Screws

(Lengths): 22 mm, 24 mm
26 mm, 28 mm
30 mm, 32 mm
34 mm, 36 mm



Ø7.0 mm Screws

(Lengths): 24 mm, 30 mm
36 mm, 42 mm
48 mm, 54 mm

TAP

DEPTH GAUGE

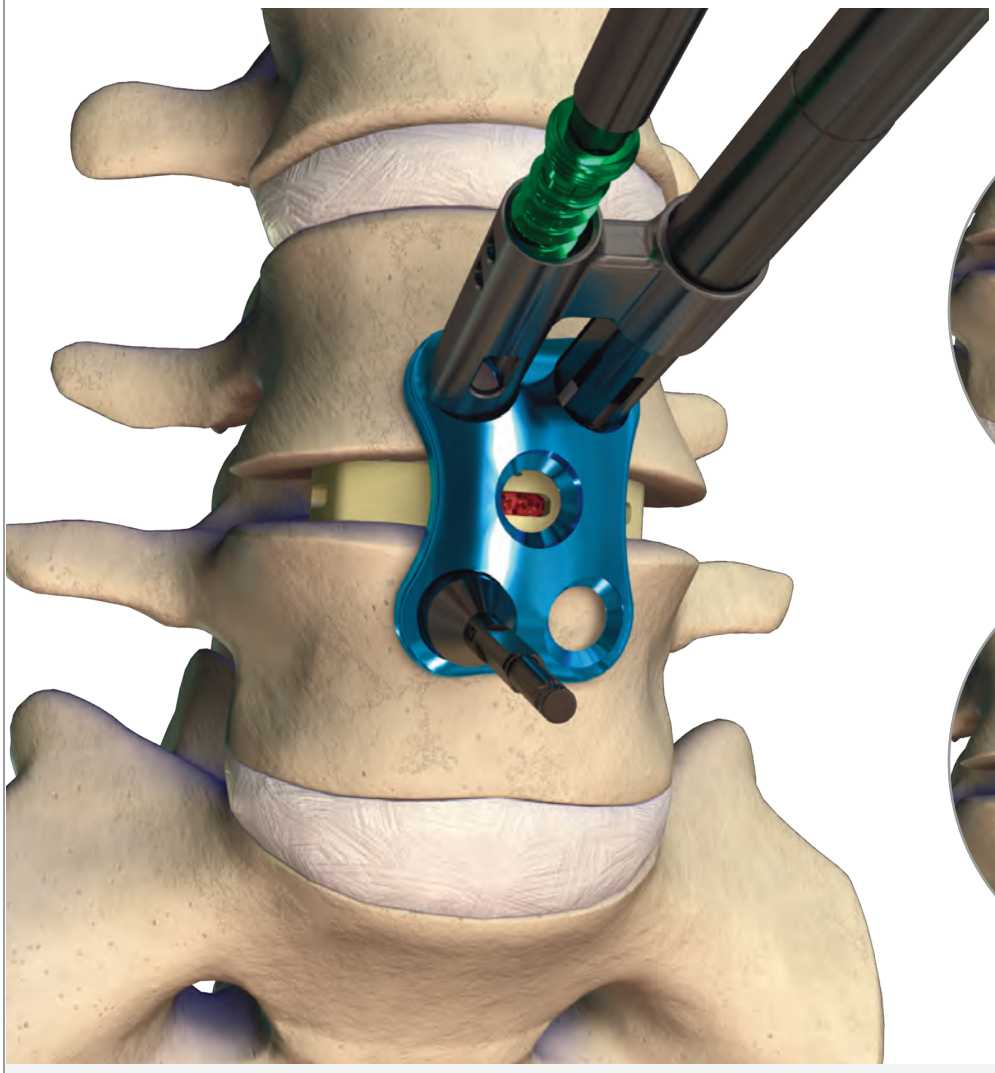
STEP 8

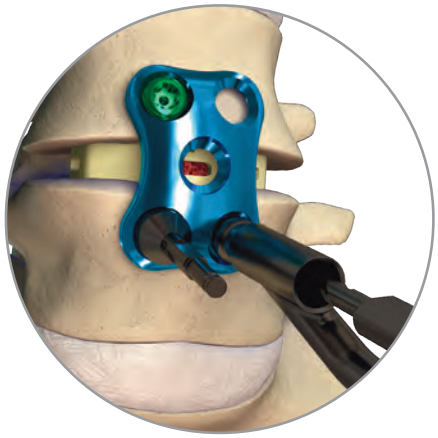
SCREW PREPARATION & INSERTION (CONT.)

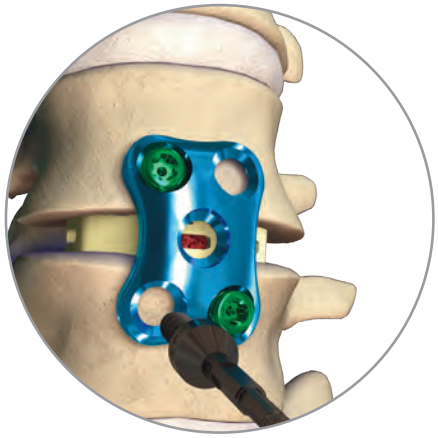
Once the appropriately sized screw is selected, insert it through the plate using the Size 25 Driver attached to the Ratcheting Hudson Handle, and preliminarily tighten the screw. The Driver has a tapered tip to provide easy insertion of the screws.

NOTE: The screw can be inserted at a conical angulation of 15°, or up to 7.5° in any direction, and lock to the plate.

Repeat Steps 7 and 8 for the remaining screws.







SIZE 25 DRIVER

STEP 9

FINAL LOCKING & REMOVAL

Final screw locking should only be performed once the plate and screw positions have been verified via intra-operative radiographs. Once the screws are tightened, they will become locked to the plate.

Use the Size 25 Driver attached to the black Torque Limiting Handle to final tighten the screws to 35 in-lbs.

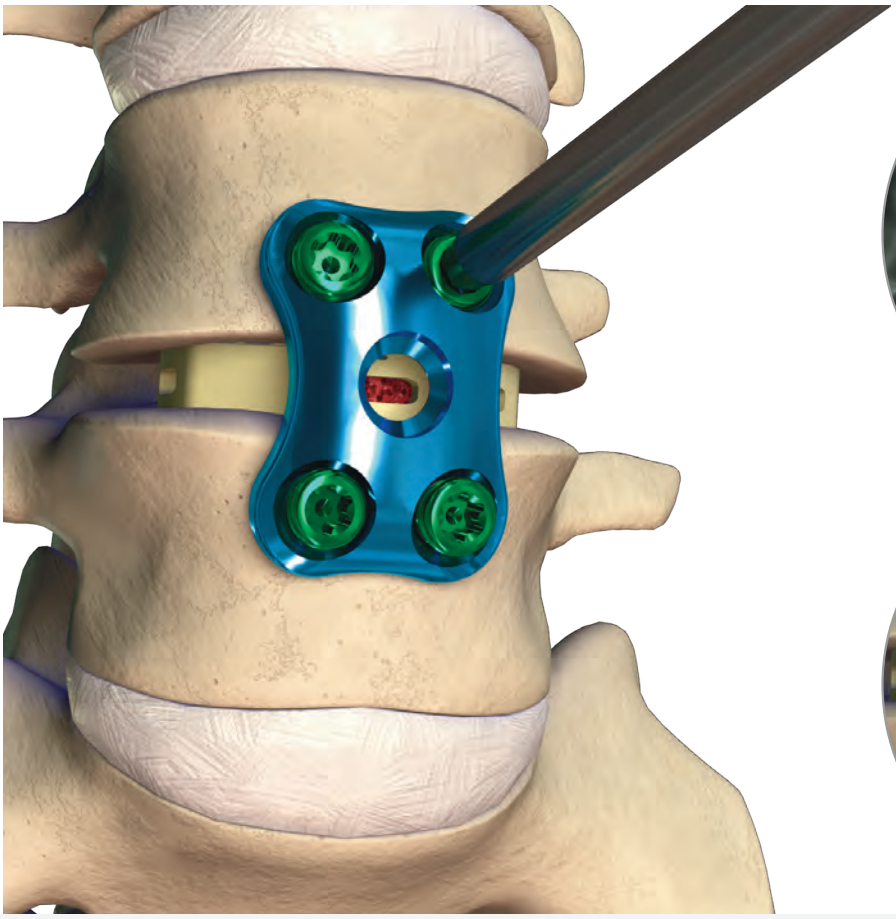
If screw removal is required, each Screw may be unlocked using the black Torque Limiting Handle attached to the Size 25 Driver.

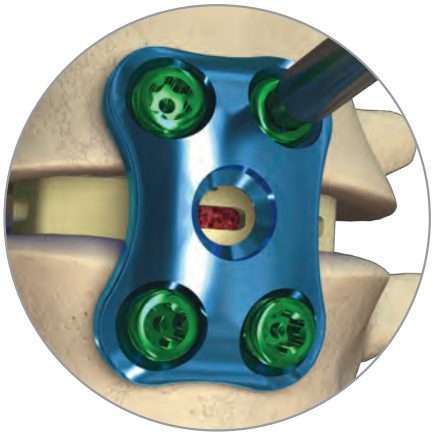
If plate removal is required, use the Plate Inserter. When the screw head engages on the locking lip of the plate, the plate will lag down to the bone and the revolutionary *tifix* Locking Technology will commence.

Due to a difference in material hardness and design, the screw head begins to deform the plate through a reshaping process, and thus forms an autogenic lock to the plate.

The Torque Limiting Handle emits an audible "click" at 35 in-lbs to signify the screw has formed an autogenic lock with the plate. Use of the Torque Limiting Handle further ensures the screw is not over tightened. No additional locking step is required.

NOTE: Optionally, if realignment of the screw is required after final locking, the screw may be unlocked using the Ratcheting Hudson Handle and the Size 25 Driver. The screw may be locked and unlocked up to three times without compromising the locking mechanism.



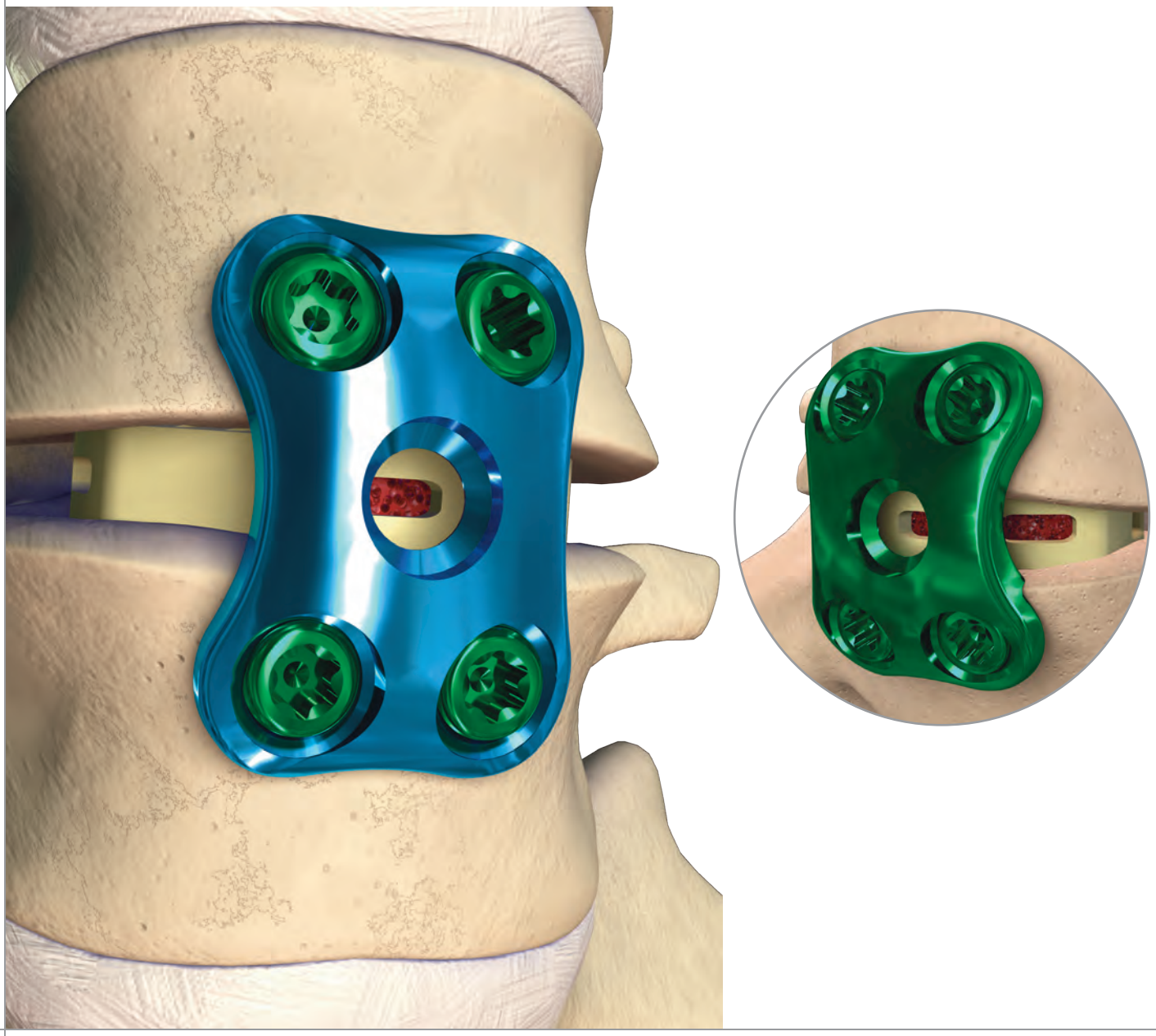


TORQUE LIMITING HANDLE

STEP 10

WOUND CLOSURE

When the construct is completed, perform a standard, multi-layer wound closure.



PRODUCT CATALOG

TRIALS

CATALOG #	DESCRIPTION	HEIGHTS*
**See special note	24 x 30 mm	9–19 mm
**See special note	28 x 36 mm	9–19 mm

*Heights are available in increments of 2 mm.

**Unique catalog numbers exist for each Trial in each footprint, height, and degree of lordosis. Please contact your local sales representative with any questions you may have about the ALEUTIAN ALIF Interbody System.

***10° & 15° Trials available upon request.

24 x 30 mm 5° TRIALS***
HEIGHTS* (mm): 9, 11, 13, 15, 17, & 19

28 x 36 mm 5° TRIALS***
HEIGHTS* (mm): 9, 11, 13, 15, 17, & 19

IMPLANTS

CATALOG #	DESCRIPTION	HEIGHTS*
**See special note	24 x 30 mm	9–19 mm
**See special note	28 x 36 mm	9–19 mm

*Heights are available in increments of 2 mm.

**Unique catalog numbers exist for each implant size and degree. Please contact your local sales representative with any questions you may have about the ALEUTIAN ALIF Interbody System.

***9 mm only available in 5° & 10° lordosis. 21 mm available upon request.

24 x 30 mm 5°, 10°, & 15° IMPLANTS
HEIGHTS* (mm): 9***, 11, 13, 15, 17, & 19

28 x 36 mm 5°, 10°, & 15° IMPLANTS
HEIGHTS* (mm): 9***, 11, 13, 15, 17, & 19

INSTRUMENTS

CATALOG #	DESCRIPTION
702-90001	#2 Straight Curette
702-90002	#4 Straight Curette
702-90162	#2 Forward Angled Curette
702-90003	#4 Forward Angled Curette
702-90163	#2 Serrated Curette

CATALOG #	DESCRIPTION
702-90164	#4 Serrated Curette
702-90165	#2 30° Forward Curette
702-90166	#4 30° Forward Curette
602-90010	Curette Connector Shaft
702-90210	Curette Handle

#2 STRAIGHT CURETTE

#4 STRAIGHT CURETTE

#2 FORWARD ANGLED CURETTE

#4 FORWARD ANGLED CURETTE

#2 SERRATED CURETTE

#4 SERRATED CURETTE

#2 30° FORWARD CURETTE

#4 30° FORWARD CURETTE

CURETTE CONNECTOR SHAFT

CURETTE HANDLE

INSTRUMENTS

CATALOG #	DESCRIPTION
702-90058	5 mm Disc Spreader
702-90059	7 mm Disc Spreader
702-90060	9 mm Disc Spreader
702-90061	11 mm Disc Spreader
702-90062	13 mm Disc Spreader

CATALOG #	DESCRIPTION
702-90063	15 mm Disc Spreader
702-90064	17 mm Disc Spreader
702-90065	19 mm Disc Spreader
602-90225	Fixed T-Handle with Hudson

5 mm DISC SPREADER

7 mm DISC SPREADER

9 mm DISC SPREADER

11 mm DISC SPREADER

13 mm DISC SPREADER

15 mm DISC SPREADER

17 mm DISC SPREADER

19 mm DISC SPREADER

FIXED T-HANDLE WITH HUDSON

INSTRUMENTS

CATALOG #	DESCRIPTION
702-90068	Large Cobb
702-90067	Small Cobb
702-90158	15 mm Chisel
702-90159	17 mm Chisel
702-90208	Pusher
702-90098	13″ 4 mm Anterior Pituitary Rongeur 45°

CATALOG #	DESCRIPTION
702-90157	13″ 6 mm Anterior Pituitary Rongeur 45°
702-90099	13″ 4 mm Anterior Pituitary Rongeur with Teeth
702-90100	13″ 6 mm Anterior Pituitary Rongeur with Teeth
702-90101	8 mm Double Action Rongeur
702-90066	Large Scalpel Blade Holder
702-90182	Small Scalpel Blade Holder

LARGE COBB

SMALL COBB

15 mm CHISEL

17 mm CHISEL

PUSHER

13″ 4 & 6 mm ANTERIOR PITUITARY RONGEUR 45°

13″ 4 & 6 mm ANTERIOR PITUITARY RONGEUR WITH TEETH

8 mm DOUBLE ACTION RONGEUR

LARGE SCALPEL BLADE HOLDER

SMALL SCALPEL BLADE HOLDER

INSTRUMENTS

CATALOG #	DESCRIPTION
2008-90018	Anterior Insertion Ramp
702-90103	Angled Rasp
702-90183	Convex Rasp
702-90105	Implant Inserter
702-90156	In-Situ Adjuster

CATALOG #	DESCRIPTION
702-90167	Trial Inserter
702-90102	Implant Removal Tool
702-90052	Large Mallet
702-90225	Slap Hammer

ANTERIOR INSERTION RAMP

ANGLED RASP

CONVEX RASP

IMPLANT INSERTER

IN-SITU ADJUSTER

TRIAL INSERTER

IMPLANT REMOVAL TOOL

LARGE MALLET

SLAP HAMMER

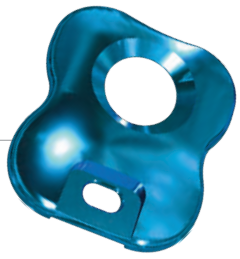
IMPLANTS

CATALOG #	DESCRIPTION
Ø6.0 mm Screws*	
1201-16022	22 mm
1201-16026	26 mm
1201-16030	30 mm
1408-40F20	17 x 20 mm Buttress Plate
1408-40F22	17 x 22 mm Buttress Plate
1408-40F24	17 x 24 mm Buttress Plate

*Ø6.0 mm screws in lengths (mm) 24, 28, 32, 34, 36 and Ø7.0 mm screws in lengths (mm) 24, 30, 36, 42, 48, 54 are available by request only.

Ø6.0 mm SCREWS*
Lengths (mm): 22, 26, & 30

BUTTRESS PLATES
17 x 20, 17 x 22, & 17 x 24 mm



INSTRUMENTS

CATALOG #	DESCRIPTION
1208-90005	Ratcheting Hudson Handle
1408-90003	20 mm Freehand Awl
1408-90002	20 mm Freehand Drill
1208-90004	Size 25 Driver
1408-90006	Plate Holder

RATCHETING HUDSON HANDLE

20 mm FREEHAND AWL

20 mm FREEHAND DRILL

SIZE 25 DRIVER

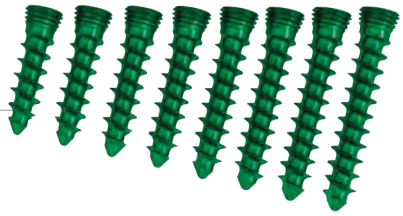
PLATE HOLDER

IMPLANTS

CATALOG #	DESCRIPTION
*See special note	Ø6.0 mm Screws
*See special note	Ø7.0 mm Screws
*See special note	Sacral Plates
*See special note	One-level Lumbar Plates
*See special note	Two-level Lumbar Plates

*Unique catalog numbers exist for each screw length in each diameter and for each plate size & level. Please contact your local sales representative with any questions you may have about ordering from the CAYMAN Anterior Plate System.

Ø6.0 mm SCREWS
Lengths (mm): 22, 24, 26, 28, 30, 32, 34, & 36



Ø7.0 mm SCREWS
Lengths (mm): 24, 30, 36, 42, 48, & 54

SACRAL PLATES
Lengths (mm): 32, 34, 36, 38, 40, 42, 44, & 46

ONE-LEVEL LUMBAR PLATES
Lengths (mm): 32, 34, 36, 38, 40, 42, 44, & 46

TWO-LEVEL LUMBAR PLATES
Lengths (mm): 74, 76, 80, 84, 88, 92, 96, & 100

INSTRUMENTS

CATALOG #	DESCRIPTION
1208-90005	Ratcheting Hudson Handle
1208-90038	20 mm Spring Loaded Awl
1208-90037	20 mm Fixed Awl
1408-90003	20 mm Freehand Awl
1208-90000	Ø3.5 x 20 mm Drill
1208-90001	Ø4.5 x 20 mm Drill
1208-90002	Ø3.5 x 65 mm Drill
1208-90003	Ø4.5 x 65 mm Drill

CATALOG #	DESCRIPTION
1208-90032	Ø3.5 x 30 mm Universal Drill
1208-90033	Ø4.5 x 30 mm Universal Drill
1208-90004	Size 25 Driver
1208-90005	Size 25 Universal Driver
1208-90000	Ø6.0 mm Tap
1208-90008	Fixed Drill Guide
1208-90009	Variable Drill Guide
1208-90017	Screw-Thru Drill Guide

RATCHETING HUDSON HANDLE

20 mm SPRING LOADED AWL

20 mm FIXED AWL

20 mm FREEHAND AWL

Ø3.5 & 4.5 x 20 mm DRILL

Ø3.5 & 4. x 65 mm DRILL

Ø3.5 & 4.5 x 30 mm UNIVERSAL DRILL

SIZE 25 DRIVER

SIZE 25 UNIVERSAL DRIVER

Ø6.0 mm TAP

FIXED DRILL GUIDE

VARIABLE DRILL GUIDE

SCREW-THRU DRILL GUIDE

IMPLANTS

CATALOG #	DESCRIPTION
1208-90014	Lumbar Plate Bender
1208-90007	Plate Holder
1208-90011	Temporary Pin Inserter
1208-90010	Threaded Temporary Fixation Pin
1208-90041	Smooth Temporary Fixation Pin
1208-90029	Torque Limiting Handle, 35 in-lbs

LUMBAR PLATE BENDER

PLATE HOLDER

TEMPORARY PIN INSERTER

THREADED TEMPORARY FIXATION PIN

SMOOTH TEMPORARY FIXATION PIN

TORQUE LIMITING HANDLE, 35 in-lbs

INSTRUMENTS

CATALOG #	DESCRIPTION
1208-90035	100 mm Depth Gauge
1208-90016	Screw Extractor
1208-90034	110 mm Caliper
1208-90036	Hudson Adapter

100 mm DEPTH GAUGE

SCREW EXTRACTOR

110 mm CALIPER

HUDSON ADAPTER

PRODUCT INSERT

⚠ BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION

IMPORTANT
This booklet is designed to assist in using the ALEUTIAN® Interbody System. It is not a reference for surgical techniques.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

INDICATIONS
When used as a cervical intervertebral body fusion device, the ALEUTIAN implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the ALEUTIAN implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

When used as vertebral body replacement devices the ALEUTIAN implants are indicated for use in the thoracolumbar spine (T1 to L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body, resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The ALEUTIAN implants are designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

For all the above indications the ALEUTIAN implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

MATERIALS
The implants of the ALEUTIAN Interbody System are manufactured from PEEK-OPTIMA® LT1 Polymer (polyetheretherketone) and Tantalum per ISO and ASTM standards.

CLEANING/ REPROCESSING OF K2M SURGICAL INSTRUMENTS
K2M surgical instruments are supplied non-sterile. While it is recommended that the following steps are included in a decontamination/ reprocessing protocol the end-user bears the ultimate responsibility for the cleanliness of the device. These instructions are not intended for K2M implants or disposable surgical instruments.

Presoak the instruments with an enzymatic solution for a minimum of 5 minutes. Following the presoak the instruments should be wiped or scrubbed using a brush, cloth or sponge that does not mar the surface of the instrument. Remove soil from cannulated parts with a nylon bristle brush or appropriately sized guide wire. Rinse parts under water for one minute. Repeat the process until no visible debris remains. Clean K2M surgical instruments with an appropriate brush, cloth or sponge and low foaming, pH neutral detergent solution. The use of abrasive compounds or excessively acidic or alkaline solutions may cause damage to the instruments and should be avoided. Rinse parts under warm or hot flowing water for a minimum of 1 minute including direct contact with all surfaces for at least 10 seconds. Repeat rinsing step using distilled, reverse osmosis or deionized water. Automatic cleaning may be used in addition to manual cleaning. Do not ultrasonically clean torque limiting handles.

STERILIZATION
Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. The following steam autoclave cycles are recommended, however sterilization should be in accordance with the sterilizer manufacturer's instructions and the institution's procedures for assuring sterility.

	Autoclave Cycle	Temperature	Time	Drying Time
USA	Prevacuum	270°F (132°C)	4 minutes	30 minutes
Outside USA	Prevacuum	273°F (134°C)	3 minutes	30 minutes

Usage of an FDA cleared wrap to ensure that the device is actually sterile prior to implantation is recommended.

Use caution during sterilization and storage. Do not allow contact with metal or other hard objects that could damage the finish or prevent proper use. (See Preoperative Warnings and Precautions).

NOTE: Instruments that may have been exposed to Creutzfeldt-Jakob disease (CJD) should be treated according to the hospital's prion decontamination protocol. K2M recommends contacting the Centers for Disease Control and the World Health Organization for the most recent information on CJD transmission and deactivation.

INSTRUCTIONS FOR USE
(For complete instructions refer to the appropriate surgical technique provided by your local K2M sales representative.)

The ALEUTIAN Interbody System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques.

CONTRAINDICATIONS
1. The ALEUTIAN Interbody System is contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, drug/ alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. This device is not recommended for patients who have received prior fusion at the level(s) to be treated. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. This device is not intended for use except as indicated.

POTENTIAL ADVERSE EVENTS
1. Potential adverse events include, but are not limited to pseudoarthrosis; loosening, bending, cracking or fracture of components, or loss of fixation in the bone with possible neurologic damage, usually attributable to pseudoarthrosis, insufficient bone stock, excessive activity or lifting, or one or more of the factors listed in Contraindications, or Warnings and Precautions; infections possibly requiring removal of devices; palpable components, painful bursa, and/ or pressure necrosis; and allergies, and other reactions to device materials which, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
2. Potential risks also include those associated with any spinal surgery resulting in neurological, cardiovascular, respiratory, gastrointestinal or reproductive compromise, or death.

WARNINGS AND PRECAUTIONS
1. The ALEUTIAN Interbody System is intended for use for the indications listed. Safety and effectiveness of the implants have not been established for other applications. The implants are for single use only and are not designed to be combined with devices from other manufacturers.
2. For optimum results careful preoperative diagnosis and planning, meticulous surgical technique and extended postoperative care by experienced spinal surgeons are essential. Prior to use, the surgeon should be specifically trained in the use of this system and the asso-

ciated instrumentation to facilitate correct selection and placement of the implants. The size and shape of bones and soft tissue place limitations on the size and strength of the implants and proper selection will reduce the risk of breakage or migration of the device.

3. Patient selection and compliance is extremely important. Spinal implant surgery on patients with conditions listed under Contraindications may not be candidates for this procedure. The patient must be made aware of the limitations of the implant and that physical activity and load bearing have been implicated in premature loosening, bending or fracture of internal fixation devices. The patient should understand that a PEEK Polymer implant is not as strong as a normal, healthy bone and will fracture under normal load bearing in the absence of complete bone healing. An active, debilitated or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
4. Potential risks identified with the use of this device system which may require additional surgery include device component failure, loss of fixation, non-union, fracture of the vertebra, and neurological, vascular or visceral injury.
5. Cutting, bending, or scratching the surface of metal components can significantly reduce the strength and fatigue resistance of the implant system and should be avoided where possible. These, in turn may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the components. Especially avoid sharp or reverse bends and notches.
6. Special protection of implants and instruments during storage is recommended when exposed to corrosive environments such as moisture, salt, air, etc.
7. The ALEUTIAN Interbody implants are intended to provide temporary stabilization. If an implant remains implanted after complete healing it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus the benefits when deciding whether to remove the implant.
8. This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

PREOPERATIVE

1. Patient conditions and/or predispositions such as those previously addressed in Contraindications and Warnings and Precautions should be avoided.
2. Preoperative planning should identify degree of correction possible without neurological damage using techniques similar to other Partial Vertebral Body replacement procedures.
3. Use care in handling and storage of the implants. Prior to surgery components should be inspected for any evidence of damage or corrosion.
4. An adequate inventory of implant sizes should be available at the time of the surgery.
5. All components should be cleaned and sterilized before use.
6. Before the initial experience we recommend that the surgeon critically review all available information and consult with other surgeons having experience with the device.

OPERATIVE

1. The primary goal of this surgery is to arthrodese selected vertebrae. Adequate exposure, bony preparation and grafting are essential to achieving this result.
2. The placement of the vertebral body replacement implants should be checked radiographically prior to final tightening of the construct.
3. Care should be taken when positioning the implants to avoid neurological damage.

POSTOPERATIVE

1. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful healing.
2. Internal fixation devices are load sharing devices which maintain alignment until healing occurs. If healing is delayed or does not occur the implant could eventually break, bend or loosen. Loads produced by load bearing and activity levels will impact the longevity of the implant.
3. Implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone, even after a bone has healed. If an implant remains implanted after complete healing, it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture.
4. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and/or early revision considered.
5. Surgical implants must never be reused. An explanted PEEK implant should never be reimplanted. Even though the device appears undamaged, it may have small imperfections and internal stress patterns which may lead to early breakage.

SYMBOL KEY


Caution: Consult Accompanying Documentation


Consult Instructions For Use


Do Not Reuse

PI003-0A11-01 Rev 0
K2M Inc.
600 Hope Parkway SE
Leesburg, VA 20175
1.571.919.2000

⚠ BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION

IMPORTANT
This booklet is designed to assist in using the CAYMAN® Plate System. It is not a reference for surgical techniques.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

INDICATIONS
The CAYMAN Buttress Plates are intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

The CAYMAN Thoracolumbar Plates are indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine and for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures (L5-S1). The CAYMAN Thoracolumbar Plate System is intended to provide temporary stabilization during fusion using autograph or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities and deformities: a) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), b) pseudoarthrosis, c) spondylolysis, d) spondylolisthesis, e) fracture, f) neoplastic disease, g) unsuccessful previous fusion surgery, h) lordotic deformities of the spine, i) thoracolumbar or lumbar scoliosis, j) deformity (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy.

MATERIALS
All implant components are manufactured from CP Titanium and Ti6Al4V per ASTM and ISO standards.

CLEANING/ REPROCESSING OF K2M SURGICAL INSTRUMENTS
K2M surgical instruments are supplied non-sterile. While it is recommended that the following steps are included in a decontamination/ reprocessing protocol the end-user bears the ultimate responsibility for the cleanliness of the device. These instructions are not intended for K2M implants or disposable surgical instruments.

Presoak the instruments with an enzymatic solution for a minimum of 5 minutes. Following the presoak the instruments should be wiped or scrubbed using a brush, cloth or sponge that does not mar the surface of the instrument. Remove soil from cannulated parts with a nylon bristle brush or appropriately sized guide wire. Rinse parts under water for one minute. Repeat the process until no visible debris remains. Clean K2M surgical instruments with an appropriate brush, cloth or sponge and low foaming, pH neutral detergent solution. The use of abrasive compounds or excessively acidic or alkaline solutions may cause damage to the instruments and should be avoided. Rinse parts under warm or hot flowing water for a minimum of 1 minute including direct contact with all surfaces for at least 10 seconds. Repeat rinsing step using distilled, reverse osmosis or deionized water. Automatic cleaning may be used in addition to manual cleaning. Do not ultrasonically clean torque limiting handles.

STERILIZATION
Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. The following steam autoclave cycles are recommended, however sterilization should be in accordance with the sterilizer manufacturer's instructions and the institution's procedures for assuring sterility.

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Usage of an FDA cleared wrap to ensure that the device is actually sterile prior to implantation is recommended.

Use caution during sterilization and storage. Do not allow contact with metal or other hard objects that could damage the finish or prevent proper use. (See Preoperative Warnings and Precautions).

NOTE: Instruments that may have been exposed to Creutzfeldt-Jakob disease (CJD) should be treated according to the hospital's prion decontamination protocol. K2M recommends contacting the Centers for Disease Control and the World Health Organization for the most recent information on CJD transmission and deactivation.

INSTRUCTIONS FOR USE
The CAYMAN Plate System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. For complete instructions refer to the CAYMAN Plate System surgical technique provided by your local K2M sales representative.

CONTRAINDICATIONS
1. The CAYMAN Plate System is contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, drug/ alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. This device is not intended for use except as indicated.

POTENTIAL ADVERSE EVENTS
1. Potential adverse events associated with spinal fusion procedures include, but are not limited to pseudoarthrosis; loosening, bending, cracking or fracture of components, or loss of fixation in the bone with possible neurologic damage, usually attributable to pseudoarthrosis, insufficient bone stock, excessive activity or lifting, or one or more of the factors listed in Contraindications, or Warnings and Precautions; infections possibly requiring removal of devices; palpable components, painful bursa, and/or pressure necrosis; and allergies, and other reactions to device materials which, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
2. Potential risks also include those associated with any spinal surgery resulting in neurological, cardiovascular, respiratory, gastrointestinal or reproductive compromise, or death.

WARNINGS AND PRECAUTIONS
1. The CAYMAN Plate System is intended for use for the indications listed. Safety and effectiveness of the implants have not been established for other applications. The implants are for single use only and are not designed to be combined with devices from other manufacturers.
2. For optimum results careful preoperative diagnosis and planning, meticulous surgical technique and extended postoperative care by experienced spinal surgeons are essential. Prior to use the surgeon should be specifically trained in the use of this spinal system and the associated instrumentation to facilitate correct selection and placement of the implants. The size and shape of bones and soft tissue place limitations on the size and strength of the implants and proper selection will reduce the risk of neurological injury during implantation as well as metal fatigue leading to bending or breakage of the device.
3. Patient selection and compliance is extremely important. Spinal implant surgery on patients with conditions listed under Contraindications may not be candidates for this procedure. The patient must be made aware of the limitations of the implant and that physical activity and load bearing have been implicated in premature loosening, bending or fracture of internal fixation devices. The patient should understand that a metallic implant is not as strong as a normal, healthy bone and will fracture under normal load bearing in the absence of complete bone healing. An active, debilitated or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation.
4. Potential risks identified with the use of this device system which may require additional surgery include device component failure, loss of fixation, non-union, fracture of the vertebra, and neurological, vascular or visceral injury.
5. Cutting, bending, or scratching the surface of metal components can significantly reduce the strength and fatigue resistance of the implant system and should be avoided where possible. These, in turn may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the components. Especially avoid sharp or reverse bends and notches.
6. Special protection of implants and instruments during storage is recommended when exposed to corrosive environments such as moisture, salt, air, etc.
7. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids and alkalis which can cause corrosion. Putting dissimilar metals in contact with each other can accelerate the corrosion process which in turn may enhance fatigue fractures of implants. Thus every effort should be made to use compatible metals and alloys. Fretting or wear at the interface between components of a device may also accelerate the corrosion process and may lead to the generation of wear debris which has been associated with localized inflammatory response.
8. Implants used in spinal fusion procedures are intended to provide temporary stabilization. If an implant remains implanted after complete healing it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus the benefits when deciding whether to remove the implant.
9. This device has not been evaluated for safety and compatibility in the MR environment. The device has not been tested for heating, migration or imaging artifacts in the MR environment.

PREOPERATIVE
1. Patient conditions and/or predispositions such as those previously addressed in Contraindications and Warnings and Precautions should be avoided.
2. Preoperative testing (simple bend and where necessary, stretch testing) should identify degree of correction possible without neurological damage and levels to be spanned using techniques similar to other spinal fusion procedures.
3. Use care in handling and storage of the implants. Prior to surgery components should be inspected for any evidence of damage or corrosion.
4. An adequate inventory of implant sizes should be available at the time of the surgery.
5. All components should be cleaned and sterilized before use.
6. Before the initial experience we recommend that the surgeon critically review all available information and consult with other surgeons having experience with the device.

OPERATIVE
1. The primary goal of spinal fusion surgery is to arthrodese selected vertebrae. Adequate exposure, bony preparation and grafting are essential to achieving this result.
2. Plates used in spinal fusion procedures may be prebent to the degree of correction determined by preoperative testing however reverse bends should be avoided.
3. The placement of screws should be checked radiographically.
4. Care should be taken when positioning the implants to avoid neurological damage.
5. Use of bone cement will make removal of the implants difficult and should be avoided.

POSTOPERATIVE
1. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful healing.
2. Internal fixation devices are load sharing devices which maintain alignment until healing occurs. If healing is delayed or does not occur the implant could eventually break, bend or loosen. Loads produced by load bearing and activity levels will impact the longevity of the implant.
3. Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a bone has healed. If an implant remains implanted after complete healing, it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture.
4. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and/or early revision considered.
5. Surgical implants must never be reused. An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small imperfections and internal stress patterns which may lead to early breakage.

SYMBOL KEY


Caution: Consult Accompanying Documentation


Consult Instructions For Use


Do Not Reuse

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