K2M

COMPLEX SPINE INNOVATIONS™

SURGICAL TECHNIQUE

CAPRI™

LARGE EXPANDABLE CORPECTOMY CAGE SYSTEM

CAPRI™

TABLE OF CONTENTS

FEATURES & BENEFITS

CAPRI™ LARGE EXPANDABLE CORPECTOMY CAGE SYSTEM

- Accommodates Multiple Surgical Approaches
- In-situ Lordosis/Kyphosis Angulation
- In-situ Height Adjustment
- Interchangeable Footprint Options
- Manufactured from Titanium

CAGE DESIGN

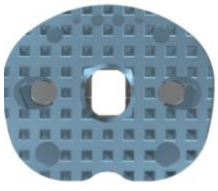
The CAPRI Large Expandable Corpectomy Cage is comprised of two components: an internal expansion tower and an external housing, which assemble together to create the cage construct. Each component is offered in footprint sizes of 17 x 22, 21 x 25, 24 x 30, and 28 x 36 mm.

Internal Expansion Tower

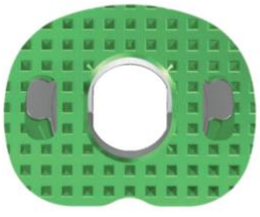
Cage Construct

External Housing

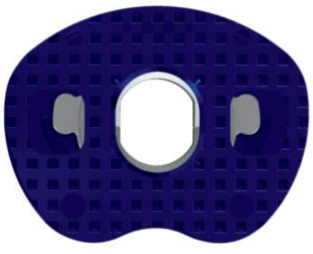
17 x 22 mm



21 x 25 mm



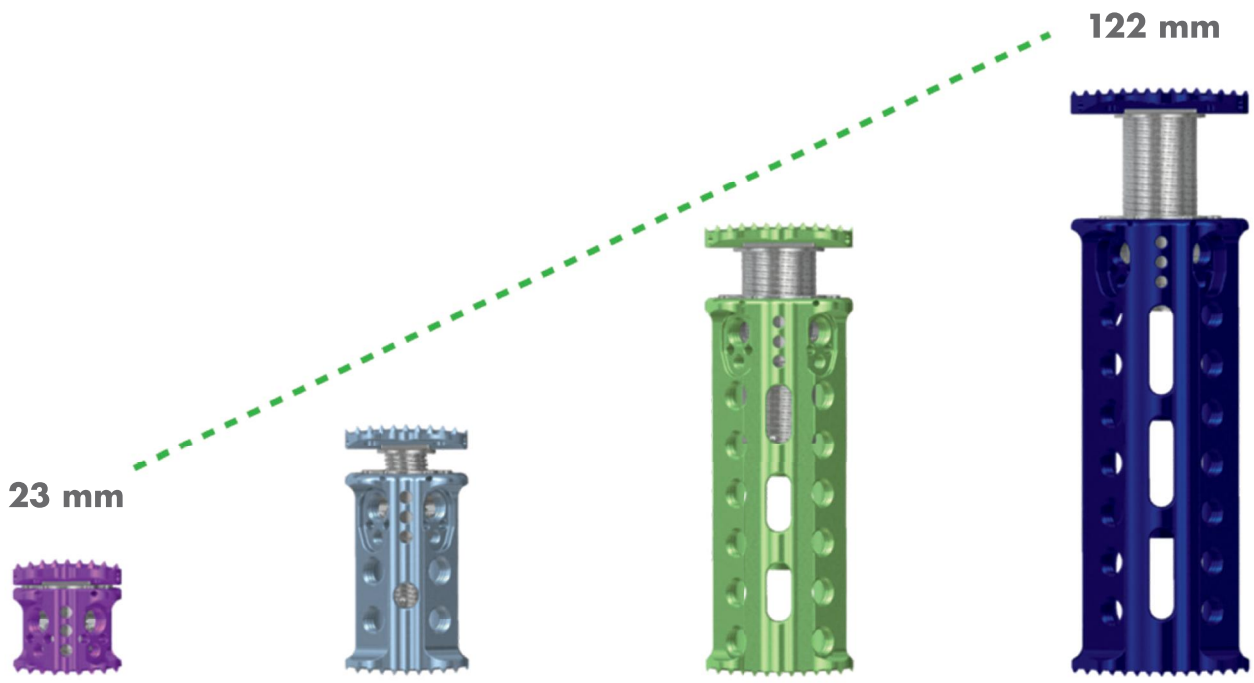
24 x 30 mm



28 x 36 mm

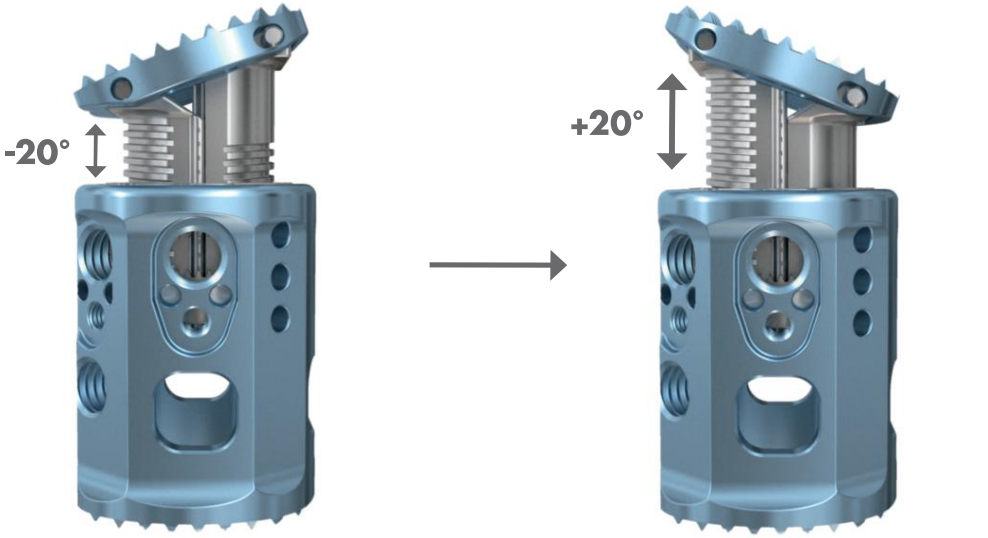
The 17 x 22 and 21 x 25 mm cages are offered in heights of 23–74 mm, while the 24 x 30 and 28 x 36 mm cages are offered in heights of 30–122 mm.

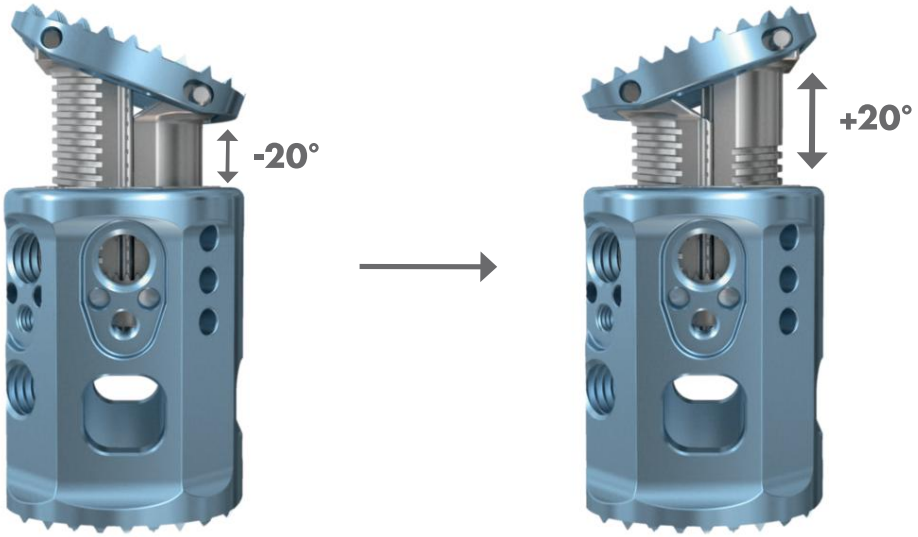
See **Appendix A** (page 26) for complete implant size options.



CAGE DESIGN (CONT.)

The CAPRI Large Expandable Copectomy Cage features in-situ height expansion and endplate angulation. The internal expansion tower allows for continuous endplate angulation adjustments from -20° to 20°.





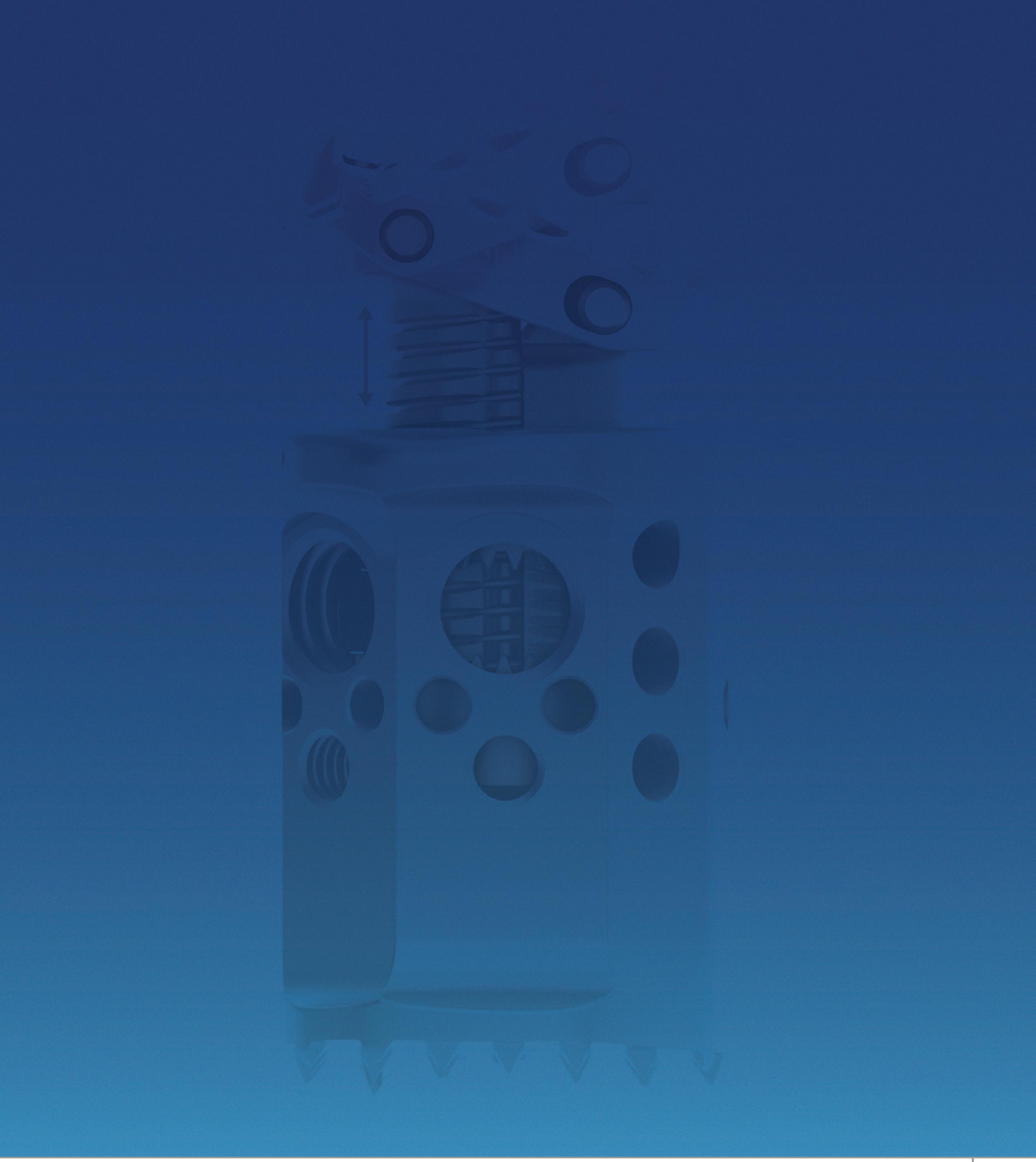
All external housings are offered with a fixed endplate of 0°. Additional fixed angulation options of 10° and 20° are available for select cage sizes.

See **Appendix A** (page 28) for complete fixed angulation options.

0°

10°

20°

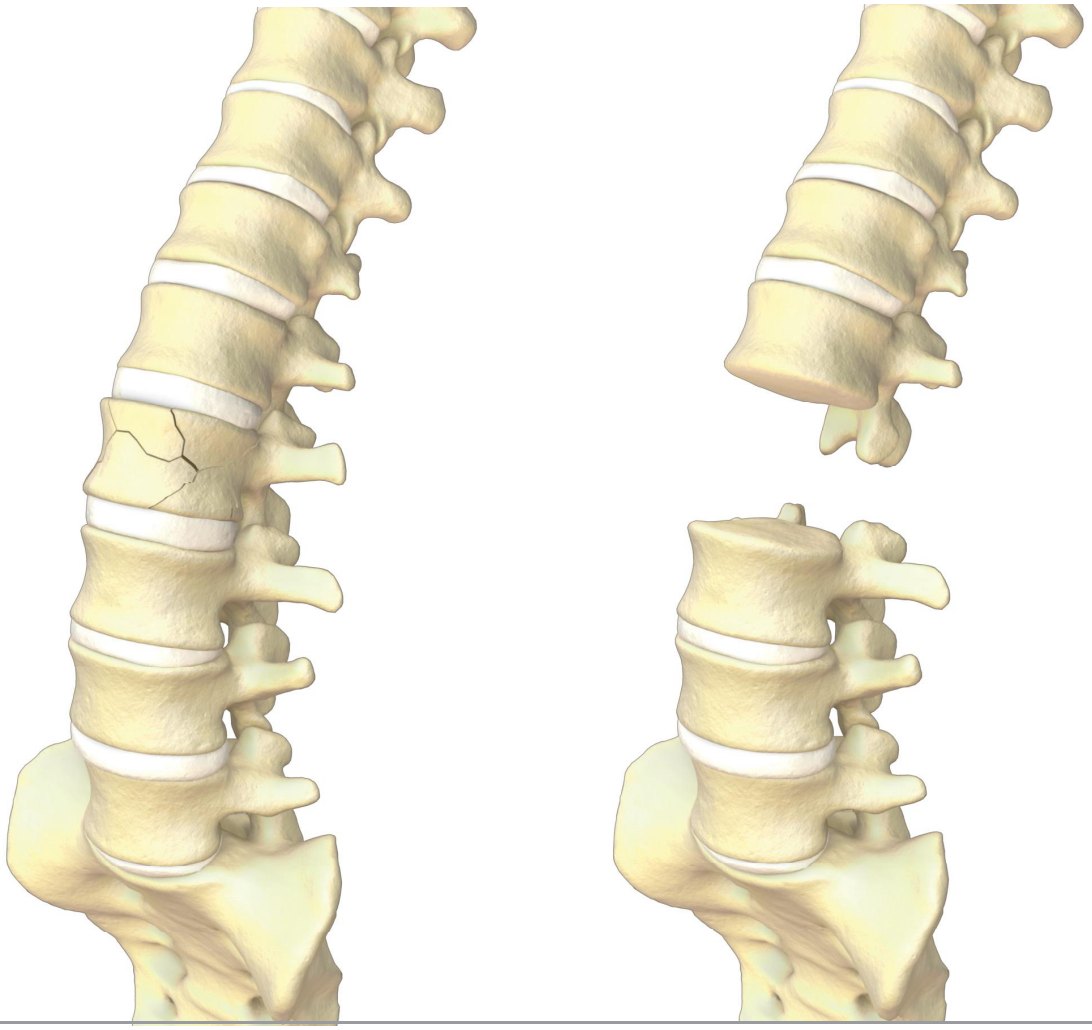


SURGICAL TECHNIQUE

STEP 1

PATIENT POSITIONING & CORPECTOMY

The CAPRI Large Expandable Corpectomy Cage is designed to accommodate anterior, lateral, and posterior approaches. Perform a standard exposure for the desired approach to the affected spinal level. Remove the affected vertebrae and discs and prepare the endplates for fusion using corpectomy instrumentation and standard disc removal, such as Malleable Retractors, a Wire Saw and Guide, Forceps, and a Cutter.

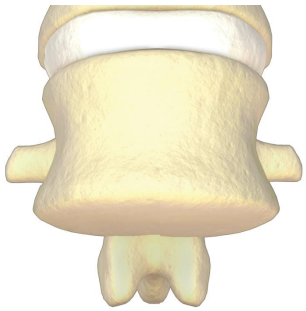


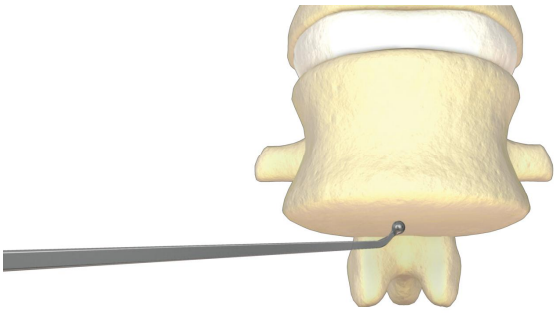
STEP 2

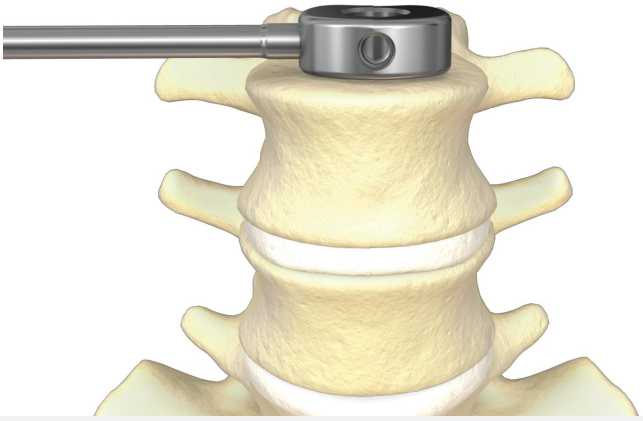
CAGE SELECTION

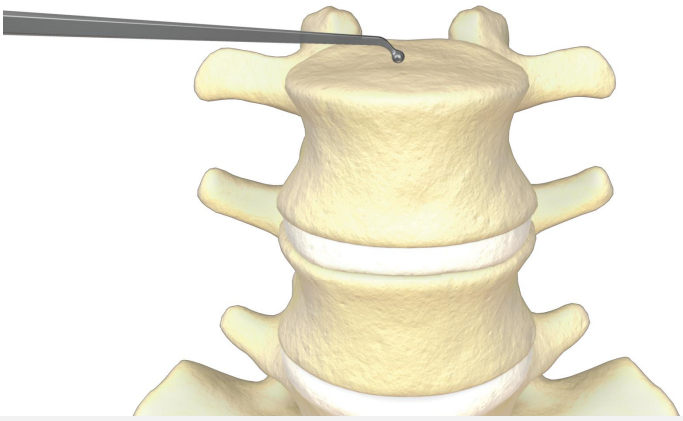
Use the Footprint Trials attached to the Trial Shaft to identify the footprint size most appropriate for the inferior and superior endplates. To determine the approximate height of the corpectomy cage, measure the prepared space using the Caliper.

If needed, use the Implant Sizing Chart to verify height and cage selection.







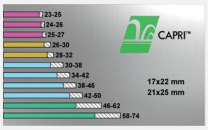


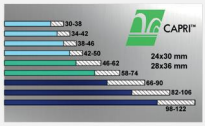
FOOTPRINT TRIALS

TRIAL SHAFT

CALIPER

IMPLANT SIZING CHART



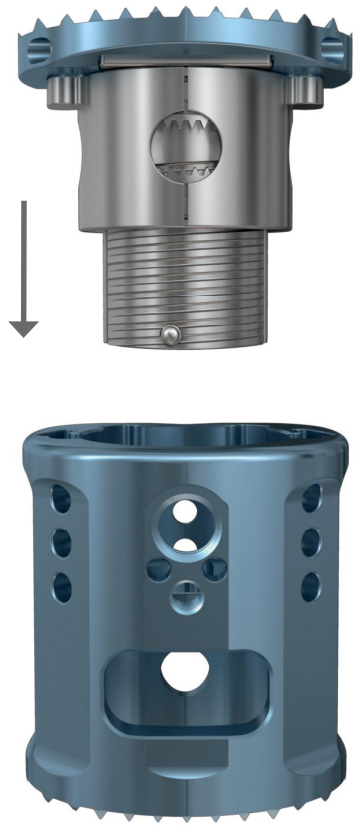


STEP 3

CAGE ASSEMBLY

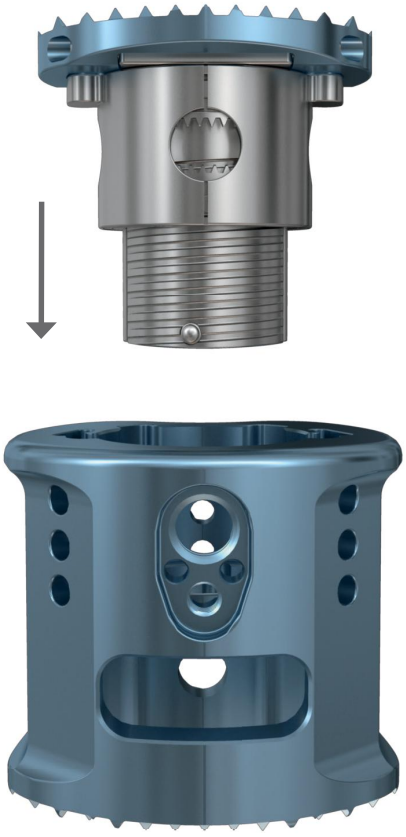
Identify the appropriate external housing and color-corresponding internal tower for the determined footprint and cage height. When properly assembled, the laser marked lines on each component will be aligned and the two pieces will snap together. If necessary, the cage can be disassembled by pulling the two pieces apart.

TIP: If using bone graft, pack the implant at this point before inserting into the space. See **Appendix B** (page 30) for estimated bone graft volumes.



As an alternative assembly option, the CAPRI Large Expandable Corpectomy Cage features interchangeable internal and external components. If desired, a 17 x 22 mm internal expansion tower may be assembled with a 21 x 25 mm external housing, or vice versa. Likewise, the 24 x 30 and 28 x 36 mm components are also interchangeable. This allows for optimized endplate sizing.

See **Appendix C** (page 32) for optimal cage assembly.



STEP 4

CAGE INSERTION

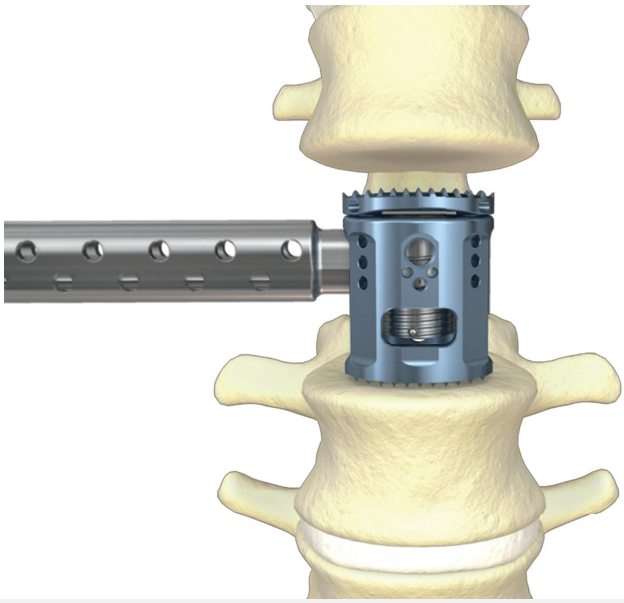
With the desired cage selected and assembled, pass the Inserter Threaded Shaft down the Inserter. Use the Short Size 20 Non-Tapered Driver to thread the Inserter onto the cage at the insertion point for the desired approach and introduce the cage into the site.

If needed, use the Curved or Angled Pusher to assist in positioning the cage.

Direct Anterior Insertion Point

(2) Direct Lateral Insertion Points

(2) Posterior Lateral Insertion Points



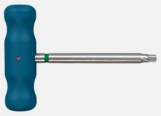
INSERTER

INSERTER THREADED SHAFT

CURVED PUSHER

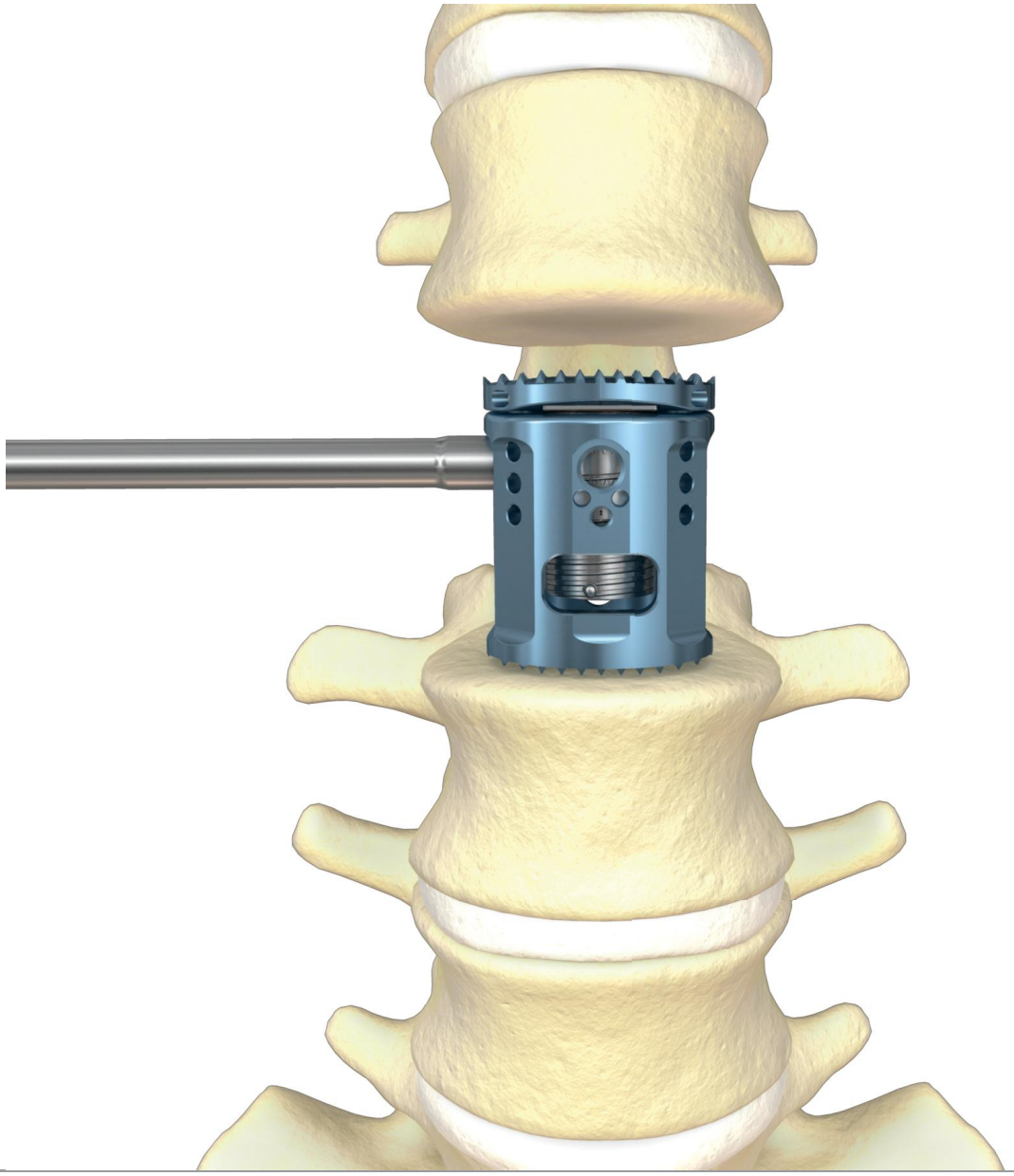
ANGLED PUSHER

SIZE 20 NON-TAPERED DRIVER, SHORT



NOTE: For an alternative insertion method, utilize the Trial Shaft threaded onto the external housing to initially position the cage. This alternative insertion method may prove more beneficial for posterior-lateral approaches where a lower profile insertion tool may be needed.

Once the cage has been positioned, the Inserter should be attached to aid in height expansion, endplate angulation, and final locking the locking screw.

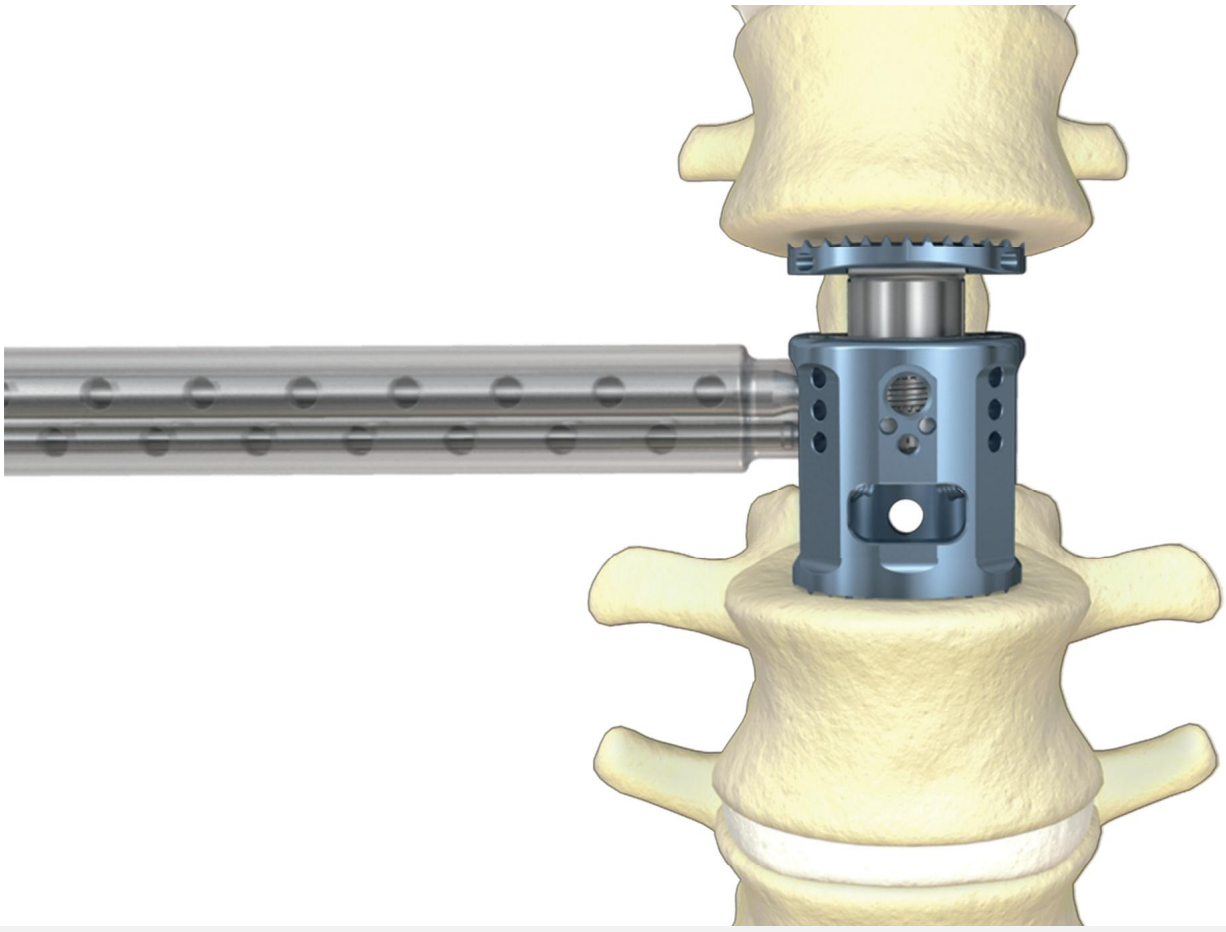


STEP 5

CAGE HEIGHT EXPANSION

To expand the CAPRI Large Expandable Corpectomy Cage, pass the Height Expansion Driver—connected to the grey 12 in-lbs Torque Limiting Handle—down the cannulated shaft of the Inserter. Turn the Driver clockwise to expand the height of the cage. When the cage has reached its maximum expansion point, stop pins will engage to prevent the cage from over expanding.

If necessary, it is possible to collapse the height of an expanded cage by turning the Height Expansion Driver counter-clockwise.



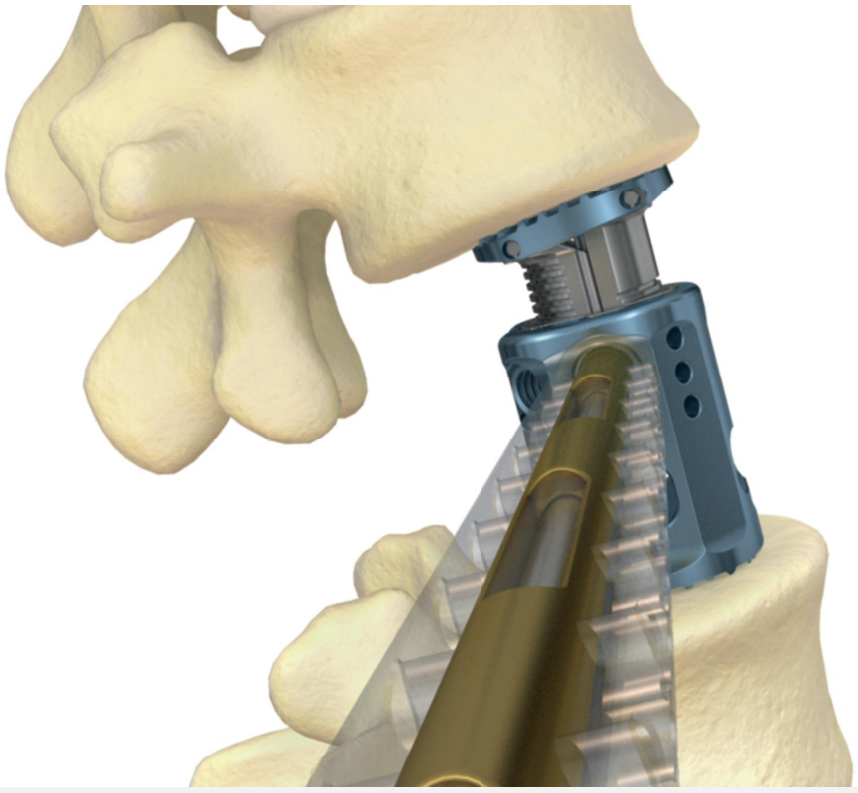
TORQUE LIMITING HANDLE, MINI AO 12 IN-LBS

HEIGHT EXPANSION DRIVER

STEP 6

ENDPLATE ANGULATION ADJUSTMENT

Once the cage has been expanded to the desired height, the Lordosis/Kyphosis (L/K) Driver can be used to adjust the angulation of the internal expansion tower endplate to match the desired lordosis or kyphosis of the adjacent vertebral body. Attach the L/K Driver to a grey 12 in-lbs Torque Limiting Handle and pass the Driver down the cannula of the Inserter.



LORDOSIS/KYPHOSIS DRIVER

STEP 6

ENDPLATE ANGULATION ADJUSTMENT (CONT.)

The orientation of the L/K Driver within the Inserter will determine whether the anterior or posterior column of the internal expansion tower will be adjusted. This can be confirmed by a visible "A" or "P" in the proximal window of the Inserter.

By turning the L/K Driver clockwise, the indicated column of the internal expansion tower will be raised. Likewise, turning the driver counter-clockwise will lower the indicated column.

Do not over expand the implant during initial height expansion where resistance is felt in the turning of the handle. This overexpansion will cause the teeth to push into the vertebral body endplate and may not allow the internal expansion tower endplate to be angulated. If this occurs, lower the height of the internal expansion tower slightly and then adjust for lordosis/kyphosis.

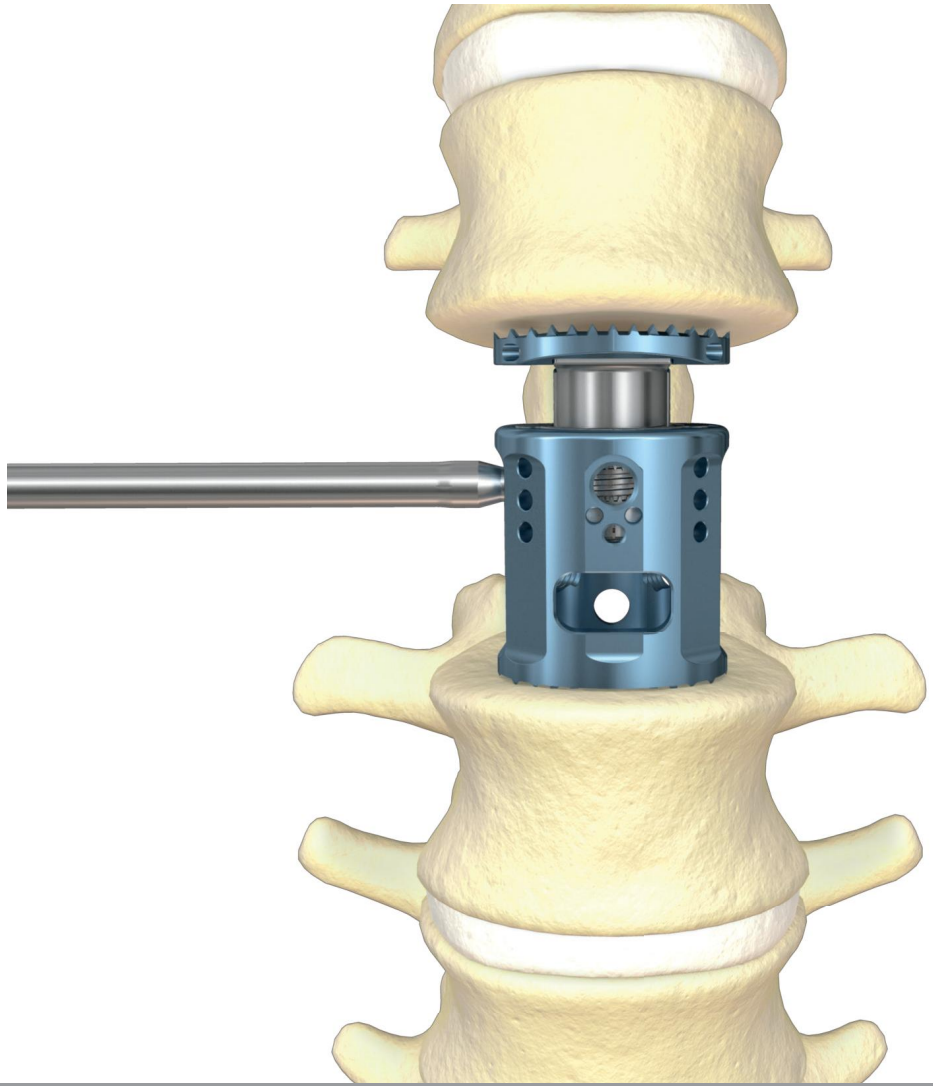
STEP 7

OPTIONAL HEIGHT & ENDPLATE ANGULATION

If the use of fluoroscopy is desired to verify the placement of the implant, the Inserter can be removed to allow easier positioning of the C-Arm. Additional adjustments to the height or angulation of the cage can be made by placing the Height Driver and L/K Driver directly into the implant to provide adjustments without reattaching the Inserter.

It should be noted that without the Inserter, there will be no window to indicate which column the L/K Driver will be adjusting. To control the desired anterior or posterior column, the indicated "A" or "P" should be facing the adjustable endplate. The Inserter should then be re-attached to final lock the cage.

See **Appendix D** (page 33) for a reference chart of approximate turns for height and endplate angulation.

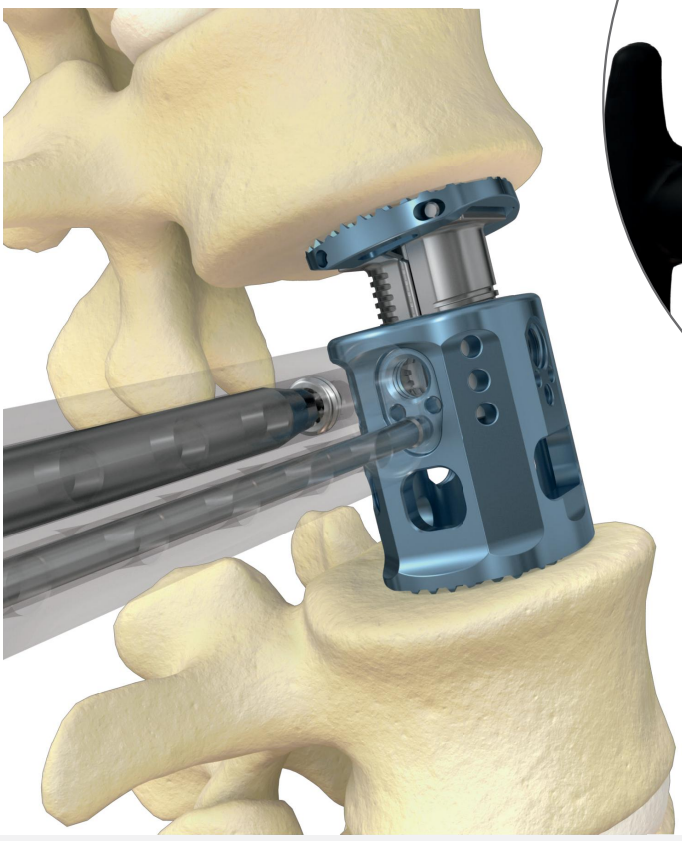


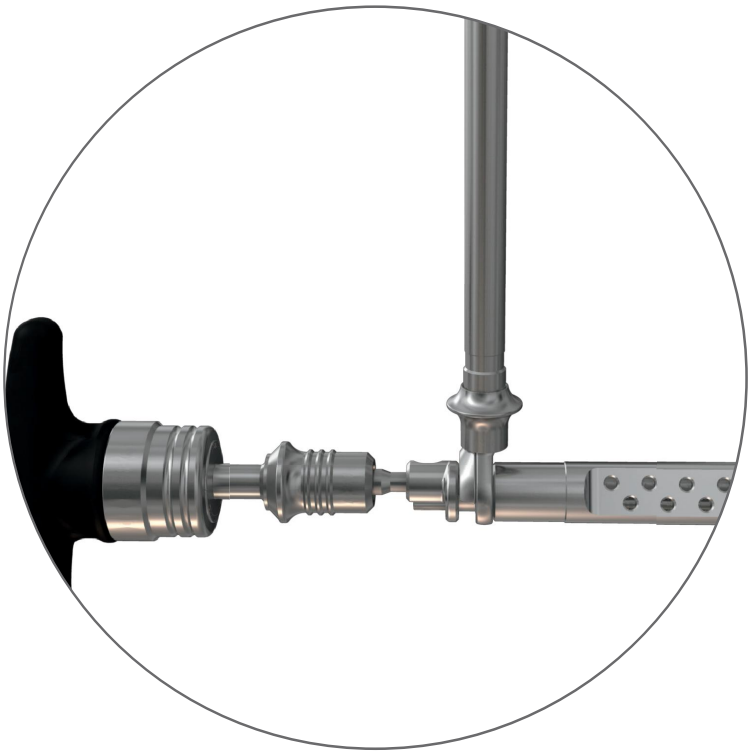
STEP 8

FINAL LOCKING

With the desired height and angulation achieved, use the Size 20 Tapered Driver to insert a locking screw through the cannula of the Inserter and provisionally "finger" tighten into the implant housing. Remove the Driver and final tighten the locking screw using the Size 20 Non-Tapered Driver attached to the black Torque Limiting Handle, in conjunction with Anti-Torque Handle. The Torque Limiting Handle achieves 5.4 Nm (48 in-lbs) for final tightening and will emit an audible "click" once it reaches the necessary torque.

NOTE: A locking screw MUST be inserted and final tightened to 5.4 Nm (48 in-lbs) in order to finalize the construct.





SIZE 20 NON-TAPERED DRIVER

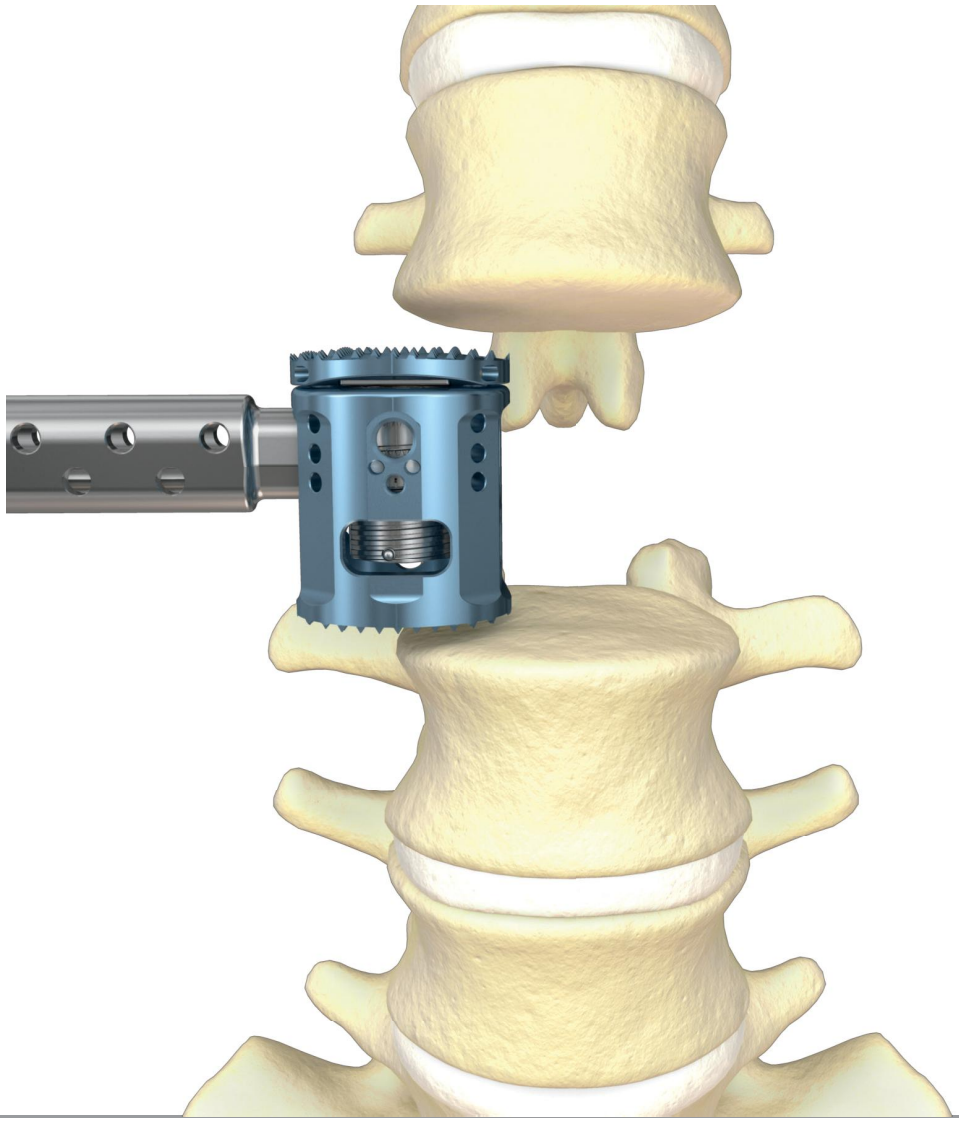
SIZE 20 TAPERED DRIVER

ANTI-TORQUE HANDLE

TORQUE LIMITING HANDLE, SQUARE

If removal of the implant is needed, re-attach the Inserter by threading the Inserter Threaded Shaft onto the external housing of the cage. Using the Size 20 Non-Tapered Driver in conjunction with the black Torque Limiting Handle, unlock and remove the locking screw. If necessary, the Lordosis/ Kyphosis Driver can be used to decrease the angulation of the Internal Expansion Tower endplate prior to removal.

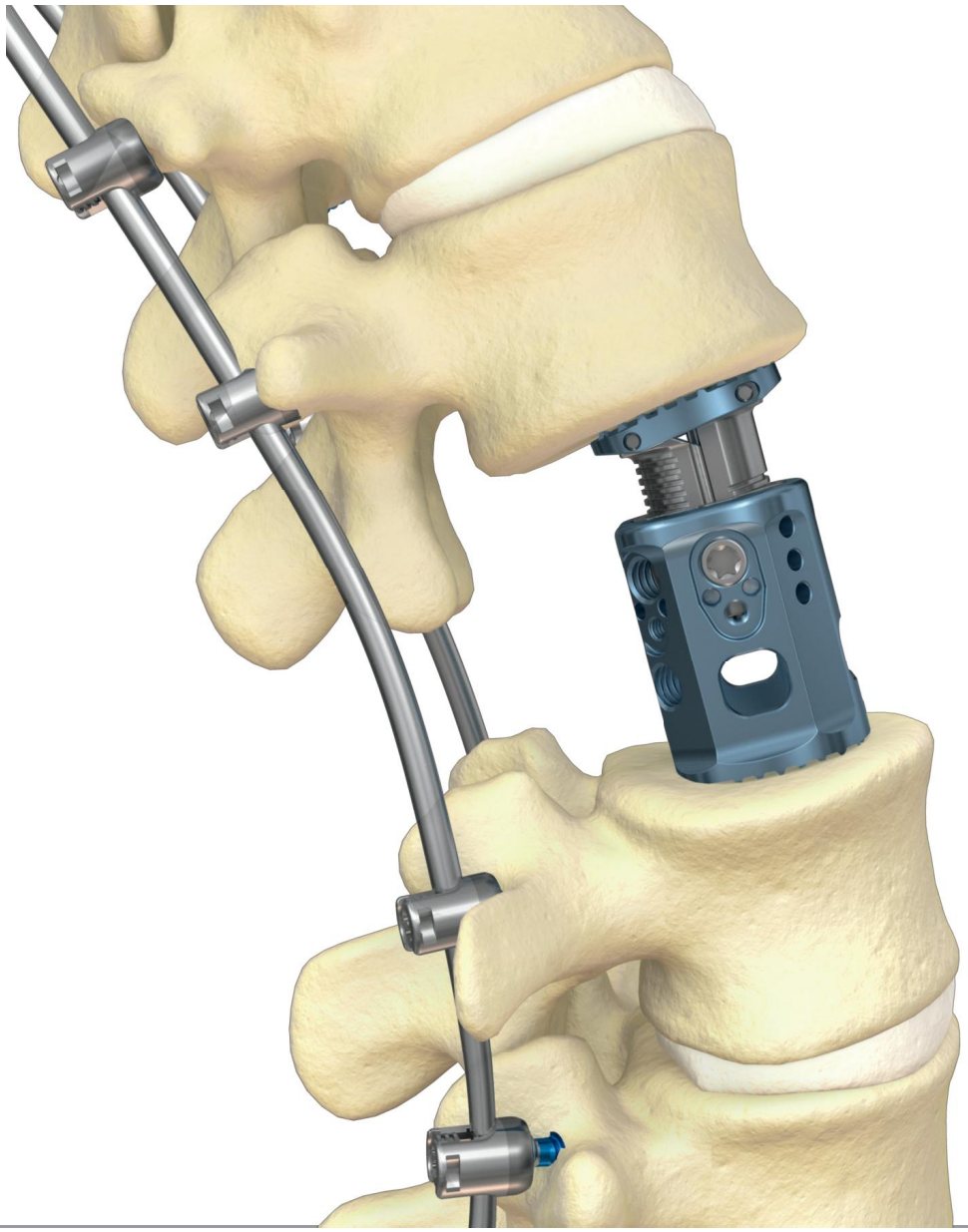
Collapse the height of the cage by inserting the Height Expansion Driver into the Inserter and turn the Driver counter-clockwise. With the cage still attached to the Inserter, remove the cage and Inserter from the corpectomy space.

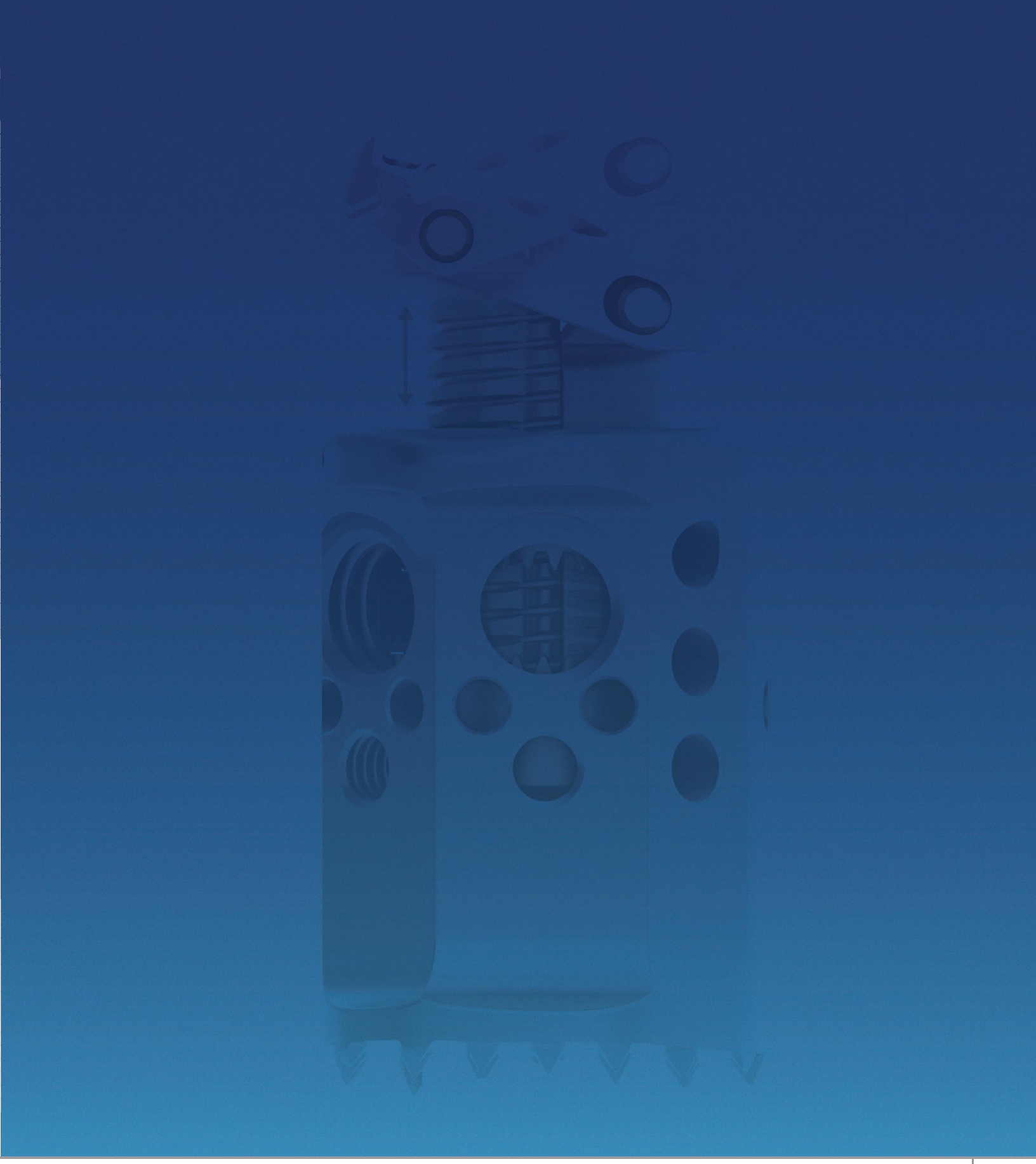


STEP 9

FINALIZING THE CONSTRUCT

Apply a supplemental internal fixation device appropriate for the implanted level, such as K2M Pedicle Screw and Hook Systems, or K2M Spinal Plate Systems, to finalize the construct.





PRODUCT CATALOG

PREPARATION INSTRUMENTS

2112-90022	17 x 22 mm Footprint Trial
2112-90023	21 x 25 mm Footprint Trial
2112-90024	24 x 30 mm Footprint Trial
2112-90025	28 x 36 mm Footprint Trial
2112-90021	Trial Shaft

2112-90043	Caliper, 150 mm
2112-90026	Curved Pusher
2112-90027	Angled Pusher
2112-90028	Bone Funnel
2112-90029	Bone Funnel Pusher
2112-90030	Implant Sizing Chart

FOOTPRINT TRIALS

17 x 22, 21 x 25, 24 x 30, 28 x 36 mm

TRIAL SHAFT

CALIPER, 150 mm

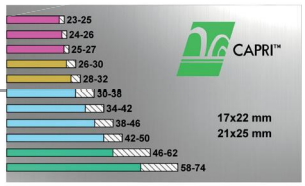
CURVED PUSHER

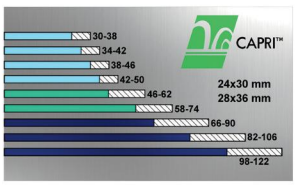
ANGLED PUSHER

BONE FUNNEL

BONE FUNNEL PUSHER

IMPLANT SIZING CHART





INSERTION INSTRUMENTS

2112-90006	Inserter
2112-90007	Height Expansion Driver
2112-90008	Lordosis/Kyphosis Driver
2112-90009	Inserter Threaded Shaft
3608-90008	Torque Limiting Handle, Mini AO, 12 in-lbs
2112-90012	Torque Limiting Handle, 48 in-lbs

INSERTER

HEIGHT EXPANSION DRIVER

LORDOSIS/KYPHOSIS DRIVER

INSERTER THREADED SHAFT

TORQUE LIMITING HANDLE, MINI AO, 12 in-lbs

TORQUE LIMITING HANDLE, 48 in-lbs

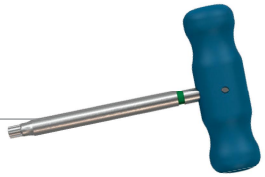
INSERTION INSTRUMENTS

2112-90010	Size 20 Tapered Driver
2112-90019	Size 20 Non-Tapered Driver
2112-90020	Size 20 Non-Tapered Driver, Short
2112-90005	Anti-Torque Handle

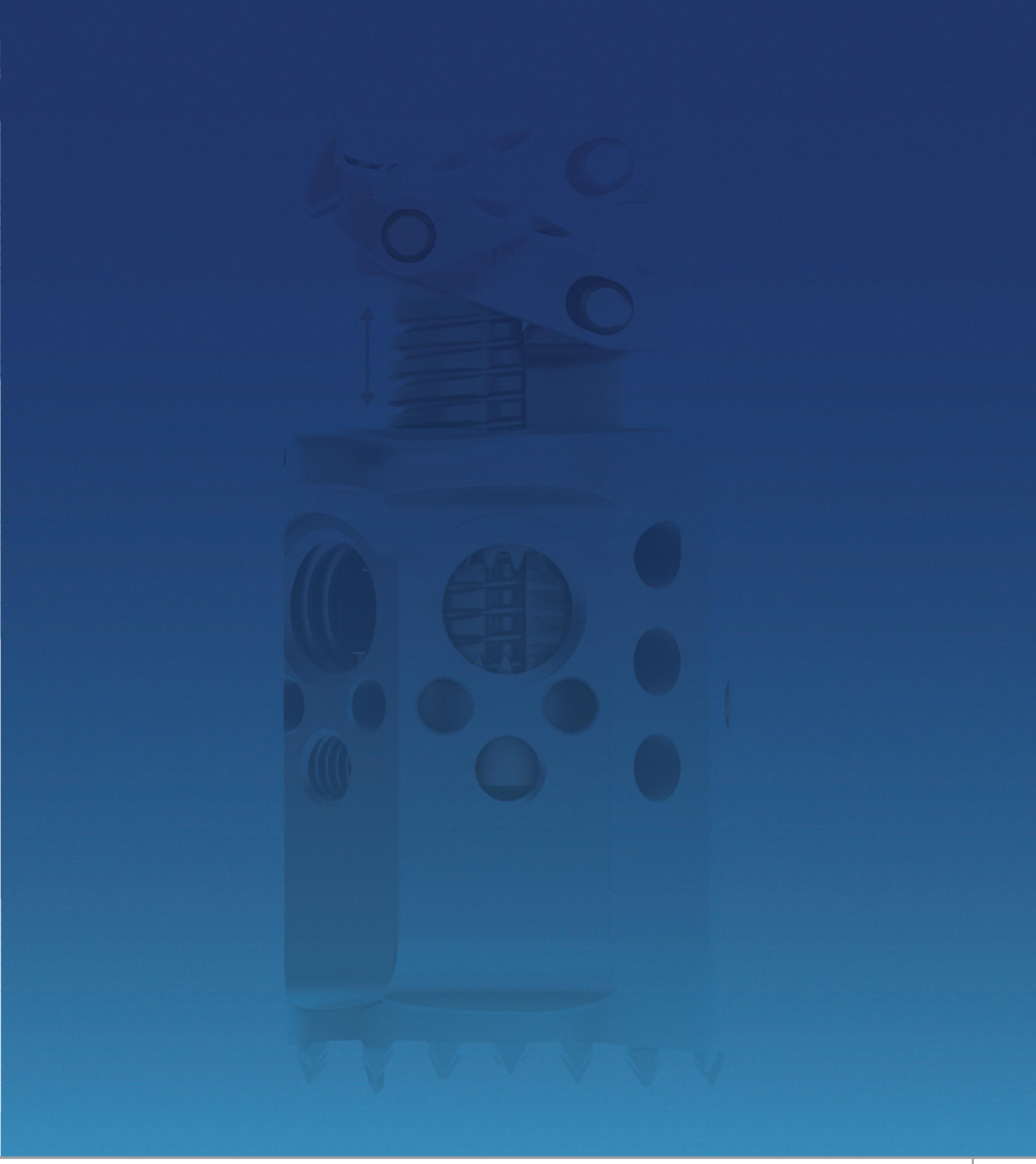
SIZE 20 TAPERED DRIVER

SIZE 20 NON-TAPERED DRIVER

SIZE 20 NON-TAPERED DRIVER, SHORT



ANTI-TORQUE HANDLE



APPENDIXES

IMPLANT SIZE OPTIONS

17 x 22 & 21 x 25 mm FOOTPRINTS

2 mm

4 mm

8 mm

16 mm

23–25 mm

26–30 mm

30–38 mm

46–62 mm

24–26 mm

28–32 mm

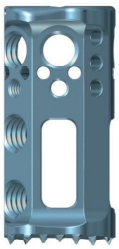
34–42 mm

58–74 mm

25–27 mm

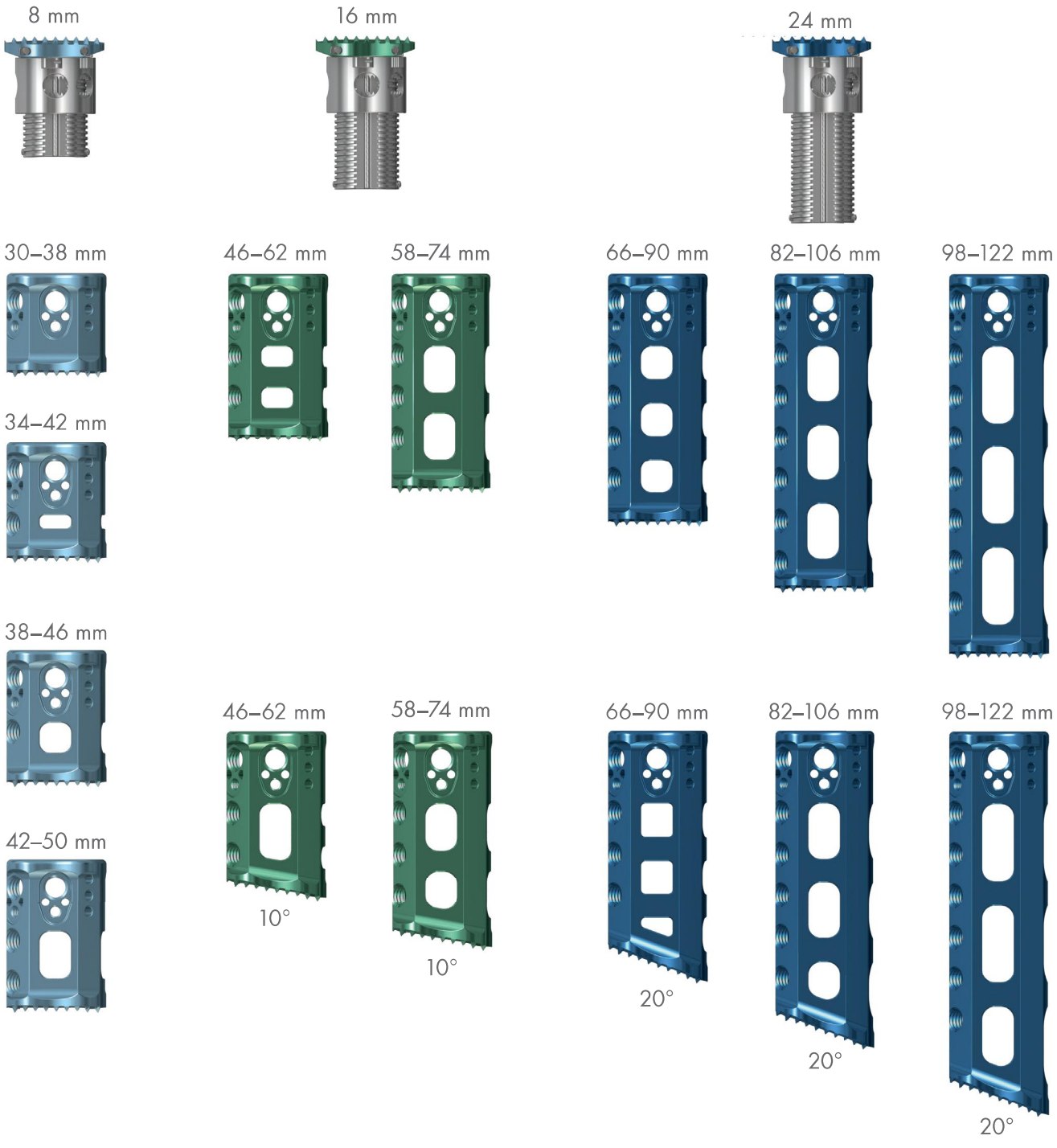
38–46 mm

42–50 mm



IMPLANT SIZE OPTIONS

24 x 30 & 28 x 36 mm FOOTPRINTS



BONE GRAFT VOLUME

Implant Size	External Housing	Internal Expansion Tower (mm)	Minimum Bone Graft Volume (cc)	Maximum Bone Graft Volume (cc)
17 x 22 mm	23–25 mm, 0°	2	1	1
	24–26 mm, 0°	2	1	1
	25–27 mm, 0°	2	1	1
	26–30 mm, 0°	4	1	1
	28–32 mm, 0°	4	1	1
	30–38 mm, 0°	8	1	2
	34–42 mm, 0°	8	2	2
	38–46 mm, 0°	8	2	3
	42–50 mm, 0°	8	3	3
	46–62 mm, 0°	16	4	4
	58–74 mm, 0°	16	5	6
21 x 25 mm	23–25 mm, 0°	2	1	1
	24–26 mm, 0°	2	1	1
	25–27 mm, 0°	2	1	1
	26–30 mm, 0°	4	1	1
	28–32 mm, 0°	4	2	2
	30–38 mm, 0°	8	2	2
	34–42 mm, 0°	8	3	3
	38–46 mm, 0°	8	3	4
	42–50 mm, 0°	8	4	4
	46–62 mm, 0°	16	5	6
	58–74 mm, 0°	16	7	8

NOTE: Cell color corresponds with implant color

BONE GRAFT VOLUME

Implant Size	External Housing	Internal Expansion Tower (mm)	Minimum Bone Graft Volume (cc)	Maximum Bone Graft Volume (cc)
24 x 30 mm	30–38 mm, 0°	8	3	5
	34–42 mm, 0°	8	5	6
	38–46 mm, 0°	8	6	7
	42–50 mm, 0°	8	8	9
	46–62 mm, 0°	16	8	11
	58–74 mm, 0°	16	12	15
	46–62 mm, 10°	16	7	10
	58–74 mm, 10°	16	12	14
	66–90 mm, 0°	24	14	18
	82–106 mm, 0°	24	20	24
	98–122 mm, 0°	24	25	29
	66–90 mm, 20°	24	13	17
	82–106 mm, 20°	24	18	23
	98–122 mm, 20°	24	24	28
28 x 36 mm	30–38 mm, 0°	8	4	5
	34–42 mm, 0°	8	6	7
	38–46 mm, 0°	8	8	9
	42–50 mm, 0°	8	10	11
	46–62 mm, 0°	16	11	13
	58–74 mm, 0°	16	16	19
	46–62 mm, 10°	16	10	12
	58–74 mm, 10°	16	15	18
	66–90 mm, 0°	24	19	23
	82–106 mm, 0°	24	26	30
	98–122 mm, 0°	24	33	37
	66–90 mm, 20°	24	17	21
	82–106 mm, 20°	24	24	28
	98–122 mm, 20°	24	31	35

NOTE: Cell color corresponds with implant color

OPTIMAL CAGE ASSEMBLY

This chart will help determine which internal expansion tower and external housing combinations can be used to get increased expansion capability with any fit discrepancies (i.e., assembling column 1 into column 3 gives you a new expansion range indicated in column 6, while showing any fit discrepancies in column 7).

Internal Expansion Tower Catalog #	Expansion (mm)	External Housing Catalog #	Height Range (mm)	Angle (°)	Expansion Range (mm)	Fit Description
2112-20422	4	2101-22722L0	25–27	0	25–29	Sticks out slightly
2112-21622	16	2101-24622L0	38–46	0	38–54	Perfect fit
2112-21622	16	2101-25022L0	42–50	0	42–58	Perfect fit
2112-20425	4	2101-22725L0	25–27	0	25–29	Sticks out slightly
2112-21625	16	2101-24625L0	38–46	0	38–54	Perfect fit
2112-21625	16	2101-25025L0	42–50	0	42–58	Perfect fit
2112-21630	16	2101-24630L0	38–46	0	38–54	Perfect fit
2112-21630	16	2101-25030L0	42–50	0	42–58	Perfect fit
2112-22430	24	2101-26230L0	46–62	0	46–70	Perfect fit
2112-22430	24	2101-26230L10	46–62	10	46–70	Perfect fit
2112-22430	24	2101-27430L0	58–74	0	58–82	Perfect fit
2112-22430	24	2101-27430L10	58–74	10	58–82	Perfect fit
2112-21636	16	2101-24636L0	38–46	0	38–54	Perfect fit
2112-21636	16	2101-25036L0	42–50	0	42–58	Perfect fit
2112-22436	24	2101-26236L0	46–62	0	46–70	Perfect fit
2112-22436	24	2101-26236L10	46–62	10	46–70	Sticks out slightly
2112-22436	24	2101-27436L0	58–74	0	58–82	Perfect fit
2112-22436	24	2101-27436L10	58–74	10	58–82	Perfect fit

NOTE: Cell color corresponds with implant color

APPROXIMATE TURNS FOR HEIGHT & ENDPLATE ANGULATION

Expansion (mm)	Footprint (mm)	Height (# turns)	Angle (# turns)	Footprint (mm)	Height (# turns)	Angle (# turns)
2	17 x 22, 21 x 25	3	4.5	24 x 30, 28 x 36	-	-
4	17 x 22, 21 x 25	6.5	6.5	24 x 30, 28 x 36	-	-
8	17 x 22, 21 x 25	12	6.5	24 x 30, 28 x 36	14	14
16	17 x 22, 21 x 25	23.5	6.5	24 x 30, 28 x 36	27	14
24	17 x 22, 21 x 25	-	-	24 x 30, 28 x 36	40.5	14

NOTE: Cell color corresponds with implant color

⚠ BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION

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

DEVICE DESCRIPTION
The CAPRI Corpectomy Cage System consists of hollow tube structures manufactured from Ti6Al4V ELI and Co-Cr-Mo, that can be implanted via posterior, anterior or lateral approaches. The implant height and endplates may be adjusted in-situ. The CAPRI cages will be offered in various footprints.

INDICATIONS
The CAPRI Corpectomy Cage Systems is a vertebral body replacement device intended for use in the thoracolumbar spine (T1 to L5) to replace collapsed, damaged, or unstable vertebral bodies due to tumor or trauma (i.e. fracture). The CAPRI Corpectomy Cage Systems is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. The CAPRI device may be used with allograft or autograft.

For all the above indications the CAPRI 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 CAPRI Corpectomy Cage Systems are manufactured from Titanium (per ASTM F3001) and Cobalt Chrome (per ASTM F1537).

CLEANING/ REPROCESSING OF K2M SURGICAL INSTRUMENTS
K2M surgical instruments are supplied non-sterile and must be thoroughly cleaned prior to sterilization. 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. Contaminated instruments should be wiped clean of visible soil at the point of use, to prevent drying of soil and contaminants in and on the device.
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.

Sterile Devices
Implant components labeled as STERILE are gamma irradiated.
CAUTION: Do not use if package is damaged. If the tamper proof seals or sterile packaging appear to be compromised or damaged, return the package and its contents to K2M.
CAUTION: The implants are intended for single use only. ⊗ Do not attempt to clean or resterilize the implants. Reprocessing of single use devices may introduce risks associated with guaranteeing sterility assurance.

STORAGE
Store sterile packages in a well-ventilated area that provides protection from dust, insects, moisture, and vermin.

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 CAPRI Corpectomy Cage Systems 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 CAPRI Corpectomy Cage Systems 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 CAPRI Corpectomy Cage Systems 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 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 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 titanium 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 CAPRI Corpectomy Cage Systems 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, 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 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 all components should be inspected and any evidence of damage or corrosion should be reported to your local K2M sales representative.
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 titanium 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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Leesburg, VA 20175
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Emergo Europe
Prinsessegracht 20
2514 AP
The Hague
The Netherlands

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2514 AP
The Hague
The Netherlands

CAPRI™

LARGE EXPANDABLE CORPECTOMY CAGE SYSTEM

The CAPRI Large Expandable Corpectomy Cage System provides an innovative solution for stabilization of the spine in cases of vertebral body resections resulting from trauma or tumor. Offered in various footprint options, this versatile system allows for in-situ height expansion and endplate angulation.

K2M

www.K2M.com

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