



COMPLEX SPINE  
INNOVATIONS™

SURGICAL TECHNIQUE

CAPRI™

LARGE EXPANDABLE CORPECTOMY CAGE SYSTEM



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# 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**



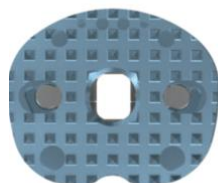
**Cage Construct**



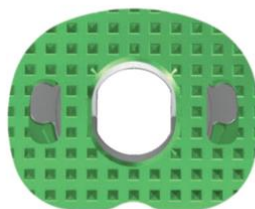
**External Housing**



**17 x 22 mm**



**21 x 25 mm**



**24 x 30 mm**

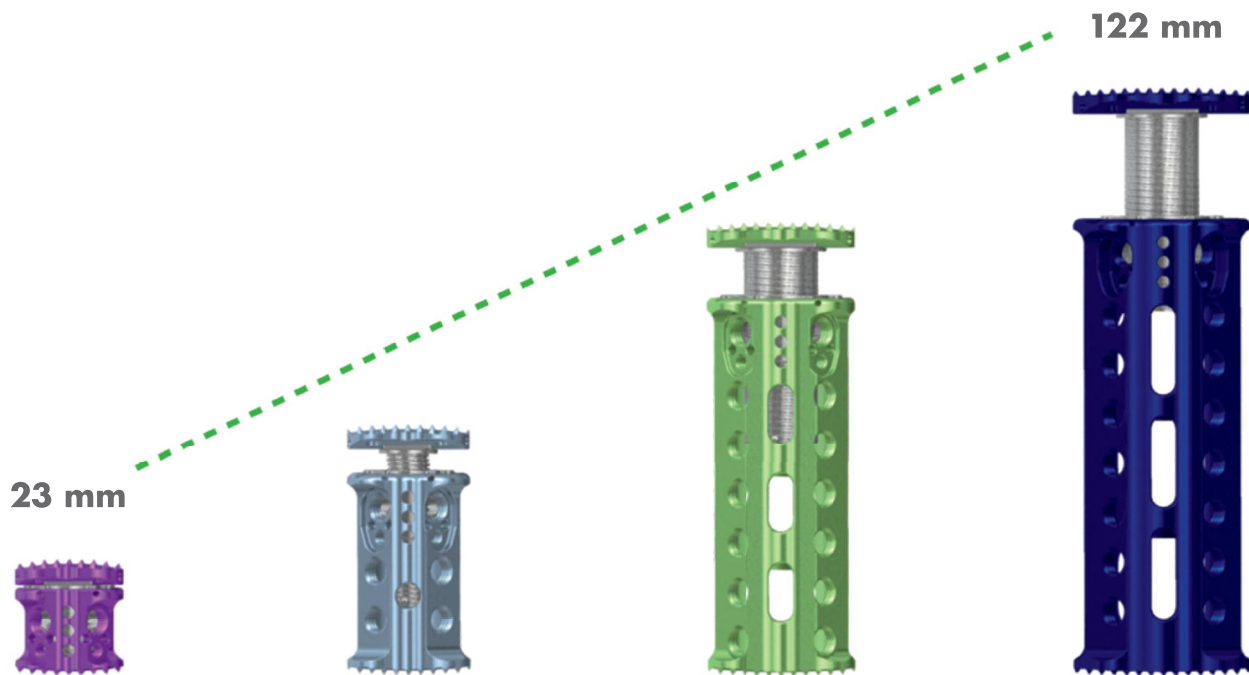


**28 x 36 mm**



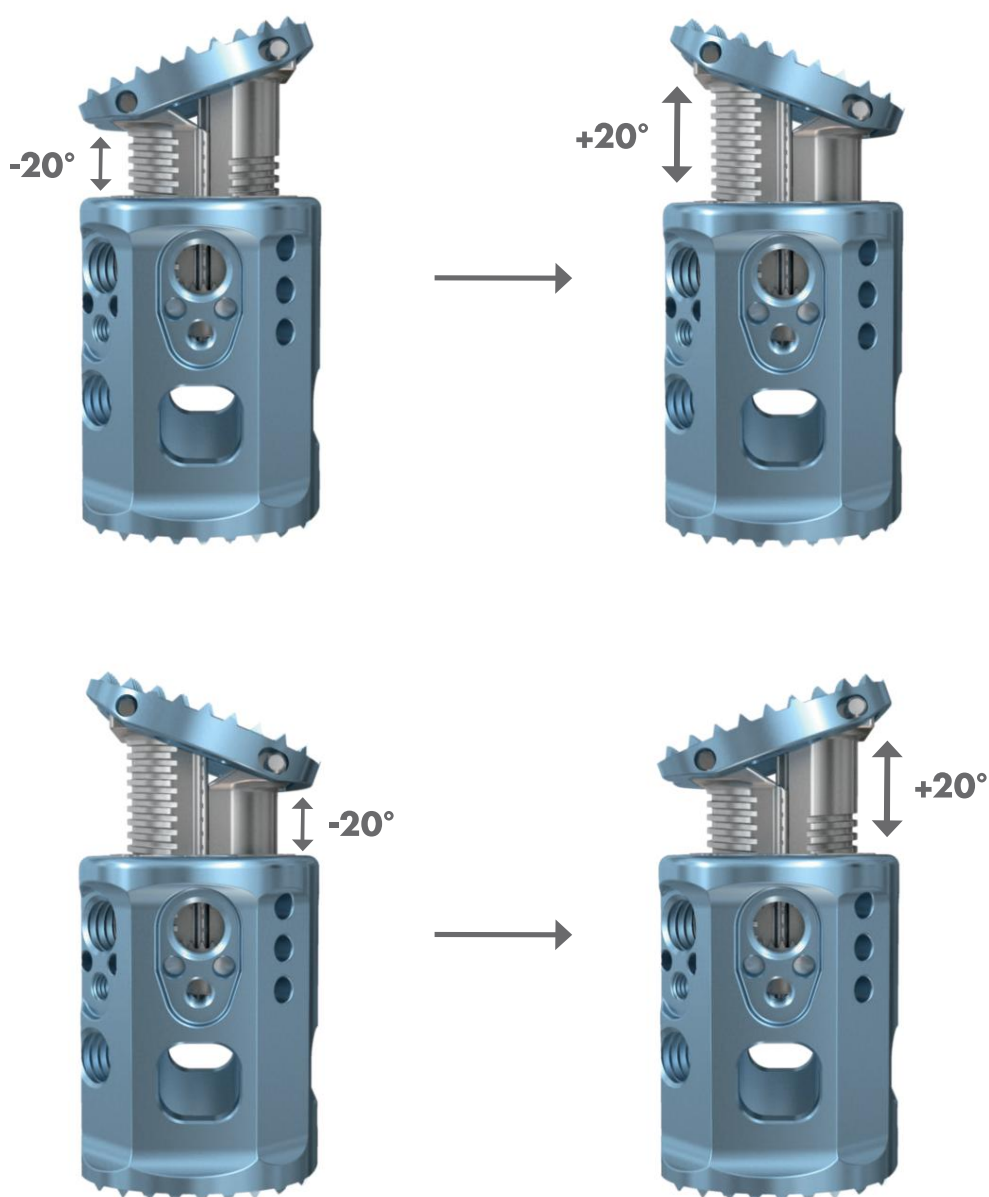
The 17 x 22 and 21 x 25 mm cages are offered in heights of 23–74 mm, while the 24 x 30 and 28 x 36 mm cages are offered in heights of 30–122 mm.

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  $-20^{\circ}$  to  $20^{\circ}$ .



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°







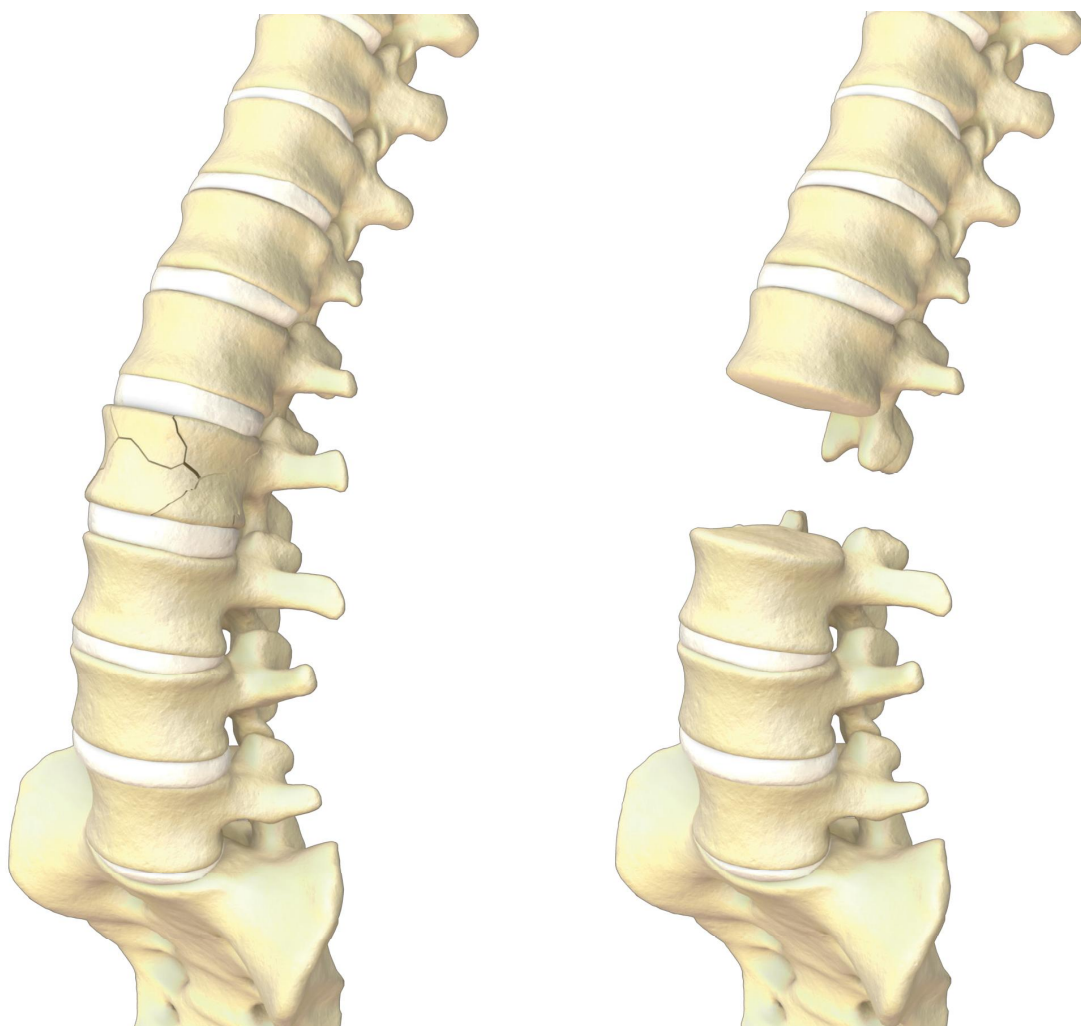


# SURGICAL TECHNIQUE

# 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.



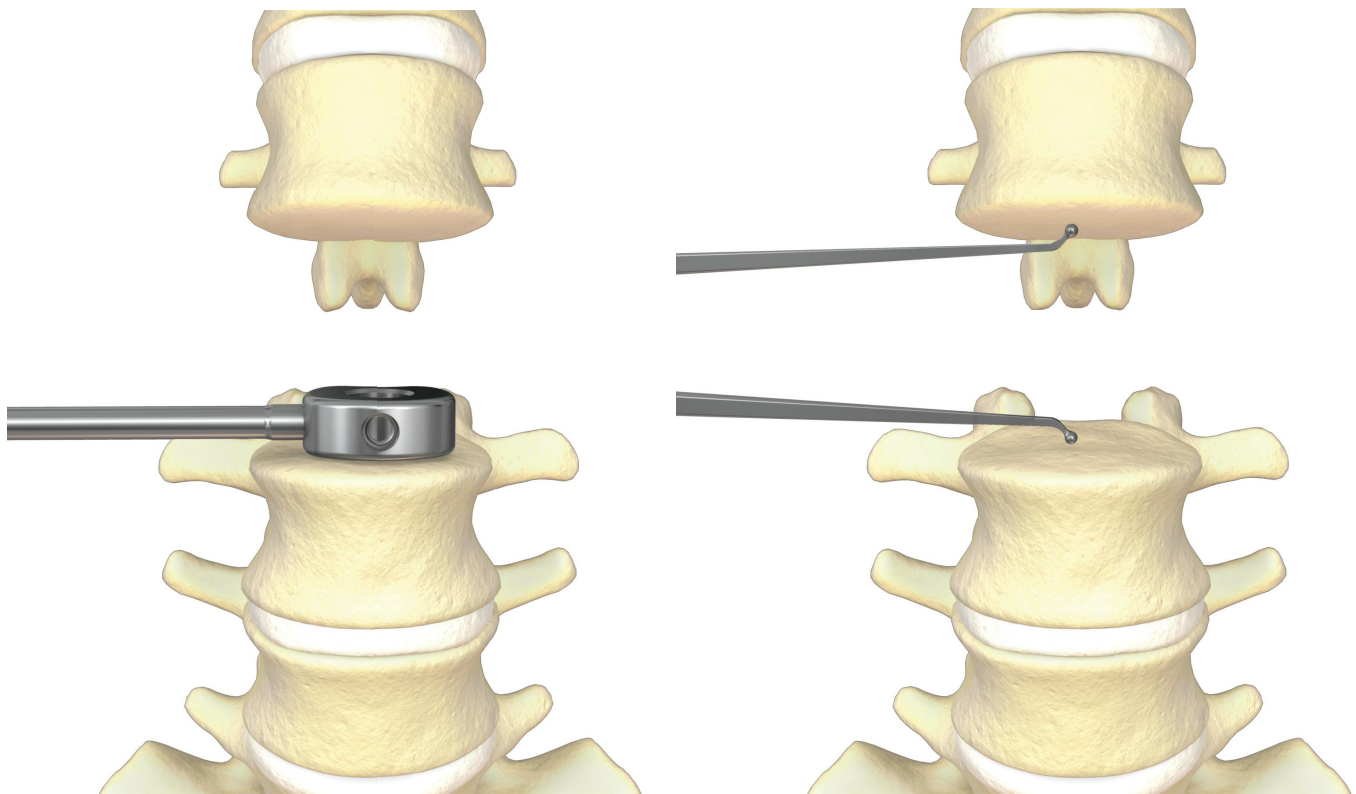


# STEP 2

## 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



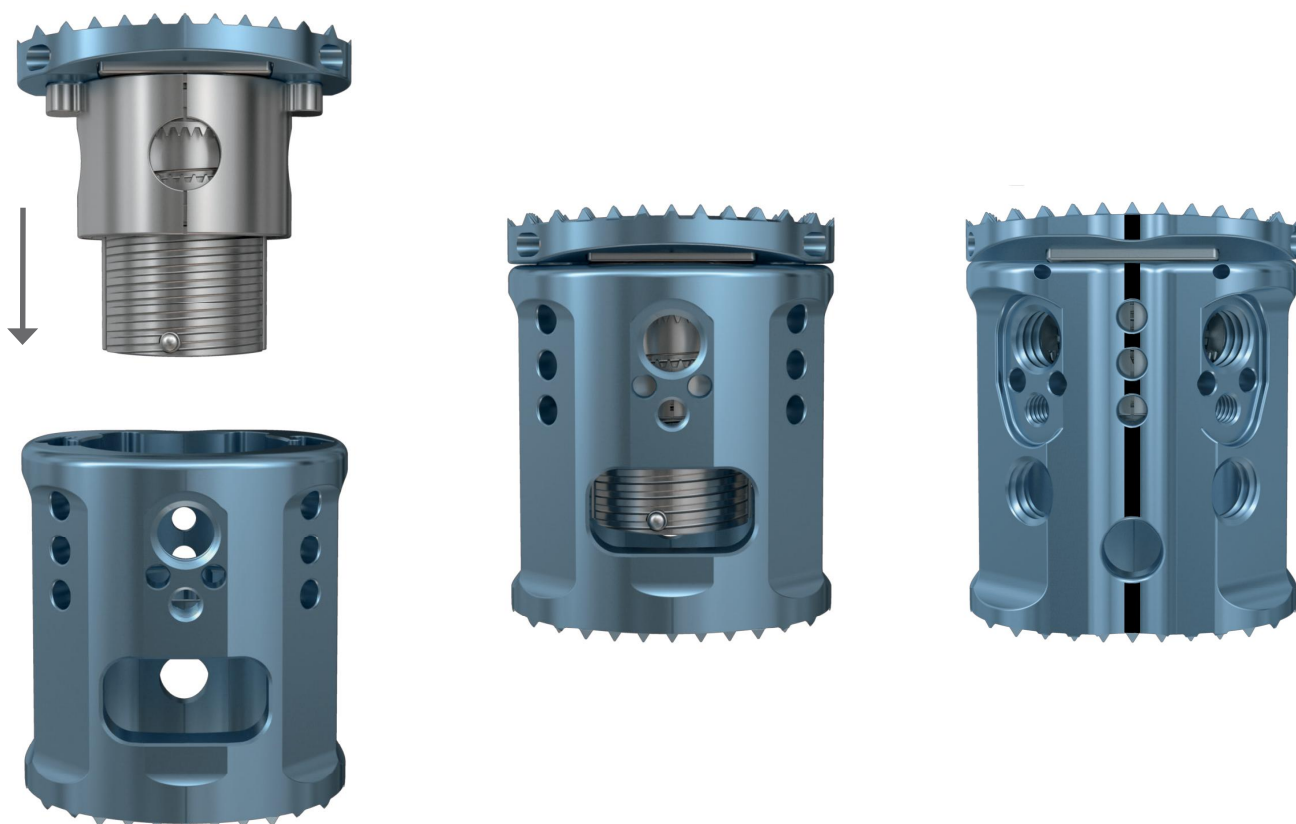
CAPRI™		CAPRI™	
23-25	17x22 mm	30-38	24x30 mm
24-26	17x22 mm	31-42	28x36 mm
25-27	21x25 mm	32-45	32-45
26-28		33-50	36-50
27-30		34-55	40-55
28-32		35-60	44-60
29-34		36-65	48-65
30-38		37-70	52-70
31-42		38-75	56-75
32-45		39-80	60-80
33-50		40-85	64-85
34-55		41-90	68-90
35-60		42-95	72-95
36-65		43-100	76-100
37-70		44-105	80-105
38-75		45-110	84-110
39-80		46-115	88-115
40-85		47-120	92-120
41-90		48-125	96-125
42-95		49-130	100-130
43-100		50-135	104-135
44-105		51-140	108-140
45-110		52-145	112-145
46-115		53-150	116-150
47-120		54-155	120-155
48-125		55-160	124-160
49-130		56-165	128-165
50-135		57-170	132-170
51-140		58-175	136-175
52-145		59-180	140-180
53-150		60-185	144-185
54-155		61-190	148-190
55-160		62-195	152-195
56-165		63-200	156-200
57-170		64-205	160-205
58-175		65-210	164-210
59-180		66-215	168-215
60-185		67-220	172-220
61-190		68-225	176-225
62-195		69-230	180-230
63-200		70-235	184-235
64-205		71-240	188-240
65-210		72-245	192-245
66-215		73-250	196-250
67-220		74-255	200-255
68-225		75-260	204-260
69-230		76-265	208-265
70-235		77-270	212-270
71-240		78-275	216-275
72-245		79-280	220-280
73-250		80-285	224-285
74-255		81-290	228-290
75-260		82-295	232-295
76-265		83-300	236-300
77-270		84-305	240-305
78-275		85-310	244-310
79-280		86-315	248-315
80-285		87-320	252-320
81-290		88-325	256-325
82-295		89-330	260-330
83-300		90-335	264-335
84-305		91-340	268-340
85-310		92-345	272-345
86-315		93-350	276-350
87-320		94-355	280-355
88-325		95-360	284-360
89-330		96-365	288-365
90-335		97-370	292-370
91-340		98-375	296-375
92-345		99-380	300-380
93-350		100-385	304-385
94-355		101-390	308-390
95-360		102-395	312-395
96-365		103-400	316-400
97-370		104-405	320-405
98-375		105-410	324-410
99-380		106-415	328-415
100-385		107-420	332-420
101-390		108-425	336-425
102-395		109-430	340-430
103-400		110-435	344-435
104-405		111-440	348-440
105-410		112-445	352-445
106-415		113-450	356-450
107-420		114-455	360-455
108-425		115-460	364-460
109-430		116-465	368-465
110-435		117-470	372-470
111-440		118-475	376-475
112-445		119-480	380-480
113-450		120-485	384-485
114-455		121-490	388-490
115-460		122-495	392-495
116-465		123-500	396-500
117-470		124-505	400-505
118-475		125-510	404-510
119-480		126-515	408-515
120-485		127-520	412-520
121-490		128-525	416-525
122-495		129-530	420-530
123-500		130-535	424-535
124-505		131-540	428-540
125-510		132-545	432-545
126-515		133-550	436-550
127-520		134-555	440-555
128-525		135-560	444-560
129-530		136-565	448-565
130-535		137-570	452-570
131-540		138-575	456-575
132-545		139-580	460-580
133-550		140-585	464-585
134-555		141-590	468-590
135-560		142-595	472-595
136-565		143-600	476-600
137-570		144-605	480-605
138-575		145-610	484-610
139-580		146-615	488-615
140-585		147-620	492-620
141-590		148-625	496-625
142-595		149-630	500-630
143-600		150-635	504-635
144-605		151-640	508-640
145-610		152-645	512-645
146-615		153-650	516-650
147-620		154-655	520-655
148-625		155-660	524-660
149-630		156-665	528-665
150-635		157-670	532-670
151-640		158-675	536-675
152-645		159-680	540-680
153-650		160-685	544-685
154-655		161-690	548-690
155-660		162-695	552-695
156-665		163-700	556-700
157-670		164-705	560-705
158-675		165-710	564-710
159-680		166-715	568-715
160-685		167-720	572-720
161-690		168-725	576-725
162-695		169-730	580-730
163-700		170-735	584-735
164-705		171-740	588-740
165-710		172-745	592-745
166-715		173-750	596-750
167-720		174-755	600-755
168-725		175-760	604-760
169-730		176-765	608-765
170-735		177-770	612-770
171-740		178-775	616-775
172-745		179-780	620-780
173-750		180-785	624-785
174-755		181-790	628-790
175-760		182-795	632-795
176-765		183-800	636-800
177-770		184-805	640-805
178-775		185-810	644-810
179-780		186-815	648-815
180-785		187-820	652-820
181-790		188-825	656-825
182-795		189-830	660-830
183-800		190-835	664-835
184-805		191-840	668-840
185-810		192-845	672-845
186-815		193-850	676-850
187-820		194-855	680-855
188-825		195-860	684-860
189-830		196-865	688-865
190-835		197-870	692-870
191-840		198-875	696-875
192-845		199-880	700-880
193-850		200-885	704-885
194-855		201-890	708-890
195-860		202-895	712-895
196-865		203-900	716-900
197-870		204-905	720-905
198-875		205-910	724-910
199-880		206-915	728-915
200-885		207-920	732-920
201-890		208-925	736-925
202-895		209-930	740-930
203-900		210-935	744-935
204-905		211-940	748-940
205-910		212-945	752-945
206-915		213-950	756-950
207-920		214-955	760-955
208-925		215-960	764-960
209-930		216-965	768-965
210-935		217-970	772-970
211-940		218-975	776-975
212-945		219-980	780-980
213-950		220-985	784-985
214-955		221-990	788-990
215-960		222-995	792-995
216-965		223-1000	796-1000
217-970		224-1005	800-1005
218-975		225-1010	804-1010
219-980		226-1015	808-1015
220-985		227-1020	812-1020
221-990		228-1025	816-1025
222-995		229-1030	820-1030
223-1000		230-1035	824-1035
224-1005		231-1040	828-1040
225-1010		232-1045	832-1045
226-1015		233-1050	836-1050
227-1020		234-1055	840-1055
228-1025		235-1060	844-1060
229-1030		236-1065	848-1065
230-1035		237-1070	852-1070
231-1040		238-1075	856-1075
232-1045		239-1080	860-1080
233-1050		240-1085	864-1085
234-1055		241-1090	868-1090
235-1060		242-1095	872-1095
236-1065		243-1100	876-1100
237-1070		244-1105	880-1105
238-1075		245-1110	884-1110
239-1080		246-1115	888-1115
240-1085		247-1120	892-1120
241-1090		248-1125	896-1125
242-1095		249-1130	900-1130
243-1100		250-1135	904-1135
244-1105		251-1140	908-1140
245-1110		252-1145	912-1145
246-1115		253-1150	916-1150
247-1120		254-1155	920-1155
248-1125		255-1160	924-1160
249-1130		256-1165	928-1165
250-1135		257-1170	932-1170
251-1140		258-1175	936-1175
252-1145		259-1180	940-1180
253-1150		260-1185	944-1185
254-1155		261-1190	948-1190
255-1160		262-1195	952-1195
256-1165		263-1200	956-1200
257-1170		264-1205	960-1205
258-1175		265-1210	964-1210
259-1180		266-1215	968-1215
260-1185		267-1220	972-1220
261-1190		268-1225	976-1225
262-1195		269-1230	980-1230
263-1200		270-1235	984-1235
264-1205		271-1240	988-1240
265-1210		272-1245	992-1245
266-1215		273-1250	996-1250
267-1220		274-1255	1000-1255
268-1225		275-1260	1004-1260
269-1230		276-1265	1008-1265
270-1235		277-1270	1012-1270
271-1240		278-1275	1016-1275
272-1245		279-1280	1020-1280
273-1250		280-1285	1024-1285
274-1255		281-1290	1028-1290
275-1260		282-1295	1032-1295

# STEP 3

## CAGE ASSEMBLY

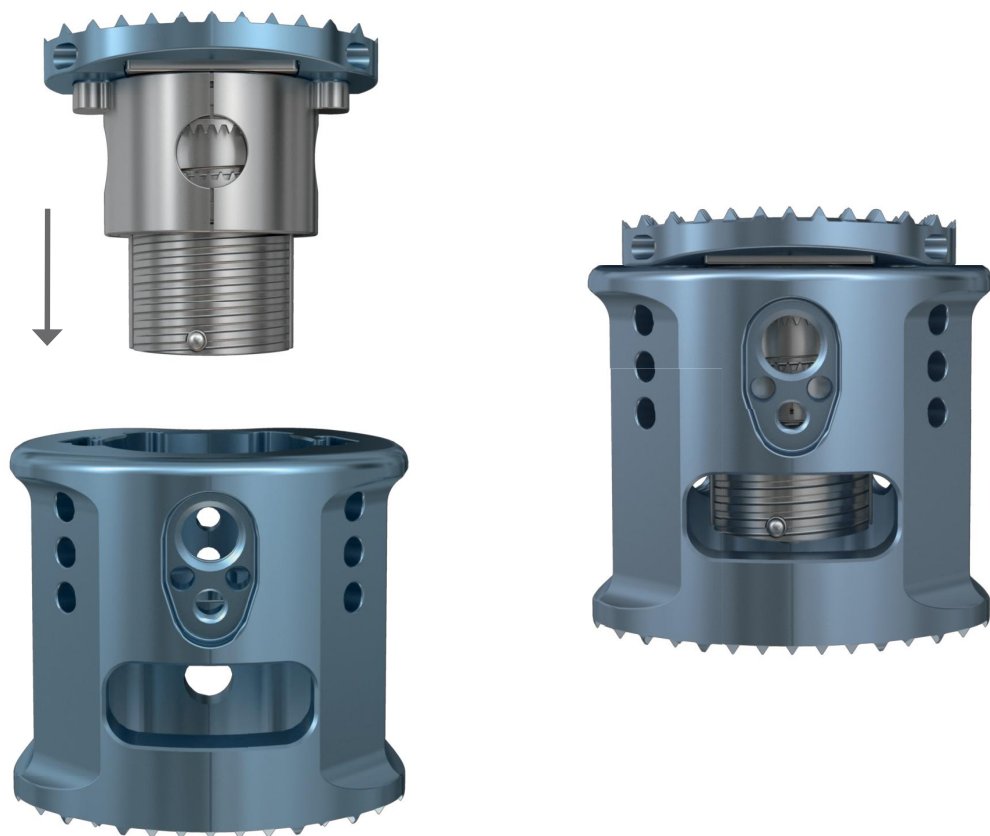
Identify the appropriate external housing and color-corresponding internal tower for the determined footprint and cage height. When properly assembled, the laser marked lines on each component will be aligned and the two pieces will snap together. If necessary, the cage can be disassembled by pulling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



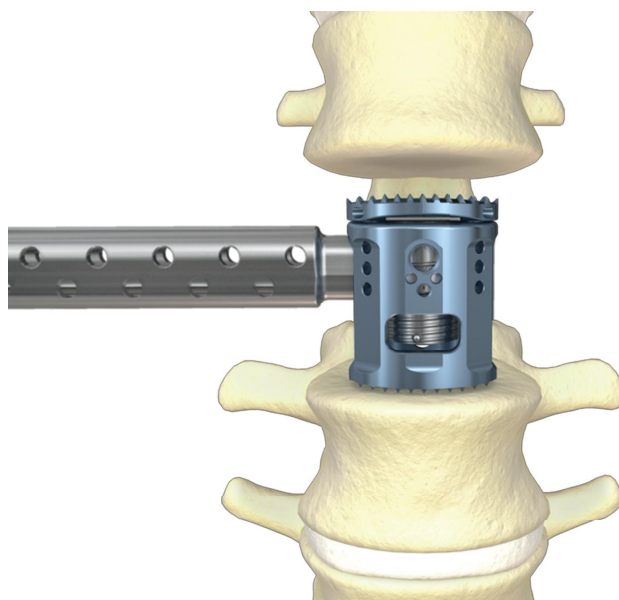
**Direct Anterior  
Insertion Point**



**(2) Direct Lateral  
Insertion Points**



**(2) Posterior Lateral  
Insertion Points**



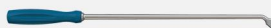
INSERTER



INSERTER THREADED SHAFT



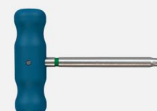
CURVED PUSHER



ANGLED PUSHER

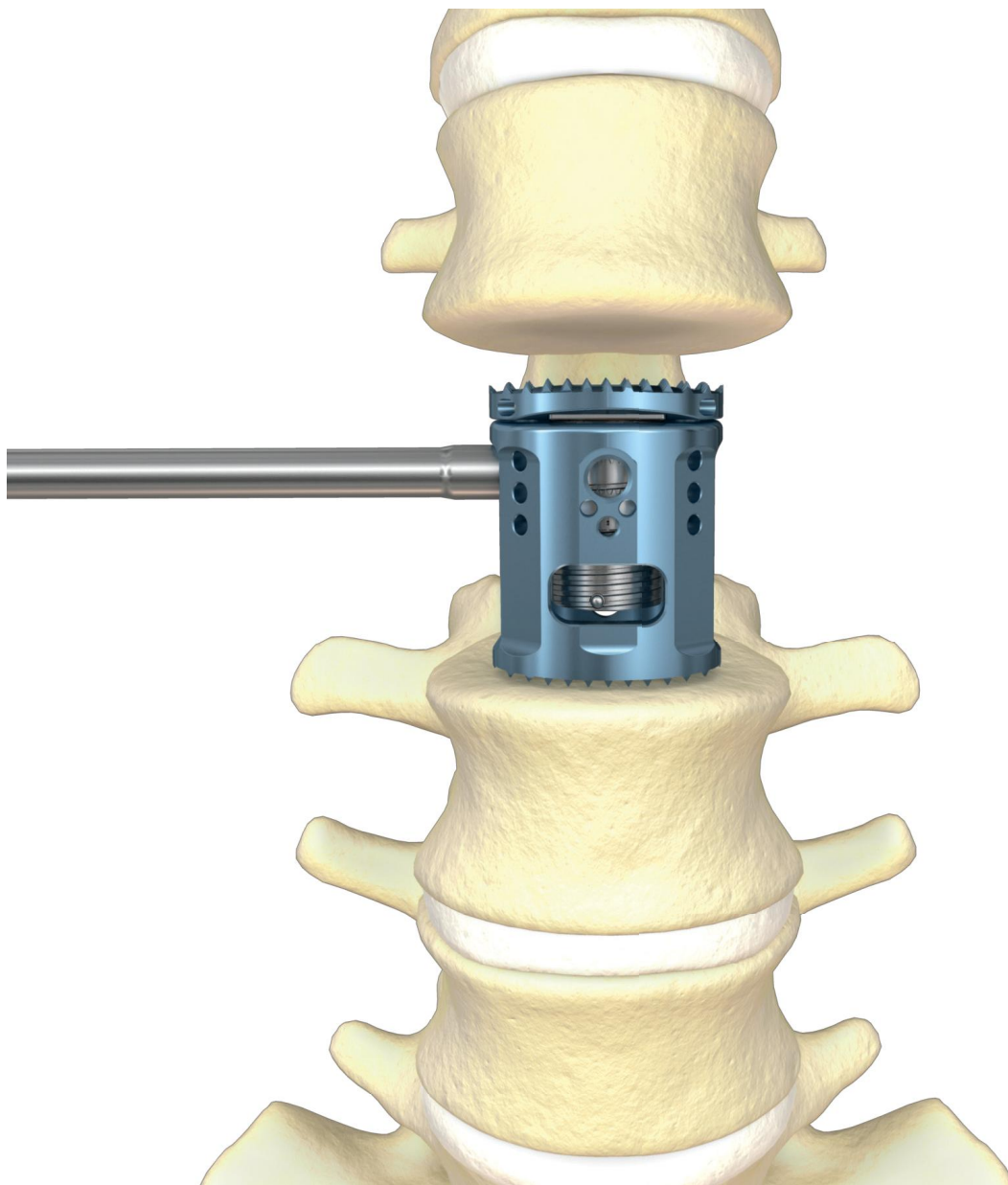


SIZE 20 NON-TAPERED  
DRIVER, SHORT



**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.

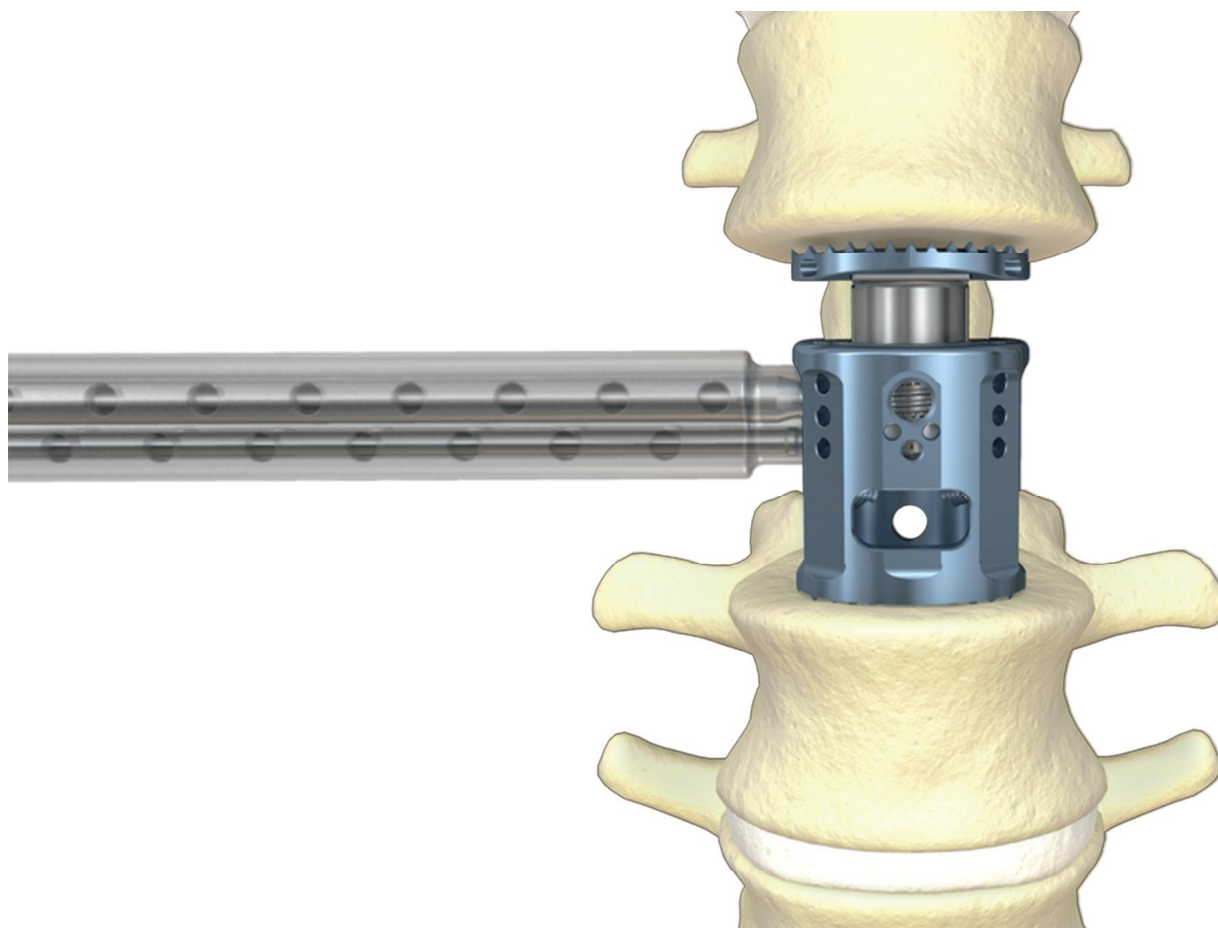


# STEP 5

## 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 Insert. 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

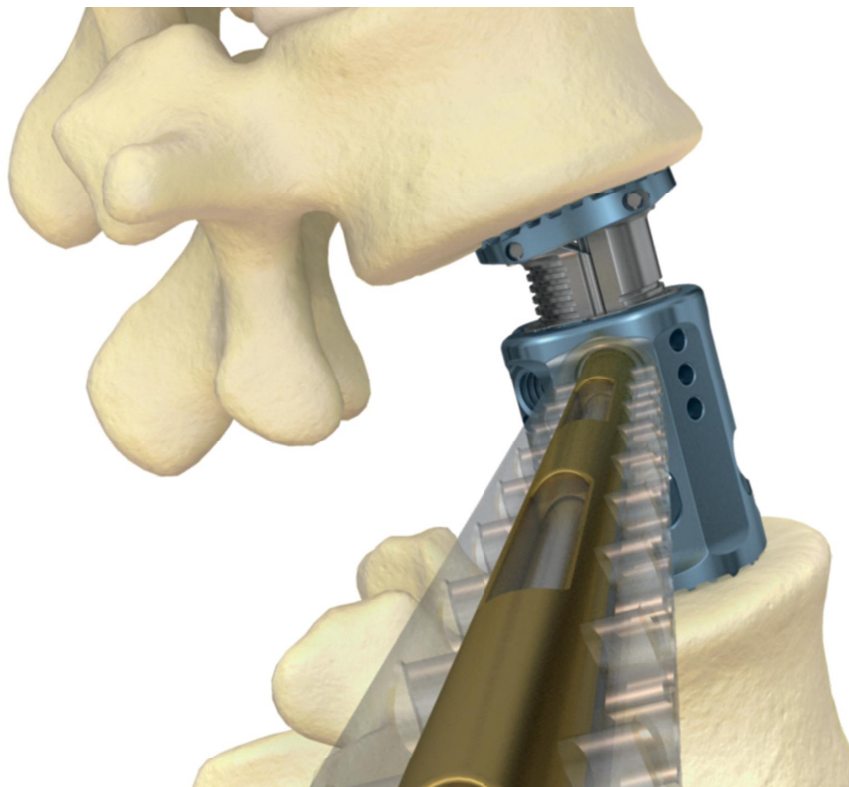




# STEP 6

## 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 Insert.



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

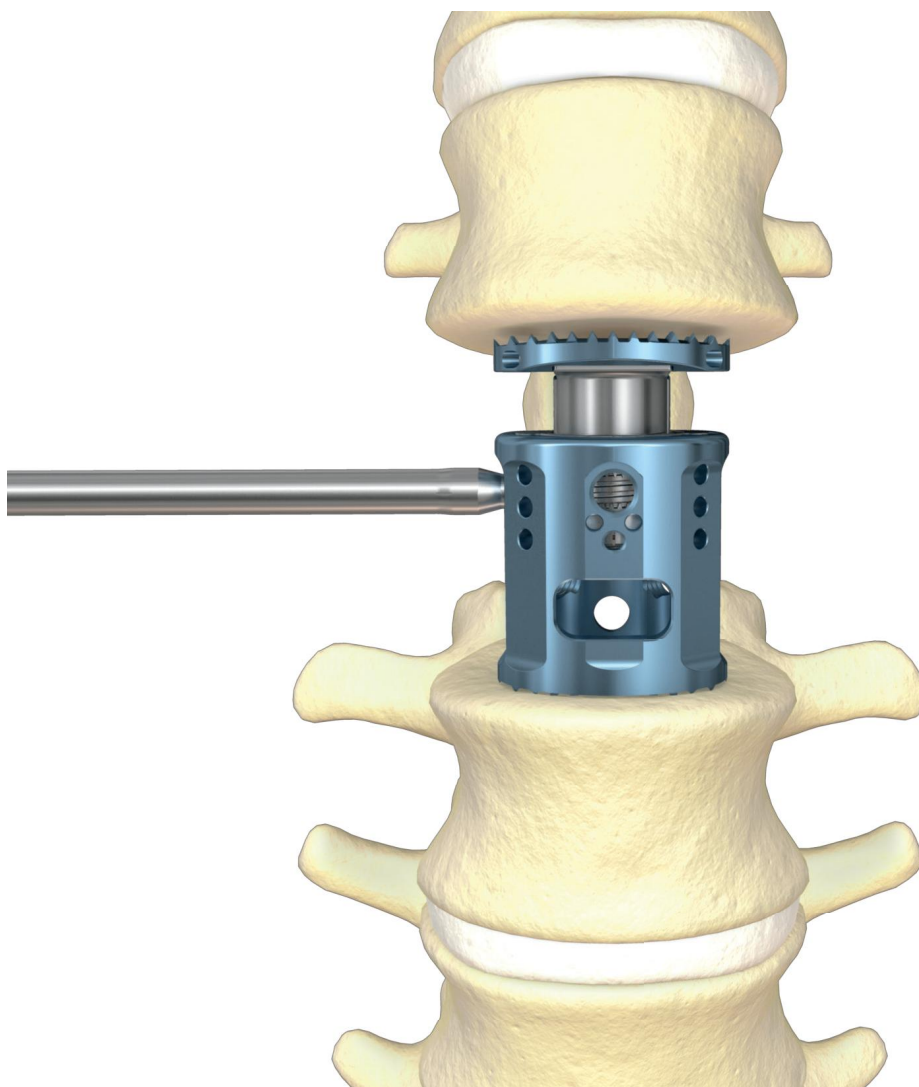
## OPTIONAL HEIGHT & ENDPLATE ANGULATION

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.





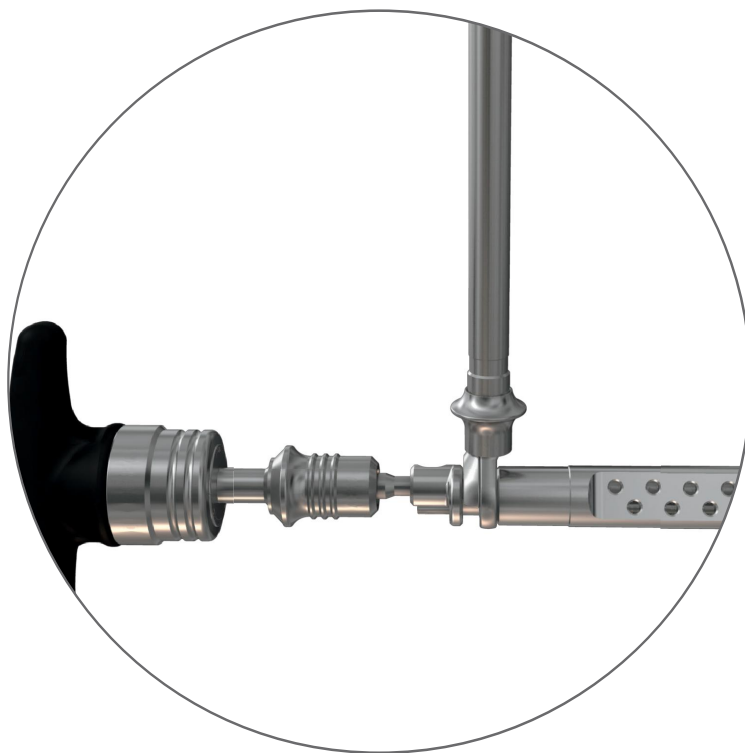
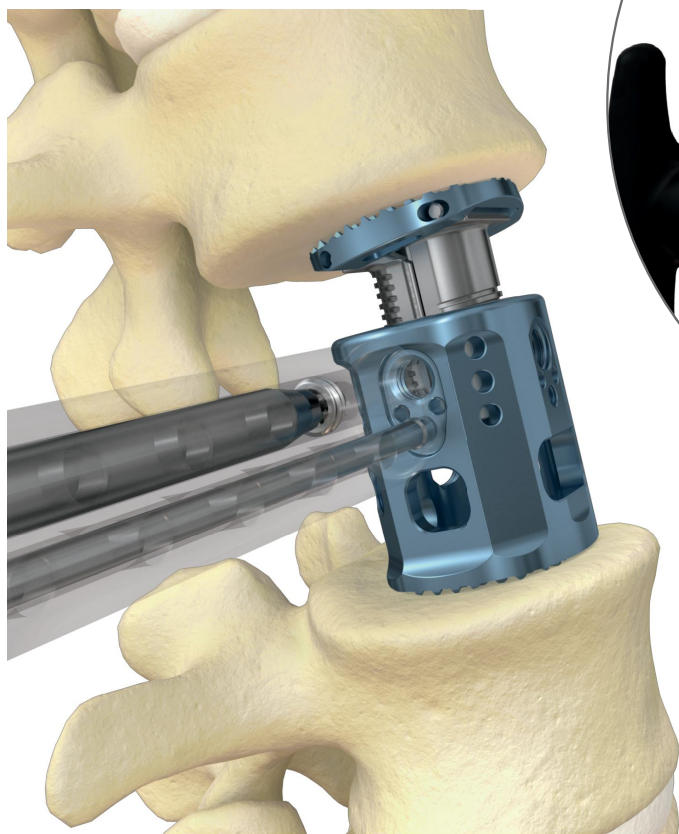
# STEP 8

## 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.

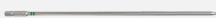
**NOTE:** A locking screw **MUST** be inserted and final tightened to 5.4 Nm (48 in-lbs) in order to finalize the construct.



SIZE 20 NON-TAPERED  
DRIVER



SIZE 20 TAPERED  
DRIVER



ANTI-TORQUE  
HANDLE



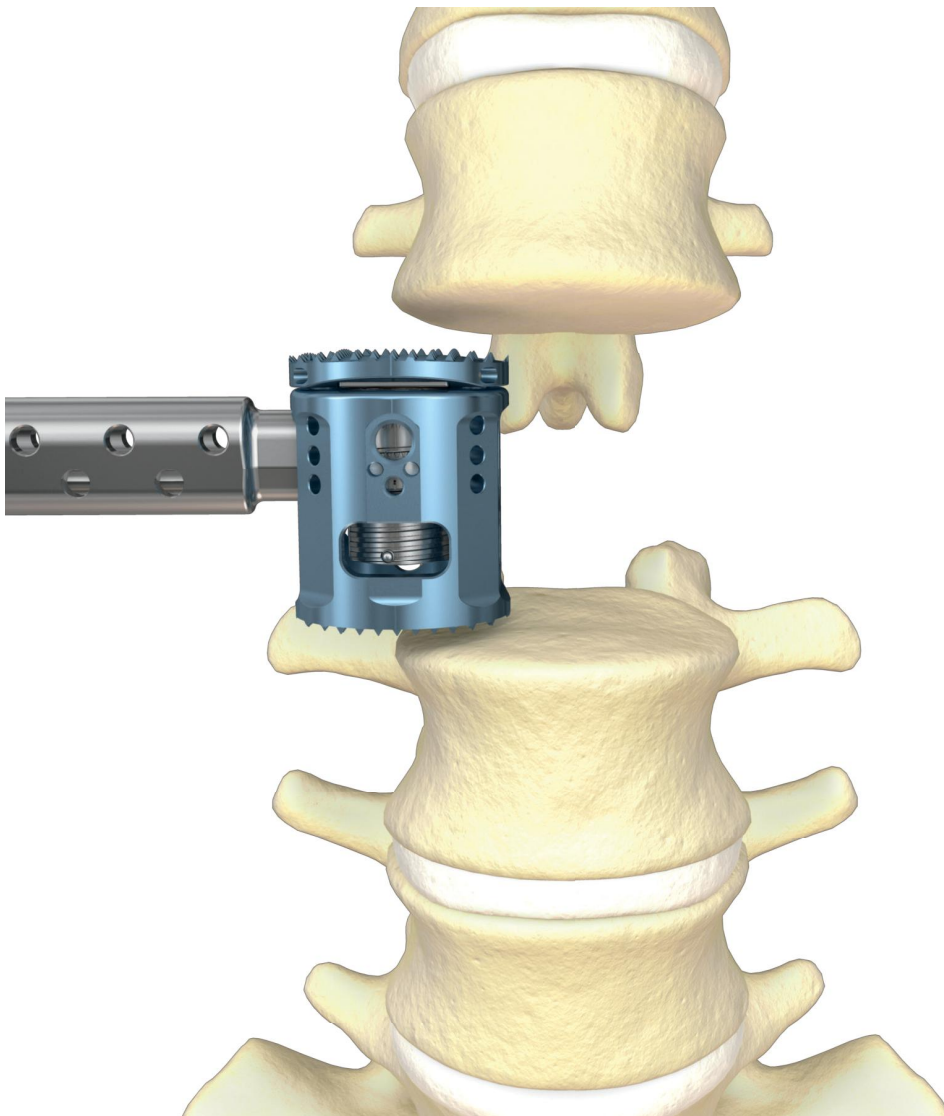
TORQUE LIMITING HANDLE, SQUARE





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.

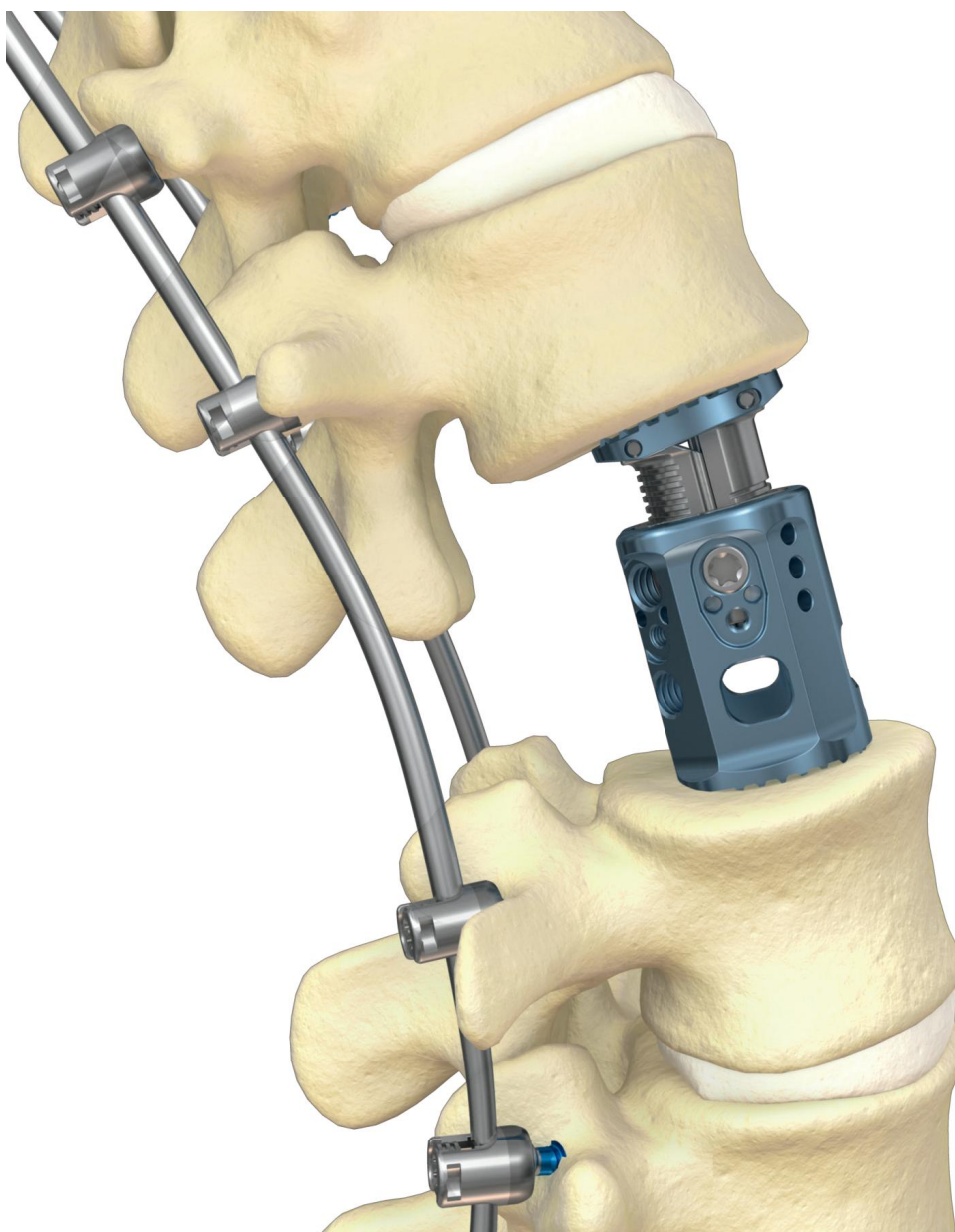
Collapse the height of the cage by inserting the Height Expansion Driver into the Inserter and turn the Driver counter-clockwise. With the cage still attached to the Inserter, remove the cage and Inserter from the corpectomy space.



# 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



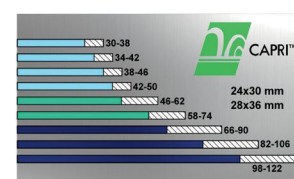
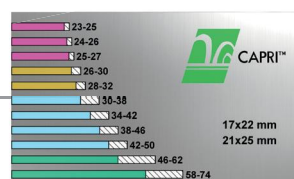
### BONE FUNNEL



### BONE FUNNEL PUSHER



### IMPLANT SIZING CHART





## INSERTION INSTRUMENTS

2112-90006	Insertor
2112-90007	Height Expansion Driver
2112-90008	Lordosis/Kyphosis Driver
2112-90009	Insertor 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

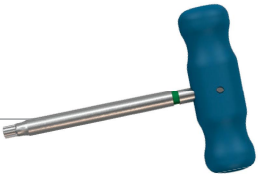
SIZE 20 TAPERED DRIVER



SIZE 20 NON-TAPERED DRIVER



SIZE 20 NON-TAPERED DRIVER, SHORT



ANTI-TORQUE HANDLE



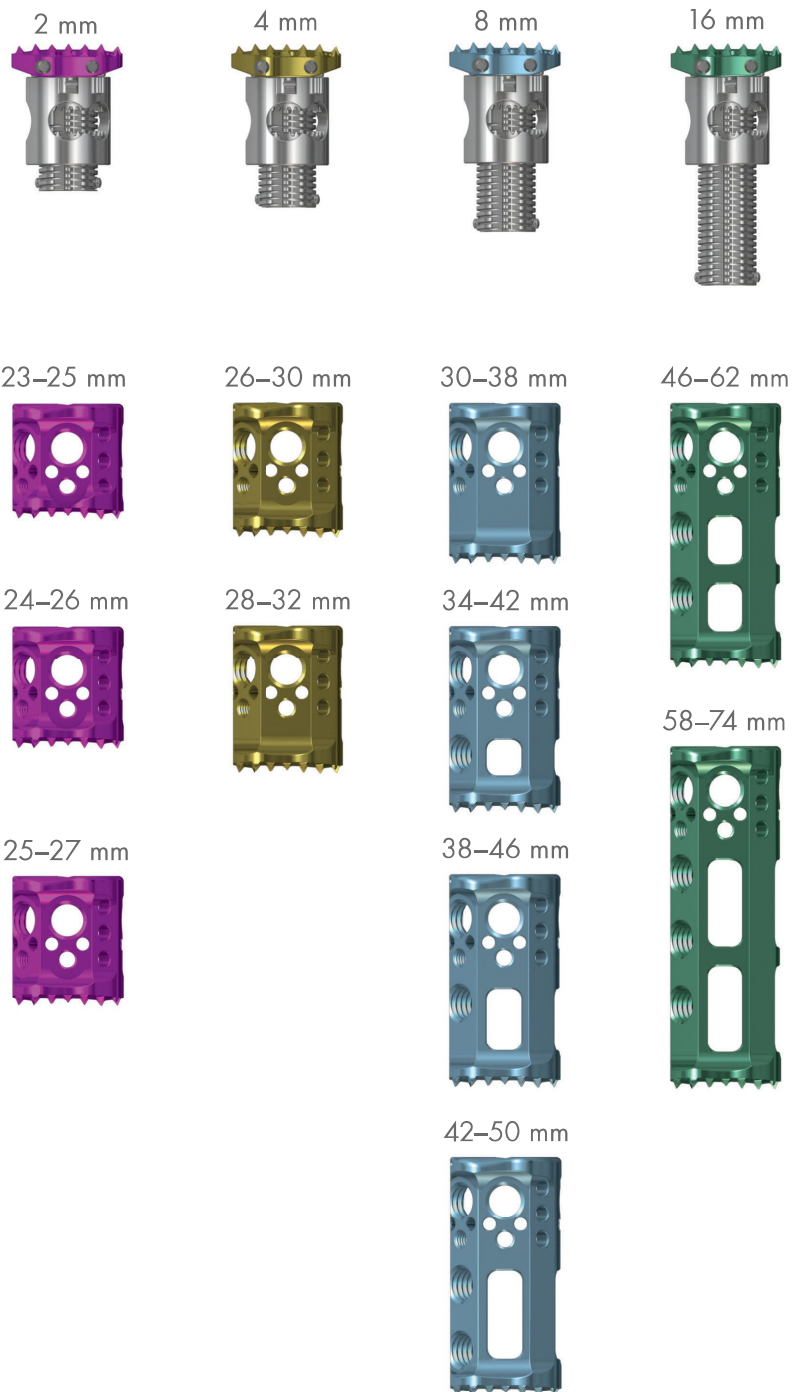


# APPENDIXES



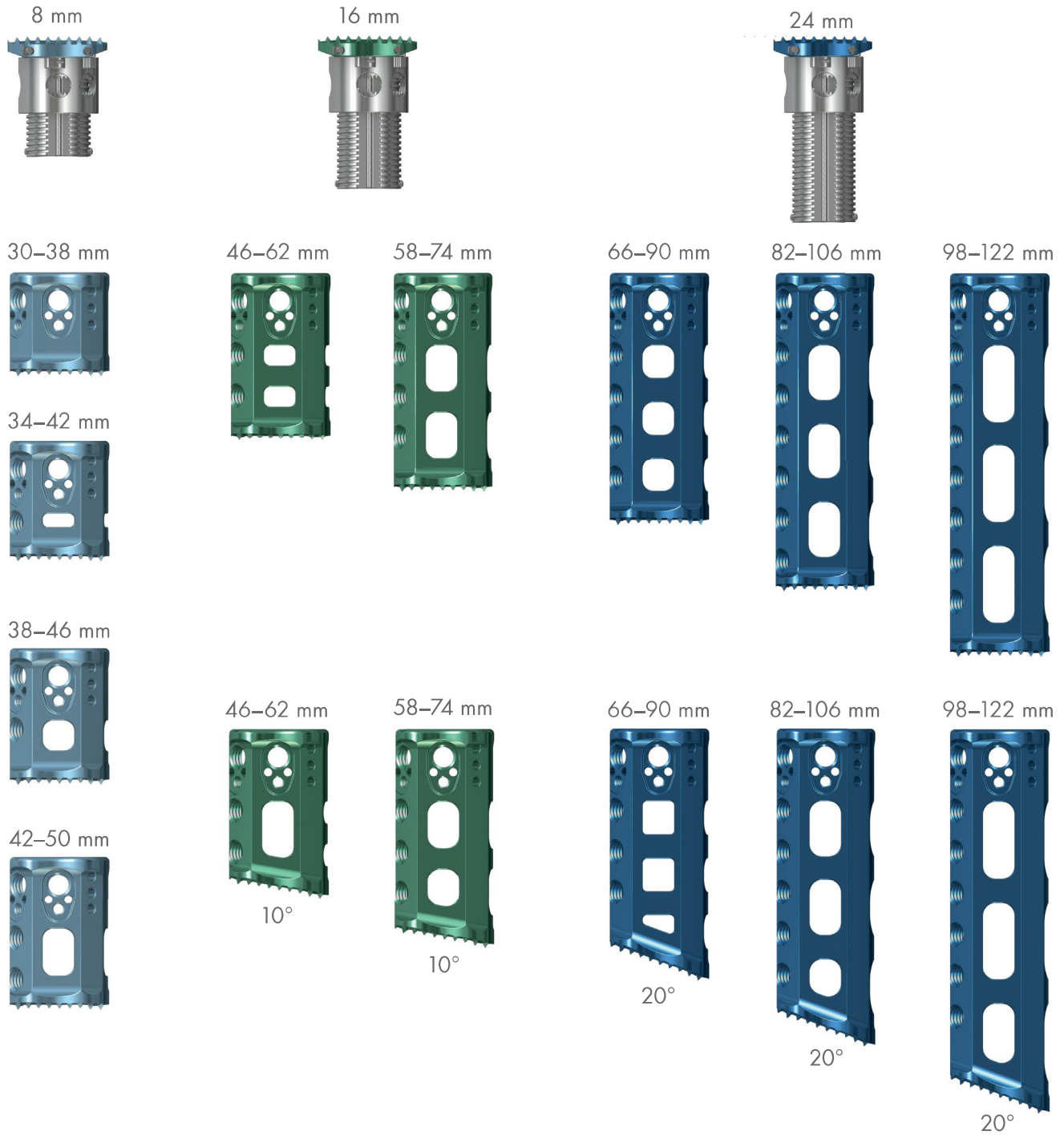
## IMPLANT SIZE OPTIONS

## 17 x 22 &amp; 21 x 25 mm FOOTPRINTS



# 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 &amp; 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

This booklet is designed to assist in using the CAPRI™ Corpectomy Cage Systems. 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.

### 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.
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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 arthrodesis 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

PI025-0A11-03 Rev 0  
K2M, Inc.  
600 Hope Parkway  
Leesburg, VA 20175  
1.571.919.2000

Emergo Europe  
Prinsessegracht 20  
2514 AP  
The Hague  
The Netherlands





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#### SYMBOL KEY



Caution: Consult Accompanying Documentation



Consult Instructions For Use



Do Not Reuse

PI025-2A11-01 Rev 1  
K2M, Inc.  
600 Hope Parkway  
Leesburg, VA 20175  
1.571.919.2000

Emergo Europe  
Prinsessegracht 20  
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.



[www.K2M.com](http://www.K2M.com)

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