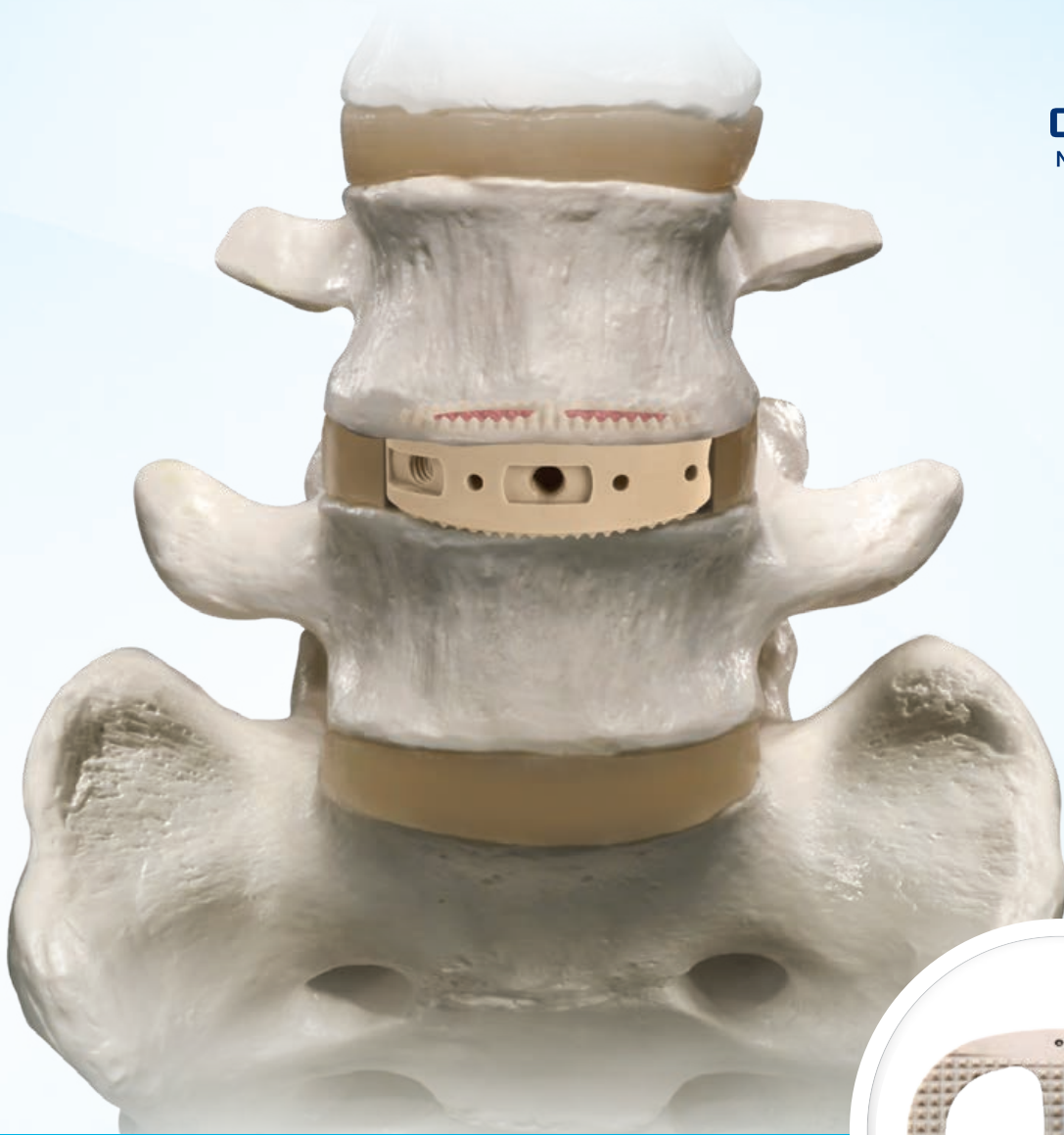




CONTINENTAL[®]

ALIF System | A PATRIOT[®] Spacer



Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.

Life moves us 

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

SURGICAL TECHNIQUE GUIDE

CONTINENTAL[®]

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CONTINENTAL[®]

ALIF System | A PATRIOT[®] Spacer

CONTINENTAL[®] is a comprehensive ALIF system designed to treat degenerative lumbar diseases. The implant is available in an oval-shaped footprint with bi-convex surfaces and is offered in numerous footprints, heights, and sagittal profiles, providing versatility to match various patient anatomies. CONTINENTAL[®] is a PEEK radiolucent polymer spacer with an optional titanium plasma spray (TPS) coating.

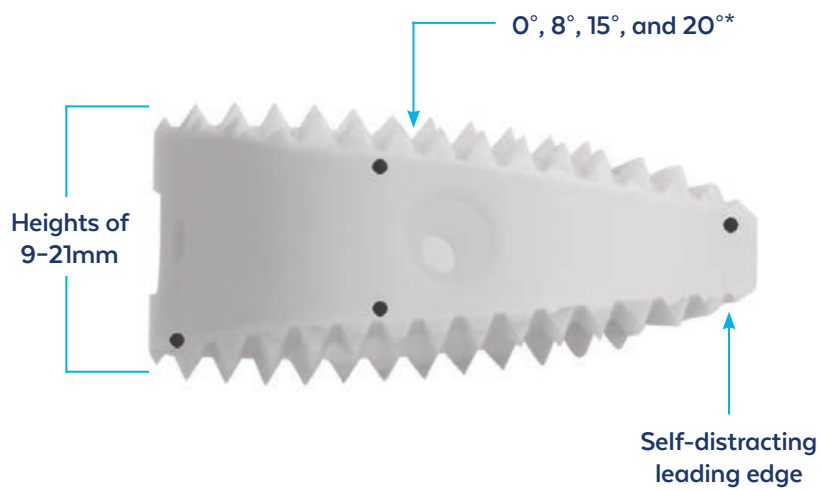
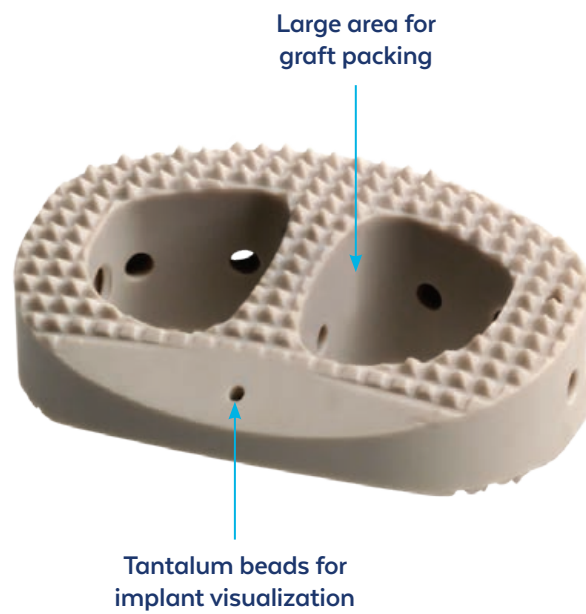
Included in the CONTINENTAL[®] system are innovative instruments designed to streamline the anterior lumbar fusion procedure.



CONTINENTAL[®]



CONTINENTAL[®] TPS



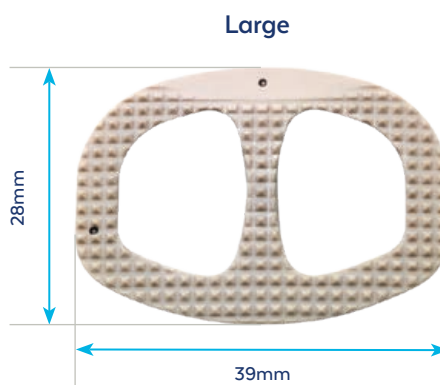
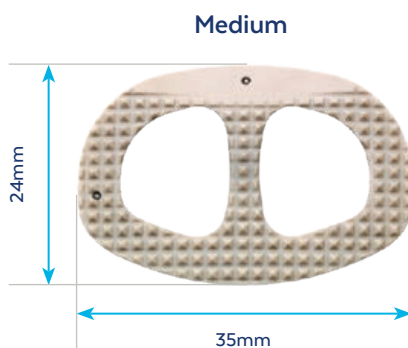
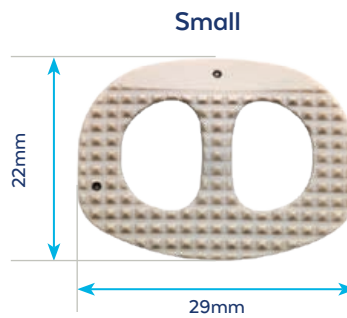
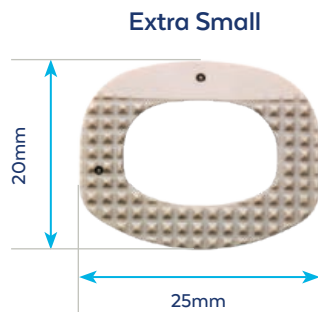
*Additionally available in medium footprint only

IMPLANT OVERVIEW

Specifications

- **Footprints:** 20x25, 22x29, 24x35, and 28x39mm
- **Sagittal profiles:** 0°, 8°, 15°, and 20°*
- **Heights:** 9-21mm in 2mm increments

Footprint Options



INSTRUMENT OVERVIEW

SCRAPERS



CONTINENTAL® Scrapers, 8°









Height	Part No.
9mm	664.929
11mm	664.931
13mm	664.933
15mm	664.935
17mm	664.937
19mm	664.939
21mm	664.941

TRIALS

CONTINENTAL® Extra Small Trials




Height	Lordotic Angle	Part No.
9mm	0°	664.009
11mm	0°	664.011
13mm	0°	664.013
15mm	0°	664.015
17mm	0°	664.017

TRIALS (CONT'D)

CONTINENTAL® Small Trials



0°



8°



15°

Height	Lordotic Angle	Part No.
9mm	0°	664.109
11mm	0°	664.111
13mm	0°	664.113
15mm	0°	664.115
17mm	0°	664.117
9mm	8°	664.209
11mm	8°	664.211
13mm	8°	664.213
15mm	8°	664.215
17mm	8°	664.217
11mm	15°	664.311
13mm	15°	664.313
15mm	15°	664.315
17mm	15°	664.317

CONTINENTAL® Medium Trials



0°



8°



15°

Height	Lordotic Angle	Part No.
9mm	0°	664.409
11mm	0°	664.411
13mm	0°	664.413
15mm	0°	664.415
17mm	0°	664.417
19mm	0°	664.419
21mm	0°	664.421
9mm	8°	664.509
11mm	8°	664.511
13mm	8°	664.513
15mm	8°	664.515
17mm	8°	664.517
19mm	8°	664.519
21mm	8°	664.521
11mm	15°	664.611
13mm	15°	664.613
15mm	15°	664.615
17mm	15°	664.617
19mm	15°	664.619
21mm	15°	664.621
13mm	20°	664.633
15mm	20°	664.635
17mm	20°	664.637
19mm	20°	664.639
21mm	20°	664.641

CONTINENTAL® Large Trials



Height	Lordotic Angle	Part No.
9mm	5°	664.759
11mm	8°	664.711
13mm	8°	664.713
15mm	8°	664.715
17mm	8°	664.717
19mm	8°	664.719
21mm	8°	664.721
13mm	15°	664.813
15mm	15°	664.815
17mm	15°	664.817
19mm	15°	664.819
21mm	15°	664.821

TRIAL SIZERS

CONTINENTAL® Trial Sizers, 8°



Height	Part No.
9mm	664.909
11mm	664.911
13mm	664.913
15mm	664.915
17mm	664.917
19mm	664.919
21mm	664.921

TRIAL AND IMPLANT INSERTION



Slide Hammer 622.410



Implant/Trial Insertion Tool 664.500



Implant/Trial Insertion Sleeve 664.501



Implant/Trial Holder Assembly 664.500 and 664.501

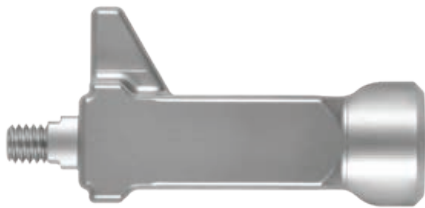
The Implant/Trial Holder is provided as two separate components.



Straight Impactor 664.502



T-Handle 601.800



CONTINENTAL® Attachment Tip 676.670



ALIF Inserter/Distractor Tip Driver 676.655



ALIF Inserter/Distractor 676.650



PATRIOT® CONTINENTAL® Distractor/Inserter 664.508

Includes Inner Shaft, Front Shaft, Rear Shaft, and Distractor/Inserter.

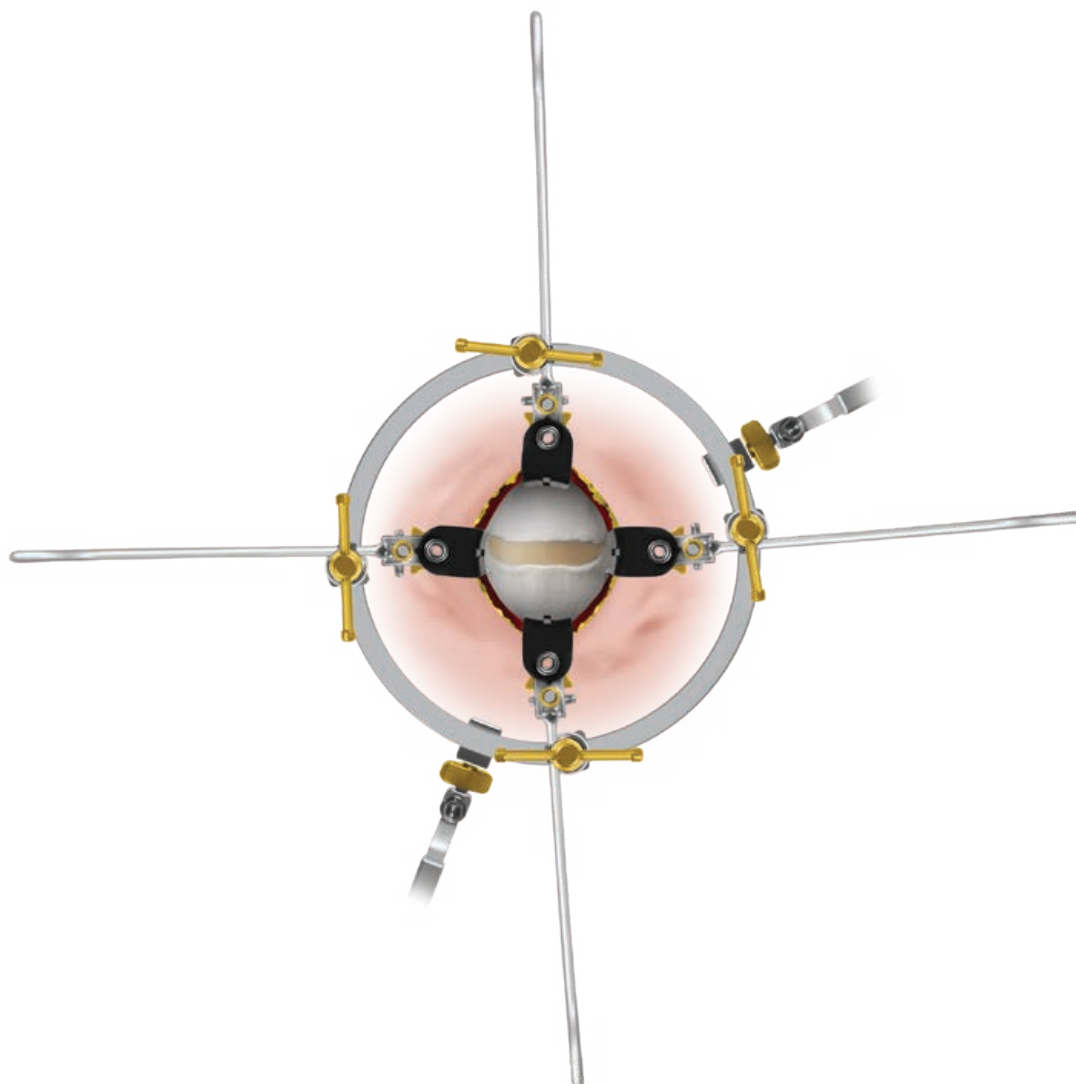
SURGICAL TECHNIQUE

CONTINENTAL[®]

Refer to the package insert (reprinted in the back of this manual) for information on intended use/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

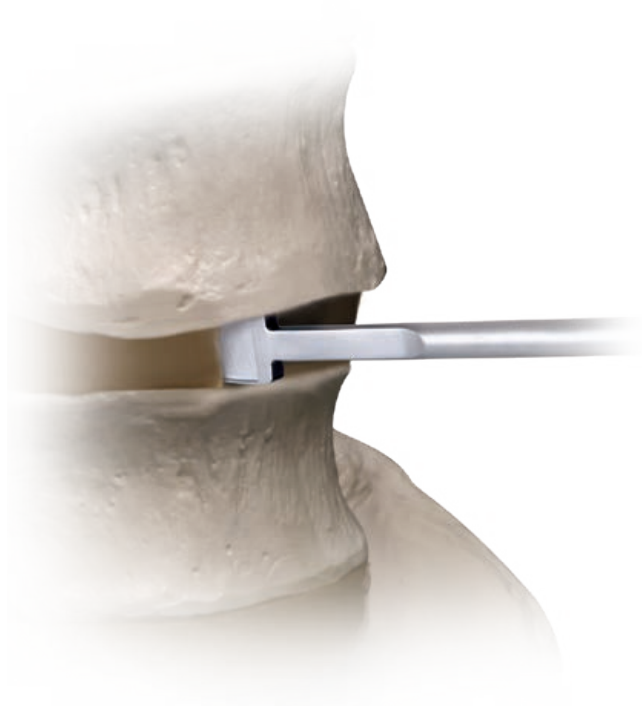
STEP 1 APPROACH

For the purposes of this technique guide, a standard mini-open anterior approach is used. The patient is placed supine, and access to the disc space may be created using the MARS[®] Anterior Retractor.



STEP 2 PREPARATION

Anterior disc preparation instruments may be used to expose the disc. Remove the disc material using rongeurs and other suitable instruments. **CONTINENTAL® Scrapers** may be used to remove superficial layers of the cartilaginous endplates. The posterior and lateral walls of the annulus should be preserved to provide peripheral support. Careful disc removal and endplate preparation maximizes the potential for a successful fusion.



STEP 3 DISTRACTION AND SIZING

Place the tip of the **PATRIOT® CONTINENTAL® Distractor/Inserter** within the disc space and distract to the desired level. The tips of the distractor/inserter should be aligned with the anterior vertebral midline. Alternatively, trials, sizers, or scrapers can be used for distraction.

To use trials or sizers, attach the **Trial or Sizer** to the **Implant/Trial Holder Assembly**. Begin with the smallest trial and insert, using larger sizes until the desired distraction is achieved. Determine which trial best fits the prepared disc space. A secure fit is desirable in order to maintain disc height and stabilize the segment. Confirm trial placement using fluoroscopy and tactile feel. The **Slide Hammer** can be attached to the impaction cap for slight impaction or removal during insertion.

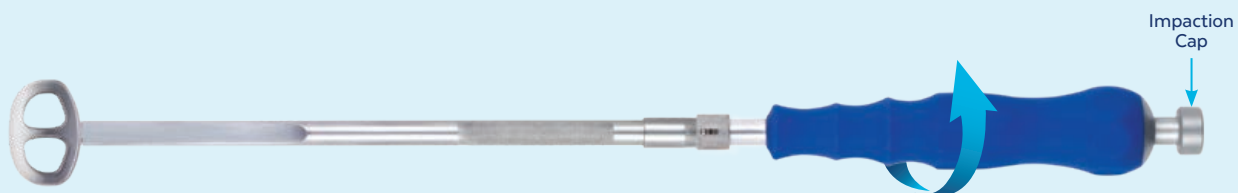
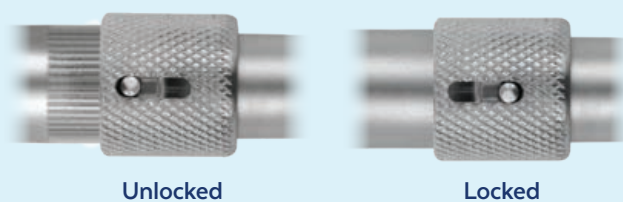
To use scrapers, select the appropriate size, insert horizontally, and rotate to the desired distraction and to determine the appropriate height.

Note: Use caution while using scrapers for distraction to avoid damage to the endplates.



⚙️ USING THE IMPLANT/TRIAL HOLDER ASSEMBLY

Ensure the Implant/Trial Holder Assembly is in the unlocked position. Thread the trial or implant onto the holder by rotating the handle clockwise. Lock the holder by pushing the locking nut forward. Insert the trial or implant. To disengage, unlock and rotate the handle counterclockwise.

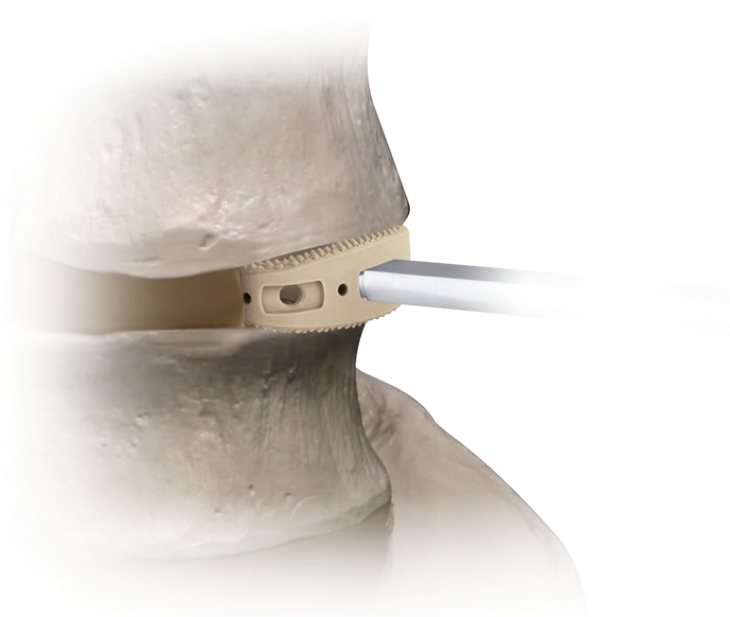


STEP 4 IMPLANT INSERTION

Option A: Using the Implant/Trial Holder

Select the appropriate size implant and attach it to the Implant/Trial Holder by threading the holder clockwise. Lock the holder by sliding the lock forward.

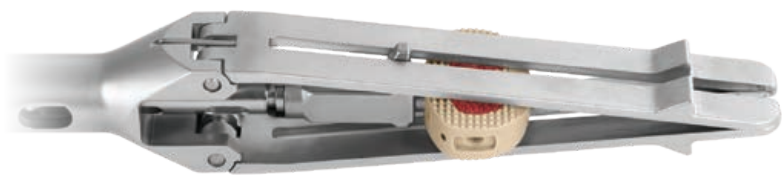
Note: Refer to Step 3 for instructions on loading the implant onto the Implant/Trial Holder.



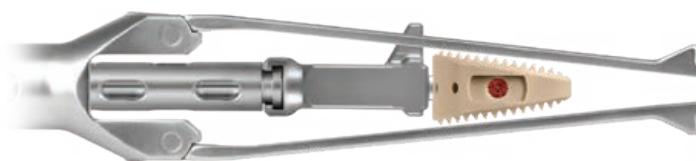
Option B: Using the ALIF Inserter/Distractor

Insert the distraction arms of the **ALIF Inserter/Distractor** into the disc space until the depth stops are flush against the anterior rim of the vertebral bodies. Rotate the T-handle clockwise while applying light pressure to advance the implant into the disc space.

Note: Refer to page 17 for instructions on loading the implant onto the ALIF Inserter/Distractor.



Position before insertion

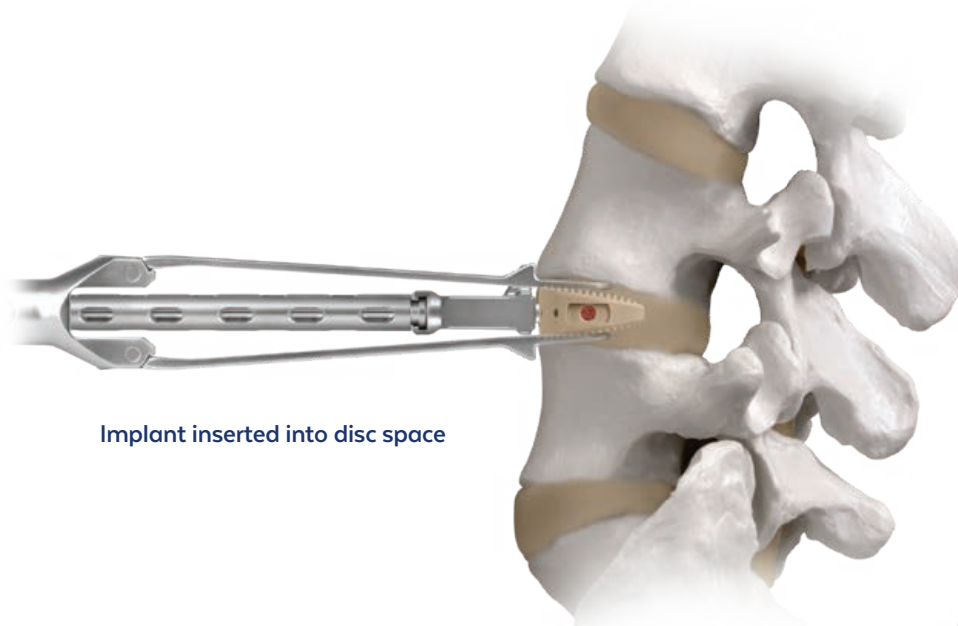


Position during insertion

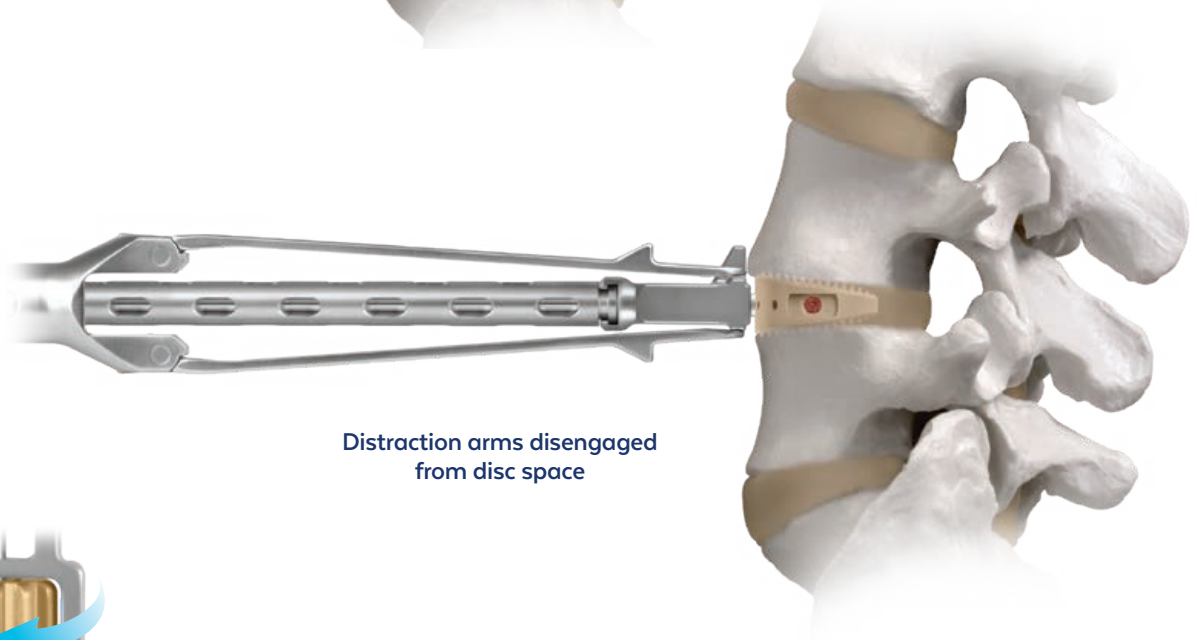


IMPLANT INSERTION (CONT'D)

Once the ejection prong on the **Attachment Tip** contacts the vertebral body, the implant is fully inserted. Continue to rotate the T-handle clockwise; this pulls the distraction arms out of the disc space, leaving the implant in the disc space. Rotate the gold knob counterclockwise to disengage the implant. The ALIF Inserter/Distractor can be removed.



Implant inserted into disc space



Distraction arms disengaged
from disc space

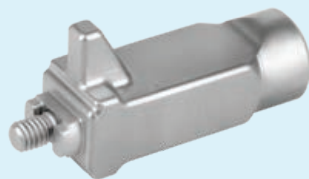


Rotate gold knob
counterclockwise to
disengage implant

ASSEMBLING THE ALIF INSERTER/DISTRACTOR: PREPARING THE ATTACHMENT TIP

The attachment tip accompanies the ALIF Inserter/Distractor, pictured below.

The CONTINENTAL® Attachment Tip connects to all CONTINENTAL® implants.

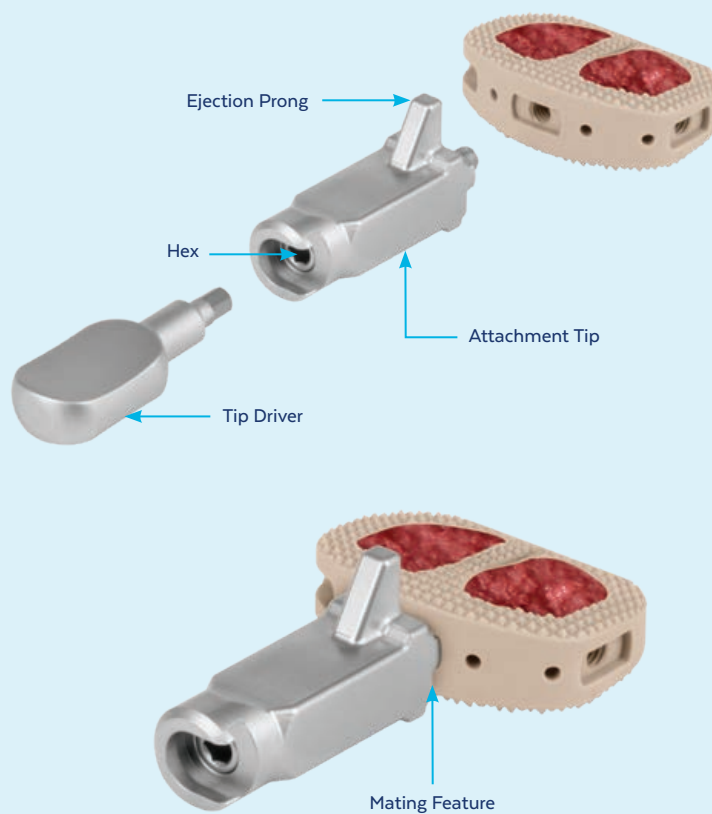


CONTINENTAL® Attachment Tip

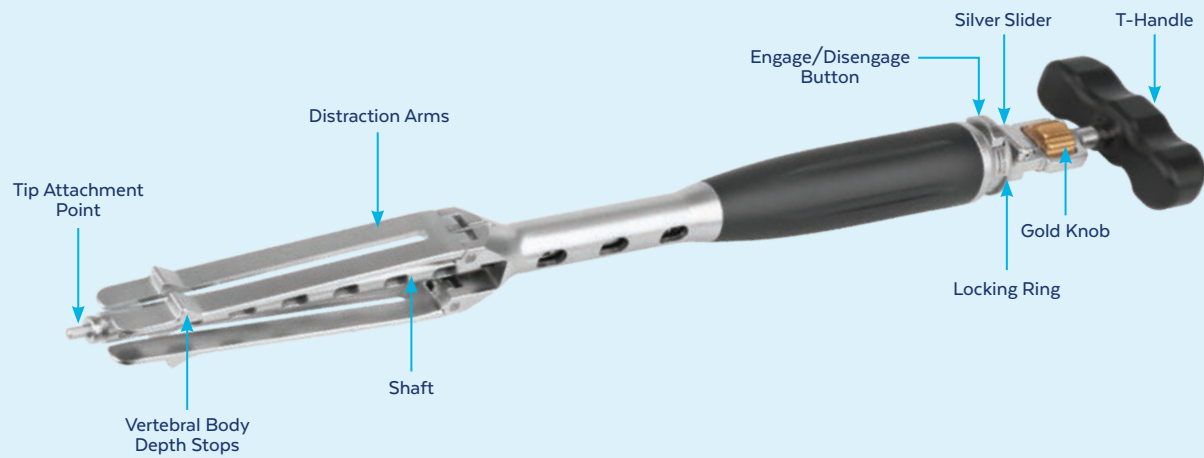
Engage the tip connections to the mating implant features, aligning the ejection prong with the implant.

To secure the implant, use the **Tip Driver** to rotate the hex of the tip until it is finger tight.

Pack autogenous or allogenic bone graft into the graft chamber of the selected implant.* The Attachment Tip is ready to be loaded onto the ALIF Inserter/Distractor.



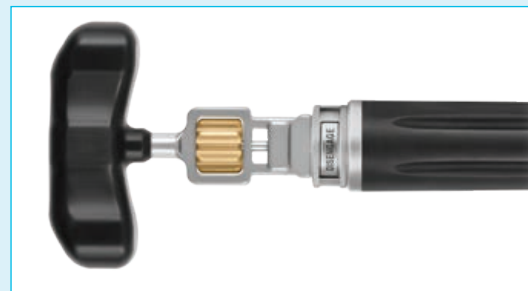
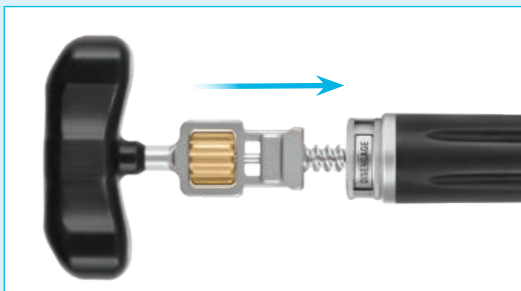
ASSEMBLING THE ALIF INSERTER/DISTRACTOR: CONNECTING THE ATTACHMENT TIP



Locate the engage/disengage button on the inserter/distractor. This button engages and disengages the thread.



Ensure the disengage button is depressed and slide the main shaft down by pushing the T-handle until it bottoms out. The tip attachment point will be exposed past the ends of the distraction arms.



Tip attachment point retracted

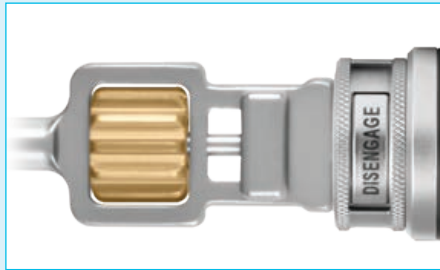


Tip attachment point exposed

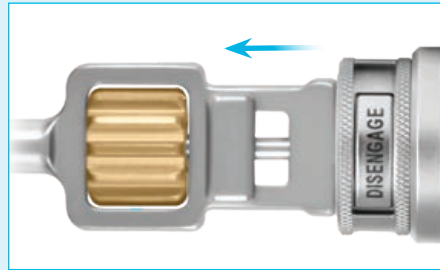
ASSEMBLING THE ALIF INSERTER/DISTRACTOR: CONNECTING THE ATTACHMENT TIP

Pull the silver slider back to retract the exposed hex on the tip attachment point, slide the tip on from the side, and release the slider.

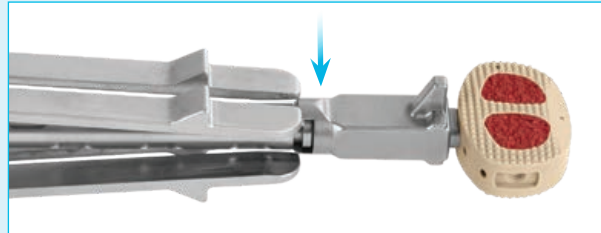
If the slider does not fully return to its initial position, rotate the gold knob until the slider returns and is flush against the front of the slot. At this point, the tip is locked onto the main shaft.



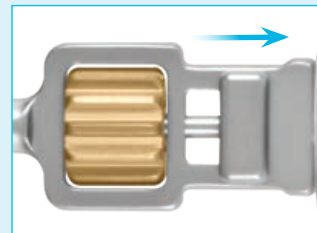
Starting position,
hex exposed



Pull the silver slider back to
retract the exposed hex

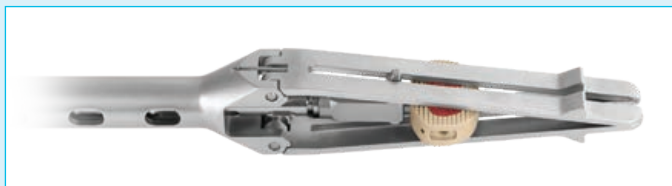


Slide the attachment tip on
from the side



Release the slider to lock the
attachment tip to the main shaft

Pull the shaft back until the distal ends of the distraction arms touch. Press the engage button and rotate the locking ring 90°. The implant is ready to be inserted.



Distraction arms touching



Press the
engage button



Rotate the
locking ring 90°

Option C: Using the PATRIOT® CONTINENTAL® Distractor/Inserter

Select an appropriate size implant and attach it to the Distractor/Inserter. Insert the tips of the Distractor/Inserter into the disc space.

To advance the implant by rotating

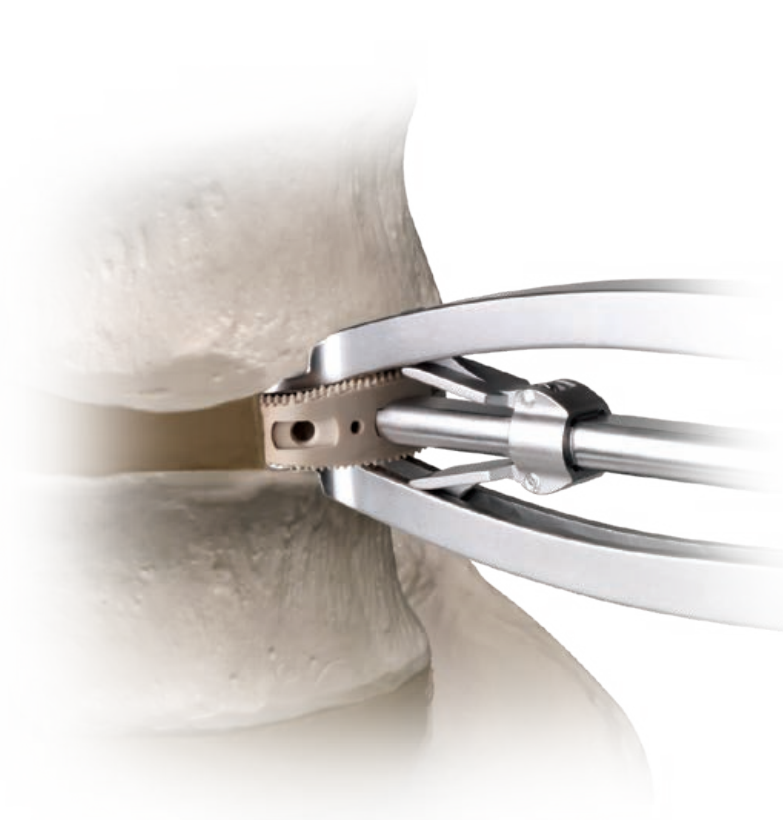
Rotate the advancement knob at the end of the Distractor/Inserter clockwise to advance the implant into the disc space.

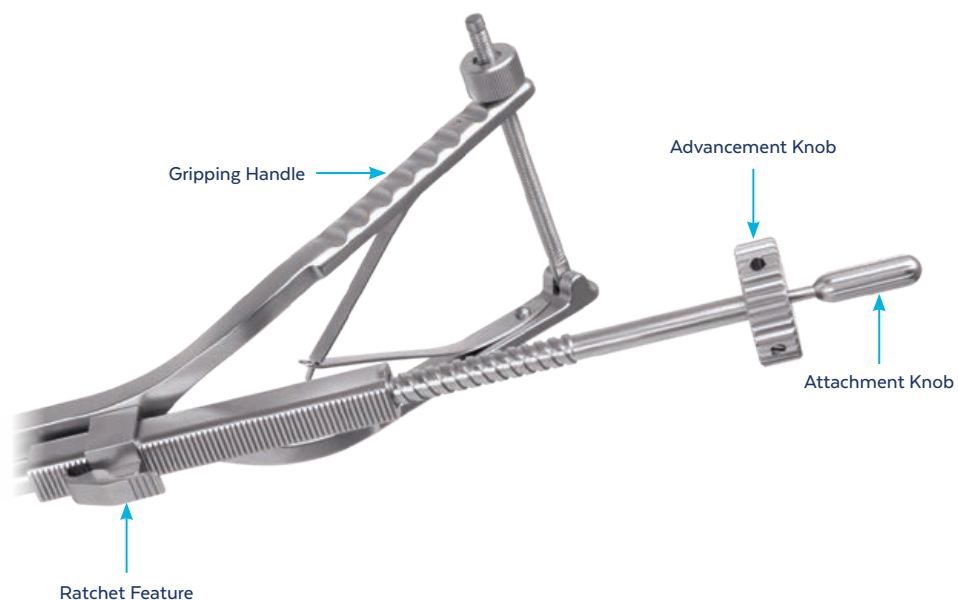
To advance the implant by ratcheting

Push the rear shaft to advance the implant into the disc space. The ratchet feature allows the implant to advance. If needed, the implant may be retracted by releasing the tab and sliding the rear shaft back.

Manual distraction may be applied using either the advancement knob or the ratchet feature by compressing the gripping handle. Care should be taken while using the gripping feature to avoid over-distraction.

A secure fit is desirable in order to maintain disc height and stabilize the segment, and can be confirmed using fluoroscopy and tactile feel. The **Straight Impactor** can be used for further positioning.

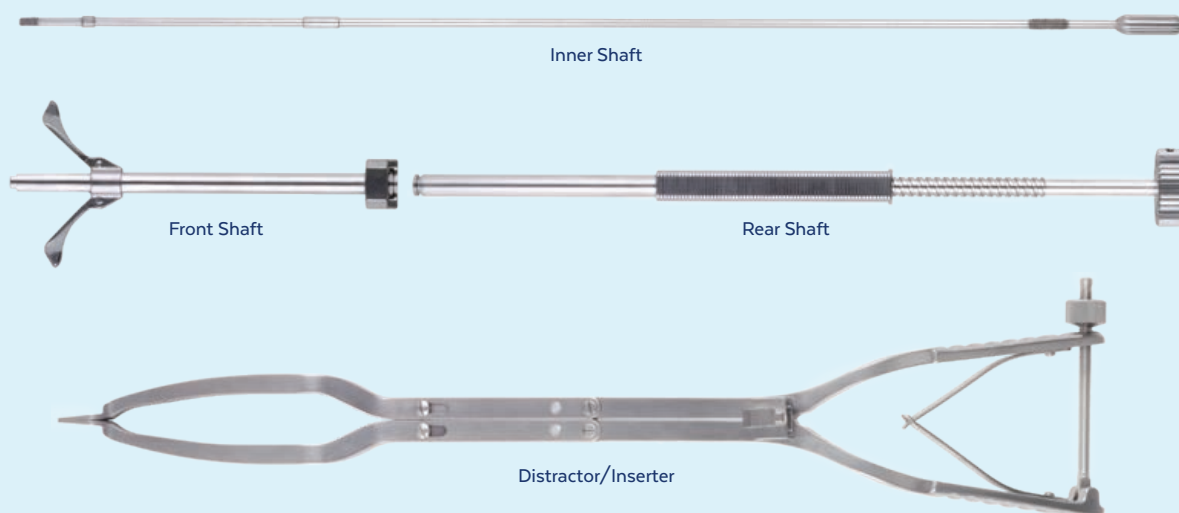




ASSEMBLING AND DISASSEMBLING THE DISTRACTOR/INSERTER

The Distractor/Inserter is provided as four separate components. To assemble, place the Distractor/Inserter on the table. Open the Distractor/Inserter by compressing the handle, and tightening the speed nut. Insert the rear shaft into the ratchet feature of the Distractor/Inserter with the ridges facing up. Compress the wings on the front shaft and insert them into the grooves on the arms. Connect the front shaft to the rear shaft, then insert the inner shaft through the assembly. Release the speed nut and retract the shaft assembly to prepare for inserting the spacer.

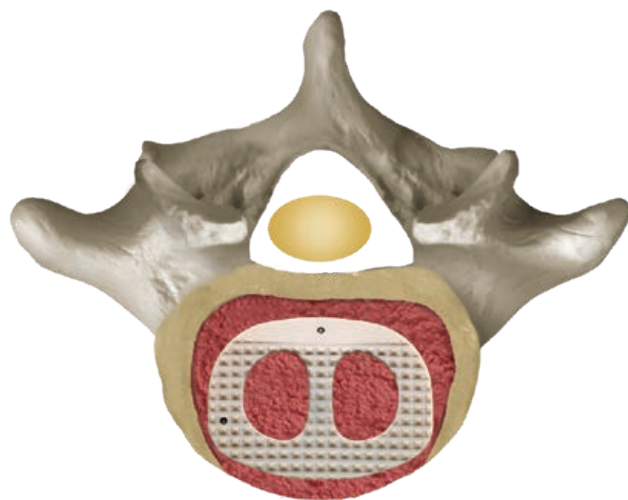
To disassemble, reverse the above steps. The Distractor/Inserter must be disassembled for cleaning purposes.



FINAL POSITION



Final Position - Anterior View



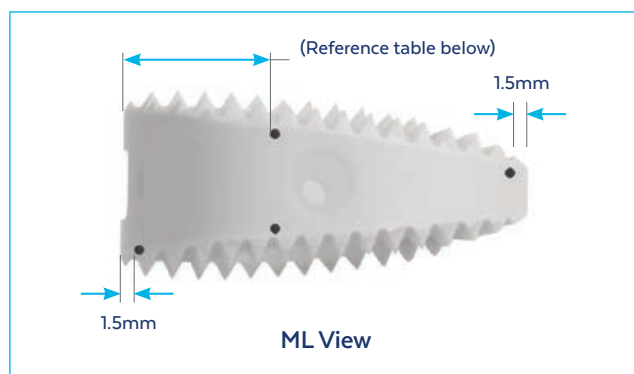
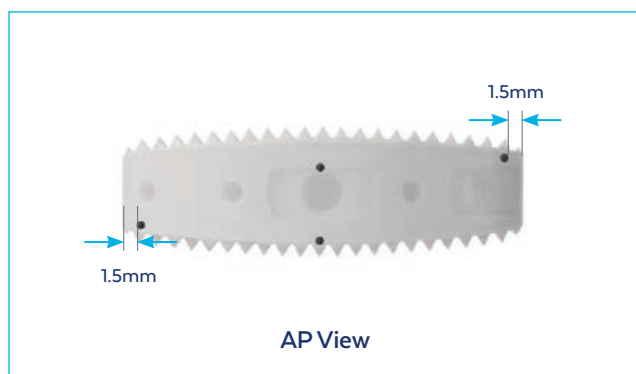
Final Position - Axial View

SUPPLEMENTAL FIXATION

CONTINENTAL® and CONTINENTAL® TPS are to be used with supplemental fixation such as CREO® (posterior pedicle screws) or CITADEL® (anterior lumbar plate system). Refer to the corresponding supplemental fixation system surgical technique guide for specific instructions.



Final position with CITADEL® Plate



Position of Radiographic Markers

Footprint	XS	S	M	L
Distance	7.5mm	7mm	9mm	9.5mm

CONTINENTAL[®] IMPLANT SETS

1 CONTINENTAL[®] Instrument Set 964.905

Trial Sizers

Part No.	Height	Lordotic Angle	Qty
664.909	9mm	8°	1
664.911	11mm	8°	1
664.913	13mm	8°	1
664.915	15mm	8°	1
664.917	17mm	8°	1
664.919	19mm	8°	1
664.921	21mm	8°	1

Small Trials

Part No.	Height	Lordotic Angle	Qty
664.209	9mm	8°	1
664.211	11mm	8°	1
664.213	13mm	8°	1
664.215	15mm	8°	1
664.217	17mm	8°	1
664.311	11mm	15°	1
664.313	13mm	15°	1
664.315	15mm	15°	1
664.317	17mm	15°	1

Medium Trials

Part No.	Height	Lordotic Angle	Qty
664.509	9mm	8°	1
664.511	11mm	8°	1
664.513	13mm	8°	1
664.515	15mm	8°	1
664.517	17mm	8°	1
664.611	11mm	15°	1
664.613	13mm	15°	1
664.615	15mm	15°	1
664.617	17mm	15°	1

964.005 CONTINENTAL[®] ALIF Graphic Case

2 CONTINENTAL[®] Standard Implant Set 964.901

Small Implants

Part No.	Height	Lordotic Angle	Qty
364.209	9mm	8°	1
364.211	11mm	8°	2
364.213	13mm	8°	2
364.215	15mm	8°	2
364.217	17mm	8°	1
364.311	11mm	15°	1
364.313	13mm	15°	1
364.315	15mm	15°	1
364.317	17mm	15°	1

Medium Implants

Part No.	Height	Lordotic Angle	Qty
364.509	9mm	8°	1
364.511	11mm	8°	2
364.513	13mm	8°	2
364.515	15mm	8°	2
364.517	17mm	8°	1
364.611	11mm	15°	1
364.613	13mm	15°	1
364.615	15mm	15°	1
364.617	17mm	15°	1

Additionally Available CONTINENTAL[®] Implants

Part No.	Description
364.651	Medium, 20°, 11mm
364.653	Medium, 20°, 13mm
364.655	Medium, 20°, 15mm
364.657	Medium, 20°, 17mm
364.659	Medium, 20°, 19mm
364.661	Medium, 20°, 21mm

964.001 Implant Module, Standard

3 CONTINENTAL[®] Extra Small Implant Set 964.902

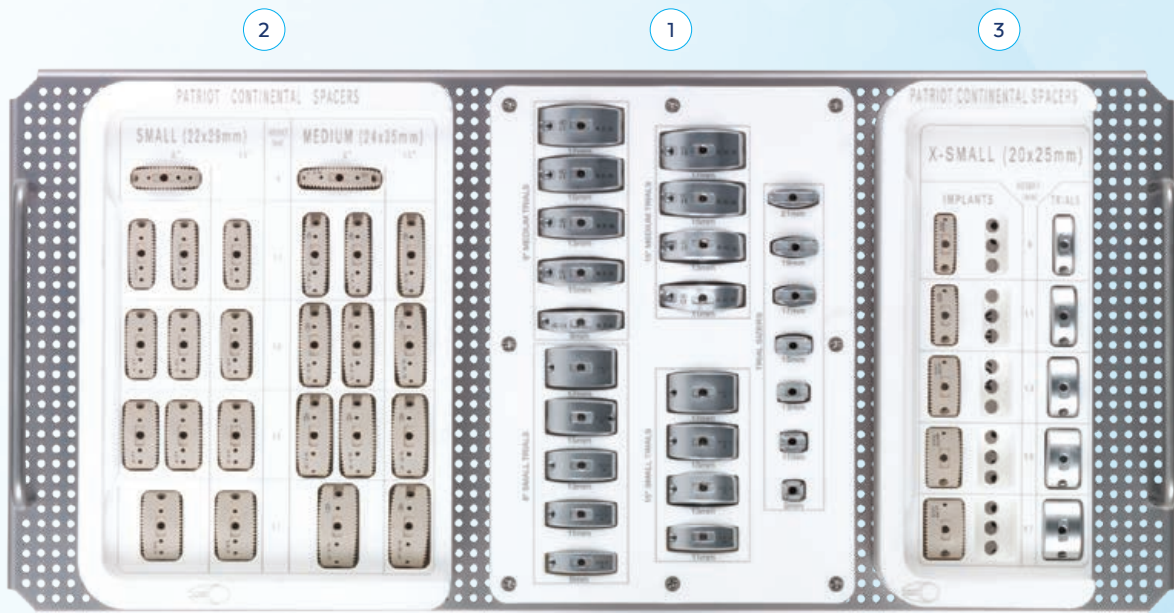
Extra Small Implants

Part No.	Height	Lordotic Angle	Qty
364.009	9mm	0°	1
364.011	11mm	0°	1
364.013	13mm	0°	1
364.015	15mm	0°	1
364.017	17mm	0°	1

Extra Small Trials

Part No.	Height	Lordotic Angle	Qty
664.009	9mm	0°	1
664.011	11mm	0°	1
664.013	13mm	0°	1
664.015	15mm	0°	1
664.017	17mm	0°	1

964.002 Implant Module, X-Small



CONTINENTAL[®]

IMPLANT SETS (CONT'D)

4 CONTINENTAL[®] Additional Small and Medium Set 964.904

Small Implants

Part No.	Height	Lordotic Angle	Qty
364.109	9mm	0°	1
364.111	11mm	0°	1
364.113	13mm	0°	1
364.115	15mm	0°	1
364.117	17mm	0°	1

Small Trials

Part No.	Height	Lordotic Angle	Qty
664.109	9mm	0°	1
664.111	11mm	0°	1
664.113	13mm	0°	1
664.115	15mm	0°	1
664.117	17mm	0°	1

Medium Implants

Part No.	Height	Lordotic Angle	Qty
364.409	9mm	0°	1
364.411	11mm	0°	1
364.413	13mm	0°	1
364.415	15mm	0°	1
364.417	17mm	0°	1
364.519	19mm	8°	1
364.521	21mm	8°	1
364.619	19mm	15°	1
364.621	21mm	15°	1

Medium Trials

Part No.	Height	Lordotic Angle	Qty
664.409	9mm	0°	1
664.411	11mm	0°	1
664.413	13mm	0°	1
664.415	15mm	0°	1
664.417	17mm	0°	1
664.519	19mm	8°	1
664.521	21mm	8°	1
664.619	19mm	15°	1
664.621	21mm	15°	1

964.004 Implant Module, Small and Medium

5 CONTINENTAL[®] Large Set 964.903

Large Implants

Part No.	Height	Lordotic Angle	Qty
364.759	9mm	5°	1
364.711	11mm	8°	1
364.713	13mm	8°	1
364.715	15mm	8°	1
364.717	17mm	8°	1
364.719	19mm	8°	1
364.721	21mm	8°	1
364.813	13mm	15°	1
364.815	15mm	15°	1
364.817	17mm	15°	1
364.819	19mm	15°	1
364.821	21mm	15°	1

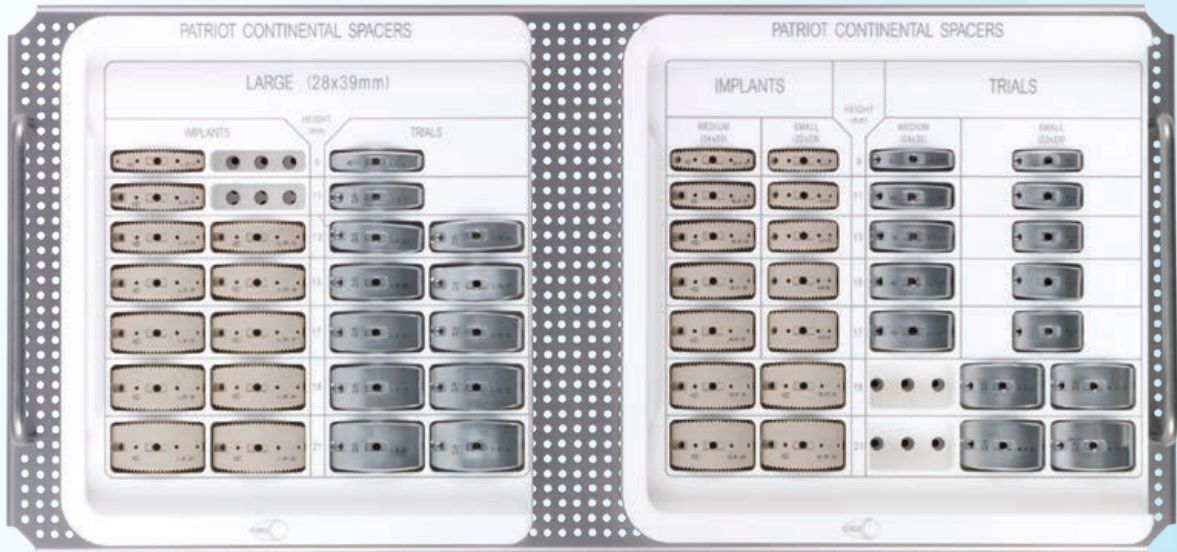
Large Trials

Part No.	Height	Lordotic Angle	Qty
664.759	9mm	5°	1
664.711	11mm	8°	1
664.713	13mm	8°	1
664.715	15mm	8°	1
664.717	17mm	8°	1
664.719	19mm	8°	1
664.721	21mm	8°	1
664.813	13mm	15°	1
664.815	15mm	15°	1
664.817	17mm	15°	1
664.819	19mm	15°	1
664.821	21mm	15°	1

964.003 Implant Module, Large

5

4



CONTINENTAL® TPS IMPLANT SETS

Standard Implant Set 964.951

Part No.	Description	Qty
364.209CS	Small, 8°, 9mm	1
364.211CS	Small, 8°, 11mm	2
364.213CS	Small, 8°, 13mm	2
364.215CS	Small, 8°, 15mm	2
364.217CS	Small, 8°, 17mm	1
364.311CS	Small, 15°, 11mm	1
364.313CS	Small, 15°, 13mm	1
364.315CS	Small, 15°, 15mm	1
364.317CS	Small, 15°, 17mm	1
364.509CS	Medium, 8°, 9mm	1
364.511CS	Medium, 8°, 11mm	2
364.513CS	Medium, 8°, 13mm	2
364.515CS	Medium, 8°, 15mm	2
364.517CS	Medium, 8°, 17mm	1
364.611CS	Medium, 15°, 11mm	1
364.613CS	Medium, 15°, 13mm	1
364.615CS	Medium, 15°, 15mm	1
364.617CS	Medium, 15°, 17mm	1
964.009	Soft Case, PATRIOT®, CONTINENTAL® TPS (32 Box)	

Small and Medium Implant Set 964.952

Part No.	Description	Qty
364.109CS	Small, 0°, 9mm	1
364.111CS	Small, 0°, 11mm	1
364.113CS	Small, 0°, 13mm	1
364.115CS	Small, 0°, 15mm	1
364.117CS	Small, 0°, 17mm	1
364.409CS	Medium, 0°, 9mm	1
364.411CS	Medium, 0°, 11mm	1
364.413CS	Medium, 0°, 13mm	1
364.415CS	Medium, 0°, 15mm	1
364.417CS	Medium, 0°, 17mm	1
364.419CS	Medium, 0°, 19mm	0
364.421CS	Medium, 0°, 21mm	0
364.519CS	Medium, 8°, 19mm	1
364.521CS	Medium, 8°, 21mm	1
364.619CS	Medium, 15°, 19mm	1
364.621CS	Medium, 15°, 21mm	1
964.009	Soft Case, PATRIOT®, CONTINENTAL® TPS (32 Box)	

Large Implant Set 964.953

Part No.	Description	Qty
364.711CS	Large, 8°, 11mm	1
364.713CS	Large, 8°, 13mm	1
364.715CS	Large, 8°, 15mm	1
364.717CS	Large, 8°, 17mm	1
364.719CS	Large, 8°, 19mm	1
364.721CS	Large, 8°, 21mm	1
364.759CS	Large, 5°, 9mm	1
364.813CS	Large, 15°, 13mm	1
364.815CS	Large, 15°, 15mm	1
364.817CS	Large, 15°, 17mm	1
364.819CS	Large, 15°, 19mm	1
364.821CS	Large, 15°, 21mm	1
964.009	Soft Case, PATRIOT®, CONTINENTAL® TPS (32 Box)	

Additionally Available CONTINENTAL® TPS Implants

Part No.	Description
364.651CS	Medium, 20°, 11mm
364.653CS	Medium, 20°, 13mm
364.655CS	Medium, 20°, 15mm
364.657CS	Medium, 20°, 17mm
364.659CS	Medium, 20°, 19mm
364.661CS	Medium, 20°, 21mm



CONTINENTAL® TPS TRIAL SETS

6 CONTINENTAL® TPS Small and Medium Trial Set 964.907

Part No.	Description	Qty
664.109	Small Trial, 0°, 9mm	1
664.111	Small Trial, 0°, 11mm	1
664.113	Small Trial, 0°, 13mm	1
664.115	Small Trial, 0°, 15mm	1
664.117	Small Trial, 0°, 17mm	1
664.409	Medium Trial, 0°, 9mm	1
664.411	Medium Trial, 0°, 11mm	1
664.413	Medium Trial, 0°, 13mm	1
664.415	Medium Trial, 0°, 15mm	1
664.417	Medium Trial, 0°, 17mm	1
664.419	Medium Trial, 0°, 19mm	0
664.421	Medium Trial, 0°, 21mm	0
664.519	Medium Trial, 8°, 19mm	1
664.521	Medium Trial, 8°, 21mm	1
664.619	Medium Trial, 15°, 19mm	1
664.621	Medium Trial, 15°, 21mm	1
964.004	CONTINENTAL® ALIF Implant Module, Small and Medium	

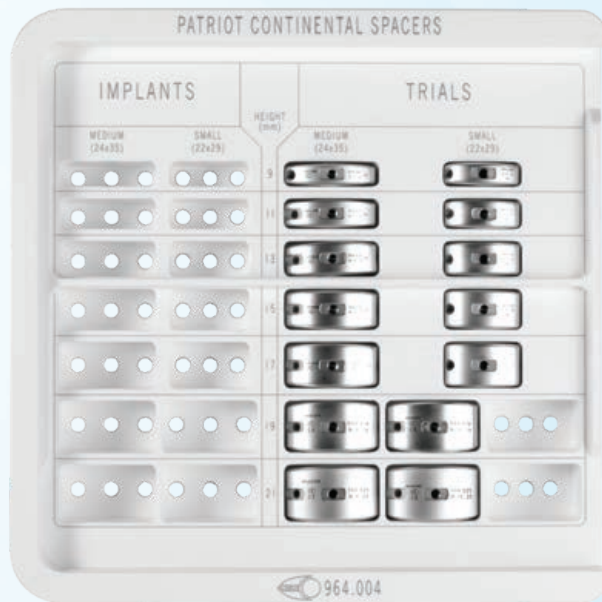
7 CONTINENTAL® Large Trial Set 964.955

Part No.	Description	Qty
664.759	Large Trial, 5°, 9mm	1
664.711	Large Trial, 8°, 11mm	1
664.713	Large Trial, 8°, 13mm	1
664.715	Large Trial, 8°, 15mm	1
664.717	Large Trial, 8°, 17mm	1
664.719	Large Trial, 8°, 19mm	1
664.721	Large Trial, 8°, 21mm	1
664.813	Large Trial, 15°, 13mm	1
664.815	Large Trial, 15°, 15mm	1
664.817	Large Trial, 15°, 17mm	1
664.819	Large Trial, 15°, 19mm	1
664.821	Large Trial, 15°, 21mm	1
964.010	Trial Module, PATRIOT®, CONTINENTAL® Large	

Additionally Available CONTINENTAL® Trials

Part No.	Description
664.633	Medium Trial, 20°, 13mm
664.635	Medium Trial, 20°, 15mm
664.637	Medium Trial, 20°, 17mm
664.639	Medium Trial, 20°, 19mm
664.641	Medium Trial, 20°, 21mm

6



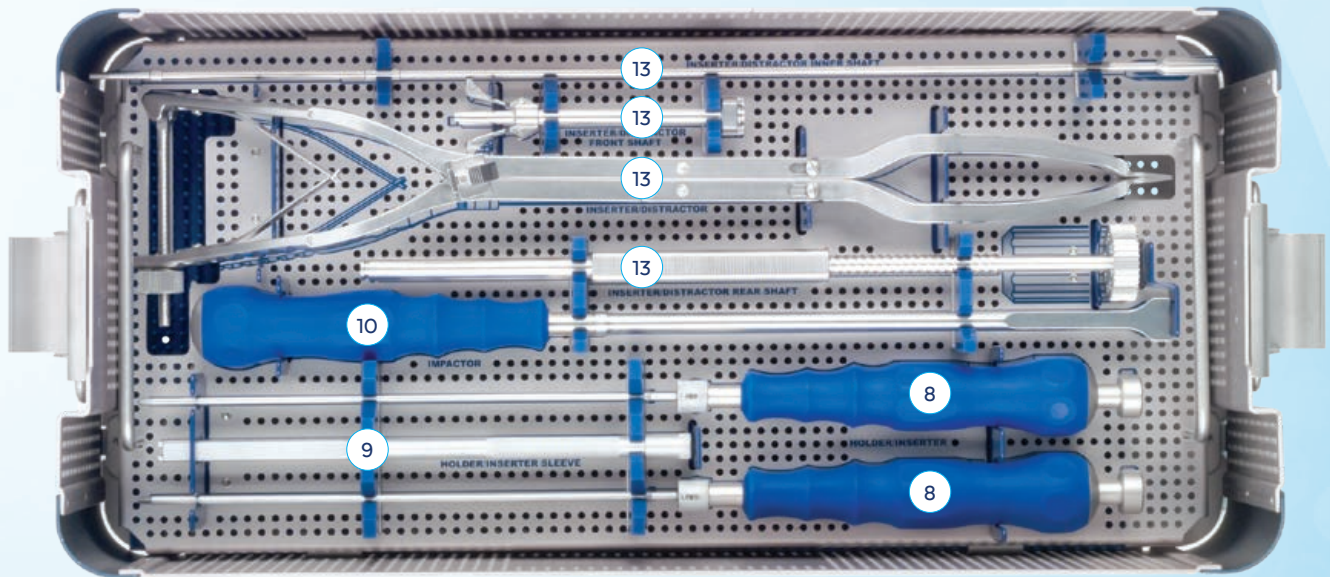
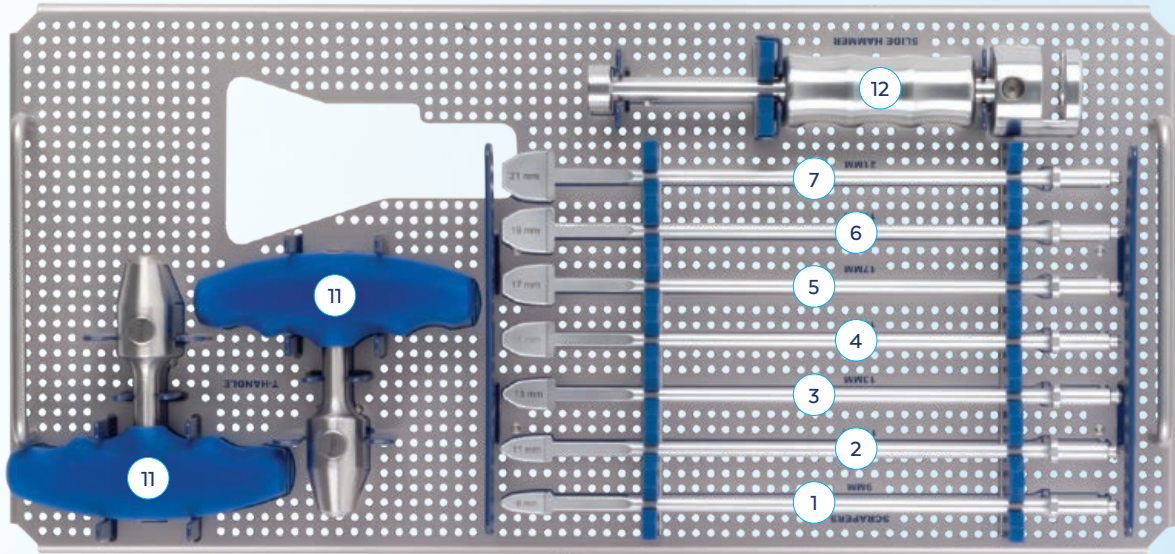
7



CONTINENTAL®

INSTRUMENT SET II 964.906

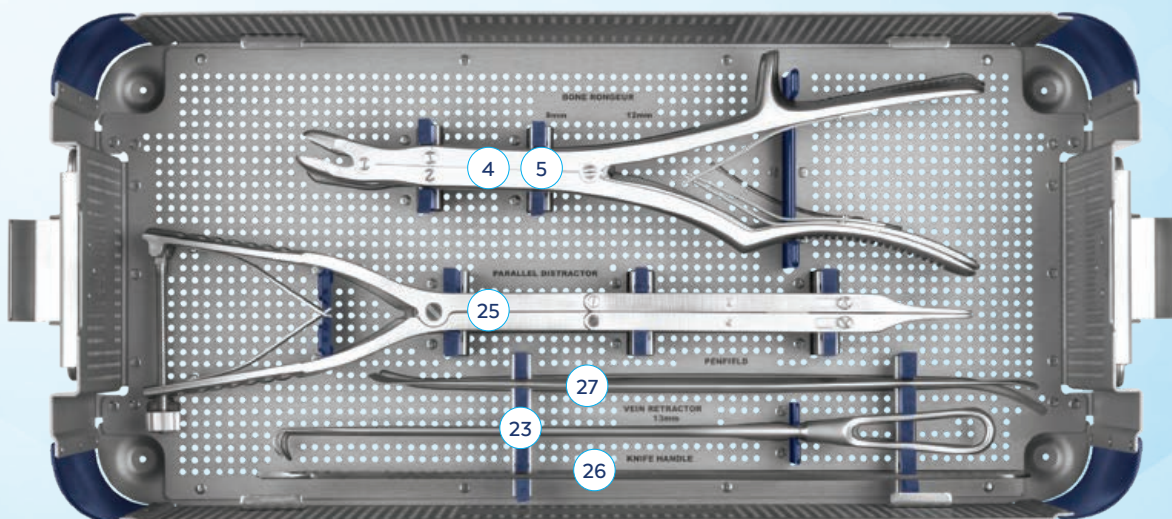
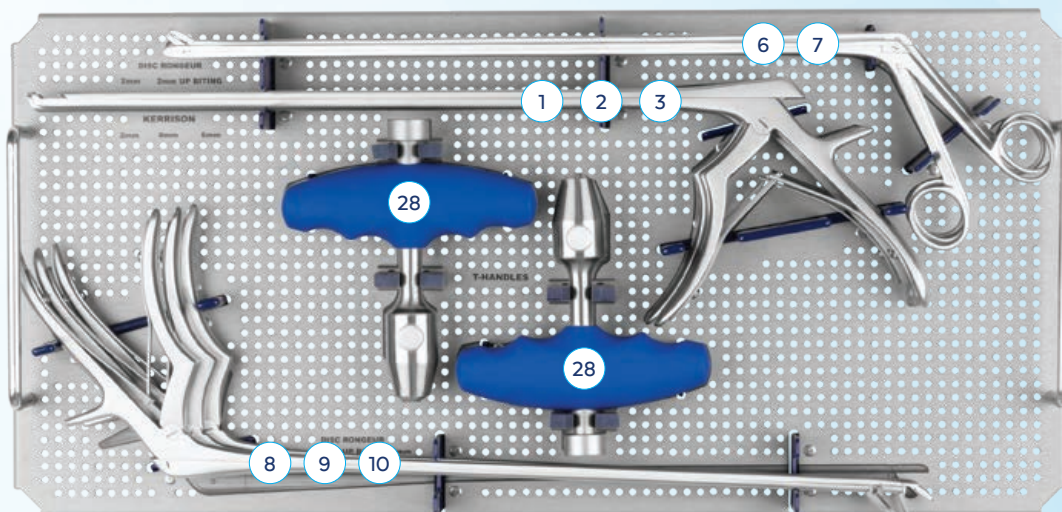
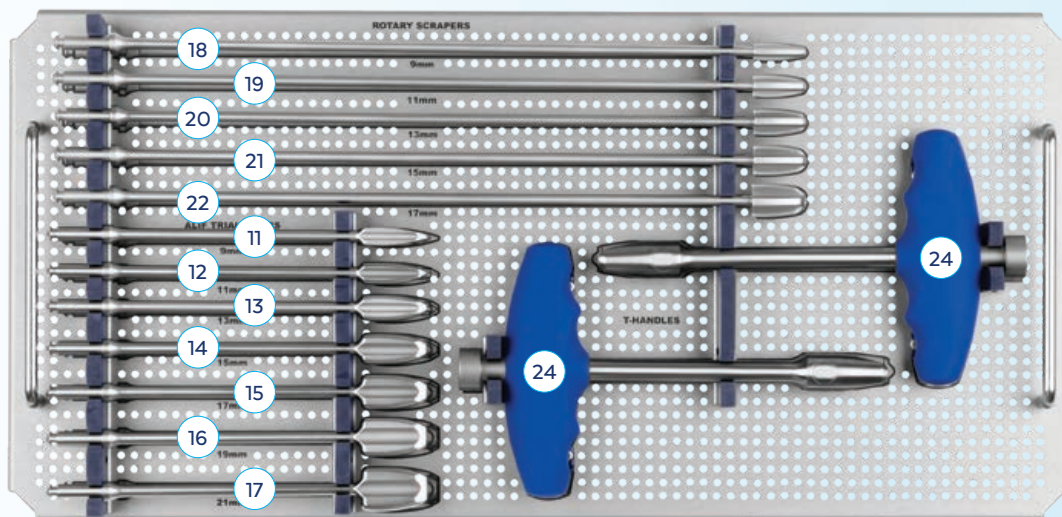
	Instruments	Qty
1	664.929 CONTINENTAL® Scraper 8°, 9mm	1
2	664.931 CONTINENTAL® Scraper 8°, 11mm	1
3	664.933 CONTINENTAL® Scraper 8°, 13mm	1
4	664.935 CONTINENTAL® Scraper 8°, 15mm	1
5	664.937 CONTINENTAL® Scraper 8°, 17mm	1
6	664.939 CONTINENTAL® Scraper 8°, 19mm	1
7	664.941 CONTINENTAL® Scraper 8°, 21mm	1
8	664.500 Implant/Trial Insertion Tool	2
9	664.501 Implant/Trial Insertion Sleeve	2
10	664.502 Straight Impactor	1
11	601.800 T-Handle	2
12	622.410 Slide Hammer	1
13	664.508 PATRIOT® CONTINENTAL® Distractor/Inserter	1
	676.610 INDEPENDENCE® Ramp Distractor Guide, Small	1
	676.611 INDEPENDENCE® Ramp Distractor Guide, Medium	1
	676.612 INDEPENDENCE® Ramp Distractor Guide, Large	1
	676.613 INDEPENDENCE® Ramp Distractor, Shaft	1
	964.006 CONTINENTAL® Instrument Graphic Case	



ANTERIOR DISC PREP I

INSTRUMENT SET 925.901

	Instruments	Qty
1	625.201 Kerrison, 2mm	1
2	625.202 Kerrison, 4mm	1
3	625.203 Kerrison, 6mm	1
4	625.301 Bone Rongeur, Double Acting, 8mm	1
5	625.302 Bone Rongeur, Double Acting, 12mm	1
6	625.303 Disc Rongeur, 2mm	1
7	625.304 Disc Rongeur, 2mm, Up Biting	1
8	625.305 Disc Rongeur, 4mm	1
9	625.306 Disc Rongeur, 4mm, Up Biting	1
10	625.307 Disc Rongeur, 6mm	1
11	625.609 ALIF Trial Sizer, 9mm	1
12	625.611 ALIF Trial Sizer, 11mm	1
13	625.613 ALIF Trial Sizer, 13mm	1
14	625.615 ALIF Trial Sizer, 15mm	1
15	625.617 ALIF Trial Sizer, 17mm	1
16	625.619 ALIF Trial Sizer, 19mm	1
17	625.621 ALIF Trial Sizer, 21mm	1
18	625.709 Rotary Scraper, 9mm	1
19	625.711 Rotary Scraper, 11mm	1
20	625.713 Rotary Scraper, 13mm	1
21	625.715 Rotary Scraper, 15mm	1
22	625.717 Rotary Scraper, 17mm	1
23	625.801 Vein Retractor	1
24	625.804 T-Handle with Impaction Cap, Long	2
25	625.805 Parallel Distractor	1
26	625.806 Knife Handle	1
27	625.811 Long Penfield	1
28	675.005 T-Handle with Impaction Cap	2
	925.101 Graphic Case I	

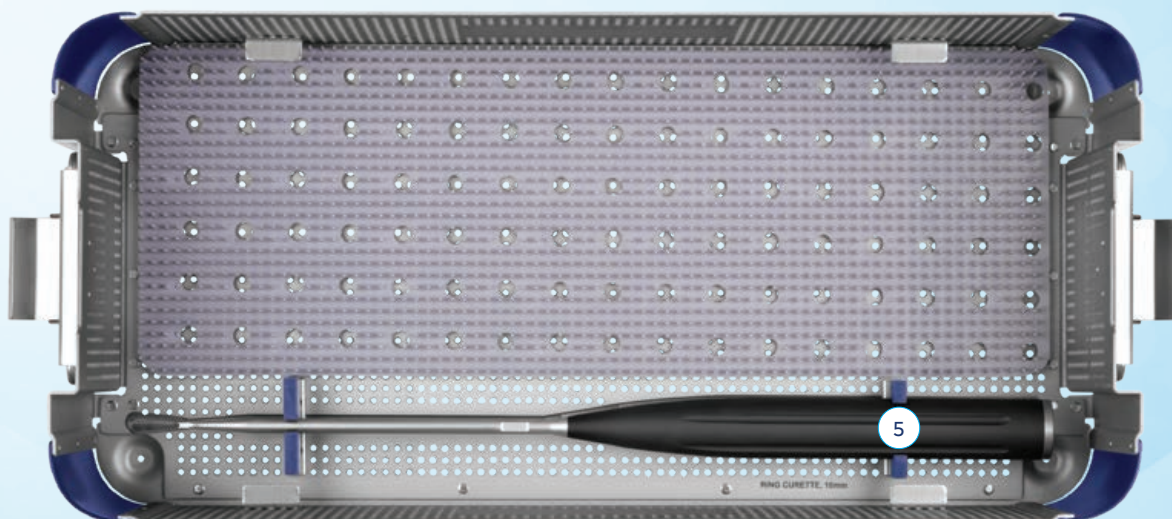
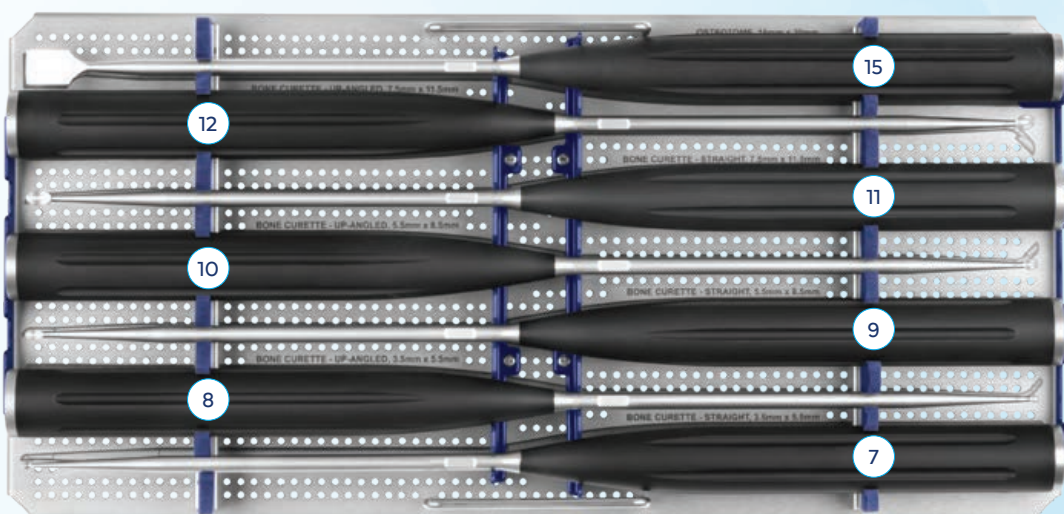


ANTERIOR DISC PREP II INSTRUMENT SET 925.902

	Instruments	Qty
1	625.101 Cobb Elevator, 18mm	1
2	625.102 Cobb Elevator, Angled, 18mm	1
3	625.103 Cobb Elevator, 23mm	1
4	625.104 Cobb Elevator, Angled, 23mm	1
5	625.401 Ring Curette, 10mm	1
6	625.402 Ring Curette, 15mm	1
7	625.403 Bone Curette, 3.5x5.5mm, Straight	1
8	625.404 Bone Curette, 3.5x5.5mm, Up-Angled	1
9	625.405 Bone Curette, 5.5x8.5mm, Straight	1
10	625.406 Bone Curette, 5.5x8.5mm, Up-Angled	1
11	625.407 Bone Curette, 7.5x11.5mm, Straight	1
12	625.408 Bone Curette, 7.5x11.5mm, Up-Angled	1
13	625.501 Dual Rasp	1
14	625.502 Angled Rasp	1
15	625.803 Osteotome, 16x20mm	1
	925.102 Graphic Case II	

Additionally Available Instruments

625.409	Bone Curette, 9.5x14.5mm, Straight
625.410	Bone Curette, 9.5x14.5mm, Up-Angled
625.411	Bone Curette, 11.5x17.5mm, Straight
625.412	Bone Curette, 11.5x17.5mm, Up-Angled
625.413	Bone Curette, 13.5x20.5mm, Straight
625.414	Bone Curette, 13.5x20.5mm, Up-Angled



IMPORTANT INFORMATION ON PATRIOT® LUMBAR SPACERS

DESCRIPTION

PATRIOT® Spacers (including CONSTITUTION®, SIGNATURE®, CONTINENTAL®, TransContinental®, and TransContinental® M) are thoracolumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. Each of the PATRIOT® spacers provides a different shape to accommodate various surgical approaches to the spine. CONSTITUTION® PLIF Spacers are inserted using a posterior or transforaminal approach. SIGNATURE® TLIF Spacers are inserted using a transforaminal or lateral approach. CONTINENTAL® ALIF Spacers are inserted using an anterior, anterolateral, or lateral approach. TransContinental® and TransContinental® M Spacers are inserted using an anterior, anterolateral, or lateral approach. All approaches may be used in the lumbar spine; only anterior, anterolateral, or lateral approaches may be used in the thoracic spine. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion. Each spacer has an axial hole to allow grafting material to be packed inside the spacer.

PATRIOT® Spacers are made from radiolucent PEEK polymer (ASTM F2026) with titanium alloy or tantalum markers (ASTM F560). SIGNATURE® R Spacers also include an internal titanium alloy or commercially pure titanium (ASTM F67) component, and TransContinental® M Spacers also include an integrated titanium alloy nut. The SIGNATURE® Ti Spacer is made from titanium alloy or commercially pure titanium. The titanium alloy is TAV (ASTM F136) or TAN (ASTM F1295). PATRIOT® TPS Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

INDICATIONS

PATRIOT® Spacers (including CONSTITUTION®, SIGNATURE®, CONTINENTAL®, TransContinental®, and TransContinental® M) are interbody fusion devices indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. PATRIOT® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices ($\geq 20^\circ$ lordosis) must be used with at least anterior supplemental fixation. All PATRIOT® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

WARNINGS

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- neurological injury, and
- vascular or visceral injury.

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis, or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture.

Patients with previous spinal surgery at the involved level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

Components of this system should not be used with components of any other system or manufacturer.

The components of this system are manufactured from radiolucent PEEK polymer, commercially pure titanium, titanium alloy, and tantalum. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical, and functional reasons.

These warnings do not include all adverse effects that could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

Use this device as supplied and in accordance with the handling and use information provided below.

PRECAUTIONS

The implantation of intervertebral fusion devices should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

Surgical implants must never be reused. An explanted implant must never be reimplanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

For optimal implant performance, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the system.

MRI SAFETY INFORMATION



The PATRIOT® Spacers are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg

Under the scan conditions defined above, the PATRIOT® Spacers are expected to produce a maximum temperature rise of less than or equal to 3.9°C after 15 minutes of continuous scanning.

The image artifact caused by the device is not expected to extend beyond 35mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

CONTRAINDICATIONS

Use of these devices is contraindicated in patients with the following conditions:

1. Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has a suspected or documented allergy, foreign body sensitivity, or known intolerance to any of the implant materials.
2. Signs of local inflammation.
3. Prior fusion at the level(s) to be treated.
4. Severe osteoporosis, which may prevent adequate fixation.
5. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risk versus the benefits to the patient.
6. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
7. Any patient not willing to cooperate with postoperative instructions.
8. Any condition not described in the indications for use.
9. Fever or leukocytosis.
10. Pregnancy.
11. Any other condition that would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevations of the white blood count (WBC), or a marked left shift in the WBC differential count.
12. Any case not needing a fusion.
13. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
14. These devices must not be used for pediatric cases or where the patient still has general skeletal growth.
15. Spondylolisthesis unable to be reduced to Grade 1.
16. Any case where the implant components selected for used would be too large or too small to achieve a successful result.
17. Any case that requires the mixing of metals from two different components or systems.
18. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
19. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

COMPLICATIONS AND POSSIBLE ADVERSE EFFECTS

Prior to surgery, patients should be made aware of the following possible adverse effects in addition to the potential need for additional surgery to correct these effects:

- Loosening, bending or breakage of components
- Displacement/migration of device components
- Tissue sensitivity to implant material
- Potential for skin breakdown and/or wound complications
- Non-union or delayed union or mal-union
- Infection
- Nerve damage, including loss of neurological function (sensory and/or

IMPORTANT INFORMATION ON PATRIOT® LUMBAR SPACERS

motor), paralysis, dysesthesia, hyperesthesia, paresthesia, radiculopathy, reflex deficit, cauda equina syndrome

- Dural tears, cerebral spinal fluid leakage
- Fracture of vertebrae
- Foreign body reaction (allergic) to components or debris
- Vascular or visceral injury
- Change in spinal curvature, loss of correction, height and/or reduction
- Urinary retention or loss of bladder control or other types of disorders of the urogenital system
- Ileus, gastritis, bowel obstruction or other types of gastrointestinal system compromise
- Reproductive system compromise including impotence, sterility, loss of consortium and sexual dysfunction.
- Pain or discomfort
- Bursitis
- Decrease in bone density due to stress shielding
- Loss of bone or fracture of bone above or below the level of surgery
- Bone graft donor site pain, fracture, and/or delayed wound healing
- Restriction of activities
- Lack of effective treatment of symptoms for which surgery was intended
- Need for additional surgical intervention
- Death

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING AND USE

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion (i.e. rust, pitting), discoloration, excessive scratches, notches, debris, residue, flaking, wear, cracks, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

Implants are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidentally contaminated.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.

8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10⁻⁶. Sterile products are packaged in a heat sealed, double pouch or container/pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants and instruments that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated to ensure an SAL of 10⁻⁶. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in² total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes
Steam	Pre-vacuum	134°C (273°F)	3 Minutes	30 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (U.S.A.) Law Restricts this Device to Sale by or on the Order of a Physician.

	CATALOGUE NUMBER		STERILIZED BY IRRADIATION
	LOT NUMBER		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
	QUANTITY		PRESCRIPTION USE ONLY

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Globus Medical
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