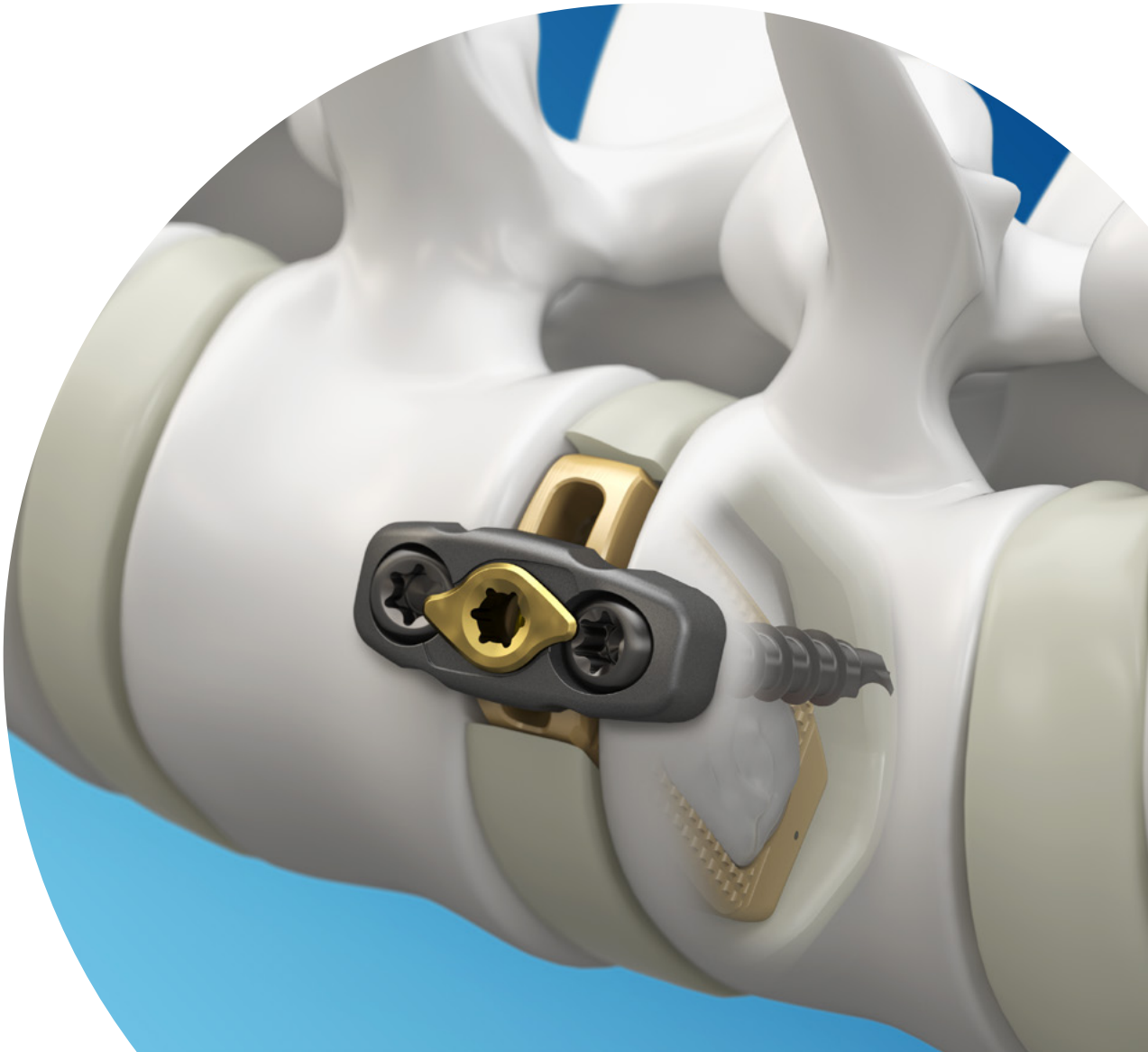
Medtronic

Surgical Technique

Pivox™

Oblique Lateral Spinal System with Infuse™ Bone Graft



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Implant Overview

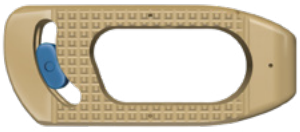
Interbody Spacers

Interbody Heights: 8mm, 10mm, 12mm, 14mm, 16mm, 18mm

Lengths: 40mm, 45mm, 50mm, 55mm, 60mm

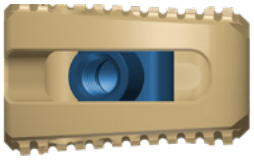
Width:

20mm

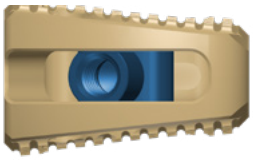


Lordotic options:

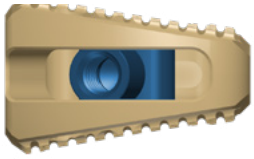
6°



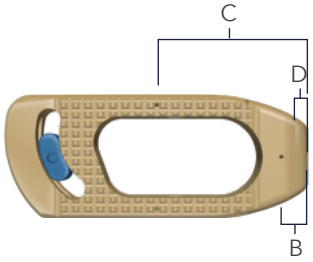
12°



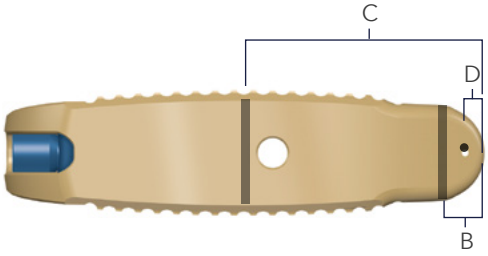
18°



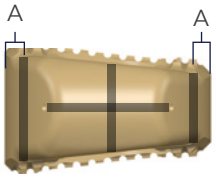
X-ray marker locations:



Axial View



A/P View



Lateral View

A Distance from marker to anterior and posterior edge	B Distance from marker to lateral edge	C Distance from marker to lateral edge	D Distance from marker to lateral edge
1.75mm	5mm	40mm Length: 20mm 45mm Length: 22.5mm 50mm Length: 25mm 55mm Length: 27.5mm 60mm Length: 30mm	2mm

Posterior Height Calculations

Width	Lordosis	Listed Height†	Posterior Height†
20	6°	x	x-2.1
20	12°	x	x-4.2
20	18°	x	x-6.3

†Teeth add 1mm to overall height.

Plates

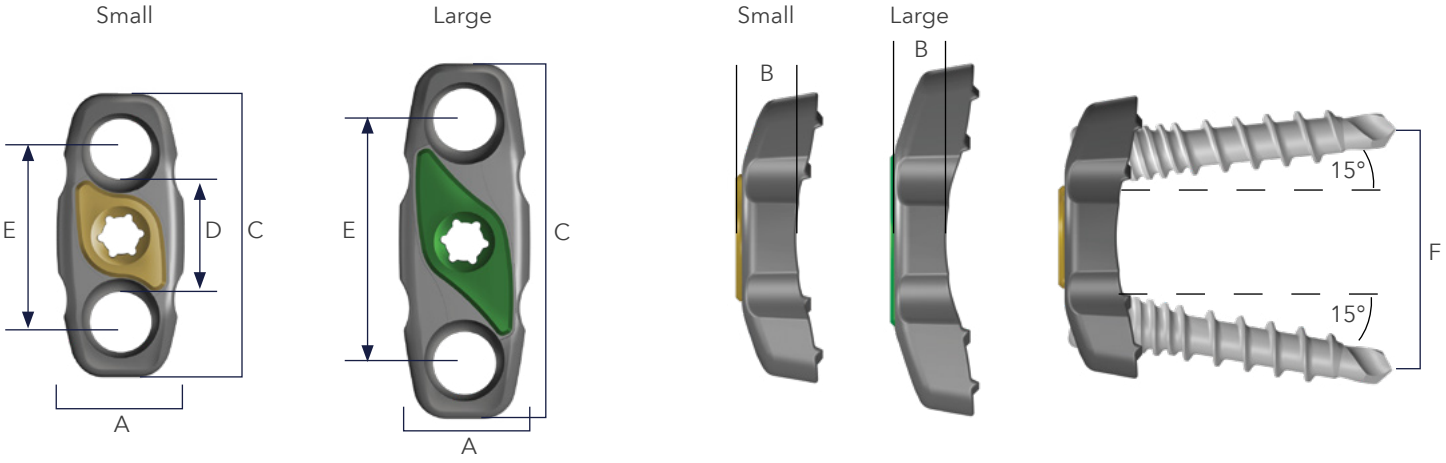


Plate Dimensions

		Small	Large
A	Width	12.0mm	12.0mm
B	Thickness including the Locking Cap	5.9mm	5.4mm
C	Overall Length	28.4mm	34.6mm
D	Distance Between Screws	10.9mm	17.3mm
E	Distance Between Center of Screws	15.3mm	21.3mm

Screw Size	Plate Size	Vertical Distance Between Screw Tip (F)
20	Small	23.6
25	Small	25.3
30	Small	27.1
35	Small	28.8
40	Small	30.5
45	Small	32.3
50	Small	34.0
20	Large	30.0
25	Large	31.7
30	Large	33.5
35	Large	35.2
40	Large	36.2
45	Large	38.7
50	Large	40.4

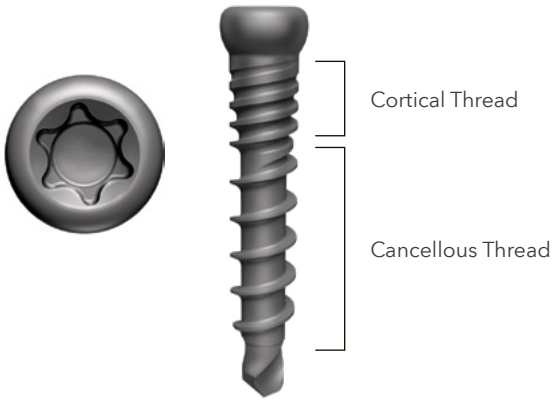
Correlation with Interbody Implants:

Interbody Size	0 deg, 6 deg, 12 deg, 18 deg
8mm	Small Plate
10mm	Small Plate
12mm	Small Plate with All-In-One Inserter†
14mm	Large Plate
16mm	Large Plate
18mm	Large Plate

† Plate must be centered on Interbody for screws to clear Interbody

Screws

- Lengths: 20mm, 25mm, 30mm, 35mm, 40mm, 45mm and 50mm standard
- Inner Diameter: 3.7mm
  Outer Diameter: 5.5mm
- Cancellous Thread Pitch: 3.2mm
  Cortical Thread Pitch: 1.6mm
- Self-drilling and Self-tapping Screws
- Dual Thread Design



Instruments

OLIF25™ All-In-One Inserter
2140010

OLIF25™ All-In-One Inserter Shaft
2140020

Screw Guide, Small
2140011

Screw Guide, Large
2140012

Interbody Inserter
2161000

Interbody Inserter Threaded Shaft
2161001

OLIF Slaphammer
2151130

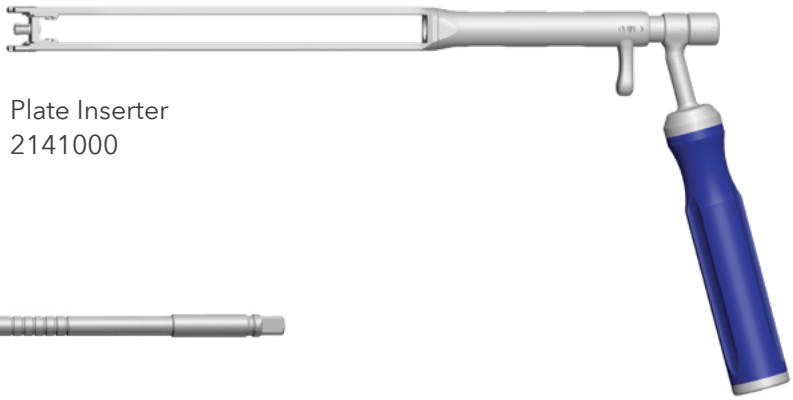


Plate Inserter
2141000

OLIF Screwdriver
2150100

Quick-connect Ratcheting Silicone Handle
9339082

Straight Awl - bevel tip
2151130

Interbody Remover
2162000

Plate Trial, Small
2143001

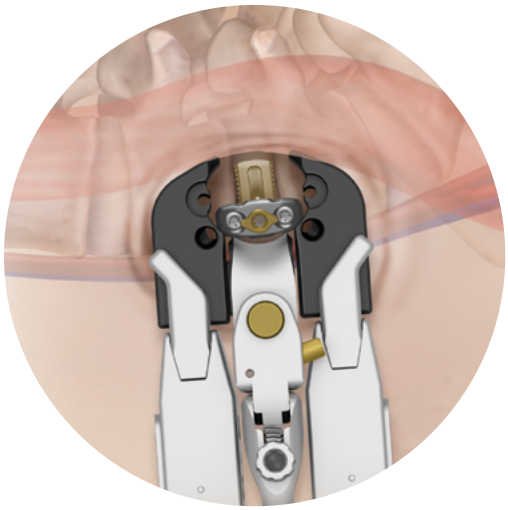
Plate Trial, Large
2143002

Interbody Trial Inserter
2163000

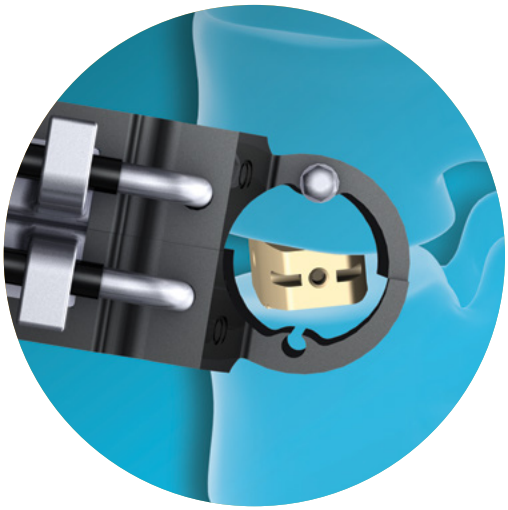
Interbody Trialing Size Options			
Width	Length	Degrees	Height
20mm	45mm and 55mm	6° 12° 18°	8mm, 10mm, 12mm, 14mm and 16mm 10mm, 12mm, 14mm, 16mm and 18mm 12mm, 14mm, 16mm and 18mm

Access

The Pivox™ oblique lateral spinal system can be used during an OLIF25™ procedure or a DLIF procedure, depending upon the surgeon's preference and anatomical considerations. Refer to the appropriate procedure surgical technique for access and disc preparation instructions. Infuse™ bone graft is approved with Pivox™ for use in the OLIF25™ procedure only.



OLIF25™ Procedure



DLIF Procedure

Trialing

After the disc space is prepared and any osteophytes are removed, select the appropriate implant sizes using the Interbody trials and plate trials. Thread the trial inserter into the appropriate interbody trial until the splines lock the assembly into a fixed orientation **(Figure 1)**.

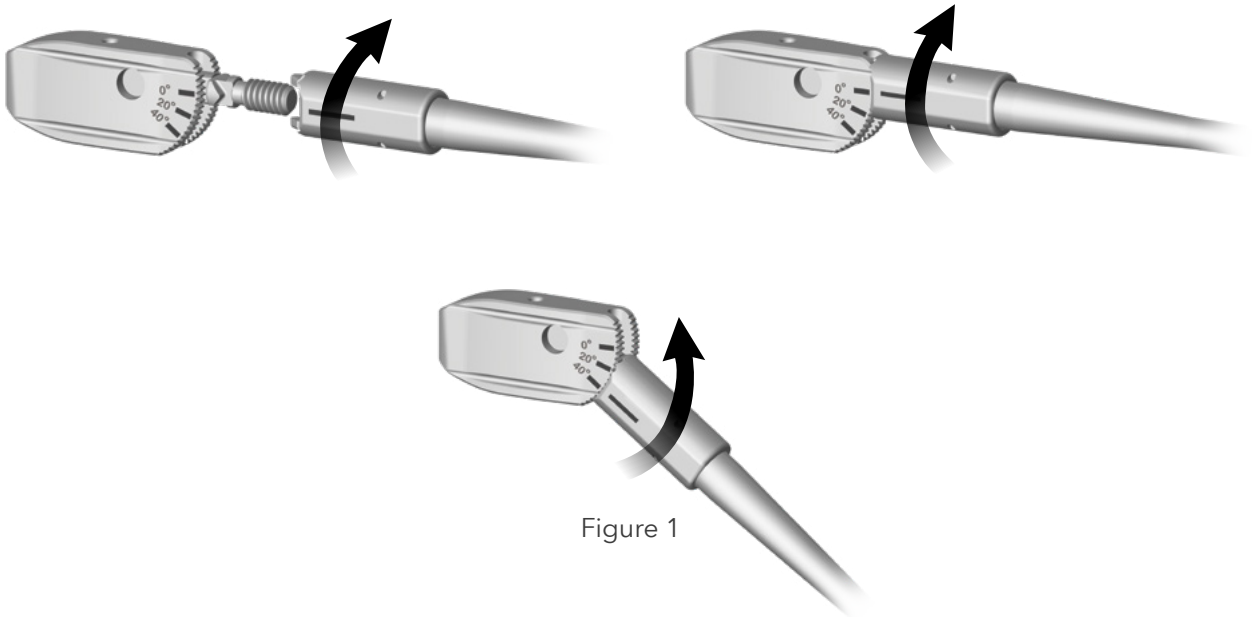


Figure 1

Trials are available in 45mm and 55mm lengths which can be used to select between 40mm, 45mm, 50mm, 55mm, or 60mm interbody options. Impact the trial into the disc space under lateral fluoroscopy in order to place it in the desired anterior/posterior position **(Figure 2)**. Final impaction should be completed under A/P flouroscopy to assess the length of the trial in the disc space. A properly-sized trial should be centered with the spinous process bisecting the trial. It should span the disc space to sit on the dense apophyseal ring on both sides. When choosing an interbody length, remember that if the interbody and plate will be inserted together the proximal end of the interbody will not countersink into the disc space, so the interbody should span the entire disc space and sit flush with the proximal side of the vertebral body **(Figures 3 and 4)**.

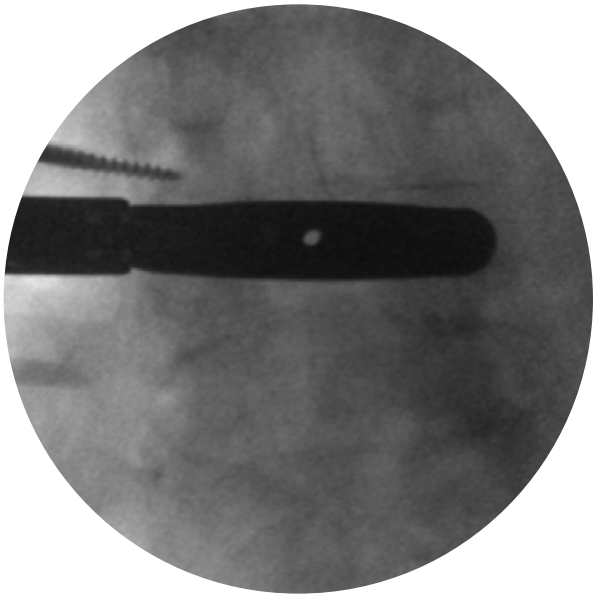


Figure 2

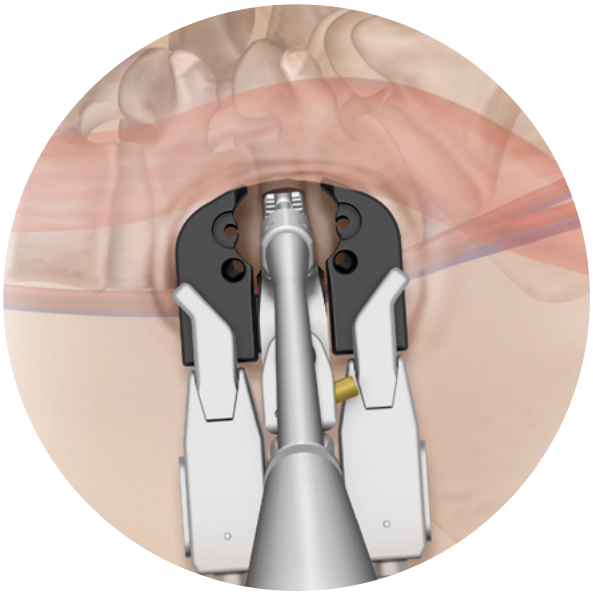


Figure 3

The retractor is shown with flat blades and an optional.

Each trial has two grooves in the coronal plane to visualize when the trial is completely orthogonal in the disc space. On a true lateral view, with the trial in the orthogonal position, both grooves will be visible.

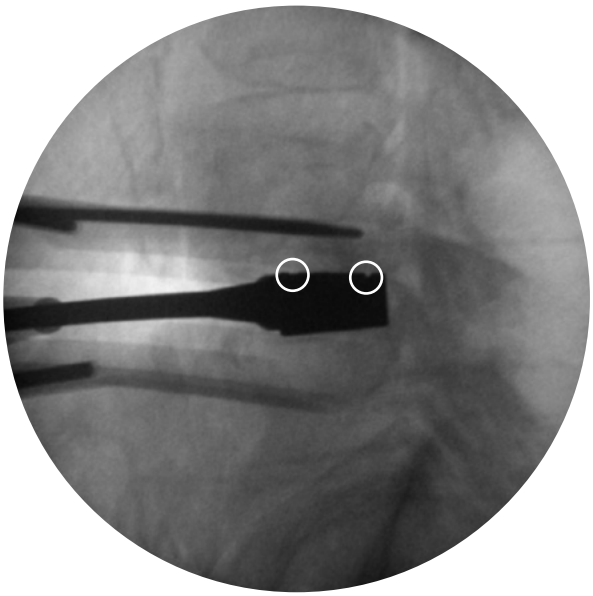


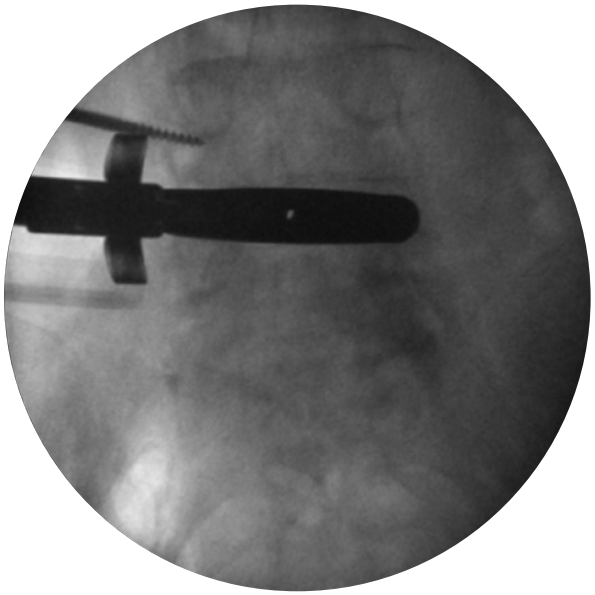
Figure 4

Plate trials can be placed over the trial inserter to select the appropriate plate length. The plate should span across the disc space such that each screw hole is positioned over a vertebral body without intersecting the interbody implant. When possible, the small plate should be used to maximize contact with the cortical bone in the corner of the vertebral body. Use of an appropriately sized plate will reduce the risk of injury to segmental vessels **(Figures 5 and 6)**.

Interbody Size	0 deg, 6 deg, 12 deg, 18 deg
8mm	Small Plate
10mm	Small Plate
12mm	Small Plate with All-In-One Inserter†
14mm	Large Plate
16mm	Large Plate
18mm	Large Plate

† Plate must be centered on Interbody for screws to clear Interbody

Figure 5



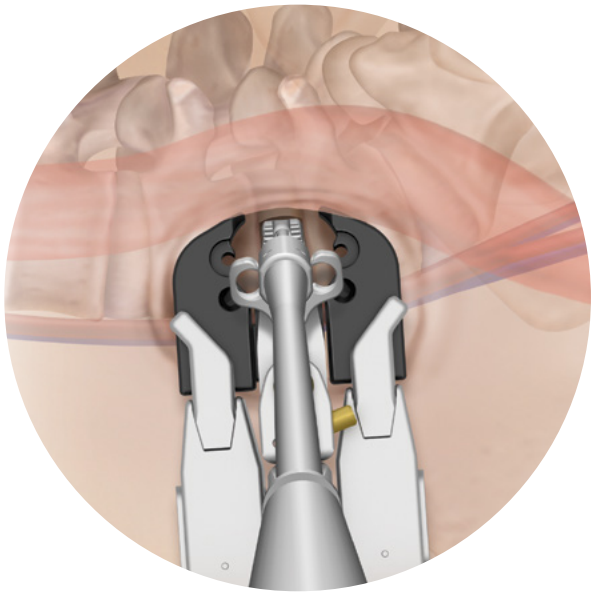


Figure 6

Bone Graft Preparation and Placement

Pivox™ spinal system implant may be used with Infuse™ bone graft or autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

If using Infuse™ bone graft:

- An appropriate amount of Infuse™ bone graft should be used according to the internal volume of the Pivox™ implant. Refer to the Fill Guidelines on pages 35-36 for the appropriate kit(s) to be used with the corresponding Pivox™ implant.
- At this time, prepare the appropriate Infuse™ bone graft kit(s). Refer to pages 28-31 for preparation instructions.
- Following a minimum of 15 minutes, and no more than 2 hours, use forcept to roll the wetted collagen sponge(s) and place in the implant's central cavity **(Figure 7a)**.

Figure 7a

Helpful Tip

If desired, a resorbable polyglactin 910 suture (e.g. VICRYL™* suture) may be wrapped around the exterior of the implant to secure Infuse™ bone graft during implantation **(Figure 7b)**.

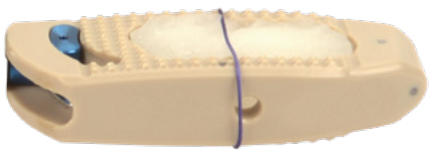


Figure 7b

Implantation

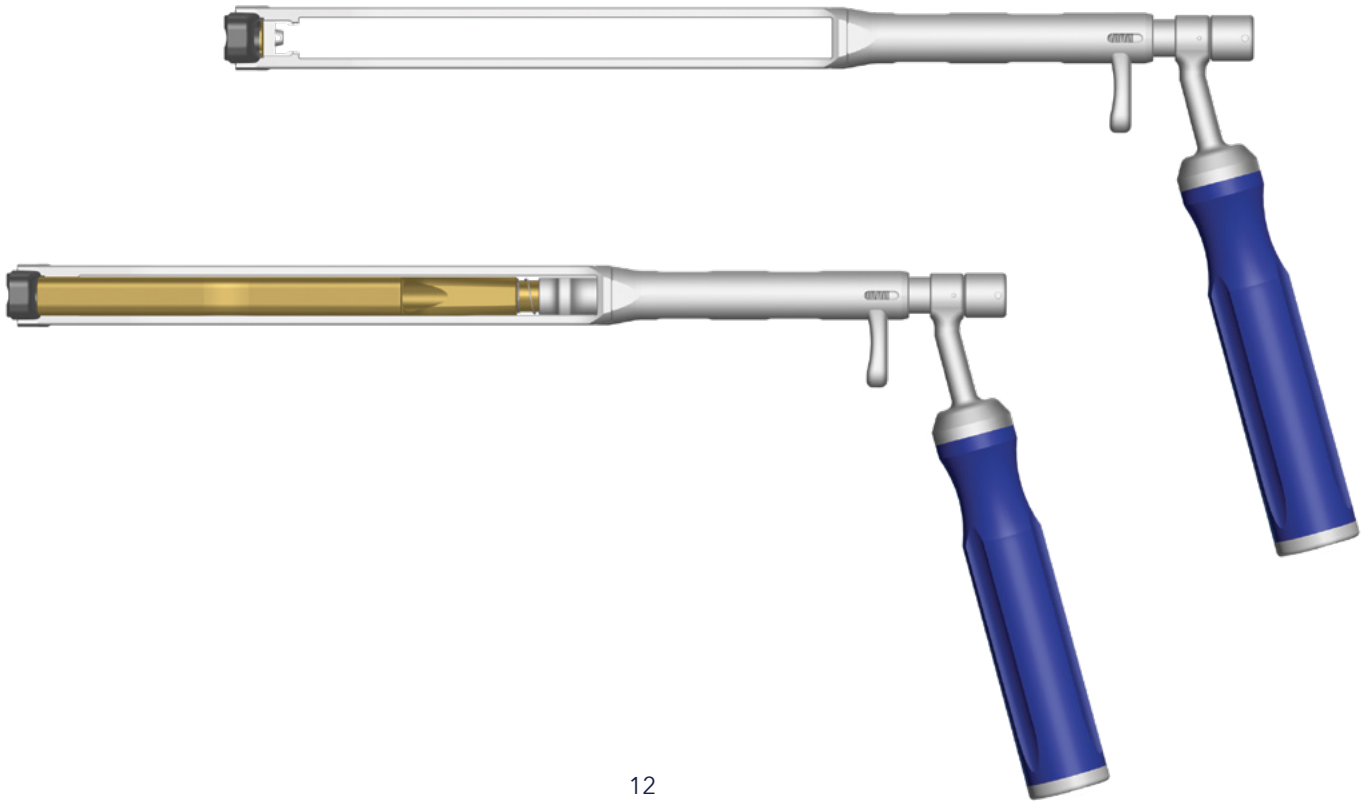
Once trialing is complete, the plate and interbody can be inserted together using the All-In-One inserter or separately using the interbody inserter and plate inserter. Before inserting the Pivox™ interbody, place Infuse™ bone graft or autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft in the interbody's central cavity.

Inserter options

1. All-In-One Inserter

2. Interbody Inserter

3. Plate Inserter or Plate Inserter with Screw Guide



Implantation with All-In-One Inserter

To insert the interbody and plate together, assemble the All-In-One inserter. It may be used with or without the screw guide. If the screw guide will be used, insert the screw guide that corresponds with the selected plate size into the All-In-One inserter. It will snap into place **(Figure 8)**.

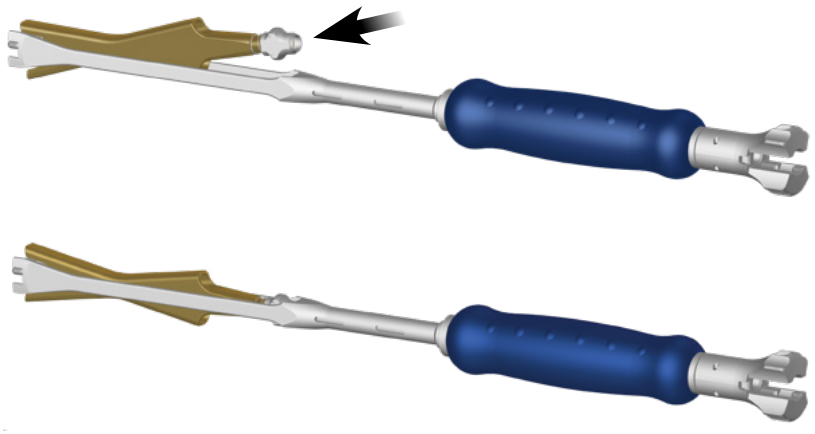


Figure 8

Slide the Inserter Shaft into the All-In-One inserter **(Figure 9)**.

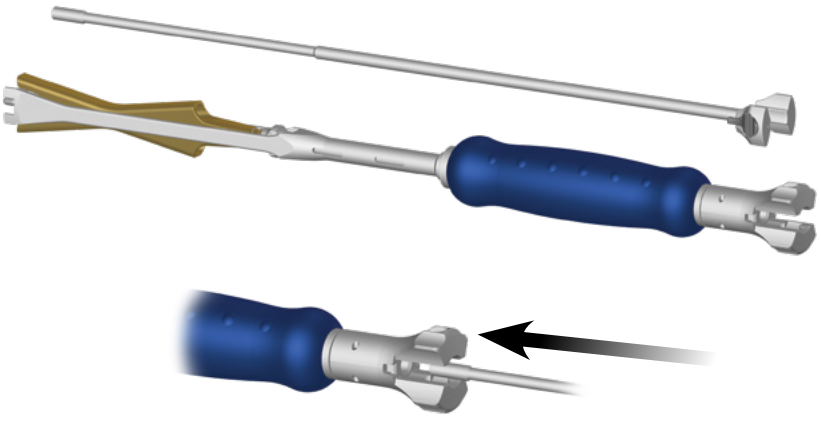


Figure 9

The inserter shaft will click into place when it is fully seated **(Figure 10)**.

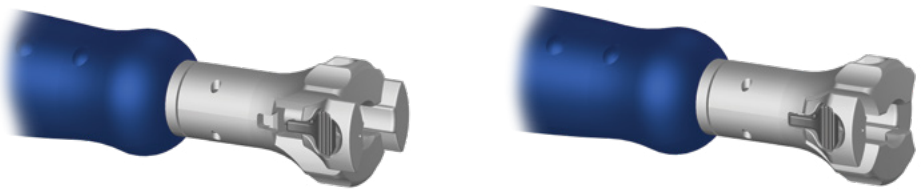


Figure 10

The plate is placed between the brackets on the All-In-One inserter and is held loosely with a slip fit. It will be secured once the Interbody is threaded into place **(Figure 11)**.

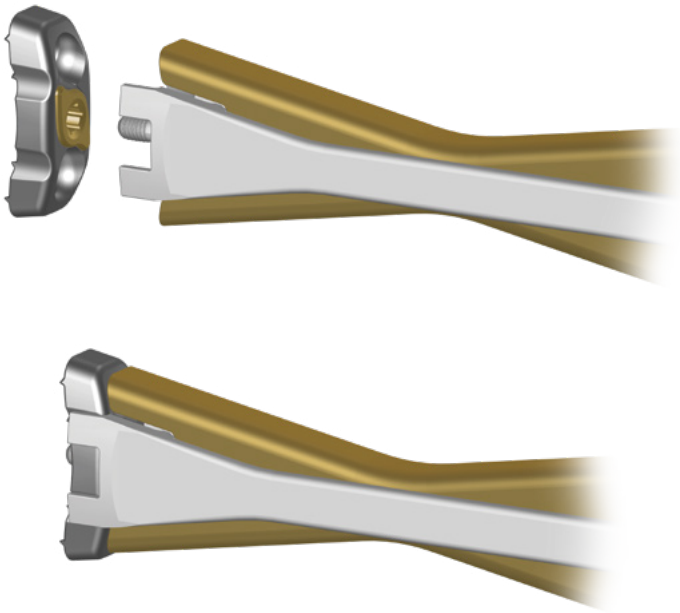


Figure 11

Thread the inserter shaft into the interbody until the interbody is locked rigidly into the preferred orientation **(Figure 12)**. Threading into the titanium swivel plate helps the inserter maintain a secure connection to the interbody. The interbody can be attached in line with the inserter shaft or at up to a 40 degree angle. Attaching the interbody at an angle will avoid obstacles such as the iliac crest and enable implantation without the instruments leaving the boundary of the retractor **(Figure 13)**.

Figure 12

Figure 13

A mallet is then used to insert the interbody while monitoring placement under lateral and AP fluoroscopy. If the interbody is attached in line with the disc space, the All-In-One inserter enters obliquely and can then be turned orthogonally to place the interbody across the disc space. Alternatively, the connection between the All-In-One inserter and implants can be loosened and retightened in a more oblique trajectory as needed to achieve interbody impaction into the desired anterior/posterior position. This allows the surgeon to insert the Interbody through an OLIF25™ trajectory without performing an orthogonal maneuver.

By the time the interbody spacer is approximately 50% into the disc space it should be aligned in the desired orthogonal position. This is completed with the fluoroscopy in the lateral position. The final positioning of the interbody should be completed under AP fluoroscopy to ensure the interbody is aligned in the medial/lateral plane. The surgeon can affect the anterior/posterior placement of the interbody by modifying when the interbody is rotated into the orthogonal position. Early rotation of the interbody leads to more anterior placement, while late rotation leads to more posterior placement. Occasionally an anterior incision location or anatomic constraints like the iliac crest will inhibit orthogonal placement.

The recommended position of the plate during interbody insertion is parallel to the disc space **(Figure 14)**. This allows maximum visualization of the vertebral segment during insertion. The plate is then rotated into its final position after the interbody is in place. Ensure that the plate is not countersunk into the disc space which will restrict the ability to rotate the plate into place. The plate could also be inserted in its final position. **(Figure 15)**.

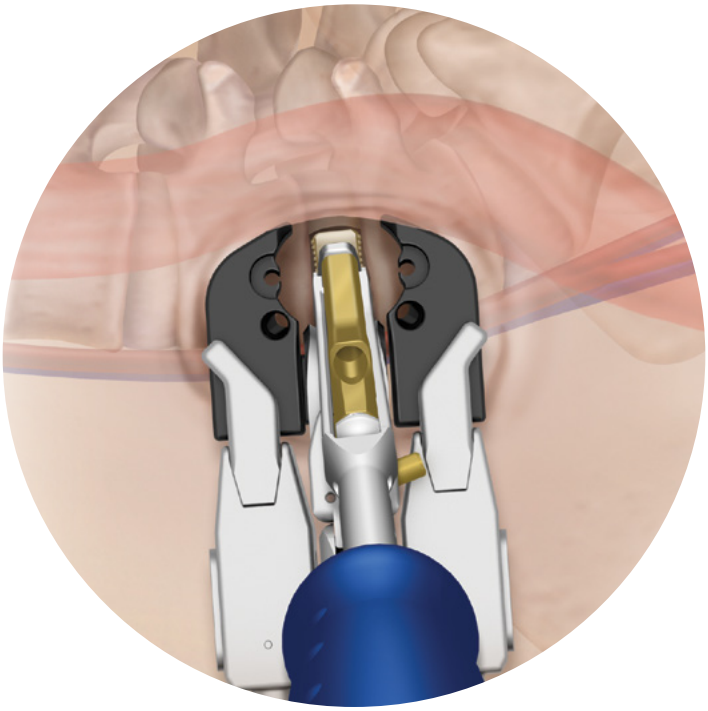


Figure 14

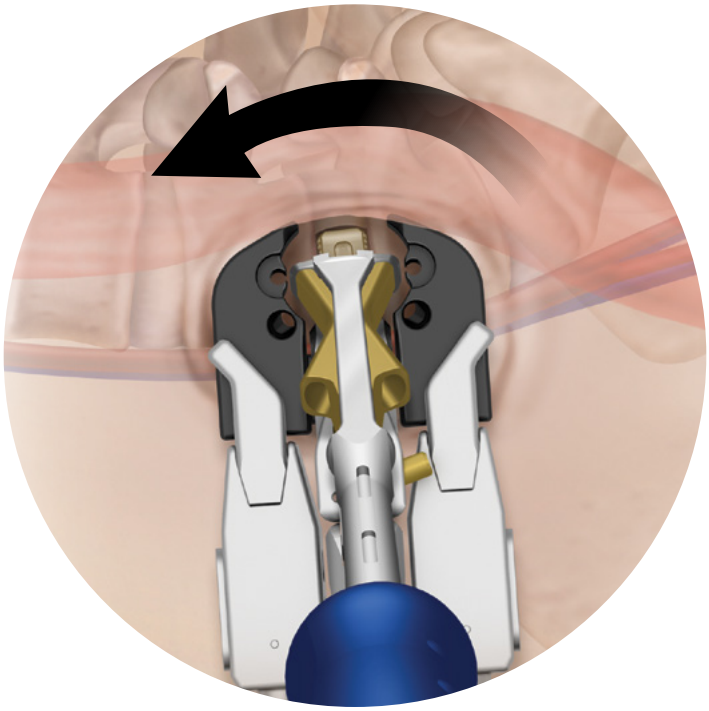


Figure 15

When the interbody is in place, rotate the inserter shaft counter-clockwise (1 full turn) to loosen the connection between the interbody and plate. Orient the plate into its final location over the disc space and lock in place by rotating the inner shaft clockwise **(Figure 16)**. Final impaction of the interbody and plate may be necessary to make the plate flush with the vertebral body. Osteophytes may need to be removed in order to get the plate flush with the vertebrae. The ability of the plate to pivot around the interbody facilitates placement in the oblique corridor where it is not disrupting the lumbar plexus or psoas muscle.

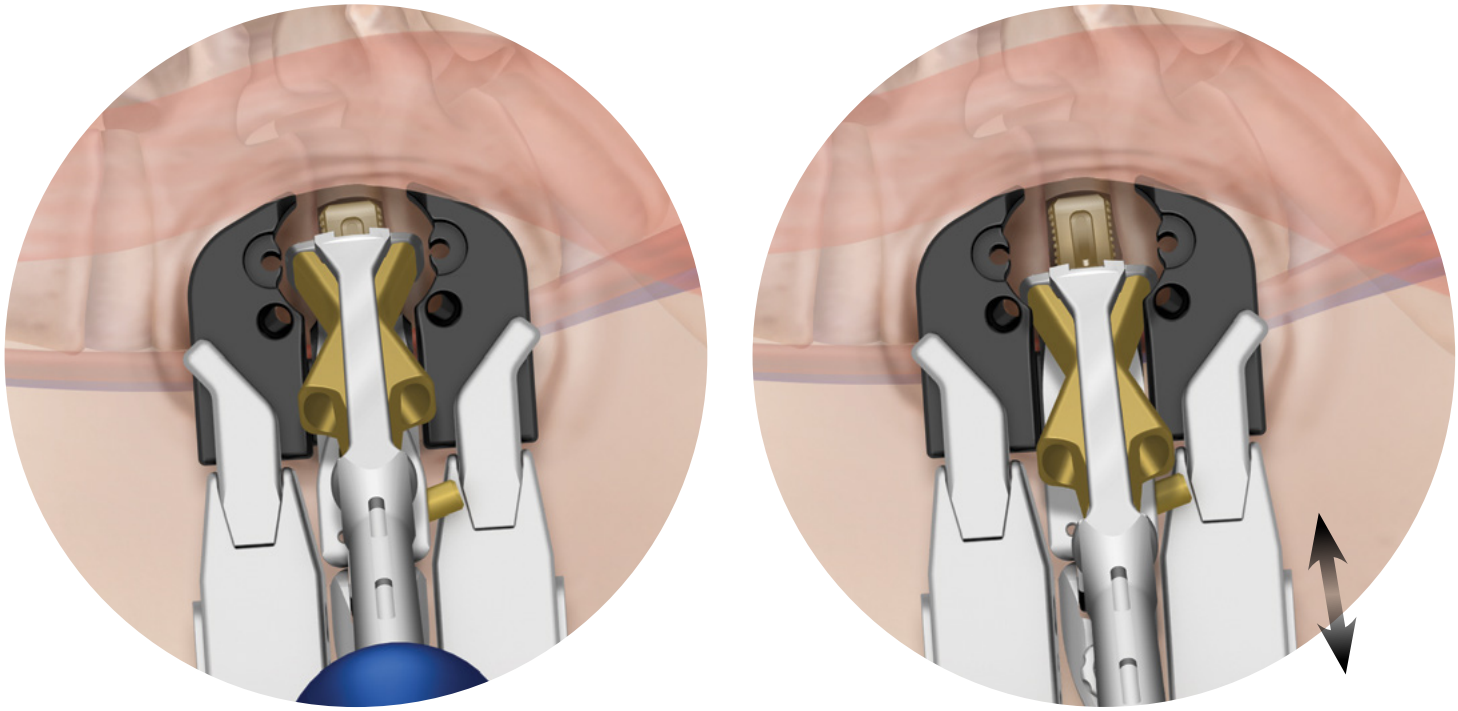


Figure 16

Remove the inserter shaft to clear the pathway for screw insertion **(Figure 17)**.

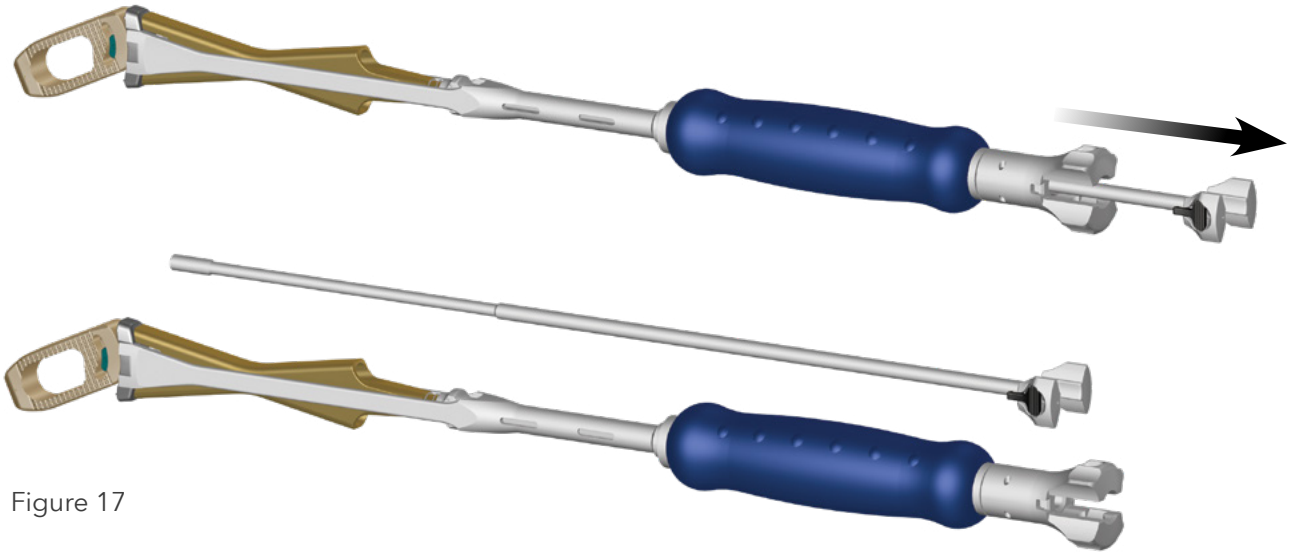


Figure 17

The maximum screw length can be estimated based upon the interbody as shown in the following images and charts **(Figure 18)**. The screws feature a self-tapping awl tip so that it is not required to awl or tap for screw insertion. This aggressive tip is not intended for bicortical fixation. One way to ensure that the tip of the screw is within the vertebral body is to select a screw that doesn't pass the posterior or distal edges of the interbody spacer.

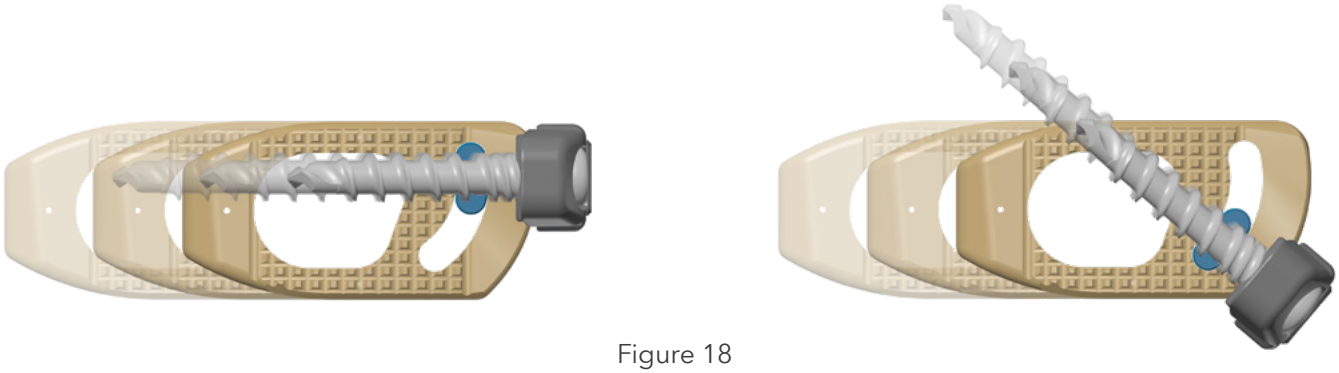


Figure 18

The longest screw that will be within the contralateral edge of the interbody depends on the interbody length and plate orientation **(Figure 19)**.

	Longest Screw with tip within the contralateral edge of the Interbody		
IB Length	0˚	20˚	40˚
40mm	40mm	40mm	45mm
45mm	45mm	45mm	50mm
50mm	50mm	50mm	50mm
55mm	50mm	50mm	50mm
60mm	50mm	50mm	50mm

Figure 19

The longest screw that will be within the posterior edge of the interbody depends on the interbody width and plate orientation **(Figure 20)**.

	Longest screw with tip within posterior edge of interbody	
IB Width	20˚	40˚
20mm	35mm	30mm

Figure 20

Use the awl to create a pilot hole for screw insertion. The bevel tip awl should be oriented with the point facing the endplate. Although the screw has an awl tip for easy insertion, creating a pilot hole will help to avoid skiving off the vertebral body. If the surgeon prefers to eliminate a step, a mallet tap on the screwdriver with the screw in place will create a pilot hole without use of the awl **(Figure 21)**.

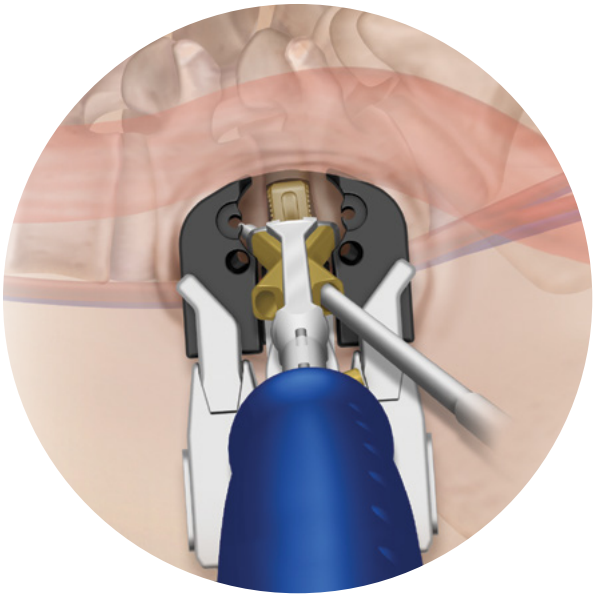


Figure 21

After creating the first pilot hole, use the screwdriver to provisionally insert a screw into that hole **(Figures 22 and 23)**. It is not recommended to completely tighten the screw through the guide. The screwdriver includes an indicator line to help prevent overtightening. When the line is aligned with the top of the screw insertion guide the screw head is 2mm from its final position. Use the awl through one hole, then insert that screw before moving to the next hole to awl, then screw.

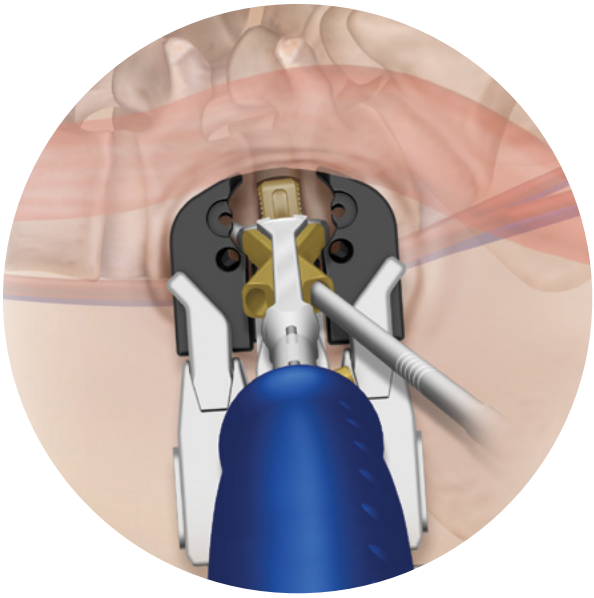


Figure 22

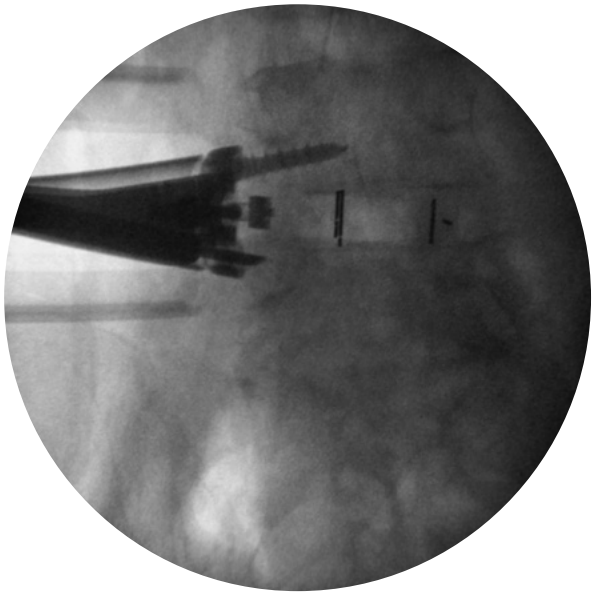


Figure 23

Replace the inner shaft and rotate counterclockwise to remove the All-In-One inserter from the interbody **(Figure 24)**. Use the screwdriver for final tightening of the screws. Heads of the screws should recess into the plate with enough room to engage locking cap. "Two finger tightening" should be sufficient to fully seat the screws without stripping the bone/screw interface. A clockwise method of screw tightening is recommended. Turn each screw one-half turn only, one at a time and make several tightening sequences. Two screwdrivers may be used to tighten each screw simultaneously. This will prevent the plate from lifting up on one side during tightening. With both screws tightened, use the same screwdriver to rotate the locking cap to prevent the screws from backing out. Use the locking cap's visual and tactile feedback to confirm that it is rotated into the locked position **(Figure 25)**.

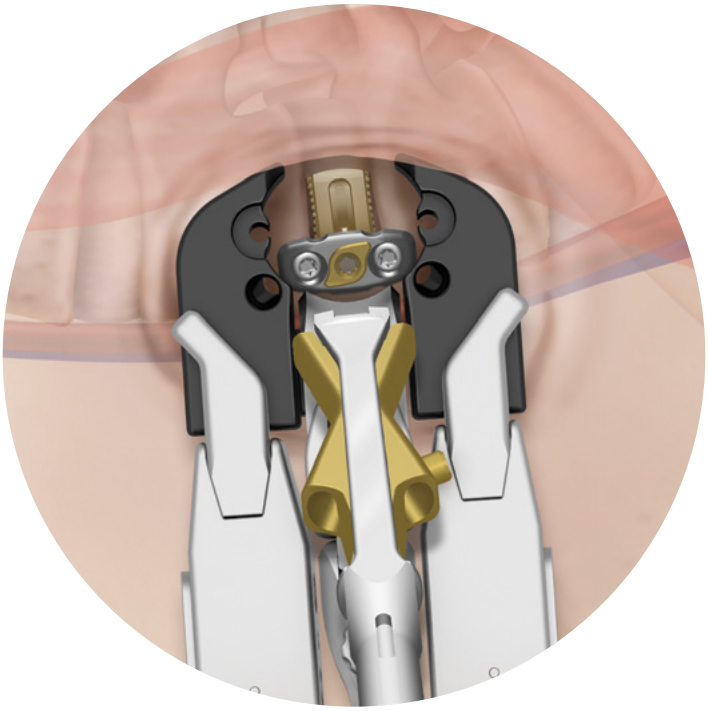


Figure 24

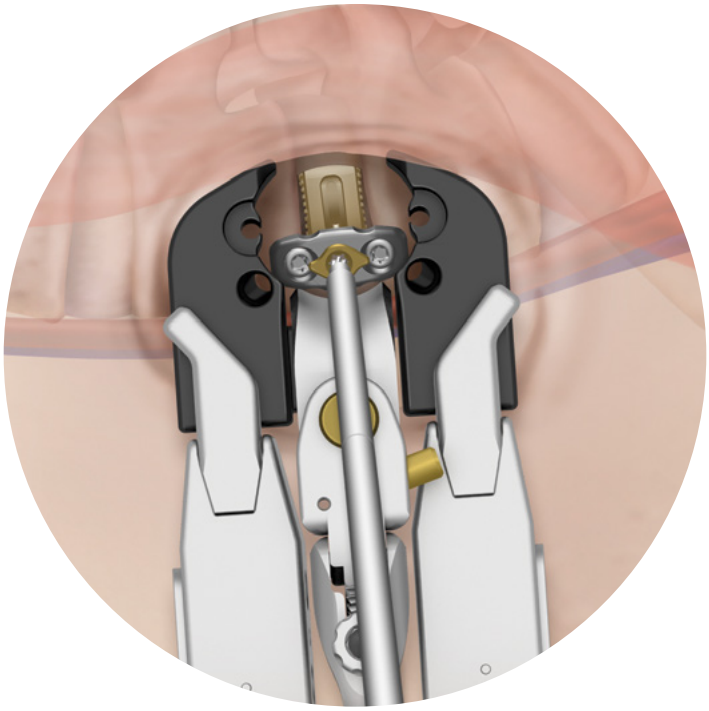


Figure 25

Insertion with Interbody Inserter

The interbody spacer can be implanted separately from the plate using the Interbody Inserter. Insert the Pivox™ interbody threaded shaft into the Pivox™ interbody inserter **(Figure 26)**. Thread the inserter into the interbody until it is tightly secured into the desired position **(Figure 27)**.

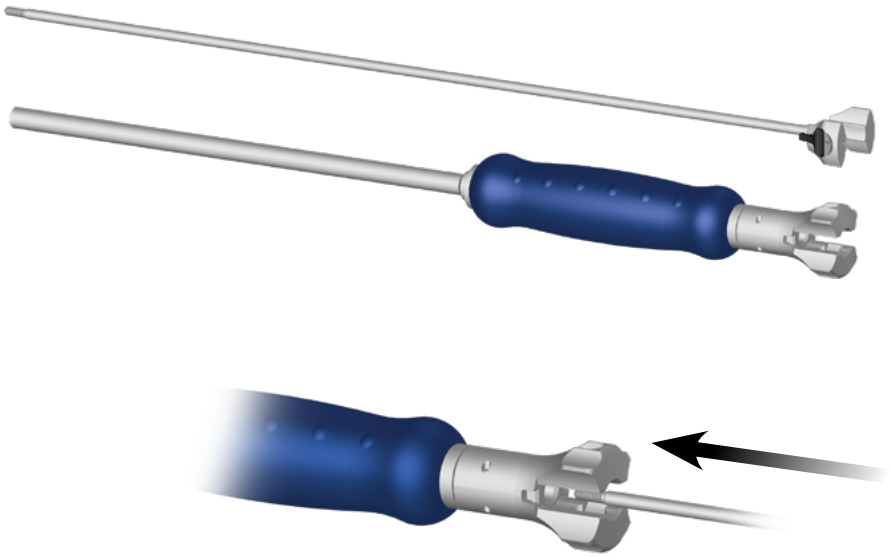


Figure 26

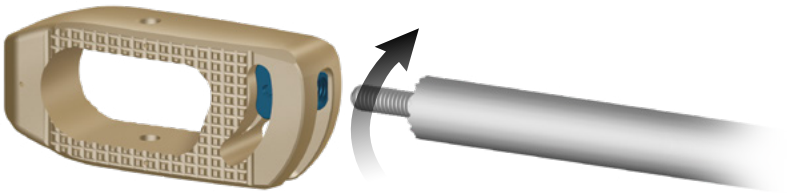


Figure 27

During insertion, the interbody inserter to interbody connection can be loosened to modify the angle of the interbody on the inserter **(Figure 28)**. This allows the surgeon to insert the interbody through an OLIF25™ trajectory without performing an orthogonal maneuver **(Figure 29)**. Use a mallet to impact the interbody into place until the x-ray markers indicate that it is centered in the disc space and spans the disc space to sit on the dense apophyseal ring on both sides **(Figure 30)**. With the interbody in the final placement, rotate the Pivox™ interbody threaded shaft counter clockwise to release the interbody from the inserter.

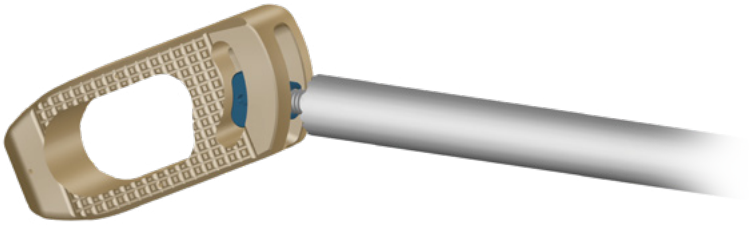


Figure 28

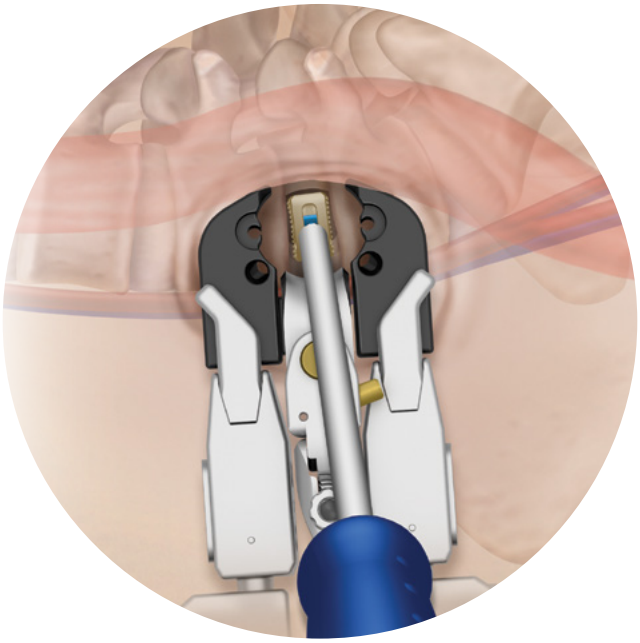


Figure 29

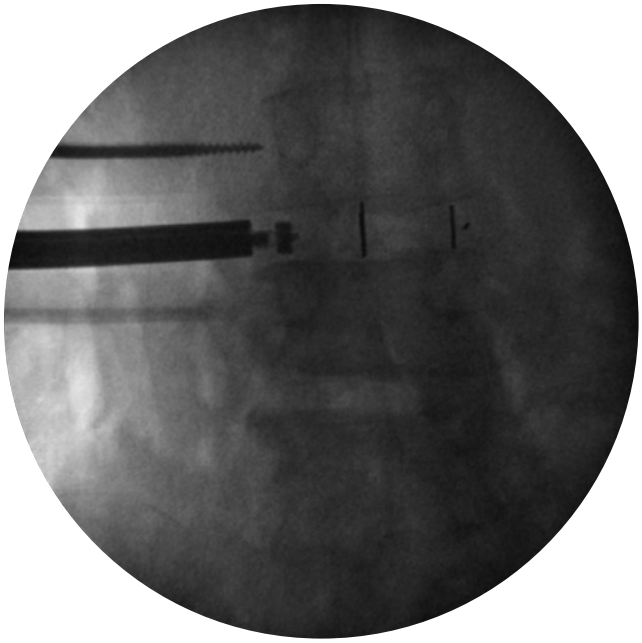


Figure 30

Insertion with Plate Inserter

The plate can be inserted independently of the interbody using the Pivox™ plate inserter. Use the plate trial to select the appropriately sized plate. The recommendations for plate size based on interbody height are on page 3. Like the All-In-One inserter, the plate inserter can be used without the screw guide **(Figure 31)**. If the screw guide will be used, insert the screw guide that corresponds to the selected plate size into the plate inserter. It will snap into place **(Figure 32)**. Load the plate onto the plate inserter by pulling the outer sleeve back, putting the plate in place. Release the outer sleeve to lock the plate on the inserter **(Figures 31 and 32)**.

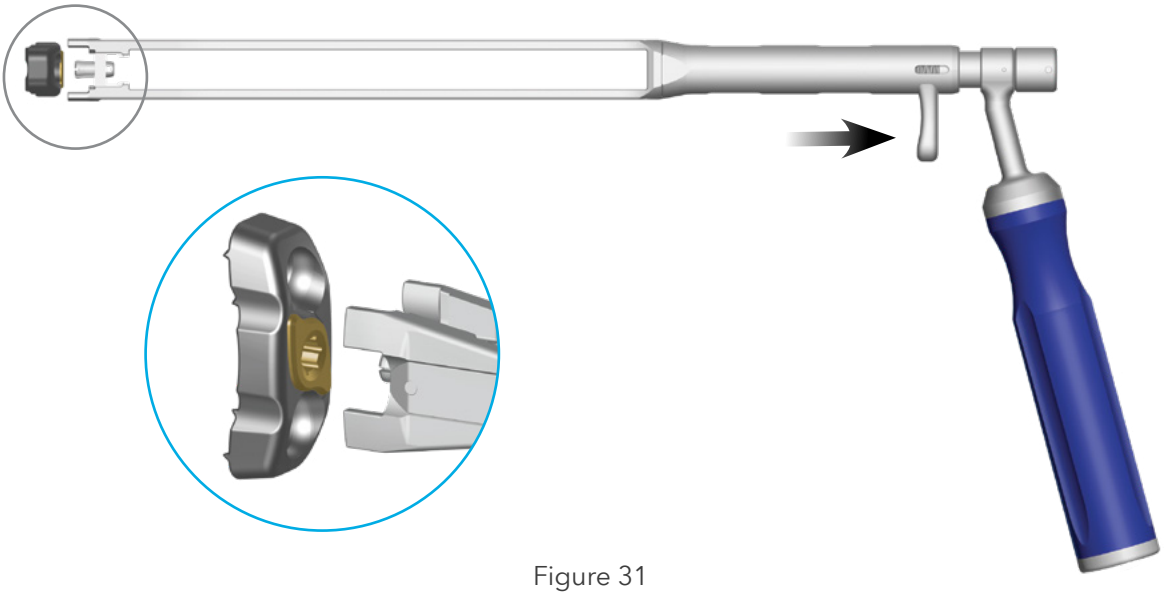


Figure 31

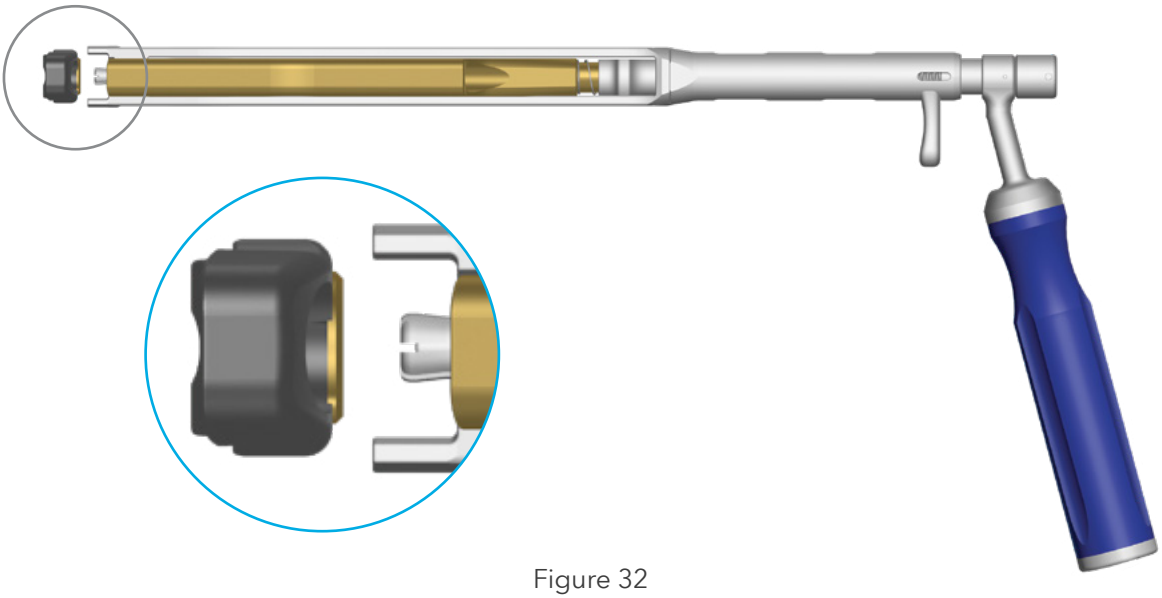


Figure 32

Position the plate over the disc space, taking care to avoid the sympathetic chain and segmental vessels. Align the plate to optimize screw trajectory, noting that the screws are not directed too far posterior. Care should be taken that no tissues are trapped under the plate as it is rotated into position.

Use the awl to create a pilot hole for each screw. With freehand plate insertion the Interbody is not holding the plate in position so the surgeon must take care to hold it into position during screw insertion to prevent skiving off the vertebral body or twisting the plate. When using the plate inserter without the screw guide leave the awl in place, then provisionally insert the screw in the other hole. Remove the awl and provisionally insert the second screw before sequentially tightening both screws. Use the screwdriver to insert each screw **(Figure 33)**.

Release the plate from the plate inserter by pulling the outer sleeve toward you. Use the screwdriver to rotate the locking cap to prevent the screws from backing out **(Figure 34)**.

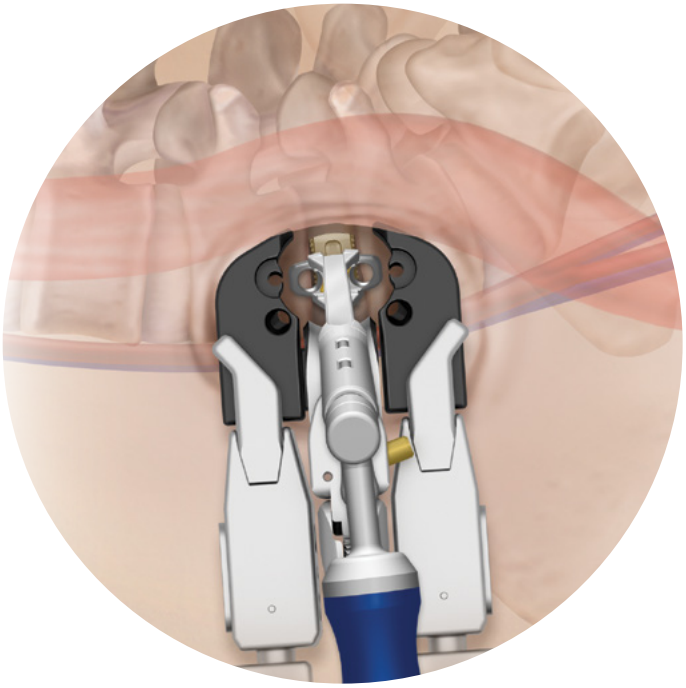


Figure 33

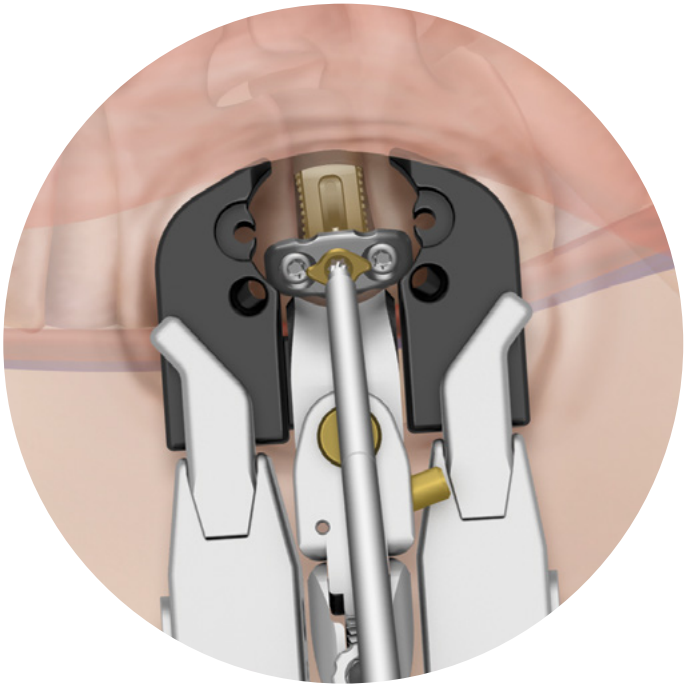
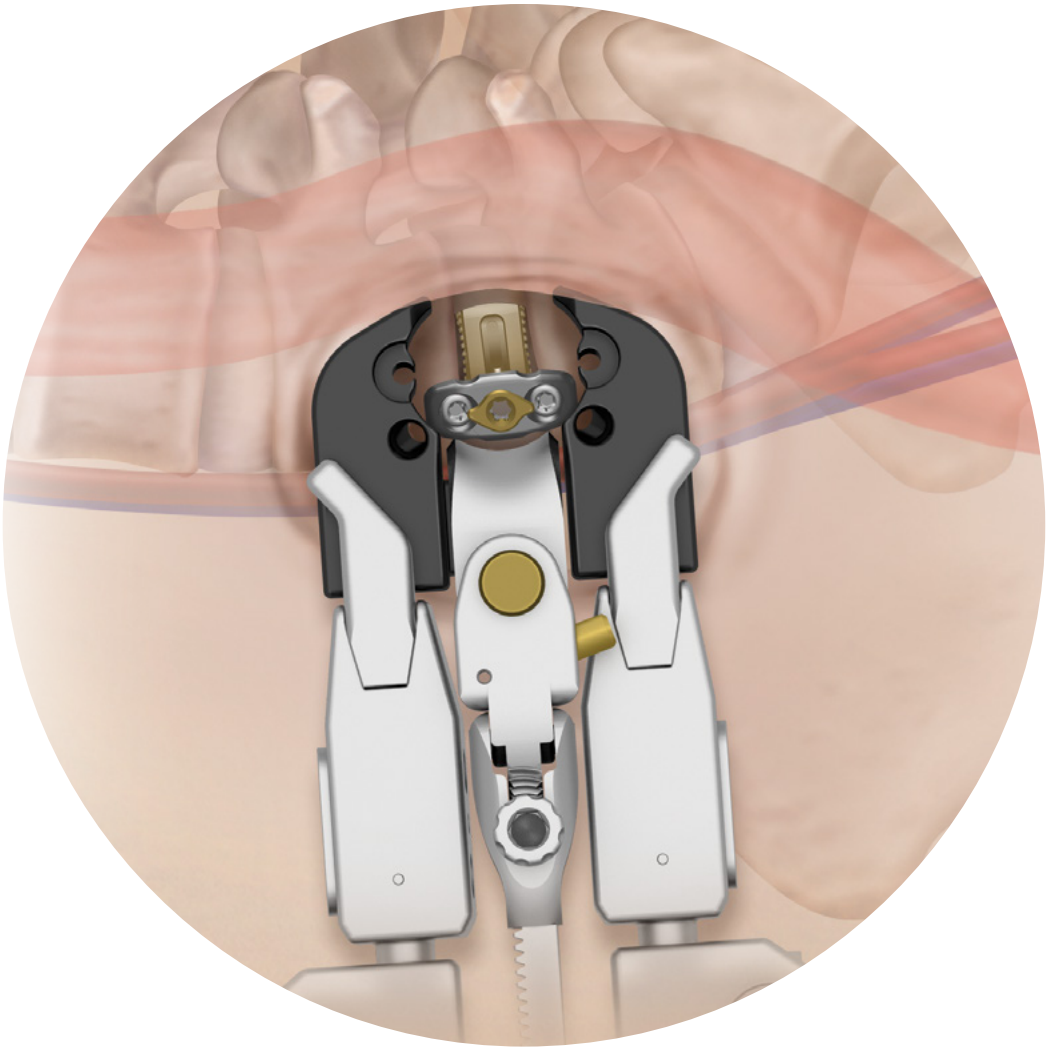


Figure 34

Note
The preferred position of the plate is anterior to the psoas in the oblique corridor, but remember that the segmental vessels may move closer to the disc as they move anterior.

Final Placement



Explantation

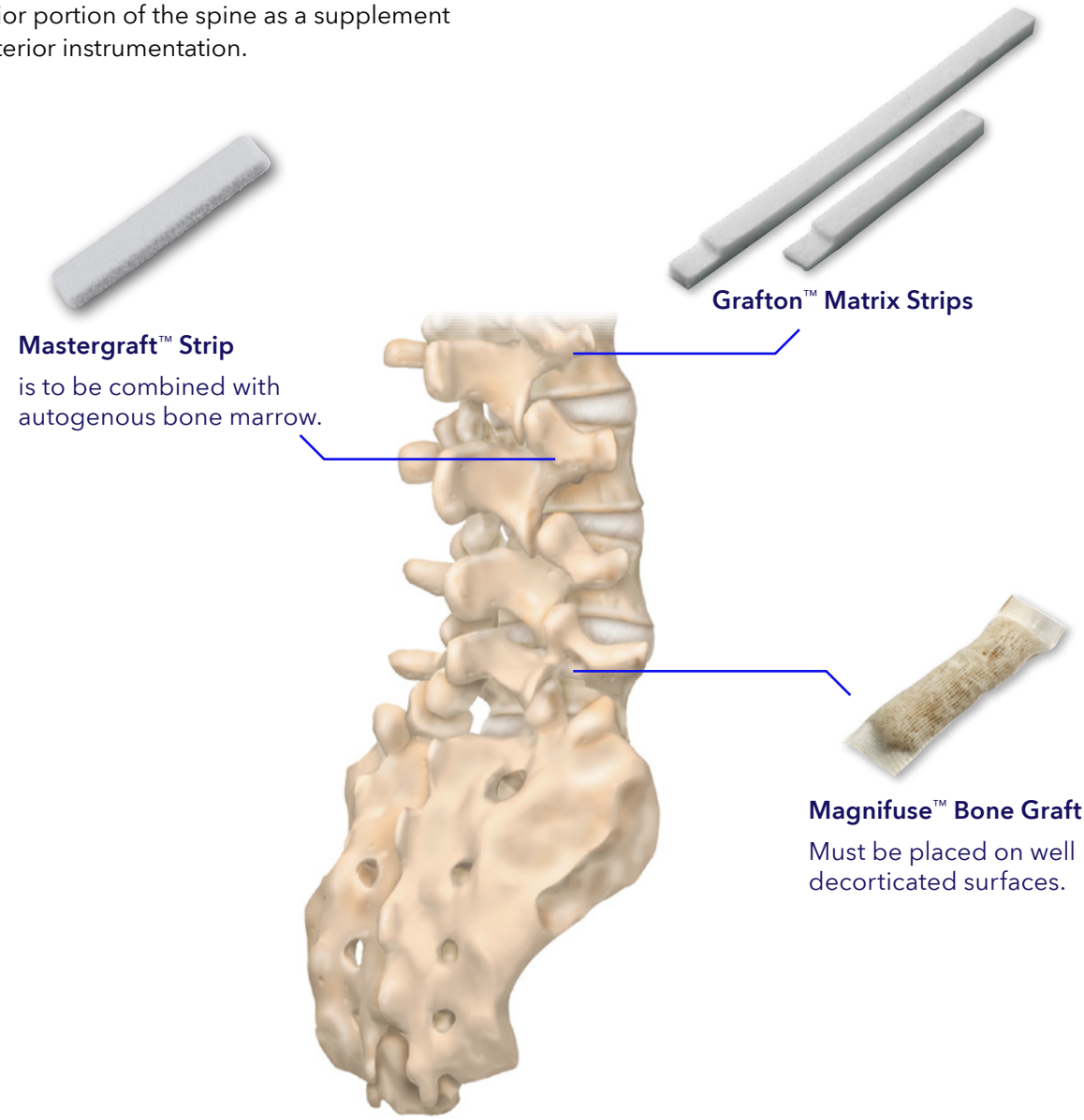
Should it be necessary to reposition or remove the Pivox™ plate, use the screwdriver to rotate the locking cap into the “unlocked” position. Attach the plate inserter, then use the screwdriver to remove each of the screws. To remove or reposition the interbody, thread the interbody remover tool into the interbody and use the slap hammer if needed.

Bone Graft Options for Supplemental Fixation

When posterior fixation is used, a number of Medtronic bone graft options are available as fillers for bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. Precise placement of the bone graft (autograft or allograft bone) is essential to facilitate fusion. These options are intended to be used as a supplement to posterior instrumentation.

Note

Infuse™ bone graft is not approved for use in the posterior portion of the spine as a supplement to posterior instrumentation.



Mastergraft™ Strip

is to be combined with autogenous bone marrow.

Grafton™ Matrix Strips

Magnifuse™ Bone Graft

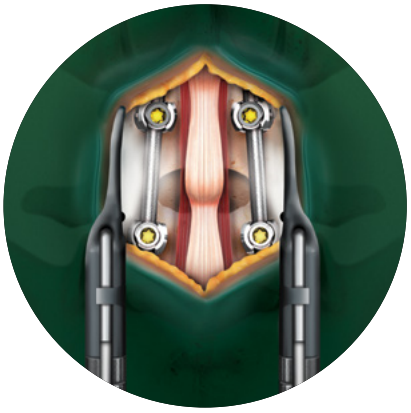
Must be placed on well decorticated surfaces.

Supplemental Fixation

When used together, the Pivox™ oblique lateral spinal system components (cage, plate and screws) can be used to treat patients with DDD at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. If desired, the Pivox™ interbody spacer can be used with approved anterior or posterior supplemental fixation. When Pivox™ interbody spacer is used to provide anterior column support in patients diagnosed with degenerative scoliosis it must be used as an adjunct to pedicle screw fixation.

CD Horizon™ Longitude™ II Multi-level Percutaneous Fixation System

CD Horizon Solera™ Voyager™ Spinal System



CD Horizon Solera™ Cortical Screw Procedure

Preparation Instructions for Infuse™ Bone Graft Component

7510050 XX Small Kit (0.7cc)

(1) 10mL vial

(1) 1.05mg vial

(1) ACS ½" × 2" (1.25cm × 5.08cm) 0.7cc graft volume

Note: You will need to prepare a sterile and non-sterile field before beginning product preparation.

Total preparation time: Allow at least 15 minutes for preparation and an additional 15 minutes for protein to bind to collagen sponge.

In non-sterile field

1

Observing proper sterile technique, open the outer Absorbable Collagen Sponge (ACS) package and place the inner package containing the one ½" × 2" collagen sponge in the sterile field. Open and place one of the two 3mL syringe/needles in the sterile field.

2

Using one needle and 3mL syringe/needle, withdraw 0.9mL of sterile water for injection.

3

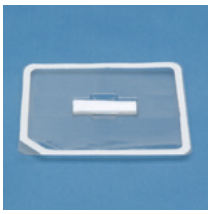
Reconstitute the rhBMP-2 with 0.9mL of sterile water.

4

Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing. Inspect the solution. If dark particles are observed, do not use and return to sponsor.

In sterile field

5

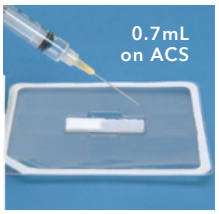


Open the inner ACS package leaving the collagen sponge in the plastic tray.

6

In the sterile field use the 3mL syringe/needle to withdraw 0.7mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

7



Uniformly distribute 0.7mL of reconstituted rhBMP-2 on the ½" × 2" collagen sponge. Inspect the sponge. If dark particles are observed, do not use and return to sponsor.

⚠ Allow wetted collagen sponges to stand for a minimum of 15 minutes. Use within 2 hours. DO NOT use irrigation or suction near implanted device. Note: During handling avoid excessive squeezing of the wetted sponge.

7510100 X Small Kit (1.4cc)

(2) 10mL vial

(2) 1.05mg vial

(1) ACS 1" × 2" (2.5cm × 5.08cm) 1.4cc graft volume

Note: You will need to prepare a sterile and non-sterile field before beginning product preparation.

Total preparation time: Allow at least 15 minutes for preparation and an additional 15 minutes for protein to bind to collagen sponge.

In non-sterile field

1

Observing proper sterile technique, open the outer Absorbable Collagen Sponge (ACS) package and place the inner package containing the one 1" × 2" collagen sponge in the sterile field. Open and place two 3mL syringes/needles into the sterile field.

2

Using one of the two remaining 3mL syringes/needles withdraw 0.9mL of sterile water for injection.

3

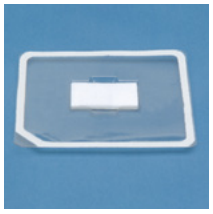
Reconstitute one vial of the rhBMP-2 with 0.9mL of sterile water.

4

Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing. Using a second 3mL syringe/needle repeat steps 2-3 with the remaining vial of sterile water and vial of rhBMP-2. Inspect the solution in both vials. If dark particles are observed, do not use and return to sponsor.

In sterile field

5

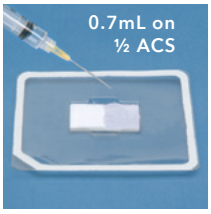


Open the inner ACS package leaving the collagen sponge in the plastic tray.

6

In the sterile field use the 3mL syringe/needle to withdraw 0.7mL of reconstituted rhBMP-2 from the first vial held by the person in the non-sterile field.

7

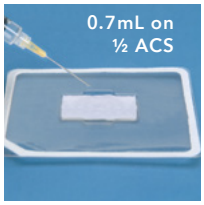


Uniformly distribute 0.7mL of reconstituted rhBMP-2 on half of the 1" × 2" collagen sponge.

8

In the sterile field use the second 3mL syringe/needle to withdraw 0.7mL of reconstituted rhBMP-2 from the second vial held by the person in the non-sterile field.

9



Uniformly distribute 0.7mL of reconstituted rhBMP-2 on the other half of the 1" × 2" collagen sponge. The total amount of reconstituted rhBMP-2 delivered to the sponge is 1.4mL. Inspect the sponge. If dark particles are observed, do not use and return to sponsor.

Allow wetted collagen sponges to stand for a minimum of 15 minutes. Use within 2 hours. DO NOT use irrigation or suction near implanted device. Note: During handling avoid excessive squeezing of the wetted sponge.

7510200 Small Kit (2.8cc)

(1) 10mL vial

(1) 4.2mg vial

(2) ACS 1" × 2" (2.54cm × 5.08cm) 2.8cc graft volume

Note: You will need to prepare a sterile and non-sterile field before beginning product preparation.

Total preparation time: Allow at least 15 minutes for preparation and an additional 15 minutes for protein to bind to collagen sponge.

In non-sterile field

1

Observing proper sterile technique, open the outer ACS package and place the inner package containing the two 1" × 2" collagen sponges in the sterile field. Open and place one of the two 5mL syringes/needles into the sterile field.

2

Using the other 5mL syringe/needle, withdraw 3.2mL of sterile water for injection.

3

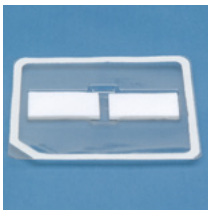
Reconstitute the rhBMP-2 with 3.2mL of sterile water.

4

Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing.

In sterile field

5

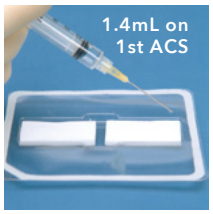


Open the inner ACS package leaving all collagen sponges in the plastic tray.

6

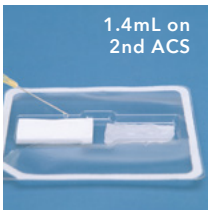
In the sterile field use the 5mL syringe/needle to withdraw 1.4mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

7



Uniformly distribute 1.4mL of reconstituted rhBMP-2 on one of the 1" × 2" collagen sponges.

8



Using the same 5mL syringe/needle, repeat steps 6 and 7 for the remaining 1" × 2" collagen sponge.

Allow wetted collagen sponges to stand for a minimum of 15 minutes. Use within 2 hours. DO NOT use irrigation or suction near implanted device. Note: During handling avoid excessive squeezing of the wetted sponge.

7510400 Medium Kit (5.6cc)

(2) 10mL vial

(2) 4.2mg vials

(4) ACS 1" × 2" (2.54cm × 5.08cm) 5.6cc graft volume

Note: You will need to prepare a sterile and non-sterile field before beginning product preparation.

Total preparation time: Allow at least 15 minutes for preparation and an additional 15 minutes for protein to bind to collagen sponge.

In non-sterile field

1

Observing proper sterile technique, open the outer ACS package and place the inner package containing the four 1" × 2" collagen sponges in the sterile field. Open and place two of the four 5mL syringes/needles into the sterile field.

2

Using one of the two remaining 5mL syringes/needles, withdraw 3.2mL of sterile water for injection.

3

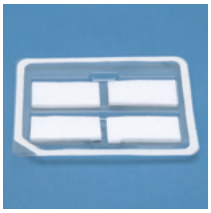
Reconstitute one vial of the rhBMP-2 with 3.2mL of sterile water.

4

Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing. Using a second 5mL syringe/needle, repeat steps 2 and 3 with the remaining vial of sterile water and vial of rhBMP-2.

In sterile field

5

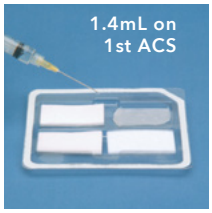


Open the inner ACS package leaving all collagen sponges in the plastic tray.

6

In the sterile field use the 5mL syringe/needle to withdraw 1.4mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

7



Uniformly distribute 1.4mL of reconstituted rhBMP-2 on one of the 1" × 2" collagen sponges.

8

Using the same 5mL syringe/needle, repeat steps 6 and 7 for the second 1" × 2" collagen sponge.

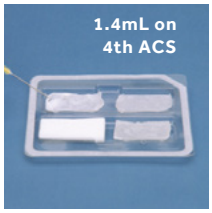
9

In the sterile field use the second 5mL syringe/needle to withdraw 1.4mL of reconstituted rhBMP-2 from the second vial held by the person in the non-sterile field.

10

Uniformly distribute 1.4 mL of reconstituted rhBMP-2 on the third 1" × 2" collagen sponge.

11



Using the second 5mL syringe/needle, repeat steps 9 and 10 for the fourth 1" × 2" collagen sponge.

Allow wetted collagen sponges to stand for a minimum of 15 minutes. Use within 2 hours. DO NOT use irrigation or suction near implanted device. Note: During handling avoid excessive squeezing of the wetted sponge.

Product Ordering Information

Pivox™ Spinal System Instruments SPS02793

Part Number	Description	Qty
2140010	All-In-One Inserter	1
2140020	All-In-One Inserter Shaft	1
2140011	Screw Guide, Small	1
2140012	Screw Guide, Large	1
2161000	Interbody Inserter	1
2161001	Interbody Inserter Threaded Shaft	1
2141000	Plate inserter	1
2151140	OLIF Slaphamer	1
2150100	OLIF Screwdriver	2
9339082	Quick-Connect Ratcheting Silicone Handle	2
2151130	Straight Awl - Bevel Tip	1
2162000	Interbody Remover	1
2143001	Plate Trial, Small	1
2143002	Plate Trial, Large	1
2163000	Interbody Trial Inserter	3

Pivox™ 20mm Interbody Trials (6 degrees) SPS02794

Part Number	Description	Qty
2171145	Trial, 6 degrees, 8×45	1
2171155	Trial, 6 degrees, 8×55	1
2171245	Trial, 6 degrees, 10×45	1
2171255	Trial, 6 degrees, 10×55	1
2171345	Trial, 6 degrees, 12×45	1
2171355	Trial, 6 degrees, 12×55	1
2171445	Trial, 6 degrees, 14×45	1
2171455	Trial, 6 degrees, 14×55	1
2171545	Trial, 6 degrees, 16×45	1
2171555	Trial, 6 degrees, 16×55	1

Pivox™ 20mm Interbody Trials (12 and 18 degrees) SPS02795

Part Number	Description	Qty
2172245	Trial, 12 degrees, 10×45	1
2172255	Trial, 12 degrees, 10×55	1
2172345	Trial, 12 degrees, 12×45	1
2172355	Trial, 12 degrees, 12×55	1
2172445	Trial, 12 degrees, 14×45	1
2172455	Trial, 12 degrees, 14×55	1
2172545	Trial, 12 degrees, 16×45	1
2172555	Trial, 12 degrees, 16×55	1
2172645	Trial, 12 degrees, 18×45	1
2172655	Trial, 12 degrees, 18×55	1
2173345	Trial, 18 degrees, 12×45	1
2173355	Trial, 18 degrees, 12×55	1
2173445	Trial, 18 degrees, 14×45	1
2173455	Trial, 18 degrees, 14×55	1
2173545	Trial, 18 degrees, 16×45	1
2173555	Trial, 18 degrees, 16×55	1
2173645	Trial, 18 degrees, 18×45	1
2173655	Trial, 18 degrees, 18×55	1

Pivox™ 20mm Interbody (6 Degrees) SPS02799

Part Number	Description	Qty
2111140	Interbody, 20mm, 6 Degree, 8mm × 40mm	1
2111145	Interbody, 20mm, 6 Degree, 8mm × 45mm	2
2111150	Interbody, 20mm, 6 Degree, 8mm × 50mm	2
2111155	Interbody, 20mm, 6 Degree, 8mm × 55mm	2
2111160	Interbody, 20mm, 6 Degree, 8mm × 60mm	1
2111240	Interbody, 20mm, 6 Degree, 10mm × 40mm	1
2111245	Interbody, 20mm, 6 Degree, 10mm × 45mm	2
2111250	Interbody, 20mm, 6 Degree, 10mm × 50mm	2
2111255	Interbody, 20mm, 6 Degree, 10mm × 55mm	2
2111260	Interbody, 20mm, 6 Degree, 10mm × 60mm	1
2111340	Interbody, 20mm, 6 Degree, 12mm × 40mm	1
2111345	Interbody, 20mm, 6 Degree, 12mm × 45mm	2
2111350	Interbody, 20mm, 6 Degree, 12mm × 50mm	2
2111355	Interbody, 20mm, 6 Degree, 12mm × 55mm	2
2111360	Interbody, 20mm, 6 Degree, 12mm × 60mm	1
2111440	Interbody, 20mm, 6 Degree, 14mm × 40mm	1
2111445	Interbody, 20mm, 6 Degree, 14mm × 45mm	2
2111450	Interbody, 20mm, 6 Degree, 14mm × 50mm	2
2111455	Interbody, 20mm, 6 Degree, 14mm × 55mm	1
2111460	Interbody, 20mm, 6 Degree, 14mm × 60mm	1
2111540	Interbody, 20mm, 6 Degree, 16mm × 40mm	1
2111545	Interbody, 20mm, 6 Degree, 16mm × 45mm	1
2111550	Interbody, 20mm, 6 Degree, 16mm × 50mm	1
2111555	Interbody, 20mm, 6 Degree, 16mm × 55mm	1
2111560	Interbody, 20mm, 6 Degree, 16mm × 60mm	1

Pivox™ Plate and Screw Set SPS02797

Part Number	Description	Qty
2140120	Screw, 5.5 × 20mm	2
2140125	Screw, 5.5 × 25mm	4
2140130	Screw, 5.5 × 30mm	4
2140135	Screw, 5.5 × 35mm	4
2140140	Screw, 5.5 × 40mm	4
2140145	Screw, 5.5 × 45mm	4
2140150	Screw, 5.5 × 50mm	4
2140001	Small 2-Hole Plate	4
2140002	Large 2-Hole Plate	4

Pivox™ 20mm Interbody (12 and 18 degrees) SPS02800

Part Number	Description	Qty
2112245	Interbody, 12 degrees, 10×45	1
2112250	Interbody, 12 degrees, 10×50	1
2112255	Interbody, 12 degrees, 10×55	1
2112260	Interbody, 12 degrees, 10×60	1
2112345	Interbody, 12 degrees, 12×45	1
2112350	Interbody, 12 degrees, 12×50	1
2112355	Interbody, 12 degrees, 12×55	1
2112360	Interbody, 12 degrees, 12×60	1
2112445	Interbody, 12 degrees, 14×45	1
2112450	Interbody, 12 degrees, 14×50	1
2112455	Interbody, 12 degrees, 14×55	1
2112460	Interbody, 12 degrees, 14×60	1
2112545	Interbody, 12 degrees, 16×45	1
2112550	Interbody, 12 degrees, 16×50	1
2112555	Interbody, 12 degrees, 16×55	1
2112560	Interbody, 12 degrees, 16×60	1
2112645	Interbody, 12 degrees, 18×45	1
2112650	Interbody, 12 degrees, 18×50	1
2112655	Interbody, 12 degrees, 18×55	1
2112660	Interbody, 12 degrees, 18×60	1
2113345	Interbody, 18 degrees, 12×45	1
2113350	Interbody, 18 degrees, 12×50	1
2113355	Interbody, 18 degrees, 12×55	1
2113360	Interbody, 18 degrees, 12×60	1
2113445	Interbody, 18 degrees, 14×45	1
2113450	Interbody, 18 degrees, 14×50	1
2113455	Interbody, 18 degrees, 14×55	1
2113460	Interbody, 18 degrees, 14×60	1
2113545	Interbody, 18 degrees, 16×45	1
2113550	Interbody, 18 degrees, 16×50	1
2113555	Interbody, 18 degrees, 16×55	1
2113645	Interbody, 18 degrees, 18×45	1
2113650	Interbody, 18 degrees, 18×50	1
2113655	Interbody, 18 degrees, 18×55	1

Infuse™ Bone Graft Components

Infuse™ Bone Graft Components	
7510050	Infuse™ Bone Graft XX Small Kit One (1) Vial of Sterile rhBMP-2 (1.05 mg) One (1) Package of 1 Absorbable Collagen Sponge (ACS) ½″ × 2″ (1.25 cm × 5 cm) One (1) Vial of Sterile Water for Injection (10 mL) Two (2) Sterile 3 mL Syringes with 20 G 1½″ Needle
7510100	Infuse™ Bone Graft X Small Kit Two (2) Vials of Sterile rhBMP-2 (1.05 mg) One (1) Package of 1 Absorbable Collagen Sponge (ACS) 1″ × 2″ (2.5 cm × 5 cm) Two (2) Vials of Sterile Water for Injection (10 mL) Four (4) Sterile 3 mL Syringes with 20 G 1½″ Needle
7510200	Infuse™ Bone Graft Small Kit One (1) Vial of Sterile rhBMP-2 (4.2 mg) One (1) Package of 2 Sterile Absorbable Collagen Sponges (ACS) 1″ × 2″ (2.5cm × 5cm) One (1) Vial of Sterile Water for Injection (10 mL) Two (2) Sterile 5 mL Syringes with 20G 1½″ Needle
7510400	Infuse™ Bone Graft Medium Kit Two (2) Vials of Sterile rhBMP-2 (4.2 mg) One (1) Package of 4 Sterile Absorbable Collagen Sponges (ACS) 1″ × 2″ (2.5cm × 5cm) Two (2) Vials of Sterile Water for Injection (10 mL) Four (4) Sterile 5 mL Syringes with 20G 1½″ Needle

Fill Guidelines

Pivox™ Implant		Infuse™ Bone Graft		
Part Numbers	Description (20mm Interbody)	Part Number(s)	Kit Size(s)	Reconstituted rhBMP-2/ACS Volume (cc)
2111140	20mm wide, 6 deg, 8×40	7510100	XS	1.4
2111145	20mm wide, 6 deg, 8×45	7510100	XS	1.4
2111150	20mm wide, 6 deg, 8×50	7510100 + 7510050	XS+XXS	2.1
2111155	20mm wide, 6 deg, 8×55	7510200	S	2.8
2111160	20mm wide, 6 deg, 8×60	7510200	S	2.8
2111240	20mm wide, 6 deg, 10×40	7510100	XS	1.4
2111245	20mm wide, 6 deg, 10×45	7510100 + 7510050	XS+XXS	2.1
2111250	20mm wide, 6 deg, 10×50	7510200	S	2.8
2111255	20mm wide, 6 deg, 10×55	7510200 + 7510050	S+XXS	3.5
2111260	20mm wide, 6 deg, 10×60	7510200 + 7510100	S+XS	4.2
2111340	20mm wide, 6 deg, 12×40	7510100 + 7510050	XS+XXS	2.1
2111345	20mm wide, 6 deg, 12×45	7510200	S	2.8
2111350	20mm wide, 6 deg, 12×50	7510200 + 7510050	S+XXS	3.5
2111355	20mm wide, 6 deg, 12×55	7510200 + 7510100	S+XS	4.2
2111360	20mm wide, 6 deg, 12×60	7510200 + 7510100	S+XS	4.2
2111440	20mm wide, 6 deg, 14×40	7510100 + 7510050	XS+XXS	2.1
2111445	20mm wide, 6 deg, 14×45	7510200 + 7510050	S+XXS	3.5
2111450	20mm wide, 6 deg, 14×50	7510200 + 7510100	S+XS	4.2
2111455	20mm wide, 6 deg, 14×55	7510200 + 7510100	S+XS	4.2
2111460	20mm wide, 6 deg, 14×60	7510400	M	5.6
2111540	20mm wide, 6 deg, 16×40	7510200	S	2.8
2111545	20mm wide, 6 deg, 16×45	7510200 + 7510050	S+XXS	3.5
2111550	20mm wide, 6 deg, 16×50	7510200 + 7510100	S+XS	4.2
2111555	20mm wide, 6 deg, 16×55	7510400	M	5.6
2111560	20mm wide, 6 deg, 16×60	7510400 + 7510050	M+XXS	6.3
2112245	20mm wide, 12 deg, 10×45	7510100 + 7510050	XS+XXS	2.1
2112250	20mm wide, 12 deg, 10×50	7510200	S	2.8
2112255	20mm wide, 12 deg, 10×55	7510200	S	2.8
2112260	20mm wide, 12 deg, 10×60	7510200 + 7510050	S+XXS	3.5
2112345	20mm wide, 12 deg, 12×45	7510100 + 7510050	XS+XXS	2.1
2112350	20mm wide, 12 deg, 12×50	7510200	S	2.8
2112355	20mm wide, 12 deg, 12×55	7510200 + 7510050	S+XXS	3.5
2112360	20mm wide, 12 deg, 12×60	7510200 + 7510100	S+XS	4.2
2112445	20mm wide, 12 deg, 14×45	7510200	S	2.8
2112450	20mm wide, 12 deg, 14×50	7510200 + 7510050	S+XXS	3.5
2112455	20mm wide, 12 deg, 14×55	7510200 + 7510100	S+XS	4.2
2112460	20mm wide, 12 deg, 14×60	7510400	M	5.6
2112545	20mm wide, 12 deg, 16×45	7510200 + 7510050	S+XXS	3.5
2112550	20mm wide, 12 deg, 16×50	7510200 + 7510100	S+XS	4.2

Pivox™ Implant		Infuse™ Bone Graft		
Part Numbers	**Description (20mm Interbody)**	**Part Number(s)**	**Kit Size(s)**	**Reconstituted rhBMP-2/ACS Volume (cc)**
2112555	20mm wide, 12 deg, 16×55	7510400	M	5.6
2112560	20mm wide, 12 deg, 16×60	7510400	M	5.6
2112645	20mm wide, 12 deg, 18×45	7510200 + 7510100	S+XS	4.2
2112650	20mm wide, 12 deg, 18×50	7510200 + 7510100	S+XS	4.2
2112655	20mm wide, 12 deg, 18×55	7510400	M	5.6
2112660	20mm wide, 12 deg, 18×60	7510400 + 7510100	M+XS	7
2113345	20mm wide, 18 deg, 12×45	7510100 + 7510050	XS+XXS	2.1
2113350	20mm wide, 18 deg, 12×50	7510200	S	2.8
2113355	20mm wide, 18 deg, 12×55	7510200 + 7510050	S+XXS	3.5
2113360	20mm wide, 18 deg, 12×60	7510200 + 7510100	S+XS	4.2
2113445	20mm wide, 18 deg, 14×45	7510200	S	2.8
2113450	20mm wide, 18 deg, 14×50	7510200 + 7510050	S+XXS	3.5
2113455	20mm wide, 18 deg, 14×55	7510200 + 7510100	S+XS	4.2
2113460	20mm wide, 18 deg, 14×60	7510200 + 7510100	S+XS	4.2
2113545	20mm wide, 18 deg, 16×45	7510200 + 7510050	S+XXS	3.5
2113550	20mm wide, 18 deg, 16×50	7510200 + 7510100	S+XS	4.2
2113555	20mm wide, 18 deg, 16×55	7510200 + 7510100	S+XS	4.2
2113645	20mm wide, 18 deg, 18×45	7510200 + 7510050	S+XXS	3.5
2113650	20mm wide, 18 deg, 18×50	7510200 + 7510100	S+XS	4.2
2113655	20mm wide, 18 deg, 18×55	7510400	M	5.6

Important Product Information

Important Information on the Pivox™ Oblique Lateral Spinal System

PURPOSE

The Pivox™ oblique lateral spinal system consists of fusion devices (interbody cages) intended to stabilize and promote bone fusion during the normal healing process following surgical correction of disorders of the spine and temporary implants (plates and bone screws) intended for anterior column screw fixation . The product should be implanted only by a physician thoroughly knowledgeable in the implant's material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations.

The Pivox™ oblique lateral spinal system is intended for *in vivo* use, to provide stabilization, to promote bone fusion between two adjacent lumbar vertebral bodies, and is to be used with autogenous bone graft and allograft material to facilitate fusion.

DESCRIPTION

The Pivox™ oblique lateral spinal system consists of interbody cages, plates, and bone screws.

The Pivox™ oblique lateral spinal system interbody cages are available in various widths, heights, and lordosis inserted between two lumbar vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft or allograft and must be used with supplemental fixation. The cages are manufactured from medical grade polyetheretherketone (PEEK) and titanium alloy with tantalum markers and are provided sterile.

The Pivox™ oblique lateral spinal system plates and bone screws are available in a broad range of sizes intended for anterior column screw fixation and stabilization during the normal healing process following surgical correction of disorders of the spine. Fixation is provided by bone screws inserted into the vertebral body of the lumbar spine using an anterior, lateral, or oblique approach. The Pivox™ plate and bone screws are made from titanium alloy and are provided sterile.

Medical grade titanium and medical grade PEEK may be used together. Never use titanium or titanium alloy implants with stainless steel in the same construct.

No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

INDICATIONS

The Pivox™ oblique lateral spinal system interbody cage is designed to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

The Pivox™ oblique lateral spinal system interbody cage is used for patients diagnosed with DDD at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

Certain sizes of the Pivox™ oblique lateral spinal system interbody cage may be used with Infuse™ bone graft in single-level Oblique Lateral Interbody Fusion (OLIF) procedures from L2-L5 in patients diagnosed with DDD, as defined above. Consult the labeling for the Infuse™ bone graft/Medtronic interbody fusion device for information on the specific sizes of Pivox™ oblique lateral spinal system approved for use with Infuse™ bone graft, as well as specific information regarding contraindications, warnings, and precautions associated with Infuse™ bone graft. Infuse™ bone graft is not indicated for use in a Direct Lateral Interbody Fusion (DLIF) surgical approach.

Additionally, the Pivox™ oblique lateral spinal system can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a minimally invasive or open lateral or oblique approach. Infuse™ bone graft is not indicated for use in patients with this condition.

The Pivox™ oblique lateral spinal system plate and bone screw components are indicated as a supplemental fixation device for the lumbosacral levels, anterior below the bifurcation (L5-S1) of the vascular structures, and oblique or lateral above the bifurcation (L1-L5) of the vascular structures. The indications and contraindications of spinal instrumentation systems should be understood by the surgeon. The plate and bone screw components are indicated for use in the temporary stabilization of the anterior lumbar spine during the development of spinal fusions in patients with: 1) degenerative disc disease (DDD) defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies; 2) trauma (including fractures); 3) tumors; 4) deformity defined as kyphosis, lordosis, or scoliosis; 5) pseudarthrosis; and/or 6) failed previous fusions.

When used together, the Pivox™ oblique lateral spinal system components can be used to treat patients with DDD at one or two contiguous levels from
L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis
or retrolisthesis at the involved levels.

CONTRAINDICATIONS

The Pivox™ oblique lateral spinal system is not intended for posterior surgical implantation. Contraindications include, but are not limited to:

- Any case needing to mix metals from different components.
- Any case not described in the indications.
- Any medical or surgical condition which would preclude the benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any patient unwilling to cooperate with postoperative instructions.
- Any case not needing a bone graft and fusion or where fracture healing
  is not required.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.
- Fever or leukocytosis.
- For interbody cage, patients with known hereditary or acquired bone friability or calcification problems.
- For interbody cage, prior fusion at the level to be treated.
- Infection local to the operative site and/or signs of local inflammation.
- Mental illness.
- Morbid obesity.
- Pregnancy.
- Spondylolisthesis unable to be reduced to Grade 1.
- Suspected or documented allergy or intolerance to the component materials.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.

Nota bene: although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- **Severe bone resorption.**
- **Osteomalacia.**
- **Severe osteoporosis.**

Warning: this plate device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

POTENTIAL ADVERSE EVENTS

All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events or complications includes, but is not limited to:

- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Cessation of any potential growth of the operated portion of the spine.
- Change in mental status.
- Development of respiratory problems (e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
- Disassembly, bending, and/or breakage of any or all of the components.
- Disc disruption or degeneration at, above, or below the level of surgery.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, and/or meningitis.
- Damage to the anterior vasculature
- Damage to the peritoneum,
- Early or late loosening of the components and implant migration.
- For interbody cage, cauda equina syndrome.
- For plate device, atelectasis, ileus, gastritis.
- For plate device, dysphagia.
- For plate device, pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain.
- For plate device, bursitis.
- Foreign body (allergic) reaction to the implants, debris, corrosion products including metallosis, staining, tumor formation, and/or autoimmune disease.
- Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, or autograft, or at the bone graft harvest site at, above, and/or below the level of surgery.
- Gastrointestinal complications.
- Graft donor site complications including pain, fracture, infection, or wound healing problems.
- Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or cardiovascular system compromise.
- Herniated nucleus pulposus and/or retropulsed graft.
- Gastrointestinal and/or reproductive system compromise including sterility and loss of consortium.
- Infection.
- Loss of bowel and/or bladder control or other types of urological system compromise.
- Loss of neurologial function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss, and/or spasms.
- Loss of spinal mobility or function and inability to perform the activities of daily living.
- Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, arachnoiditis, and/or muscle loss.
- Non-union (or pseudarthrosis), delayed union, and mal-union.
- Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Subsidence of the interbody cage device into vertebral body(ies).
- Tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of implants or instruments.
- Wound necrosis or wound dehiscence.
- Death.

Note: additional surgery may be necessary to correct some of these potential adverse events.

WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results.

The Pivox™ oblique lateral spinal system plate and bone screw components are temporary implants used for the correction and stabilization of the spine. This system is also intended to augment the development of spinal fusion by providing temporary stabilization. This plate and bone screw system is not intended to be the sole means of spinal support. An interbody cage must be part of the spinal fusion procedure in which the Pivox™ oblique lateral spinal system plate and bone screws are utilized. Use of the plate and bone screw device without interbody fusion may not be successful.

Use of the Pivox™ oblique lateral spinal system interbody cage component in lumbar interbody fusion procedures without autogenous bone graft or allograft may not be successful.

No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly, and/or breakage of the device(s) will eventually occur.

Preoperative and operating procedures including knowledge of surgical techniques, proper selection and placement of the implant, and good reduction are important considerations in the success of surgery. Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous spinal surgery. This system should not be used in any case not described in the indications.

Never reuse an internal fixation device under any circumstances. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Damage of the thread will reduce the stability of the instrumentation. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion.

A device that has been implanted should never be reused, reprocessed, or resterilized under any circumstances. Sterile packaged devices are never to be resterilized. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of these implants and create a risk of contamination of
the implants which could result in patient injury, illness, or death.

Physician note: although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

Based on fatigue testing results, when using the Pivox™ oblique lateral spinal system cage, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of this system.

!USA For US Audiences Only

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

Brief Summary

NOTE: The Perimeter™, Clydesdale™, Divergence-L™, and Pivox™ devices must be used with any supplemental fixation system cleared for use in the lumbar spine.

- In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Reduced ossification of the frontal and parietal bones of the skull was noted infrequently (<3%) in fetuses of rabbit dams immunized to rhBMP-2; however, there was no effect noted in limb bud development. There are no adequate and well controlled studies in human pregnant women. Women of childbearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible orthopedic treatments.
- Women of childbearing potential should be advised that antibody formation to rhBMP-2 or its influence on fetal development has not been completely assessed. In the clinical trial supporting the safety and effectiveness of the Infuse™ bone graft/LT-Cage™ lumbar tapered fusion device, 2/277 (0.7%) patients treated with Infuse™ bone graft component and 1/127 (0.8%) patients treated with autograft bone developed antibodies to rhBMP-2. The effect of maternal antibodies to rhBMP-2, as might be present for several months following device implantation, on the unborn fetus is unknown. Additionally, it is unknown whether fetal expression of BMP-2 could re-expose mothers who were previously antibody positive. Theoretically, re-exposure may elicit a more powerful immune response to BMP-2 with possible adverse consequences for the fetus. However, pregnancy did not lead to an increase in antibodies in the rabbit study. Studies in genetically altered mice indicate that BMP-2 is critical to fetal development and that a lack of BMP-2 activity may cause neonatal death or birth defects. It is not known if anti-BMP-2 antibodies may affect fetal development or the extent to which these antibodies may reduce BMP-2 activity.
- Infuse™ bone graft should not be used immediately prior to or during pregnancy. Women of childbearing potential should be advised not to become pregnant for one year following treatment with the Infuse™ bone graft/Medtronic interbody fusion device.
- The safety and effectiveness of the Infuse™ bone graft/Medtronic interbody fusion device in nursing mothers has not been established. It is not known if BMP-2 is excreted in human milk.

Brief summary of indications, contraindications, and warnings for:

Infuse™ Bone Graft/LT-Cage™ Lumbar Tapered Fusion Device

Infuse™ Bone Graft/Inter Fix™ Threaded Fusion Device

Infuse™ Bone Graft/Inter Fix™ RP Threaded Fusion Device

Infuse™ Bone Graft/Perimeter™ Interbody Fusion Device

Infuse™ Bone Graft/Clydesdale™ Spinal System

Infuse™ Bone Graft/Divergence-L™ Anterior/Oblique Lumbar Fusion System

Infuse™ Bone Graft/Pivox™ Oblique Lateral Spinal System

The Infuse™ bone graft/Medtronic interbody fusion device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1, who may also have up to Grade I spondylolisthesis or Grade 1 retrolisthesis at the involved level.

The following interbody devices and surgical approaches may be used with Infuse™ bone graft:

- The LT-Cage™ lumbar tapered fusion device, implanted via an anterior open or an anterior laparoscopic approach at a single level.
- The Inter Fix™ or Inter Fix™ RP threaded fusion device, implanted via an anterior open approach at a single level.
- The Perimeter™ interbody fusion device implanted via a retroperitoneal anterior lumbar interbody fusion (ALIF) at a single level from L2-S1 or an oblique lateral interbody fusion (OLIF) approach at a single level from L5-S1.
- The Clydesdale™ spinal system, implanted via an OLIF approach at a single level from L2-L5.
- The Divergence-L™ anterior/oblique lumbar fusion system interbody device implanted via an ALIF approach at a single level from L2-S1 or an OLIF approach at a single level from L5-S1.
- The Pivox™ oblique lateral spinal system implanted via an OLIF approach at a single-level from L2-L5.

The Infuse™ bone graft/Medtronic interbody fusion device consists of two components containing three parts – a spinal fusion cage, a recombinant human bone morphogenetic protein, and a carrier/scaffold for the bone morphogenetic protein and resulting bone. **These components must be used as a system for the prescribed indication described above. The bone morphogenetic protein solution component must not be used without the carrier/scaffold component or with a carrier/scaffold component different from the one described in this document. The Infuse™ bone graft component must not be used without the Medtronic interbody fusion device component.**

NOTE: The Inter Fix™ threaded fusion device and the Inter Fix™ RP Threaded Fusion Device may be used together to treat a spinal level. The LT-Cage™ lumbar tapered fusion device, the Perimeter™ interbody fusion device, the Clydesdale™ spinal system, the Divergence-L™ anterior/oblique lumbar fusion system, and the Pivox™ oblique lateral spinal system implants are not to be used in conjunction with either the Inter Fix™ or Inter Fix™ RP implants to treat a spinal level.

The Infuse™ bone graft/Medtronic interbody fusion device is contraindicated for patients with a known hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen, or to other components of the formulation and should not be used in the vicinity of a resected or extant tumor, in patients with any active malignancy, or patients undergoing treatment for a malignancy; in patients who are skeletally immature; in pregnant women; or in patients with an active infection at the operative site or with an allergy to titanium, titanium alloy, or polyetheretherketone (PEEK).

There are no adequate and well-controlled studies in human pregnant women. In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Women of child bearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible orthopedic treatments. The safety and effectiveness of this device has not been established in nursing mothers. Women of child- bearing potential should be advised to not become pregnant for one year following treatment with this device.

Please see the Infuse™ bone graft package insert for the complete list of indications, warnings, precautions, adverse events, clinical results, definition of DDD, and other important medical information. The package insert also matches the sizes of those sized devices that are indicated for use with the appropriate Infuse™ bone graft kit. An electronic version of the package insert may be found at www.medtronic.com/manuals.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience.

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Consult instructions for use at this website
www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat™* Reader with the browser.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

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