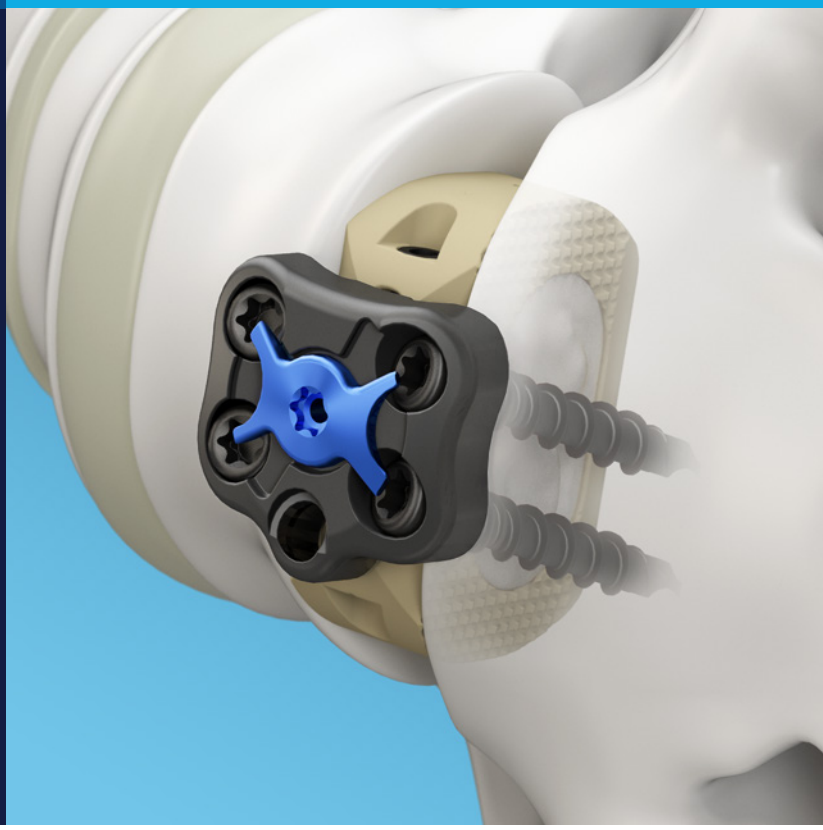
SURGICAL
TECHNIQUE

Divergence-L™

Anterior/Oblique Lumbar Fusion System with Infuse™ Bone Graft



Medtronic

MICHELSON TECHNOLOGY AT WORK

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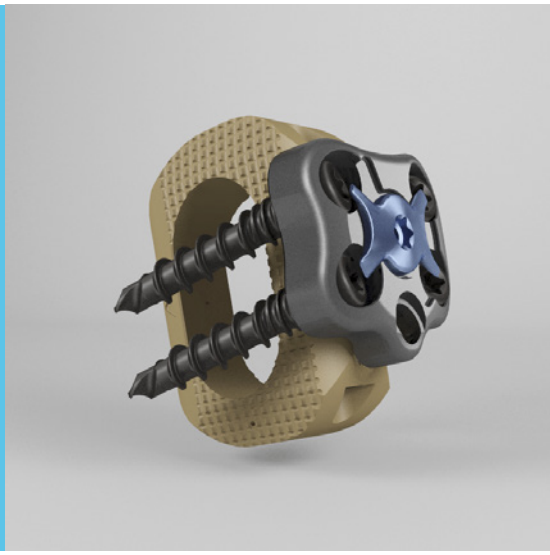
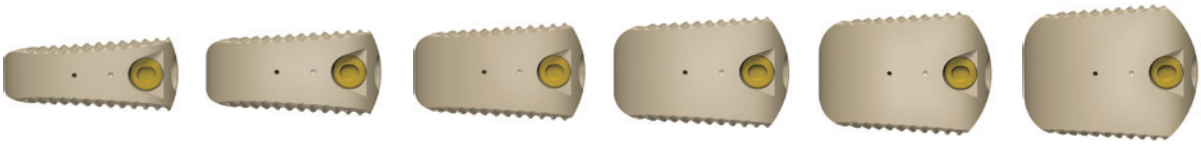


IMPLANT OVERVIEW

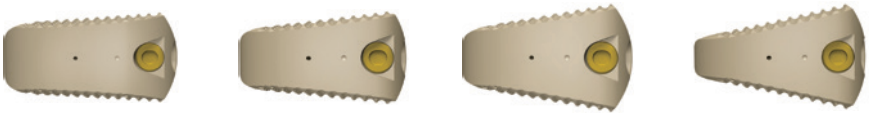
Interbody Spacers

Multiple heights: 10mm, 12mm, 14mm, 16mm, 18mm and 20mm



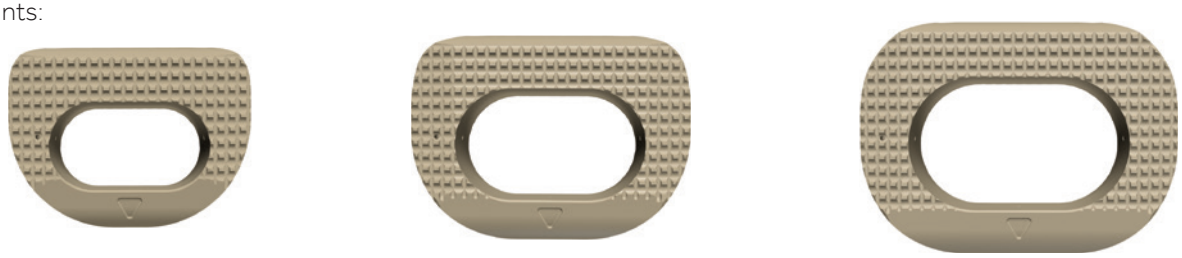
10mm 12mm 14mm 16mm 18mm 20mm

Multiple lordotic options:



6° 12° 18° 24°

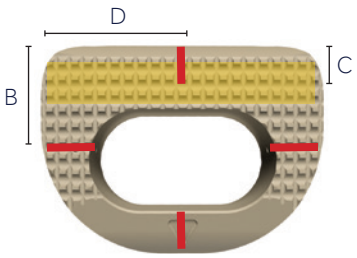
Multiple footprints:



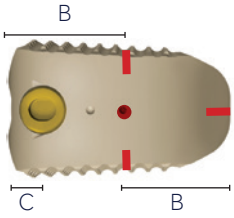
Small—32mm × 25mm Medium—37mm × 29mm Large—42mm × 32mm

X-ray Markers

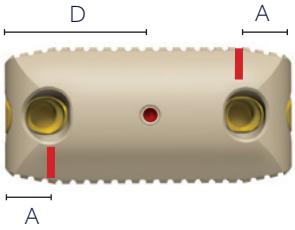
Axial View



Lateral View



AP View



Markers are flush with the endplate surfaces.
Measurements are taken from the center of the marker.

	A Distance from marker to lateral edge	B Distance from marker to anterior edge	C Distance from pivot rod to anterior edge	D Distance from lateral edge to center marker
Small	4mm	12.5mm	4.5mm	16mm
Medium	3.5mm	14.5mm	4.5mm	18.5mm
Large	3mm	16mm	4.5mm	21mm

Plates

Multiple plate sizes: 10mm, 12mm, 14mm, 16mm, 18mm and 20mm

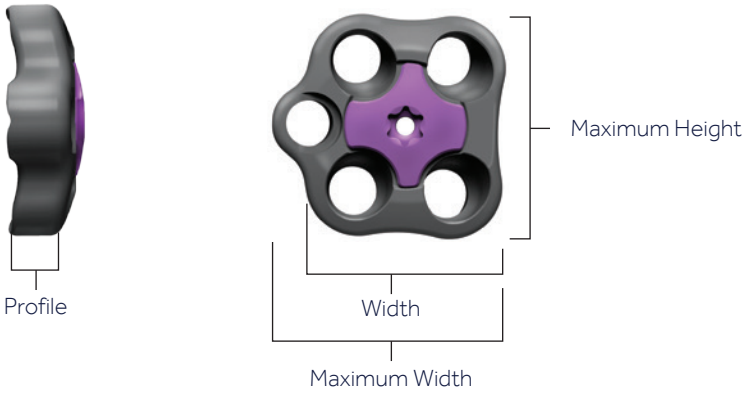
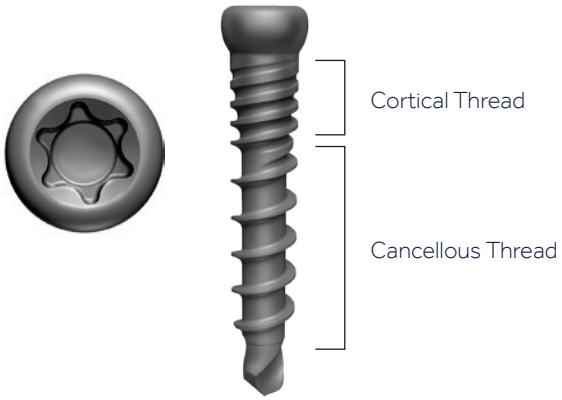


Plate Dimensions

Plate Color	Plate Size	Maximum Height	Screw to Screw	Width	Maximum Width	Plate Profile	Graft Size
	10mm	24mm	11.27mm	22.75mm	27mm	5.35mm	10mm
	12mm	26mm	13.27mm	22.75mm	27mm	5.35mm	12mm
	14mm	28mm	15.27mm	22.75mm	27mm	5.35mm	14mm
	16mm	30mm	17.27mm	22.75mm	27mm	5.35mm	16mm
	18mm	32mm	19.27mm	22.75mm	27mm	5.10mm	18mm
	20mm	34mm	21.27mm	22.75mm	27mm	4.90mm	20mm

Screws

- Lengths: 20mm, 25mm, 30mm, 35mm and 40mm 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



INSTRUMENT SET

Trialing

Plate Trial
10mm, 12mm, 14mm,
16mm, 18mm, 20mm

Trial
Small, Medium, Large
6°, 12°, 18°, 24°
10mm, 12mm, 14mm,
16mm, 18mm, 20mm
Trials to match each implant

Trial Handle
2150330

Plate Trial Handle
2150340

Implantation

O51 Screw Guide
10mm, 12mm, 14mm,
16mm, 18mm, 20mm

O51 Freehand Inserter
2150400

O51 Simple IB Inserter
2150200

ALIF Screw Guide
10mm, 12mm, 14mm,
16mm, 18mm, 20mm

ALIF Freehand Inserter
2160400

ALIF Simple IB Inserter
2160200

ALIF Simple Plate Inserter
2160300

O51 Simple Plate Inserter
2150300

Inserter Handle
2151100

Threaded Shaft
2151200

Slap Hammer
2151140

Implantation continued

Straight Awl, Trocar Tip
2152130

Screwdriver, T25
2150100
Self-retaining

Straight Awl, Bevel Tip
2151130

Screw Depth Sleeve
2151160

Quick Connect Ratcheting Silicone Handle
9339082

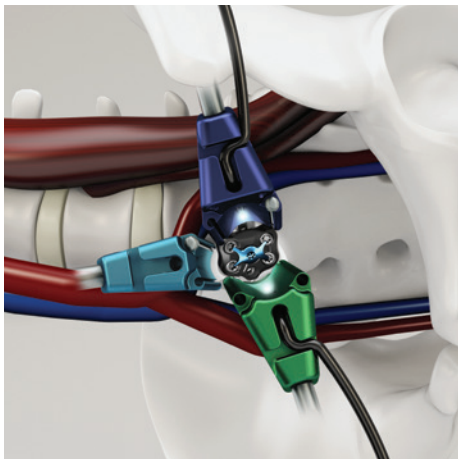
Loading Block
2150600/2160600

Explantation

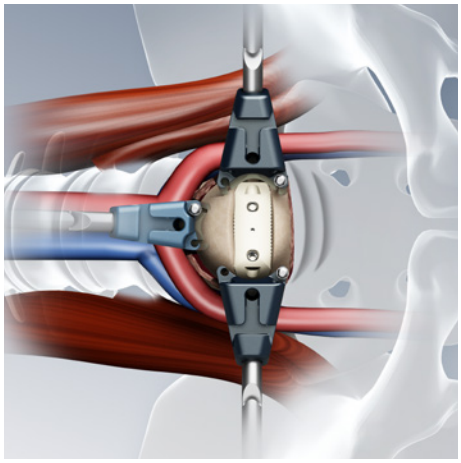
Interbody Remover
2151150

ACCESS

The Divergence-L Anterior/Oblique Lumbar Fusion System can be used via an OLIF51 Procedure or an ALIF Procedure, depending upon the surgeon's preference and anatomical considerations. Refer to the appropriate procedure surgical technique for access instructions.



OLIF51 Procedure



ALIF Procedure

TRIALING

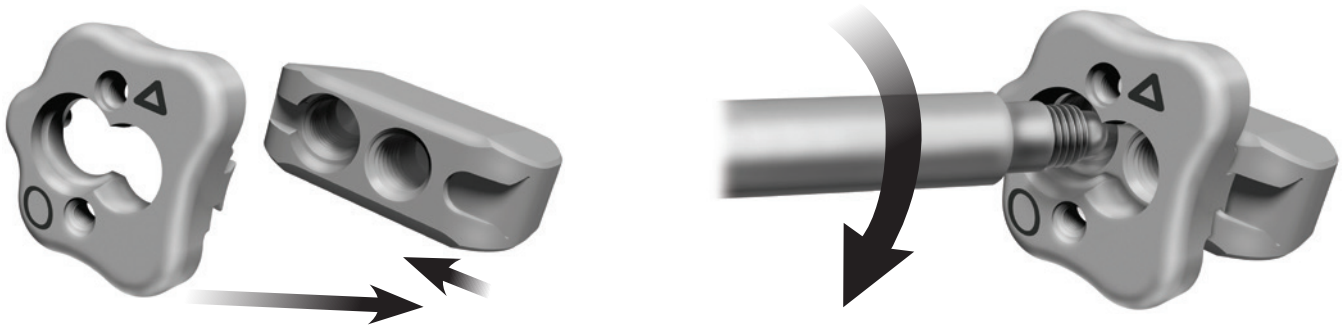
After the disc space is prepared, trial the disc space. Select the appropriate interbody sizes using the Interbody Trials and Plate Trials. There are two options for trialing.

Option 1: Trial Interbody and Plate Together (Page 8)

Option 2: Trial Interbody and Plate Separately (Page 9)

Option 1: Trial Interbody and Plate Together

Assemble the Interbody Trial and Plate Trial simultaneously by sliding the Plate Trial onto the Interbody Trial. Insert the Trial Handle into the appropriate hole marked either "O" for OLIF or "Δ" for ALIF and rotate clockwise to secure. Next, use the Trials to confirm the appropriate-sized interbody, plate height, and footprint **(Figure 1)**.



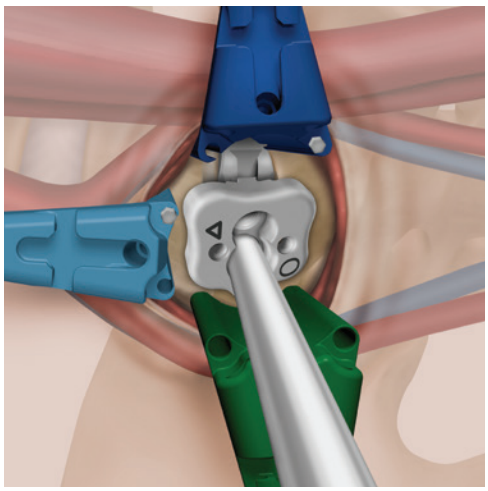


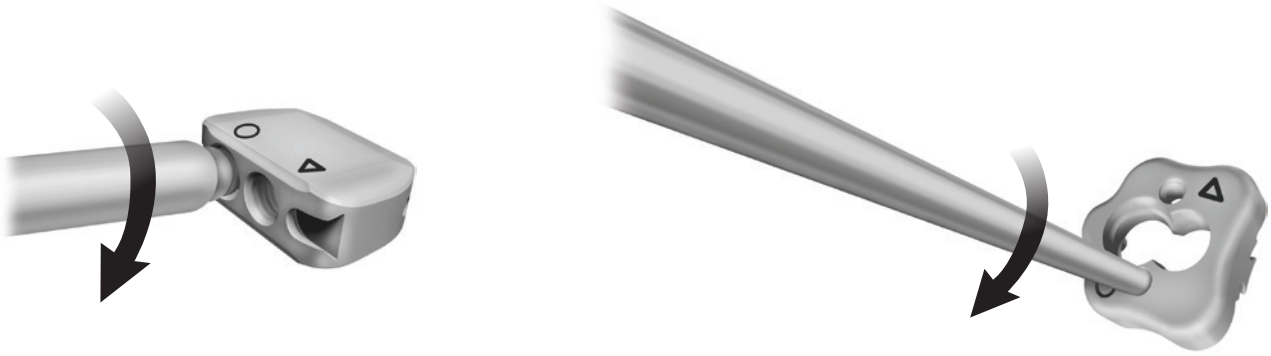
Figure 1

Option 2: Trial Interbody and Plate Separately

Screw the Trial Handle and Interbody Trial together using the appropriate hole marked either "O" for OLIF or "Δ" for ALIF and rotate clockwise to secure. Use the Trial to confirm the appropriate-sized interbody, plate height and footprint **(Figure 2)**. Then assemble the Plate Trial and Plate Trial Handle together using the hole marked either "O" for OLIF or "Δ" for ALIF. Use the Plate Trial to confirm the correct plate size **(Figure 3)**.

Note

For enhanced visualization and distraction of the disc space for plate trialing, the Trial Handle may be removed from the Trial once it is positioned in the disc space.



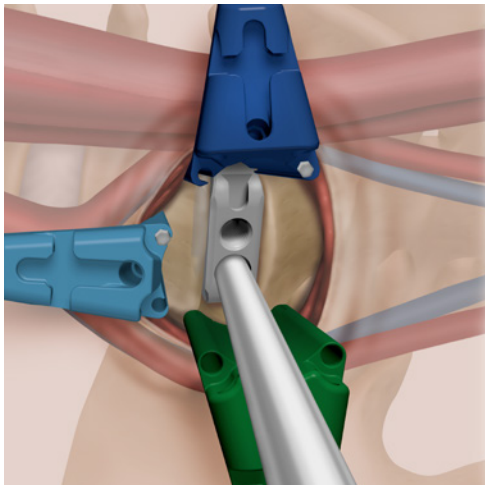


Figure 2

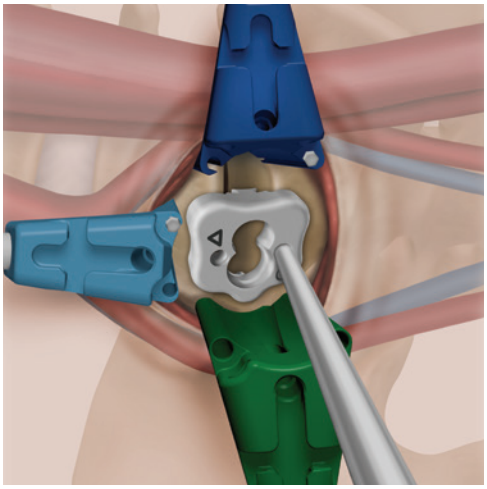


Figure 3

PLACEMENT OF BONE GRAFT

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 Divergence-L implant. Refer to the Fill Guidelines on page 40 for the appropriate kit(s) to be used with the corresponding Divergence-L implant.
- At this time, prepare the appropriate Infuse Bone Graft kits(s). Refer to pages 29-34 for Preparation Instructions.
- Following a minimum of 15 minutes, and no more than 2 hours, use forceps to roll the wetted collagen sponge(s) and place in the implant's central cavity **(Figure 4)**.

If autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft is used instead of Infuse Bone Graft, place the graft in the implant's central cavity.

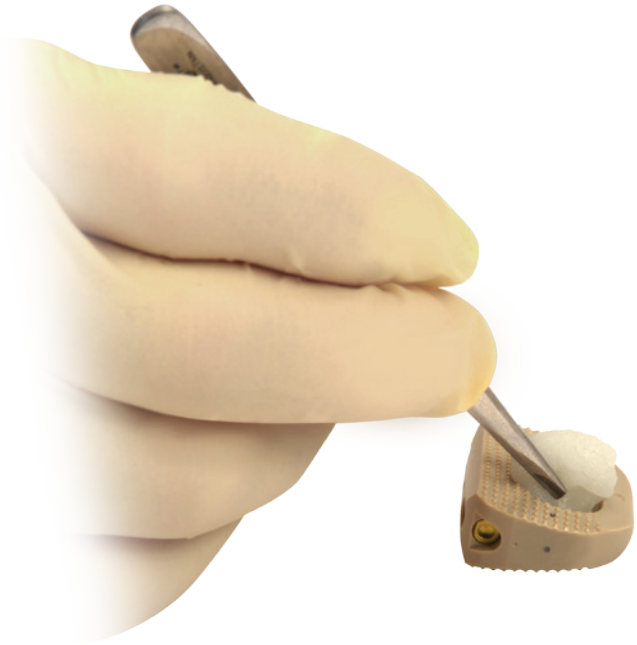


Figure 4

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 4a)**.

Figure 4a

IMPLANTATION

Following the trialing step, there are three options **(Figures 5, 6 and 7)** for interbody insertion. Load the appropriate Plate into the Loading Block **(Figure 8)**. The Loading Block may also be used to measure and load screws into the Self-retaining Screwdriver.

Note
Divergence-L 18-degree and 24-degree cages must be used with supplemental, anterior fixation.

Figure 5

Option 1: Screw Guide Inserter Option, page 11 **(Figure 5)**

Figure 6

Option 2: Freehand Inserter Option, page 16 **(Figure 6)**

Figure 7

Option 3: Simple Interbody Inserter and Simple Plate Inserter Option, page 21 **(Figure 7)**

Loading Block

Figure 8

Option 1: Screw Guide Inserter Option

To assemble the Inserter, take the Inserter Handle and attach the appropriate Screw Guide by aligning the notch on the Inserter Handle. Then turn the knob on the Inserter Handle clockwise to tighten the Screw Guide to the Inserter Handle **(Figure 9)**. Next load the Plate onto the Screw Guide from the Loading Block **(Figure 10)**.

Note
The Screw Guides are labeled to match the corresponding Plate sizes.

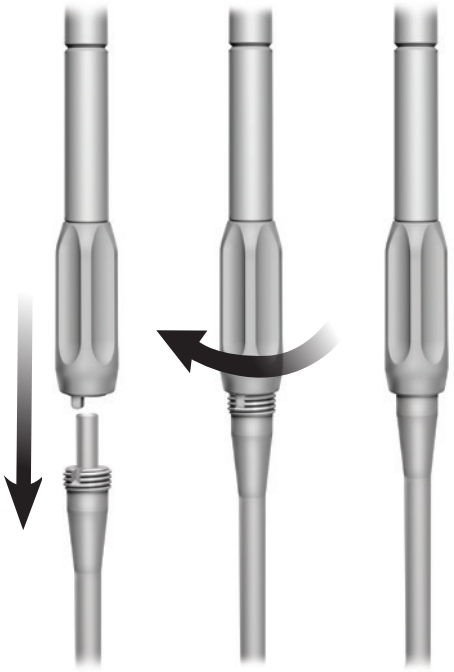


Figure 9

Loading Block

Figure 10

Once the Plate is attached, insert the Threaded Shaft through the end of the Inserter Handle. Turn the Threaded Shaft clockwise to engage past the capture threads, and allow the Threaded Shaft to fall into place. To attach the Interbody, turn the knob at the end of the Inserter Handle to thread the Threaded Shaft into the Interbody **(Figure 11)**.

Note
For ease of assembly, hold the Inserter vertically with the Interbody on the table to best thread the Threaded Shaft into the implant.

Note
To ensure correct assembly of the OLIF Inserter the "O" on the top of the O51 Screw Guide, O51 Plate and Interbody should align (**Figure 12**).

To ensure correct assembly of the ALIF Inserter the "Δ" on the top of the ALIF Screw Guide, ALIF Plate and Interbody should align (**Figure 13**).

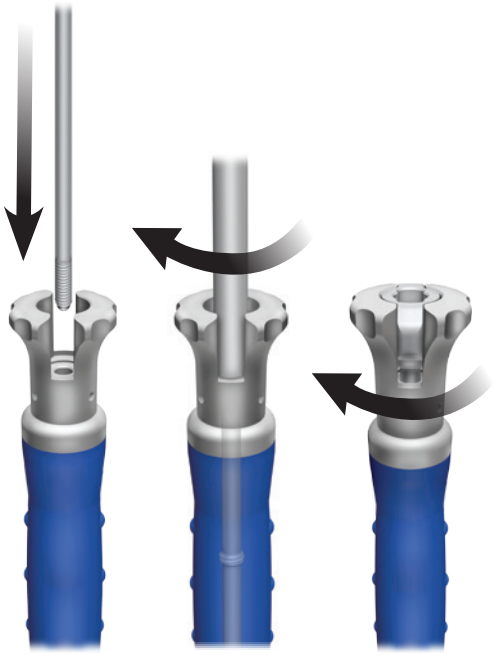


Figure 11

Figure 12

Figure 13

Final Assembly

With the Plate and the Interbody attached, insert the Interbody into the disc space **(Figure 14)**.

Note

Once the Interbody is positioned, turn the Inserter Handle knob one-quarter turn to allow the Plate to rotate ±10 degrees in the sagittal plane (**Figure 15**). The Inserter Handle knob can be retightened once the Plate is positioned.

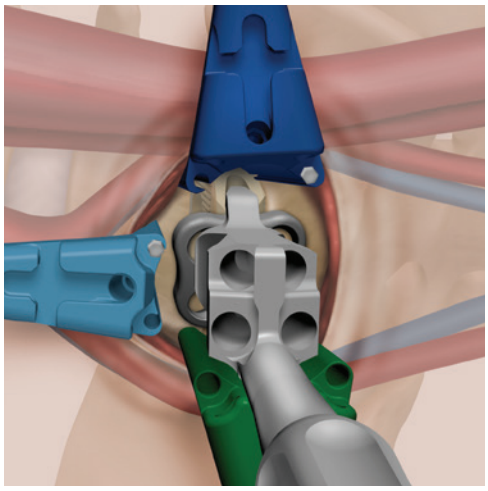


Figure 14

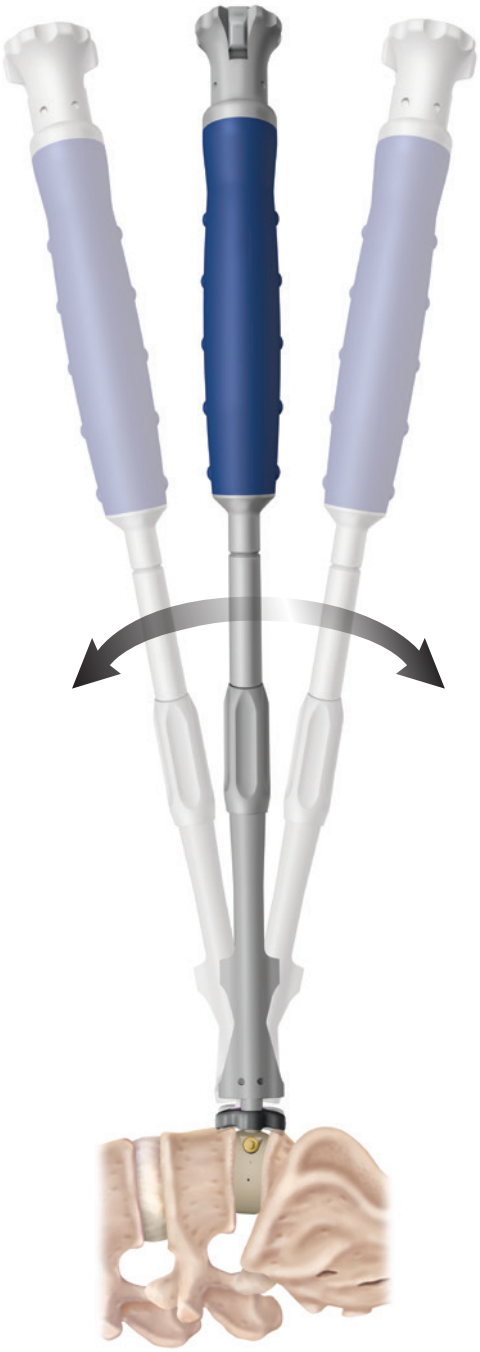


Figure 15

Once the Interbody and Plate are positioned, insert the Awl through the Screw Guide and make a pilot hole for the Screw **(Figure 16)**. Select the appropriate screw lengths and load the Screws into the Loading Block **(Figure 17)**. The Screws are inserted using the T25 Screwdriver **(Figure 18)**.

Note
The T25 Screwdriver will retain the screws. Screws are intended for single use.

Note
Use the Screw Sleeve to limit over-tightening of the Screws. The Screws may require additional tightening to fully seat them once the Screw Sleeve bottoms out.

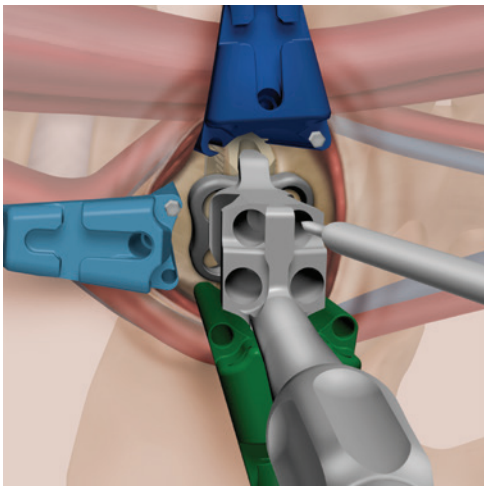


Figure 16

Loading Block

Figure 17

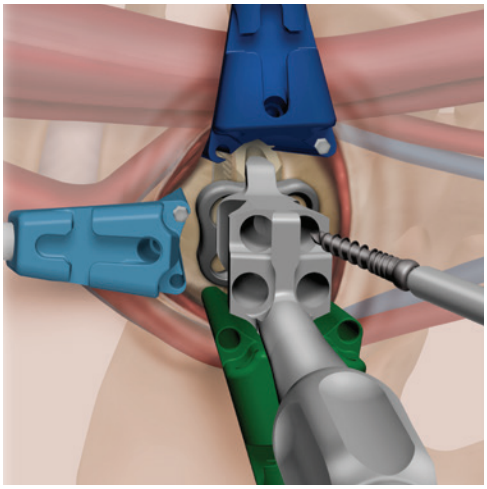


Figure 18

To remove the Inserter, turn the knob at the end of the Inserter Handle until the Threaded Shaft can be removed. Remove the Threaded Shaft from the Inserter Handle then pull back on the Inserter Handle to release it from the Plate **(Figure 19)**.

Use the T25 Screwdriver to ensure that all of the Screws are fully tightened. A clockwise method of Screw tightening is recommended. Turn each Screw one half turn only, one at a time and make several tightening sequences **(Figure 20)**. To engage the locking Plate, insert the T25 Screwdriver into the center of the Plate and turn clockwise until it locks **(Figure 21)**.

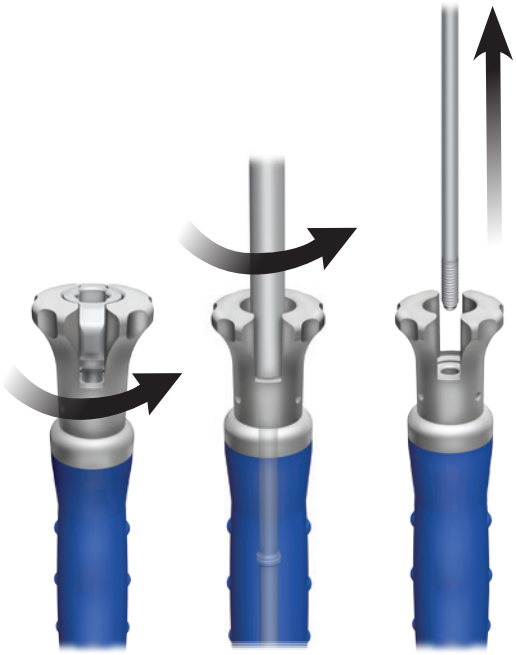


Figure 19

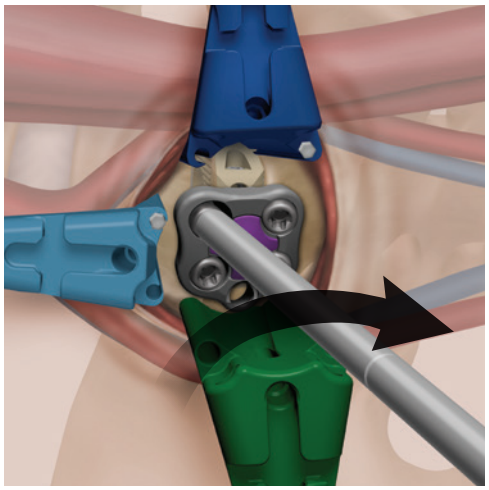


Figure 20

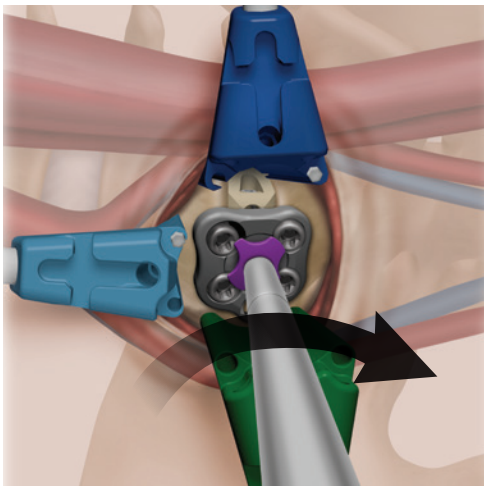


Figure 21

Option 2:
Freehand Inserter Option

To assemble the Inserter, take the Inserter Handle and attach the appropriate Freehand Inserter by aligning the notch on the Inserter Handle **(Figure 22)**. Then turn the knob on the Inserter Handle clockwise to tighten the Freehand Inserter to the Inserter Handle. Next load the Plate onto the Freehand Inserter from the Loading Block **(Figure 23)**.

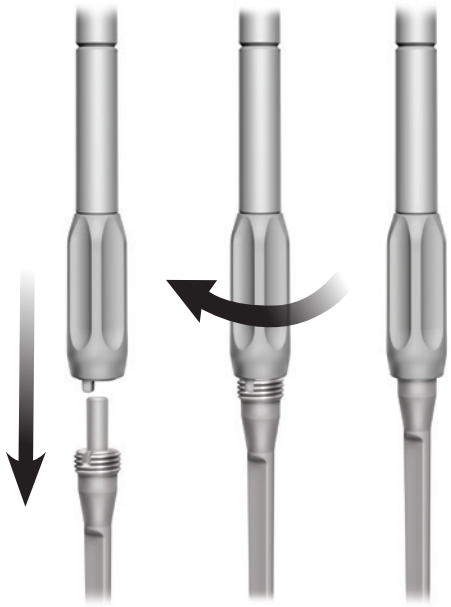


Figure 22

Figure 23

Once the Plate is attached, insert the Threaded Shaft through the end of the Inserter Handle. Turn the Threaded Shaft clockwise to engage past the capture threads, and allow the Threaded Shaft to fall into place. To attach the Interbody turn the knob at the end of the Inserter Handle to thread the Threaded Shaft into the Interbody **(Figure 24)**.

Note
For ease of assembly, hold the Inserter vertically with the Interbody on the table to best thread the Threaded Shaft into the implant.

Note
To ensure correct assembly of the OLIF Inserter the "O" on the top of the O51 Freehand Inserter, O51 Plate and Interbody should align (**Figure 25**).

To ensure correct assembly of the ALIF Inserter the "Δ" on the top of the ALIF Freehand Inserter, ALIF Plate and Interbody should align (**Figure 25**).

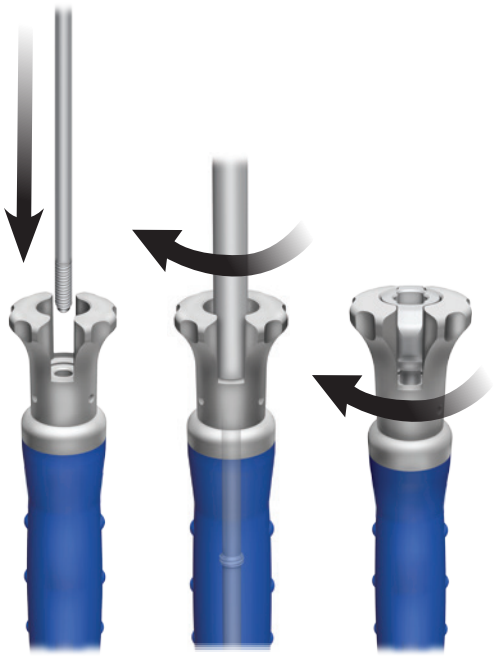


Figure 23

Figure 24

Final Assembly

With the Plate and the Interbody attached insert the Interbody into the disc space **(Figure 26)**.

Note

Once the Interbody is positioned, turn the Inserter Handle knob one-quarter turn to allow the Plate to rotate ±10 degrees in the sagittal plane (**Figure 27**). The Inserter Handle knob can be retightened once the Plate is positioned.

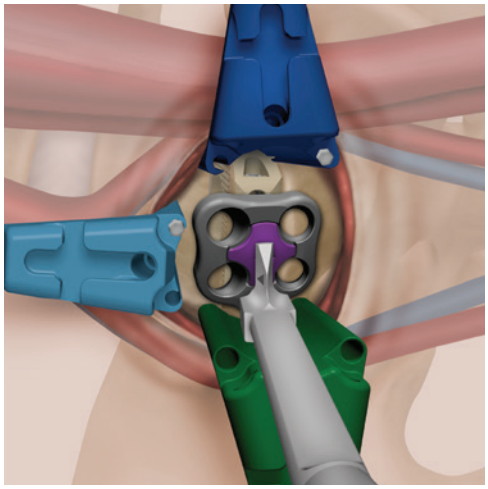


Figure 26

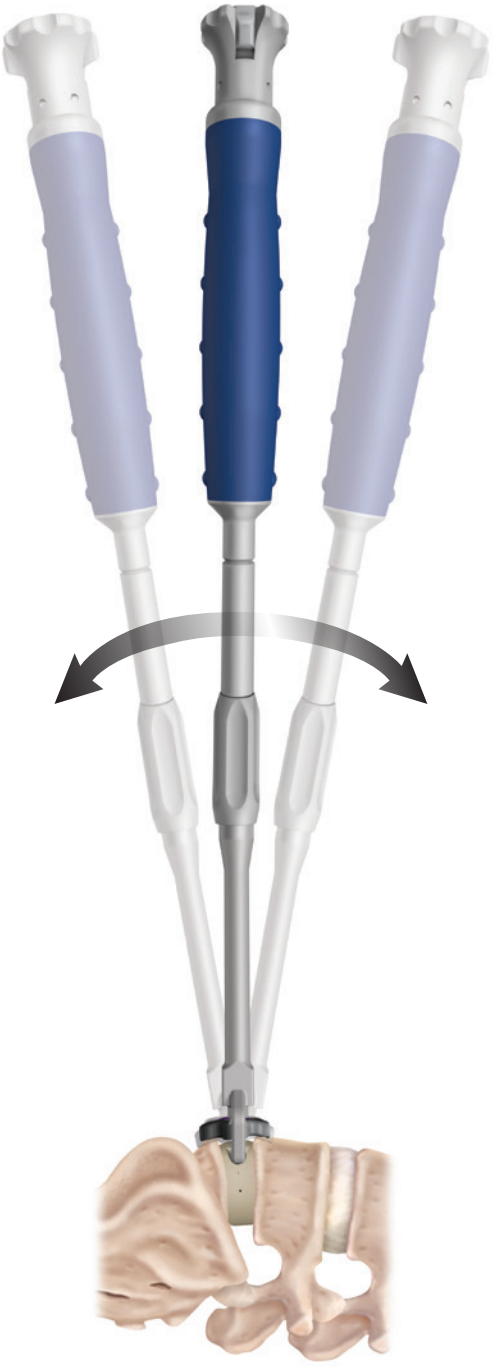


Figure 27

Once the Interbody and Plate are positioned, insert the Awl through the screw holes in the Plate and make a pilot hole for the Screw **(Figure 28)**. Select the appropriate Screw lengths and load them into the Loading Block. The Screws may be inserted using the T25 Screwdriver **(Figure 29)**.

Note
The T25 Screwdriver will retain the Screws.
Screws are intended for single use.

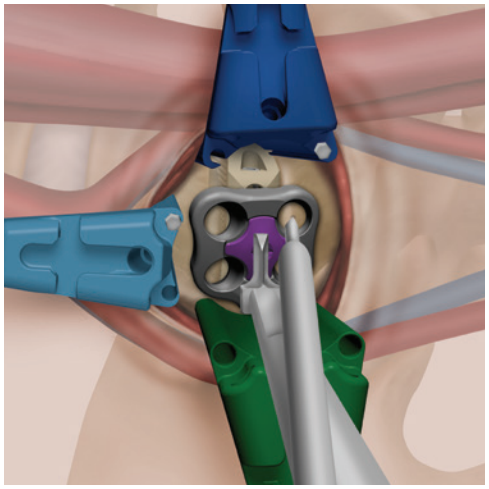


Figure 28

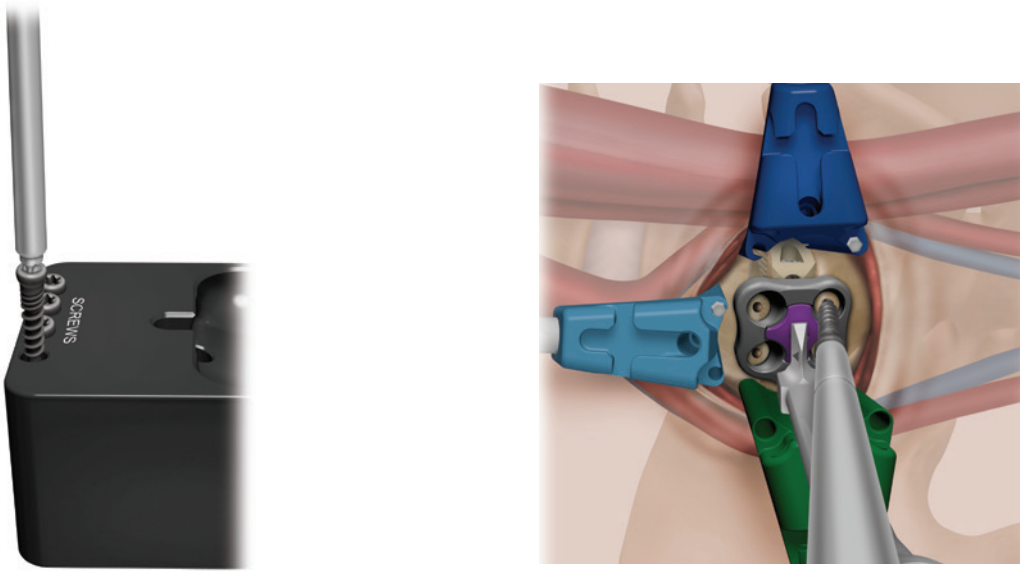


Figure 29

To remove the Inserter, turn the knob at the end of the Inserter Handle until the Threaded Shaft may be removed. Remove the Threaded Shaft from the Inserter Handle then pull back on the Inserter Handle to release it from the Plate **(Figure 30)**.

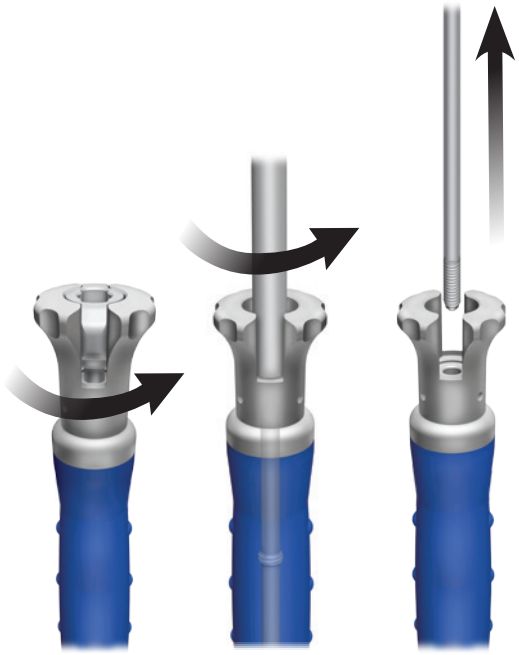


Figure 30

Use the T25 Screwdriver to ensure that all of the Screws are fully tightened. A clockwise method of Screw tightening is recommended. Turn each Screw one-half turn only, one at a time and make several tightening sequences **(Figure 31)**. To engage the locking Plate insert the T25 Screwdriver into the center of the Plate and turn clockwise until it locks **(Figure 32)**.

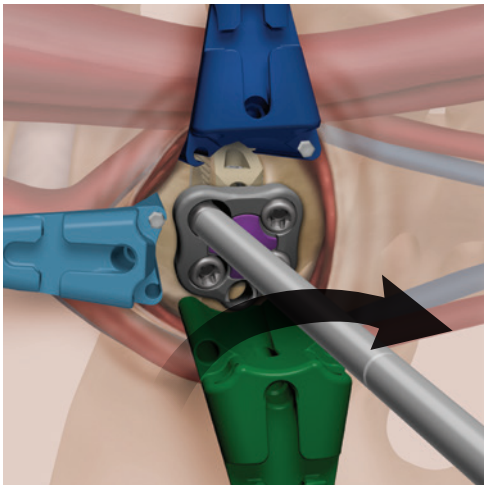


Figure 31

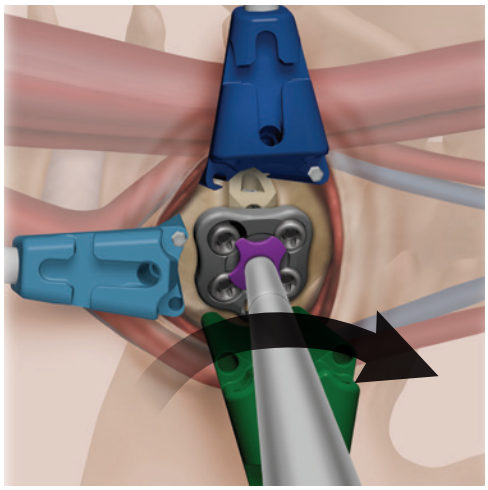


Figure 32

Option 3: Simple Interbody Inserter and Simple Plate Inserter Option

To assemble the Inserter, take the Inserter Handle and attach the appropriate Simple IB Inserter by aligning the notch on the Inserter Handle **(Figure 33)**. Then turn the knob on the Inserter Handle clockwise to tighten the Simple IB Inserter to the Inserter Handle. Insert the Threaded Shaft through the end of the Inserter Handle **(Figure 34)**. Turn the Threaded Shaft clockwise to engage past the capture threads, and allow the Threaded Shaft to fall into place. Thread the Threaded Shaft into the implant.

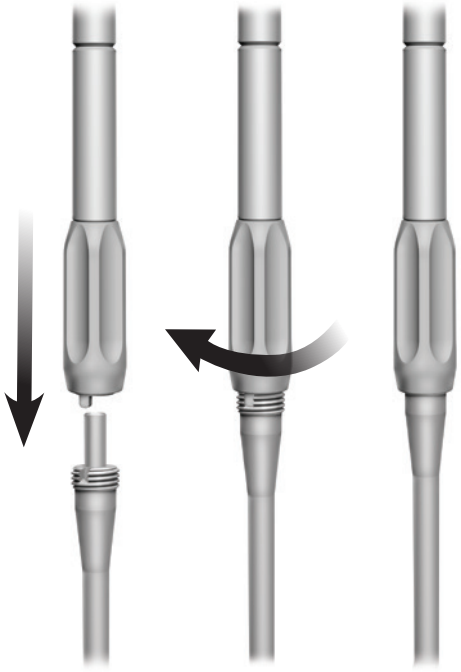


Figure 33

Note
For ease of assembly, hold the Inserter vertically with the Interbody on the table to best thread the Threaded Shaft into the implant.

Note
To ensure correct assembly of the OLIF Inserter, the "O" on the top of the O51 Simple IB Inserter and Interbody should align (**Figure 35**).

To ensure correct assembly of the ALIF Inserter, the "Δ" on the top of the ALIF Simple IB Inserter and Interbody should align (**Figure 35**).

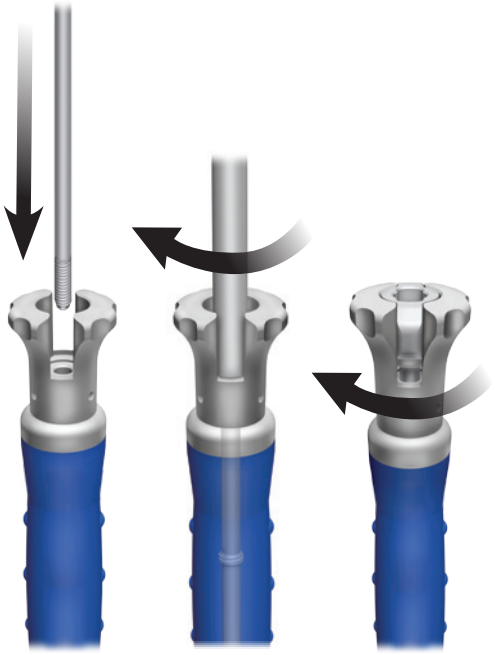


Figure 34

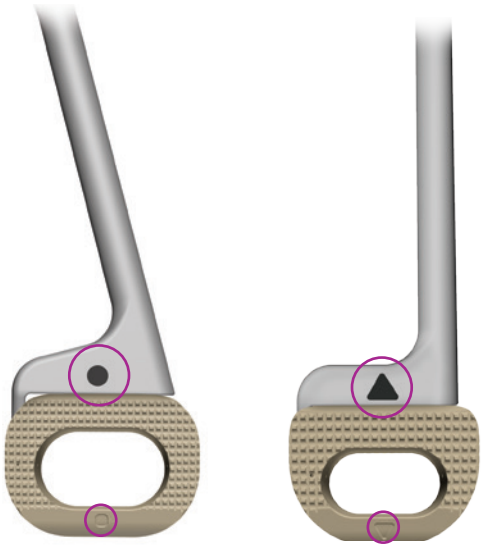


Figure 35

Then insert the Interbody into the disc space **(Figure 36)**. To remove the Inserter, turn the knob at the end of the Inserter Handle until the Inserter Handle may be removed **(Figure 37)**.

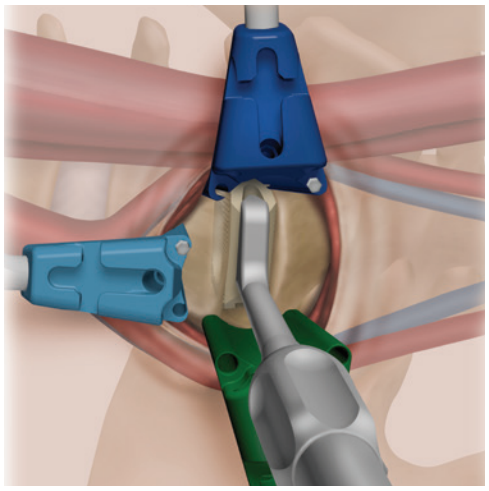


Figure 36

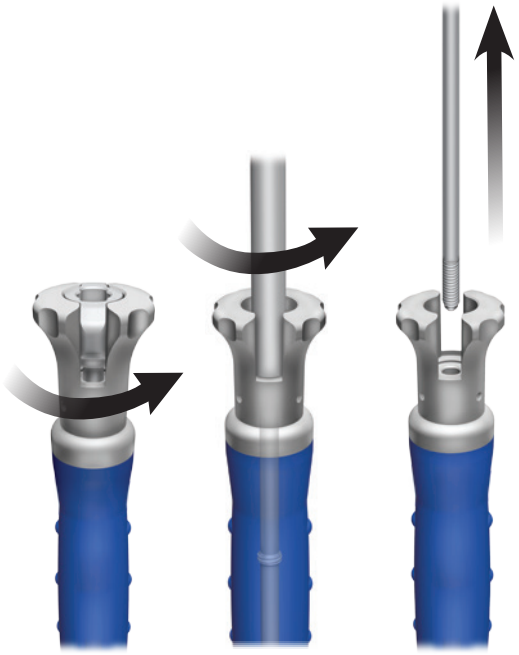
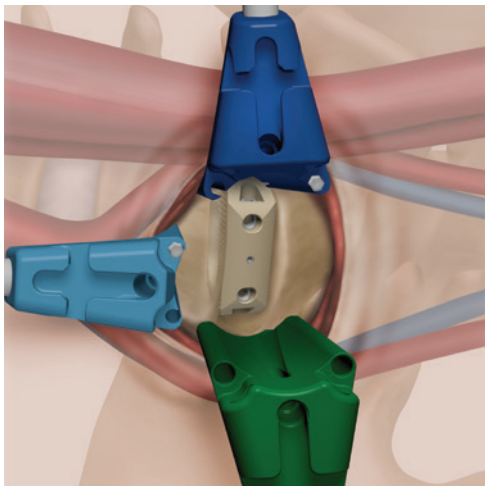


Figure 37



Final Placement

Next, load the Plate onto the Simple Plate Inserter from the Loading Block **(Figure 38)**. Once the Plate is positioned **(Figure 40)**, insert the Awl through the Screw holes in the Plate to make a pilot hole for the Screw **(Figure 41)**.

Note

To ensure correct assembly of the OLIF Inserter, the "O" on the top of the O51 Simple Plate Inserter and Interbody should align **(Figure 39)**.

To ensure correct assembly of the ALIF Inserter, the "Δ" on the top of the ALIF Simple Plate Inserter and Interbody should align **(Figure 39)**.

Figure 38

Figure 39

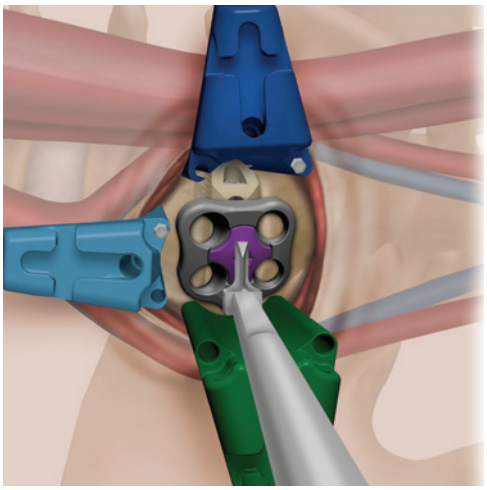


Figure 40

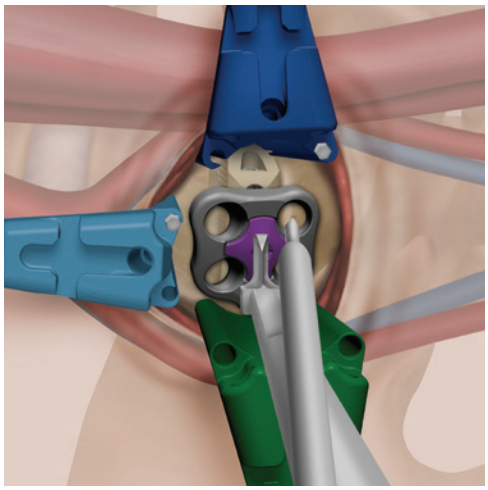


Figure 41

Select the appropriate Screw lengths and load them into the Loading Block **(Figure 42)**. The Screws may be inserted using the T25 Screwdriver **(Figure 43)**.

To remove the Inserter, pull back on the Simple Plate Inserter to release it from the Plate.

Use the T25 Screwdriver to ensure that all of the Screws are fully tightened. A clockwise method of Screw tightening is recommended. Turn each Screw one-half turn only, one at a time and make several tightening sequences **(Figure 44)**. To engage the locking Plate insert the T25 Screwdriver into the center of the Plate and turn clockwise until it locks **(Figure 45)**.

Note
The T25 Screwdriver will retain the Screw. Screws are intended for single use.

Figure 42

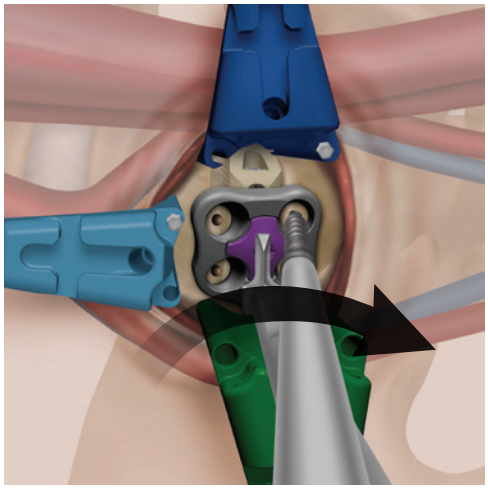


Figure 43

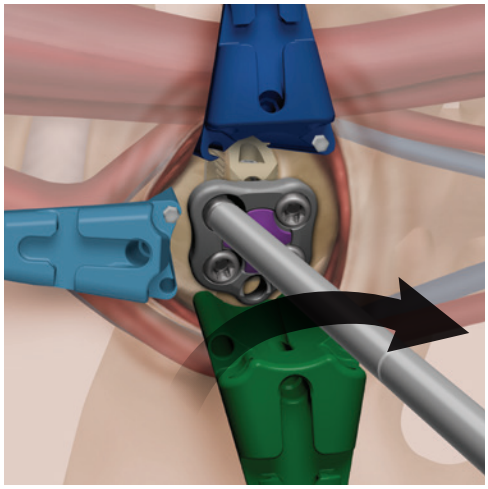


Figure 44

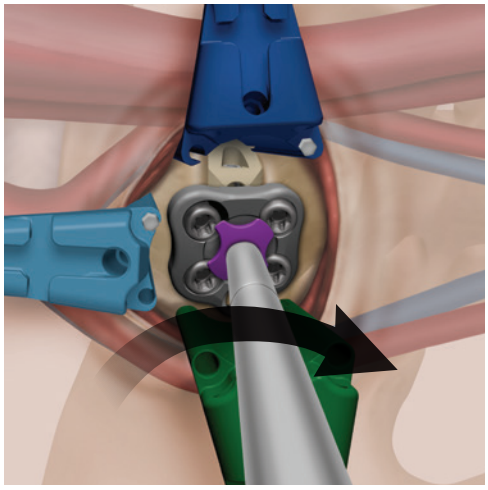
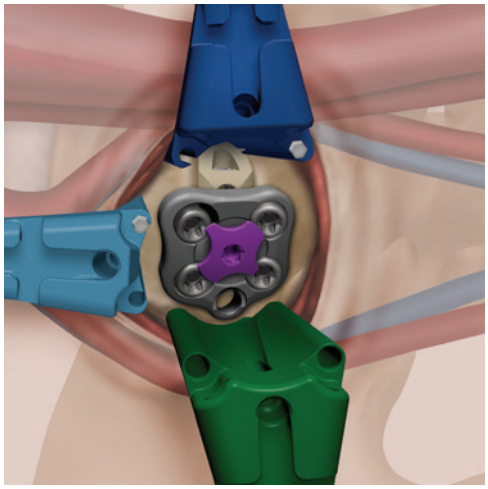
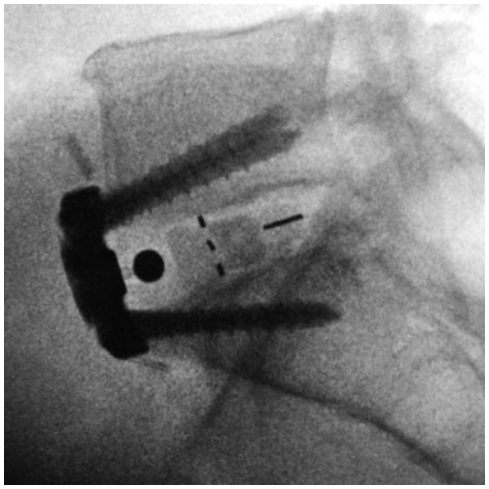


Figure 45

FINAL PLACEMENT

Note
It is recommended to use RDX²™ Membrane Allograft after final placement of implants to reduce scar formation and inflammation.

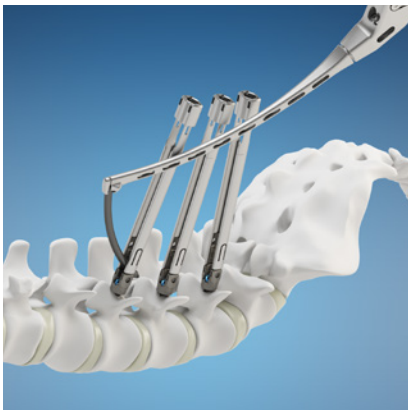




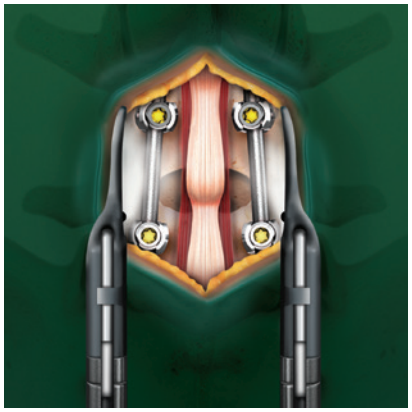
SUPPLEMENTAL FIXATION

Supplemental instrumentation must be used if only the Interbody is used. The interbody fusion device may be used with any Medtronic posterior or anterior fixation system which has been cleared for use in the lumbar spine. If the Divergence-L 18-degree or 24-degree options are used, the supplemental fixation must include anterior fixation. Supplemental instrumentation must be used when the Divergence-L Interbody is used in the treatment of degenerative disc disease (DDD) of the lumbar spine. When the Divergence-L Interbody is used to provide anterior column support in patients diagnosed with deformity it must be used as an adjunct to pedical screw fixation. Refer to the appropriate surgical technique for supplemental instrumentation instructions. Some examples of these fixation systems are shown below **(Figure 46)**.

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



CD Horizon Solera® Voyager™ Spinal System



CD Horizon Solera Screws

Figure 46

EXPLANTATION

Insert the T25 Screwdriver into the locking Plate at the center of the O51 Plate and turn counterclockwise until it unlocks **(Figure 48)**. Use the T25 Screwdriver to remove the Screws and O51 Plate **(Figure 49)**. Next clamp the Interbody Remover to both sides of the Interbody and remove from the disc space **(Figure 50)**.

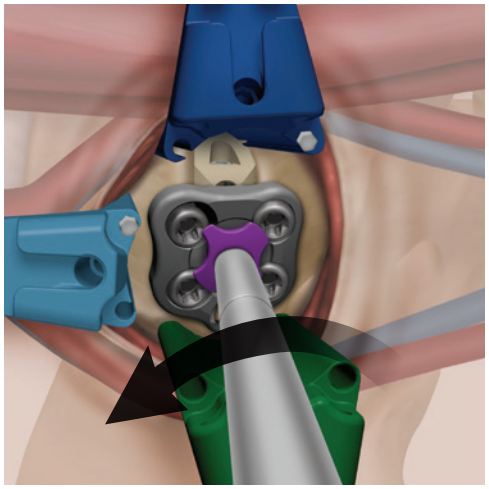


Figure 48

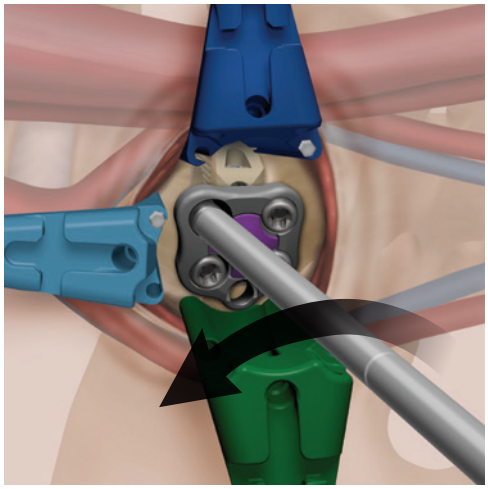


Figure 49

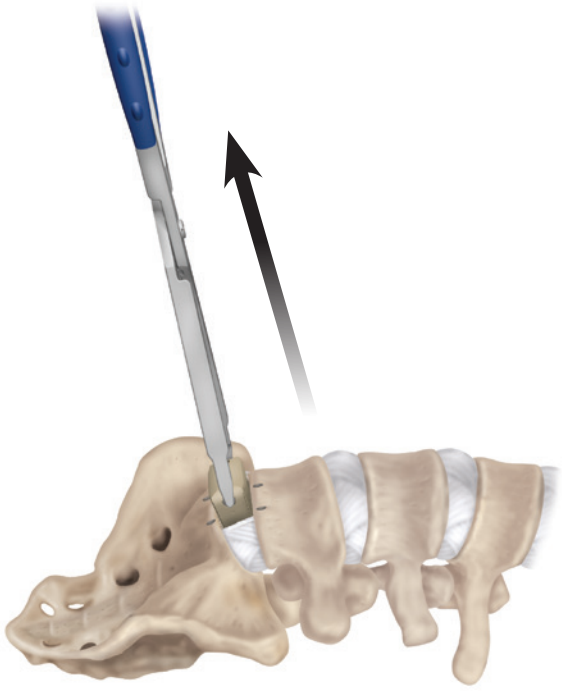


Figure 50

PREPARATION INSTRUCTIONS
FOR INFUSE BONE GRAFT COMPONENT

7510050 XX Small Kit (0.7cc)

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.

(1) 5mL vial

(1) 1.05mg vial

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

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

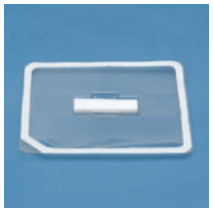
Reconstitute the rhBMP-2 with 0.9mL of sterile water.

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

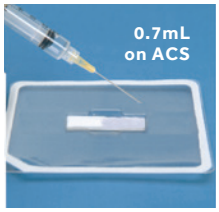


Open the inner ACS package leaving the collagen sponge in the plastic tray.

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)

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.

(2) 5mL vials

(2) 1.05mg vials

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

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

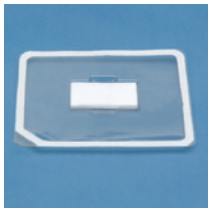
Reconstitute one vial of the rhBMP-2 with 0.9mL of sterile water.

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

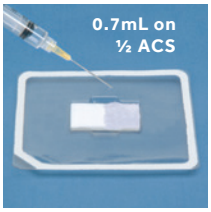


Open the inner ACS package leaving the collagen sponge in the plastic tray.

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

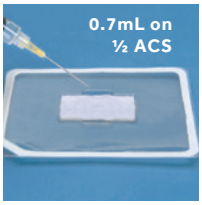


Uniformly distribute 0.7mL of reconstituted rhBMP-2 on half of the 1" × 2" collagen sponge.

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)

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.

(1) 5mL vial

(1) 4.2mg vial

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

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

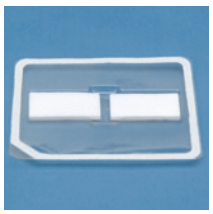
Reconstitute the rhBMP-2 with 3.2mL of sterile water.

4

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

IN STERILE FIELD

5

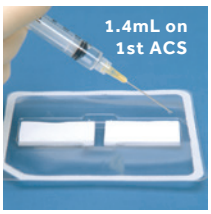


Open the inner ACS package leaving all collagen sponges in the plastic tray.

6

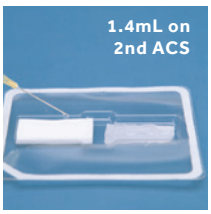
In the sterile field use the 5mL syringe/needle to withdraw 1.4mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

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) 5mL vials

(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

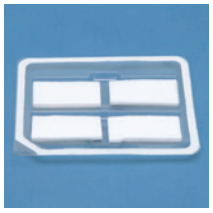
Reconstitute one vial of the rhBMP-2 with 3.2mL of sterile water.

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.

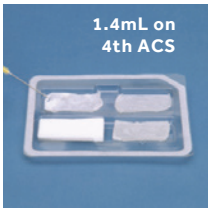
9

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.

7510600 Large Kit (8.0cc)

(1) 10mL vial

(1) 12mg vial

(6) ACS 1" × 2" (2.54cm × 5.08cm) 8.0cc 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 six 1" × 2" collagen sponges in the sterile field. Open and place one of the two 10mL syringes/needles into the sterile field.

2

Using the other 10mL syringe/needle, withdraw 8.4mL of sterile water for injection.

3

Reconstitute the rhBMP-2 with 8.4mL 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 10mL syringe/needle to withdraw 4.0mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

7

Uniformly distribute 4.0mL of reconstituted rhBMP-2 on three of the 1" × 2" collagen sponges.

8

Using the same 10mL syringe/needle, repeat steps 6 and 7 for the remaining 1" × 2" collagen sponges.

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.

7510800 Large II Kit (8.0cc)

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.

(1) 10mL vial

(1) 12mg vial

(1) ACS 3" × 4" (7.62cm × 10.16cm) 8.0cc graft volume

IN NON-STERILE FIELD

1

Observing proper sterile technique, open the outer ACS package and place the inner package containing the 3" × 4" collagen sponge in the sterile field. Open and place one of the two 10mL syringes/needles into the sterile field.

2

Using the other 10mL syringe/needle, withdraw 8.4mL of sterile water for injection.

3

Reconstitute the rhBMP-2 with 8.4mL of sterile water.

4

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

IN STERILE FIELD

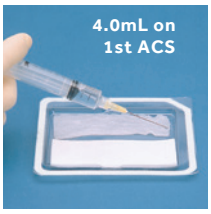
5

Open the inner ACS package. Using sterile scissors, cut the 3" × 4" collagen sponge into two 1 1/2" × 4" strips. Return the cut collagen sponges to the plastic tray.

6

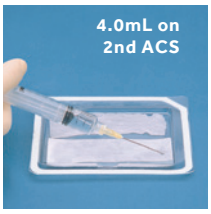
In the sterile field use the 10mL syringe/needle to withdraw 4.0mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

7



Uniformly distribute 4.0mL of reconstituted rhBMP-2 on one of the 1 1/2" × 4" collagen sponges.

8



Using the 10mL syringe/needle, repeat steps 6 and 7 for the remaining 1 1/2" × 4" 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

Instrument Set

Part #	Description	Quantity
2151100	Inserter Handle	2
2151200	Threaded Shaft	2
2150100	Screwdriver, T25	2
2152130	Straight Awl – Trocar Tip	1
2151130	Straight Awl – Bevel Tip	1
2151140	Slaphammer	1
9339082	Quick-connect Ratcheting Silicone Handle	2
2151150	Interbody Remover	1
2150340	Plate Trial Handle	2
2151160	Screw Sleeve	2
2150310	Plate Trial, 10mm	1
2150312	Plate Trial, 12mm	1
2150314	Plate Trial, 14mm	1
2150316	Plate Trial, 16mm	1
2150318	Plate Trial, 18mm	1
2150320	Plate Trial, 20mm	1
2150330	Trial Handle	2

OLIF51v Instrument Set

Part #	Description	Quantity
2150210	O51 Screw Guide, 10mm	1
2150212	O51 Screw Guide, 12mm	1
2150214	O51 Screw Guide, 14mm	1
2150216	O51 Screw Guide, 16mm	1
2150218	O51 Screw Guide, 18mm	1
2150220	O51 Screw Guide, 20mm	1
2150300	O51 Simple Plate Inserter	1
2150600	O51 Loading Block	1
2150400	O51 Freehand Inserter	1
2150200	O51 Simple IB Inserter	1

ALIF Instrument Set

Part #	Description	Quantity
2160210	ALIF Screw Guide, 10mm	1
2160212	ALIF Screw Guide, 12mm	1
2160214	ALIF Screw Guide, 14mm	1
2160216	ALIF Screw Guide, 16mm	1
2160218	ALIF Screw Guide, 18mm	1
2160220	ALIF Screw Guide, 20mm	1
2160300	ALIF Simple Plate Inserter	1
2160600	ALIF Loading Block	1
2160400	ALIF Freehand Inserter	1
2160200	ALIF Simple IB Inserter	1

Interbody Trials

Part #	Description	Quantity
2156410	Trial, Small, 6 degrees, 10mm	1
2156412	Trial, Small, 6 degrees, 12mm	1
2156414	Trial, Small, 6 degrees, 14mm	1
2156416	Trial, Small, 6 degrees, 16mm	1
2156510	Trial, Medium, 6 degrees, 10mm	1
2156512	Trial, Medium, 6 degrees, 12mm	1
2156514	Trial, Medium, 6 degrees, 14mm	1
2156516	Trial, Medium, 6 degrees, 16mm	1
2156610	Trial, Large, 6 degrees, 10mm	1
2156612	Trial, Large, 6 degrees, 12mm	1
2156614	Trial, Large, 6 degrees, 14mm	1
2156616	Trial, Large, 6 degrees, 16mm	1
2152410	Trial, Small, 12 degrees, 10mm	1
2152412	Trial, Small, 12 degrees, 12mm	1
2152414	Trial, Small, 12 degrees, 14mm	1
2152416	Trial, Small, 12 degrees, 16mm	1
2152510	Trial, Medium, 12 degrees, 10mm	1
2152512	Trial, Medium, 12 degrees, 12mm	1
2152514	Trial, Medium, 12 degrees, 14mm	1
2152516	Trial, Medium, 12 degrees, 16mm	1
2152612	Trial, Large, 12 degrees, 12mm	1
2152614	Trial, Large, 12 degrees, 14mm	1
2152616	Trial, Large, 12 degrees, 16mm	1
2156418	Trial, Small, 6 degrees, 18mm	1
2156420	Trial, Small, 6 degrees, 20mm	1
2156518	Trial, Medium, 6 degrees, 18mm	1
2156520	Trial, Medium, 6 degrees, 20mm	1
2156618	Trial, Large, 6 degrees, 18mm	1
2156620	Trial, Large, 6 degrees, 20mm	1
2152418	Trial, Small, 12 degrees, 18mm	1
2152420	Trial, Small, 12 degrees, 20mm	1
2152518	Trial, Medium, 12 degrees, 18mm	1
2152520	Trial, Medium, 12 degrees, 20mm	1
2152618	Trial, Large, 12 degrees, 18mm	1
2152620	Trial, Large, 12 degrees, 20mm	1

Interbody Trials continued

Part #	Description	Quantity
2158412	Trial, Small, 18 degrees, 12mm	1
2158414	Trial, Small, 18 degrees, 14mm	1
2158416	Trial, Small, 18 degrees, 16mm	1
2158418	Trial, Small, 18 degrees, 18mm	1
2158420	Trial, Small, 18 degrees, 20mm	1
2158514	Trial, Medium, 18 degrees, 14mm	1
2158516	Trial, Medium, 18 degrees, 16mm	1
2158518	Trial, Medium, 18 degrees, 18mm	1
2158520	Trial, Medium, 18 degrees, 20mm	1
2158616	Trial, Large, 18 degrees, 16mm	1
2158618	Trial, Large, 18 degrees, 18mm	1
2158620	Trial, Large, 18 degrees, 20mm	1
2154416	Trial, Small, 24 degrees, 16mm	1
2154418	Trial, Small, 24 degrees, 18mm	1
2154420	Trial, Small, 24 degrees, 20mm	1
2154516	Trial, Medium, 24 degrees, 16mm	1
2154518	Trial, Medium, 24 degrees, 18mm	1
2154520	Trial, Medium, 24 degrees, 20mm	1
2154618	Trial, Large, 24 degrees, 18mm	1
2154620	Trial, Large, 24 degrees, 20mm	1

OLIF51 Plates and Screws Set

Part #	Description	Quantity
2150010	O51 Plate, 10mm	2
2150012	O51 Plate, 12mm	2
2150014	O51 Plate, 14mm	2
2150016	O51 Plate, 16mm	2
2150018	O51 Plate, 18mm	1
2150020	O51 Plate, 20mm	1
2150120	Screws, 20mm	6
2150125	Screws, 25mm	6
2150130	Screws, 30mm	6
2150135	Screws, 35mm	6
2150140	Screws, 40mm	6

ALIF Plates and Screws

Part #	Description	Quantity
2160010	ALIF Plate, 10mm	2
2160012	ALIF Plate, 12mm	2
2160014	ALIF Plate, 14mm	2
2160016	ALIF Plate, 16mm	2
2160018	ALIF Plate, 18mm	1
2160020	ALIF Plate, 20mm	1
2150120	Screws, 20mm	6
2150125	Screws, 25mm	6
2150130	Screws, 30mm	6
2150135	Screws, 35mm	6
2150140	Screws, 40mm	6

Core Interbody Configuration

Part #	Description	Quantity
2151110	Interbody, Small, 6 degrees, 10mm	2
2151112	Interbody, Small, 6 degrees, 12mm	2
2151114	Interbody, Small, 6 degrees, 14mm	2
2151116	Interbody, Small, 6 degrees, 16mm	1
2151210	Interbody, Medium, 6 degrees, 10mm	2
2151212	Interbody, Medium, 6 degrees, 12mm	2
2151214	Interbody, Medium, 6 degrees, 14mm	2
2151216	Interbody, Medium, 6 degrees, 16mm	1
2151310	Interbody, Large, 6 degrees, 10mm	2
2151312	Interbody, Large, 6 degrees, 12mm	2
2151314	Interbody, Large, 6 degrees, 14mm	2
2151316	Interbody, Large, 6 degrees, 16mm	1
2152110	Interbody, Small, 12 degrees, 10mm	2
2152112	Interbody, Small, 12 degrees, 12mm	2
2152114	Interbody, Small, 12 degrees, 14mm	2
2152116	Interbody, Small, 12 degrees, 16mm	1
2152210	Interbody, Medium, 12 degrees, 10mm	2
2152212	Interbody, Medium, 12 degrees, 12mm	2
2152214	Interbody, Medium, 12 degrees, 14mm	2
2152216	Interbody, Medium, 12 degrees, 16mm	1
2152312	Interbody, Large, 12 degrees, 12mm	2
2152314	Interbody, Large, 12 degrees, 14mm	2
2152316	Interbody, Large, 12 degrees, 16mm	1

Additional Interbody Configuration

Part #	Description	Quantity
2151118	Interbody, Small, 6 degrees, 18mm	1
2151120	Interbody, Small, 6 degrees, 20mm	1
2151218	Interbody, Medium, 6 degrees, 18mm	1
2151220	Interbody, Medium, 6 degrees, 20mm	1
2151318	Interbody, Large, 6 degrees, 18mm	1
2151320	Interbody, Large, 6 degrees, 20mm	1
2152118	Interbody, Small, 12 degrees, 18mm	1
2152120	Interbody, Small, 12 degrees, 20mm	1
2152218	Interbody, Medium, 12 degrees, 18mm	1
2152220	Interbody, Medium, 12 degrees, 20mm	1
2152318	Interbody, Large, 12 degrees, 18mm	1
2152320	Interbody, Large, 12 degrees, 20mm	1
2153112	Interbody, Small, 18 degrees, 12mm	1
2153114	Interbody, Small, 18 degrees, 14mm	1
2153116	Interbody, Small, 18 degrees, 16mm	1
2153118	Interbody, Small, 18 degrees, 18mm	1
2153120	Interbody, Small, 18 degrees, 20mm	1
2153214	Interbody, Medium, 18 degrees, 14mm	1
2153216	Interbody, Medium, 18 degrees, 16mm	1
2153218	Interbody, Medium, 18 degrees, 18mm	1
2153220	Interbody, Medium, 18 degrees, 20mm	1
2153316	Interbody, Large, 18 degrees, 16mm	1
2153318	Interbody, Large, 18 degrees, 18mm	1
2153320	Interbody, Large, 18 degrees, 20mm	1
2154116	Interbody, Small, 24 degrees, 16mm	1
2154118	Interbody, Small, 24 degrees, 18mm	1
2154120	Interbody, Small, 24 degrees, 20mm	1
2154216	Interbody, Medium, 24 degrees, 16mm	1
2154218	Interbody, Medium, 24 degrees, 18mm	1
2154220	Interbody, Medium, 24 degrees, 20mm	1
2154318	Interbody, Large, 24 degrees, 18mm	1
2154320	Interbody, Large, 24 degrees, 20mm	1

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 (5 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 (5 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 (5 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 (5 mL) Four (4) Sterile 5 mL Syringes with 20G 1½" Needle
7510600	Infuse Bone Graft Large Kit One (1) Vial of Sterile rhBMP-2 (12mg) One (1) Package of 6 Sterile Absorbable Collagen Sponges (ACS) 1" × 2" (2.5cm × 5cm) One (1) Vial of Sterile Water for Injection (10mL) Two (2) Sterile 10mL Syringes with 20G 1½" Needle
7510800	Infuse Bone Graft Large II Kit One (1) Vial of Sterile rhBMP-2 (12mg) One (1) Package of 1 Sterile Absorbably Collagen Sponge (ACS) 3" × 4" (7.5cm × 10cm) One (1) Vial of Sterile Water for Injection (10mL) Two (2) Sterile 10mL Syringes with 20G 1½" Needle

FILL
GUIDELINES

Divergence-L		Infuse Bone Graft		
Part Number	Description	Part Number(s)	Kit Sizes(s)	Reconstituted rhBMP-2/ACS Volume (cc)
2151110	10mm wide, 6 deg, 32 × 25	7510100	XS	1.4
2151112	12mm wide, 6 deg, 32 × 25	7510100 + 7510050	XS+XXS	2.1
2151114	14mm wide, 6 deg, 32 × 25	7510200	S	2.8
2151116	16mm wide, 6 deg, 32 × 25	7510200	S	2.8
2151118	18mm wide, 6 deg, 32 × 25	7510200 + 7510050	S+XXS	3.5
2151120	20mm wide, 6 deg, 32 × 25	7510200 + 7510100	S+XS	4.2
2151210	10mm wide, 6 deg, 37 × 29	7510200	S	2.8
2151212	12mm wide, 6 deg, 37 × 29	7510200 + 7510050	S+XXS	3.5
2151214	14mm wide, 6 deg, 37 × 29	7510200 + 7510100	S+XS	4.2
2151216	16mm wide, 6 deg, 37 × 29	7510200 + 7510100	S+XS	4.2
2151218	18mm wide, 6 deg, 37 × 29	7510400	M	5.6
2151220	20mmwide, 6 deg, 37 × 29	7510400	M	5.6
2151310	10mm wide, 6 deg, 42 × 32	7510200 + 7510050	S+XXS	3.5
2151312	12mm wide, 6 deg, 42 × 32	7510200 + 7510100	S+XS	4.2
2151314	14mm wide, 6 deg, 42 × 32	7510400	M	5.6
2151316	16mm wide, 6 deg, 42 × 32	7510400 + 7510050	M+XXS	6.3
2151318	18mm wide, 6 deg, 42 × 32	7510600 or 7510800	L or LII	8
2151320	20mm wide, 6 deg, 42 × 32	7510600 or 7510800	L or LII	8
2152110	10mm wide, 12 deg, 32 × 25	7510100	XS	1.4
2152112	12mm wide, 12 deg, 32 × 25	7510100 + 7510050	XS+XXS	2.1
2152114	14mm wide, 12 deg, 32 × 25	7510100 + 7510050	XS+XXS	2.1
2152116	16mm wide, 12 deg, 32 × 25	7510200	S	2.8
2152118	18mm wide, 12 deg, 32 × 25	7510200 + 7510050	S+XXS	3.5
2152120	20mm wide, 12 deg, 32 × 25	7510200 + 7510050	S+XXS	3.5
2152210	10mm wide, 12 deg, 37 × 29	7510200	S	2.8
2152212	12mm wide, 12 deg, 37 × 29	7510200	S	2.8
2152214	14mm wide, 12 deg, 37 × 29	7510200 + 7510050	S+XXS	3.5
2152216	16mm wide, 12 deg, 37 × 29	7510200 + 7510100	S+XS	4.2
2152218	18mm wide, 12 deg, 37 × 29	7510400	M	5.6
2152220	20mm wide,12 deg, 37 × 29	7510400	M	5.6
2152312	12mm wide, 12 deg, 42 × 32	7510200 + 7510100	S+XS	4.2
2152314	14mm wide, 12 deg, 42 × 32	7510200 + 7510100	S+XS	4.2
2152316	16mm wide, 12 deg, 42 × 32	7510400	M	5.6
2152318	18mm wide, 12 deg, 42 × 32	7510400 + 7510100	M+XS	7
2152320	20mm wide, 12 deg, 42 × 32	7510600 or 7510800	L or LII	8
2153112	12mm wide, 18 deg, 32 × 25	7510100	XS	1.4
2153114	14mm wide, 18 deg, 32 × 25	7510100 + 7510050	XS+XXS	2.1
2153116	16mm wide, 18 deg, 32 × 25	7510200	S	2.8
2153118	18mm wide, 18 deg, 32 × 25	7510200	S	2.8
2153120	20mm wide, 18 deg, 32 × 25	7510200 + 7510050	S+XXS	3.5

Divergence-L		Infuse Bone Graft		
Part Number	**Description**	**Part Number(s)**	**Kit Sizes(s)**	**Reconstituted rhBMP-2/ACS Volume (cc)**
2153214	14mm wide, 18 deg, 37 × 29	7510200	S	2.8
2153216	16mm wide, 18 deg, 37 × 29	7510200 + 7510100	S+XS	4.2
2153218	18mm wide, 18 deg, 37 × 29	7510200 + 7510100	S+XS	4.2
2153220	20mm wide, 18 deg, 37 × 29	7510400	M	5.6
2153316	16mm wide, 18 deg, 42 × 32	7510400	M	5.6
2153318	18mm wide, 18 deg, 42 × 32	7510400 + 7510050	M+XXS	6.3
2153320	20mm wide, 18 deg, 42 × 32	7510400 + 7510100	M+XS	7
2154116	16mm wide, 24 deg, 32 × 25	7510100 + 7510050	XS+XXS	2.1
2154118	18mm wide, 24 deg, 32 × 25	7510200	S	2.8
2154120	20mm wide, 24 deg, 32 × 25	7510200 + 7510050	S+XXS	3.5
2154216	16mm wide, 24 deg, 37 × 29	7510200 + 7510050	S+XXS	3.5
2154218	18mm wide, 24 deg, 37 × 29	7510200 + 7510100	S+XS	4.2
2154220	20mm wide, 24 deg, 37 × 29	7510200 + 7510100	S+XS	4.2
2154318	18mm wide, 24 deg, 42 × 32	7510400	M	5.6
2154320	20mm wide, 24 deg, 42 × 32	7510400 + 7510050	M+XXS	6.3

IMPORTANT PRODUCT INFORMATION

IMPORTANT INFORMATION ON THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM

PURPOSE

The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System consists of temporary implants (plates and bone screws) intended for anterior screw fixation, and fusion devices (interbody cages) intended to stabilize and promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician thoroughly knowledgeable in the implant's material and surgical aspects and instructed as to its mechanical and material applications and limitations. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone material, or Infuse™ Bone Graft (as designated below with the Divergence-L™ Anterior/Oblique Lumbar interbody cages), to facilitate fusion.

DESCRIPTION

The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System consists of plates, bone screws, and interbody cages. The DIVERGENCE-L™ Anterior/Oblique Lumbar plates and bone screws are available in a broad range of size offerings intended for anterior 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 or oblique approach. The DIVERGENCE-L™ Anterior/Oblique Lumbar plate and bone screws are made from titanium alloy and are provided sterile. Additionally, the DIVERGENCE-L™ Anterior/Oblique Lumbar interbody cages may be used as supplemental fixation when used in conjunction with posterior fixation devices to treat deformity conditions in the thoracic and lumbar spine. The hollow geometry of the implants allows them to be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone, or Infuse™ Bone Graft (as designated below),. The cages are manufactured from medical grade polyetheretherketone (PEEK) and titanium alloy with tantalum markers 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 DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody cage is intended for interbody fusion in skeletally mature patients and is to be used with supplemental fixation instrumentation cleared for use in the lumbar spine. The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 (except as defined for use with Infuse™ Bone Graft above).. These 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. Additionally, the DIVERGENCE-L™ Interbody device is indicated for use in patients diagnosed with deformity conditions as an adjunct to fusion. These patients should have had six months of non- operative treatment. The DIVERGENCE-L™ Interbody device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The Divergence-L™ Anterior/Oblique Lumbar Fusion Interbody cage is also required to be used with autogenous bone graft . These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique.

The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion plate and bone screw components are indicated as a supplemental fixation device for the lumbosacral level, anterior below the bifurcation (L5-S1) of the vascular structures or anterior oblique above the bifurcation (L1-L5) of the vascular structures. The indications and contraindications of spinal instrumentation systems should be well 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.

Certain sizes of the Divergence-L™ Anterior/Oblique Lumbar Fusion System Interbody device may also be used with Infuse™ Bone Graft for patients diagnosed with DDD, as defined above. The device may be implanted at a single level using an Anterior Lumbar Interbody Fusion (ALIF) approach from L2-S1. The device may also be implanted at a single level using an Oblique Lateral Interbody Fusion (OLIF) approach from L5 to S1. The Divergence-L™ Anterior/Oblique Lumbar Fusion System Interbody device is intended for use with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine when used to treat DDD. Consult the labeling for the Infuse™ Bone Graft/Medtronic Interbody Fusion Device for additional information on the specific sizes of the Divergence-L™ Anterior/Oblique Lumbar Fusion System Interbody device approved for use with Infuse™ Bone Graft, as well as specific information regarding contraindications, warnings, and precautions associated with Infuse™ Bone Graft.

CONTRAINDICATIONS

The DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion 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.

Nota bene: this device system is intended for Anterior/Oblique Lumbar intervertebral body fusions only when used to treat DDD. 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.
- Death.
- 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.
- 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, 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 bone graft, 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.

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 DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System plate and bone screw components are only temporary implants used for the correction and stabilization of the spine. This system is also intended to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System is utilized. Use of a plate device without bone graft material may not be successful.

Use of the DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System Interbody Cage component in lumbar interbody fusion procedures without bone graft 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 DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion 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.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, contact Medtronic.

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone: 800 933 2635 (USA)
901 396 3133 (Outside USA)
Fax: 901 396 0356

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel: + 31 45 566 80 00

BRIEF SUMMARY

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.

SUMMARY OF INDICATIONS

SUMMARY OF INDICATIONS FOR RDX$_2$™

RDX$_2$™ Membrane Allograft is intended for homologous use in soft tissue applications for the reduction of scar tissue formation and reduction of inflammation. RDX$_2$™ Membrane Allograft can be used as a wound coverering following procedures including: ACDF, ALIF, Cervical Spinal Fusion, Corpectomy, Craniotomy, Decompression, Facet Screws, Facetectomy, Foraminotomy, Growth Rod, Hardware Removal, Hemilaminectomy, Laminectomy, Microdiscectomy, Ostectomy, PLIF, Posterior Spinal Fusion, Scar Repair, Spinal Cord Stimulator, and XLIF.

Medtronic

Medtronic
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

Medtronic Canada
Canadian Headquarters

99 Hereford Street
Brampton, ON L6Y 0R3

(905) 460-3800
(800) 268-5346

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.

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

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132

(901) 396-3133
(800) 876-3133
Customer Service: (800) 933-2635

medtronic.ca