Medtronic

Surgical Technique

Clydesdale™

Spinal System with Infuse™ Bone Graft

As described by:

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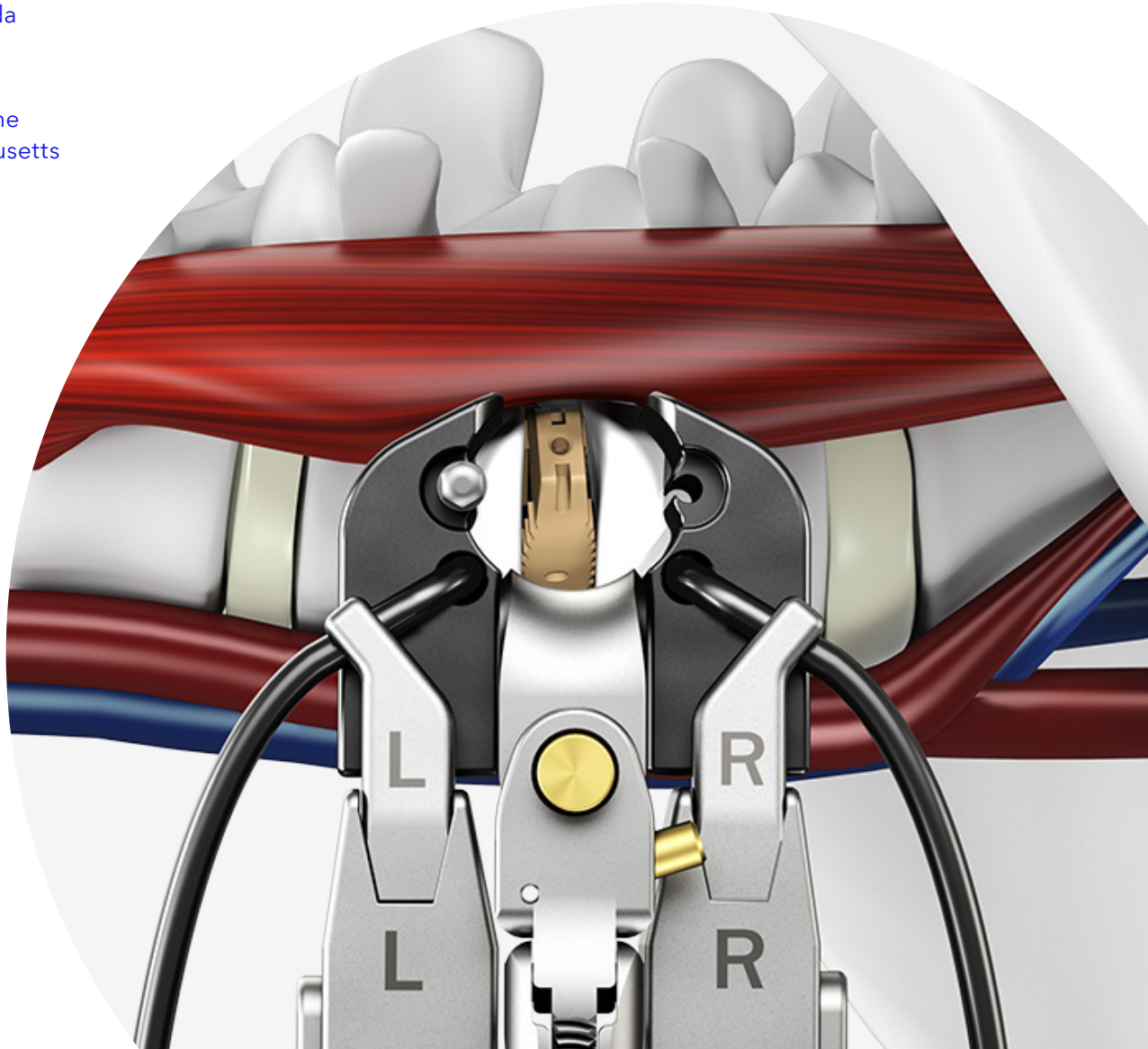

Addressing segmental sagittal correction and disc height restoration in lateral access cases.
Helping achieve desired fusion through trusted proven predictable bone grafting.

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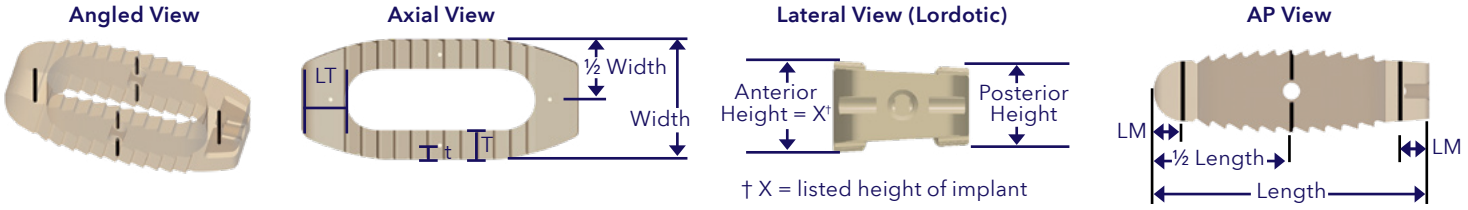
Implant Overview

Implant Dimensions and X-Ray Marker Locations



	Anterior Height (X) (mm)	Posterior Height (mm)	Width (W) (mm)	Wall Thickness (T) (mm)	Lateral Wall thickness (LT) (mm)	Length (L) (mm)	Distance from marker to anterior edge (t) (mm)	Distance from lateral marker to lateral edge (LM) (mm)
18mm 0 Degree	8, 10, 12, 14, 16	8, 10, 12, 14, 16	18	3.5	8.0	40, 45, 50, 55	1.75	5.25
18mm 6 Degree	8, 10, 12, 14, 16	X-2.0	18	3.5	8.0	40, 45, 50, 55, 60	1.75	5.25
22mm 6 Degree	8, 10, 12, 14, 16	X-2.3	22	5.5	8.0	40, 45, 50, 55, 60	2.75	5.25
22mm 12 Degree	10, 12, 14, 16	X-4.6	22	5.5	8.0	40, 45, 50, 55, 60	2.75	5.25

Instrument Set

Implant Instruments

18mm Standard Trials 6 degree

8mm Trial/Distractor
45mm (2986845) I
50mm (2986850) II
55mm (2986855) III

10mm Trial/Distractor
45mm (2986045) I
50mm (2986050) II
55mm (2986055) III

12mm Trial/Distractor
45mm (2986245) I
50mm (2986250) II
55mm (2986255) III

14mm Trial/Distractor
45mm (2986445) I
50mm (2986450) II
55mm (2986455) III

16mm Trial/Distractor
45mm (2986645) I
50mm (2986650) II
55mm (2986655) III

22mm DL Trials 6 degree

8mm Trial/Distractor
45mm (2988845)
50mm (2988850)
55mm (2988855)

10mm Trial/Distractor
45mm (2988045)
50mm (2988050)
55mm (2988055)

12mm Trial/Distractor
45mm (2988245)
50mm (2988250)
55mm (2988255)

14mm Trial/Distractor
45mm (2988445)
50mm (2988450)
55mm (2988455)

16mm Trial/Distractor
45mm (2988645)
50mm (2988650)
55mm (2988655)

22mm DL Trials 12 degree

8mm Trial/Distractor
45mm (2989845)
50mm (2989850)
55mm (2989855)

10mm Trial/Distractor
45mm (2989045)
50mm (2989050)
55mm (2989055)

12mm Trial/Distractor
45mm (2989245)
50mm (2989250)
55mm (2989255)

14mm Trial/Distractor
45mm (2989445)
50mm (2989450)
55mm (2989455)

16mm Trial/Distractor
45mm (2989645)
50mm (2989650)
55mm (2989655)

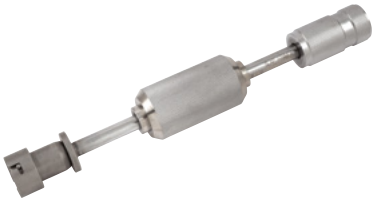
Implant Instruments

Threaded Inserter
(2982001)

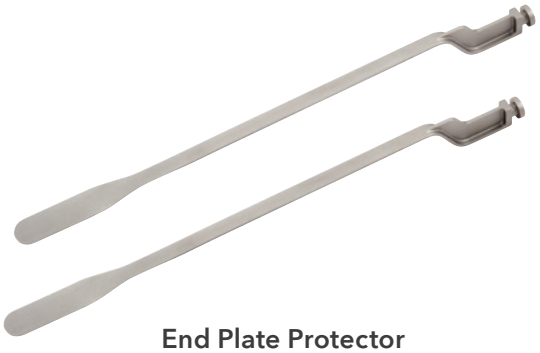
DL Inserter
(2942001)

Removal Tool
(2982002)

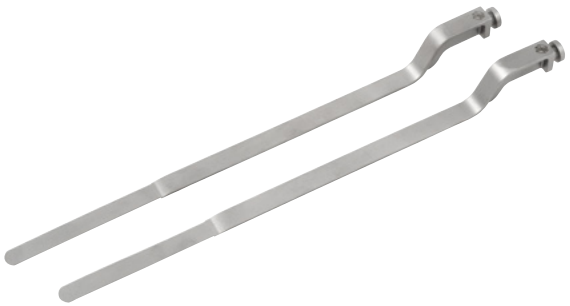
Slap Hammer
(9074002)



DL Slap Hammer
(2942049)



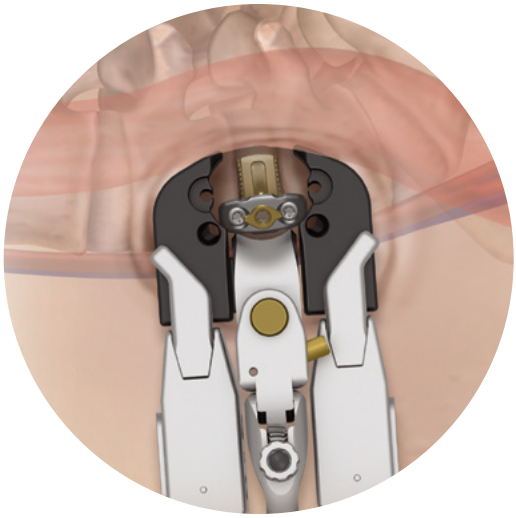
End Plate Protector
18mm (2942058)



End Plate Protector
10mm (2942037)

Access

The Clydesdale™ spinal system is to be implanted using an OLIF25™ procedure. Refer to the OLIF25™ procedure surgical technique for access and disc preparation instructions.



OLIF25™ Procedure

Trialing

The disc space is sequentially distracted with trials until adequate disc space height is obtained and adequate foraminal size is restored.

The trials are passed through the retractors obliquely and then are turned to allow the surgeon to place them orthogonally across the disc space. A mechanical or digital protractor may be used to further assess the oblique and lordotic angles of entry into the disc space, but the location of the trials is confirmed using fluoroscopy or image guidance **(Figures 1–2b)**.

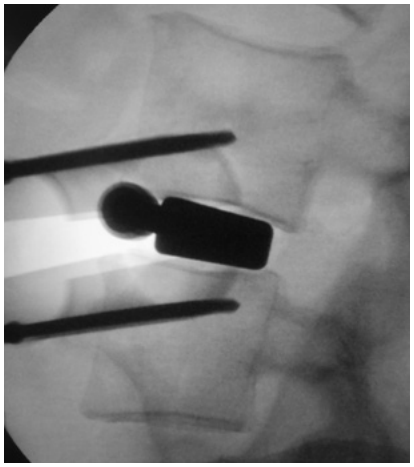


Figure 1

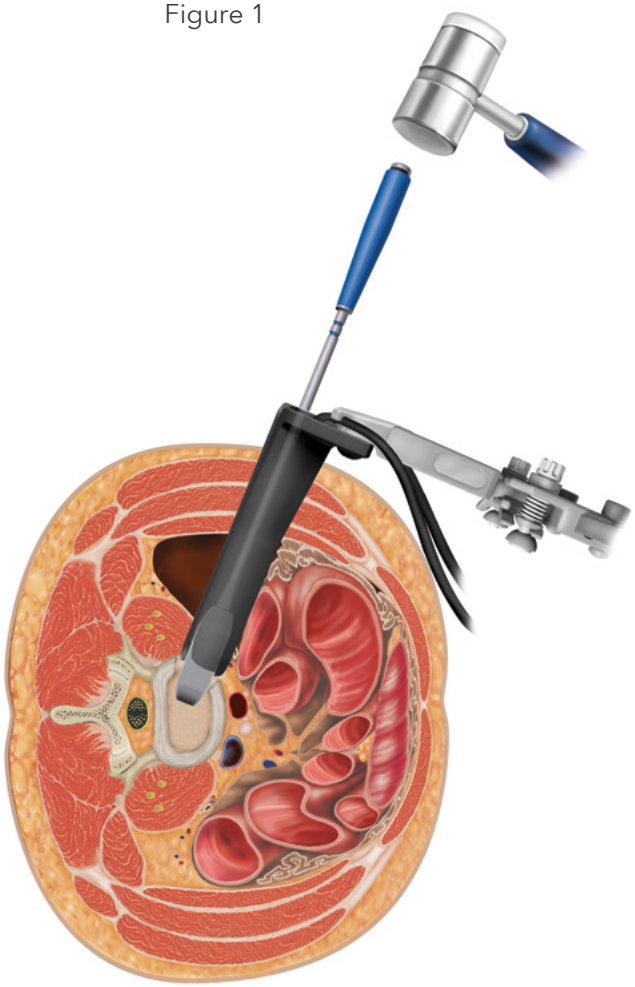


Figure 2b

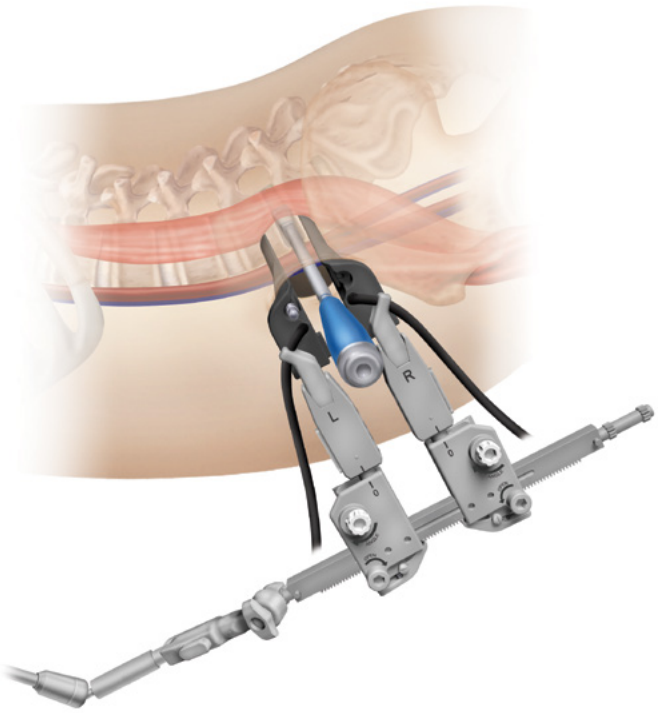


Figure 2a

The trial is impacted into the disc space. A properly-sized trial should be centered with the spinous process and should span the entire apophysis ring in order to reach fully across the vertebral body end plate **(Figures 3a–3b)**.

To help achieve desired lordosis, trials are inserted at each level to be treated in order to loosen the ligaments and add lordotic angle in preparation for insertion of the properly sized Clydesdale™ spinal system implant.

Helpful Tip

When using 22mm trials, it may be necessary to open the retractor blades more to allow the passing of the larger trial.

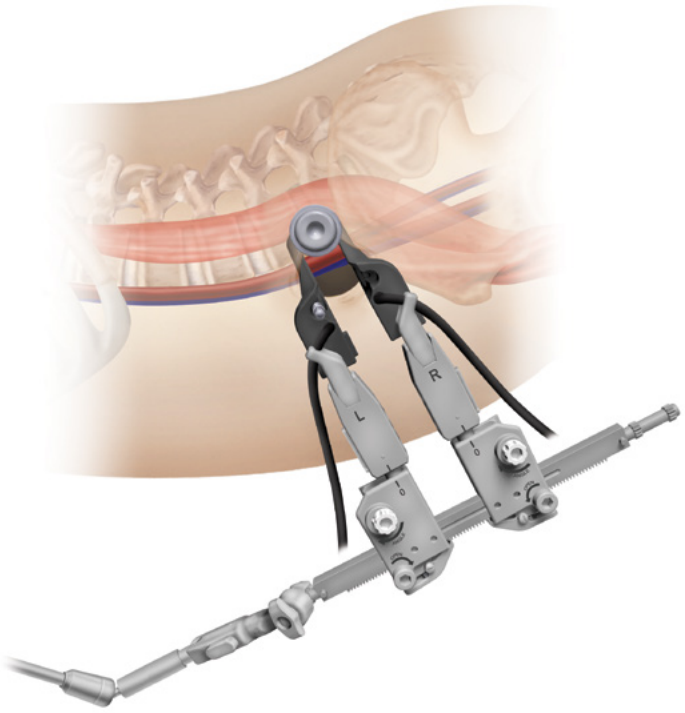


Figure 3a

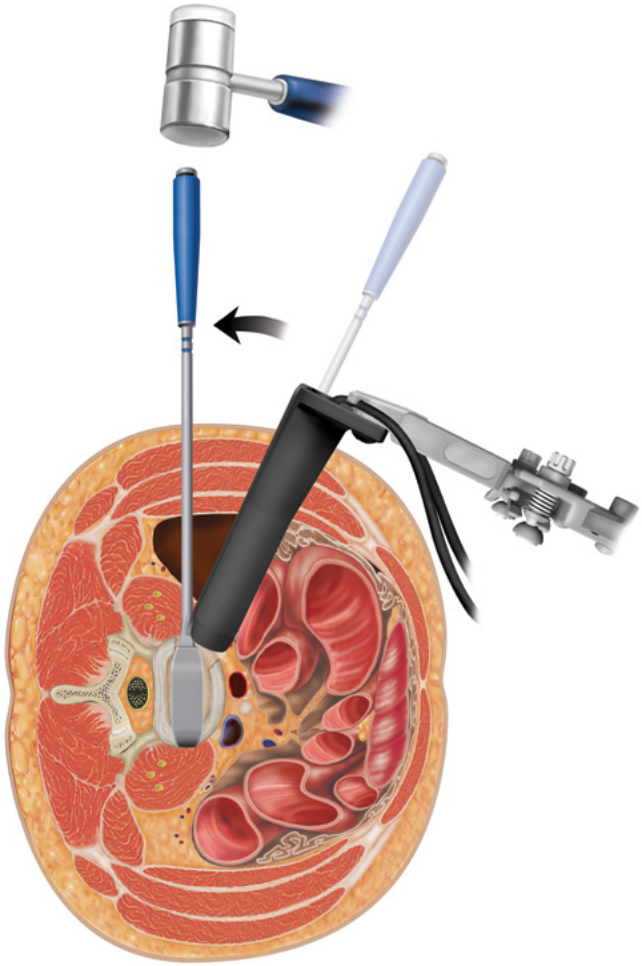


Figure 3b

Placement of Bone Graft

Clydesdale™ 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 Clydesdale™ implant. Refer to the Fill Guidelines on pages 22-23 for the appropriate kit(s) to be used with the corresponding Clydesdale™ implant **(Figure 4)**.
- At this time, prepare the appropriate Infuse™ bone graft kit(s). Refer to pages 15 -18 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)**.

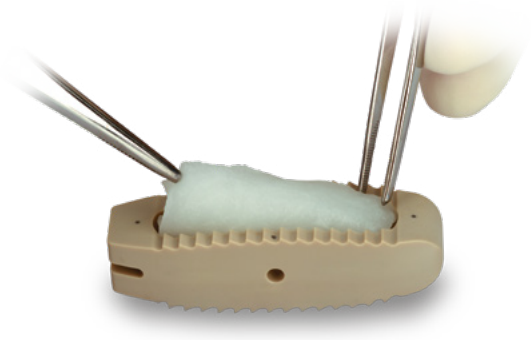
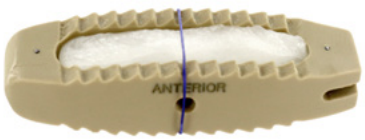


Figure 4

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.



Implant Placement

Once trialing is complete, the corresponding Clydesdale™ spinal system implant is attached to the Inserter **(Figure 5)**. If using a lordotic implant, take note of the anterior side of the implant, marked ANTERIOR.

Before inserting the Clydesdale™ spinal system implant, place autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, or Infuse™ bone graft, in the implant's central cavity.

A mallet is then used to gently insert the implant while monitoring placement under AP fluoroscopy. The inserter enters obliquely and can then be turned orthogonally to allow the surgeon to place it orthogonally across the disc space **(Figures 6a and 6b)**. A mechanical or digital protractor may be used to further assess the oblique and lordotic angles of entry into the disc space, but the location of the implant is confirmed using fluoroscopy or image guidance.

Important

For disassembly/reassembly and cleaning information on the DL inserter (part number 2942001), refer to the reprocessing instructions for lateral inserters.

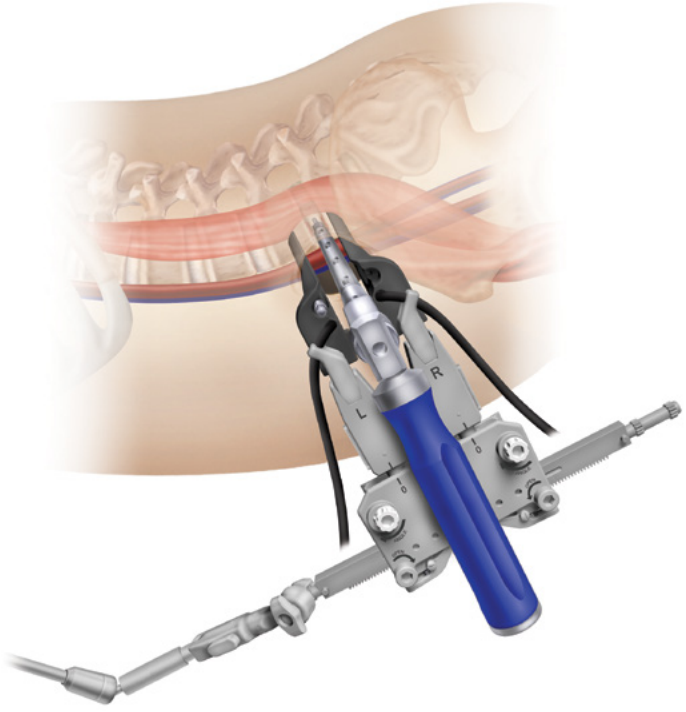
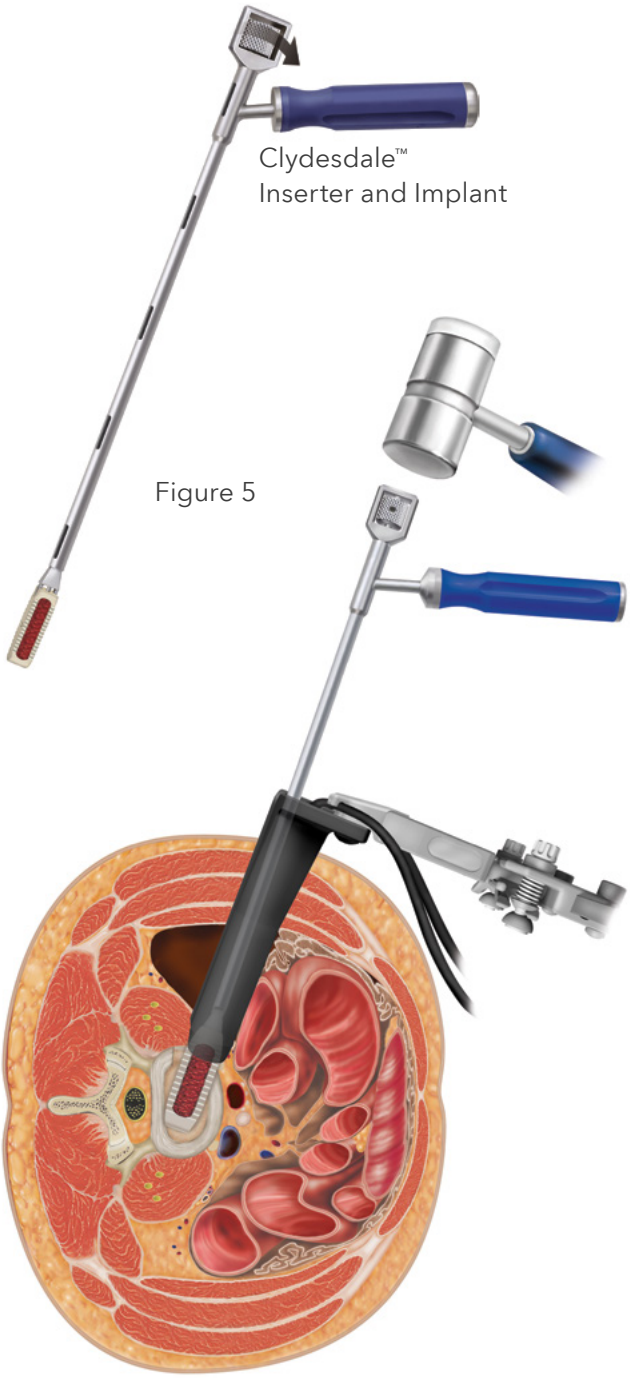


Figure 6a



Clydesdale™
Inserter and Implant

Figure 5

Figure 6b

Near complete rotation and alignment of the implant should be complete by the time approximately 50–75% of the implant is inserted into the disc space while fluoroscopy is in lateral position **(Figures 7a and 7b)**. The implant is easily viewed during this insertion due to the oblique view portal through the retractors. Then, the final positioning of implant should be completed under AP fluoroscopy. Care should be taken to ensure the Clydesdale™ spinal system implant is aligned properly.

After the implant is positioned in the center of the disc space from a medial/lateral perspective, the inserter is unthreaded from the implant and removed.

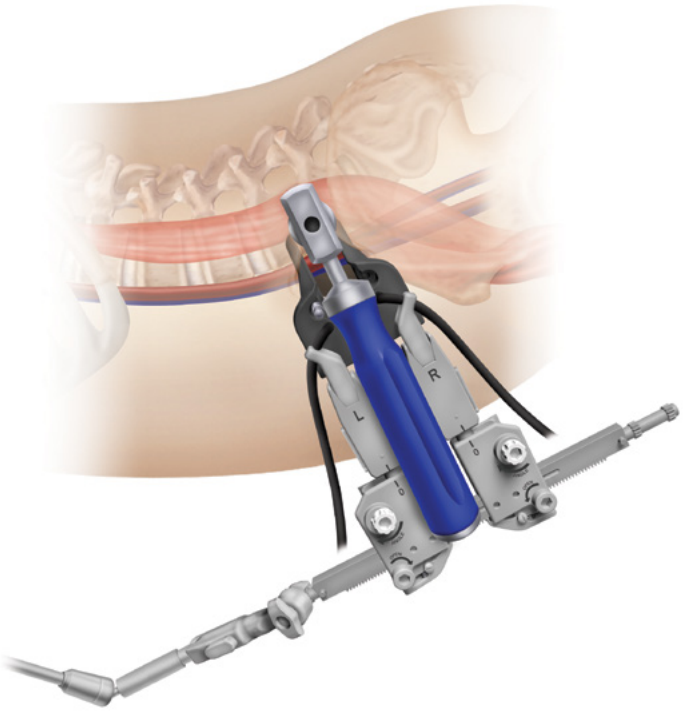


Figure 7a

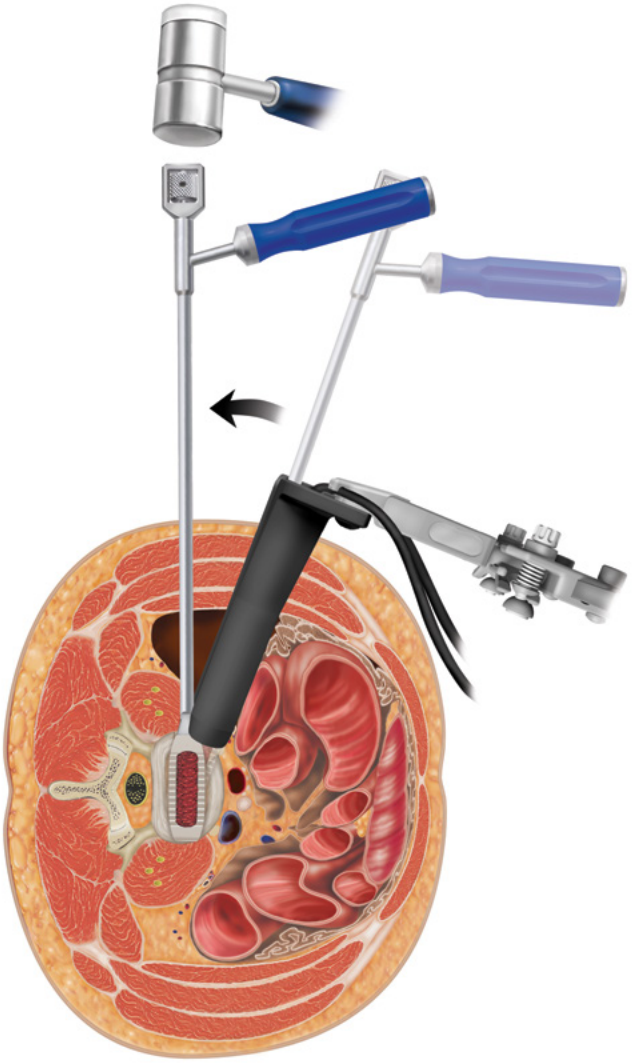
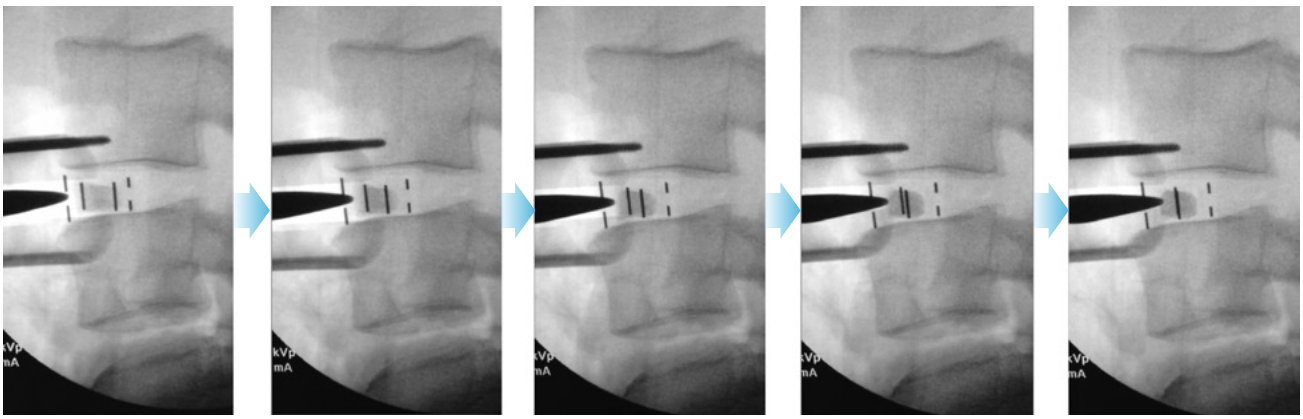


Figure 7b

Helpful Tip



If more orthogonal orientation is desired after implantation, the implant may be rotated eccentrically into alignment.

The anterior/posterior position of the implant can be influenced by how far the implant is impacted prior to rotating into the orthogonal position.

Closure

After the Clydesdale™ spinal system implant with autograft material and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, or Infuse™ bone graft has been inserted into the disc space, the stability pin may be unthreaded and removed.

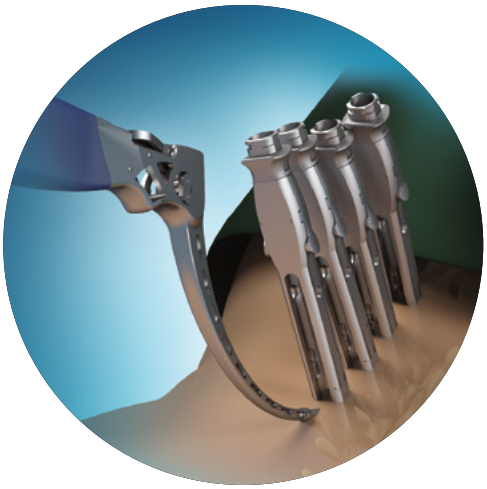
The retractor is then detached from the flex arm and the retractor blades are carefully withdrawn from the surgical site. As the retractor is removed, the muscle and fat layers can be visualized closing back into place.

The surgical site is irrigated appropriately and the fascia over the external oblique is then closed with interrupted synthetic absorbable suture.

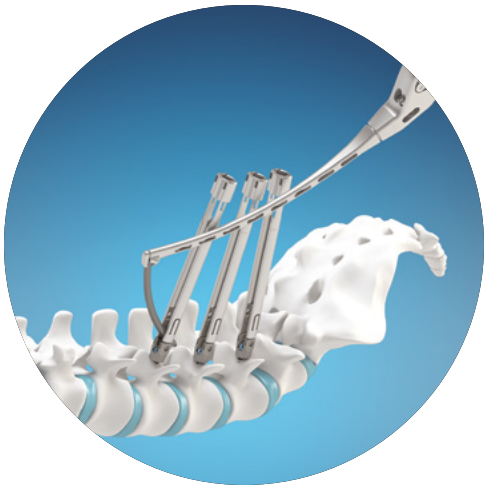
Finally, the subcutaneous layers and skin are closed and the skin is sealed with skin adhesive.

Fixation

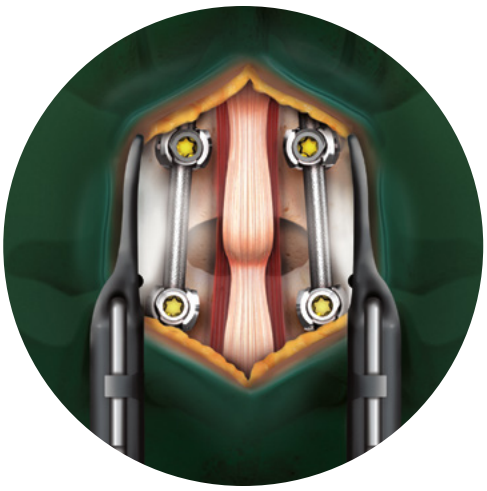
Supplemental instrumentation is then placed according to the appropriate surgical technique. When Clydesdale™ spinal system is used for Degenerative Disc Disease indications, it can be used with any posterior or anterior fixation system cleared for use in the lumbar spine. When Clydesdale™ is used to provide anterior column support in patients diagnosed with degenerative scoliosis it must be used as an adjunct to pedicle screw fixation. Examples of Medtronic fixation systems include:



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



CD Horizon Solera™ Voyager™ System



CD Horizon™ Solera™ Screws

Pivox™ Oblique Lateral Fusion Plate and Screws

See the product Instructions for Use for more detailed information.

Explantation

Should it be necessary to remove or reposition the Clydesdale™ Spinal System implant, the removal tool may be used.

To remove the implant, first fit the tips of the removal tool with the divots at the end of the implant **(Figure 8)**. Next, depress the trigger to lock onto the implant. Finally, attach the slap hammer to the removal tool and gently impact the Slap Hammer to facilitate implant removal **(Figure 9)**.

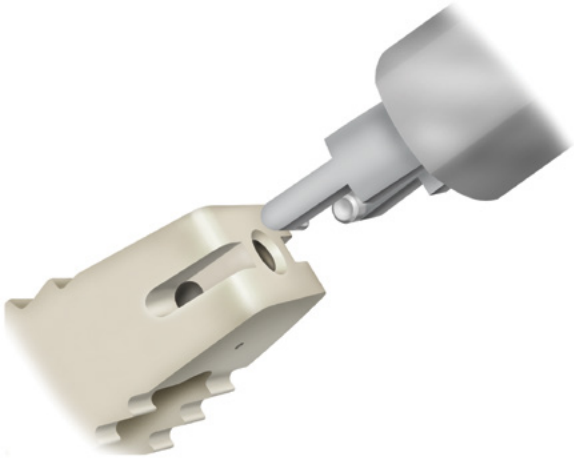


Figure 8

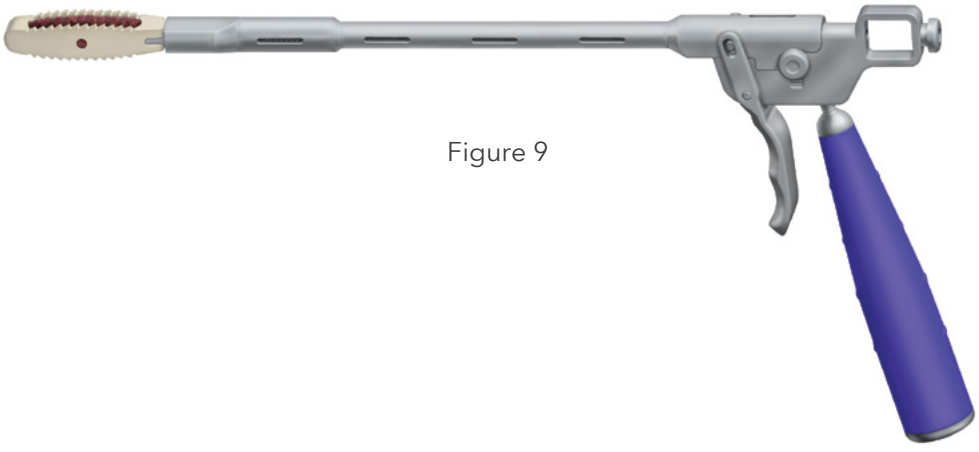


Figure 9

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

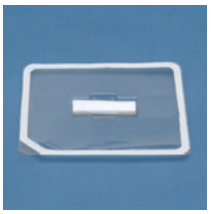
Reconstitute the rhBMP-2 with 0.9mL of sterile water.

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

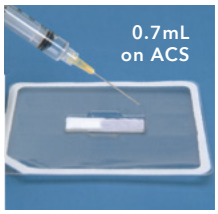


Open the inner ACS package leaving the collagen sponge in the plastic tray.

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

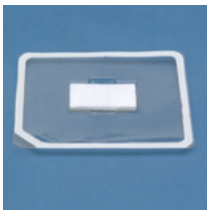
Reconstitute one vial of the rhBMP-2 with 0.9mL of sterile water.

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

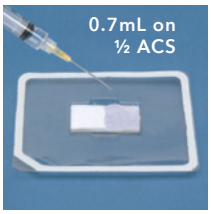


Open the inner ACS package leaving the collagen sponge in the plastic tray.

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

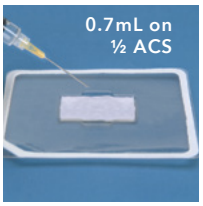


Uniformly distribute 0.7mL of reconstituted rhBMP-2 on half of the 1" × 2" collagen sponge.

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

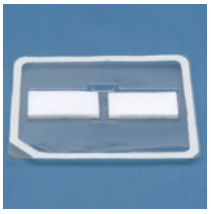
Reconstitute the rhBMP-2 with 3.2mL of sterile water.

4

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

In sterile field

5

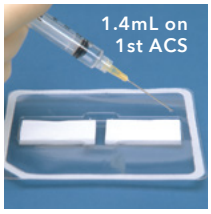


Open the inner ACS package leaving all collagen sponges in the plastic tray.

6

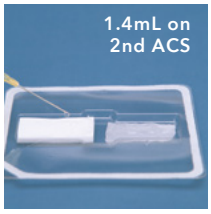
In the sterile field use the 5mL syringe/needle to withdraw 1.4mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

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

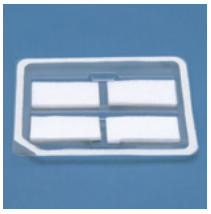
Reconstitute one vial of the rhBMP-2 with 3.2mL of sterile water.

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

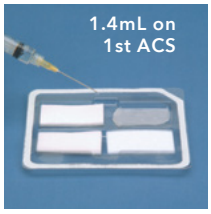


Open the inner ACS package leaving all collagen sponges in the plastic tray.

6

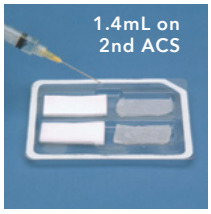
In the sterile field use the 5mL syringe/needle to withdraw 1.4mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

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.

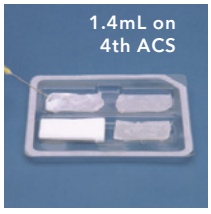
9

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

Instrument Case 2
SPS02027 – Clydesdale™ 18mm Trial and Inserter Removal Trays

Part Number	Description	Quantity
Trials		
2986845	8mm × 45mm DL Trial	1
2986850	8mm × 50mm DL Trial	1
2986855	8mm × 55mm DL Trial	1
2986045	10mm × 45mm DL Trial	1
2986050	10mm × 50mm DL Trial	1
2986055	10mm × 55mm DL Trial	1
2986245	12mm × 45mm DL Trial	1
2986250	12mm × 50mm DL Trial	1
2986255	12mm × 55mm DL Trial	1
2986445	14mm × 45mm DL Trial	1
2986450	14mm × 50mm DL Trial	1
2986455	14mm × 55mm DL Trial	1
2986645	16mm × 45mm DL Trial	1
2986650	16mm × 50mm DL Trial	1
2986655	16mm × 55mm DL Trial	1
Instruments		
9074002	Slap Hammer	1
2982002	DL Removal Tool	1
2982001	Threaded Inserter	1

DL Support Set - Disc Preparation Instruments
SPS02408 - Disc Preparation Tray 1

Part Number	Description	Quantity
2942001	DL Inserter	1
2942049	DL Slap Hammer	1
2942037	10mm Endplate Protector	2
2942058	18mm Endplate Protector	2
2942026	8mm Rotate Distractor	1
2942028	10mm Rotate Distractor	1
2942030	12mm Rotate Distractor	1
2942032	14mm Rotate Distractor	1
2942020	Osteotome	1
2942017	Dilator Holder	1
74-619-106	6mm Pituitary Rongeur	1

DL Support Set - Disc Preparation Instruments
SPS02408 - Disc Preparation Tray 2

Part Number	Description	Quantity
2942035	10mm Straight Cobb	1
2942036	18mm Straight Cobb	1
2942014	5.5mm 90 degree Push Curette	1
2942015	5.5mm 45 degree Pull Curette	1
2942016	5.5mm 90 degree Pull Curette	1
2942012	Uterine Curette	1
2942018	Flat Rasp	1
2942019	Curved Rasp	1
2942023	14mm Wedge Distractor	1
2942024	18mm Wedge Distractor	1

Disposable Cases
SPS00589 – Disposables

Part Number	Description	Quantity
NIM-Spine Probes, Dilator, Light Source, and Knife		
9450015	NIM-Spine 23cm Ball-tip Probe	1
9450069	NIM X-Pak Probe	1
9560658	MAST Quadrant Illumination System	1
9450070	5.3mm Dilator (Plastic)	1
1563-00	Bayoneted Discectomy Knife	1
945NRE1003	Electrode SD Needle Recording	1
945NSD2750	NIM Stimulated Dilator	1
1590-00	190mm Bayonet Bipolar	1
9560781	Case DL Disposable	1

Clydesdale™ 22mm DL Trials
SPS02418

Part Number	Description	Quantity
6° Clydesdale™ 22mm Trial Set		
2988845	8mm × 45mm	1
2988850	8mm × 50mm	1
2988855	8mm × 55mm	1
2988045	10mm × 45mm	1
2988050	10mm × 50mm	1
2988055	10mm × 55mm	1
2988245	12mm × 45mm	1
2988250	12mm × 50mm	1
2988255	12mm × 55mm	1
2988445	14mm × 45mm	1
2988450	14mm × 50mm	1
2988455	14mm × 55mm	1
2988645	16mm × 45mm	1
2988650	16mm × 50mm	1
2988655	16mm × 55mm	1

Clydesdale™ 22mm DL Trials
SPS02419

Part Number	Description	Quantity
12° Clydesdale™ 22mm Trial Set		
2989045	10mm × 45mm	1
2989050	10mm × 50mm	1
2989055	10mm × 55mm	1
2989245	12mm × 45mm	1
2989250	12mm × 50mm	1
2989255	12mm × 55mm	1
2989445	14mm × 45mm	1
2989450	14mm × 50mm	1
2989455	14mm × 55mm	1
2989645	16mm × 45mm	1
2989650	16mm × 50mm	1
2989655	16mm × 55mm	1

Clydesdale™ Spinal System Implants			
Part Number	Description	Graft Volume (cc)	Quantity
0° Clydesdale™ 18mm Spinal System SPS02157			
2969840	8mm × 40mm	1.70cc	1
2969845	8mm × 45mm	2.13cc	1
2969850	8mm × 50mm	2.51cc	1
2969855	8mm × 55mm	2.87cc	1
2969040	10mm × 40mm	2.14cc	1
2969045	10mm × 45mm	2.67cc	1
2969050	10mm × 50mm	3.15cc	1
2969055	10mm × 55mm	3.59cc	1
2969240	12mm × 40mm	2.61cc	1
2969245	12mm × 45mm	3.26cc	1
2969250	12mm × 50mm	3.82cc	1
2969255	12mm × 55mm	4.37cc	1
2969440	14mm × 40mm	3.08cc	1
2969445	14mm × 45mm	3.82cc	1
2969450	14mm × 50mm	4.51cc	1
2969455	14mm × 55mm	5.15cc	1
2969640	16mm × 40mm	3.54cc	1
2969645	16mm × 45mm	4.38cc	1
2969650	16mm × 50mm	5.18cc	1
2969655	16mm × 55mm	5.94cc	1

Clydesdale™ Spinal System Implants			
Part Number	Description	Graft Volume (cc)	Quantity
6° Clydesdale™ 18mm Spinal System SPS02156			
2968840	8mm × 40mm	1.54cc	1
2968845	8mm × 45mm	1.91cc	1
2968850	8mm × 50mm	2.27cc	1
2968855	8mm × 55mm	2.59cc	1
2968860	8mm × 60mm	2.96cc	1
2968040	10mm × 40mm	1.94cc	1
2968045	10mm × 45mm	2.41cc	1
2968050	10mm × 50mm	2.85cc	1
2968055	10mm × 55mm	3.24cc	1
2968060	10mm × 60mm	3.73cc	1
2968240	12mm × 40mm	2.40cc	1
2968245	12mm × 45mm	2.98cc	1
2968250	12mm × 50mm	3.53cc	1
2968255	12mm × 55mm	4.03cc	1
2968260	12mm × 60mm	4.56cc	1
2968440	14mm × 40mm	2.88cc	1
2968445	14mm × 45mm	3.56cc	1
2968450	14mm × 50mm	4.22cc	1
2968455	14mm × 55mm	4.81cc	1
2968460	14mm × 60mm	5.45cc	1
2968640	16mm × 40mm	3.34cc	1
2968645	16mm × 45mm	4.13cc	1
2968650	16mm × 50mm	4.89cc	1
2968655	16mm × 55mm	5.60cc	1
2968660	16mm × 60mm	6.12cc	1

Clydesdale™ Spinal System Implants			
Part Number	Description	Graft Volume (cc)	Quantity
6° Clydesdale™ 22mm Spinal System SPS02416			
2926840	8mm × 40mm	1.59cc	1
2926040	10mm × 40mm	1.99cc	1
2926240	12mm × 40mm	2.46cc	1
2926440	14mm × 40mm	2.93cc	1
2926640	16mm × 40mm	3.40cc	1
2926845	8mm × 45mm	1.96cc	1
2926045	10mm × 45mm	2.47cc	1
2926245	12mm × 45mm	3.04cc	1
2926445	14mm × 45mm	3.61cc	1
2926645	16mm × 45mm	4.18cc	1
2926850	8mm × 50mm	2.32cc	1
2926050	10mm × 50mm	2.90cc	1
2926250	12mm × 50mm	3.58cc	1
2926450	14mm × 50mm	4.27cc	1
2926650	16mm × 50mm	4.94cc	1
2926855	8mm × 55mm	2.64cc	1
2926055	10mm × 55mm	3.29cc	1
2926255	12mm × 55mm	4.08cc	1
2926455	14mm × 55mm	4.87cc	1
2926655	16mm × 55mm	5.66cc	1
2926860	8mm × 60mm	3.01cc	1
2926060	10mm × 60mm	3.78cc	1
2926260	12mm × 60mm	4.61cc	1
2926460	14mm × 60mm	5.51cc	1
2926660	16mm × 60mm	6.35cc	1

Clydesdale™ Spinal System Implants			
Part Number	Description	Graft Volume (cc)	Quantity
12° Clydesdale™ 22mm Spinal System SPS02417			
2922040	10mm × 40mm	1.78cc	1
2922240	12mm × 40mm	2.26cc	1
2922440	14mm × 40mm	2.73cc	1
2922640	16mm × 40mm	3.21cc	1
2922045	10mm × 45mm	2.21cc	1
2922245	12mm × 45mm	2.77cc	1
2922445	14mm × 45mm	3.35cc	1
2922645	16mm × 45mm	3.93cc	1
2922050	10mm × 50mm	2.60cc	1
2922250	12mm × 50mm	3.28cc	1
2922450	14mm × 50mm	3.98cc	1
2922650	16mm × 50mm	4.65cc	1
2922055	10mm × 55mm	2.94cc	1
2922255	12mm × 55mm	3.74cc	1
2922455	14mm × 55mm	4.53cc	1
2922655	16mm × 55mm	5.33cc	1
2922060	10mm × 60mm	3.11cc	1
2922260	12mm × 60mm	3.94cc	1
2922460	14mm × 60mm	4.84cc	1
2922660	16mm × 60mm	5.75cc	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 (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

Clydesdale™ Spinal System Implant			Infuse™ Bone Graft		
Part Number	**QTY**	**Size (H × L)**	**Part Number(s)**	**Kit Size(s)**	**Reconstituted rhBMP-2/ACS Volume (cc)**
0 deg, 18 mm					
2969840	1	8 × 40mm	7510100	XS	1.4
2969845	1	8 × 45mm	7510100+7510050	XS+XXS	2.1
2969850	1	8 × 50mm	7510200	S	2.8
2969855	1	8 × 55mm	7510200	S	2.8
2969040	1	10 × 40mm	7510100+7510050	XS+XXS	2.1
2969045	1	10 × 45mm	7510200	S	2.8
2969050	1	10 × 50mm	7510200+7510050	S+XXS	3.5
2969055	1	10 × 55mm	7510200+7510050	S+XXS	3.5
2969240	1	12 × 40mm	7510200	S	2.8
2969245	1	12 × 45mm	7510200+7510050	S+XXS	3.5
2969250	1	12 × 50mm	7510200+7510100	S+XS	4.2
2969255	1	12 × 55mm	7510200+7510100	S+XS	4.2
2969440	1	14 × 40mm	7510200	S	2.8
2969445	1	14 × 45mm	7510200+7510100	S+XS	4.2
2969450	1	14 × 50mm	7510200+7510100	S+XS	4.2
2969455	1	14 × 55mm	7510400	M	5.6
2969640	1	16 × 40mm	7510200+7510050	S+XXS	3.5
2969645	1	16 × 45mm	7510200+7510100	S+XS	4.2
2969650	1	16 × 50mm	7510400	M	5.6
2969655	1	16 × 55mm	7510400	M	5.6
6 deg, 18 mm					
2968840	1	8 × 40mm	7510100	XS	1.4
2968845	1	8 × 45mm	7510100+7510050	XS+XXS	2.1
2968850	1	8 × 50mm	7510100+7510050	XS+XXS	2.1
2968855	1	8 × 55mm	7510200	S	2.8
2968860	1	8 × 60mm	7510200	S	2.8
2968040	1	10 × 40mm	7510100+7510050	XS+XXS	2.1
2968045	1	10 × 45mm	7510100+7510050	XS+XXS	2.1
2968050	1	10 × 50mm	7510200	S	2.8
2968055	1	10 × 55mm	7510200+7510050	S+XXS	3.5
2968060	1	10 × 60mm	7510200+7510050	S+XXS	3.5
2968240	1	12 × 40mm	7510100+7510050	XS+XXS	2.1
2968245	1	12 × 45mm	7510200	S	2.8
2968250	1	12 × 50mm	7510200+7510050	S+XXS	3.5
2968255	1	12 × 55mm	7510200+7510100	S+XS	4.2
2968260	1	12 × 60mm	7510200+7510100	S+XS	4.2
2968440	1	14 × 40mm	7510200	S	2.8
2968445	1	14 × 45mm	7510200+7510050	S+XXS	3.5
2968450	1	14 × 50mm	7510200+7510100	S+XS	4.2
2968455	1	14 × 55mm	7510200+7510100	S+XS	4.2
2968460	1	14 × 60mm	7510400	M	5.6
2968640	1	16 × 40mm	7510200+7510050	S+XXS	3.5
2968645	1	16 × 45mm	7510200+7510100	S+XS	4.2
2968650	1	16 × 50mm	7510200+7510100	S+XS	4.2
2968655	1	16 × 55mm	7510400	M	5.6
2968660	1	16 × 60mm	7510400+7510050	M+XXS	6.3

Clydesdale™ Spinal System Implant			Infuse™ Bone Graft		
Part Number	**QTY**	**Size (H × L)**	**Part Number(s)**	**Kit Size(s)**	**Reconstituted rhBMP-2/ACS Volume (cc)**
6 deg, 22 mm					
2926840	1	8 × 40mm	7510100	XS	1.4
2926040	1	10 × 40mm	7510100+7510050	XS+XXS	2.1
2926240	1	12 × 40mm	7510100+7510050	XS+XXS	2.1
2926440	1	14 × 40mm	7510200	S	2.8
2926640	1	16 × 40mm	7510200+7510050	S+XXS	3.5
2926845	1	8 × 45mm	7510100+7510050	XS+XXS	2.1
2926045	1	10 × 45mm	7510100+7510050	XS+XXS	2.1
2926245	1	12 × 45mm	7510200	S	2.8
2926445	1	14 × 45mm	7510200+7510050	S+XXS	3.5
2926645	1	16 × 45mm	7510200+7510100	S+XS	4.2
2926850	1	8 × 50mm	7510100+7510050	XS+XXS	2.1
2926050	1	10 × 50mm	7510200	S	2.8
2926250	1	12 × 50mm	7510200+7510050	S+XXS	3.5
2926450	1	14 × 50mm	7510200+7510100	S+XS	4.2
2926650	1	16 × 50mm	7510200+7510100	S+XS	4.2
2926855	1	8 × 55mm	7510200	S	2.8
2926055	1	10 × 55mm	7510200+7510050	S+XXS	3.5
2926255	1	12 × 55mm	7510200+7510100	S+XS	4.2
2926455	1	14 × 55mm	7510200+7510100	S+XS	4.2
2926655	1	16 × 55mm	7510400	M	5.6
2926860	1	8 × 60mm	7510200	S	2.8
2926060	1	10 × 60mm	7510200+7510100	S+XS	4.2
2926260	1	12 × 60mm	7510200+7510100	S+XS	4.2
2926460	1	14 × 60mm	7510400	M	5.6
2926660	1	16 × 60mm	7510400+7510050	M+XXS	6.3
12 deg, 22 mm					
2922040	1	10 × 40mm	7510100	XS	1.4
2922240	1	12 × 40mm	7510100+7510050	XS+XXS	2.1
2922440	1	14 × 40mm	7510200	S	2.8
2922640	1	16 × 40mm	7510200+7510050	S+XXS	3.5
2922045	1	10 × 45mm	7510100+7510050	XS+XXS	2.1
2922245	1	12 × 45mm	7510200	S	2.8
2922445	1	14 × 45mm	7510200+7510050	S+XXS	3.5
2922645	1	16 × 45mm	7510200+7510100	S+XS	4.2
2922050	1	10 × 50mm	7510200	S	2.8
2922250	1	12 × 50mm	7510200+7510050	S+XXS	3.5
2922450	1	14 × 50mm	7510200+7510100	S+XS	4.2
2922650	1	16 × 50mm	7510200+7510100	S+XS	4.2
2922055	1	10 × 55mm	7510200	S	2.8
2922255	1	12 × 55mm	7510200+7510050	S+XXS	3.5
2922455	1	14 × 55mm	7510200+7510100	S+XS	4.2
2922655	1	16 × 55mm	7510400	M	5.6
2922060	1	10 × 60mm	7510200+7510050	S+XXS	3.5
2922260	1	12 × 60mm	7510200+7510100	S+XS	4.2
2922460	1	14 × 60mm	7510200+7510100	S+XS	4.2
2922660	1	16 × 60mm	7510400	M	5.6

Important Product Information

Important Information on Clydesdale™ Spinal System

Purpose

This device is a PEEK (Polyetheretherketone) interbody fusion device intended for stabilization use and to 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 who is thoroughly knowledgeable in the implant's material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations.

Description

The Clydesdale™ spinal system consists of PEEK cages of various widths and heights, which include Tantalum markers. These devices can be inserted between two lumbar or lumbosacral 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 and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone, or Infuse™ bone graft as designated below.

Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

Indications

The Clydesdale™ spinal system is intended to be used in interbody fusion procedures for patients diagnosed with Degenerative Disc Disease (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. When used for these indications, the Clydesdale™ spinal system is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Certain sizes of the Clydesdale™ spinal system may be used with Infuse™ bone graft in single-level Oblique Lateral Interbody Fusion (OLIF) procedures from L2 to 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 the Clydesdale™ 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 Clydesdale™ spinal system can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. Infuse™ bone graft is not indicated for use in patients with this condition.

These patients should be skeletally mature and have had six months of nonoperative treatment. The Clydesdale™ spinal system is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion. These implants may be implanted via a minimally invasive lateral approach.

Contraindications

This device is not intended for cervical spine use. Contraindications include, but are not limited to:

- Infection local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to composite materials.
- Any case not needing a fusion.
- Any case not described in the indications.
- Any patient unwilling to cooperate with postoperative instructions.
- Patients with a known hereditary or acquired bone friability or calcification problem.
- Pediatric cases or where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.

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

Potential Adverse Events

Adverse effects may occur when the device is used either with or without associated instrumentation. The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include but are not limited to:

- Implant migration.
- Breakage of the device(s).
- Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
- Pressure on the surrounding tissues or organs.
- Damage to the peritoneum.
- Loss of proper spinal curvature, correction, height, and/or reduction.
- Infection.
- Bone fracture or stress shielding at, above, or below the level of surgery.
- Non-union (or pseudoarthrosis).
- Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain.
- Neurovascular compromise including paralysis, temporary or permanent retrograde ejaculation in males, or other types of serious injury.
- Cerebral spinal fluid leakage.
- Hemorrhage of blood vessels and/or hematomas.
- Damage to the anterior vasculature.
- Discitis, arachnoiditis, and/or other types of inflammation.
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.

- Bone graft donor site complication.
- Inability to resume activities of normal daily living.
- Early or late loosening or movement of the device(s).
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Retropulsed graft.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Loss of or increase in spinal mobility or function.
- Reproductive system compromise including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
- Change in mental status.
- Cessation of any potential growth of the operated portion of the spine.
- Death.

Warnings and Precautions

Warning: When used in deformity procedures, undersizing the implant may limit endplate engagement and potentially lead to implant migration and/or expulsion.

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. Use of this product without bone graft or in cases that do not develop a union will not be successful.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those with a previous surgery.

A device that has been implanted should never be reused, reprocessed, or resterilized under any circumstances. Sterile packaged devices should also never be resterilized. Reuse, reprocessing, or resterilization 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.

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.

Medtronic