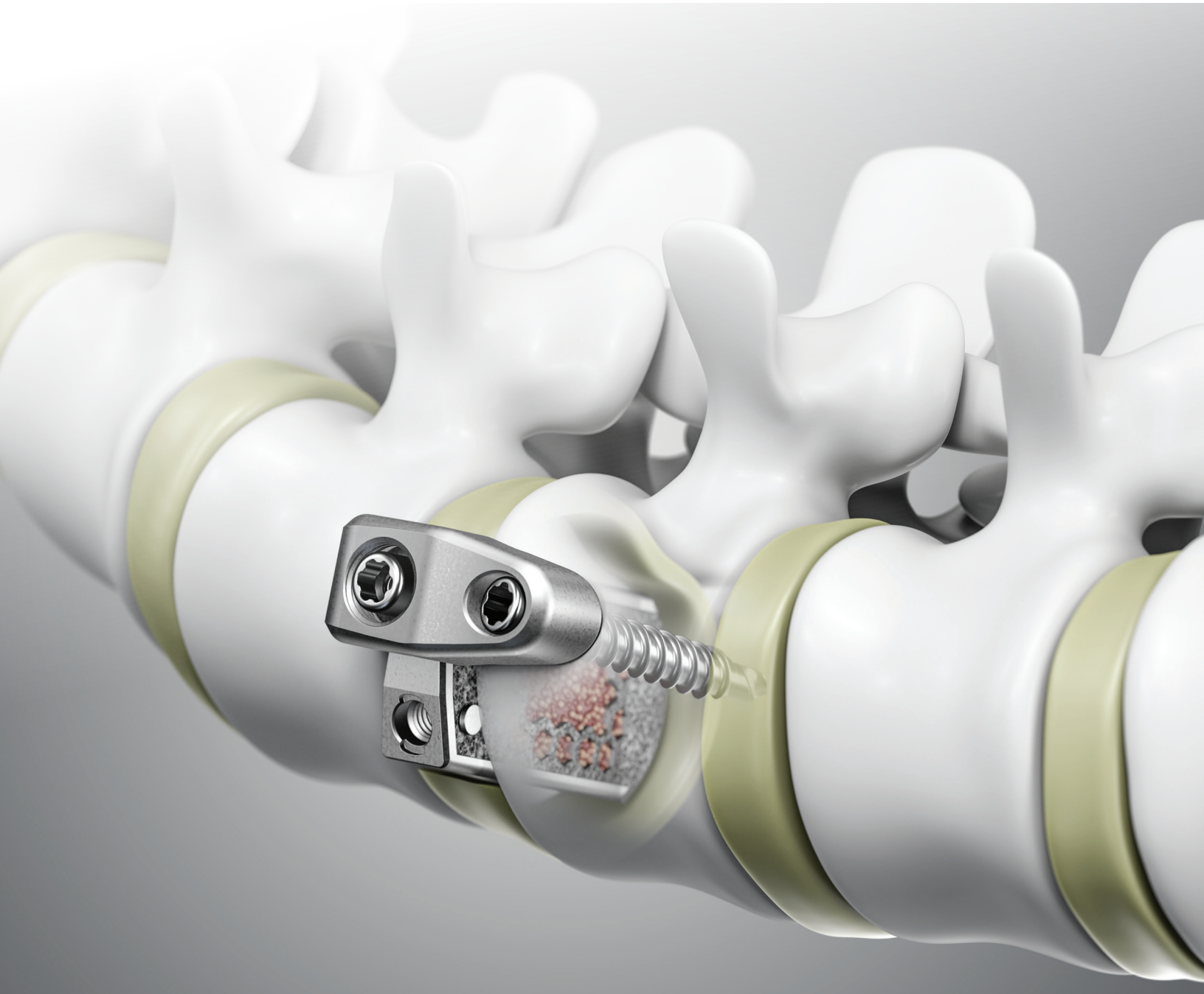
Medtronic

SURGICAL TECHNIQUE

Anteralign™ TL

Spinal System with Infuse™ bone graft



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System overview

The Anteralign™ TL spinal system is a streamlined implant system intended to be used in two different spinal approaches and five procedures: SynergyOLIF25™, SynergyDLIF™, OLIF25™, DLIF, and Prone Lateral procedures (**Figure 1**). This can be accomplished with minimal instrumentation as compared to Clydesdale™ spinal system.

Figure 1

The Anteralign™ TL implant is intended to be used in spinal fusion procedures on skeletally mature patients with symptomatic Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion. The Anteralign™ spinal system with Titan nanoLOCK™ surface technology is intended for use with supplemental internal fixation systems cleared for use in the lumbar spine.

Additionally, the Anteralign™ spinal system with Titan nanoLOCK™ surface technology can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

An optional mini-plate is provided to help prevent migration of the implant (**Figure 2**). The mini-plate can be attached either through a lateral or oblique manner.

Figure 2

The Anteralign™ spinal system was designed to be used with both navigation and fluoroscopy. For details on the navigated workflow, please refer to page 12 of this Anteralign™ TL Surgical Technique. If using the Anteralign™ TL spinal system in conjunction with the Mazor™ robotic guidance platform, refer to page 17.

The inserter can be used with all the Anteralign™ TL trials and implants. The foot of the inserter features a line to help with proper orientation of the implant on the inserter. The Anteralign™ TL implant and trials are marked with a circle for OLIF25™ and a rectangle for DLIF orientations (**Figures 3 and 7**).

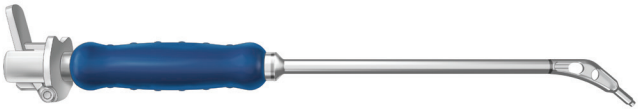
Figure 3

Instrument overview

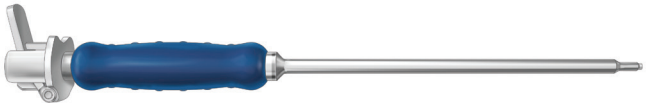
Anteralign™ Inserter
4680004 and 4680005

Loading Block
4680011

Anteralign™ Navigation Inserter
NAV4680003



Angled Awl
4680000 and 4680001



Straight Awl
4680002 and 4680003

Mini-plate Inserter
4680006 and 4680007

Torque Limiting Handle
G307407

Bolt Driver
4680010

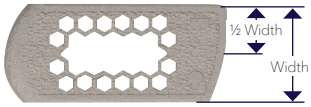
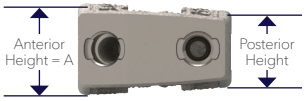
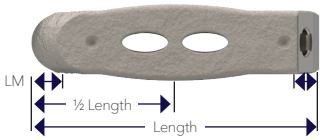
Straight Screwdriver
4680009†

Ball Joint Driver
4680008†

†Standard Anteralign Drivers are retention drivers.
Non-retention driver options are available for order as shelf items.
Non-Retention Straight Screwdriver 4680018
Non-Retention Ball Joint Driver 4680017

Implant overview

Implant Dimensions

Angled View	Axial View	Lateral View (Lordotic)	AP View
		 A = listed height of implant	

	Anterior Height (A)(mm)	Posterior Height (per Height)	Posterior Height	Width	Anterior/ Posterior Wall Thickness	Proximal Wall Thickness (per Length)	Distal Lateral Wall Thickness (per Length)	Length
20mm 6 Degree	8, 10, 12, 14	5.9, 7.9, 9.9, 11.9	A-2.1	20	2.1	10.25, 10.275, 10.45, 11.075	7.15, 8.4, 9.45, 10.075, 12.125	40, 45, 50, 55, 60
20mm 12 Degree	10, 12, 14	5.8, 7.8, 9.8	A-4.2	20	2.1	10.25, 10.275, 10.45, 11.075,	8.4, 9.45, 10.075, 12.125	45, 50, 55, 60
23mm 6 Degree	8, 10, 12, 14	5.6, 7.6, 9.6, 11.6	A-2.4	23	2.1	10.25, 10.25, 10.45, 11.075, 10.275	7.15, 8.4, 9.45, 10.075, 12.125	40, 45, 50, 55, 60
23mm 12 Degree	10, 12, 14	5.2, 7.2, 9.2	A-4.8	23	2.1	10.25, 10.25, 10.45, 11.075, 10.275	7.15, 8.4, 9.45, 10.075, 12.125	40, 45, 50, 55, 60
23mm 18 Degree	12, 14, 16	4.7, 6.7, 8.7	A-7.3	23	2.1	10.25, 10.45, 11.075, 10.275	8.4, 9.45, 10.075, 12.125	45, 50, 55, 60
23mm 24 Degree	14, 16	4.2, 6.2	A-9.8	23	2.1	10.45, 11.075, 10.275	9.45, 10.075, 12.125	50, 55, 60

Patient positioning

The surgeon should consider ease of access in determining which side of the patient to approach.

Correction can be achieved equally from either the convex or concave side of the curve.

The recommended position is for the patient to be placed in the lateral decubitus position and positioned so that the top of the iliac crest is in line with the break of the surgical table.

Use of a radiolucent Jackson Spine flat table top or a breakable Jackson table is recommended. If a flat table is used, a bump should be placed under the patient's flank on the side facing down. Bend the patient's arms at the elbow if the O-arm™ imaging system will remain parked during the procedure. The patient is secured to the surgical table with tape at three locations (**Figure 4**).

Refer to the appropriate procedural surgical technique for patient positioning instructions.

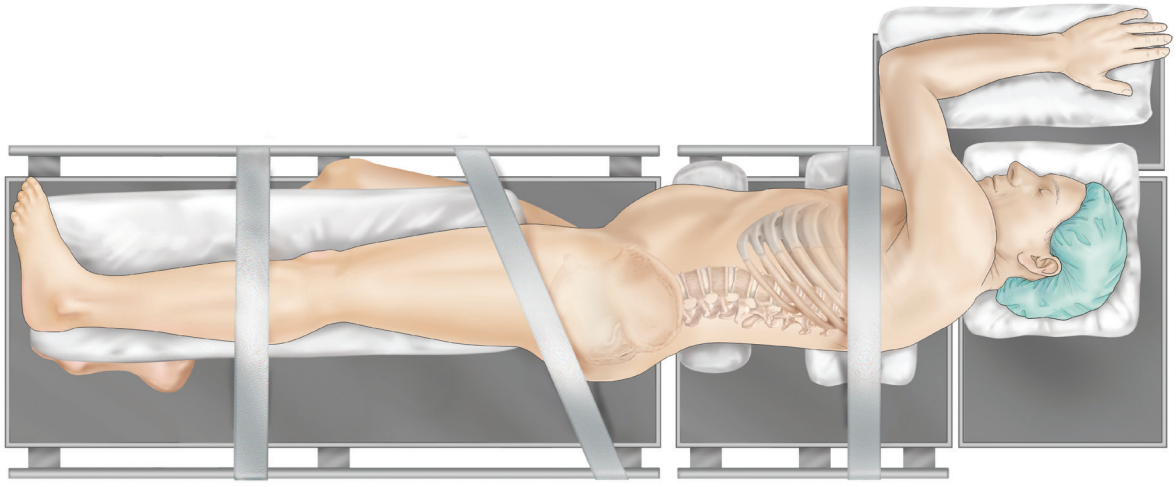


Figure 4

Access

The Anteralign™ TL trials and implants can be used during an OLIF25™ procedure or a DLIF procedure, depending upon the surgeon's preference and anatomical considerations (**Figures 5 and 6**). Refer to the appropriate procedure surgical technique for access and disc preparation instructions.

During initial room setup, confirm all instruments are present and functioning properly.

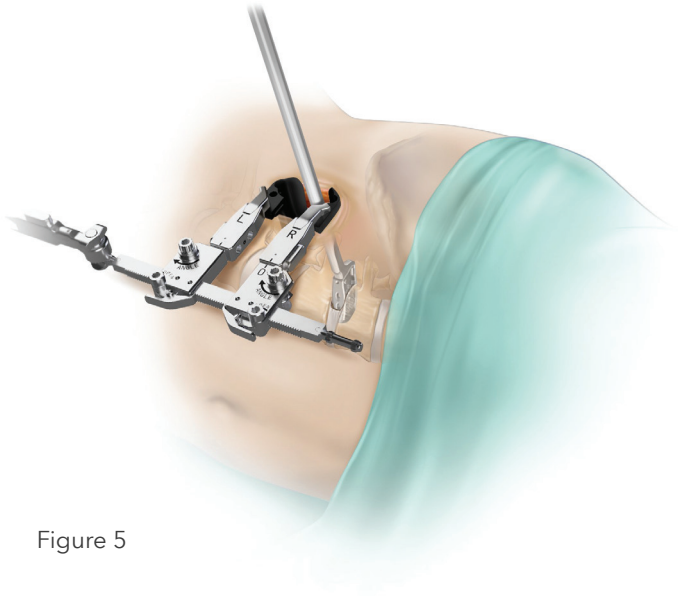


Figure 5

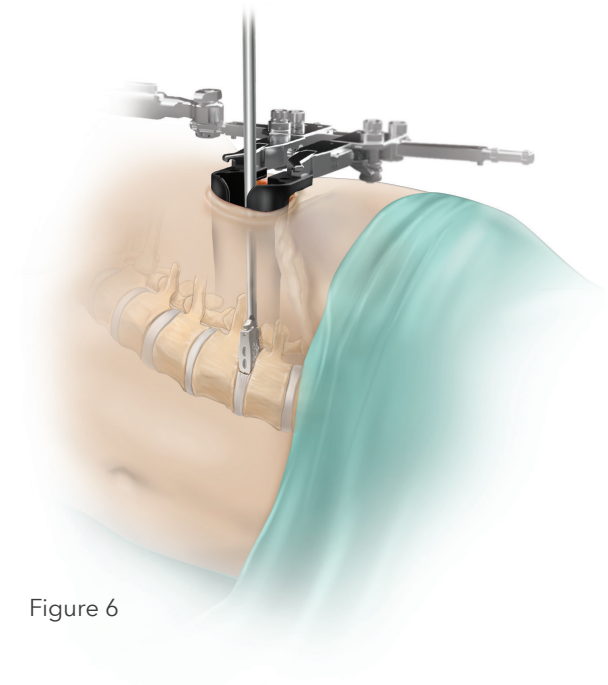


Figure 6

Trialing

After the disc space is prepared and any osteophytes are removed, select the appropriate implant sizes using the interbody trials. When using the Anteralign™ TL trial, the surgeon must choose whether to use the system in a straight lateral orientation or an oblique (20° offset) orientation.

To use the trial in a straight orientation, align the black line on the Inserter with the rectangle on the trial. To use the trial in an oblique orientation, align the black line on the inserter with the circle on the trial (**Figure 7**).

Figure 7

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

For a DLIF approach, the trials are passed through the retractors direct laterally, and for an OLIF approach, 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 (**Figure 8**).

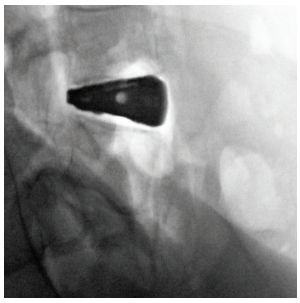


Figure 8

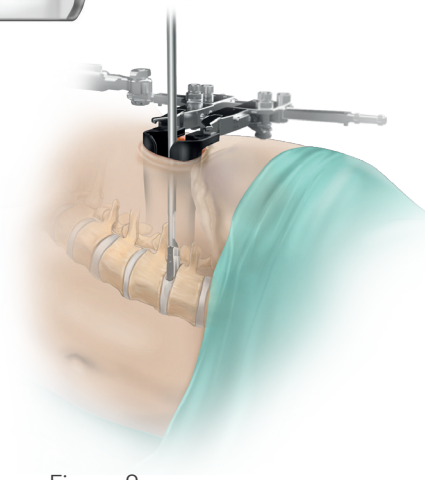


Figure 9

The trial is impacted into the disc space. The TL trials are not to be centered on the spinous process. The distal end should mark a trial that spans the apophyseal ring. The physical marking indicator/line on the nav station will dictate what length implant. (**Figure 9**).

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 Anteralign™ TL implant. Trials are available in 60mm length only. Visual markers will confirm 40mm and 50mm lengths when trial is co-axial in AP view under fluoroscopy (**Figure 10**).

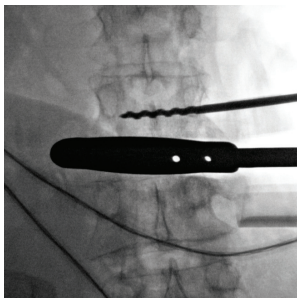


Figure 10

Impact the trial into the disc space in order to place it in the desired anterior/posterior position. The trial should be impacted into the disc space until the tip of the nose is aligned with the contralateral edge of the disc space, and the trial is orthogonal. If the desired length of the trial is less than 60mm, the trial will stick out of the ipsilateral side of the disc space.

Sequentially trial until the desired implant size is obtained.

If needed, attach the slap hammer to the distal end of the inserter to remove the previous trial from the disc space (**Figure 11**).

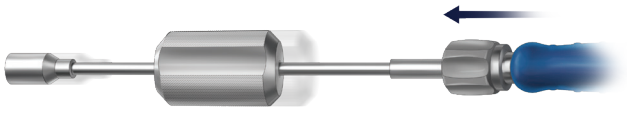


Figure 11

Note

When choosing an interbody length, remember that if the interbody will be used with a mini-plate, the proximal end of the interbody should not countersink into the disc space, so the interbody should span the entire disc space and sit flush with the proximal side of the vertebral body. A 2mm offset option is available for the mini-plate if the interbody is slightly countersunk or an osteophyte is present.

Placement of bone graft

- The Anteralign™ TL spinal system implant may be used with Grafton™ DBF bone graft, autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate or a combination thereof (**Figure 12**).
- An appropriate amount of bone graft should be used according to the internal volume of the Anteralign™ TL implant. Refer to the graft volume chart at the end of this technique. If using Grafton™ DBF, refer to the IFU for handling and preparation steps.
- Alternatively, the Anteralign™ TL spinal system implant may be used with Infuse bone graft in procedures wherein the implant is placed using an OLIF (antepsoas) approach at a single level from L2-L5.
- If using Infuse bone graft:
  - An appropriate amount of Infuse™ bone graft should be used according to the internal volume of the Anteralign™ TL implant. Refer to the Fill Guidelines on page 32 for the appropriate kit(s) to be used with the corresponding Anteralign™ TL implant.
  - At this time, prepare the appropriate Infuse™ bone graft kit(s). Refer to pages 25-30 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. Confirm sponge(s) are evenly distributed throughout the cavity **(Figure 12b)**.
  - If desired, a resorbable polyglactic 910 suture (Polysorb™ suture) may be wrapped around the exterior of the implant to secure Infuse™ bone graft during implantation.

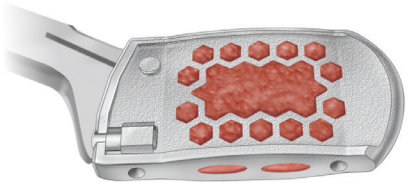


Figure 12

Figure 12b

Figure 13

Implant placement

Once trialing is complete, the interbody can be inserted. Please note correct implant orientation during inserter attachment. To use the interbody implant in a straight orientation, align the black line on the inserter with the rectangle on the implant. To use the implant in an oblique orientation, align the black line on the inserter with the circle on the implant (**Figure 13**).

Place the inner shaft into the inserter (**Figure 14**). Place the implant, with bone graft inserted, onto the inserter in the desired orientation. Tighten inner shaft clockwise until it will no longer advance. The ratchet mechanism will hold tension until reversed counterclockwise. Place the implant into the disc space, confirming location with fluoroscopy or navigation. Unthread the Inserter from the implant and remove the Inserter.

Figure 14

Mini-plate fixation is an available anti-migration feature for the Anteralign™ TL interbody. This is helpful during patient repositioning to prone for supplemental fixation. This option can be attached to the Anteralign™ TL implant *in situ* or prepared on the back table as an all-in-one approach. The mini-plate inserter is used to insert the assembled mini-plate and interbody implant (**Figure 15**).

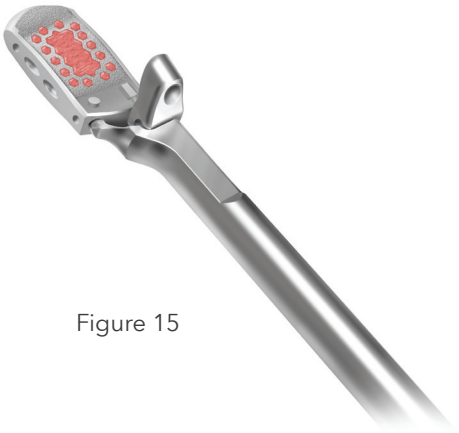


Figure 15

Optional mini-plate fixation:

Align the mini-plate on the loading block in the desired placement (lateral or oblique) and in the desired direction (cephalad or caudal). Attach the mini-plate to the mini-plate inserter by inserting the mini-plate inserter shaft into the mini-plate inserter and rotating the knob on the proximal end of the mini-plate inserter shaft. Dock the mini-plate inserter shaft into the large threaded hole of the mini-plate. A black line on the mini-plate inserter will match a black line on the mini-plate when loaded in the desired orientation (**Figure 16**).

Figure 16

Dock the mini-plate inserter into the inserter hole of the interbody. With the inserter still attached, thread the bolt to the implant with the bolt driver and ratcheting handle by going through the mini-plate inserter, and provisionally tighten for a rigid assembly. There are two awl options included in the Anteralign™ instrument set, the fixed and angled awl. The instrument is designed with an inner shaft and outer sleeve to cover the awl tip. The instrument can be docked into the miniplate bone screw hole first and be malleted to have the distal end protrude out of the housing and make the pilot hole. Both awl options protrude a length of 15 mm and are 3.35 mm in diameter at the distal tip. The lever on the side of the awl can be used to release. The green driver handle (G307407, included in the Anteralign™ instrument set) is ratcheting and torque limiting. Do not overtighten or torque-limit the mini-plate to the interbody at this point. This assembly can be executed in-situ or on the back table prior to introducing to the operative field.

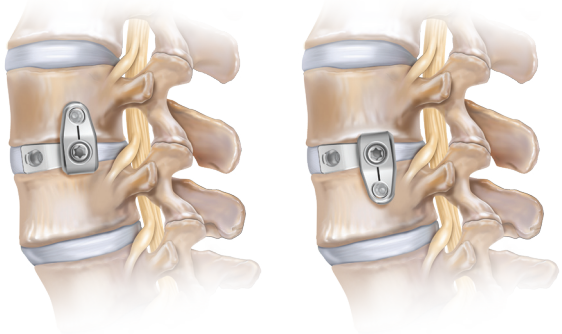


Figure 17

Remove the mini-plate inserter. Place a screw through the hole on the mini-plate to attach to the vertebral body using the ratcheting torque-limiting handle. Final tighten/torque-limit the screw . This will ensure the appropriate force is applied for proper locking of the screw into the mini-plate.

Final tighten/torque limit the mini-plate bolt once the screw is locked using the ratcheting torque-limiting handle. This will ensure the appropriate force is applied for proper locking of the mini-plate to the interbody (**Figures 17 and 18**).

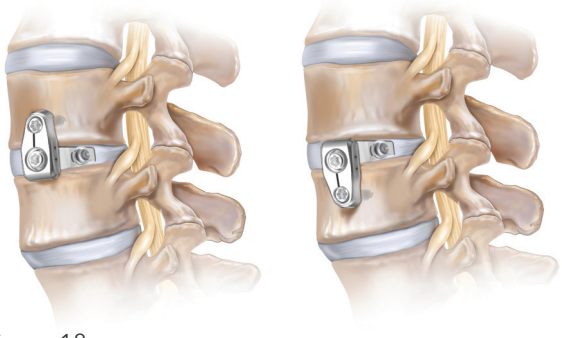


Figure 18

All Anteralign™ TL implants are sterile-packed. To confirm the length of the screws, use the depth gauge on the loading block indicating 20, 30, 40, and 50 mm lengths.

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.

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 the lateral position. The implant is easily viewed during this insertion due to the oblique view portal through the retractors.

Then, the final positioning of the implant should be completed under AP fluoroscopy. Care should be taken to ensure the Anteralign™ TL 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 19**).

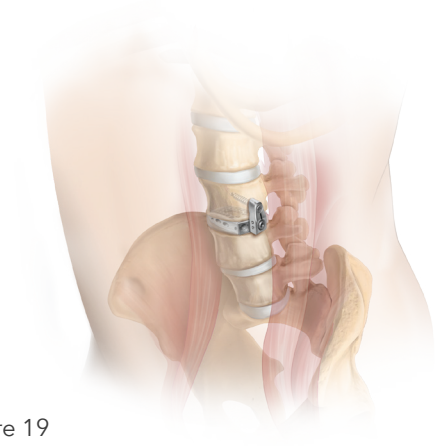


Figure 19

Closure

After the Anteralign™ TL 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 and the retractors removed.

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

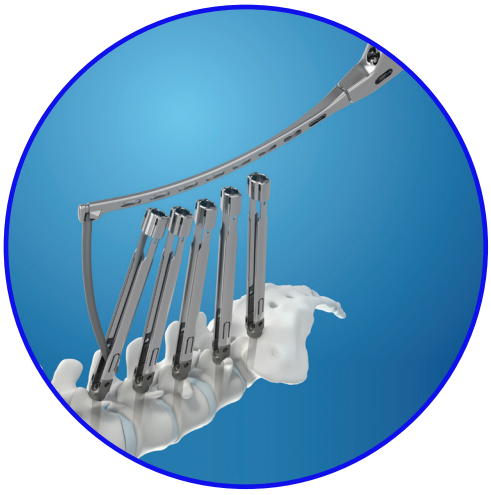
Finally, the subcutaneous layers and skin are closed and the skin is sealed with skin adhesive.

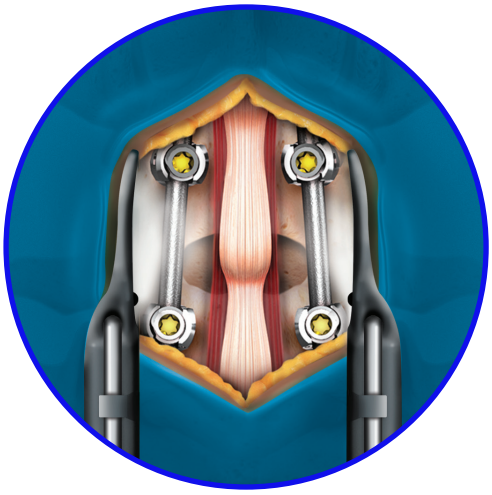
Fixation

Supplemental instrumentation is then placed according to the appropriate surgical technique. When Anteralign™ TL spinal system is used for Degenerative Disc Disease indications, it can be used with any posterior fixation system cleared for use in the lumbar spine. When Anteralign™ TL spinal system 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™ Solera™ Voyager™ 5.5 spinal system and CD Horizon™ Solera™ 5.5/6.0 spinal system.

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

- Mastergraft™ Strips
- Grafton™ Matrix Strips
- Magnifuse™ Bone Graft





Explantation

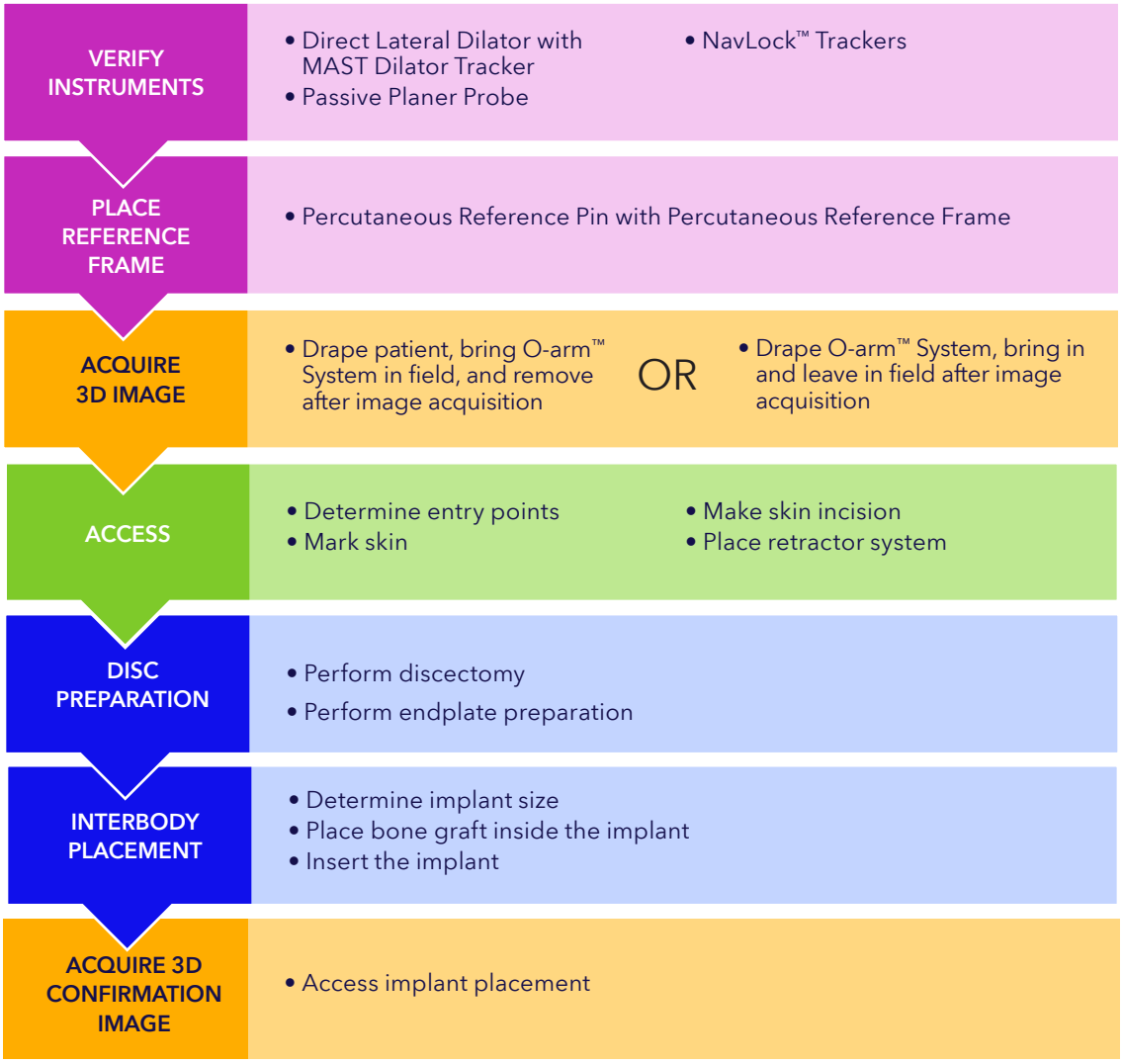
Should it be necessary to remove or reposition the Anteralign™ TL spinal system implant, the slap hammer may be used.

To remove the implant, first thread the Inserter into the interbody implant. Next, attach the slap hammer to the distal end of the inserter to remove.

If the optional mini-plate was used, remove it before removing the interbody.

Attach the mini-plate inserter to the mini-plate, then utilizing the assembly of the quick-connect handle with the bolt driver, decouple the mini-plate from the interbody.

Navigated Anteralign™ TL spinal system workflow



Workflow selections

In order to determine size for Anteralign™ TL trial and/or implant, user must make appropriate selections within the StealthStation™ navigation system software.

The Anteralign™ TL spinal system uses a single inserter for both trials and implants, therefore one Anteralign™ TL toolcard contains both trials and implants. Once Anteralign™ TL toolcard is selected, assign the navigated inserter a NavLock™ tracker. Green, gray, orange, and violet NavLock™ trackers can be used with the Anteralign™ TL inserters (**Figure 20**).

There are two verification options with the Anteralign™ TL inserter:

1. Verify the NavLock™ tracker with an instrument such as an awl. Then, change NavLock™ tracker to pair with the Anteralign™ TL toolcard (**Figure 21**).
2. Verify the NavLock™ tracker with the Anteralign™ TL inserter. To do this, the Tip field must be set to Verify Inserter (**Figure 22**). The inner threaded shaft must be placed in the reference frame divot.

Figure 20

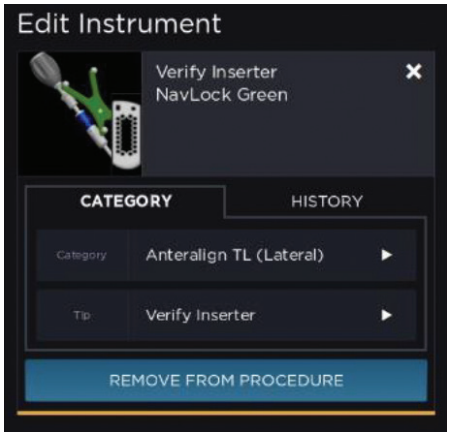


Figure 21

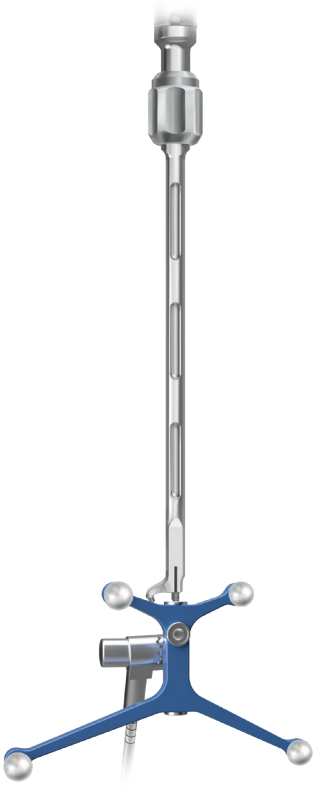


Figure 22

Once the procedure is selected, the user must select the orientation of the inserter onto the trial/ implant. The options are straight or angled (**Figure 23**). Historically the angled option has been used for the oblique approaches and the straight option has been used for the direct lateral approach, but this is not required.

The foot of the inserter features a line to help with proper orientation of the implant or trial on the inserter. The Anteralign™ TL implants and trials are marked with a circle for the angled orientation and a rectangle for the straight orientation (**Figure 24**).

Once the Navigated Inserter Tip selection is made, the user must select the Configuration. The Configuration options are A or B. Due to the multiple options within the Anteralign™ TL spinal system, this option allows the software to track the instruments in space intraoperatively. The NavLock™ tracker aligns with either the A or B positioning designation etched on the Navigated Anteralign™ TL inserter. In the toolcard, select configuration A or B to correspond with the A/B orientation of the NavLock™ tracker on the Navigated Anteralign™ TL inserter. Please reference Table 1 for configuration based on procedure and camera position.

When the above category selections are made, the user can move on to the implant/trial selections.

In order to make the Anteralign™ TL spinal system streamlined and efficient, only commonly used sizes are offered as options within the platform. To make this selection process more efficient, options not available have not been included. In the situation where an implant is not available for the corresponding trial selected, the banner will read, “No Corresponding Implant Size" (**Figure 25**). Similarly, when a size is selected for which there is no implant or trial available, the banner will read "invalid implant selection."

The first implant attribute selection is the “Projection Type”. The options are Trial or Implant.

Within the implant section in the toolcard, the user can select attributes of the trial to determine the desired size.

Use the slider functions to select the length and width of the trial. Anterior height and lordosis angle will default to the smallest available option. Selected options can be confirmed in the banner located at the bottom of the toolcard.

It is important to confirm selections so that navigated projections match physical system components.

Once the desired size trial is selected, the user can change the “Projection Type” from Trial to Implant and all selected attributes will apply to Implant for a more efficient workflow.

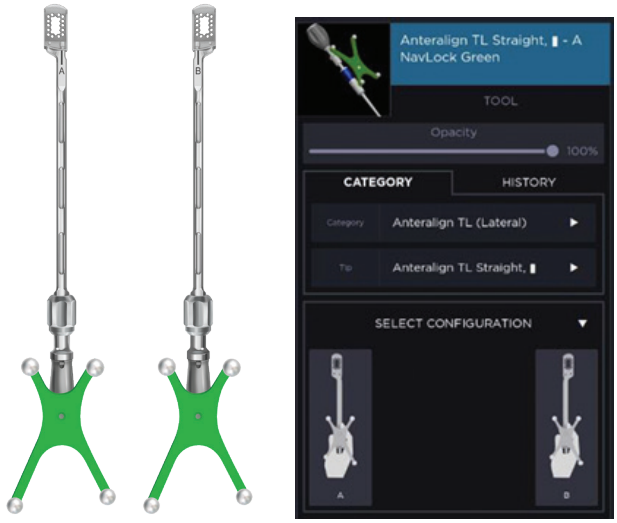


Figure 23

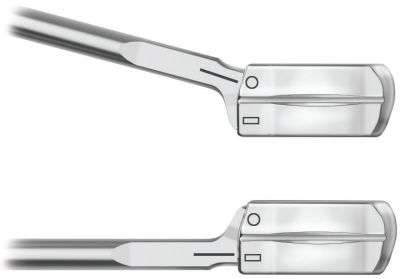


Figure 24

	Camera Position	
	Head	Foot
TL Angled (OLIF25™ procedure*)	°B	▪A
TL Straight (DLIF* or OLIF25™ procedure*)	°A	▪B

*Assumes patient is in right lateral decubitus position. (Left side up)

Table 1

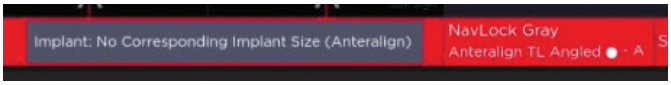


Figure 25

Trial insertion

The disc space is sequentially distracted with trials until adequate disc space height is obtained and adequate foraminal size is restored by selecting appropriate trial width, length, and lordosis angle (**Figure 26**).

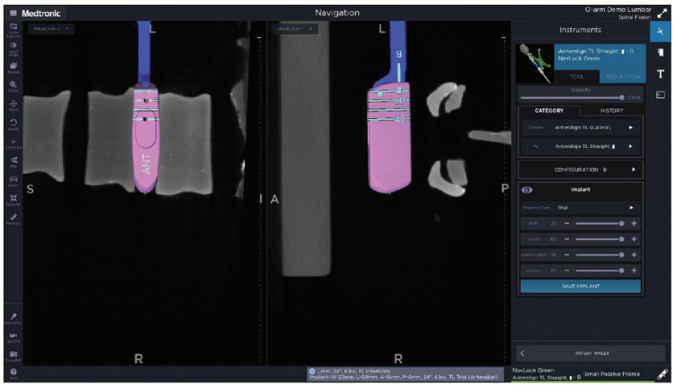


Figure 26

Trials are available in 8mm, 10mm, 12mm, 14mm, and 16mm heights. Anteralign™ TL trials are available in 60mm length only. However, a yellow virtual marker on the navigated Anteralign™ TL trial can be used to display other lengths (40mm, 45mm, 50mm and 55mm). Adjust the slider for length on the StealthStation™ system to use the virtual markers. If other size options are desired, follow the SynergyDLIF™ and SynergyOLIF25™ Surgical Techniques using non-navigated instruments for the trialing step.

For a DLIF approach, the trials are passed through the retractors direct laterally, and for an OLIF approach 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. On the StealthStation™ system, select the appropriately sized trial. Insert the Anteralign™ TL trial with a NavLock™ tracker into the disc space until the desired height is established by way of proper placement and alignment of the trial.

Confirm proper placement and alignment of the trial. Remove the NavLock™ tracker and then use a slap hammer from the trial set if needed to remove the trial.

Helpful hint

Keep in mind that when moving bony anatomy, it will not be detected on the StealthStation™ monitor. During navigation, it is important to frequently confirm navigational accuracy by touching the tip of the navigated disc prep instrument on known anatomical points, including accuracy checkpoints, and comparing the position to the instrument tip in the image with its physical location. If needed, re-verification will be performed before continuation of the procedure.

Helpful hint

Please note that the Anteralign™ TL inserter is not symmetric and the projection tool references the center point of the trial/implant. This will appear offset if the user saves any projections from a symmetric disc prep tool.

Interbody placement

Before inserting the Anteralign™ TL spinal system implant, place bone graft in the implant's central cavity as previously described on page 7 of this Anteralign™ TL Surgical Technique. The StealthStation™ software calls out the bone graft volume for the selected implant size, displayed on the gray banner on the bottom right of the StealthStation™ screen. Or, refer to the graft volume chart at the back of this technique. Attach the Anteralign™ TL spinal system implant to the navigated inserter. On the StealthStation™ system, select the appropriately sized implant. Use a mallet to gently insert the implant. The navigated inserter is then unthreaded from the implant and removed (**Figures 27 and 28**).

Notes

There is no all-in-one navigated interbody/mini-plate inserter. Using the navigated inserter to place the interbody while also using the mini-plate requires *in situ* placement. For details, refer to the mini-plate placement section of the technique.

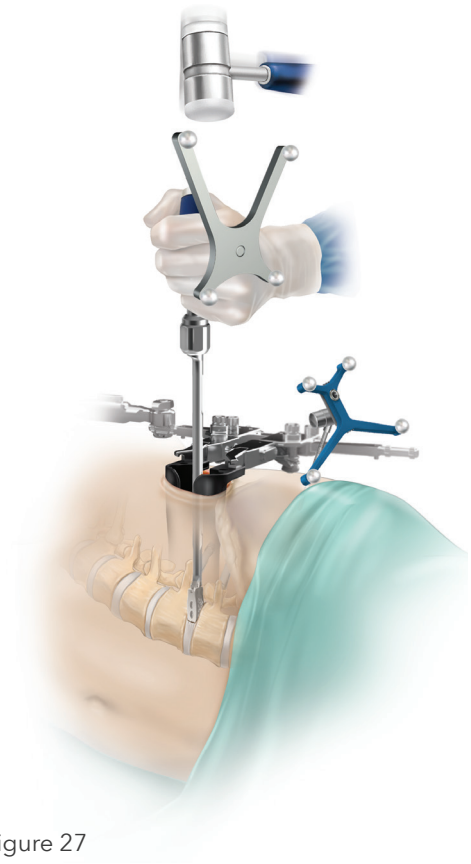


Figure 27

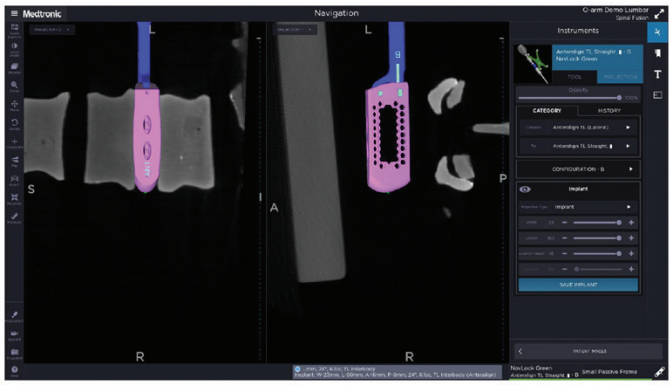
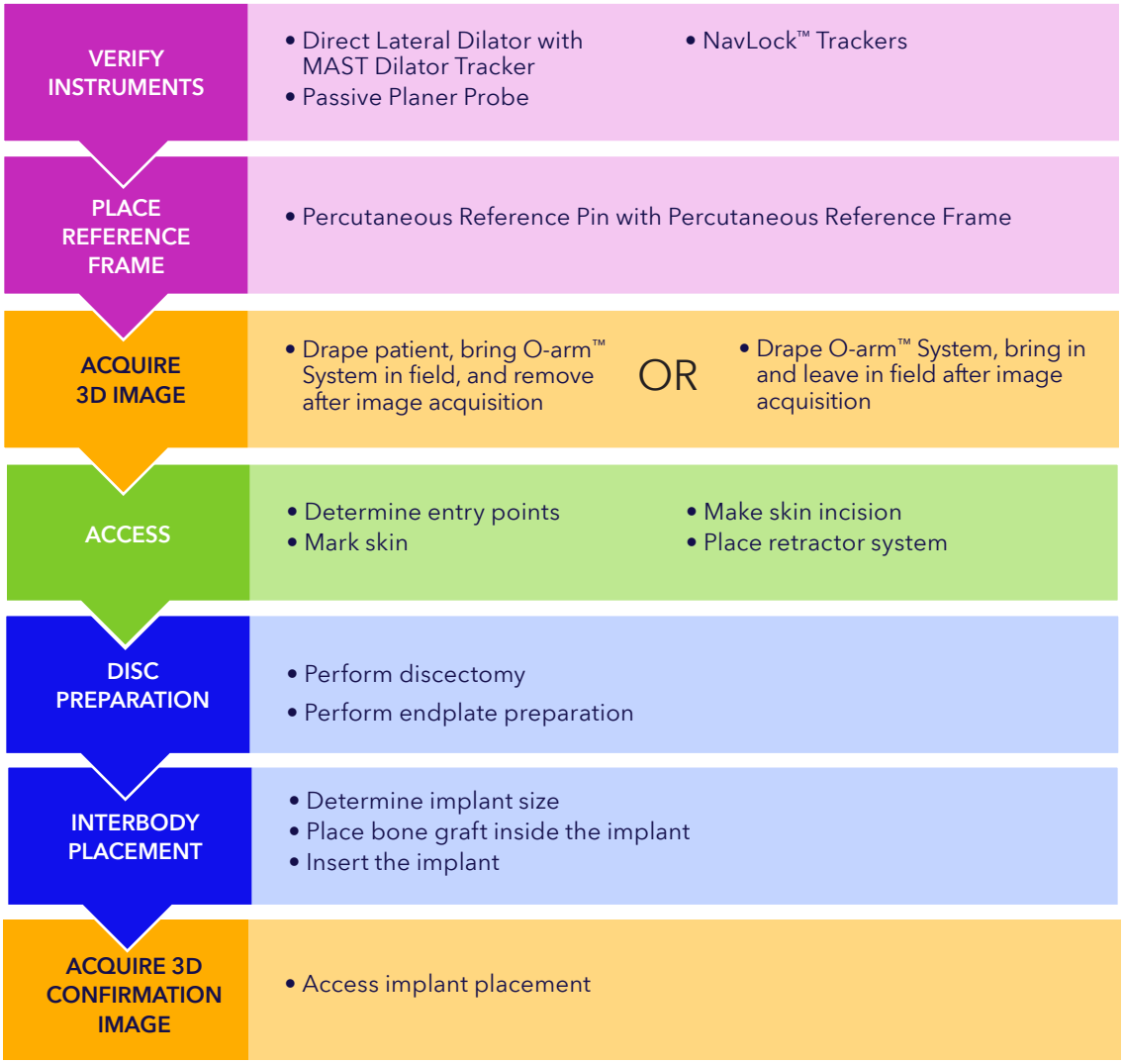


Figure 28

Anteralign™ TL workflow using Mazor™ robotic guidance platform

The following steps describe the use of the Anteralign™ spinal system when used in conjunction with Mazor™ robotic guidance platform. Refer to the applicable manual listed in the "Description" section for complete indications, warnings, precautions, and important medical information on Mazor™ robotic guidance platform and associated instruments.



To determine the Anteralign™ TL trial and/or implant size, user must make the appropriate selections within the Mazor™ platform software. The Anteralign™ TL spinal system uses a single inserter for both trials and implants, therefore one Anteralign™ TL toolcard contains the trials and the implants.

Once the Anteralign™ TL toolcard is selected, assign the navigated inserter a NavLock™ tracker. Green, gray, orange, violet, black, and blue NavLock™ trackers can be used with the Anteralign™ TL inserter. There are two verification options with the Anteralign™ TL inserter.

1. Verify the NavLock™ tracker with an instrument such as an awl. Then, change the NavLock™ tracker to pair with the Anteralign™ TL toolcard.
2. Verify the NavLock™ tracker with the Anteralign™ TL inserter. To do this, the Tip field must be set to Verify Inserter. The inner threaded shaft must be placed in the robotic or patient reference frame divot.

Once the inserter is verified, the user must choose the straight or angled tip in the software to match the physical assembly. Typically, the angled option is used for oblique approaches and the straight option is used for direct lateral approaches, but this is not required. The foot of the inserter features a line to help with proper orientation of the implant or trial on the inserter. The Anteralign™ TL implants and trials are marked with a circle for the angled orientation and a rectangle for the straight orientation. The tip field is set to Anteralign™ TL Angled or Anteralign™ TL Straight to match the orientation of the attached implant or trial (**Figure 29**).

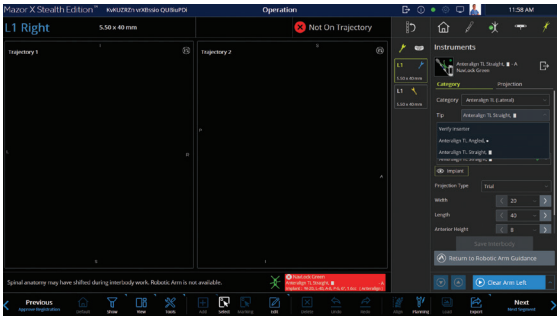


Figure 29

Note

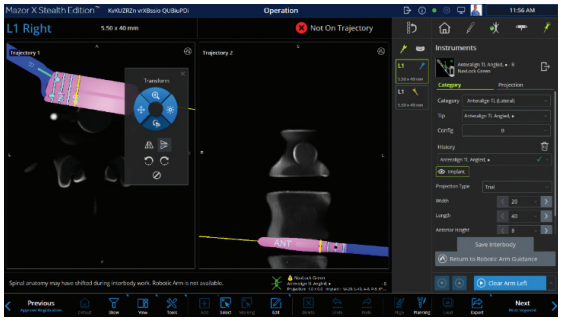
The option to flip the implant view is offered so users can see the differences in the A/B configuration. Depending on whether the user is viewing the inserter from a patient's head or feet, a different letter (A or B) can be seen on the inserter. The A or B letters allow users to clearly see if there is a difference in orientation of the implant/inserter on the screen versus the physical assembly in hand.

Once the navigated inserter tip selection is made, the next selection to be made is Configuration, these options are A or B. Due to the multiple options within the Anteralign™ TL spinal system, this option allows the software to track the instruments in space intraoperatively. When facing the camera, the NavLock™ tracker aligns with either the A or B positioning designation etched on the navigated Anteralign™ TL inserter. In the toolcard, select configuration A or B to correspond with the A/B orientation of the NavLock™ tracker on the navigated Anteralign™ TL inserter.

Once the configuration selections are made, the user can move on to the implant/trial selections. To make this selection process efficient, only available sizes are offered as options within the platform software. In situations where an implant is not available for the corresponding trial, the software will display "Invalid implant selection".

The first implant attribute selection is the "Projection Type". The options are trial or implant. Within the implant section in the software toolcard, the user can select attributes of the trial to determine the desired size. Use the slider functions to select the length and width of the trial. Anterior height and lordosis angle will default to the smallest option available. Selected options can be confirmed in the banner located at the bottom of the software toolcard. It is important to confirm selections so the navigated projections match the physical system components. Once the desired trial size is selected, the user can change the "Projection Type" from trial to implant and all selected attributes will be applied in the software.

Prior to flipping Trajectory 1



After flipping Trajectory 1

Trial Selection

The disc space is sequentially distracted using the trials until adequate disc space height is obtained and adequate foraminal size is restored by selecting appropriate trial width, length, and lordosis angle.

Anteralign ™ TL spinal system trials are available in 8mm, 10mm, 12mm, 14mm, and 16mm heights. All trials are 60mm in length. Lengths of 40mm, 45mm, 50mm, 55mm, and 60mm can be determined virtually within the software. If other size options are desired, follow the SynergyDLIF™ and SynergyOLIF25™ procedure surgical techniques using non-navigated instruments for the trialing step.

The trials are passed through the retractors direct laterally or obliquely. On the Mazor™ system workstation, select the appropriately sized trial. Insert the Anteralign™ TL trial with a Nav Lock™ tracker attached into the disc space until the desired height is established by way of proper placement and alignment of the trial (**Figure 30**). Confirm proper placement and alignment of the trial. Remove the NavLock™ tracker and then use a slap hammer from the trial set, if needed, to remove the trial.

Note

Keep in mind that when moving bony anatomy, it will not be detected on the Mazor™ system workstation monitor. During navigation, it is important to frequently confirm navigational accuracy by touching the tip of the navigated probe on known anatomical points and/or accuracy checkpoints and comparing the position of the instrument tip in the image with its physical location. If needed, reverification will be performed before continuation of the procedure.

Note

At any point during the procedure, navigation accuracy can be evaluated using the first Direct Lateral Dilator/MAST Dilator Tracker on known bony landmarks.

Note

Please note that the Anteralign™ TL inserter is not symmetric and the projection tool references the center point of the trial/implant. This will appear offset if the user saves any projections from a symmetric disc prep tool.

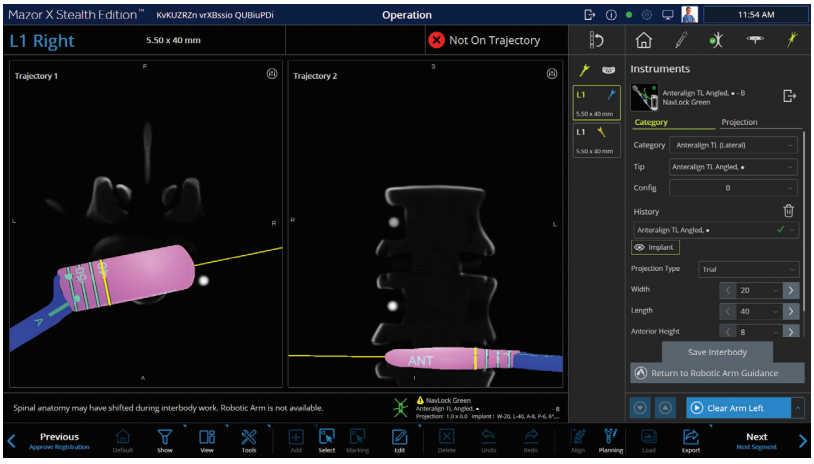


Figure 30

Interbody Placement

Before inserting the Anteralign™ TL spinal system implant, place autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft in the central cavity of the implant. Attach the Anteralign™ TL spinal system implant to the navigated inserter. On the Mazor™ system workstation, select the appropriate implant size. Use a mallet to gently insert the implant (**Figure 31**). The navigated inserter is then unthreaded from the implant and removed.

Note

There is no all-in-one navigated interbody/mini-plate inserter. Using the navigated inserter to place the interbody while also using the mini-plate requires in situ placement. For details, refer to the mini-plate placement section of the technique.

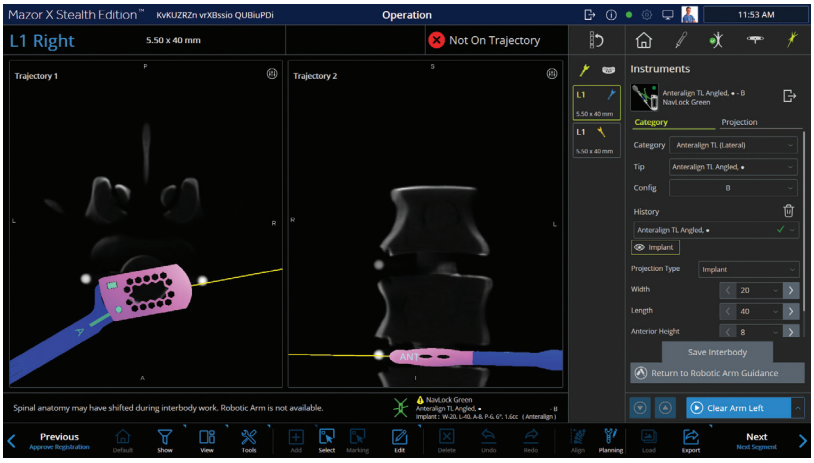
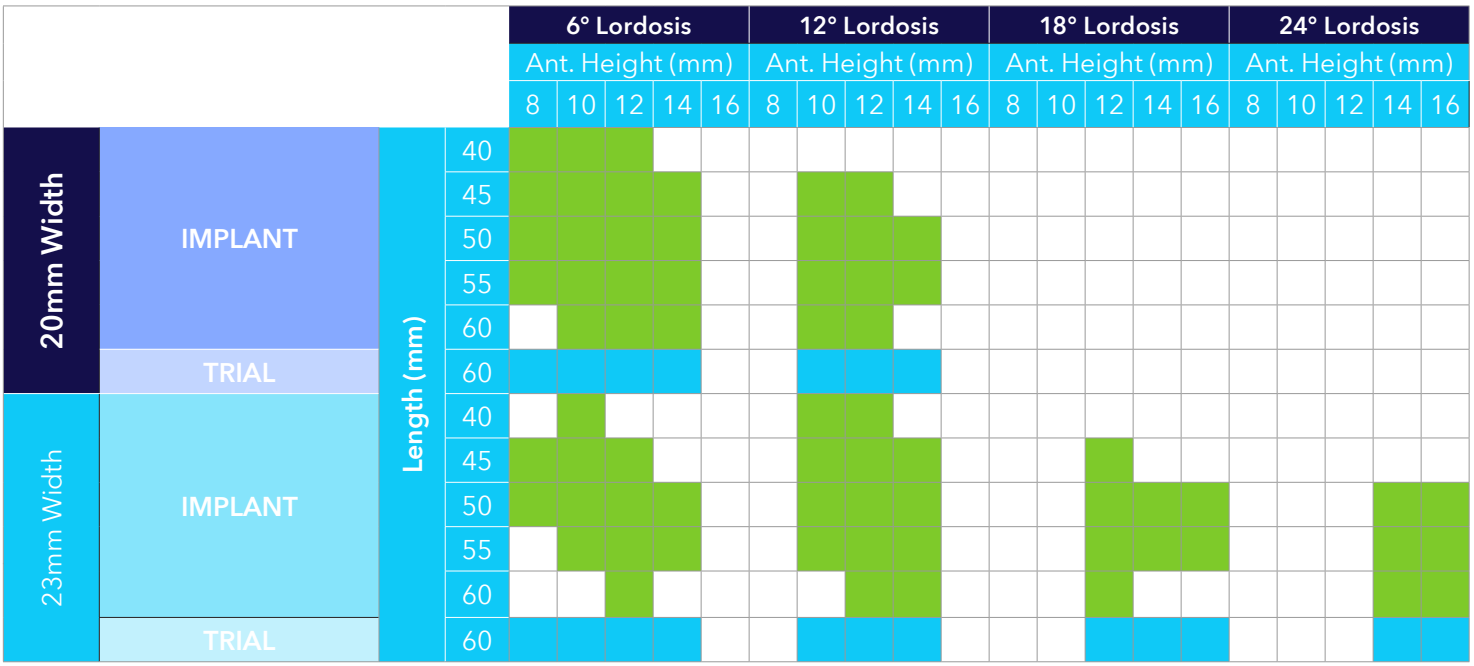


Figure 31

Product ordering information

Implant Sizing



Graft Volume

6° 20 Width

Part Number	Description	Graft Volume (cc^3)
46260840	Ti 6° 20w 8 × 40mm	1.585
46260845	Ti 6° 20w 8 × 45mm	1.823
46260850	Ti 6° 20w 8 × 50mm	2.160
46260855	Ti 6° 20w 8 × 55mm	2.385
46261040	Ti 6° 20w 10 × 40mm	2.213
46261045	Ti 6° 20w 10 ×45mm	2.562
46261050	Ti 6° 20w 10 × 50mm	3.010
46261055	Ti 6° 20w 10 × 55mm	3.353
46261060	Ti 6° 20w 10 × 60mm	3.797
46261240	Ti 6° 20w 12 × 40mm	2.829
46261245	Ti 6° 20w 12 × 45mm	3.287
46261250	Ti 6° 20w 12 × 50mm	3.844
46261255	Ti 6° 20w 12 × 55mm	4.296
46261260	Ti 6° 20w 12 × 60mm	4.849
46261445	Ti 6° 20w 14 × 45mm	4.012
46261450	Ti 6° 20w 14 × 50mm	4.678
46261455	Ti 6° 20w 14 × 55mm	5.239
46261460	Ti 6° 20w 14 × 60mm	5.902

12° 20 Width

Part Number	Description	Graft Volume (cc^3)
46221045	Ti 12° 20w 10 × 45mm	2.161
46221050	Ti 12° 20w 10 × 50mm	2.549
46221055	Ti 12° 20w 10 × 55mm	2.825
46221060	Ti 12° 20w 10 × 60mm	3.203
46221245	Ti 12° 20w 12 × 45mm	2.903
46221250	Ti 12° 20w 12 × 50mm	3.403
46221255	Ti 12° 20w 12 × 55mm	3.797
46221260	Ti 12° 20w 12 × 60mm	4.292
46221450	Ti 12° 20w 14 × 50mm	4.237
46221455	Ti 12° 20w 14 × 55mm	4.740

Graft Volume (continued)

6° 23 Width

Part Number	Description	Graft Volume (cc^3)
46360845	Ti 6° 23w 8 × 45mm	2.202
46360850	Ti 6° 23w 8 × 50mm	2.608
46361040	Ti 6° 23w 10 × 40mm	2.681
46361045	Ti 6° 23w 10 × 45mm	3.103
46361050	Ti 6° 23w 10 × 50mm	3.648
46361055	Ti 6° 23w 10 × 55mm	4.062
46361245	Ti 6° 23w 12 × 45mm	3.986
46361250	Ti 6° 23w 12 × 50mm	4.662
46361255	Ti 6° 23w 12 × 55mm	5.208
46361260	Ti 6° 23w 12 × 60mm	5.880
46361450	Ti 6° 23w 14 × 50mm	5.677
46361455	Ti 6° 23w 14 × 55mm	6.355

12° 23 Width

Part Number	Description	Graft Volume (cc^3)
46321040	Ti 12° 23w 10 × 40mm	2.203
46321045	Ti 12° 23w 10 × 45mm	2.543
46321050	Ti 12° 23w 10 × 50mm	3.001
46321055	Ti 12° 23w 10 × 55mm	3.331
46321240	Ti 12° 23w 12 × 40mm	2.976
46321245	Ti 12° 23w 12 × 45mm	3.450
46321250	Ti 12° 23w 12 × 50mm	4.047
46321255	Ti 12° 23w 12 × 55mm	4.512
46321260	Ti 12° 23w 12 × 60mm	5.105
46321445	Ti 12° 23w 14 ×45mm	4.333
46321450	Ti 12° 23w 14 × 50mm	5.061
46321455	Ti 12° 23w 14 × 55mm	5.659
46321460	Ti 12° 23w 14 × 60mm	6.383

18° 23 Width

Part Number	Description	Graft Volume (cc^3)
46381245	Ti 18° 23w 12 × 45mm	2.921
46381250	Ti 18° 23w 12 × 50mm	3.430
46381255	Ti 18° 23w 12 × 55mm	3.810
46381260	Ti 18° 23w 12 × 60mm	4.317
46381450	Ti 18° 23w 14 × 50mm	4.468
46381455	Ti 18° 23w 14 × 55mm	4.983
46381650	Ti 18° 23w 16 × 50mm	5.497
46381655	Ti 18° 23w 16 × 55mm	6.145

24° 23 Width

Part Number	Description	Graft Volume (cc^3)
46341450	Ti 24° 23w 14 × 50mm	3.810
46341455	Ti 24° 23w 14 × 55mm	4.239
46341460	Ti 24° 23w 14 × 60mm	4.796
46341650	Ti 24° 23w 16 × 50mm	4.844
46341655	Ti 24° 23w 16 × 55mm	5.407
46341660	Ti 24° 23w 16 × 60mm	6.085

Instruments

SPS03005 Instrument Set

Part Number	Description	Qty
4680000	Angled Awl Sleeve	1
4680001	Angled Awl Shaft	1
4680002	Straight Awl Sleeve	1
4680003	Straight Awl Shaft	1
4680004	Inserter Interbody/Trial	2
4680005	Inserter Interbody/Trial Shaft	2
4680006	Miniplate Inserter	1
4680007	Miniplate Shaft	1
4680008	Balljoint Driver	1
4680009	Straight Driver	1
4680010	Bolt Driver	1
4680011	Loading Block	1
4680013	Dual-Ended Slaphammer	1
G307407	Quick-Connect Ratcheting Silicone Handle	2

SPS03006 Navigated Instrument Set

Part Number	Description	Qty
4680000	Angled Awl Sleeve	1
4680001	Angled Awl Shaft	1
4680002	Straight Awl Sleeve	1
4680003	Straight Awl Shaft	1
4680006	Miniplate Inserter	1
4680007	Miniplate Shaft	1
4680008	Balljoint Driver	1
4680009	Straight Driver	1
4680010	Bolt Driver	1
4680011	Loading Block	1
4680013	Dual-Ended Slaphammer	1
G307407	Quick-Connect Ratcheting Silicone Handle	2

SPS03007 Anteralign™ TL Trials

Part Number	Description	Qty
46812608	Trial 6dg 20w 8 × 60mm	1
46812610	Trial 6dg 20w 10 × 60mm	1
46812612	Trial 6dg 20w 12 × 60mm	1
46812614	Trial 6dg 20w 14 × 60mm	1
46812210	Trial 12dg 20w 10 × 60mm	1
46812212	Trial 12dg 20w 12 × 60mm	1
46812214	Trial 12dg 20w 14 × 60mm	1
46813608	Trial 6dg 23w 8 × 60mm	1
46813610	Trial 6dg 23w 10 × 60mm	1
46813612	Trial 6dg 23w 12 × 60mm	1
46813614	Trial 6dg 23w 14 × 60mm	1
46813210	Trial 12dg 23w 10 × 60mm	1
46813212	Trial 12dg 23w 12 × 60mm	1
46813214	Trial 12dg 23w 14 × 60mm	1
46813812	Trial 18dg 23w 12 × 60mm	1
46813814	Trial 18dg 23w 14 × 60mm	1
46813816	Trial 18dg 23w 16 × 60mm	1
46813414	Trial 24dg 23w 14 × 60mm	1
46813416	Trial 24dg 23w 16 × 60mm	1

Implants

SPS03011 Miniplate and Bone Screws

Part Number	Description	Qty
4675020	Bone Screw 5.0 × 20mm	2
4675030	Bone Screw 5.0 × 30mm	2
4675040	Bone Screw 5.0 × 40mm	2
4675050	Bone Screw 5.0 × 50mm	2
46831220	Miniplate Small 12 × 20mm	2
46831223	Miniplate Large 12 × 23mm	2
46841220	Miniplate 12 × 20mm Offset 2.5mm	2
46841223	Miniplate 12 × 23mm Offset 2.5mm	2

SPS03012 Anteralign™ TL 6°

Part Number	Description	Qty
46260840	Spacer Ti 6dg 20w 8 × 40mm	1
46260845	Spacer Ti 6dg 20w 8 × 45mm	2
46260850	Spacer Ti 6dg 20w 8 × 50mm	2
46260855	Spacer Ti 6dg 20w 8 × 55mm	1
46261040	Spacer Ti 6dg 20w 10 × 40mm	1
46261045	Spacer Ti 6dg 20w 10 × 45mm	2
46261050	Spacer Ti 6dg 20w 10 × 50mm	2
46261055	Spacer Ti 6dg 20w 10 × 55mm	2
46261060	Spacer Ti 6dg 20w 10 × 60mm	1
46261240	Spacer Ti 6dg 20w 12 × 40mm	1
46261245	Spacer Ti 6dg 20w **12 × 45mm**	2
46261250	Spacer Ti 6dg 20w **12 × 50mm**	2
46261255	Spacer Ti 6dg 20w **12 × 55mm**	2
46261260	Spacer Ti 6dg 20w **12 × 60mm**	1
46261445	Spacer Ti 6dg 20w **14 × 45mm**	1
46261450	Spacer Ti 6dg 20w **14 × 50mm**	2
46261455	Spacer Ti 6dg 20w **14 × 55mm**	2
46261460	Spacer Ti 6dg 20w **14 × 60mm**	1
46360845	Spacer Ti 6dg 23w **8 × 45mm**	1
46360850	Spacer Ti 6dg 23w **8 × 50mm**	1
46361040	Spacer Ti 6dg 23w **10 × 40mm**	1
46361045	Spacer Ti 6dg 23w **10 × 45mm**	1
46361050	Spacer Ti 6dg 23w **10 × 50mm**	1
46361055	Spacer Ti 6dg 23w **10 × 55mm**	1
46361245	Spacer Ti 6dg 23w **12 × 45mm**	1
46361250	Spacer Ti 6dg 23w **12 × 50mm**	1
46361255	Spacer Ti 6dg 23w 12 × 55mm	1
46361260	Spacer Ti 6dg 23w 12 × 60mm	1
46361450	Spacer Ti 6dg 23w 14 × 50mm	1
46361455	Spacer Ti 6dg 23w 14 × 55mm	1

SPS03013 Anteralign™ TL 12°

Part Number	Description	Qty
46221045	Spacer Ti 12DG 20w 10 × 45mm	1
46221050	Spacer Ti 12DG 20w 10 × 50mm	2
46221055	Spacer Ti 12DG 20w 10 × 55mm	1
46221060	Spacer Ti 12DG 20w 10 × 60mm	1
46221245	Spacer Ti 12DG 20w 12 × 45mm	1
46221250	Spacer Ti 12DG 20w 12 × 50mm	2
46221255	Spacer Ti 12DG 20w 12 × 55mm	2
46221260	Spacer Ti 12DG 20w 12 × 60mm	1
46221450	Spacer Ti 12DG 20w 14 × 50mm	1
46221455	Spacer Ti 12DG 20w 14 × 55mm	1
46321040	Spacer Ti 12DG 23w 10 × 40mm	1
46321045	Spacer Ti 12DG 23w 10 × 45mm	2
46321050	Spacer Ti 12DG 23w 10 × 50mm	2
46321055	Spacer Ti 12DG 23w 10 × 55mm	1
46321240	Spacer Ti 12DG 23w 12 × 40mm	1
46321245	Spacer Ti 12DG 23w 12 × 45mm	2
46321250	Spacer Ti 12DG 23w 12 × 50mm	2
46321255	Spacer Ti 12DG 23w 12 × 55mm	2
46321260	Spacer Ti 12DG 23w 12 × 60mm	1
46321445	Spacer Ti 12DG 23w 14 × 45mm	1
46321450	Spacer Ti 12DG 23w 14 × 50mm	2
46321455	Spacer Ti 12DG 23w 14 × 55mm	2
46321460	Spacer Ti 12DG 23w 14 × 60mm	1

SPS03016 Anteralign™ TL HL

Part Number	Description	Qty
46381245	Spacer Ti 18DG 23w 12 × 45mm	1
46381250	Spacer Ti 18DG 23w 12 × 50mm	1
46381255	Spacer Ti 18DG 23w 12 × 55mm	1
46381260	Spacer Ti 18DG 23w 12 × 60mm	1
46381450	Spacer Ti 18DG 23w 14 × 50mm	1
46381455	Spacer Ti 18DG 23w 14 × 55mm	1
46381650	Spacer Ti 18DG 23w 16 × 50mm	1
46381655	Spacer Ti 18DG 23w 16 × 55mm	1
46341450	Spacer Ti 24DG 23w 14 × 50mm	1
46341455	Spacer Ti 24DG 23w 14 × 55mm	1
46341460	Spacer Ti 24DG 23w 14 × 60mm	1
46341650	Spacer Ti 24DG 23w 16 × 50mm	1
46341655	Spacer Ti 24DG 23w 16 × 55mm	1
46341660	Spacer Ti 24DG 23w 16 × 60mm	1

Preparation Instructions for Infuse™ Bone Graft Component

7510050 XX Small Kit (0.7cc)

Notes

You will need to prepare a sterile and nonsterile 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) 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

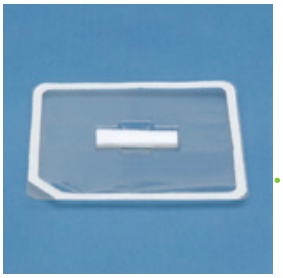
Reconstitute the rhBMP-2 with 0.9mL of sterile water.

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.

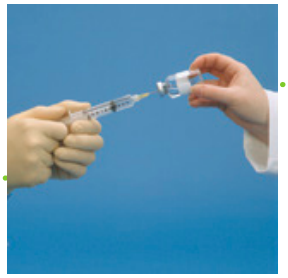
In non-sterile field

5



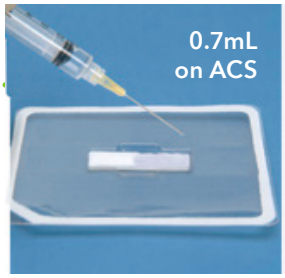
Open the inner ACS package leaving the collagen sponge in the plastic tray.

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)

Notes

You will need to prepare a sterile and nonsterile 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) 10mL 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 needle and 3mL syringe/needle, withdraw 0.9mL of sterile water for injection.

3

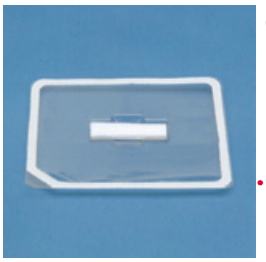
Reconstitute the rhBMP-2 with 0.9mL of sterile water.

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 non-sterile field

5

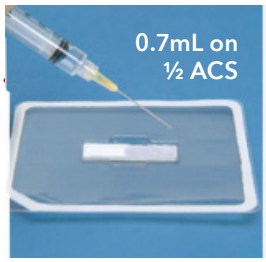


Open the inner ACS package leaving the collagen sponge in the plastic tray.

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

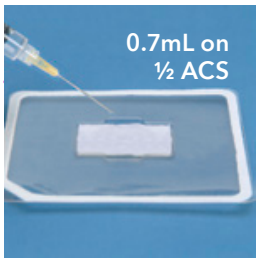


Uniformly distribute 0.7mL of reconstituted rhBMP-2 on the ½" × 2" collagen sponge. Inspect the sponge. If dark particles are observed, do not use and return to sponsor.

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 nonsterile 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)

Notes

You will need to prepare a sterile and nonsterile 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) 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 non-sterile field

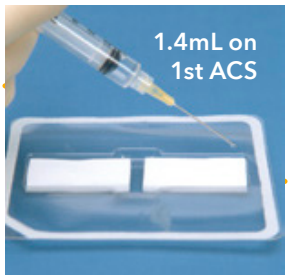
5

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

6

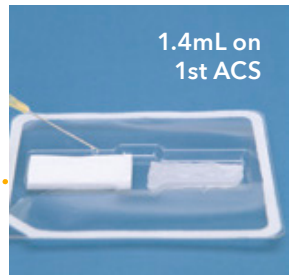
In the sterile field use the 3mL syringe/ needle to withdraw 0.7mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

7



Uniformly distribute 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)

Notes

You will need to prepare a sterile and nonsterile 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) 10mL vials

(2) 4.2mg vial

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

In non-sterile field

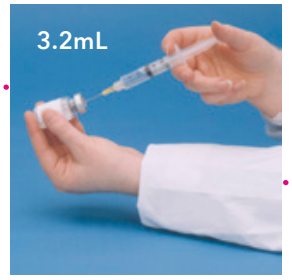
1

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



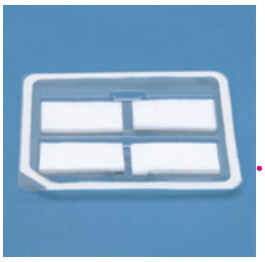
Reconstitute one vial of the rhBMP-2 with 3.2mL of sterile water.

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.

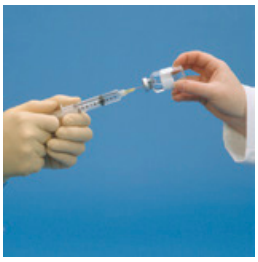
In non-sterile field

5



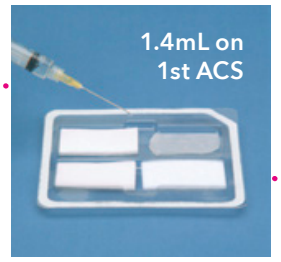
Open the inner ACS package leaving all collagen sponges in the plastic tray.

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.

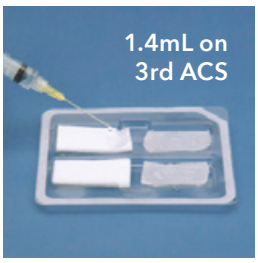
8

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

9

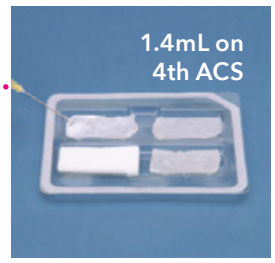
In the sterile field use the second 5mL syringe/ needle to withdraw 1.4mL of reconstituted rhBMP-2 from the second vial held by the person in the non-sterile field.

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)

Notes

You will need to prepare a sterile and nonsterile 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

(6) ACS 1" × 2" (2.54cm × 5.08cm) 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 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

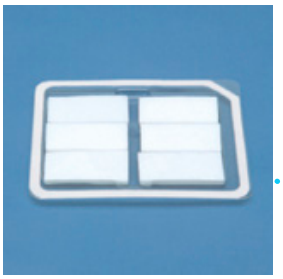
Reconstitute the rhBMP-2 with 8.4mL of sterile water.

4

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

In non-sterile field

5



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

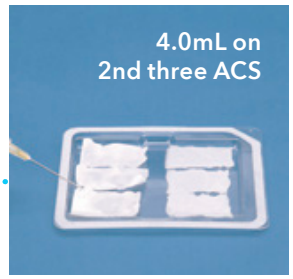
6

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.

7510600 Large Kit (8.0cc)

Notes

You will need to prepare a sterile and nonsterile 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

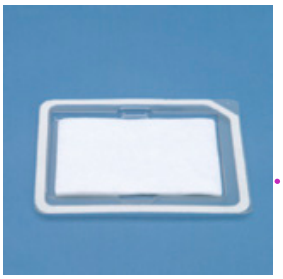
Reconstitute the rhBMP-2 with 8.4mL of sterile water.

4

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

In non-sterile field

5

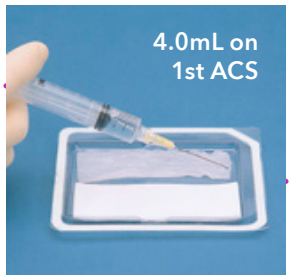


Open the inner ACS package. Using sterile scissors, cut the 3" × 4" collagen sponge into two 1 1/2" × 4" strips. Return the cut collagen sponges to the plastic tray.

6

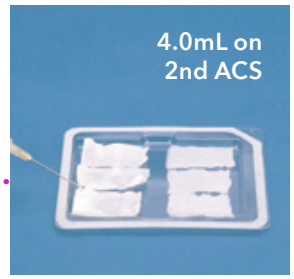
In the sterile field use the 10mL syringe/needle to withdraw 4.0mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

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.

Infuse™ bone graft components

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

Infuse™ Bone Graft Fill Guidelines

Infuse™ Bone Graft/Anteralign™ Spinal System TL Combinations					
Anteralign™ Spinal System TL Interbody Cage			Appropriate Infuse™ Bone Graft Kit		Reconstituted rhBMP-2/ ACS graft volume
Lordosis, Width	Part #	Size (height X length)	Part #	Kit name (size in cc)	
6 deg, 20 mm	46260840	8 x 40mm	7510100	X Small (1.4)	1,4
	46260845	8 x 45mm	7510100	X Small (1.4)	1,4
	46260850	8 x 50mm	"7510100+ 7510050"	"X Small (1.4)+ XX Small (0.7)"	2,1
	46260855	8 x 55mm	"7510100+ 7510050"	"X Small (1.4)+ XX Small (0.7)"	2,1
	46261040	10 x 40mm	"7510100+ 7510050"	"X Small (1.4)+ XX Small (0.7)"	2,1
	46261045	10 x 45mm	7510200	Small (2.8)	2,8
	46261050	10 x 50mm	7510200	Small (2.8)	2,8
	46261055	10 x 55mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
	46261060	10 x 60mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
	46261240	12 x 40mm	7510200	Small (2.8)	2,8
	46261245	12 x 45mm	7510200	Small (2.8)	2,8
	46261250	12 x 50mm	"7510200+ 7510050"	Small (2.8)+ XX Small (0.7)	3,5
	46261255	12 x 55mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46261260	12 x 60mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46261445	14 x 45mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46261450	14 x 50mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46261455	14 x 55mm	7510400	Medium (5.6)	5,6
	46261460	14 x 60mm	7510400	Medium (5.6)	5,6

Infuse™ Fill Guidelines					
Anteralign™ Spinal System TL Interbody Cage			Appropriate Infuse™ Bone Graft Kit		Reconstituted rhBMP-2/ ACS graft volume
Lordosis, Width	Part #	Size (height X length)	Part #	Kit name (size in cc)	
12 deg, 20 mm	46221045	10 x 45mm	"7510100+ 7510050"	"X Small (1.4)+ XX Small (0.7)"	2,1
	46221050	10 x 50mm	7510200	Small (2.8)	2,8
	46221055	10 x 55mm	7510200	Small (2.8)	2,8
	46221060	10 x 60mm	7510200	Small (2.8)	2,8
	46221245	12 x 45mm	7510200	Small (2.8)	2,8
	46221250	12 x 50mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
	46221255	12 x 55mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
	46221260	12 x 60mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46221450	14 x 50mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46221455	14 x 55mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
6 deg, 23 mm	46360845	8 x 45mm	"7510100+ 7510050"	"X Small (1.4)+ XX Small (0.7)"	2,1
	46360850	8 x 50mm	7510200	Small (2.8)	2,8
	46361040	10 x 40mm	7510200	Small (2.8)	2,8
	46361045	10 x 45mm	7510200	Small (2.8)	2,8
	46361050	10 x 50mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
	46361055	10 x 55mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46361245	12 x 45mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46361250	12 x 50mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46361255	12 x 55mm	7510400	Medium (5.6)	5,6
	46361260	12 x 60mm	7510400	Medium (5.6)	5,6
	46361450	14 x 50mm	7510400	Medium (5.6)	5,6
	46361455	14 x 55mm	"7510400+ 7510050"	"Medium (5.6)+ XX Small (0.7)"	6,3

Infuse™ Fill Guidelines					
Anteralign™ Spinal System TL Interbody Cage			Appropriate Infuse™ Bone Graft Kit		Reconstituted rhBMP-2/ ACS graft volume
Lordosis, Width	Part #	Size (height X length)	Part #	Kit name (size in cc)	
12 deg, 23 mm	46321040	10 x 40mm	"7510100+ 7510050"	"X Small (1.4)+ XX Small (0.7)"	2,1
	46321045	10 x 45mm	7510200	Small (2.8)	2,8
	46321050	10 x 50mm	7510200	Small (2.8)	2,8
	46321055	10 x 55mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
	46321240	12 x 40mm	7510200	Small (2.8)	2,8
	46321245	12 x 45mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
	46321250	12 x 50mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46321255	12 x 55mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46321260	12 x 60mm	7510400	Medium (5.6)	5,6
	46321445	14 x 45mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46321450	14 x 50mm	7510400	Medium (5.6)	5,6
	46321455	14 x 55mm	7510400	Medium (5.6)	5,6
	46321460	14 x 60mm	"7510400+ 7510050"	"Medium (5.6)+ XX Small (0.7)"	6,3
18 deg, 23mm	46381245	12 x 45mm	7510200	Small (2.8)	2,8
	46381250	12 x 50mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
	46381255	12 x 55mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
	46381260	12 x 60mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46381450	14 x 50mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46381455	14 x 55mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46381650	16 x 50mm	7510400	Medium (5.6)	5,6
	46381655	16 x 55mm	"7510400+ 7510050"	"Medium (5.6)+ XX Small (0.7)"	6,3
24 deg, 23mm	46341450	14 x 50mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46341455	14 x 55mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46341460	14 x 60mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46341650	16 x 50mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46341655	16 x 55mm	7510400	Medium (5.6)	5,6
	46341660	16 x 60mm	"7510400+ 7510050"	"Medium (5.6)+ XX Small (0.7)"	6,3

Important information on the Anteralign™ spinal system with Titan nanoLOCK™ surface technology

PURPOSE

The Anteralign™ spinal system with Titan nanoLOCK™ surface technology is a fusion device intended to stabilize and promote bone fusion between two adjacent lumbar vertebral bodies during the normal healing process following surgical correction of disorders of the spine. The Anteralign™ spinal system with Titan nanoLOCK™ surface technology is intended for in vivo use and is to be used with autogenous bone graft and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate to facilitate fusion. 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.

DESCRIPTION

The Anteralign™ spinal system with Titan nanoLOCK™ surface technology consists of interbody cages, mini plates, and bone screws. The Anteralign™ spinal system interbody cage, known as Anteralign™ TL, is an additive manufactured titanium cage available in various heights, widths, and lengths with different lordosis options to accommodate patient anatomy. It is inserted between two lumbar vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The Anteralign TL interbody fusion device is rectangular shaped with a large hollow region in the center to house autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate or Infuse™ bone graft (as designated). The design incorporates honeycomb windows and an open void to allow bone growth through the implant.

The interbody device is treated with Titan surface technology, where nanoLOCK™ surface technology (MMN) is designed to improve fixation to the adjacent bone. The nanoLOCK™ surface technology provides a microscopic-roughened surface with nano-scale features. The nanoLOCK™ surface technology is specifically engineered to have nano-textured features at a nanometer (10^{-9}) level, which have demonstrated the ability to elicit an endogenous cellular and biochemical response attributed to these nanotextured features in vitro. The nanoLOCK™ surface technology demonstrates the elements to be considered a nanotechnology as outlined in the FDA nanotechnology guidance.

Anteralign™ TL implants are provided sterile and are intended to be used with supplemental fixation cleared for use in lumbar spine (L2-S1) procedures and may be implanted via a minimally invasive OLIF or minimally invasive or open DLIF approach (except as defined for use with Infuse™ bone graft below).

Mini plates and screws are provided as options for anti-migration of the Anteralign™ TL interbody. The miniplate is additively manufactured from titanium powder with a machined-wrought titanium bolt. The miniplate may be positioned either laterally or obliquely and oriented in either cephalad or caudal direction on the TL cage. The bone screw, which is manufactured from wrought titanium, is then placed through the miniplate intrinsic screw hole. Miniplates and bone screws are offered in different sizes and are provided sterile.

Stainless steel and titanium implants are not compatible. They must not be used together in a construct.

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

INDICATIONS FOR USE

Anteralign™ spinal system with Titan nanoLOCK™ surface technology interbody cages with macro-, micro-, and nano- roughened surface textured features are intended to be used in spinal fusion procedures on skeletally mature patients with symptomatic Degenerative Disc Disease (DDD, defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis, at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion. These patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. These patients should have had six months of nonoperative treatment prior to treatment with this device.

Additionally, the Anteralign™ spinal system with Titan nanoLOCK™ surface technology can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity.

The Anteralign™ spinal system with Titan nanoLOCK™ surface technology is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate or a combination thereof. These implants may be implanted via a minimally invasive OLIF or minimally invasive or open DLIF approach (except as defined for use with Infuse™ bone graft below). The Anteralign™ spinal system must be used with a posterior supplemental internal spinal fixation cleared for use in the lumbar spine.

Miniplate and bone screw components are provided as an option for anti-migration for the lumbosacral levels oblique or lateral above the bifurcation (L2-L5) of the vascular structures. Indications and contraindications of spinal instrumentation systems should be understood by the surgeon.

Certain sizes of the Anteralign TL™ interbody device may also be used with Infuse™ Bone Graft for patients diagnosed with DDD, as defined above, who are skeletally mature and have had six months of non-operative treatment. The device may be implanted at a single level using an Oblique Lateral Interbody Fusion (OLIF) approach from L2- L5 and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. Consult the labeling for the Infuse™ Bone Graft/Medtronic Interbody Fusion Device for information on the specific sizes of the Anteralign™ Spinal System TL interbody device 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.

CONTRAINDICATIONS

This device is not intended for cervical spine use.
Contraindications include:

- Cases where there is translational instability (spondylolisthesis of any grade or retrolisthesis) at the level treated unless posterior supplemental fixation is used to augment stability.
- Cases where posterior elements were removed such that it introduces instability at the level(s) treated unless posterior supplemental fixation is used to augment stability.
- Severe osteoporosis.
- Patients having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Infection local to the operative site.

- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- 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.
- Cases not needing a fusion.
- Cases not described in the indications.
- Patients unwilling to cooperate with postoperative instructions.
- Patients with a known hereditary or acquired bone friability or calcification problem
- Pediatric cases, nor where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Cases where implant components selected for use would be too large or too small to achieve successful results.
- Cases requiring mixing metals from two different components or systems.
- Patients in which implant use 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 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:

- Implant migration.
- Breakage of the device.
- Foreign body reaction to implants including possible tumor formation, auto immune disease, and/or scarring.
- Pressure on surrounding tissues or organs.
- 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.
- Discitis, arachnoiditis, and/or other types of inflammation.
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
- Autogenous bone graft donor site complication.
- Inability to resume activities of normal daily living.
- Early or late loosening of the device.
- Urinary retention, 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 spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or autogenous 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

When used in deformity procedures, under sizing implants 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 results. Supplemental fixation systems which may be used with this device include the CD Horizon™ spinal system, TSRH™ spinal system, Dynalok™ Classic spinal system, Z-Plate II™ anterior fixation system, Pyramid™ anterior plate fixation system, and/or their successors. When additional support instrumentation is used, refer to the package insert for requirements and limitations related to those devices. Use of this product without autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone aspirate may 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 successful use of the system. Further, proper selection and compliance of patients greatly affect results. Patients who smoke were 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 without a previous spinal surgery.

This device was designed for single patient use only. Do not reprocess or reuse this product. Reuse or reprocessing may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

PRECAUTIONS

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

IMPLANT SELECTION

Selection of proper size, shape, and design of implants for each patient is crucial to success of the procedure. Surgical implants are subject to repeated stresses in use, and their strength is limited by

the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage, bending, or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

DEVICE FIXATION
Installation and positional adjustment of implants must only be done with special ancillary instruments and equipment supplied and designated by Medtronic. In the interests of patient safety, it is therefore recommended that Medtronic implants are not used with devices from any other source.

PREOPERATIVE
- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the contraindications should be avoided.
- Care should be used when handling and storing implants. Implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.
- The surgeon should be familiar with the various components before using the equipment and should personally verify all devices and necessary instruments are present before surgery.
- The size of devices should also be determined prior to surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
- Additional sterile implants and instruments should be available in case of an unexpected need.

INTRAOPERATIVE
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implants may cause injury to patients or operative personnel.
- To ensure proper fusion below and around the location of the fusion, autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate must be used.
- Bone cement should not be used because this material may make removal of these components difficult or impossible.

POSTOPERATIVE
The surgeon's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
- Detailed instructions on use and limitations of the device should be given to the patient.
- Patients must be warned that loosening, and/or breakage of the device are complications which may occur as a result of excessive weight bearing, muscular activity or sudden jolts or shock to the spine.
- To allow maximum chances for a successful surgical result, patients or devices should not be exposed to mechanical vibrations that may loosen the device construct. Patients should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. Patients should be advised not to smoke or consume excess alcohol during the bone fusion process.
- Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- It is important that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if components loosen, migrate, and/ or break, devices should be revised and/or removed immediately before serious injury occurs.
- The implants are interbody devices and are intended to stabilize the operative area during the fusion process.
- Retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

PACKAGING
If devices are individually packaged, the packages for each of the implants and/or instruments should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure there is no damage prior to use. Once the seal on the sterile package is broken, the product should not be re-sterilized. Damaged packages or products should not be used and should be returned to Medtronic.

STERILE IMPLANTS
Implants are provided sterile and should only be used if they are marked sterile and clearly labeled as such in an unopened sterile package provided by the company. Only sterile products should be placed in the operative field. Implants should never be reprocessed.

CLEANING AND DECONTAMINATION
Instruments have reprocessing instructions enclosed within the product packaging. Refer to these detailed instructions for further information on the general considerations, cleaning, and sterilization procedures. These reprocessing instructions can also be found at http://manuals.medtronic.com/ according to the product part number.

PRODUCT COMPLAINTS
To report product problems, contact Medtronic.

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

Brief Summary

NOTE: The Perimeter™, Clydesdale™, Divergence-L™, and Pivox™, and Anteralign™ Spinal System TL 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

Infuse™ Bone Graft/Anteralign™ Spinal System with Titan nanoLOCK™ Surface Technology

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 Anteralign™ Spinal System LS 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 Anteralign™ Spinal System TL interbody device 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, the Pivox™ oblique lateral spinal system, and the Anteralign™ 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.

Important information on the Mazor X Stealth Edition™ robotic guidance system

The Mazor X™ system is indicated for precise positioning of surgical instruments or spinal implants during general spinal surgery. It may be used in open or minimally invasive or percutaneous procedures.

Mazor X™ system 3D imaging capabilities provide a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects.

The Mazor X™ system navigation tracks the position of instruments, during spinal surgery, in relation to the surgical anatomy and identifies this position on diagnostic or intraoperative images of a patient.

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

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

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

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

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