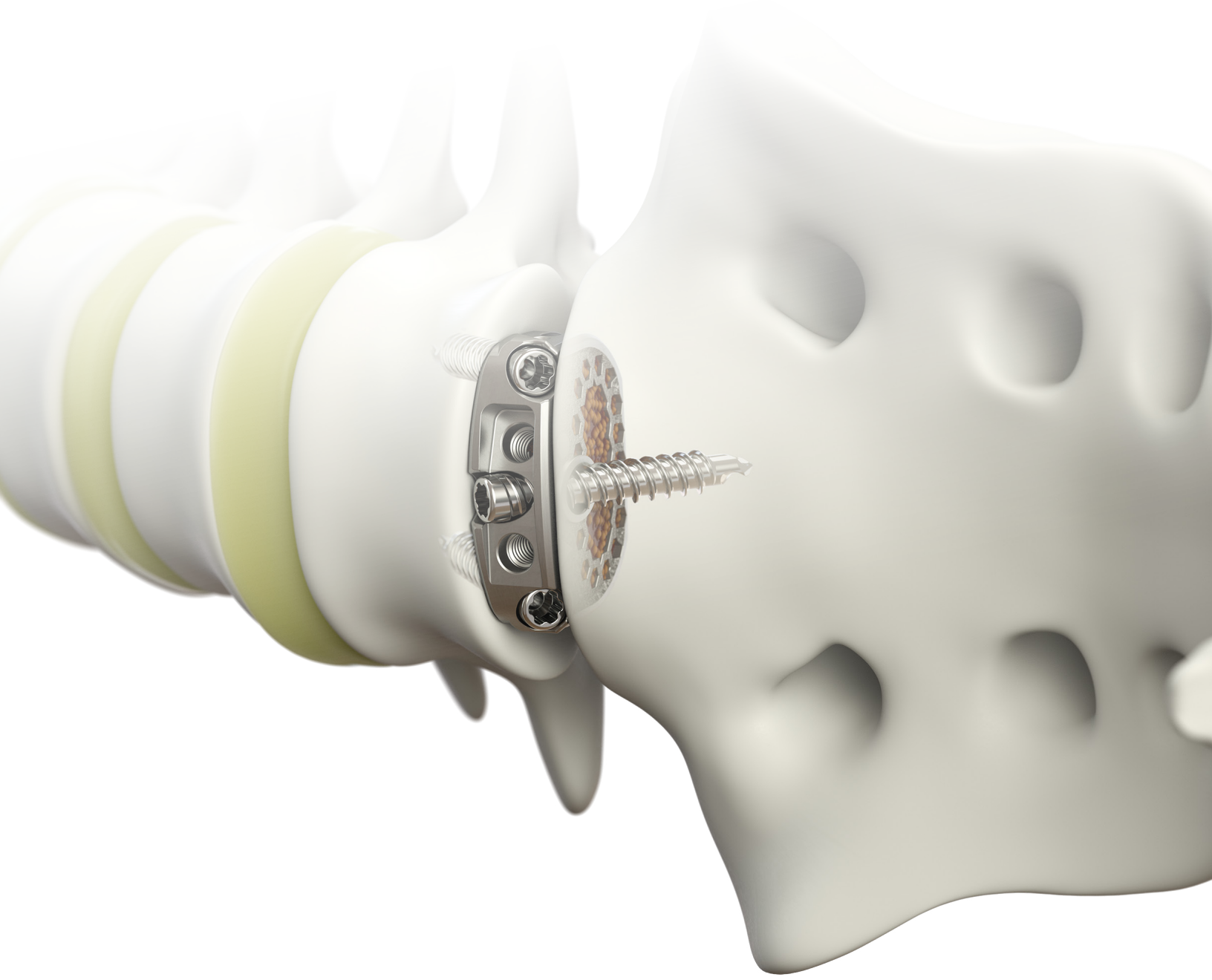
Medtronic

SURGICAL TECHNIQUE

Anteralign™ LS

Spinal system with Infuse™ bone graft



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System overview

The Anteralign™ LS spinal system is a streamlined Implant system intended to be used in anterior and oblique spinal approaches and four procedures: SynergyOLIF51™, SynergyALIF™, OLIF51™, and ALIF (**Figure 1**).

Note
The Anteralign™ LS spinal system can only be navigated via the OLIF51™ procedure on Mazor™ robotic guidance platform.

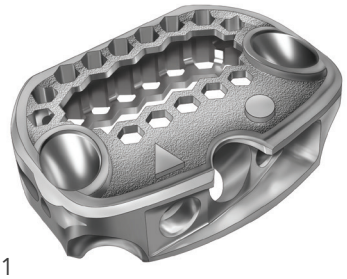


Figure 1

The Anteralign™ LS 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 to be used as a standalone device at <16° when all three intrinsic screws are used (**Figure 2**).

Figure 2

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. Anteralign™ LS is intended to be used as a standalone device for 6- or 12-degree size offerings when all three intrinsic screws are used. Without use of all three intrinsic screws, supplemental fixation is required. Anteralign™ LS system is intended for use with supplemental internal fixation systems cleared for use in the lumbar spine.

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

The inserter can be used with all the Anteralign™ trials and implants. The foot of the inserter features a line to help with proper orientation of the implant on the inserter. The Anteralign™ LS implant and trials are marked with a circle for oblique (20° offset) and a triangle for straight orientations (**Figure 3**).

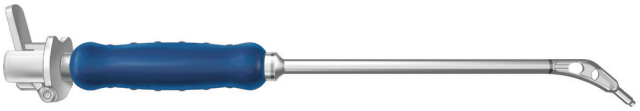
Figure 3

Instrument overview

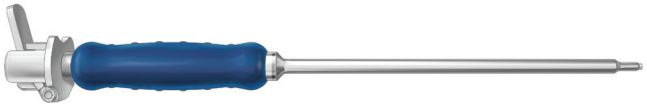
Anteralign™ Inserter
4680004 and 4680005

Loading Block
4680011

Anteralign™ Navigated Inserter
NAV4680003



Angled Awl
4680000 and 4680001



Straight Awl
4680002 and 4680003

Straight Screwdriver
4680009†

Ball Joint Driver
4680008†

Torque Limiting Handle
G307407

†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

Access

The Anteralign™ LS trials and implants can be used during an OLIF51™ procedure or an ALIF procedure, depending upon the surgeon's preference and anatomical considerations (**Figures 4 and 5**). 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.

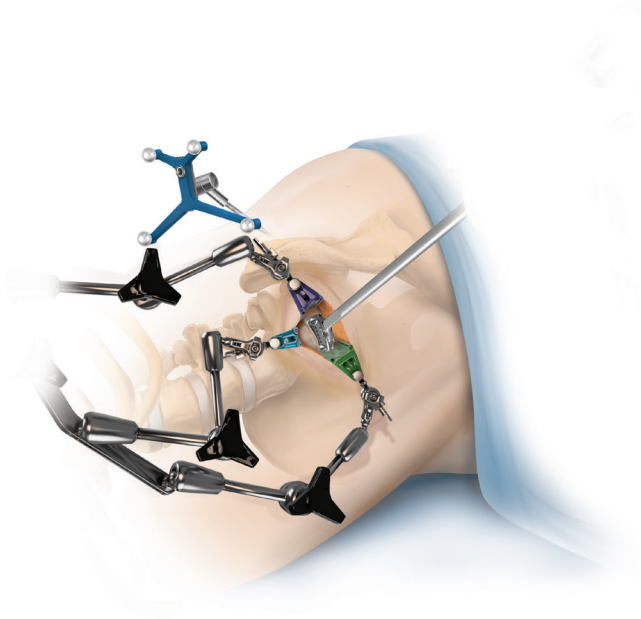


Figure 4

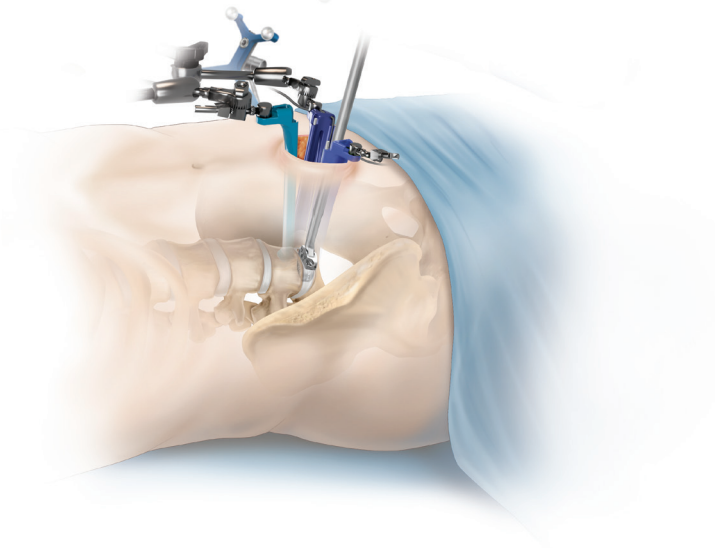


Figure 5

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™ LS 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 6**).

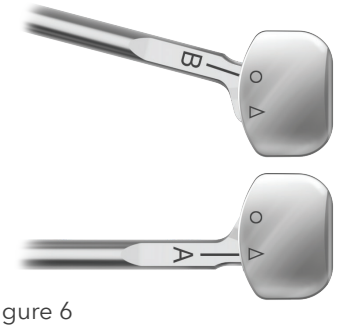


Figure 6

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

Tighten the inner shaft to secure the trial to the inserter. A clicking sound from the anti-backout ratchet plate will be heard while tightening Continue tightening until the trial is firmly attached to the inserter.

The trial is impacted into the disc space. A properly sized trial should be centered with the spinous process and should span the entire apophyseal ring in order to reach fully across the vertebral body end plate.

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

Sequentially trial, checking the size via fluoroscopy, until the desired implant size is obtained.

If removal force is too high, attach the slap hammer to the distal end of the inserter to remove the trial from the disc space (**Figure 7**).

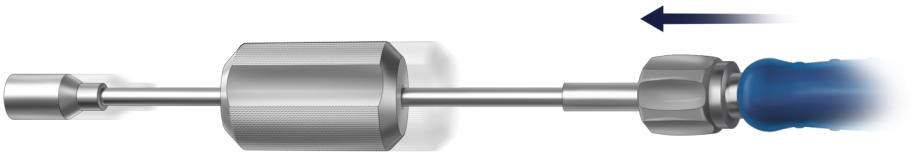


Figure 7

Placement of bone graft

The Anteralign™ LS spinal system implant may be used with Grafton™ DBF bone graft hydrated with bone marrow aspirate, autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft (**Figure 8**).

- An appropriate amount of bone graft should be used according to the internal volume of the Anteralign™ LS 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™ LS spinal system implant may be used with Infuse bone graft.
- If using Infuse™ bone graft:
  - An appropriate amount of Infuse™ bone graft should be used according to the internal volume of the Anteralign™ LS implant. Refer to the Fill Guidelines on page 34 for the appropriate kit(s) to be used with the corresponding Anteralign™ LS implant.
  - At this time, prepare the appropriate Infuse™ bone graft kit(s). Refer to pages 27-32 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 8b)**.
  - If desired, a resorbable polyglactic 910 suture (e.g. VICRYL™ Suture) may be wrapped around the exterior of the implant to secure Infuse™ bone graft during implantation.

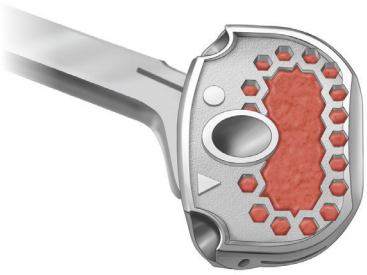


Figure 8

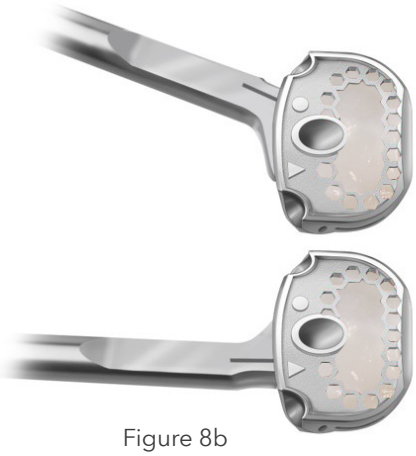


Figure 8b

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 triangle 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 9**). Typically, the angled option has been used for the oblique approach and the straight option has been used for ALIF approach, but this is not required.

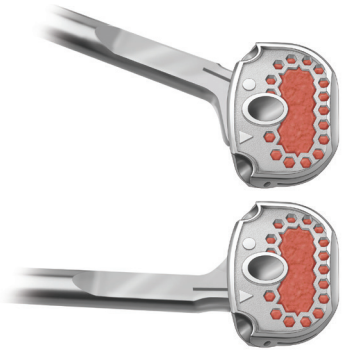


Figure 9

Ensure the inner shaft is in the inserter. Place the implant, with bone graft inserted, onto the inserter in the desired orientation. Tighten the inner shaft to secure the implant to the inserter. A clicking sound from the anti-backout ratchet plate will be heard while tightening. Continue tightening until the trial is firmly attached to the inserter (**Figure 10**). Place the implant into the disc space, confirming location with fluoroscopy or navigation. Unthread the inserter from the implant and remove the inserter.

Figure 10

Pilot hole preparation

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 on the implant first and be malleted to have the distal end protrude out of the housing and make the pilot hole (**Figure 11**). Both awl options protrude a length of 15mm and are 3.35mm in diameter at the distal tip. The lever on the side of the awl can be used to release (**Figure 12**).

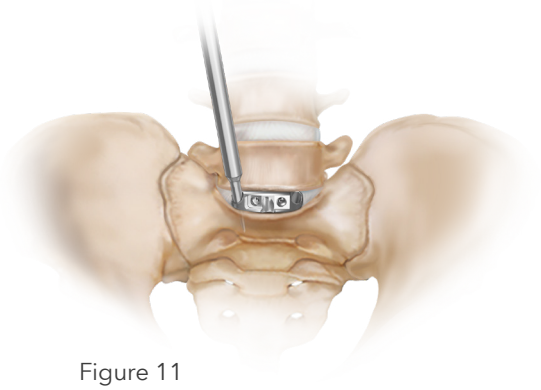


Figure 11

Intrinsic screw fixation

To insert the screws, choose the desired screw length. Place the screw in the loading block, if desired, and insert the driver. The straight or ball joint driver can be used based off surgeon preference. Insert the screw into the Implant and tighten. Repeat with remaining screws.

The screw contains a ti-on-ti locking mechanism and tapered fit into the screw hole to prevent backout.

Note

When using Anteralign™ LS spinal system with an OLIF51™ approach, the screws are oriented to have two screws in the cephalad direction and one screw in the caudad direction. For an ALIF approach, the screws can be placed in either direction as per surgeon preference.

Note

When using the Anteralign™ LS implant as a standalone device, it is recommended to orient two screws cephalad and one screw caudal.

Note

In addition to the retention drivers that come standard in the set, non-retention straight screwdriver and ball joint driver can be ordered if preferred. If a non-retention driver is chosen for screw insertion, it is recommended to use bone wax to retain the screw on the screwdriver shaft.

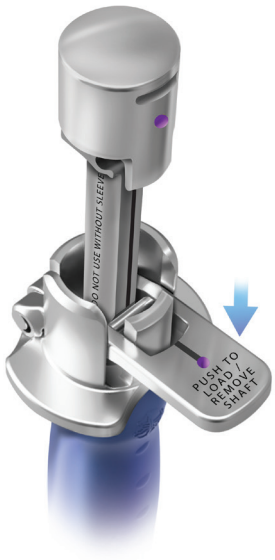


Figure 12

Closure

After the Anteralign™ LS implant with autograft material and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate has been inserted into the disc space, the stability pin may be unthreaded and removed. The retractor is then detached from the flex arm and the retractor blades are carefully withdrawn from the surgical site. As the retractor is removed, the muscle and fat layers can be visualized closing back into place.

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

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

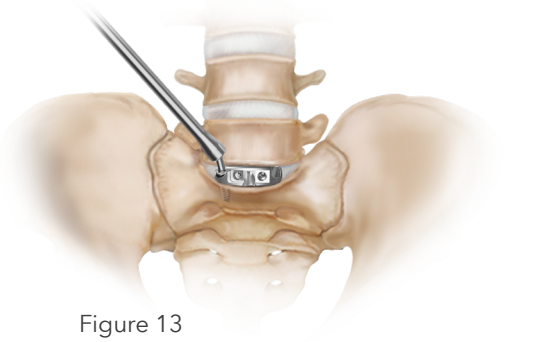


Figure 13

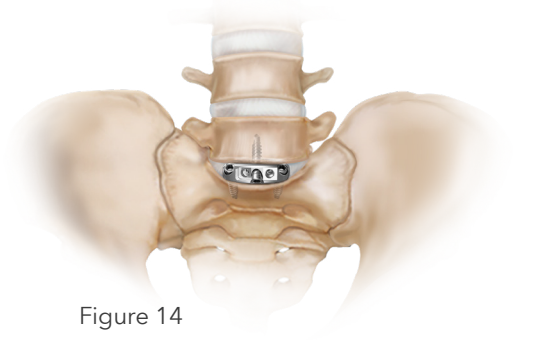


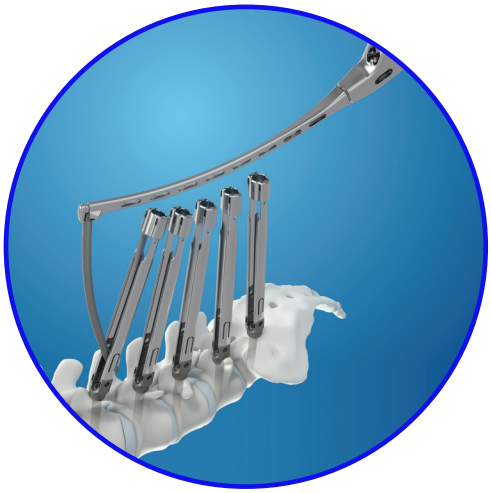
Figure 14

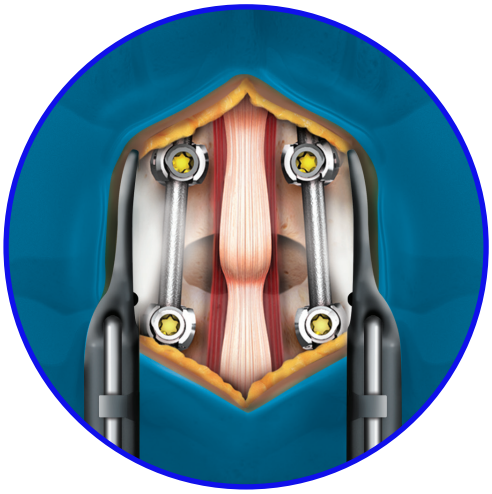
Fixation

Supplemental instrumentation must be placed if the physician chooses to use less than three of the Anteralign™ screws. The interbody fusion device can be used with any supplemental fixation systems cleared for use in the lumbar spine. However, all Anteralign™ LS interbody devices greater than 16° must include the usage of supplemental fixation. Any size cage used in patients as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity conditions must include the usage of supplemental fixation. Refer to the appropriate surgical technique for supplemental instrumentation instructions. 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



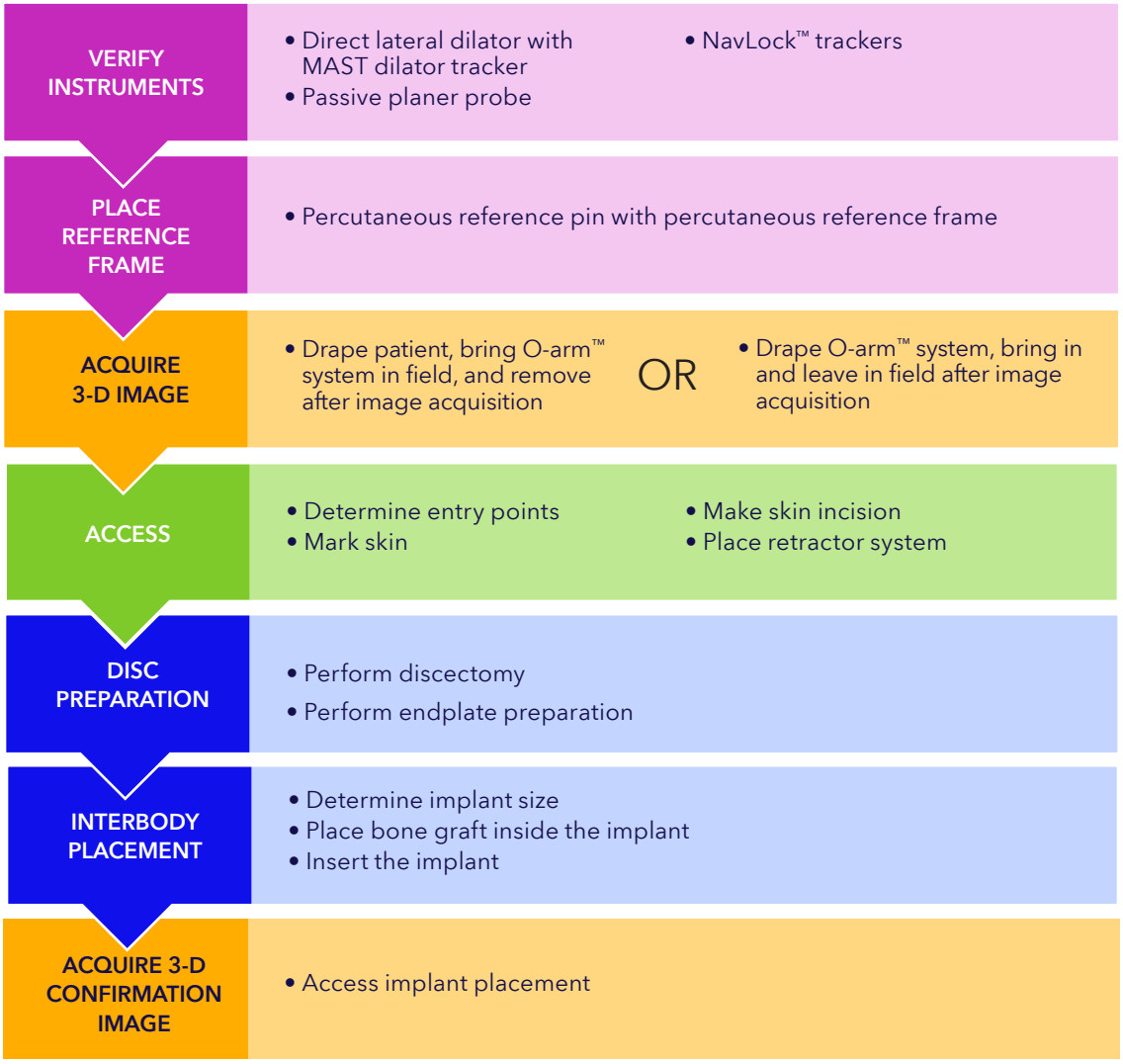


Explantation

Should it be necessary to remove or reposition the Anteralign™ LS spinal system implant, the slap hammer may be used. Use the screwdriver to remove any screws. Reattach the inserter to the implant and remove, using the slap hammer.

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

Navigated Anteralign™ LS spinal system workflow



StealthStation™ navigation set-up

For a navigated surgery, the OR should be equipped with the O-arm™ image acquisition system, the Mobile Viewing Station (MVS), and the StealthStation™ system. Consult the StealthStation™ system and O-arm™ imaging system manuals for complete indications, warnings, precautions, important medical information, and instruction on equipment and OR set-up, reference frame placement, registration, and StealthStation™ spine software workflow such as correct procedure selection, instrument verification, and image acquisition.

Important
Ensure the reference frame is properly secured to anatomy. Neglecting to verify that the reference frame is secured could result in navigational inaccuracy if the hardware moves in relation to the anatomy after registration is complete.

Workflow selections

Inserter verification

To determine Anteralign™ LS trial and/or implant size, the must make appropriate selections within the StealthStation™ system software.

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

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

1. Verify the NavLock™ tracker with an instrument such as an awl. Then, change NavLock™ tracker to pair with the Anteralign toolcard.
2. Verify the NavLock™ tracker with the Anteralign™ LS inserter. To do this, the Tip field must be set to Verify Inserter. The inner threaded shaft must be placed in the reference frame divot (**Figure 15**).

The inner threaded shaft may need to be pushed forward to expose the threaded shaft. Once the inserter is verified, the user must choose the straight or angled tip to match the physical assembly. Typically, the angled option has been used for the oblique approach and the straight option has been used for ALIF 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™ LS 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™ LS Angled or Anteralign™ LS Straight to match the orientation of the attached implant or trial. 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™ LS 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™ LS inserter (**Figure 16**). In the toolcard, select configuration A or B to correspond with the A/B orientation of the NavLock™ tracker on the navigated Anteralign™ LS inserter (**Figure 17**).

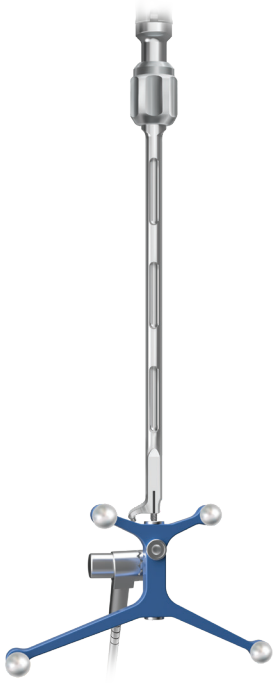


Figure 15

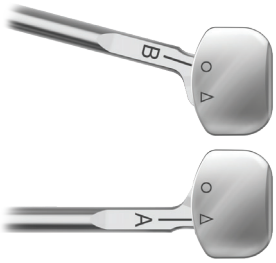


Figure 16

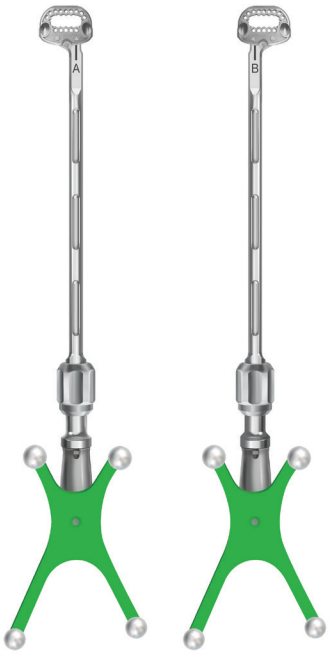


Figure 17

When the above category selections are made, the user can move on to the Implant/Trial selections. In an effort to make the Anteralign™ LS spinal system streamlined and efficient, only available 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, the banner will read, "No corresponding implant size" (**Figure 18**). In the situation where a size is selected where there is no implant or trial available, it will say "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 footprint 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 the implant for a more efficient workflow.

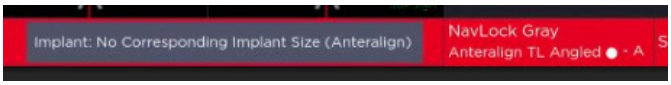


Figure 18

Navigated 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 (**Figures 19a and 19b**).

Anteralign™ LS Spinal System Trials are available in 8mm, 10mm, 12mm, 14mm, 16mm, and 18mm, 20mm heights, small, medium, and large footprints, and 6, 12-, 18-, 24-, and 30-degree lordoses. If other size options are desired, follow the Synergy ALIF™ and SynergyOLIF51™ surgical techniques using non-navigated instruments for the trialing step. The trials are passed through the retractors direct anteriorly or obliquely. On the StealthStation™ system, select the appropriately sized trial. Insert the Anteralign™ 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.

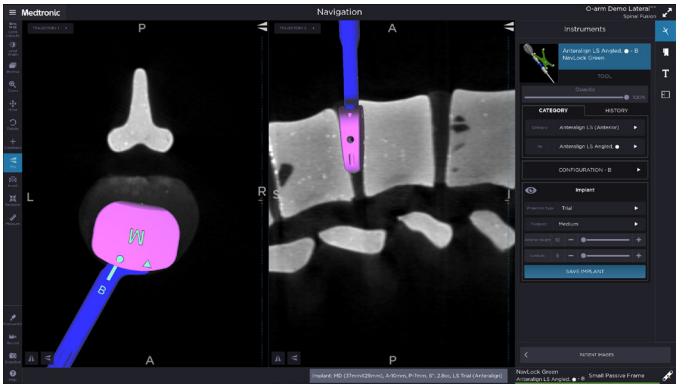


Figure 19a

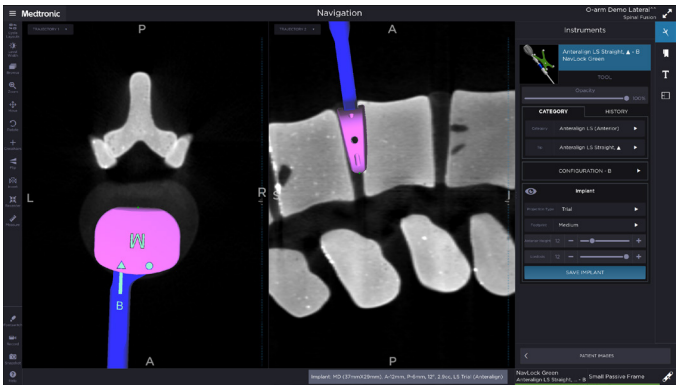


Figure 19b

Note

Keep in mind that when moving bony anatomy, it will not be detected on the StealthStation™ system monitor. During navigation, it is important to frequently confirm navigational accuracy by touching the tip of the probe 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 should be performed before continuation of the procedure.

Note

At any point during the procedure, navigation accuracy can be evaluated by using the first direct lateral dilator/MAST dilator tracker on known bony landmarks.

Note

Please note that the Anteralign™ 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.

Navigated interbody placement

Before inserting the Anteralign™ LS spinal system implant, place 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 in the implant's central cavity. Attach the Anteralign™ LS spinal system implant to the navigated inserter. On the StealthStation™ system, select the appropriately sized implant. Use a mallet to gently insert the implant (**Figures 20 – 23**). The navigated inserter is then unthreaded from the implant and removed.

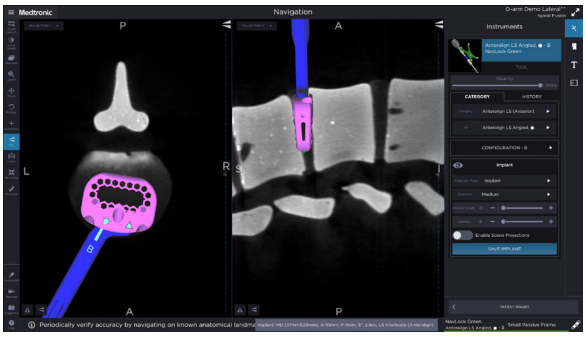


Figure 20

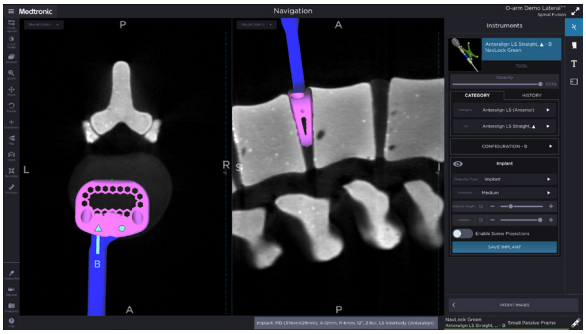


Figure 21

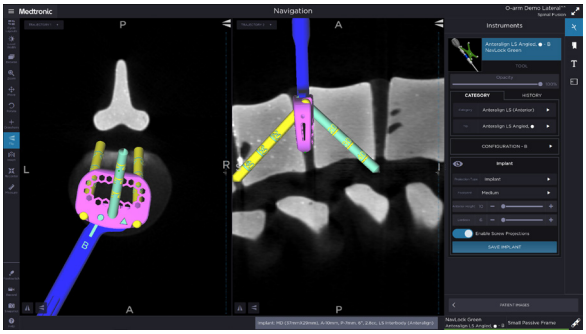


Figure 22

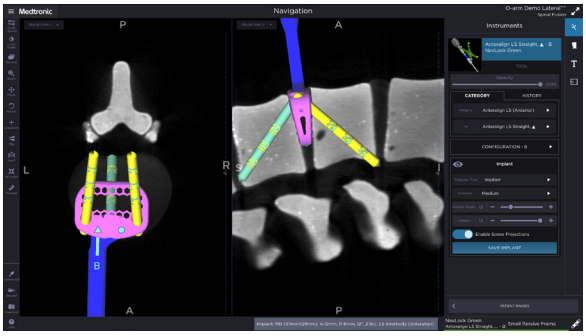
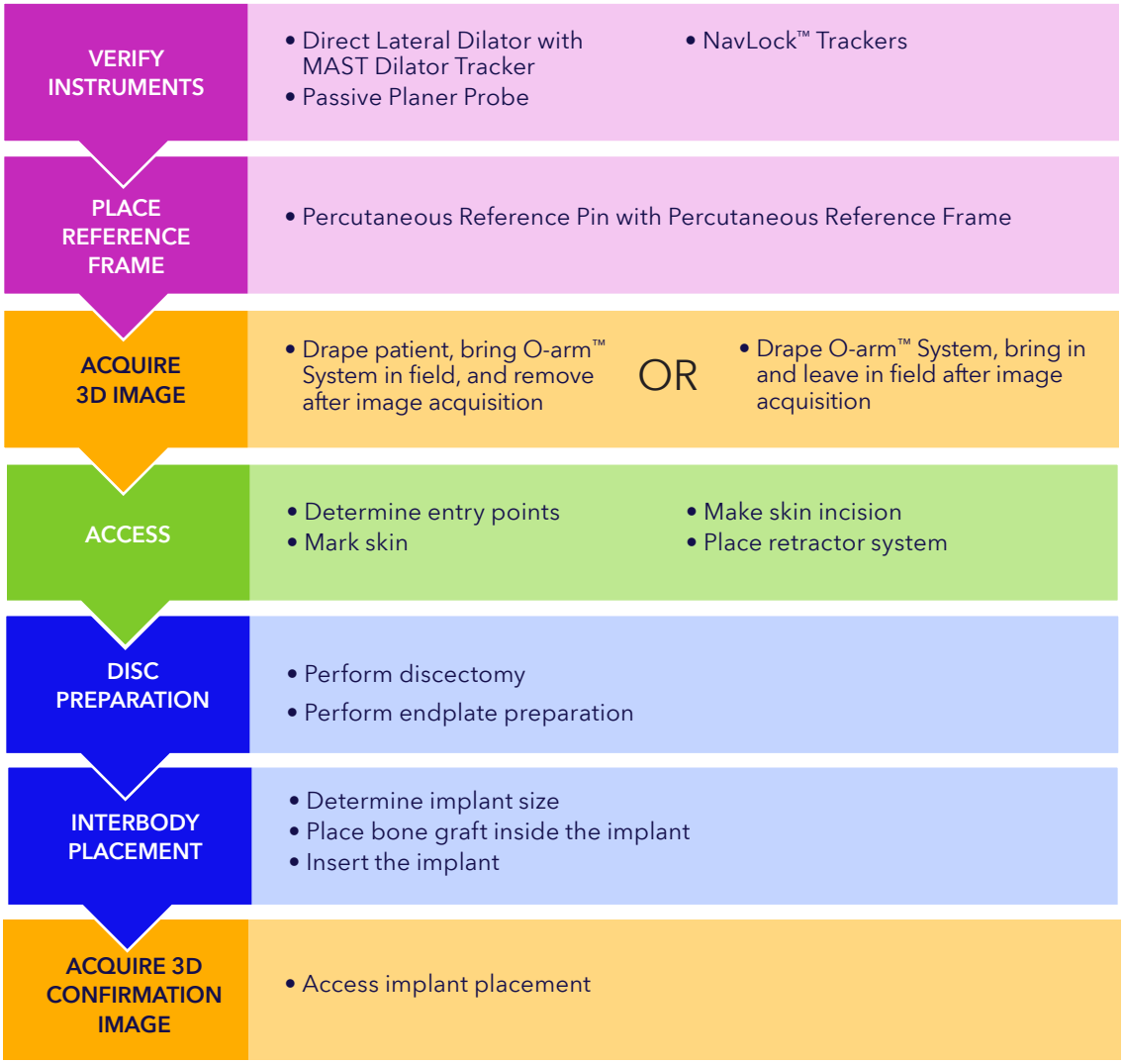


Figure 23

Anteralign™ LS 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 for complete indications, warnings, precautions, and important medical information on Mazor™ robotic guidance platform and associated instruments.



Set-up

For a surgery using the Mazor™ robotic guidance system, the OR should be equipped with the O-arm™ image acquisition system including the Mobile Viewing Station (MVS), or a compatible C-arm, and the Mazor™ platform. Consult the Mazor™ platform and O-arm™ imaging system manuals for complete indications, warnings, precautions, important medical information, and instruction on equipment and OR set-up, reference frame placement, registration, and Mazor™ procedural workflow such as correct procedure selection, instrument verification, image acquisition, and camera positioning.

Workflow selections with Mazor™ robotic guidance platform

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

After robotic guidance of screw preparation and insertion is complete and prior to moving on to navigated interbody steps, it is recommended to perform the Accuracy Check to ensure navigation is still accurate and the patient reference frame hasn't experienced motion.

Without unlocking the robotic arm shoulder, clear the robotic arm up or to the left. Disconnect the Schanz Bridge from the Schanz Connector by loosening the Schanz Connector Screw and the Schanz Connector Socket Screw.

Planning

Planning can be used to estimate the amount of correction and associated implant size based on surgeon preferences.

- The Anteralign™ LS implant system should be selected to begin interbody planning.
- There is a dropdown menu to select the implant footprint, anterior height, and lordosis. (**Figure 24**).
- Projections of both the screws and inserter can be toggled on and off for visualization. The tool can be projected in either the straight or angled orientation.
  - **Note that the screws do not show threads and have graduations that show length. The graduations start 20mm from the screw/cage interface with the distal most line representing the 40mm mark. The total screw length projection is 50mm**.
- The implant can also be flipped in the transverse plane to invert screw trajectories.
- There is also a simulate feature that can be toggled on and off to estimate correction and height restoration (**Figure 25**).

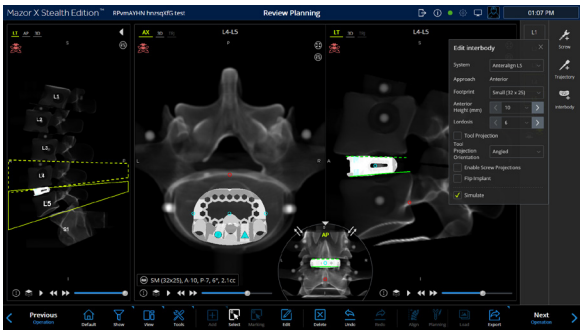


Figure 24

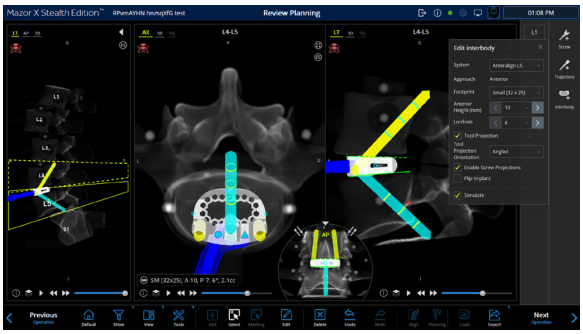


Figure 25

Inserter verification

To determine size for Anteralign™ LS trial and/or implant, user must make appropriate selections within the Mazor™ platform software. The Anteralign™ spinal system uses a single inserter for both trials and implants, therefore one Anteralign™ system toolcard contains both trials and implants. Once the Anteralign™ LS system toolcard is selected, assign the navigated inserter a NavLock™ tracker. Green, gray, orange, blue, black, and violet NavLock™ trackers can be used with the Anteralign™ system inserter. There are two verification options with the Anteralign™ LS system inserter:

1. Verify the NavLock™ tracker with an instrument such as an awl. Then, change the NavLock™ tracker to pair with the Anteralign™ system toolcard.
2. Verify the NavLock™ tracker with the Anteralign™ LS system inserter. To do this, the "Verify Inserter" tip must be selected to verify the inserter (**Figure 26**).

The inner threaded shaft must be placed in the reference frame divot (**Figure 27**). Ensure the inner threaded shaft is placed as perpendicular to the divot as possible when verifying. The inner threaded shaft may need to be pushed forward to expose the threaded shaft.

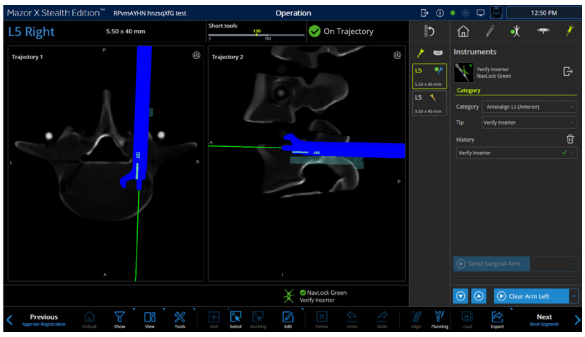


Figure 26

Figure 27

Tip selection

Once the inserter is verified, the user must choose the Straight or Angled Tip to match the physical assembly in the tip field on the Mazor™ system workstation (**Figure 28**). Typically, the angled option has been used for the oblique approach and the straight has been used according to surgeon preference.

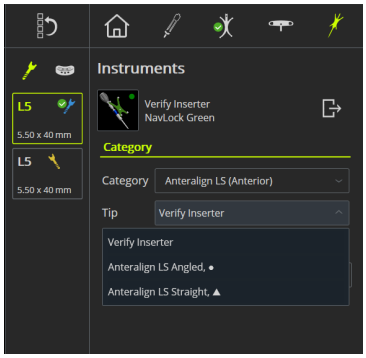


Figure 28

Note
The Anteralign™ LS spinal system can only be navigated via an OLIF51™ procedure on Mazor™ robotic guidance platform.

The foot of the inserter features a line to help with proper orientation of the implant or trial on the inserter. Thread the inserter completely until the inserter is fully seated to the implant or trial. Ensure there are no gaps between the inserter and implant or trial. The Anteralign™ LS system implants and trials are marked with a circle (O) for the angled orientation and a triangle (Δ) for the straight orientation (**Figures 29a and 29b**). The tip field is set to Anteralign™ LS Angled (O) or Anteralign™ LS Straight (Δ) to match the orientation of the attached implant or trial. View the images on the Mazor™ system workstation to ensure that the proper orientation is selected.

Figure 29a

Figure 29b

Orientation selection

Once the navigated inserter tip selection is made, the next selection to be made is the option A or option B configuration. Due to the multiple options within the Anteralign™ LS spinal system, the configuration option allows the system 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™ LS inserter (**Figure 30**). In the toolcard, select configuration A or B to correspond with the A/B orientation of the NavLock™ tracker on the navigated Anteralign™ LS inserter (**Figure 31**). View the images on the Mazor™ system workstation as a guide to show how to hold the assembled NavLock™ tracker and inserter when determining the NavLock™ tracker configuration.

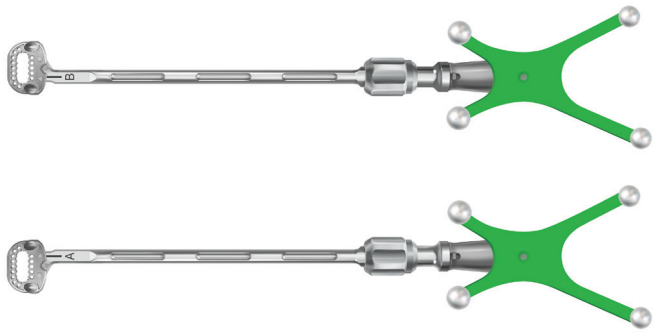


Figure 30

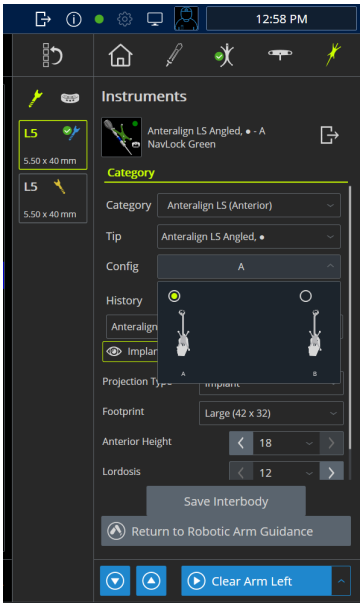


Figure 31

Navigated trial insertion with Mazor™ robotic guidance platform

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

When the above category selections are made, the user can move on to the implant/trial selections. Not all implants have a corresponding trial. There is a single situation that only applies to the Small 6° 32 × 25 × 8mm trial where an implant is not available for the corresponding trial. In that case, the trial image on the Mazor™ system workstation will show "DISTRACTION ONLY" (**Figure 32**).

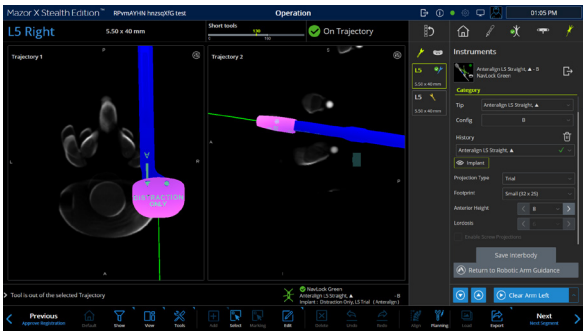


Figure 32

Anteralign™ LS spinal system trials are available in 8mm, 10mm, 12mm, 14mm, 16mm, 18mm, and 20mm heights, small, medium, and large footprints, and 6, 12-, 18-, 24-, and 30-degree lordosis. The trials are passed through the retractors obliquely. On the Mazor™ system, select the appropriately sized trial. Insert the Anteralign™ 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 instrument 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 monitor. During navigation, it is important to frequently confirm navigational accuracy by touching the tip of the probe 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.

Note

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

Note

Please note that the Anteralign™ system 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.

Navigated implant placement with Mazor™ robotic guidance platform

In the navigation task, under the Anteralign™ system toolcard, the first implant attribute selection is the “Projection Type”. The options are Trial or Implant. Within the Implant section in the toolcard, there are three key selections related to the Implant or Trial dimensions: footprint, anterior height, and lordosis. Use the dropdown function to select the footprint of the implant/trial. These selections are to be made in the toolcard to match the virtual implant/trial with the implant/trial hardware being used (anterior height and lordosis will default to the smallest available option). Once the footprint, anterior height, and lordosis have been selected, a virtual CAD model of the implant/trial will be visible on the Mazor™ platform screen. Selected options can be confirmed in the banner located at the bottom of the toolcard (**Figure 33**). It is important to confirm selections so that navigated projections match physical system components. Once the desired size is selected, the user can change the “Projection Type” from trial to implant and it will default to the closest size implant for a more efficient workflow. Adjust to the appropriate size implant as needed.

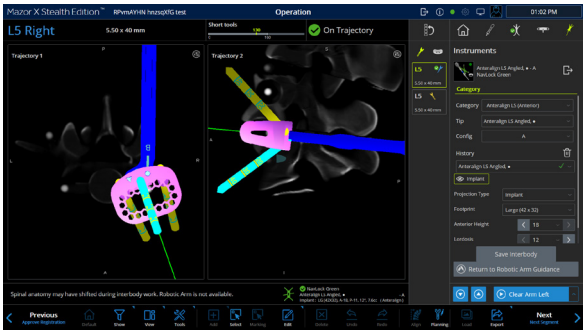


Figure 33

Before inserting the Anteralign™ LS 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™ LS spinal system implant to the navigated inserter. Select the appropriately sized implant on the Mazor™ system workstation. Use a mallet to gently insert the implant. The navigated inserter is then unthreaded from the implant and removed.

Product ordering information

Implant Measurements

	Foot Print (W X L)	Anterior Height (A)(mm)	Posterior Height (Per Foot Print)	Posterior Height	Proximal Wall Thickness (Per Foot Print)	Distal Wall Thickness (Per Foot Print)	Lateral Wall Thickness (Per Foot Print)
Small 6˚	32 X 25	10	7.38	A-2.62	9.5	3.75	4
		12	9.38				
		14	11.38				
		16	13.38				
		20	17.38				
Medium 6˚	37 X 29	10	6.96	A-3.04	11.9	4.75	4.5
		12	8.96				
		14	10.96				
		16	12.96				
Large 6˚	42 X 32	10	6.65	A-3.35	11.9	4.75	4.75
		12	8.65				
		14	10.65				
		16	12.65				
Small 12˚	32 X 25	10	4.74	A-5.26	9.5	3.75	4
		12	6.74				
		14	8.74				
		16	10.74				
		18	12.74				
Medium 12˚	37 X 29	10	3.90	A-6.1	11.9	4.75	4.5
		12	5.90				
		14	7.90				
		16	9.90				
		18	11.90				
		20	13.90				
Large 12˚	42 X 32	12	5.27	A-7.26* A-6.73	11.9	4.75	4**, 4.75
		14	7.27				
		16	9.27				
		18	11.27				
Small 18˚	32 X 25	12	4.08	A-7.92	9.5	3.75	4
		14	6.08				
		16	8.08				
		18	10.08				
		20	12.08				

* Anterior height 12 / Posterior Height 4.74 does not follow similar pattern as rest in grouping
** Lateral Wall Thickness for Anterior height 12 does not follow similar pattern as rest in grouping

Implant Measurements

	Foot Print (W X L)	Anterior Height (A)(mm)	Posterior Height (Per Foot Print)	Posterior Height	Proximal Wall Thickness (Per Foot Print)	Distal Wall Thickness (Per Foot Print)	Lateral Wall Thickness (Per Foot Print)
Medium 18˚	37 X 29	14	4.81	A-9.19	11.9	4.75	4.5
		16	6.81				
		18	8.81				
		20	10.81				
Large 18˚	42 X 32	16	5.86	A-10.14	11.9	4.75	4.75
		18	7.86				
		20	9.86				
Small 24˚	32 X 25	16	5.37	A-10.63	9.5	3.75	4
		18	7.37				
		20	9.37				
Medium 24˚	37 X 29	18	5.67	A-12.33	11.9	4.75	4.5
		20	7.67				
Large 24˚	42 X 32	18	4.40	A-13.6	11.9	4.75	4.75
		20	6.40				
Medium 30˚	37 X 29	20	4.46	A-15.54	11.9	4.75	4.5

Graft Volume

Part Number	Description	Graft Volume (cc^3)
46500610	SM TI 6° 32 × 25 × 10mm	2,1
46500612	SM TI 6° 32 × 25 × 12mm	2,8
46500614	SM TI 6° 32 × 25 × 14mm	3,4
46500616	SM TI 6° 32 × 25 × 16mm	4,0
46500620	SM TI 6° 32 × 25 × 20mm	1,6
46501210	SM TI 12° 32 × 25 × 10mm	1,6
46501212	SM TI 12° 32 × 25 × 12mm	2,3
46501214	SM TI 12° 32 × 25 × 14mm	2,9
46501216	SM TI 12° 32 × 25 × 16mm	3,5
46501218	SM TI 12° 32 × 25 × 18mm	4,1
46501812	SM TI 18° 32 × 25 × 12mm	1,8
46501814	SM TI 18° 32 × 25 × 14mm	2,4
46501816	SM TI 18° 32 × 25 × 16mm	3,0
46501818	SM TI 18° 32 × 25 × 18mm	3,6
46501820	SM TI 18° 32 × 25 × 20mm	4,3
46502416	SM TI 24° 32 × 25 × 16mm	2,5
46502418	SM TI 24° 32 × 25 × 18mm	3,1
46502420	SM TI 24° 32 × 25 × 20mm	3,8
46503018	SM TI 30° 32 × 25 × 18mm	2,6
46510610	MD TI 6° 37 × 29 × 10mm	2,8
46510612	MD TI 6° 37 × 29 × 12mm	3,6
46510614	MD TI 6° 37 × 29 × 14mm	4,4
46510616	MD TI 6° 37 × 29 × 16mm	5,2
46511210	MD TI 12° 37 × 29 × 10mm	2,1
46511212	MD TI 12° 37 × 29 × 12mm	2,9

Part Number	Description	Graft Volume (cc^3)
46511214	MD TI 12° 37 × 29 × 14mm	3,7
46511216	MD TI 12° 37 × 29 × 16mm	4,5
46511218	MD TI 12° 37 × 29 × 18mm	5,3
46511220	MD TI 12° 37 × 29 × 20mm	6,0
46511814	MD TI 18° 37 × 29 × 14mm	2,9
46511816	MD TI 18° 37 × 29 × 16mm	3,7
46511818	MD TI 18° 37 × 29 × 18mm	4,5
46511820	MD TI 18° 37 × 29 × 20mm	5,3
46512418	MD TI 24° 37 × 29 × 18mm	3,7
46512420	MD TI 24° 37 × 29 × 20mm	4,5
46513020	MD TI 30° 37 × 29 × 20mm	3,8
46520610	LG TI 6° 42 × 32 × 10mm	4,2
46520612	LG TI 6° 42 × 32 × 12mm	5,3
46520614	LG TI 6° 42 × 32 × 14mm	6,5
46520616	LG TI 6° 42 × 32 × 16mm	7,7
46521212	LG TI 12° 42 × 32 × 12mm	4,1
46521214	LG TI 12° 42 × 32 × 14mm	5,3
46521216	LG TI 12° 42 × 32 × 16mm	6,5
46521218	LG TI 12° 42 × 32 × 18mm	7,6
46521816	LG TI 18°G 42 × 32 × 16mm	5,3
46521818	LG TI 18° 42 × 32 × 18mm	6,4
46521820	LG TI 18° 42 × 32 × 20mm	7,6
46522418	LG TI 24° 42 × 32 × 18mm	5,2
46522420	LG TI 24° 42 × 32 × 20mm	6,4

SPS03008 Anteralign™ LS Spinal System Trials Set/SPS03335 Anteralign™ LS Spinal System Extended Trials Set

Part number	Description	Quantity
46820608	Small 6˚ 32 X 25 X 8MM	1
46820610	Small 6˚ 32 X 25 X 10MM	1
46820612	Small 6˚ 32 X 25 X 12MM	1
46820614	Small 6˚ 32 X 25 X 14MM	1
46820616*	Small 6˚ 32 X 25 X 16MM	1
46820210	Small 12˚ 32 X 25 X 10MM	1
46820212	Small 12˚ 32 X 25 X 12MM	1
46820214	Small 12˚ 32 X 25 X 14MM	1
46820216	Small 12˚ 32 X 25 X 16MM	1
46820218	Small 12˚ 32 X 25 X 18MM	1
46820812*	Small 18˚ 32 X 25 X 12MM	1
46820814*	Small 18˚ 32 X 25 X 14MM	1
46820816*	Small 18˚ 32 X 25 X 16MM	1
46820818*	Small 18˚ 32 X 25 X 18MM	1
46820820*	Small 18˚ 32 X 25 X 20MM	1
46820416*	Small 24˚ 32 X 25 X 16MM	1
46820418*	Small 24˚ 32 X 25 X 18MM	1
46820420*	Small 24˚ 32 X 25 X 20MM	1
46821610	Medium 6˚ 37 X 25 X 10MM	1
46821612	Medium 6˚ 37 X 25 X 12MM	1
46821614	Medium 6˚ 37 X 25 X 14MM	1
46821616	Medium 6˚ 37 X 25 X 16MM	1
46821618	Medium 6˚ 37 X 25 X 18MM	1
46821210	Medium 12˚ 37 X 25 X 10MM	1
46821212	Medium 12˚ 37 X 25 X 12MM	1
46821214	Medium 12˚ 37 X 25 X 14MM	1
46821216	Medium 12˚ 37 X 25 X 16MM	1
46821218	Medium 12˚ 37 X 25 X 18MM	1
46821220*	Medium 12˚ 37 X 25 X 20MM	1
46821814	Medium 18˚ 37 X 25 X 14MM	1
46821816	Medium 18˚ 37 X 25 X 16MM	1
46821818	Medium 18˚ 37 X 25 X 18MM	1
46821820*	Medium 18˚ 37 X 25 X 20MM	1
46821418*	Medium 24˚ 37 X 25 X 18MM	1
46821420	Medium 24˚ 37 X 25 X 20MM	1
46821320	Medium 30˚ 37 X 25 X 20MM	1
46822610	Large 6˚ 42 X 25 X 10MM	1
46822612	Large 6˚ 42 X 25 X 12MM	1
46822614	Large 6˚ 42 X 25 X 14MM	1
46822616*	Large 6˚ 42 X 25 X 16MM	1
46822212	Large 12˚ 42 X 25 X 12MM	1
46822214	Large 12˚ 42 X 25 X 14MM	1
46822216	Large 12˚ 42 X 25 X 16MM	1
46822218	Large 12˚ 42 X 25 X 18MM	1
46822816*	Large 18˚ 42 X 25 X 16MM	1
46822818*	Large 18˚ 42 X 25 X 18MM	1
46822820*	Large 18˚ 42 X 25 X 20MM	1
46822418*	Large 24˚ 42 X 25 X 18MM	1
46822420*	Large 24˚ 42 X 25 X 20MM	1

*Only in the extended trial set.

SPS03005 Instrument Set

Part number	Description	Quantity
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	Mini-plate Inserter	1
4680007	Mini-plate Shaft	1
4680008	T20 Balljoint Driver	1
4680009	T20 Screwdriver	1
4680010	T20 Long Screwdriver	1
4680011	Loading Block	1
4680013	Dual-ended Slaphammer	1
G307407	Quick-connect Ratcheting Silicone Handle	2

SPS03006 Navigated Instrument Set

Part number	Description	Quantity
4680000	Angled Awl Sleeve	1
4680001	Angled Awl Shaft	1
4680002	Straight Awl Sleeve	1
4680003	Straight Awl Shaft	1
4680006	Mini-plate Inserter	1
4680007	Mini-plate Shaft	1
4680008	T20 Balljoint Driver	1
4680009	T20 Screwdriver	1
4680010	T20 Long Screwdriver	1
4680011	Loading Block	1
4680013	Dual-ended Slaphammer	1
G307407	Quick-connect Ratcheting Silicone Handle	2
NAV4680003	Navigated Interbody Inserter	2

SPS03017 Anteralign™ LS Spinal System 6°

Part number	Description	Quantity
46500610	Titanium Spacer 6° 32 × 25 × 10mm	2
46500612	Titanium Spacer 6° 32 × 25 × 12mm	2
46500614	Titanium Spacer 6° 32 × 25 × 14mm	2
46500616	Titanium Spacer 6° 32 × 25 × 16mm	1
46510610	Titanium Spacer 6° 37 × 29 × 10mm	2
46510612	Titanium Spacer 6° 37 × 29 × 12mm	2
46510614	Titanium Spacer 6° 37 × 29 × 14mm	2
46510616	Titanium Spacer 6° 37 × 29 × 16mm	1
46520610	Titanium Spacer 6° 42 × 32 × 10mm	2
46520612	Titanium Spacer 6° 42 × 32 × 12mm	2
46520614	Titanium Spacer 6° 42 × 32 × 14mm	2
46520616	Titanium Spacer 6° 42 × 32 × 16mm	2
4675020	Bone Screw 5.0 X 20mm	3
4675025	Bone Screw 5.0 X 25mm	5
4675030	Bone Screw 5.0 X 30mm	3
4675040	Bone Screw 5.0 X 40mm	3
4675050	Bone Screw 5.0 X 50mm	3

SPS03018 Anteralign™ LS Spinal System 12°

Part number	Description	Quantity
46501210	Titanium Spacer, 12° 32 × 25 × 10mm	2
46501212	Titanium Spacer, 12° 32 × 25 × 12mm	2
46501214	Titanium Spacer, 12° 32 × 25 × 14mm	2
46501216	Titanium Spacer, 12° 32 × 25 × 16mm	2
46501218	Titanium Spacer, 12° 32 × 25 × 18mm	1
46511210	Titanium Spacer, 12° 37 × 29 × 10mm	1
46511212	Titanium Spacer, 12° 37 × 29 × 12mm	2
46511214	Titanium Spacer, 12° 37 × 29 × 14mm	2
46511216	Titanium Spacer, 12° 37 × 29 × 16mm	2
46511218	Titanium Spacer, 12° 37 × 29 × 18mm	2
46511220	Titanium Spacer, 12° 37 × 29 × 10mm	1
46521212	Titanium Spacer, 12° 42 × 32 × 12mm	2
46521214	Titanium Spacer, 12° 42 × 32 × 14mm	2
46521216	Titanium Spacer, 12° 42 × 32 × 16mm	2
46521218	Titanium Spacer, 12° 42 × 32 × 18mm	2
4675020	Bone Screw 5.0 X 20mm	3
4675025	Bone Screw 5.0 X 25mm	5
4675030	Bone Screw 5.0 X 30mm	3
4675040	Bone Screw 5.0 X 40mm	3
4675050	Bone Screw 5.0 X 50mm	3

SPS03019 Anteralign™ LS Spinal System HL

Part number	Description	Quantity
46501812	Titanium Spacer, 18° 32 × 25 × 12mm	1
46501814	Titanium Spacer, 18° 32 × 25 × 14mm	1
46501816	Titanium Spacer, 18° 32 × 25 × 16mm	1
46501818	Titanium Spacer, 18° 32 × 25 × 18mm	1
46501820	Titanium Spacer, 18° 32 × 25 × 20mm	1
46511814	Titanium Spacer, 18° 37 × 29 × 14mm	1
46511816	Titanium Spacer, 18° 37 × 29 × 16mm	1
46511818	Titanium Spacer, 18° 37 × 29 × 18mm	1
46511820	Titanium Spacer, 18° 37 × 29 × 20mm	1
46521816	Titanium Spacer, 18° 42 × 32 × 16mm	1
46521818	Titanium Spacer, 18° 42 × 32 × 18mm	1
46521820	Titanium Spacer, 18° 42 × 32 × 20mm	1
46502416	Titanium Spacer, 24° 32 × 25 × 16mm	1
46502418	Titanium Spacer, 24° 32 × 25 × 18mm	1
46502420	Titanium Spacer, 24° 32 × 25 × 20mm	1
46512418	Titanium Spacer, 24° 37 × 29 × 18mm	1
46512420	Titanium Spacer, 24° 37 × 29 × 20mm	1
46522418	Titanium Spacer, 24° 42 × 32 × 18mm	1
46522420	Titanium Spacer, 24° 42 × 32 × 20mm	1
46513020	Titanium Spacer, 30° 37 × 29 × 20mm	1
4675020	Bone Screw 5.0 X 20mm	3
4675025	Bone Screw 5.0 X 25mm	5
4675030	Bone Screw 5.0 X 30mm	3
4675040	Bone Screw 5.0 X 40mm	3
4675050	Bone Screw 5.0 X 50mm	3

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

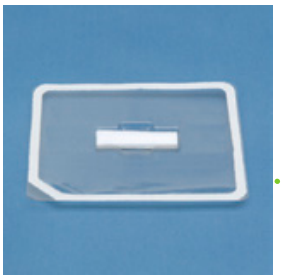
Reconstitute the rhBMP-2 with 0.9mL of sterile water.

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

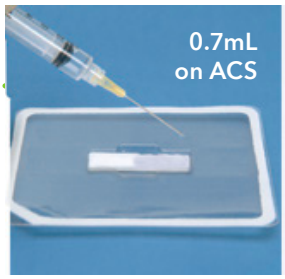


Open the inner ACS package leaving the collagen sponge in the plastic tray.

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

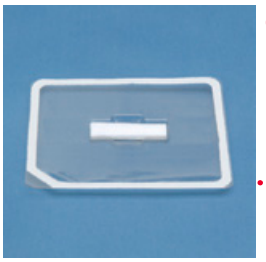
Reconstitute the rhBMP-2 with 0.9mL of sterile water.

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

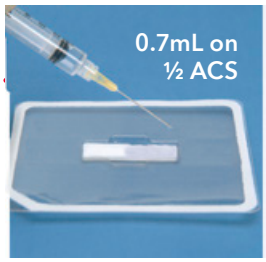


Open the inner ACS package leaving the collagen sponge in the plastic tray.

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

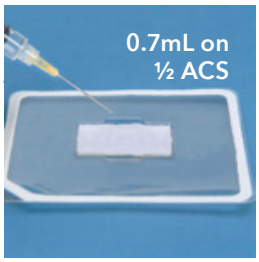


Uniformly distribute 0.7mL of reconstituted rhBMP-2 on the ½" × 2" collagen sponge. Inspect the sponge. If dark particles are observed, do not use and return to sponsor.

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

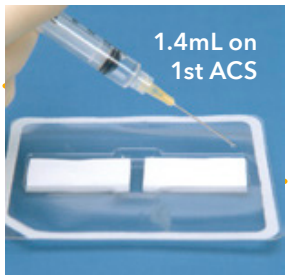
5

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

6

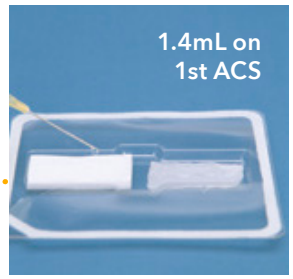
In the sterile field use the 3mL syringe/ needle to withdraw 0.7mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

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

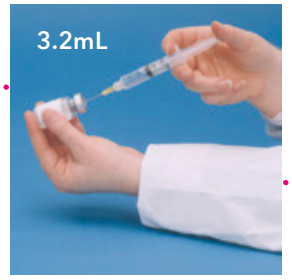
1

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



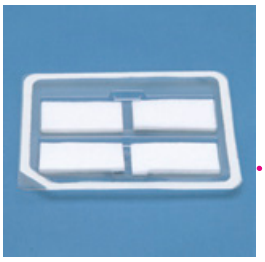
Reconstitute one vial of the rhBMP-2 with 3.2mL of sterile water.

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.

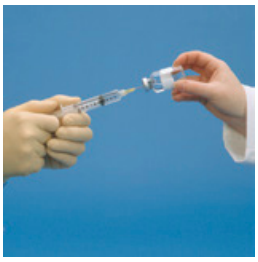
In non-sterile field

5



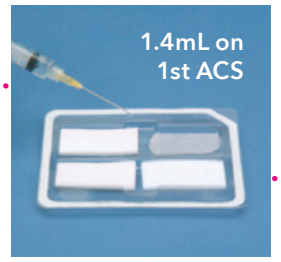
Open the inner ACS package leaving all collagen sponges in the plastic tray.

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.

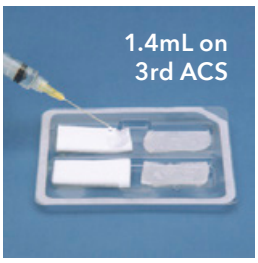
8

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

9

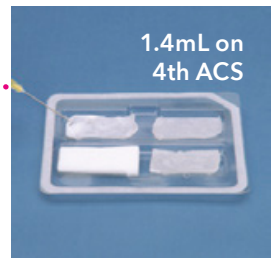
In the sterile field use the second 5mL syringe/ needle to withdraw 1.4mL of reconstituted rhBMP-2 from the second vial held by the person in the non-sterile field.

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

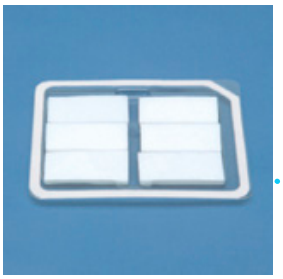
Reconstitute the rhBMP-2 with 8.4mL of sterile water.

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.

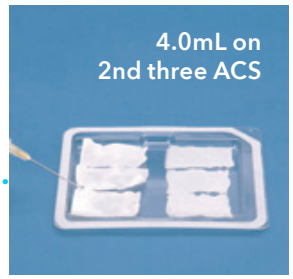
6

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

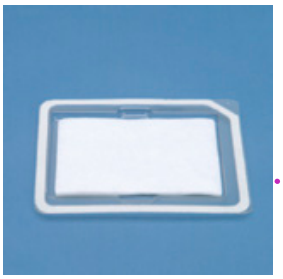
Reconstitute the rhBMP-2 with 8.4mL of sterile water.

4

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

In non-sterile field

5

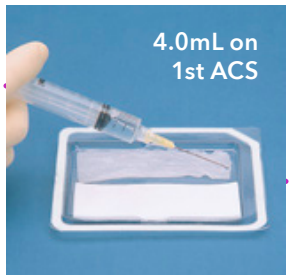


Open the inner ACS package. Using sterile scissors, cut the 3" × 4" collagen sponge into two 1 1/2" × 4" strips. Return the cut collagen sponges to the plastic tray.

6

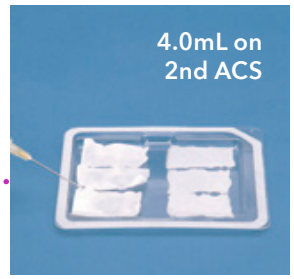
In the sterile field use the 10mL syringe/needle to withdraw 4.0mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

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™ Fill Guidelines

Infuse™ Bone Graft/Anteralign™ Spinal System LS Combinations					
Anteralign™ Spinal System LS			Appropriate Infuse™ Bone Graft Kit		Reconstituted rhBMP-2/ ACS graft volume
Footprint, Lordosis	Part #	Size (height)	Part #	Kit name (size in cc)	
SMALL, 6 deg	46500610	10mm	"7510100+ 7510050"	X Small (1.4)+ XX Small (0.7)	2,1
	46500612	12mm	7510200	Small (2.8)	2,8
	46500614	14mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
	46500616	16mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
MEDIUM, 6 deg	46510610	10mm	7510200	Small (2.8)	2,8
	46510612	12mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
	46510614	14mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46510616	16mm	7510400	Medium (5.6)	5,6
LARGE, 6 deg	46520610	10mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46520612	12mm	7510400	Medium (5.6)	5,6
	46520614	14mm	"7510400+ 7510050"	"Medium (5.6)+ XX Small (0.7)"	6,3
	46520616	16mm	"7510600 or 7510800"	"Large (8.0) or Large II (8.0)"	8
SMALL, 12 deg	46501210	10mm	7510100	X Small (1.4)	1,4
	46501212	12mm	"7510100+ 7510050"	"X Small (1.4)+ XX Small (0.7)"	2,1
	46501214	14mm	7510200	Small (2.8)	2,8
	46501216	16mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
	46501218	18mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
MEDIUM, 12 deg	46511210	10mm	"7510100+ 7510050"	"X Small (1.4)+ XX Small (0.7)"	2,1
	46511212	12mm	7510200	Small (2.8)	2,8
	46511214	14mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
	46511216	16mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46511218	18mm	7510400	Medium (5.6)	5,6
	46511220	20mm	7510400	Medium (5.6)	5,6

Infuse™ Bone Graft/Anteralign™ Spinal System LS Combinations					
Anteralign™ Spinal System LS			Appropriate Infuse™ Bone Graft Kit		Reconstituted rhBMP-2/ ACS graft volume
Footprint, Lordosis	Part #	Size (height)	Part #	Kit name (size in cc)	
LARGE, 12 deg	46521212	12mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
	46521214	14mm	7510400	Medium (5.6)	5,6
	46521216	16mm	"7510400+ 7510050"	"Medium (5.6)+ XX Small (0.7)"	6,3
	46521218	18mm	"7510600 or 7510800"	"Large (8.0) or Large II (8.0)"	8
SMALL, 18 deg	46501812	12mm	7510100	X Small (1.4)	1,4
	46501814	14mm	"7510100+ 7510050"	"X Small (1.4)+ XX Small (0.7)"	2,1
	46501816	16mm	7510200	Small (2.8)	2,8
	46501818	18mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
MEDIUM, 18 deg	46511814	14mm	7510200	Small (2.8)	2,8
	46511816	16mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
	46511818	18mm	"7510200+ 7510100"	"Small (2.8)+ X Small (1.4)"	4,2
LARGE, 18 deg	46521816	16mm	7510400	Medium (5.6)	5,6
	46521818	18mm	"7510400+ 7510050"	"Medium (5.6)+ XX Small (0.7)"	6,3
SMALL, 24 deg	46502416	16mm	7510200	Small (2.8)	2,8
	46502418	18mm	7510200	Small (2.8)	2,8
MEDIUM, 24 deg	46512418	16mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5
LARGE, 24 deg	46522418	18mm	7510400	Medium (5.6)	5,6
MEDIUM, 30 deg	46513020	20mm	"7510200+ 7510050"	"Small (2.8)+ XX Small (0.7)"	3,5

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 surgeon 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 TL and LS interbody cages, mini plates, and bone screws.

Anteralign™ Spinal System TL and LS interbody cages are additive manufactured titanium cages available in various heights, widths, lengths, and lordotic angles to accommodate patient anatomy. The TL cage is rectangular shaped whereas the LS cage is oval shaped. The interbodies are inserted between two lumbar vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The interbodies have a central cavity that allows them to be packed with 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 Anteralign™ Spinal System TL interbody cages are provided sterile and are intended to be used with supplemental fixation cleared for use in lumbar spine (L2- S1). The TL interbody may be implanted via a minimally invasive OLIF or minimally invasive or open DLIF approach.

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. Miniplates are only to be used with the TL interbody.

The Anteralign™ LS interbody cage may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a standalone device, the Anteralign LS interbody cage is intended to be used with three screws and must have standard lordosis (<16°). The Anteralign™ LS interbody cage is intended to be used in the lumbar sacral region between L2 and S1 and may be implanted via open or minimally invasive procedures for OLIF 51 or ALIF approaches.

The interbody designs incorporate honeycomb windows and an open void to allow bone growth through the implant.

The interbody device is treated with Titan Surface Technology, where Titan nanoLOCK™ Surface Technology (MMN) is designed to improve fixation to the adjacent bone. The Titan nanoLOCK™ Surface Technology provides a microscopicroughened surface with nano-scale features. The Titan 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 Titan nanoLOCK™ Surface Technology demonstrates the elements to be considered a Nanotechnology as outlined in the FDA Nanotechnology Guidance.

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

Anteralign Spinal System with Titan nanoLOCK™ Surface Technology System interbody cages with macro-, micro-, and nanoroughened 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 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.

The Anteralign TL interbody 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 TL interbody for the lumbosacral levels oblique or lateral above the bifurcation (L2-L5) ozf 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.

The Anteralign Spinal System with Titan nanoLOCK™ Surface Technology TL interbody may be implanted via a minimally invasive OLIF or minimally invasive or open DLIF approach (except as defined for use with Infuse™ Bone Graft above).

The Anteralign™ LS interbody cage may be used as a stand-alone device or in conjunction with supplemental fixation. The Anteralign LS™ interbody fusion device may be inserted via minimally invasive or open anterior or oblique approach at one or two contiguous levels from L2 to S1. These approaches include anterior and oblique. When used as a stand-alone device, the Anteralign™ LS cage must be used with 3 screws with devices that have standard lordosis (≤16°). If the surgeon chooses to use less than 3 screws or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability. When used in patients as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity

conditions, additional supplemental fixation (e.g. posterior fixation) must be used. Additionally, cages with lordosis angles ≥16˚ are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation).

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

CONTRAINDICATIONS

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. 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.

PRECAUTION

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.

For US Audiences Only

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

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.

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.

Medtronic
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

Medtronic
Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133
(800) 876-3133

Customer Service:
(800) 933-2635

medtronic.com

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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