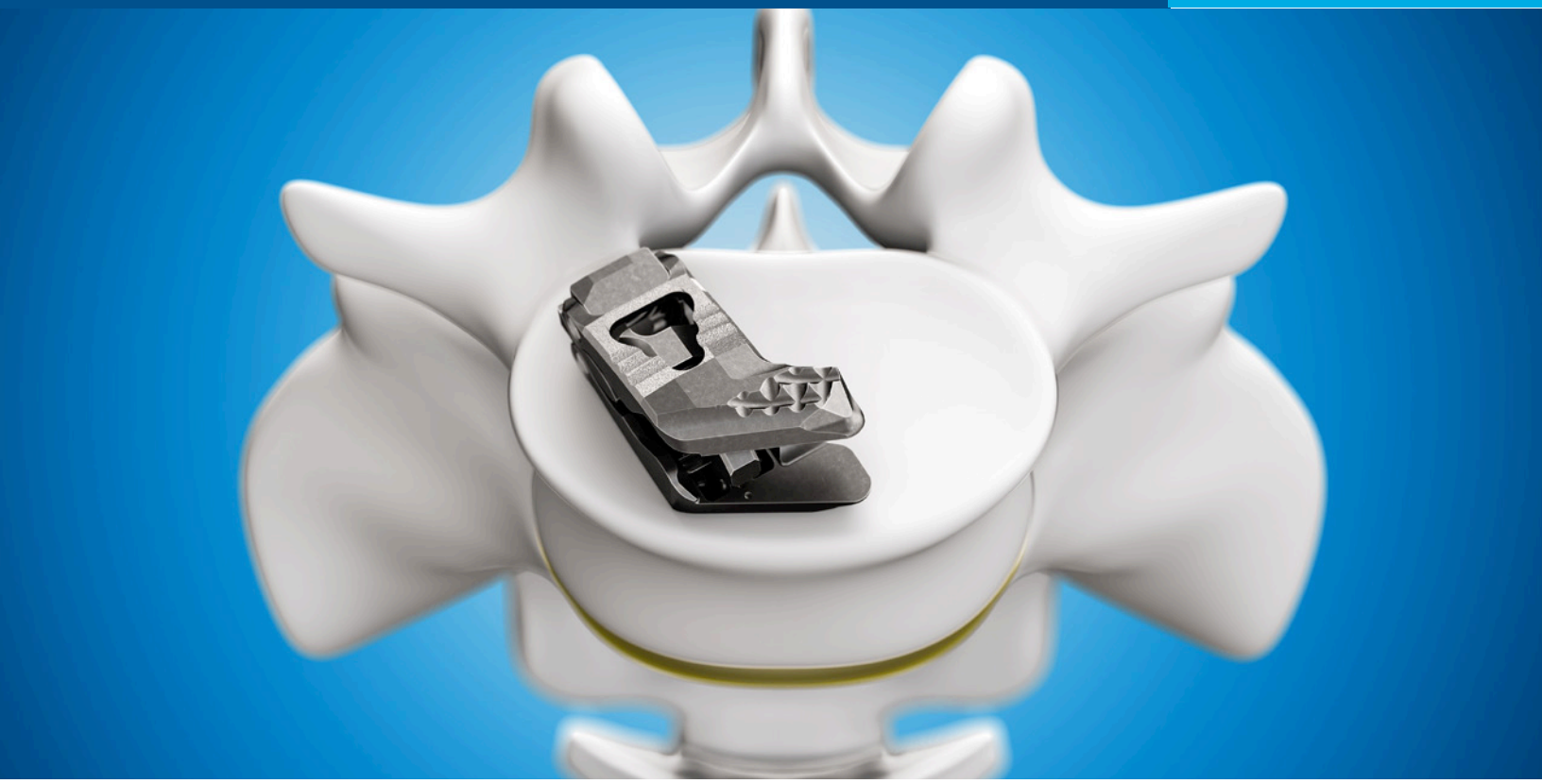
Catalyft™ PL

Expandable Interbody System



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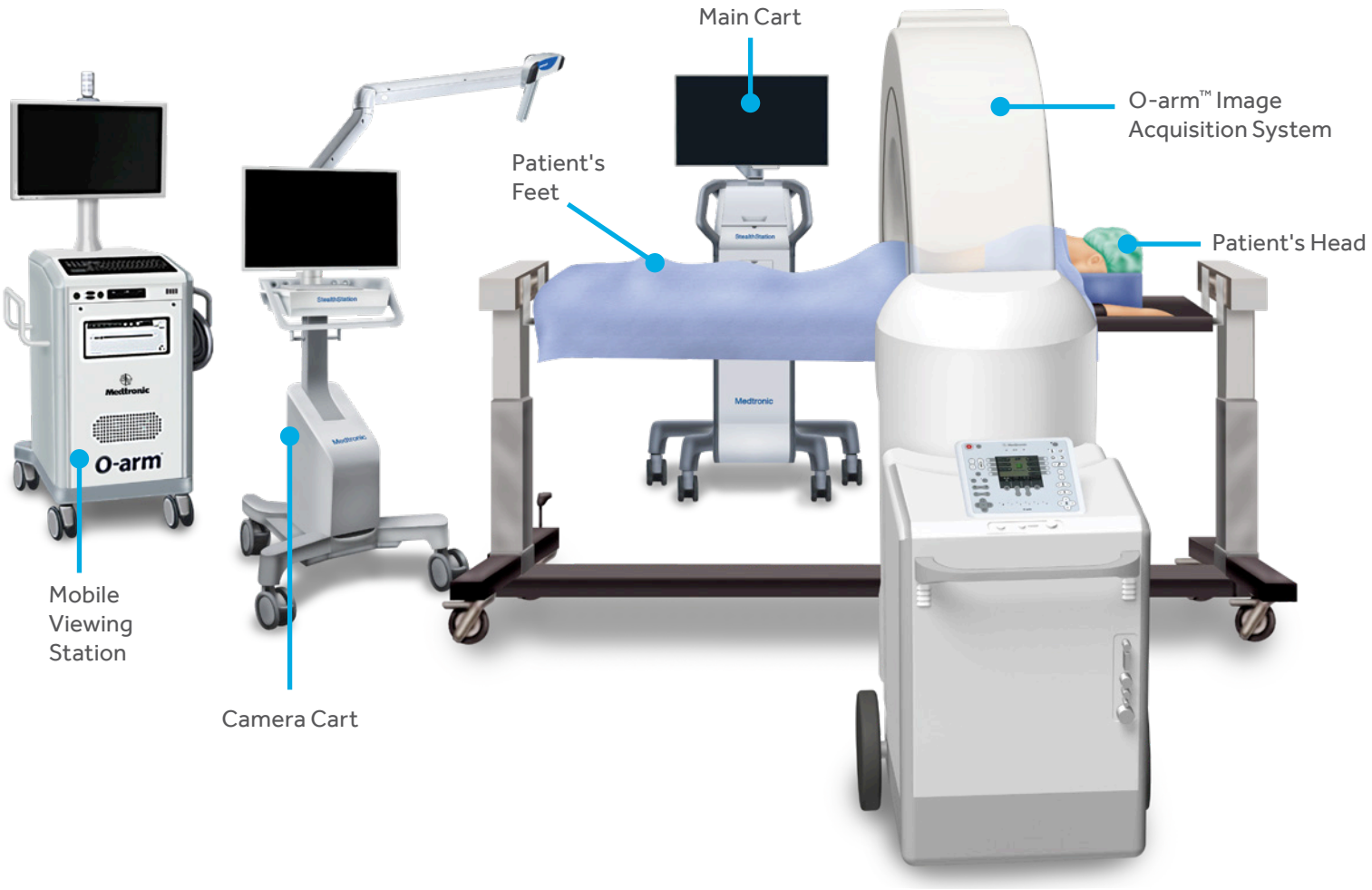
NAVIGATION TECHNOLOGY
SET-UP

For a navigated surgery, the OR should be equipped with the O-arm™ Image Acquisition System, the Mobile Viewing Station (MVS), and the StealthStation™ S7 or S8 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.



SITE ACCESS
DISC PREPARATION

Perform surgical site access and disc preparation per the surgeon's usual manner. The main goal is to remove extruded fragments, decompress neural elements, and provide entry into the disc space for distraction, with minimal or no nerve root retraction (**Figures 1 and 2**). Note that the patient must be properly positioned and/or stabilized during surgery, per the surgeon's chosen approach.

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. Pre-pack the disc space per the surgeon's usual manner, taking into consideration patient specific needs.

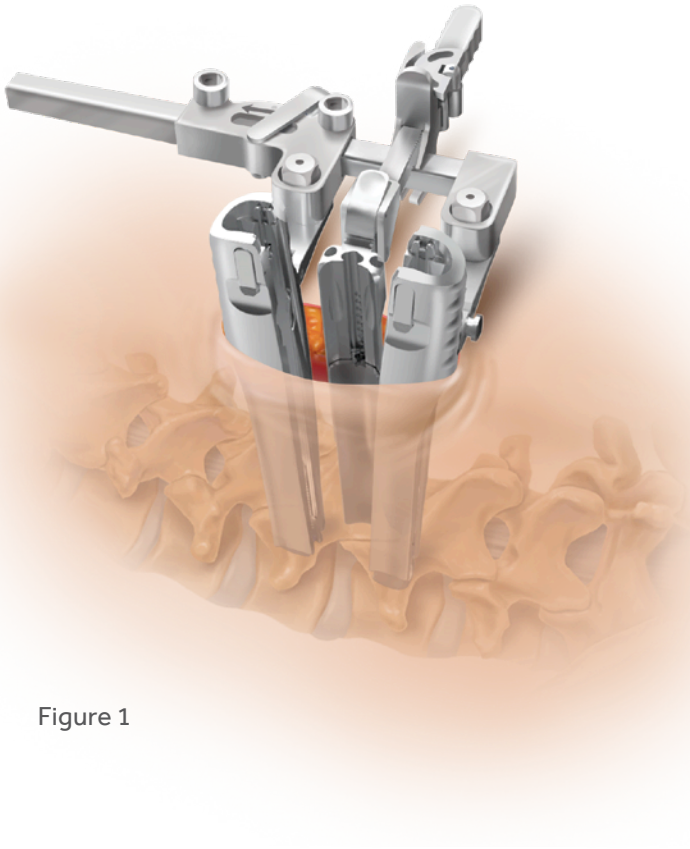


Figure 1

Figure 2

TRIALING
WITH CATALYFT™ PL TRIALS

The Catalyft™ PL Trials or Navigated Trials ("Trials") can be used to determine the desired profile, length, starting height, and position of the implant. Trials are available in both the Catalyft™ PL and Catalyft™ PL40 profiles (**Figure 3**).

Trials are available in 7mm, 9mm, and 11mm heights which correspond to the available implant heights of 7mm, 9mm, and 11mm.

Radiographic features on the Trial are intended to assist in the selection of the desired length, position, and orientation of the implant within the disc space when used with intra-operative fluoroscopy.

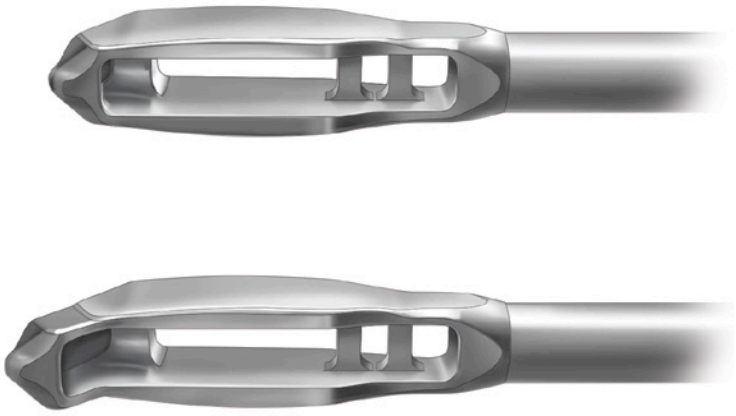


Figure 3

Standard Trialing

For standard trialing , insert the Trial into the disc space and advance the tip of the Trial to the anterior apophyseal ring for maximum endplate coverage.

Confirm the size and position of the Trial using fluoroscopy.

The Trial should fit snugly into the disc space. Select a taller Trial height to achieve the desired fit if needed.

The Slap Hammer can be attached to the Trial to help remove the Trial from the disc space after trialing.

Note
It is recommended to begin the trialing sequence with the 7mm Trial to avoid injury to the bony endplates. Increase Trial height from 7mm to 9mm to 11mm as needed to achieve the desired fit.

Note
Use caution to maneuver around soft tissue upon insertion and removal of the Trials, particularly with the PL40 profile.

TRIALING
WITH ROTATING SHAVERS

The following steps explain the use of the Catalyft™ Expandable Interbody System when used in conjunction with the StealthStation™ System. Refer to the applicable manual listed in the "Description" section for complete indications, warnings, precautions, and important medical information on StealthStation™ and associated instruments.

Attach Navigated Rotating Shaver to NavLock™ Tracker until it is fully engaged (**Figure 4**).

On the StealthStation™ System, choose the "Tool" tab to select an appropriately sized Navigated Rotating Shaver. The Navigated Rotating Shaver heights are available in 1mm increments from 7 to 14mm. Insert the Navigated Rotating Shaver into the disc space in the direction parallel to the endplates, and progressively increase Shaver sizes from small to large using tactile feedback during rotation (**Figure 5**).

The Virtual Trial feature on the StealthStation™ System may be used to project a cylindrical overlay to represent implant lengths (**Figure 6**).

To activate this feature, select both Catalyft™ Inserter Tool Card and Posterior Disc Prep Tool Card.

Next, select the "Virtual Trial" tab under "Projection".

Finally, select the profile (PL or PL40) and length (short or long) corresponding to the implant of interest. The cylindrical overlay will show in the length of the implant that has been selected (**Figure 7**).

Note

The virtual trial cylindrical overlay does not show the specific shape of the Catalyft™ PL or Catalyft™ PL40 implant. Instead, the cylindrical overlay is the shape of the Shaver.

The Navigated Catalyft™ PL Trials should be used for final disc space sizing and implant selection. When using the Navigated Rotating Shavers, use caution to avoid damage or disruption to the bony endplate as this may lead to unwanted settling of the implant and/or inability to fully realize lordosis restoration.

Figure 4

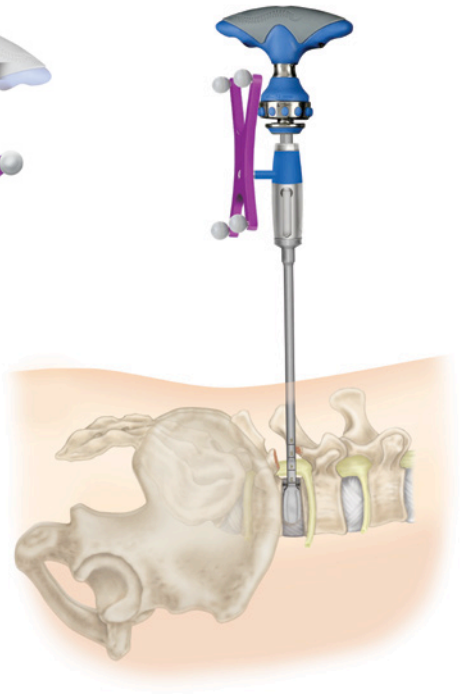


Figure 5

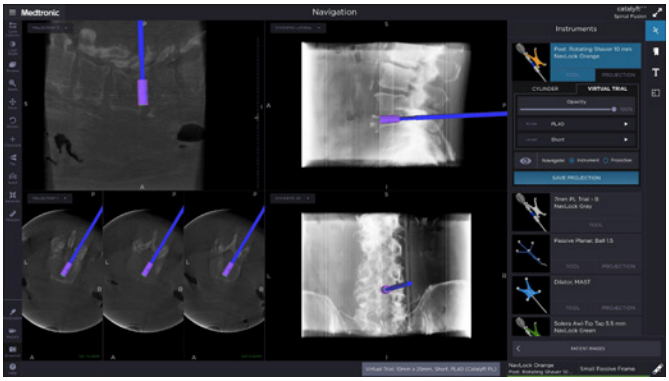


Figure 6

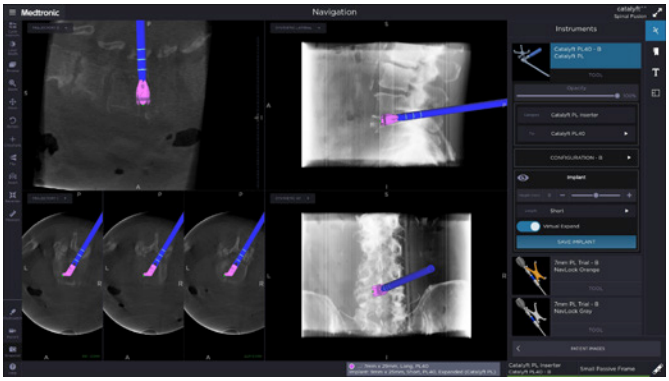


Figure 7

TRIALING
WITH NAVIGATED CATALYFT PL TRIALS

Attach Catalyft™ PL Navigated Trial to NavLock™ Tracker until it is fully engaged.

Ensure that the NavLock™ Tracker is positioned such that the navigation array will face the StealthStation™ Camera and the tip of the Trial will be pointing medially when inserted.

The NavLock™ Tracker will align with either the A or B positioning designation etched on the Catalyft™ PL Navigated Trial (**Figure 8**).

Within the NavLock™ tool card on the StealthStation™ System, choose "Catalyft™ PL Trials" as the category.

Select the corresponding Trial from the "Tip" drop down (ex. 7mm PL Trial).

Select A or B configuration to correspond with the A/B orientation of the NavLock™ Tracker on the Catalyft™ PL Navigated Trial.

Insert the Catalyft™ PL Navigated Trial into the disc space and advance the tip of the Trial to the anterior apophyseal ring for maximum endplate coverage.

Select either PL or PL40 profile from the "Profile" drop down.

Note
The profile selection menu is only available when the using the PL Trials. It is not available when using the PL40 Trials.

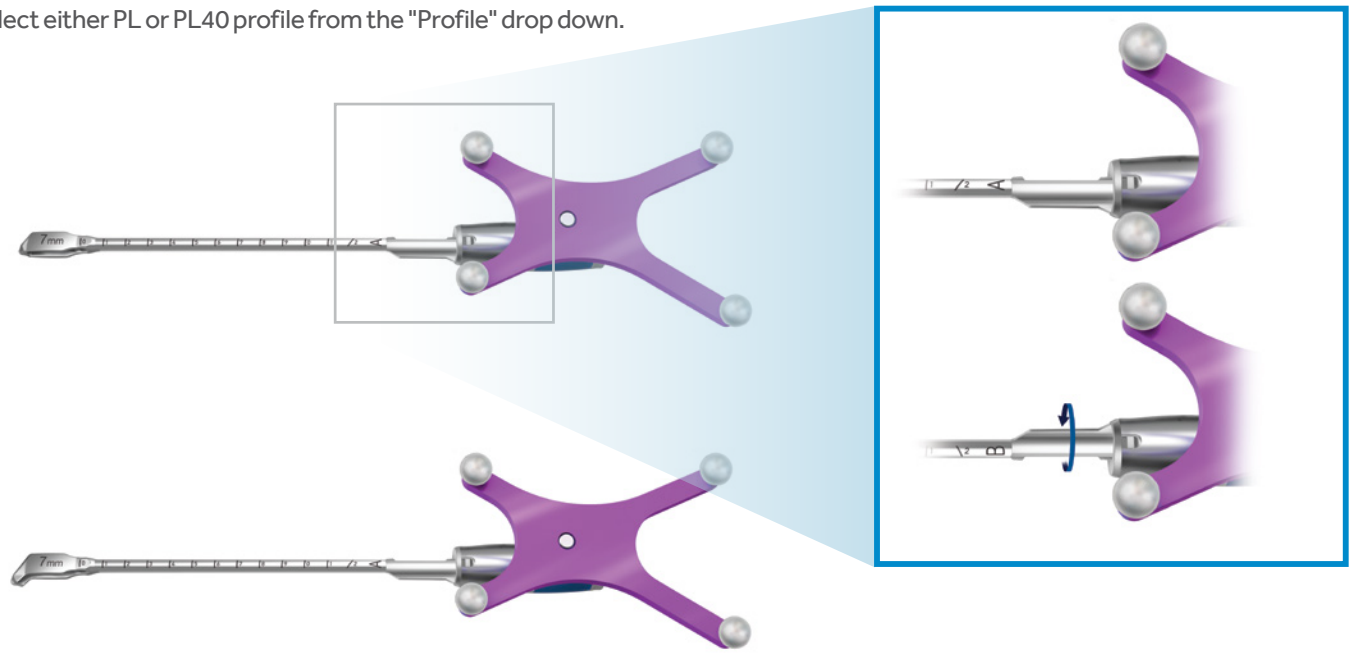


Figure 8

Select the length from the "Length" drop down menu. Green indicators shown on the Trial on the StealthStation™ System correspond to the Short and Long implant lengths.

The Catalyft™ PL Navigated Trial should fit snugly into the disc space. Select a taller Trial height to achieve the desired fit if needed (**Figure 9**).

The Slap Hammer can be attached to the Trial to help remove the Trial from the disc space after trialing. To use the Slap Hammer, first remove the NavLock™ Tracker from the Catalyft™ PL Navigated Trial (**Figure 10**).

Next, connect the Navigated Trial Adapter to the Catalyft™ PL Navigated Trial.

The Slap Hammer can now be connected to the Navigated Trial Adapter.

Note
The virtual trial size and position can be saved on the StealthStation™ and used for reference later. To save an image of the Virtual Trial once the Trial is in place, choose the "Projection" tab; then choose "Save Virtual Trial."

Note
It is recommended to begin the trialing sequence with the 7mm Trial to avoid injury to the bony endplates. Increase Trial height from 7mm to 9mm to 11mm as needed to achieve the desired fit.

Note
Use caution to maneuver around soft tissue upon insertion and removal of the Trials, particularly with the PL40 profile.

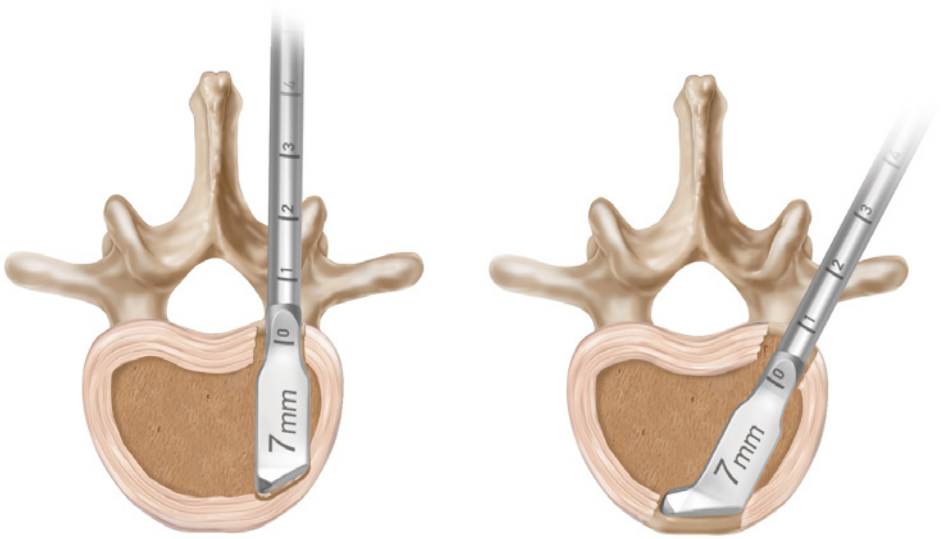


Figure 9

Figure 10

IMPLANTATION
INSERTER ASSEMBLY

1. Insert the Catalyft™ PL Inserter inner sleeve into the Catalyft™ PL Inserter (**Figure 11**).
2. Rotate the Catalyft™ PL Inserter Inner Sleeve clockwise until it spins freely and is firmly captured in the Catalyft™ PL Inserter (**Figure 12**).

Figure 11

Note
Once fully assembled, the Catalyft™ PL Inserter Inner Sleeve should be retained in the Catalyft™ PL Inserter.

Note
Inserter assembly (Inserter, Inner Sleeve, and Driver) should be taken apart prior to cleaning and sterilization.

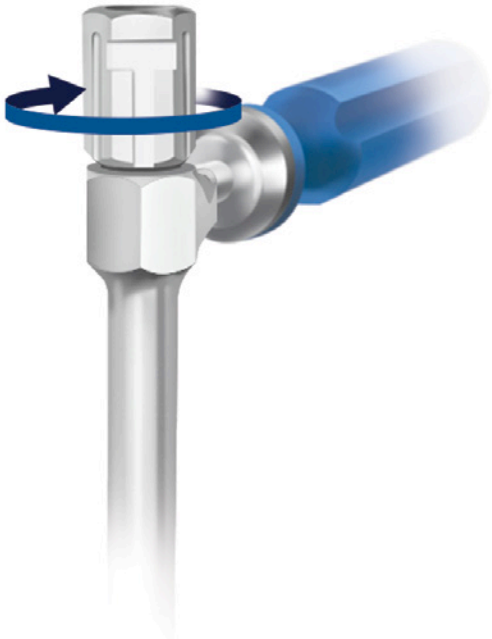


Figure 12

IMPLANTATION
NAVIGATED INSERTER ASSEMBLY

1. Insert the Catalyft™ PL Inserter Inner Sleeve into the Navigated Catalyft™ PL Inserter (**Figure 13**).
2. Rotate the Catalyft™ PL Inserter Inner Sleeve clockwise until it spins freely and is firmly captured in the Navigated Catalyft™ PL Inserter (**Figure 14**).

Figure 13

Note
Once fully assembled, the Catalyft™ PL Inserter Inner Sleeve should be retained in the Navigated Catalyft™ PL Inserter.

Note
Inserter assembly (Inserter, Inner Sleeve, and Driver) should be taken apart prior to cleaning and sterilization.

Figure 14

NAVIGATED INSERTER VERIFICATION

To verify the Navigated Catalyft™ PL Inserter, thread the Catalyft™ PL Nav Verification Tool into the shaft of the Nav Catalyft™ PL Inserter until it is fully seated (**Figure 15**). Within the Navigated Catalyft™ PL Inserter tool card, select "Verification Tool" as the instrument tip. Place the tip of the assembly into the Reference Frame divot (**Figure 16**). Hold perpendicular and visible to the camera until a confirmation color is seen.

- Successful verification is indicated by a chime and a transition to green on the instrument toolcard.
- Failed verification is indicated by a "bonk" sound and indicates that the instrument may be positioned improperly in the divot or is bent/damaged. Inspect the instrument; if it is bent/damaged, do not use.
- If no sound is heard when the instrument is touched to the divot, this may indicate that the camera cannot see either the instrument or the frame.

Important
Posterior Disc Prep instruments and Trials are verified with default instruments and not the actual tip.

Note
To verify the Navigated Catalyft™ PL Inserter, the Verification Tool must first be selected as the "Tip" option in the Inserter tool card.

Figure 15

Figure 16

IMPLANTATION
ATTACH IMPLANT TO INSERTER

Align the one-way prongs on the Catalyft™ PL Inserter assembly with the cut-outs on the implant as shown in **Figure 17**.

Push the Catalyft™ PL implant onto the Catalyft™ PL Inserter assembly and apply positive pressure.

Rotate the Catalyft™ PL Inserter, Inner Sleeve clockwise until the implant is fully seated and firmly attached to the Inserter assembly (**Figure 18**).

Note
The implant is designed to mate with the Inserter assembly in only one orientation. The implant should face medially when implanted. Improper orientation of the implant could cause implant or instrument damage and may cause the implant to loosen from the Inserter assembly prematurely.

Note
DO NOT insert the Catalyft™ PL Driver into the Inserter assembly until the implant has been inserted into the disc space.

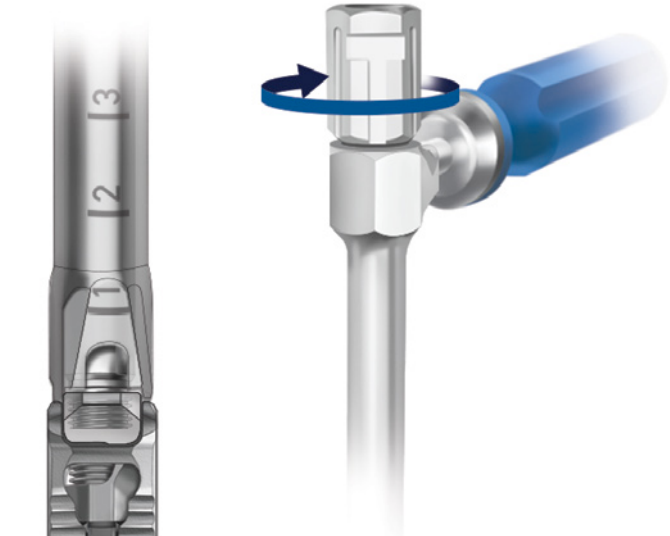


Figure 17

Figure 18

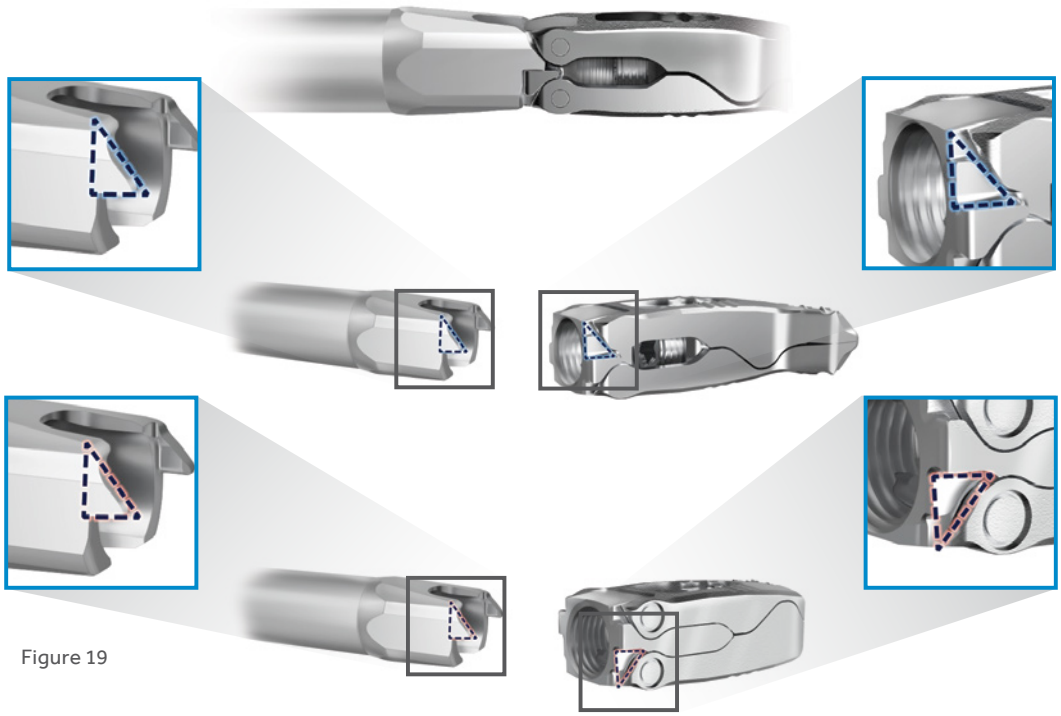


Figure 19

Note
The implant is designed to mate with the Inserter assembly in only one orientation. The implant should face medially when implanted. Improper orientation of the implant could cause implant or instrument damage and may cause the implant to loosen from the Inserter assembly prematurely (**Figure 19**).

IMPLANTATION
ATTACH IMPLANT TO NAVIGATED INSERTER

Align the one-way prongs on the Navigated Catalyft™ PL Inserter assembly with the cut-outs on the implant as shown in **Figure 20**.

Push the Catalyft™ PL implant onto the Navigated Catalyft™ PL Inserter assembly and apply pressure.

Rotate the Catalyft™ PL Inserter Inner Sleeve clockwise until the implant is fully seated and firmly attached to the Inserter assembly (**Figure 21**).

Note
DO NOT insert the Catalyft™ PL Driver into the Inserter assembly until the implant has been inserted into the disc space.

Figure 20

Figure 21

IMPLANTATION
IMPLANT POSITIONING

With the Catalyft™ PL implant in the unexpanded (fully collapsed) position, insert the implant into the disc space (**Figure 22**). A mallet may be used to facilitate implantation.

Advance the implant into the disc space until the leading edge of the implant aligns with the anterior apophyseal ring of the vertebral body (**Figure 23**).

Confirm the position of the implant with AP and Lateral fluoroscopy.

Note
Always implant the tallest height implant the disc space will accommodate in order to optimize foraminal decompression and congruence of the implant and vertebral body endplates.

Note
Use caution to maneuver around soft tissue upon insertion of the implant, particularly with the PL40 profile.

Note
The Slap Hammer can be attached to the Catalyft™ PL Inserter Inner Sleeve to aid in repositioning or removal of the implant (**Figure 24**). Ensure the Catalyft™ PL implant is fully collapsed before repositioning or removal.

Note
The Catalyft™ PL System's toxicological risk assessment was conducted for a two-implant scenario.

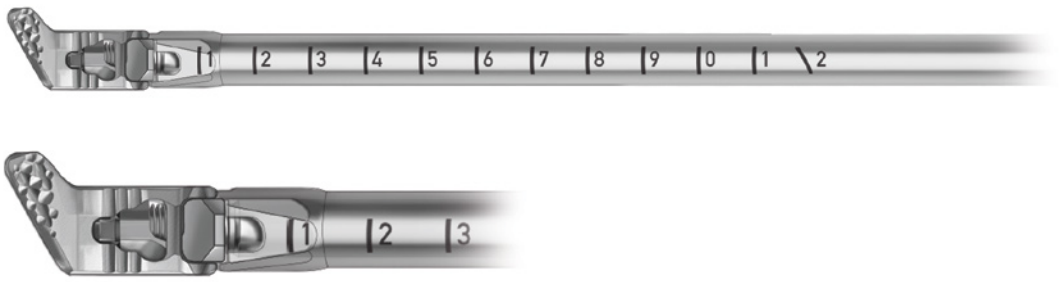
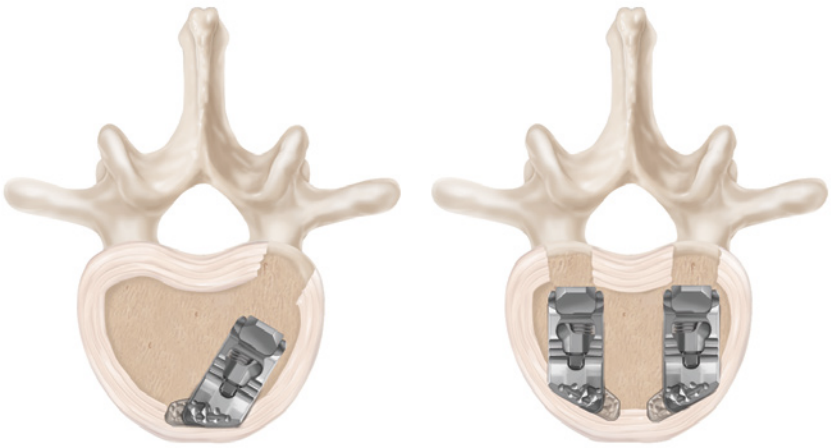


Figure 22



Catalyft™ PL or PL40
Oblique Placement Options

Catalyft™ PL or PL40
Unilateral or Bilateral Placement Option

Figure 23

Figure 24

IMPLANTATION
NAVIGATED IMPLANT POSITIONING

Ensure that the Navigation Tracker on the Navigated Catalyft™ PL Inserter is positioned such that the navigation array will face the StealthStation™ Camera, and the tip of the implant faces medially during implantation. Depress the button on the Navigated Catalyft™ PL Inserter handle to allow the Tracker to be rotated 180° if needed (**Figure 25**). If the button is sticking, binding, or grinding, refer to the functional inspection section of IFU for instructions regarding lubrication.

The Navigation Tracker will align with either the A or B positioning designation etched on the Navigated Catalyft™ PL Inserter (**Figure 26**).

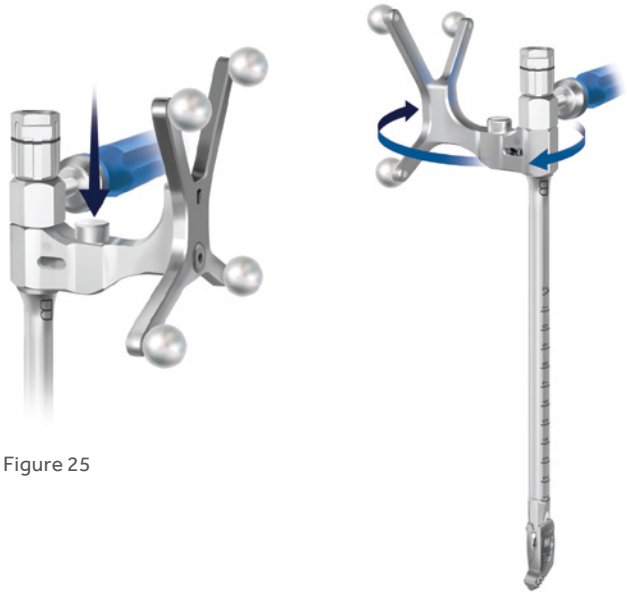


Figure 25

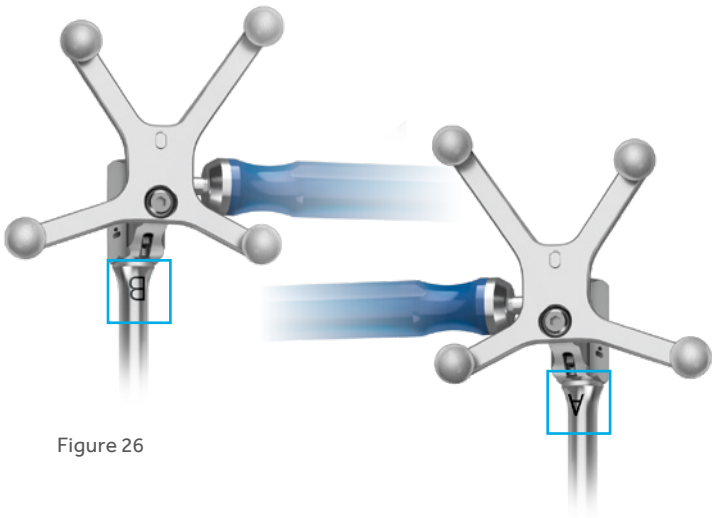


Figure 26

Within the Catalyft™ PL Inserter tool card on the StealthStation™ System, select "Catalyft™ PL" or "Catalyft™ PL40" from the "Tip" drop down menu. This selection should correspond with the implant.

Select A or B configuration to correspond with the A/B orientation on the Navigated Catalyft™ PL Inserter.

Next, select the correct implant height and implant length.

With the Catalyft™ PL implant in the unexpanded (fully collapsed) position, insert the implant into the disc space. A mallet may be used to facilitate implantation.

Advance the implant into the disc space until the leading edge of the implant aligns with the anterior apophyseal ring of the vertebral body.

Confirm the position of the implant with the StealthStation™ System.

The Virtual Expansion feature can be used to reference the fully expanded height but does not represent the actual expansion state of the interbody.

Note
This orientation should be the same as that used during trialing with the Catalyft™ PL Navigated Trial.

Note
To avoid potential navigation inaccuracy, exercise caution to prevent the application of force on the tracker that could bias the navigated instrument. In the event of suspected inaccuracy, depress the button and rotate tracker out of position, then return tracker to desired locked position.

Note
The final implant size and position can be saved on the StealthStation and used for reference later. To save an image of the implant, leave the Inserter attached to the implant once placed and choose the "Projection" tab; then choose "Save Implant."

Note
Always implant the tallest height implant the disc space will accommodate in order to optimize foraminal decompression and congruence of the implant and vertebral body endplates.

Note
Use caution to maneuver around soft tissue upon insertion of the implant, particularly with the PL40 profile.

Note
The Slap Hammer can be attached to the Catalyft™ PL Inserter Inner Sleeve to aid in repositioning or removal of the implant. Ensure the Catalyft ™ PL implant is fully collapsed before repositioning or removal.

Note
The graduated markings on the Navigated Catalyft™ PL Inserter can be used to assess the depth of the implant in the disc space. Markings are in 1cm increments measured from the posterior aspect of the implant when securely attached to the Navigated Catalyft™ PL Inserter.

Note
When using the Catalyft(tm) PL Inserter, only the collapsed position of the implant is navigated. Implant expansion is not tracked.

IMPLANTATION
LORDOTIC EXPANSION

Insert the Catalyft™ PL Driver into the Catalyft PL Inserter or Navigated Catalyft™ PL Inserter.

The Hex Driver tip will engage with the implant expansion mechanism (**Figure 27**).

Attach the Torque Limiting Handle to the Catalyft™ PL Driver (**Figure 28**).

Rotate the Torque Limiting Handle clockwise to expand the Catalyft™ PL implant (**Figure 29**).

Important
Do not strike the Torque Limiting Handle with a mallet which may result in damage to the implant.

Full expansion of the Catalyft™ PL and Catalyft™ PL40 Interbody is achieved with approximately 13 half turns of the Catalyft™ PL Driver.

The laser etching visible through the expansion gauge window indicates the progress of implant expansion. Confirm the final implant position and expansion with AP and lateral fluoroscopy.

After the implant has been expanded the desired amount, remove the Torque Limiting Handle and the Catalyft™ PL Driver from the Inserter assembly.

Tip
The numbers 1, 2, and 3 on the Catalyft™ PL Driver can be used to help track the number of revolutions during lordotic expansion.

Figure 27

Figure 28

Figure 29

IMPLANTATION
GRAFT DELIVERY

Once the interbody device is in its final position and has been expanded to the desired height, it can be packed with autogenous bone graft and/or allograft bone graft comprised of cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate directly through the Catalyft™ PL Inserter assembly.

The Graft Funnel and Graft Pusher can be used to deliver graft material through the Catalyft™ PL Inserter or Navigated Inserter and directly into the implant (**Figure 30**).

Alternatively, the Grafton™ DBF Inject System can be used to deliver graft material. If using Grafton™ DBF Inject System, refer to IFU.

If using Grafton™ DBF Inject, connect the Syringe to the Catalyft™ PL Inserter Inner Sleeve. After use, remove the Grafton™ DBF Syringe from the Catalyft™ PL Inserter Inner Sleeve.

To remove the Inserter from the implant, attach the Release Handle to the Catalyft™ PL Inserter Inner Sleeve. Rotate the Release Handle counterclockwise (**Figure 31**).

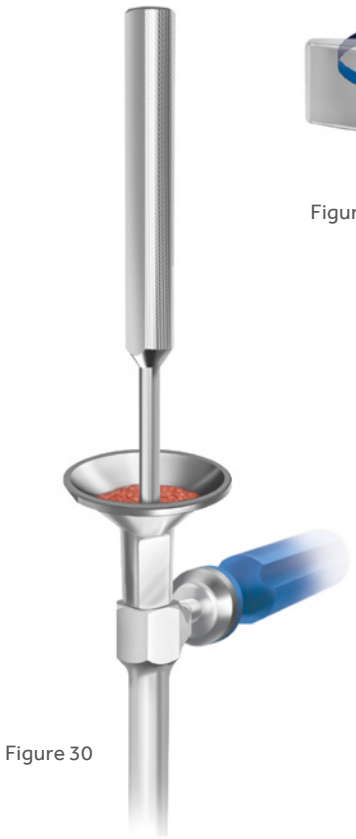


Figure 30

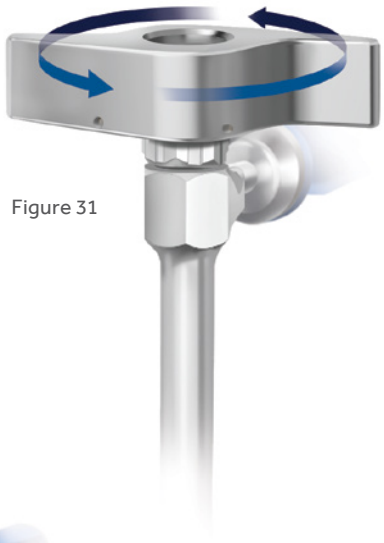


Figure 31

Implant Positioning Considerations

Note

Always implant the tallest height implant the disc space will accommodate in order to optimize foraminal decompression and congruence of the implant and vertebral body endplates.

It is important to maintain contact between the Catalyft™ PL implant and the vertebral body endplates.

Note

The Catalyft™ PL implants can generate significant expansion forces during lordotic expansion. Care should be taken to avoid endplate damage caused by excessive expansion forces. If poor bone quality is suspected, limit the amount of lordotic expansion. Placement of the leading tip of the Catalyft™ PL implants on the anterior apophyseal ring of the vertebral body is recommended.

Note

Expanding a Catalyft™ PL implant beyond the limit of the supplied Torque Limiting Handle may result in damage to the implant and instruments and may cause injury to the patient.

Important

The Catalyft™ Expandable Interbody System is to be used with supplemental internal fixation systems cleared for use in the lumbar spine.

Excessive lordotic expansion of the Catalyft™ PL implant beyond the lordotic capability of the motion segment could lead to a gap between the Catalyft™ PL implant and the vertebral body endplates. Do not leave the Catalyft™ PL implant in place with a gap between the implant and the vertebral body endplates. This could cause excessive subsidence and/or premature implant breakage.

If a gap is noticed after lordotic expansion of the implant, one or more of the following steps may be considered to correct the positioning:

1. Compress the segment posteriorly and fix the position by tightening the rod into the pedicle screw.

   Bilateral facetectomy may be required for optimal posterior compression.

2. Reduce the lordotic expansion of the Catalyft™ PL implant and fix the position by tightening the rod into the pedicle screw.
3. Remove the Catalyft™ PL implant and re-implant a taller implant (if available). Expand the Catalyft™ PL implant to the desired lordotic expansion and fix the position by tightening the rod into the pedicle screw.

IMPLANTATION
IMPLANT RE-POSITIONING/ REMOVAL

To reposition or remove the Catalyft™ PL implant after the Catalyft™ PL Inserter has been disconnected, first connect the Catlyft™ PL Extractor Sleeve to the implant as shown in **Figure 32**.

Next, pass the Auger through the Catalyft™ PL Extractor Sleeve and into the Catalyft™ PL implant. The Graft Auger can be used to clear the implant chamber and hex head of bone material and tissue (**Figure 33**).

Remove the Graft Auger.

Insert the Catalyft™ PL Driver into the Catalyft™ PL Extractor Sleeve (**Figure 34**).

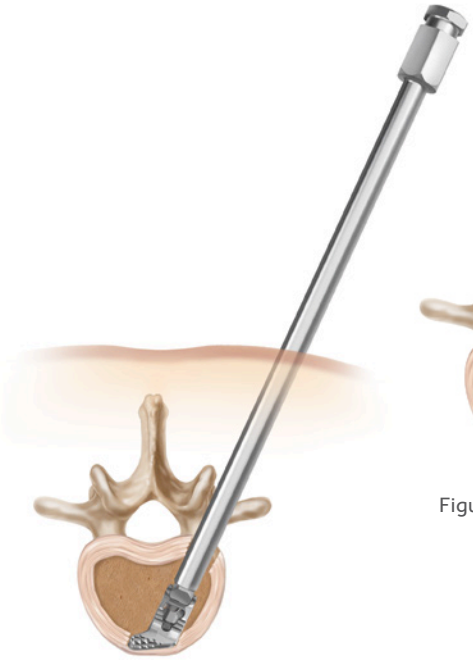


Figure 32

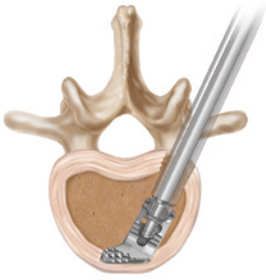


Figure 33

Figure 34

Attach the Torque Limiting Handle to the Catalyft™ PL Driver.

Rotate the Torque Limiting Handle counterclockwise to collapse the Catalyft™ PL implant (**Figure 35**).

Important
Do not strike the Torque Limiting Handle with a mallet which may result in damage to the implant.

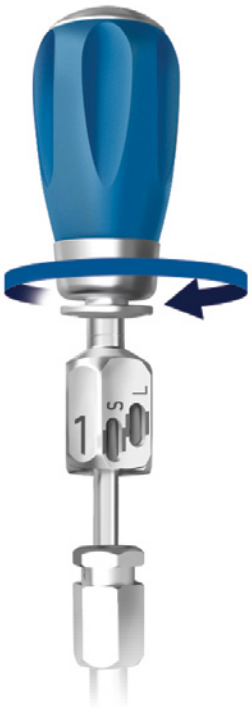


Figure 35

After the implant is fully collapsed, remove the Catalyft™ PL Driver and Torque Limiting Handle from the Catalyft™ PL Extractor Sleeve.

Attach Slap Hammer to the Catalyft™ PL Extractor Sleeve and remove/reposition the implant as needed (**Figure 36**).

Figure 36

To release the Catalyft™ PL Extractor Sleeve from the implant, attach the Release Handle to the Catalyft™ PL Extractor Sleeve and rotate counterclockwise (**Figure 37**).

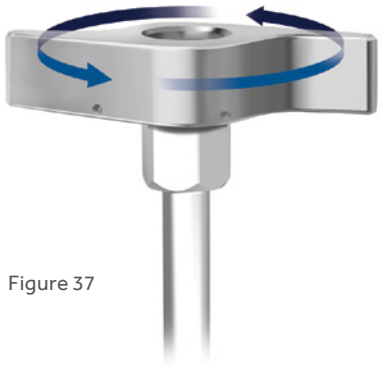


Figure 37

Note
The blue line on the Graft Auger shaft is visible until the sharp tip of the Graft Auger passes beyond the tip of the Catalyft™ PL Extractor Sleeve. When the blue line is no longer visible, the tip of the Graft Auger is unprotected (**Figure 38**).

Note
The Straight Mesh Holder (905-810) may be used to grasp and reposition the implant if needed.

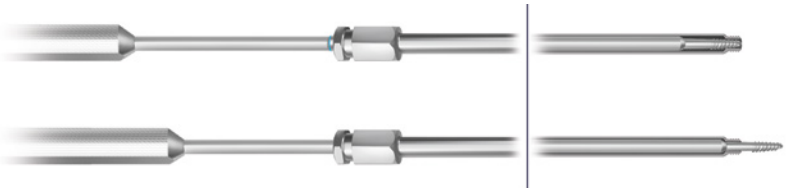


Figure 38

PRODUCT ORDERING INFORMATION

SPS03143- Catalyft™ PL Implant Set

CFN	Description	Qty/ Set
6068073	Catalyft™ PL, Short, 7mm	2
6068093	Catalyft™ PL, Short, 9mm	2
6068113	Catalyft™ PL, Short, 11mm	2
6068076	Catalyft™ PL, Long, 7mm	2
6068096	Catalyft™ PL, Long, 9mm	2
6068116	Catalyft™ PL, Long, 11mm	2
6060002	Catalyft™ PL Expandable Interbody System PL Implants Suitcase	1
6060002-01	Catalyft™ PL Expandable Interbody System PL Implants Suitcase Label	1

SPS03144 - Catalyft™ PL 40 Implant Set

Part Number	Description	Qty/ Set
6069073	Catalyft™ PL 40, Short, 7mm	2
6069093	Catalyft™ PL 40, Short, 9mm	2
6069113	Catalyft™ PL 40, Short, 11mm	1
6069076	Catalyft™ PL 40, Long, 7mm	2
6069096	Catalyft™ PL 40, Long, 9mm	2
6069116	Catalyft™ PL 40, Long, 11mm	1
6060004	Catalyft™ PL40 Expandable Interbody System PL Implants Suitcase	1

SPS03145 - Catalyft™ PL Instrument Set

Part Number	Description	Qty/ Set
6061000	Catalyft™ PL Inserter	1
6061001	Catalyft™ PL Inserter Inner Sleeve	1
6061002	Catalyft™ PL Inserter Driver	2
6061003	Extractor Sleeve	1
6061004	Inserter Pusher	1
6061005	Inserter Funnel	1
6061009	Release Handle	1
G178104	Torque Limiting Handle, 4 Nm	1
6061076	Catalyft™ PL Trial, 7mm	1
6061096	Catalyft™ PL Trial, 9mm	1
6061116	Catalyft™ PL Trial, 11mm	1
6062076	Catalyft™ PL 40 Trial, 7mm	1
6062096	Catalyft™ PL 40 Trial, 9mm	1
6062116	Catalyft™ PL 40 Trial, 11mm	1
8657011	SLAP HAMMER	1
6061011	Auger	1
6060001	Catalyft™ PL Expandable Interbody System Instrument Tray	1
1850097	Generic Lid	1

SPS03146 - Catalyft™ PL NAV Instrument Set

Part Number	Description	Qty/ Set
NAV6061000	NAV Catalyft™ PL Inserter	1
6061001	Catalyft™ PL Inserter Inner Sleeve	1
6061002	Catalyft™ PL Inserter Driver	2
6061003	Extractor Sleeve	1
6061004	Inserter Pusher	1
6061005	Inserter Funnel	1
6061009	Release Handle	1
G178104	Torque Limiting Handle, 4 Nm	1
NAV6061076	Catalyft™ PL Nav Trial, 7mm	1
NAV6061096	Catalyft™ PL Nav Trial, 9mm	1
NAV6061116	Catalyft™ PL Nav Trial, 11mm	1
NAV6062076	Catalyft™ PL 40 Nav Trial, 7mm	1
NAV6062096	Catalyft™ PL 40 Nav Trial, 9mm	1
NAV6062116	Catalyft™ PL 40 Nav Trial, 11mm	1
8657011	Slap Hammer	1
6061011	Auger	1
6061012	NAV Trial Adapter	1
NAV6061013	Catalyft™ PL NAV Inserter Verification Tool	1
6060000	Catalyft™ PL Expandable Interbody System Navigated Instrument Base	1
6060003	Catalyft™ PL Expandable Interbody System Navigated Inner Tray	1

IMPORTANT INFORMATION
ON THE CATALYFT™ EXPANDABLE INTERBODY SYSTEM

Note: not all parts may be available in each geography.

PURPOSE
This device is a fusion device intended for stabilization and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician thoroughly knowledgeable in the implant's material and surgical aspects and instructed as to its mechanical and material applications and limitations.

DESCRIPTION
The Catalyft™ PL Expandable Interbody System is an expandable titanium alloy interbody device consisting of expandable interbodies of various widths, lengths, heights, and lordotic angles to accommodate patient anatomy. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The articulating device assembly allows for placement of the implant while remaining attached to the inserter. Implants have a central cavity that allows them to be packed with autogenous bone graft and/or allograft bone graft comprised of cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate.

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

INDICATIONS
The Catalyft™ PL Expandable Interbody System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (DDD - defined by discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. Additionally, the Catalyft™ PL Expandable Interbody System can be used with patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone 6 months of non-operative treatment prior to surgery. Implants are used to facilitate fusion in the lumbar spine using autogenous bone graft and/or allograft bone graft comprised of cancellous and/or corticocancellous bone, and/or demineralized allograft bone with bone marrow aspirate. These implants are intended for use with supplemental internal fixation systems.

CONTRAINDICATIONS
The Catalyft™ PL Expandable Interbody System is not intended for cervical or thoracic spine use. Contraindications include:

- Infection local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to composite materials.
- 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
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any case where implant components selected for use would be too large or too small to achieve a successful result.
- Cases requiring the mixing of metals from two different components or systems.
- Patients having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- 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.

Take into consideration that the segmental stability can be affected by a variety of factors

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

- Implant migration.
- Breakage of the device(s).
- Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
- Pressure on the 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.
- Bone graft donor site complication.
- Inability to resume activities of normal daily living.
- Early or late loosening or movement of the device(s).

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

Note: additional surgery might become necessary to correct adverse effects.

WARNINGS AND PRECAUTIONS
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise results. Use of this product without autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone or in cases that do not develop a union will not be successful.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of implants are important considerations in the successful use of the system. Further, proper selection and compliance of the patient will 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.

Document the used implants per patient with REF and LOT, so tracking, which is required by law, is guaranteed. Implants are only for single use. Do not re-process or re-use devices labeled as single use devices. Re-processing or re-use of single use devices 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.

Physician note: although the physician 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 physician.

IMPLANT SELECTION
Selection of proper size, shape, and design of the implant 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 human anatomy. Unless great care is taken in patient selection, placement of implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage or loosening of the device before the fusion 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 accomplished with special ancillary instruments and equipment supplied and designated by Medtronic. In the interests of patient safety, do not use Medtronic implants with devices from any other source.

Never, under any circumstances, reuse a Catalyft™ PL Expandable Interbody System implant. Even when a removed implant appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.

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 taken when handling and storing the device(s). They should not be scratched or damaged. Devices should be protected during storage especially from corrosive environments.
- The surgeon should be familiar with the various devices before use and should personally verify all devices are present before surgery.
- The size of device for the case should 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 should be available in case of an unexpected need.

INTRAOPERATIVE
- The instructions in any Catalyft™ PL Expandable Interbody System surgical technique manual should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the spinal cord and/or nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implants may cause injury to the patient 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 components difficult or impossible.

POSTOPERATIVE
The physician'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. The patient must be warned that loosening, and/or breakage of the device(s) are complications which may occur as result of early or excessive weight- bearing, muscular activity, or sudden jolts or shock to the spine.
- The patient should be advised not to smoke or consume excess alcohol during period of the bone fusion process.
- The patient should be advised of the 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.
- Catalyft™ PL Expandable Interbody System 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.
- When explanting and/or disposing of a device, avoid exposure to bodily substances such as blood, tissue, etc., as contact could lead to infection or disease. Always wear and use proper equipment, taking special care with sharp objects and needles. Follow your healthcare center's policy regarding both the disposal of devices and any events of exposure.

VISUAL INSPECTION
Visually inspect all sterile-barrier packaging before use. If the sterile barrier is damaged or the integrity is compromised, do not use the product. Contact Medtronic for return information.

Visually inspect the device before use. If the device is damaged, do not use the product. Contact Medtronic for return information.

PACKAGING
Devices are supplied sterile. Packages for each of the components should be intact upon receipt. Once the seal on the sterile package is broken, the product should not be re-sterilized. If a loaner set is used, all sets and components should be carefully checked for completeness and to ensure there is no damage prior to use.

MRI INFORMATION
The Catalyft™ PL Expandable Interbody System was determined to be MR-Conditional based on non-clinical testing and engineering rationales. A patient with this device can be safely scanned immediately after device placement under the following conditions:

- Static magnetic field of 1.5 and 3.0-Tesla.
- Maximum spatial gradient magnetic field of 3000-Gauss/cm (30 T/m) or less.
- Maximum whole-body average specific absorption rate (SAR) of 2.0 -W/kg under normal operating mode for 15 minutes of scanning per pulse sequence.

Under the scan conditions defined, a worst-case interbody fusion device representative of the Catalyft™ PL Expandable Interbody System produced a maximum temperature rise < 5.0 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by a worst-case interbody fusion device representative of the Catalyft™ PL Expandable Interbody System extends approximately 13 mm for a spin echo sequence and 23 mm for a gradient echo sequence in a 3-Tesla MR system. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

If Catalyft™ PL Expandable Interbody System is used in connection with any device which is not MR Conditional, please be advised that this combination has not been tested in the MR environment and, therefore, higher heating and possible injury to the patient may occur. The presence of other implants or the health state of the patient may require a modification of the MR conditions.

Consult instructions for use included with the product and/or at this website www.medtronic.com/manuals.

Catalyft™ PL Expandable Interbody System (eManual M333023W048E)

Catalyft™ PL Expandable Interbody System- EU only (eManual M333023W048EU)

Other devices referenced in this document:

StealthStation™ S8 System Manual (Manual Document Number: 9735573)

StealthStation™ S7 System Manual (Manual Document Number: 9733782)

Navlock™ Tracker (Manual Document Number: 9734289)

NOTE: Additional instructions included in the applicable navigated instruments IFU/eManual referenced above

O-arm™ Imaging System User Manual (Manual Document Number: BI-500-00060)

Grafton DBF Inject

Medtronic

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

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

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.

The device complies with European Directive MDD 93/42/EEC

Consult instructions for use at this website.

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