Medtronic

SURGICAL TECHNIQUE

Adaptix™ PEEK

Interbody System with Nanotechnology

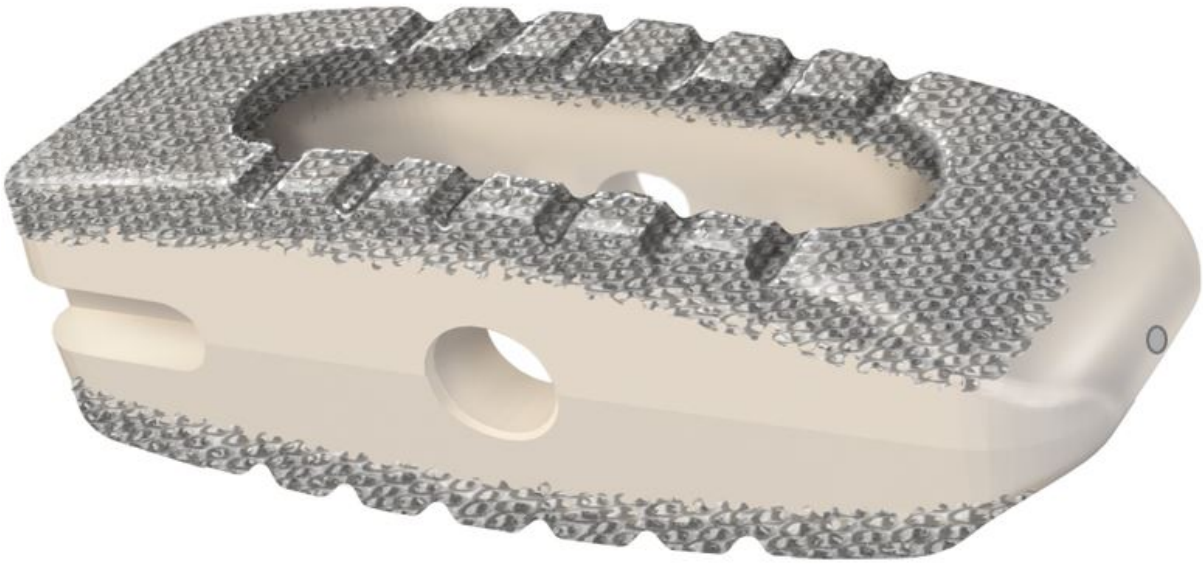


Table of contents

Further information

Consult instructions for use (IFU) included with the product and/or at this website: medtronic.com/manuals. The IFU contains the complete list of indications, warnings, precautions, and other important medical information.

Adaptix™ PEEK Interbody System with Nanotechnology

The Adaptix™ PEEK interbody system with nanotechnology was developed as an implant for stabilization of the lumbar spinal column via an open or minimally invasive transforaminal lumbar interbody fusion (TLIF) or posterior lumbar interbody fusion (PLIF) procedure. This surgical technique is designed to familiarize healthcare professionals with the surgical procedure. Please carefully read this surgical technique prior to the use of the implant.

The Adaptix™ PEEK interbody system is a bullet-shaped PEEK core implant with porous titanium endplates and nanotechnology, designed with a dolphin nose tip. The Adaptix™ PEEK interbody system can restore sagittal alignment in the lumbar spine by offering multiple heights and lengths.

Figure 1a

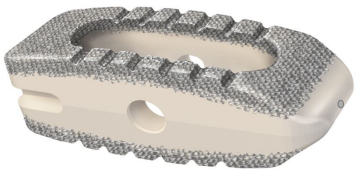


Figure 1b

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)

Note

Tantalum pin located in the tip of the dolphin nose.

Figure 2a

Figure 2b

Technology set-up

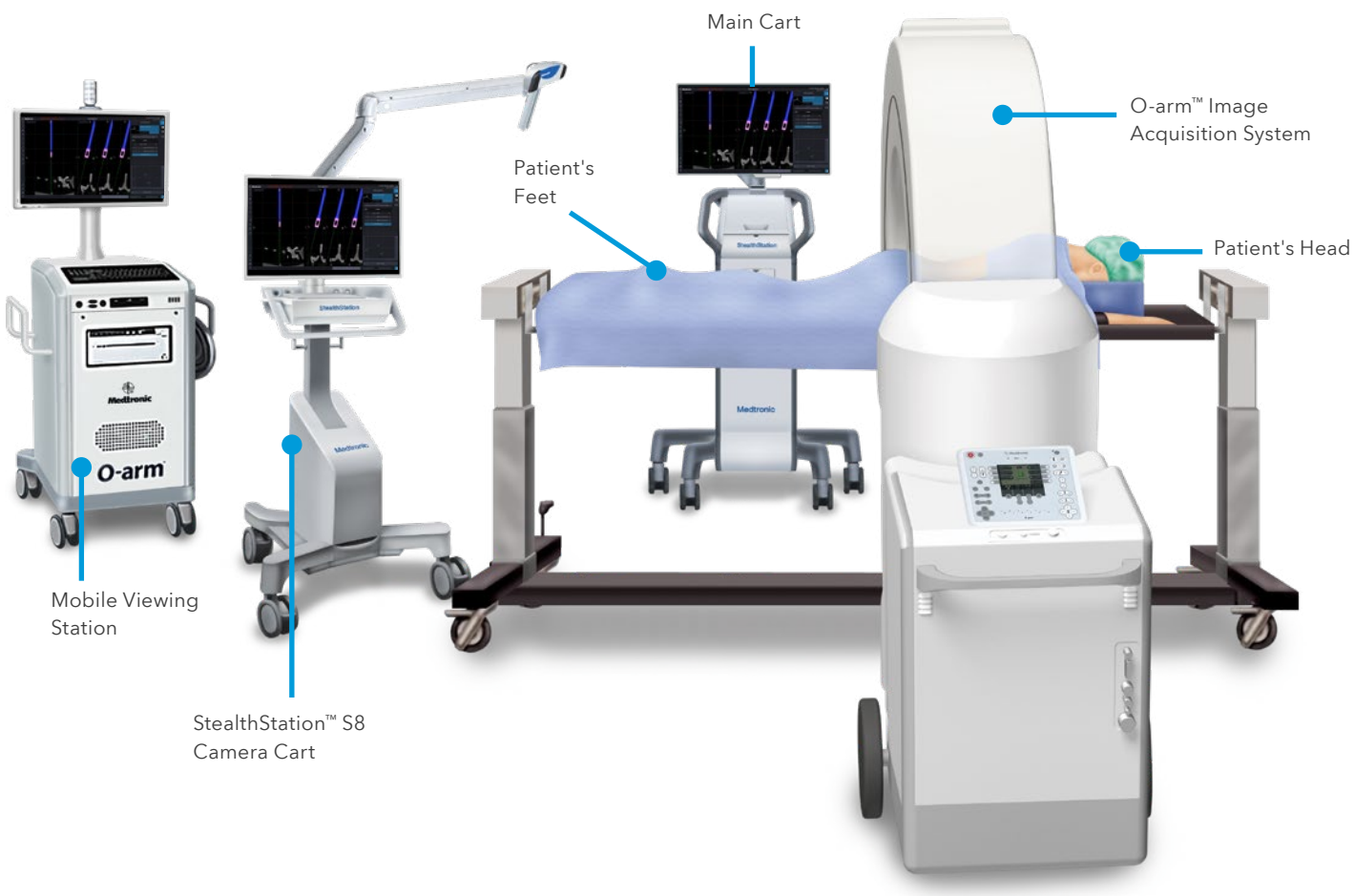
Navigation Technology Set-Up

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.

The equipment setup for Navigated Posterior Fixation Procedure has the StealthStation S8 Camera Cart positioned near the patient's feet.



Surgical site access and 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.

Note

Patient must be properly positioned and/or stabilized during surgery, per the surgeon's chosen approach.

Note

Adaptix™ nanoPEEK leverages the same instrument sets as Adaptix™ and Capstone Spinal Systems. See corresponding surgical techniques for instrument ordering.

To ensure proper fusion below and around the location of the cage, 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.

Trialing

Medtronic Capstone™ spinal system trials can be used for sizing the Adaptix™ nanoPEEK implant. Radiographic features on the trial are intended to aid in the selection of the desired length, position, and orientation of the implant within the disc space when used with intra-operative fluoroscopy.

Standard Trialing

The Adaptix™ nanoPEEK implant is 2 mm longer due to the dolphin nose tip that helps aid in insertion. The below image is an overlay of the Capstone™ trial and Adaptix™ nanoPEEK implant, illustrating their shared profiles.

Trial Selection Guide

Refer to the below table for using Capstone™ spinal system trials with Adaptix™ nanoPEEK implants:

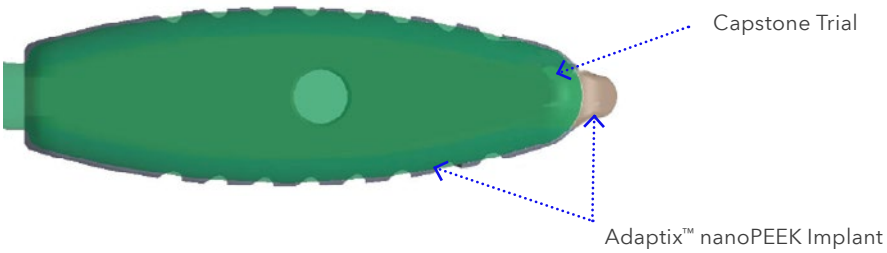
Capstone™ Trial Length	Adaptix™ nanoPEEK Implant Length
22 mm	24 mm
26 mm	28 mm
32 mm	34 mm

Insert the trial until the desired disc space height is established. A slap hammer can be used for removal.

Trialing with the Rotating Shaver or Paddle Distractors

Shaver and distractor heights are available in 1 mm increments from 8 to 14 mm. To use for trialing, insert the rotating shaver/distractor into the disc space in the direction parallel to the end plates, and progressively increase shaver sizes from small to large using tactile feedback during rotation.

For either method described above, use AP and lateral fluoroscopy to confirm proper placement.



Trialing with Navigated Rotating Shavers

The following steps explain the use of the Adaptix™ nanoPEEK 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.

On the StealthStation™ system, choose the “Tool” tab to select an appropriately sized navigated rotating shaver. The navigated rotating shaver heights are available in 1 mm increments from 7 to 14 mm. Insert the navigated rotating shaver into the disc space in the direction parallel to the end plates, and progressively increase shaver sizes from small to large using tactile feedback during rotation.

The virtual trial feature on the StealthStation™ system may be used to project a cylindrical overlay to represent implant lengths.

On the StealthStation™ System, select the appropriate Rotating Shaver size from the "Tip” drop down list. In the "Projection" tab, click "Virtual Trial" and select Adaptix PEEK from the "Family" drop down list.

The cylindrical overlay will show in the length of the implant that has been selected.

Use the virtual trial to confirm proper placement and alignment of the shaver.

Note

The virtual trial cylindrical overlay does not show the specific shape of the implant. Instead, the cylindrical overlay is the shape of the Shaver.

Note

When using the Navigated Rotating Shavers, use caution to avoid damage or disruption to the bony endplate as this may lead to implant subsidence into the vertebrae.

Trialing with Navigated Capstone™ Trials

Capstone™ navigated trials are available in 8 mm, 10 mm, 12 mm, and 14 mm heights in both 22 mm and 26 mm lengths.

If other size options are desired, use standard procedure steps using non-navigated instruments for the trialing step.

Note

Adaptix™ nanoPEEK is compatible with Capstone™ instruments. The Adaptix™ nano PEEK implant is 2 mm longer than the Capstone™ trials, therefore, it's important to ensure that the appropriate implant is selected to view the correct projection.

On the StealthStation™ system, select the appropriate trial size from the "Tip" drop down list. In the "Projection" tab, click "Virtual Trial" and select Adaptix PEEK from the "Family" drop down list.

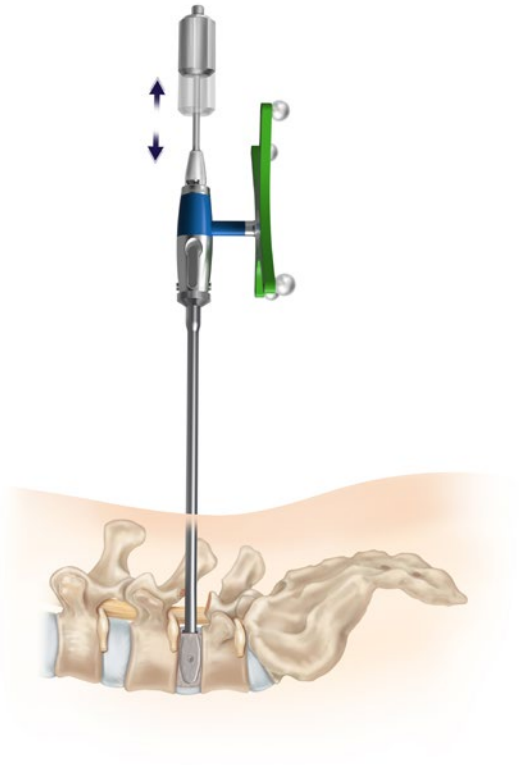
Insert the Capstone™ spinal system navigated trials with a NavLock™ tracker into the disc space until the desired disc space height is established.

Select the appropriate virtual projection length to match the desired length of the implant. Confirm proper placement and alignment of the trial from the projections shown matching the Adaptix™ nanoPEEK implant. If needed, use a slap hammer to remove the trial.

Navigated Capstone™ Trial Length	Virtual Projection Length	Adaptix™ nanoPEEK Implant Length
22 mm	24 mm	24 mm
26 mm	28 mm	28 mm
32 mm	34 mm	34 mm

Note

The navigated trials are not available for all size offerings for Adaptix™ nanoPEEK Implants.



Implantation

Attaching the Implant to the Standard or Navigated Inserter

The appropriately sized Adaptix™ nanoPEEK implant is chosen during the trialing step.

Align the Inserter with the cut-outs on the implant.

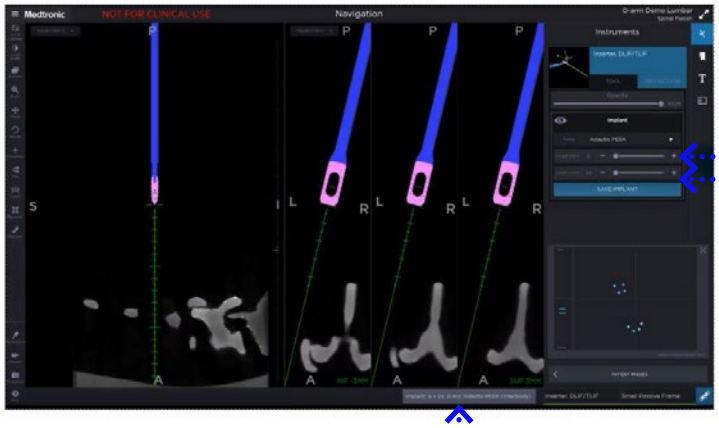
Push the Adaptix™ nanoPEEK implant onto the Inserter assembly and apply positive pressure.

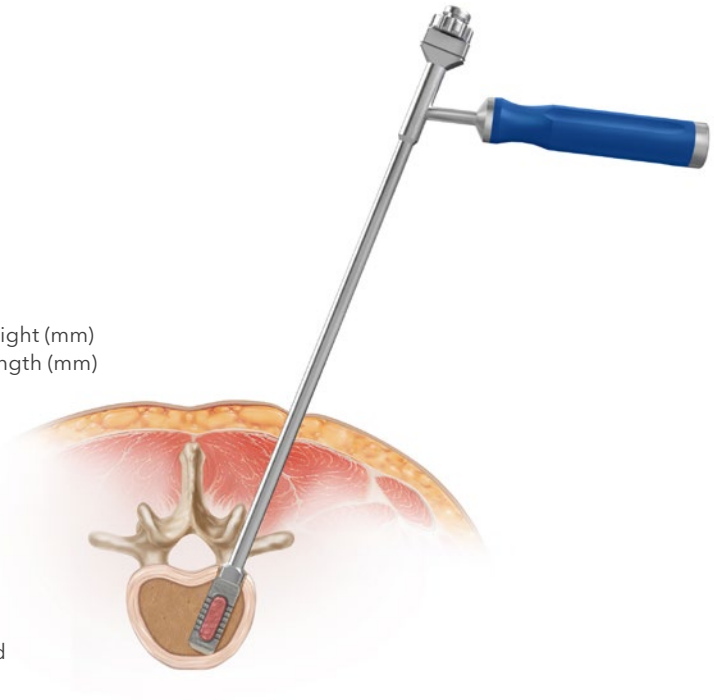
Rotate the inserter inner sleeve clockwise until the implant is fully seated and firmly attached to the Inserter before inserting.

Before inserting the implant, place appropriate bone graft material anteriorly and contralaterally, and in the implant central cavity.

The implant's central cavity may be filled with Grafton™ DBF bone graft, autograft, and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate, or a combination thereof.

Adaptix™ nanoPEEK navigation screen shown below.





Implant Positioning

Gently impact the Adaptix™ nanoPEEK implant until it is 3 mm to 4 mm ventral to the posterior margin of the posterior annulus.

Care should be taken to ensure the implant is aligned properly.

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

Note

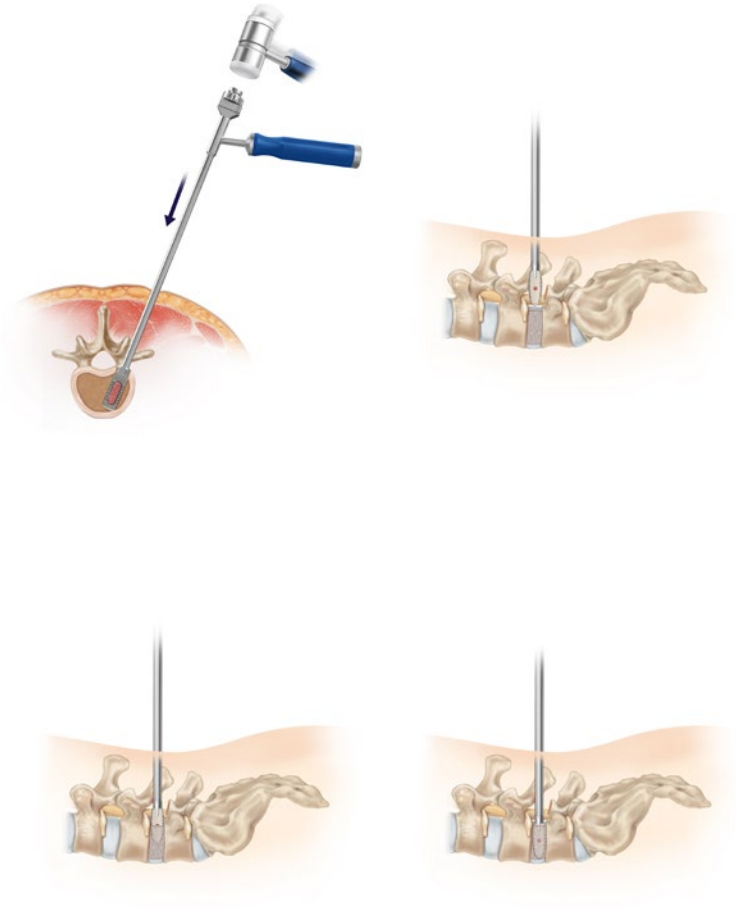
Ensure that the convex surfaces of the implant are aligned and in contact with the end plates during insertion.

Note

Do not insert the Adaptix™ nanoPEEK implant sideways and rotate into final position.

Note

All Adaptix™ PEEK implants feature a 1.5 mm tantalum pin located in the tip of the dolphin nose geometry to aid in depth placement using lateral fluoroscopy.



Navigated Implant Positioning

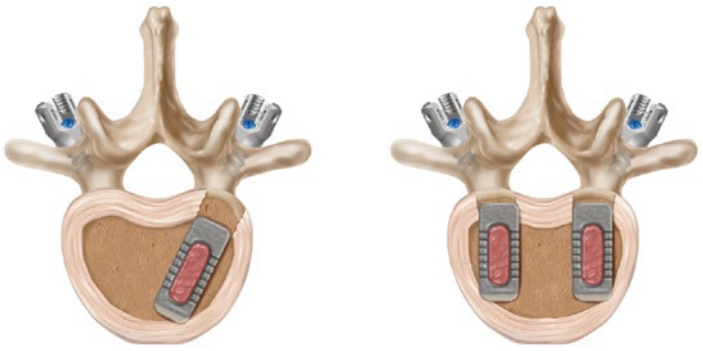
On the StealthStation™ system, click the "Tool" tab and select Adaptix™ PEEK from the "Family" drop down list. Select the appropriately sized Adaptix™ nanoPEEK implant as determined during the trialing step.

In the software, choose the “Select Projection” tab, then “Show as Implant” to adjust the implant size. Implant size must be adjusted to match selected implant. Use a mallet to gently insert the implant until it is 3 mm to 4 mm ventral to the posterior margin of the posterior annulus.

Note

To save an image of the implant in the software, leave the Inserter attached to the implant once placed and choose the “Select Projection” tab; then choose “Save Implant”.

Once the implant is positioned, unthread the Inserter from the implant and remove the Inserter.



Note

If the cage needs to be repositioned, the threaded inserter can be used.

Post-implantation steps

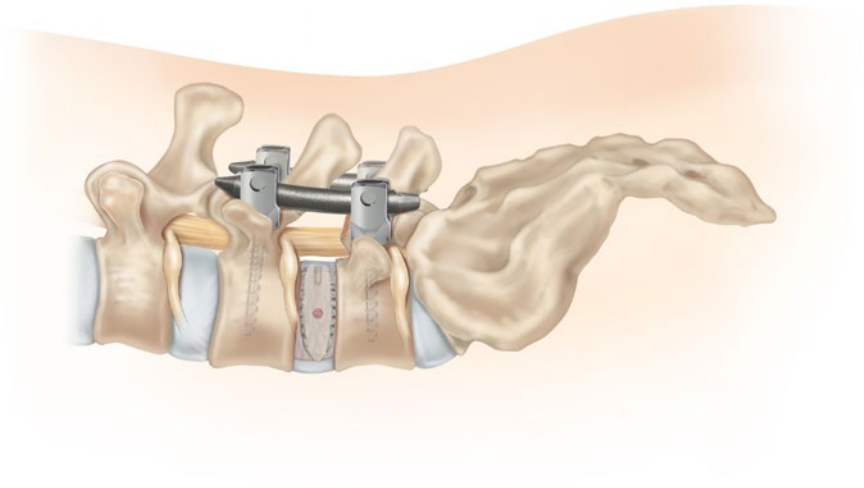
After the Adaptix™ nanoPEEK implant is placed, additional graft may be placed posteriorly to the cage as desired.

The screw-rod construct may be compressed to preload the interspace and restore lordosis.

The extradural space and foramina are probed to ensure adequate decompression of the neural elements has been achieved.

Note

The Adaptix™ nanoPEEK Interbody system is to be used with supplemental internal fixation systems cleared for use in the lumbar spine.



Explantation

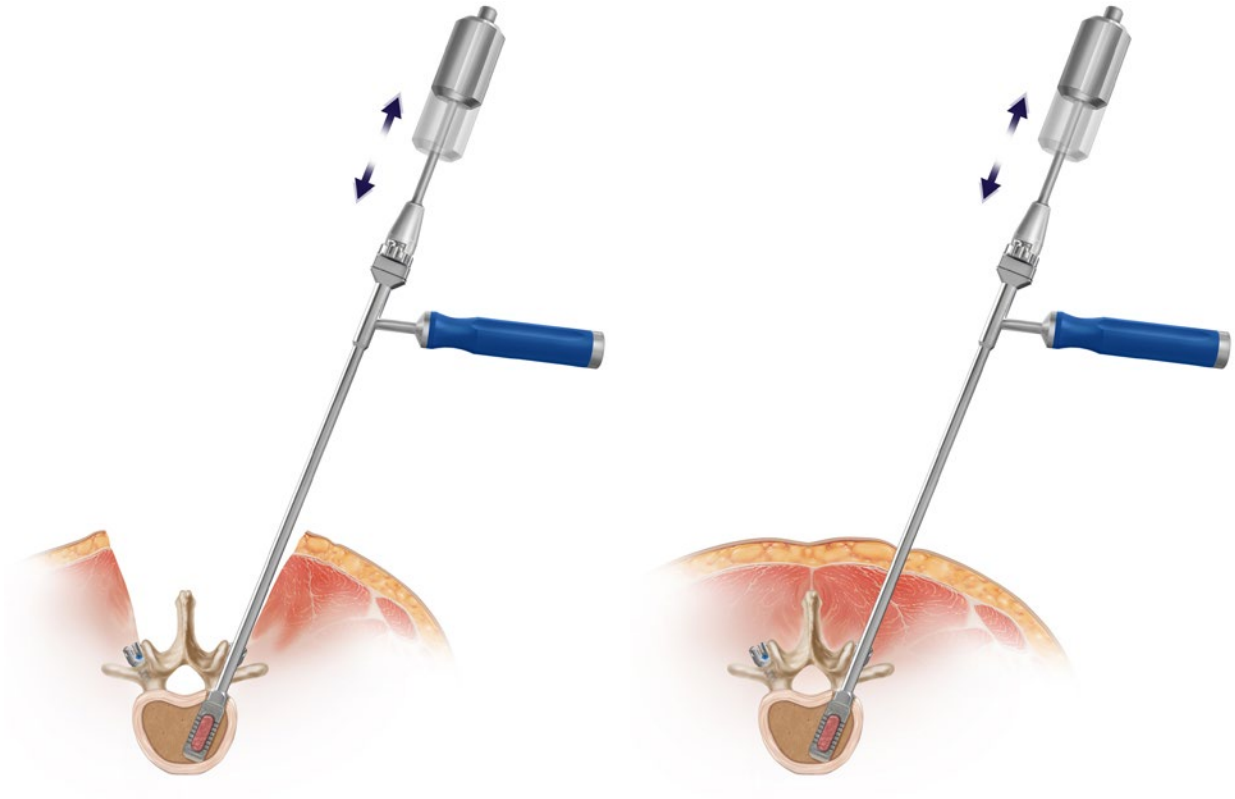
The Adaptix™ nanoPEEK implant may be removed by using the threaded inserter or extractor.

To use the threaded inserter, attach to the implant and remove it from the disc space. If needed, attach the slap hammer to the distal end of the inserter and remove.

Alternatively, use the extractor by screwing the tip of the instrument into the tapped hole in the back of the implant, and slap hammer to gently remove the construct.

Note

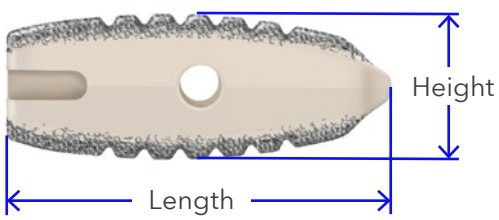
Threaded inserter may be used for extraction. Capstone Extractor tool and slap hammer may also be used for extraction. Distraction and bone removal may also be required before the implant can be removed.

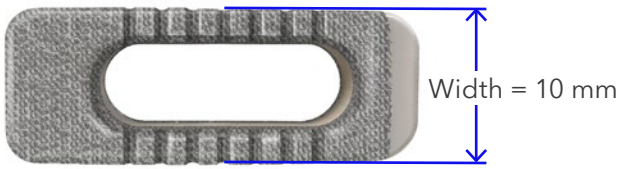


Implant size and internal volume

Adaptix™ nanoPEEK Graft Volumes				
Part Number	Length (mm)	Height (mm)	Width (mm)	Graft Volume (cc)
74332406	24	6	10	0.4
74332407	24	7	10	0.5
74332408	24	8	10	0.6
74332409	24	9	10	0.6
74332410	24	10	10	0.7
74332411	24	11	10	0.7
74332412	24	12	10	0.8
74332413	24	13	10	0.8
74332414	24	14	10	0.9
74332415	24	15	10	0.9
74332416	24	16	10	1.0
74332806	28	6	10	0.5
74332807	28	7	10	0.6
74332808	28	8	10	0.7
74332809	28	9	10	0.8
74332810	28	10	10	0.9
74332811	28	11	10	0.9
74332812	28	12	10	1.0
74332813	28	13	10	1.1
74332814	28	14	10	1.2
74332815	28	15	10	1.2
74332816	28	16	10	1.3
74333407	34	7	10	0.8
74333408	34	8	10	1.0
74333409	34	9	10	1.1
74333410	34	10	10	1.2
74333411	34	11	10	1.3
74333412	34	12	10	1.4
74333413	34	13	10	1.5
74333414	34	14	10	1.6
74333415	34	15	10	1.7
74333416	34	16	10	1.8

Size specifications





Adaptix™ nanoPEEK 24 mm and 28 mm Set		
CFN	Description	Qty
74332406	Adaptix™ PEEK Spacer with nanotechnology 24 mm × 6 mm	2
74332407	Adaptix™ PEEK Spacer with nanotechnology 24 mm × 7 mm	2
74332408	Adaptix™ PEEK Spacer with nanotechnology 24 mm × 8 mm	4
74332409	Adaptix™ PEEK Spacer with nanotechnology 24 mm × 9 mm	2
74332410	Adaptix™ PEEK Spacer with nanotechnology 24 mm × 10 mm	4
74332411	Adaptix™ PEEK Spacer with nanotechnology 24 mm × 11 mm	2
74332412	Adaptix™ PEEK Spacer with nanotechnology 24 mm × 12 mm	4
74332413	Adaptix™ PEEK Spacer with nanotechnology 24 mm × 13 mm	2
74332414	Adaptix™ PEEK Spacer with nanotechnology 24 mm × 14 mm	2
74332806	Adaptix™ PEEK Spacer with nanotechnology 28 mm × 6 mm	2
74332807	Adaptix™ PEEK Spacer with nanotechnology 28 mm × 7 mm	2
74332808	Adaptix™ PEEK Spacer with nanotechnology 28 mm × 8 mm	4
74332809	Adaptix™ PEEK Spacer with nanotechnology 28 mm × 9 mm	2
74332810	Adaptix™ PEEK Spacer with nanotechnology 28 mm × 10 mm	4
74332811	Adaptix™ PEEK Spacer with nanotechnology 28 mm × 11 mm	2
74332812	Adaptix™ PEEK Spacer with nanotechnology 28 mm × 12 mm	4
74332813	Adaptix™ PEEK Spacer with nanotechnology 28 mm × 13 mm	2

Adaptix™ nanoPEEK 34 mm Set		
CFN	Description	Qty
74333407	Adaptix™ PEEK Spacer with nanotechnology 34 mm × 7 mm	2
74333408	Adaptix™ PEEK Spacer with nanotechnology 34 mm × 8 mm	2
74333409	Adaptix™ PEEK Spacer with nanotechnology 34 mm × 9 mm	2
74333410	Adaptix™ PEEK Spacer with nanotechnology 34 mm × 10 mm	2
74333411	Adaptix™ PEEK Spacer with nanotechnology 34 mm × 11 mm	2
74333412	Adaptix™ PEEK Spacer with nanotechnology 34 mm × 12 mm	2
74333413	Adaptix™ PEEK Spacer with nanotechnology 34 mm × 13 mm	2
74333414	Adaptix™ PEEK Spacer with nanotechnology 34 mm × 14 mm	2
74333415	Adaptix™ PEEK Spacer with nanotechnology 34 mm × 15 mm	2
74333416	Adaptix™ PEEK Spacer with nanotechnology 34 mm × 16 mm	2

Important product information on O-arm™ O2 Imaging System

INDICATIONS FOR USE

The O-arm™ O2 Imaging System is a mobile x-ray system, designed or 2D and 3D imaging for adult and pediatric patients weighing 60 lbs or greater and having an abdominal thickness greater than 16 cm, and is intended to be used where a physician benefits from 2D and 3D information of anatomic structures and objects with high x-ray attenuation such as bony anatomy and metallic objects.

The O-arm™ O2 Imaging System is compatible with certain image guided surgery systems.

CONTRAINDICATIONS

The O-arm™ O2 Imaging System has no known contraindications.

Medtronic Navigation, Inc. (Boxborough)
200 Beaver Brook Road
Boxborough, MA 01719
USA
Telephone: +1-720 890 3160
Fax +1-720 890 3500
www.medtronic.com
Printed in the USA

Important product information on StealthStation™ S8 Spine System

INTENDED USE / INDICATIONS FOR USE

The StealthStation™ System, with StealthStation™ Spine software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the spine or pelvis, can be identified relative to images of the anatomy.

This can include the following spinal implant procedures, such as:

- Pedicle screw placement
- Iliosacral screw placement
- Interbody device placement

CONTRAINDICATIONS

Medical conditions that contraindicate the use of a Medtronic computer-assisted surgery system and its associated applications include any conditions which may contraindicate the medical procedure itself.

Medtronic Navigation, Inc.

200 Medtronic Drive

Lafayette, CO 80026

USA

Main 1 720 890 3200

Fax 1 720 890 3500

www.medtronic.com

Technical support:

USA 1 800 595 9709

International +1 720 890 3160

rs.navtechsupport@medtronic.com

www.medtronic.com/manuals

EC REP

Printed in the USA

℞ Only

Important product information on Adaptix™ PEEK interbody system with nanotechnology

DESCRIPTION

Adaptix™ PEEK Interbody System with Nanotechnology includes interbody fusion devices for lumbar implantation. The upper and lower surfaces of each implant incorporate a three-dimensional titanium scaffold with interconnected pores averaging 523 µm, and pore interconnections averaging 229 µm in diameter.

This product demonstrates the requirements for nanotechnology. The surface has been deliberately manipulated to produce nanoscale dimensions which exhibit specific properties. The scaffold of the Adaptix™ PEEK Interbody System is electrochemically treated to possess a controlled nanotopography composed of nanotube arrays having a pore size diameter between 30-90 nanometers. Calcium and phosphate are incorporated into the nanotube surface. These nanotube arrays have been shown to increase and accelerate calcified extracellular matrix production in vitro1 (Figure 1 and Figure 2). The scaffold with nanotubes assists in securing the implant in the intervertebral space and provides radiographic confirmation of the implant location.

The Adaptix™ PEEK Interbody implant has a rectangular shape and a large vertical cavity which is packed with bone graft material to promote fusion of the adjacent vertebral bodies. The implant is available in a variety of sizes to accommodate variations in individual patient anatomy. The Adaptix™ PEEK Interbody devices are manufactured from polyetheretherketone (PEEK-OPTIMA®) per ASTM F2026. The integral scaffold (OsteoSync) is manufactured from CP titanium as described by ASTM F67. Marker pins in these lumbar devices are manufactured from tantalum per ASTM F560.

INDICATIONS

The Adaptix™ PEEK Interbody System with Nanotechnology devices including those with macro-, micro- and nano-roughened surface textured features are intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies) at one or two contiguous spinal levels from L2-S1. These patients should have had six months of nonoperative treatment. These patients may have had a previous non-fusion spinal surgery and/or may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s).

Additionally, Adaptix™ PEEK Interbody System with Nanotechnology devices can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The Adaptix™ PEEK Interbody devices are to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate. These implants are intended for use with supplemental fixation indicated for lumbar spinal fusion procedures and may be implanted via an open or a minimally invasive posterior approach and/or transforaminal approach.

CONTRAINDICATIONS

The Adaptix™ PEEK Interbody System with Nanotechnology device is not intended for cervical spine use.

Contraindications include:

- Infection local to the operative site and/or signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any medical or surgical 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 the component materials.
- Osteopenia and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
- Any case not requiring fusion.
- Any case not described in the indications.
- Any patient unwilling to cooperate with postoperative instructions.
- Patients with a known hereditary or required bone friability or calcification problem should not be considered for this type of surgery.
- This device 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 the implant components selected for use would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any patient 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

The following potential adverse events are associated with spinal fusion surgery and may occur with use of the Adaptix™ PEEK interbody implants:

- Nonunion, delayed union.
- Infection, early or late.
- Breakage of the device.
- Pressure on the surrounding tissue or organs.
- Loss of proper spinal curvature, correction, height, and/or reduction.
- Decreased bone density due to stress shielding at, above, or below the level of surgery.
- Early or late loosening or movement of the device.
- Degenerative changes or instability of segments adjacent to fused vertebral levels.
- Scarring.
- Fracture, microfracture, resorption, damage or penetration of any szpinal bone (including pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsion of bone 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.
- Inability to resume activities of normal daily living.
- Cessation of any potential growth of the operated portion of the spine.

- Discomfort or abnormal sensation due to the surgical procedure or presence of the device.
- Implant material sensitivity, or allergic reaction to a foreign body.
- Discitis, arachnoiditis, and/or other types of inflammation.
- Bone graft donor site complication.
- Complications associated with requisite fixation such as construct loosening or breakage, or sensitivity to the material of the selected fixation system.
- Urinary retention or loss of bladder control or other types or urological system compromise.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including but not limited to bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, paralysis temporary or permanent, dural tears, tethering, compromise or compression of nerves in scar tissue and/or pain, muscle weakness, and paresthesias or other types of serious injury.
- Cerebral spinal fluid leakage.
- Spinal cord impingement or damage.
- Vascular damage could result in fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late post-operative period.
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
- Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental capacities
- Death.

WARNINGS AND PRECAUTIONS

Use of the Adaptix™ PEEK Interbody System should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics; has had experience with the implantation procedures and has had hands-on training in the use of this device, and has read and understood the Package Insert and Surgical Technique. The latest revision of the Surgical Technique is available from Nanovis Spine, at 5865 East State Rd 14 Columbia City, IN 46725, 1-877-907-6266.

Do not re-use or re-process devices labeled as single use devices. Re-use or re-processing of single use devices may compromise the structural integrity and the intended function of the device which could result in patient injury. Sterile packaged devices are never to be re-sterilized.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. This device system is not intended to be the sole means of spinal support; this system must be used with additional anterior or posterior instrumentation to augment stability. Use of this product without bone graft or in cases that do not develop a union will not be successful. 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 marrow aspirate may not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly, and/or breakage of the device(s) will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, adequate reduction, and correct selection and placement of implants are important considerations in the successful use of the system. Final positioning of the implant must be completed while implant is attached to the inserter. 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 patients without a previous spinal surgery.

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.

! USA For US audiences only.

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

Medtronic
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

Nanovis Spine, LLC.
5865 East State Road 14
Columbia City, Indiana 46725
Phone: 1-877-907-6266

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

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

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

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

Medtronic