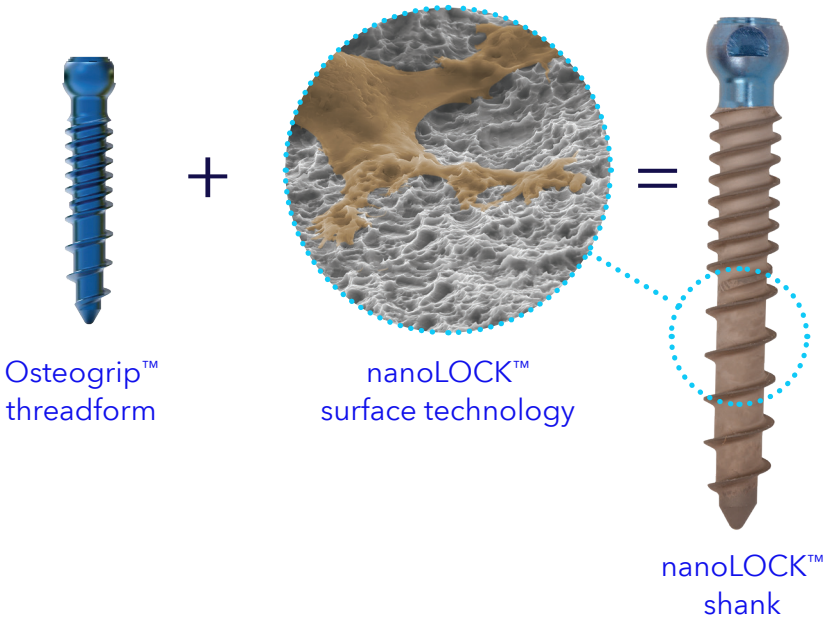
Medtronic

CD Horizon™ ModuLeX™ nanoLOCK™ surface technology shanks

nanoLOCK™ surface technology shanks:
The combining cellular-inspired surface technology with our 6th generation CD Horizon™ Spinal System – **ModuLeX™**



nanoLOCK™ surface technology vs. anodized titanium*:

- Enhanced fixation
- Equivalent ease of insertion
- Greater extraction torque

nanoLOCK™ surface technology*

- Acts as an osteoconductive scaffold for bony growth onto the implant[1,2,3]
- Proprietary blend of surfaces at macro, micro, & nano levels
- Designed to mimic osteoclastic pits[4,5]

Osteogrip™ threadform*

- Osteogrip™ Dual Lead threadform offers a 51% toggle reduction versus standard threadform design
- Osteogrip™ Dual Lead threadform offers 29% fewer insertion rotations versus standard thread design
- Osteogrip™ Dual Lead threadform offers a thread at tip for bicortical applications

nanoLOCK™ shank diameters	Color code	Shank lengths
4.5 mm		25 – 50 mm
5.5 mm		25 – 55 mm
6.5 mm		30 – 60 mm
7.5 mm		30 – 60 mm
8.5mm		40 – 55 mm

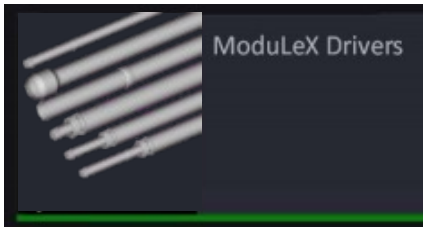
*Animal study data on file. Animal results are not necessarily indicative of human clinical performance

StealthStation™ Navigation with CD Horizon™ ModuLeX™ nanoLOCK™ surface technology shanks

What to select in the software when using nanoLOCK™ shanks in your spine procedures

1 Navigation Spine tools upgrade check

Work with your Enabling Technologies counterpart in the field to ensure that the latest Software Version 39 is installed prior to first cases



2 Shank Sizes

nanoLOCK™ shank with Osteogrip threadform

&

Annodized Ti Shank with Osteogrip threadform

=

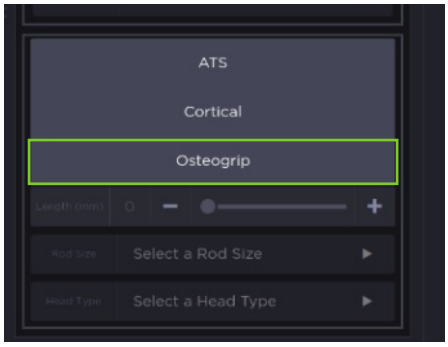
Shank Sizes									
70									70
65									65
60						N	N		60
55				N		N	N	N	55
50		N		N		N	N	N	50
45		N		N		N	N	N	45
40		N		N		N	N	N	40
35		N		N		N	N		35
32.5									32.5
30		N		N		N	N		30
27.5									27.5
25		N		N					25
22.5									22.5
20									20
	Ø4.0	Ø4.5	Ø5.0	Ø5.5	Ø6.0	Ø6.5	Ø7.5	Ø8.5	

Length (mm) — Diameter (mm) — Length (mm)

N = nanoLOCK shankblue = Osteogrip shank

3 Software selections when using nanoLOCK™ shanks

nanoLOCK™ shanks are represented in the software by **Osteogrip™** shank sizes



This updated version of Navigation software for ModuLeX™, will include multiple shank type options. Be sure to select **"Osteogrip™"** and the corresponding **width** and **length** when using **nanoLOCK™** shanks

Important product information on the CD Horizon™ spinal system

Indications

The CD Horizon™ spinal system with or without Sextant™ instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (DDD - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD Horizon™ spinal system titanium, cobalt chrome, and stainless steel implants may also be used for the same indications as an adjunct to fusion.

With the exception of DDD, CD Horizon™ Legacy™ 3.5 mm rods and associated components may be used for indications in skeletally mature patients as an adjunct to fusion. The 3.5 mm rods may be used for the specific pediatric indications noted.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, CD Horizon™ spinal system titanium, cobalt chrome, and stainless steel implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD Horizon™ spinal system is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD Horizon™ PEEK rods are intended to provide posterior supplemental fixation when used with an interbody fusion cage for patients diagnosed with DDD. These DDD patients may also have up to grade 1 spondylolisthesis or retrolisthesis at the involved level. This device is intended for 1-2 level use in the lumbosacral spine (L2 – S1) in skeletally mature patients. Devices are intended for use with an interbody fusion cage at the instrumented level and is not intended for stand-alone use.

The CD Horizon™ Spire™ plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: DDD, spondylolisthesis, trauma, and/or tumor.

To achieve additional levels of fixation, CD Horizon™ spinal system rods may be connected to the Vertex™ reconstruction system with the Vertex™ rod connector. Refer to the Vertex™ reconstruction system package insert for a list of Vertex™ indications.

Contraindications

Contraindications include:

- Active infectious process or significant risk of infection (immunocompromise).
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.

Potential Adverse Events

All adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes:

- Early or late loosening of components.
- Disassembly, bending, or breakage of components.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, or general corrosion) including metallosis, staining, tumor formation, or autoimmune disease.
- Pressure on skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, or pain.

1. Wennerberg, A., & Albrektsson, T. (2009). Effects of titanium surface topography on bone integration: a systematic review. *Clin Oral Implants Res*, 20 Suppl 4, 172-184.
2. Gittens, R.A., Olivares-Navarrete, R., Schwartz, Z, Boyan, B.D. (2014). Implant osseointegration and the role of microroughness and nanostructures: lessons for spine implants. *Acta Biomater.*, 10(8), 3363-71
3. Olivares-Navarrete, R., Hyzy S.L., Gittens, R.A., Berg, M.E., Schneider, J.M., Hotchkiss, K., Schwartz, Z., Boyan, B. D. Osteoblast lineage cells can discriminate microscale topographic features on titanium-aluminum-vanadium surfaces. *Ann Biomed Eng*. 2014 Dec; 42 (12): 2551-61.
4. Matteson, J.L., Greenspan, D.C., Tighe, T.B., Gilfoy, N., Stapleton, J.J. Assessing the hierarchical structure of titanium implant surfaces. *J Biomed Mater Res B*. [In Press] EPub 29 May 2015.
5. Hefti T, Frischherz M, Spencer ND, Hall H, Schlottig F. A comparison of osteoclast resorption pits on bone with titanium and zirconia surfaces. *Biomaterials* 2010;31:7321–7331.

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