CD Horizon™ ModuLeX™ 5.5

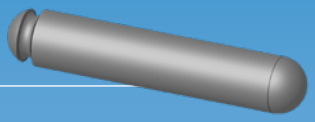
Spinal System

Fully enabled procedural solution that offers workflows for flouro, navigation, and robotic procedures in both cortical bone screw and pedicle screw trajectories.

Set Screw

- M9×1.25 Reverse Square Set Screw

NEW Rod Size



- Titanium Rod
- 5.5mm dia. × 25mm L

Tulip Head

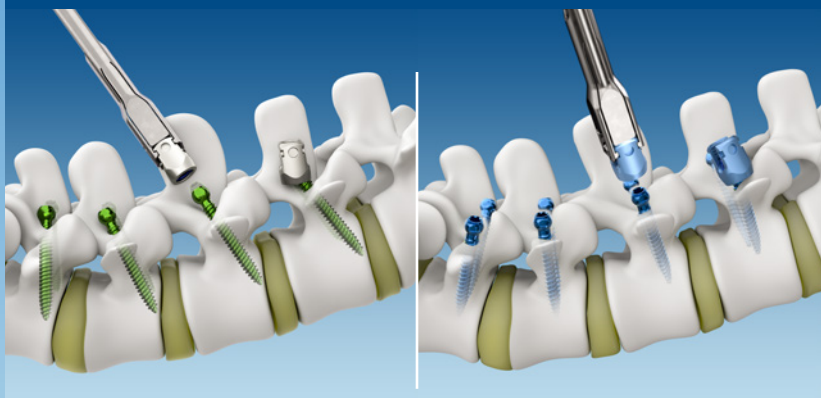
- 12.7 dia. ×16.25 H
- Compatible with full 5.5mm rod options
- One size fits all

Cortical Shank

Pedicle/ATS Shank

CORTICAL SCREW **PEDICLE SCREW**

AXIAL VIEW



SAGITTAL VIEW

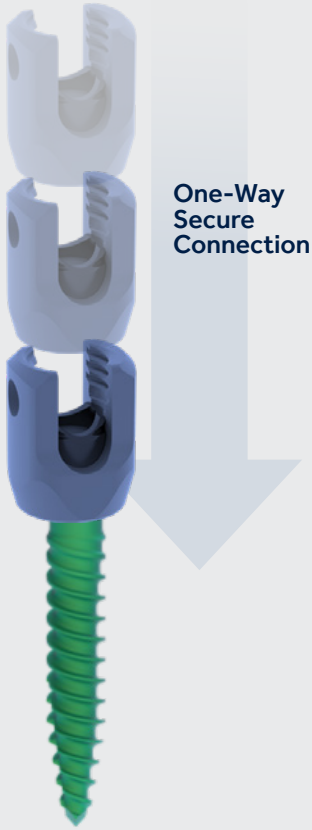
Medtronic
Further, Together

CONFIDENCE
IN THE CONNECTION

Secure Lock, patented locking mechanism for secure modular shank and head connection

"One-way" connection provides confidence in connection assembly and construct stability

Provides comparable strength and stability compared to a CD HORIZON™ LEGACY™ Spinal System[1].



MODULAR SOLUTIONS DESIGNED
FOR OPERATIVE FLEXIBILITY

- One size modular tulip head
- Compatible with the full CD Horizon™ 5.5mm rod options

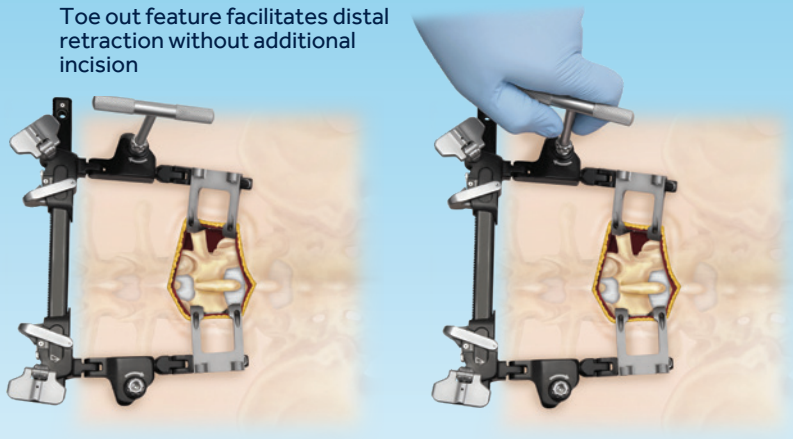
1. Based on internal testing per ASTM 1798

VERSATILE INSTRUMENTS FOR EFFICIENCY, IMPROVED VISIBILITY, AND BETTER ACCESS OF THE SURGICAL SITE

RETRACTOR

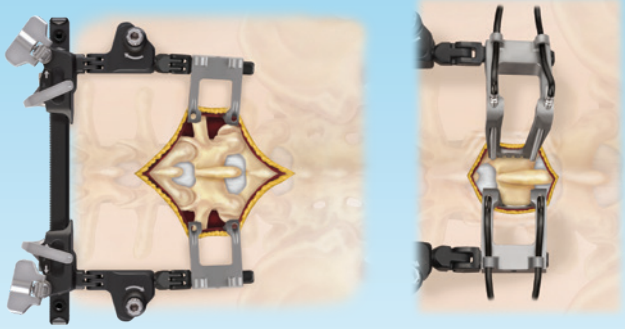
Provides midline tissue and muscle retraction with the ability to obtain a TLIF trajectory for interbody prep work and placement.

Toe out feature facilitates distal retraction without additional incision



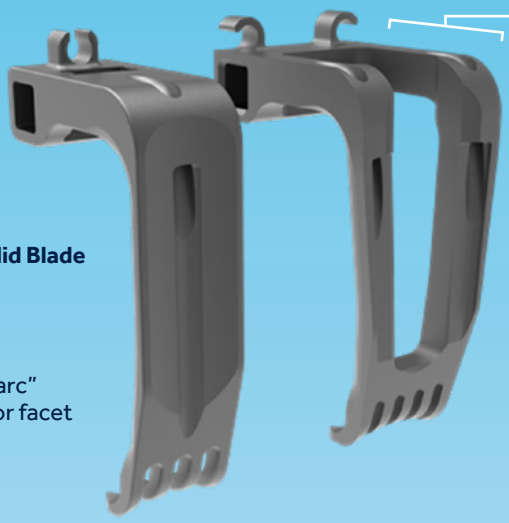
Allows for sufficient access and increased visibility of the disc space with minimal incision

Compatible with Scintillant Bent Tip or Quadrant bent tip lightsource for illumination of surgical site



Bed frame attachment using METRX or Thompson Surgical flex arm.

RETRACTOR BLADES



Minimizes radiographic obstruction and enables hand-drop maneuver

25mm
lateral offset

Hand-Drop Blade

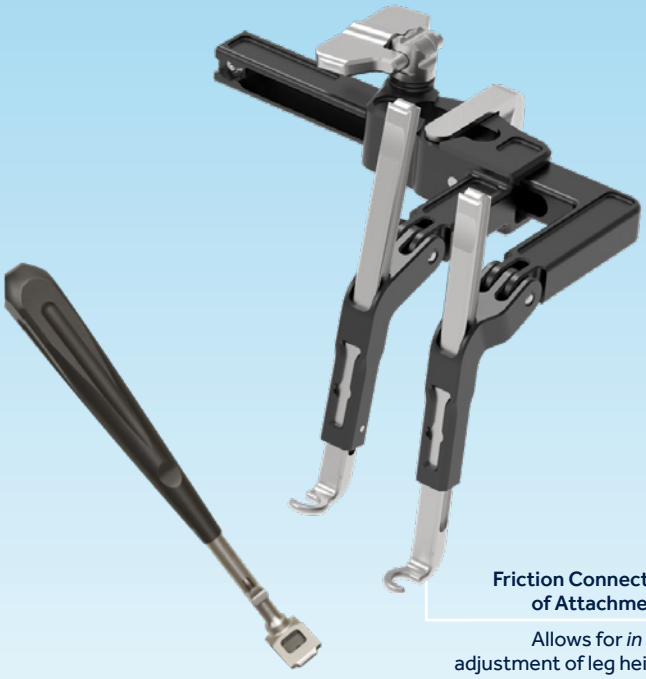
Allows for medial/lateral and cephalad/caudal instrument angulation

- 15°-37° Medial/Lateral
- 5°-22° cephalad-caudal

Solid Blade

Blade teeth features "arc" cut-out at distal end for facet clearance

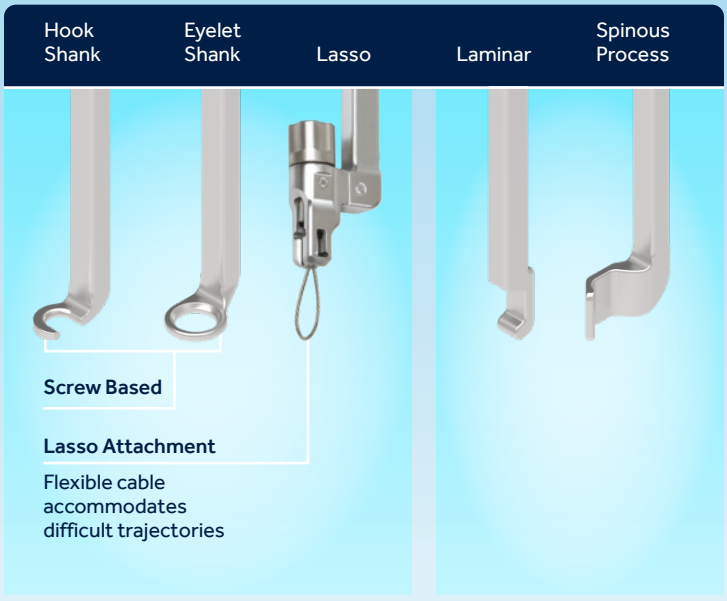
DISTRACTOR



Friction Connection of Attachments

Allows for *in situ* adjustment of leg height based on wound depth

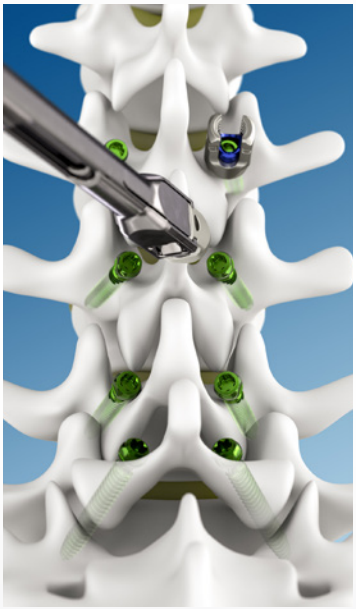
Adaptable access instruments with a variety of attachment options to fit patient anatomy and/or surgeon preference

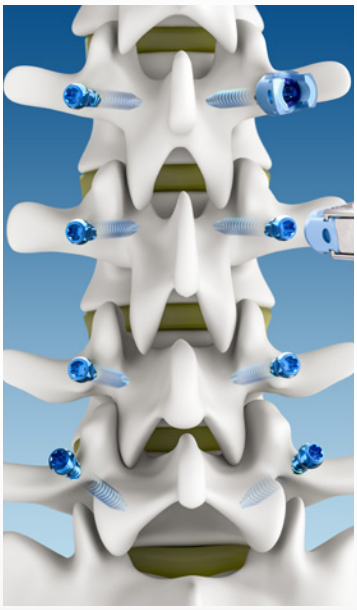


Distractor Attachments
Hook, Eyelet, Lasso

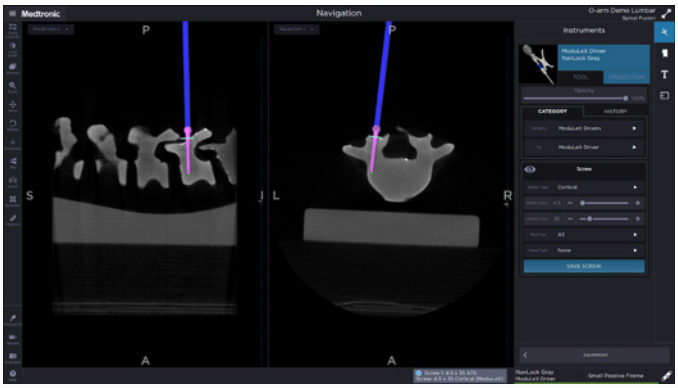
Anatomical Based Distraction
Various options for distracting off the anatomy

PROCEDURAL EFFCIENCY
YOU CAN SEE

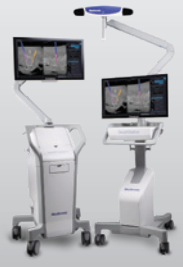




Greater visualization of patient anatomy with modular screw assembly (*in-situ*) compared to fully assembled screw



ModuLeX™ Screw Technology offers an efficient navigation workflow by allowing placement of the screw shank at the beginning of the procedure to minimize the effects of shifts in anatomy during decompression.



Mazor™ X Robotic System and StealthStation™ S8 navigation System for navigation and robotic-assisted guidance

IMPORTANTPRODUCT 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™ 3.5mm rods and associated components may be used for indications in skeletally mature patients as an adjunct to fusion. The 3.5mm 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.

Medtronic

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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.