CD HORIZON™ SOLERA™ VOYAGER™ 5.5/6.0 MM SPINAL SYSTEM

Featuring the Extended Tab ATS

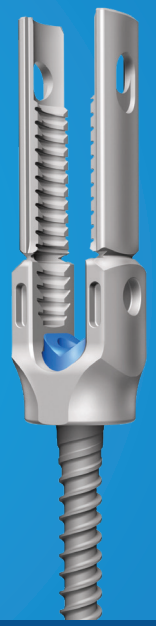
O-arm™
O2 Imaging System

Extended Tab ATS

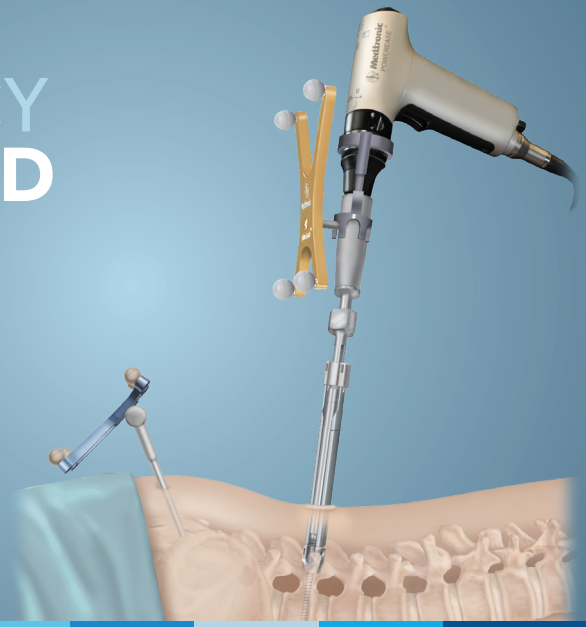
Medtronic

MICHELSON TECHNOLOGY AT WORK

INCORPORATED AWL TAP TIP VOYAGER SCREW WITH GREATER PULL-OUT FORCE

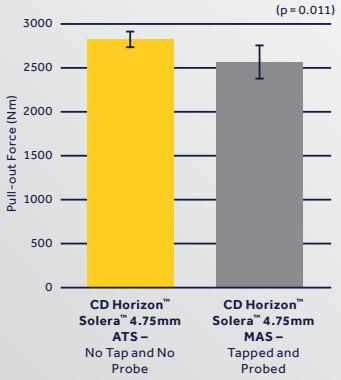


SURGICAL EFFICIENCY REDEFINED



The CD Horizon™ Solera™ ATS 6.5mm diameter achieved a pull-out force that was greater than the pull-out force of the standard 6.5mm diameter CD Horizon™ Solera™ Multi-Axial Screw.

6.5mm Screw Pull-out Results



Based on internal testing per ASTM F543-13.
ATS: Awl Tap Multi-Axial Screw

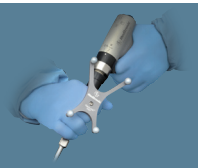
The Voyager™ 5.5/6.0 mm Extended Tab ATS has a similar bonescrew thread as the tested CD Horizon™ Solera™ ATS 4.75 bonescrew thread.

Extended Tab ATS delivers screw placement in three steps:

1. Create Pilot Hole
2. Select Screw
3. Place Screw

Surgical Synergy™ enables a fully integrated workflow

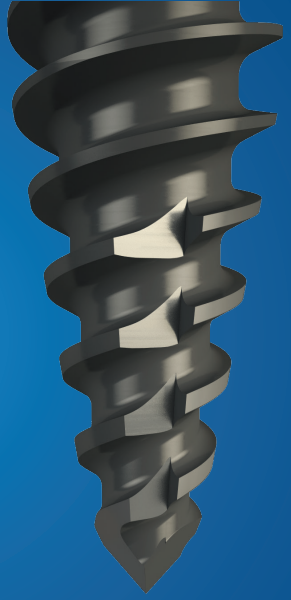
Powerease™ System



NIM Eclipse™ E4 Nerve Monitoring System

Navigation

SHORTENED SURGICAL TECHNIQUES WITH ATS



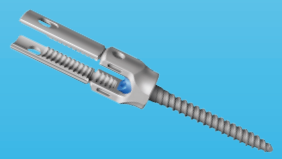
Six Steps with Cannulated Screws:

- Place PAK needle
- Place guidewire
- Tap
- Measure for screw size
- Select screw
- Place screw

Three Steps with ATS:

- Awl/burr
- Select screw
- Place screw

MEDTRONIC MAST™ PROCEDURAL SOLUTIONS FOR DEGENERATIVE FUSION



Extended Tab ATS

Incorporated Awl Tap Tip helps eliminate procedural steps compared to traditional steps.

Space-D™ Distractor Compressor System

The Space-D™ System connects onto the Voyager™ Extenders to provide controlled screw based in-situ distraction capability for accessing the disc space. It provides guidance for rod implantation and control for final compression.

Spaceview™ Retractor System

The SpaceView™ System is a versatile, low profile retractor that creates an enhanced visualization and working channel.

SET ORDERING INFORMATION VOYAGER™ 5.5/6.0 ATS PROCEDURE

Required

SPS01860	Kit Voyager™ 55/60 General Inst 1/2
SPS01861	Kit Voyager™ 55/60 General Inst 2/2
SPS01862	Kit Voyager™ 55/60 ATS Screws Sterile

Rod options

SPS01863	Kit Voyager™ 55/60 PERC RODS ST
SPS01877	Kit Voyager™ 55/60 CAPPED RODS

IMPORTANT PRODUCT INFORMATION ON THE CD HORIZON™ SPINAL SYSTEM

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 (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 may also be used for the same indications as an adjunct to fusion.

With the exception of degenerative disc disease, the CD Horizon™ Legacy™ 3.5mm rods and the CD Horizon™ Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for specific pediatric indications as noted in the device manual.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD Horizon™ Spinal System 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™ 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: degenerative disc disease (as previously defined), spondylolisthesis, trauma, and/or tumor.

In order to achieve additional levels of fixation, the 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 the Vertex™ indications of use.

Potential Adverse Events

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis, and/or pain.
- Bursitis.
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
- 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 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.
- Non-union (or pseudarthrosis), delayed union, and mal-union.
- Loss of or increase in spinal mobility or function.
- Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stresses shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Ileus, gastritis, bowel obstruction, loss of bowel control, or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- 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.
- Death.

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See the device manual for detailed information regarding the instructions for use, indications, contraindications, implant procedure, warnings, precautions and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at **www.medtronic.com**.

The NIM-ECLIPSE™ E4 System is manufactured by Medtronic Xomed, Inc.
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