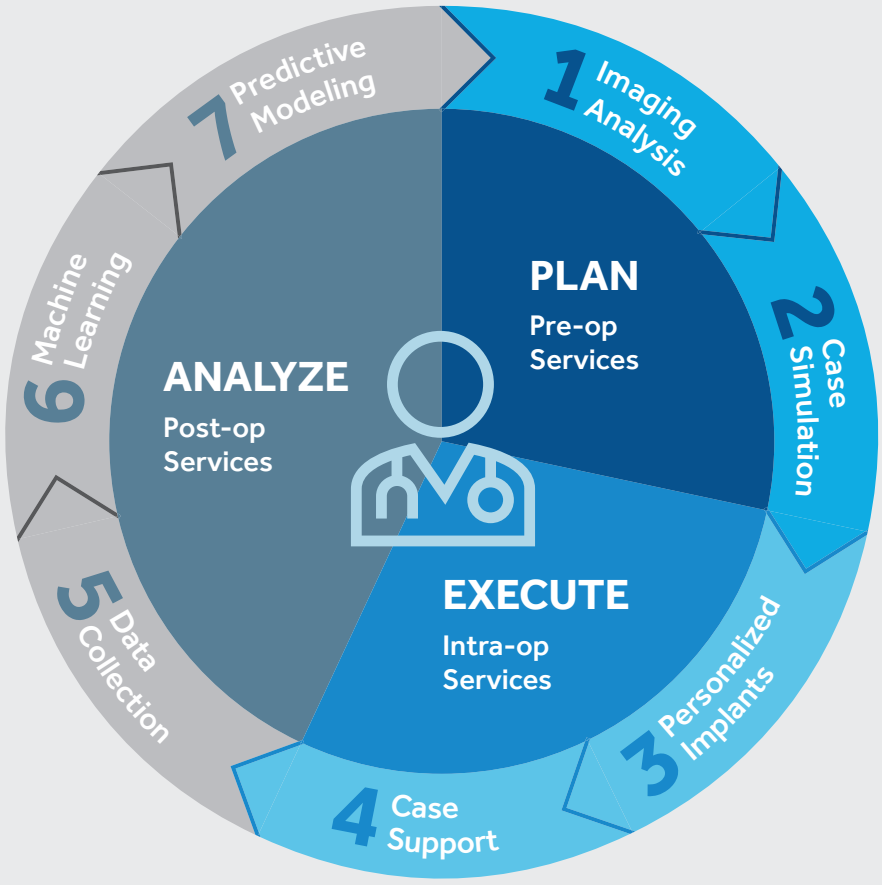
UNiD™ ASI
Adaptive Spine Intelligence

Plan. Execute. Analyze.



UNiD™ ASI leverages the aggregation of all UNiD™ procedures via a **proprietary 7-step process** that creates an **Iterative Virtuous Cycle.**

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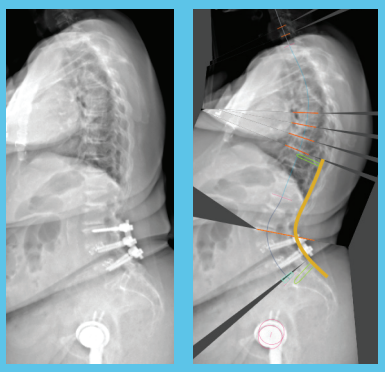
ITERATIVE VIRTUOUS CYCLE

Through the power of data collection and machine learning, a unique capability is created, allowing for a **continuous cycle of improvement**.

PLAN Pre-Op Planning Services

1 Imaging Analysis

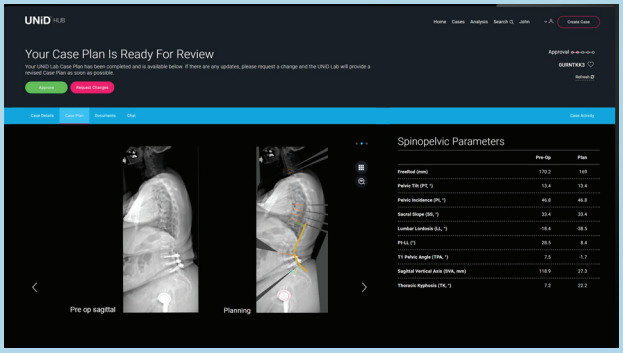
The UNiD™ cycle begins for each patient with the rapid identification of spinopelvic parameters using standard radiographs and if available, X-Rays (Calibrated X-Rays), EOS, MRI, or CT images. Integration with PACS and communication via the UNiD™ HUB supports the goal of improved patient workflows.



Pre-Op Plan

2 Case Simulation

The UNiD™ LAB engineer uses sophisticated UNID™ HUB and UNiD™ Spine Analyzer Software to simulate multiple surgical strategies for the surgeon based on the surgical strategy and surgeon preferences. The proprietary algorithms also include the latest scientific literature and proprietary predictive planning models.



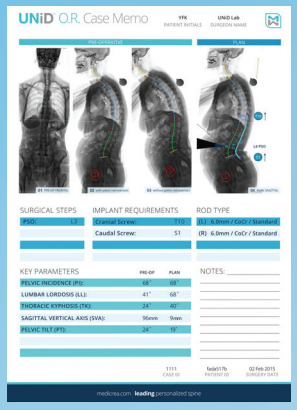
EXECUTE Intra-Op Services

3 Personalized Implants

UNiD™ TEK is a suite of technologies enhanced by the UNiD™ HUB platform and UNiD™ LAB Service. UNiD™ Rods are manufactured following surgical planning performed by a surgeon for a given patient. The UNiD™ Rod implants are fabricated with advanced in-house manufacturing technology. UNiD™ Rods are FDA cleared in the U.S. for compatibility with the CD Horizon™ Solera™ Spinal System.

4 Case Support

UNiD™ Rods are aligned with the preoperative surgical plan, helping to guide the surgery and provide intraoperative confirmation.

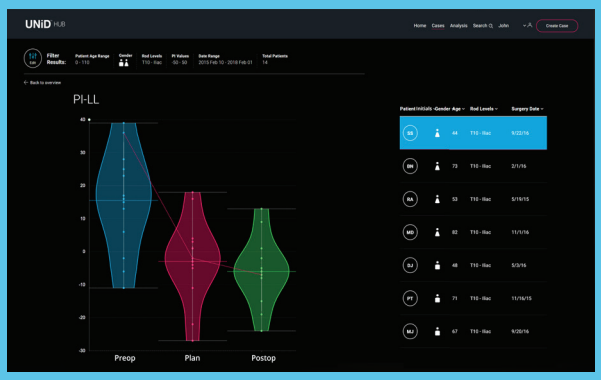


Risks associated with these spinal implants include loosening, disassembly, bending, and/or breakage of components.

ANALYZE Post-Op Services

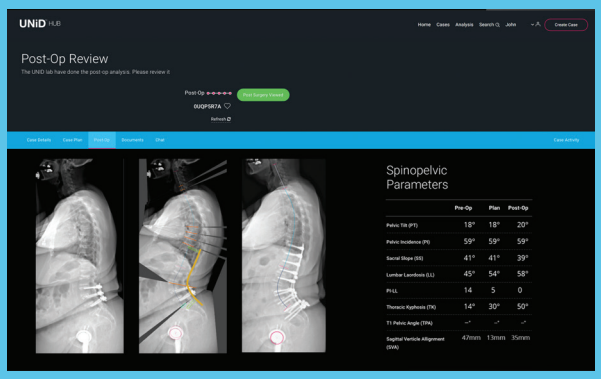
5 Data Collection

This process combines data collection, advanced analytics, and visualization within the UNiD™ HUB. Surgical cases are organized and easily accessed. Multiple output options are available for use in presentations, reports, and clinical studies.



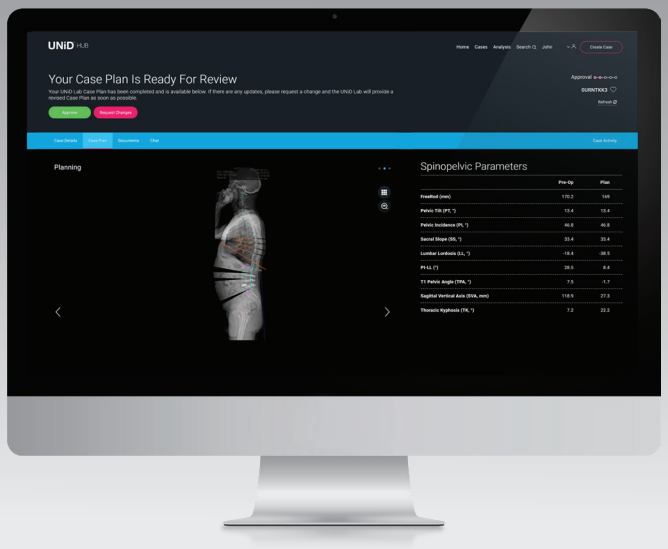
6 Machine Learning

Data scientists use machine learning to identify correlations and tendencies within the aggregated set of de-identified data. The growing pool of UNiD™ data increases the power of this cognitive insight.



7 Predictive Modeling

Proprietary predictive planning models also use machine learning to estimate compensatory mechanisms and to provide decision making support in surgical strategy. The entire UNiD™ ASI system is strengthened with every surgery and iteration.



UNiD™ LAB engineers provide spinopelvic parameters and surgical simulations based on surgeon input and preferences. UNiD™ TEK patient-specific implants are approved by the surgeon via the UNiD™ HUB. Clinical judgment and experience are required to properly use the software.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results.

IMPORTANT
PRODUCT INFORMATION

CD HORIZON™ 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, the CD Horizon™ Legacy™ 3.5mm 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 the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the 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. The device is 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 (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.

RISKS

All of the possible 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 any or all of the components.
- Disassembly, bending, or breakage of any or all of the components.
- Post-operative change in spinal curvature, loss of correction, height, or reduction.
- Infection.

PASS LP SYSTEM DESCRIPTION

The internal fixation devices are composed of screws, hooks, rods, plates, cross links, connection and locking devices .The range of different sizes and shapes of the implants allows the surgeon to adapt to the pathology and morphology of each of his patients. The implants are manufactured in titanium alloy Ti-6Al-4V ELI conforming to ISO 5832-3 specifications and ASTM F136 specifications, with the exception of the rods intended for in situ bending which are manufactured in non-alloyed titanium (CP titanium) conforming to ISO 5832-2 specifications and ASTM F67 specifications and the CoCr rods which are manufactured in cobalt chrome alloy Co-Cr28Mo6 conforming to ISO 5832-12 specifications and ASTM F1537 specifications. The Patient Specific Rod has been designed and manufactured for one specific patient. The Patient Specific Rod should be used during surgery for this patient only and should not be reused (single use only). Refer to the surgical technique brochure for additional information. If this Patient Specific Rod does not perform as intended, use the standard PASS LP rod to complete the surgery. Under no circumstances are the implants reusable.

INDICATIONS

The PASS LP spinal systems include a pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine:

- Fractures.
- Dislocation.
- Failed previous fusion (pseudarthrosis).
- Spinal stenosis.
- Degenerative spondylolisthesis with objective evidence of neurological impairment.
- Spinal deformations such as scoliosis or kyphosis.
- Loss of stability due to tumors.

The PASS LP spinal systems are also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The PASS LP also include hooks and rods and sacral/iliac screws indicated for 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, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis and failed previous fusion.

Except for rod plates, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the PASS LP spinal system implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PASS LP spinal system is intended to be used with allograft and/or autograft. Pediatric pedicle screw fixation is limited to a posterior approach.

WARNING: The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

RISKS

In addition to the risks associated with surgery of the spine without instrumentation, a number of possible undesirable effects may occur with instrumented surgery (including but not limited to):

- Detachment, deformation, mobilization, slipping, breakage of one or all of the components.
- Pain due to the surgery, the fracture, deformation and or migration of an implant.
- Fracture of the pedicle during insertion of a pedicular screw.
- Postoperative loss of correction and/or reduction of the spine, partial or total loss of the corrections achieved.

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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.

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