CD HORIZON® LEGACY™ System
Multi-Axial Reduction Screw
Surgical Technique

In both simple and complex spinal deformity reconstructions, the use of CD HORIZON® LEGACY™ System Multi-Axial Reduction Screws (MARS) can be helpful any time there is a vertical height malalignment from one screw head to the next.
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Surgical Technique

Instrument Set/Construct Assembly  2
Spondylolisthesis Reduction  3
Final Tightening  4
Graft Placement  5
Explantation  6
Product Ordering Information  7
Important Product Information  8
With the pedicles prepared, insert standard multiaxial screws at L4 and S1, and multiaxial reduction screws at L5 (Figure 1). Reduction screws may be used at all levels to facilitate seating the rod.

Position the rod ensuring that the desired final lordosis or contour has been created in the rod bend. The rod should sit fully in the saddle of the L4 and S1 screws, while remaining high in the saddle of the L5 screw.

Insert set screws into the L4 and S1 implants and provisionally tighten using the appropriate set screwdriver to secure the rod (Figure 2).

For complete instructions of use for the implant system, please refer to the appropriate surgical technique and package insert.
Spondylolisthesis Reduction

**Method 1:**
**Reduce with Set Screw**

Place the Ring Counter Torque over the implant head and maintain throughout the reduction procedure. Using the Non Break-Off Plug Starter, insert the reduction set screw into the reduction implant head and advance the set screw. This will pull the implant to the rod, translating the vertebral body of L5 posteriorly and, therefore, reducing the spondylolisthesis (Figure 3).

**Method 2:**
**Reduce with Extended Rocker**

The Extended Rocker can be used to seat the rod and provide incremental reduction. Grasp the extended head of the implant and rock down, applying pressure to the rod (Figure 4).

**Method 3:**
**Reduce with Beale Rod Reducer**

The Beale Rod Reducer can be used in conjunction with the Rod Reducer Sleeves to reduce the rod into the extended implant head. To achieve full reduction begin by using the Beale Rod Reducer. Incrementally reduce the spondylolisthesis by graduating to the 7mm and 14mm Sleeves. (Figures 5a and 5b). When the rod is fully seated in the bottom of the implant head, the reduction is complete. Bilateral reduction may be attained by simultaneously driving the set screws at L5 on both sides.
Final Tightening

Once the rod is secured in the implants, distraction and/or compression is performed to place the screws in their final position. It is highly recommended that compression be released just prior to the set screws being broken off or final tightened. This technique will help ensure that the implant head and rod are normalized to one another and thus allow for the rod to be fully seated in the implant head during the final tightening step. Once these maneuvers are performed, the set screws at L4 and S1 should be broken off.

To break off the extended tabs of the Multi-Axial Reduction Screw, place the Ring Counter Torque over the implant head with the handle of the Ring Counter Torque facing lateral. Slide the Reduction Screw Tab Breaker over the medial tab of the extended portion of the Multi-Axial Reduction Screw. Apply pressure to the Tab Breaker and break off medially (Figure 6a). While maintaining the Ring Counter Torque, the reduction set screw may be broken off using the Torx 27 (Figure 6b), then break off the lateral tab medially (Figure 6c).

If the tabs do not bend and break off easily, ensure that the set screw is fully advanced. If the set screw is not fully advanced, its threads will offer resistance and prevent the tabs from being broken off.

Important

It is highly recommended that the set screws not be broken off or final tightened under compression.
Graft Placement

Meticulous attention to bony fusion remains critical to the success of the surgical outcome, despite the use of instrumentation. Careful decortication of the transverse processes, the facet joints, and the pars interarticularis using manual instruments or a high speed burr should be accomplished. The surgeon may choose in certain instances to perform the decortication prior to the instrumentation if the decortication would prove difficult because of poor visualization. The preservation of the facet capsules of the unfused adjacent levels should be facilitated because of the implant’s reduced bone-screw interface.

Whether the procedure utilizes autograft or allograft bone, precise placement of the graft material onto the decorticated bone is essential. This can only be done with excellent visualization of the decorticated bone surfaces. Keep in mind that fusion commonly occurs from transverse process to transverse process and that interposing muscle tissue may result in the development of a pseudarthrosis. If the facet architecture is sufficiently maintained, graft material should be impacted into the facet to obtain a facet fusion. Once the instrumentation is complete and the graft material is placed, the construct should be checked radiographically.
Explantation

The CD HORIZON® LEGACY™ System set screws (plugs) may be removed using the T27 Obturator and the Self-retaining Break-off Driver. The T27 Obturator is inserted into the working end of the Self-retaining Break-off Driver, so that the knurled portion of the T27 Obturator is flush with the driver. Insert the obturator tip through the Counter Torque, which should be seated on the screw and into the plug, turning counterclockwise until the plug has been removed. The pedicle screws may be removed using either the Multi-Axial Screwdriver or the Self-retaining Screwdriver in connection with the Ratcheting Handle. First, attach the Ratcheting Handle to the modular end of the driver. Next, fully engage the hex end of the screwdriver into the screw head, then, if utilizing the Multi-Axial Screwdriver, thread the instrument sleeve into the screw head. Turn counterclockwise until the pedicle screws have been removed.

If removal of a CD HORIZON® X10 CROSSLINK® MULTI-SPAN® Plate is necessary, place the \( \frac{7}{32} \)" Torque Limiting Set Screwdriver over the midline nut and turn counterclockwise to loosen. Place the 3.0mm Hex Head Shaft Removal Driver into a standard Medtronic Quick Connect Handle. Place the tip of the 3.0mm internal hex screwdriver into the set screw and confirm that the 3.0mm tip is completely inserted and seated in the set screw so that the tip does not strip the hex. Turn the screwdriver counterclockwise to loosen the set screw from the rod.
## Product Ordering Information

<table>
<thead>
<tr>
<th>Description</th>
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5.5mm Multi-Axial Reduction Screw with Set Screw

6.35mm Multi-Axial Reduction Screw with Set Screw
Important Product Information

PURPOSE
The CD HORIZON® Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

DESCRIPTION
The CD HORIZON® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK™ Plates, staples and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Certain implant components from other Medtronic spinal systems can be used with the CD HORIZON® Spinal System. These components include TSP™ rods, hooks, screws, plates, CROSSLINK™ plates, connectors, staples and washers, GDL™ rods, hooks, connectors and CROSSLINK™ bar and connectors, LIBERTY™ rods and screws, DYNALOK® PLUS and DYNALOK CLASSIC™ bolts along with rod/bolt connectors, and Medtronic Multi-Axial rods and screws. Please note that certain components are specifically designed to connect to φ3.5mm, φ4.5mm, φ5.5mm rods or φ6.35mm rods, while other components can connect to both φ5.5mm rods and φ6.35mm rods. Care should be taken so that the correct components are used in the spinal construct.

CD HORIZON® hooks are intended for posterior use only. CD HORIZON® staples and CD HORIZON® ECLIPSE™ rods and associated screws are intended for anterior use only. However, for patients of smaller stature, CD HORIZON® 4.5mm rods and associated components may be used posteriorly.

The CD HORIZON® Spinal System implant components are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, medical grade cobalt-chromium-molybdenum alloy, or medical grade PEEK OPTIMA-L T1. Certain implant components from other Medtronic spinal systems can be used with the CD HORIZON® Spinal System.

The CD HORIZON SPIRE™ Plate is a posterior, non-pedicle supplemental fixation device intended for use as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

Certain implant components from other Medtronic spinal systems can be used with the CD HORIZON® Spinal System.

CONTRAINDICATIONS

Contraindications include, but are not limited to:
1. Active infectious process or significant risk of infection (immunocompromise).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion.
11. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
12. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
13. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
15. Any case not described in the indications.

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:
1. Severe bone resorption.
2. Osteomalacia.
3. Severe osteoporosis.

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:
1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. 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.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neumus, and/or pain.
5. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
6. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
7. Infection.
8. Dural tears, pseudodermanispole, fistula, persistent CSF leakage, meningitis.
9. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neurona, spasmns, sensory loss, tingling sensation, and/or visual defects.
10. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
11. Urinary retention or loss of bladder control or other types of urological system compromise.
12. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
13. 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.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Bone loss or decrease in bone density, possibly caused by stresses shielding.
18. Graft donor site complications including pain, fracture, or wound healing problems.
Important Product Information continued

20. 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.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Death.

NOTE: Additional surgery may be necessary to correct some of these potential adverse events.

WARNING

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown. The implants are not prosthetics.

In the absence of fusion, the instrumentation and/or one or more of its components can be expected to pull out, bend or fracture as a result of exposure to everyday mechanical stresses.

PRECAUTION

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extraneous circumstances may compromise the results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will 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, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given 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.

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

IMPLANT SELECTION

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

DEVICE FIXATION

In cases where a percutaneous posterior approach is used refer to the CD HORIZON® SEXTANT® surgical technique.

MEDTRONIC CD HORIZON® Spinal System instrumentation contains 3.5mm, 4.5mm, 5.5mm and/or 6.35mm rods and implants, which are intended to be used with device specific instruments.

For self breaking plugs, always hold the assembly with the Counter Torque device. Tighten and break-off the head of the plug to leave the assembly at optimum fixation security. After the upper part of the self breaking plug has been sheared off, further re-tightening is not necessary and not recommended. The head part should not remain in the patient. AFTER THE UPPER PART OF THE SELF BREAKING PLUG HAS BEEN SHEARED OFF, RE-ADJUSTMENT IS NOT POSSIBLE UNLESS THE PLUG IS REMOVED AND REPLACED WITH A NEW ONE. When using DTT Transverse Links, the M6 plug should be tightened to between 8 and 9 Nm. (70 to 80 inch-lbs).

CD HORIZON® PEEK RODS ARE NOT TO BE USED WITH CROSSLINK® PLATES.

PREOPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre-dispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The CD HORIZON® Spinal System components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile component sets should be available in case of an unexpected need.

INTRAOPERATIVE

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operating personnel.
3. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
4. Utilize an imaging system to facilitate surgery.
5. To insert a screw properly, a guide wire should first be used, followed by a sharp tap. Caution: Be careful that the guide-wire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the guide-wire does not advance during tapping or screw insertion. Remove the guide-wire and make sure it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.
6. CAUTION: Do not overlap or use a screw/bolt that is either too long or too large. Overlapping, using an incorrectly sized screw/bolt, or accidentally advancing the guide-wire during tap or screw/bolt insertion, may cause nerve damage, hemmorhage, or the other possible adverse events listed elsewhere in this package insert. If screws/bolts are being inserted into spinal pedicles, use as large a screw/bolt diameter as will fit into each pedicle.
7. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
8. To assure maximum stability, two or more CROSSLINK® plates or DTT Transverse Links on two bilaterally placed, continuous rods, should be used whenever possible.
9. Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or screws, especially screws or nuts that have a break-off feature. Once this is completed go back and firmly tighten all of the screws and nuts. Recheck the tightness of all nuts or screws after finishing to make sure that none loosened during the tightening of the other nuts or screws. Failure to do so may cause loosening of the other components.

POSTOPERATIVE

The physician’s postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excess weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jerks in spinal position.
2. To allow the maximum changes for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke
Important Product Information

3. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.

5. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.

6. The CD HORIZON® Spinal System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long-term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.

7. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the CD HORIZON® Spinal System components should never be reused under any circumstances.

PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Medtronic.

CLEANING AND DECONTAMINATION

Unless just removed from an unopened Medtronic package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Medtronic. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below:

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NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment. *For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.
Notes
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. Please see the package insert for the complete list of indications, warnings, precautions, and other medical information.