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

A Masterpiece In Medical Device Design
The following describes reduction of a spondylolisthesis at L5–S1 using CD HORIZON LEGACY System Reduction Multi Axial Screws.

**STEP 1**

**Construct Assembly**

With the pedicles prepared, insert standard multi axial screws at L4 and S1, and reduction multi axial 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 screw driver to secure the rod (Figure 2).
STEP 2

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 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, first use the rod reducer and graduate to the 7mm sleeve, then the 14mm sleeve while incrementally reducing the spondylolisthesis (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.
**STEP 3**

**Final Tightening**

Once the rod is completely reduced and all the set screws are fully advanced and provisionally tightened, the set screws in the multi axial screws at L4 and S1 should be broken off.

To break off the extended tabs of the Reduction Multi Axial 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 Reduction Multi Axial 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.
## Product Ordering Information

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<thead>
<tr>
<th>Description</th>
<th>Reduction Multi Axial Screw Implants and Set Screws</th>
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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 Sofamor Danek 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 Sofamor Danek spinal systems can be used with the CD HORIZON® Spinal System. These components include TSRI® rods, hooks, screws, PLATES, connectors, staples and washers; OLYTH® rods, hooks, connectors and CROSSLINK® bar and connectors; LBEST® rods and screws; DYNALOK PLUS® and DYNALOK® CLASSIC bolts along with rod/bolt connectors; and Sofamor Danek Multi-Axial rods and screws. Please note that certain components are specifically designed to connect to ø4.5mm, ø5.5mm or ø6.35mm rods, while other components can connect to both ø4.5mm and ø6.35mm rods. Care should be taken so that the correct components are used in the spinal construct.

CONTRAINDICATIONS: Use of any CD HORIZON® Spinal System component should ever be reused under any circumstances.

INDICATIONS:
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.

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

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. Disappearance, 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, tumour 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, neovascularization, and/or pain. Burstula. Tissue or nerve damage caused by improper positioning and placement of implants or instrumentation.

5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.

6. Infection.

7. Dural tears, pseudomeningoceles, fistula, persistent CSF leakage, meningitis.

8. Loss of neurological function (e.g., sensory and/or motor), including paraplegia (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, paresthesia, sensory loss, tingling sensation, and/or visual deficiencies.

9. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.

10. Urinary retention or loss of bladder control or other types of urological system compromise.

11. Scar formation possibly causing neurological compromise or compression and neuropathy and/or pain.

12. Fracture, microfracture, resection, 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. Retropatellar grafted.

13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.


15. Cessation of any potential growth of the operated portion of the spine.

16. Loss of or increase in spinal mobility or function.

17. Inability to perform the activities of daily living.

18. Bone loss or decrease in bone density, possibly caused by stress shielding.

19. Graft donor site complications including pain, fracture, or wound healing problems.

20. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.

21. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, bleeding, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.

22. Reproductive system compromise, including sterility, loss of consort, and sexual dysfunction.

23. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.

24. Change in mental status.

25. Death.

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 sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.

9. Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis.

10. Suspected or documented metal allergy or intolerance.

11. Any case not needing a bone graft and fusion.

12. Any case where the implant components selected for use would be too large or too small to achieve a successful result.

13. Any patient training inadequate tissue coverage over the operative site or inadequate bone stock or quality.

14. Any patient in which implant utilization would interfere with anatomic structures or expected physiological performance.

15. Any patient unwilling to follow postoperative instructions.

16. Any case not described in the indications.
medtronic sofamor danek cd horizon® spinal system instrumentation contains 4.5 mm, 5.5 mm and/or 6.35 mm 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 plug rod in the bone. the upper part of the plug must be 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-ajustment 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).

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 components 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 rethreaded 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 local orifice, causing a 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 guidewire during tap or screw/bolt insertion, may cause nerve damage, hemorrhage, 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. remove the instruments 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 devices will be complications which may occur as a result of excessive or early 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 jolts in spinal position.
2. to allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loose the device construction. 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 tobacco or utilize nicotine products, or to consume alcohol or non-steroidal or anti-inflammatory medications such as aspirin or ibuprofen. 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-ajustment 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).
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 component is loose, 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, the patient's or another's; (6) Potential 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 medical 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 sofamor danek.

cleaning and decontamination: unless just removed from an unopened medtronic sofamor danek 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 sofamor danek. cleaning and disinfecting of instruments can be performed with alcohol-free solvents at higher temperatures. cleaning and decontamination must include the use of neutral cleaners followed by a disinfection 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, instruments require disassembly before cleaning.

all products should be treated with care. improper use or handling may lead to damage and/or improper 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 three sets of process parameters below:

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<th>METHOD</th>
<th>CYCLE</th>
<th>TEMPERATURE</th>
<th>EXPOSURE TIME</th>
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<td>Steam</td>
<td>Gravity</td>
<td>250°F (121°C)</td>
<td>36 Minutes</td>
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<tr>
<td>Steam*</td>
<td>Gravity</td>
<td>273°F (134°C)*</td>
<td>20 Minutes*</td>
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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.

product complaints:
any health care professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, medtronic sofamor danek. further, if any of the implanted spinal system component(s) ever “malfunctions,” (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. if any medtronic sofamor danek product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. when filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

for further information:
in usa
director, customer service division
medtronic sofamor danek usa
1800 pyramid place
memphis, tennessee 38132 usa
telephone: 800-467-3133 or 901-396-3133
fax: 901-346-9738 or 901-332-3920

** authorized ec representative

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgement of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.