as described by:

Lawrence G. Lenke, M.D.
The Jerome J. Gilden Professor of Orthopaedic Surgery
Spinal Deformity Service
Orthopaedic Surgery
Washington University
School of Medicine
Chief, Spinal Service
Shriners Hospital for Children
St. Louis, Missouri
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Preface

Dear Colleagues:

Ever since Dr. Yves Cotrel designed the device for transverse traction (DTT), spinal surgeons have recognized the need for and benefit of cross-linking rods that are applied to the right and left sides of the spine posteriorly. The biomechanical benefits obtained by creating a triangular or rectangular frame with a posterior instrumentation construct are well recognized and intuitive. The design of cross-linking devices has evolved from smaller-diameter, threaded rods of lower stability (the Cotrel-Dubousset DTT) to very rigid cross-linking plates requiring preloaded eye bolts (the TSRH® CROSSLINK® Plate).

When evaluating the requirements of an optimal cross-linking device, several features come to mind: low-volume design, versatility, expandability, strength, and ease of application. The new X10 CROSSLINK® Plate has been designed with all of these important criteria in mind. The X10 CROSSLINK Plate’s significantly low-volume design allows the feet of the device to fit between screw heads, even when they are quite close together. This makes application with segmental fixation in any part of the thoracic, lumbar, or sacral spine feasible.

At the same time, the X10 CROSSLINK Plate is extremely versatile. It can easily be applied to parallel or non-parallel rods; in fact, it features all the necessary degrees of freedom to connect to rods in virtually any position imaginable. It is available in enough sizes in the fixed construct (six sizes) and the multi-span construct (seven sizes) to capture any degree of rod interconnection distance. In addition, the multi-span device provides the versatility of a central sliding mechanism coupled with a purposeful arch. Because of the low-profile nature of current segmental screw/hook constructs, flat cross-linking devices will often impinge upon both the posterior bony elements and the central neural tube. In contrast, the new X10 CROSSLINK Multi-Span™ Plate has a built-in arch that will clear those structures to allow for appropriate bone grafting underneath the device, thereby minimizing the chance of pseudarthrosis that can occasionally be produced by large, bulky, and flat cross-linking devices.

While the X10 CROSSLINK Plate offers numerous new advantages, it does not compromise maintaining the appropriate mechanical strength required in a transverse-loading device. Because the X10 CROSSLINK Multi-Span Plate’s rotating feet fit securely on the rods, biomechanical rigidity is far greater than what would be anticipated for this thinner, sleeker device. Despite its low-volume appearance, it actually maintains almost 90% of the biomechanical strength of the larger Low Profile CROSSLINK Plate device. As detailed in the technique guides for both the multi-span and fixed X10 CROSSLINK Plate Systems that follow, the versatility of the device provides for quick and reproducible attachment using a minimal number of well-designed steps and instruments. If you are intrigued by the appearance of the device, you will certainly be won over by its ease of attachment.

Please accept this invitation to try the X10 CROSSLINK Plate for yourself. I think you will certainly realize why the X10 CROSSLINK Multi-Span and Fixed Plates will quickly become the new gold standard for posterior spinal rod cross-linking devices.

Sincerely,

Lawrence G. Lenke, M.D.
Surgical Technique
Features and Benefits

X10 Crosslink Multi-Span™ Plate

- Break-off set screw technology provides assurance that the implant is completely tightened.
- Adjustable length and angulation make it possible to attach the plate to constructs in a wide range of spinal anatomies.
- Provides optimal patient matching with seven sizes, permitting an adjustable range from 28mm to 81mm.
- Multi-axial feature eliminates the need for contouring or bending.
- Anatomic design features transverse plane arch to avoid contact with the dura/posterior elements.
- Tightens easily due to true dorsal set screw access.
- Reduced implant volume provides room for fusion mass, minimizes interference with bony structure, and permits attachment even in tight lumbar spine situations.
- Run on the rod is 7.3mm.
- Attaches to rod in the coronal, sagittal, or transverse planes in any orientation.

X10 Crosslink Fixed Plate

- Break-off set screw technology provides assurance that the implant is completely tightened.
- Loads and tightens from the top for easier insertion.
- One-piece design eliminates pre-loading and intra-operative assembly.
- Run on the rod is 7.3mm.
- Provides optimal patient matching with six sizes: 16mm, 19mm, 22mm, and 25mm (28mm and 31mm are optional).
- Reduced implant volume provides room for fusion mass, minimizes interference with bony structure, and permits attachment between two spinal implants.
Surgical Technique

Instruments

- Measuring Credit Card (8110501)
- Measuring Caliper (8110502)
- 45° In Line Plate Holder (8110511)
- Forcep Plate Holder (8110510) (optional)
- 7/32" Torque-Limiting Set Screwdriver (8110535)
- Counter Torque (8110540)
- 3.0mm Hex Head Shaft, Removal Driver (8110530)
- Plate Benders (8110525)
Once all spinal implants are tightened, the appropriate size X10 CROSSLINK Multi-Span Plate is determined with one of the two measuring devices: the measuring credit card (Figure 1) or the measuring caliper (Figure 2). The number on the measuring device corresponds to the appropriate size X10 CROSSLINK Plate. When the template measurement appears to be between two available implant sizes, it is best to select the smaller plate. Extending the X10 CROSSLINK Multi-Span Plate reduces the size of the lower crossbar, minimizing metal below the center of the Plate (Figure 3). The pre-contoured X10 CROSSLINK Multi-Span Plate may be contoured, if needed, but has been designed to obviate the contouring step. If contouring is desired, see page 10 of this technique.

NOTE: In long constructs, an X10 CROSSLINK Plate should be placed in the upper one-third of the construct and another one in the lower one-third of the construct.
SURGICAL TECHNIQUE

X10 CROSSLINK Multi-Span™ Plate Placement

With the use of the plate holder, the appropriate X10 CROSSLINK Multi-Span Plate is selected and gripped (Figures 4 and 5). The rod set screws should be backed out, or in the open position, so that they do not obstruct rod introduction. The midline nut is provisionally tightened to gain control of the Multi-Span device during placement. The Plate is then placed to capture the far rod (in relation to the surgeon) of the two rods to be stabilized. Using the torque-limiting set screwdriver, this far rod set screw is provisionally tightened to anchor the device to this rod (Figure 6).
Next, the midline nut is loosened to allow the device to capture the other rod (Figure 7). Following capture of the second rod, anchor the Plate by seating the set screw (Figure 8). The midline nut is then provisionally tightened to secure the Plate (Figure 9).
A counter torque may be placed on the X10 CROSSLINK Plate to minimize torque transfer to the construct during final tightening. The screwdriver shaft is introduced through the counter torque. The set screws are sheared off using the torque-limiting set screwdriver (Figure 10). The midline nut then undergoes final tightening with the screwdriver (Figure 11). The midline nut on the CROSSLINK Multi-Span Plate is NOT a break-off set screw. An audible click from the set screwdriver will confirm that the midline nut is adequately tightened to approximately 80 in-lbs.
The rod set screws break off at approximately 60 in-lbs. (Figures 12a and 12b). The sheared-off sections of the set screws can remain housed in the shaft of the set screwdriver until removal is convenient. To remove the sheared-off sections of the set screws from the set screwdriver, hold the handle horizontally; and the broken-off sections will easily fall from the oblong port in the shaft (Figure 13).
Surgical Technique

X10 CrossLink Fixed Plate Sizing/Contouring

The appropriate size X10 CrossLink Fixed Plate is determined by using the measuring caliper (Figure 14) or the short end of the measuring credit card (Figure 15). If plate bending is desired, the plate benders may be used to contour the X10 CrossLink Fixed Plate. Prior to loading the plate into the benders, ensure the plate/rod set screws are backed out, or in the open position. Place the plate in either identical bender and place the second bender on the other end of the plate (Figure 16). Slide each of the bender sleeves toward the plate and proceed with bending (Figure 17).
SURGICAL TECHNIQUE
X10 CROSSLINK Fixed Plate Placement

The X10 CROSSLINK Fixed Plate is gripped by the plate holder, making sure the set screws are backed out, or in the open position. The configuration of the fixed plate has one foot of the device placed onto the lateral aspect of one rod and one foot of the device placed onto the medial aspect of the other rod. The device should capture both rods simultaneously during placement (Figure 18). Both set screws are provisionally tightened utilizing the set screwdriver to secure the device to the rods (Figure 19).
Surgical Technique
X 10 Crosslink Fixed Plate Final Tightening

A counter torque may be placed on the plate to minimize torque transfer to the construct. The screwdriver shaft is introduced through the counter torque. Next, the set screws are final tightened to break-off (approx. 60 in-lb.) using the screwdriver (Figure 20). The implant is then secure on both rods (Figures 21a and 21b). The sheared-off sections of the set screws can remain housed in the shaft of the set screwdriver until removal is convenient. To remove the sheared-off sections of the set screws from the set screwdriver, hold the handle horizontally; the broken-off sections will easily fall from the oblong port in the shaft (as shown on page 9, Figure 13).
SURGICAL TECHNIQUE

X10 CROSSLINK Plate Explantation

If removal of an X10 CROSSLINK Multi-Span Plate is necessary, place the torque-limiting screwdriver over the midline nut and turn counter-clockwise to loosen. Place the 3.0mm hex head shaft (removal driver) into a standard Medtronic Sofamor Danek 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 counter-clockwise to loosen the set screw from the rod.

When an X10 CROSSLINK Fixed Plate removal is necessary, place the 3.0mm internal hex screwdriver shaft into a standard Medtronic Sofamor Danek quick connect handle. Next, place the tip of the 3.0mm hex head shaft (removal driver) into the set screw and confirm that the 3.0mm tip is completely inserted so that the tip does not strip the hex. Turn the screwdriver counter-clockwise to loosen the set screw from the rod.
### SURGICAL TECHNIQUE

**Product Ordering Information**

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| **Implants** | N/A | N/A | 8115516 | 8116416 | 8105516 | 8106416 | 16mm X10 CROSSLINK Fixed Plate |
| | N/A | N/A | 8115519 | 8116419 | 8105519 | 8106419 | 19mm X10 CROSSLINK Fixed Plate |
| | N/A | N/A | 8115522 | 8116422 | 8105522 | 8106422 | 22mm X10 CROSSLINK Fixed Plate |
| | N/A | N/A | 8115525 | 8116425 | 8105525 | 8106425 | 25mm X10 CROSSLINK Fixed Plate |
| | N/A | N/A | 8115527 | 8116427 | 8105527 | 8106427 | 28mm X10 CROSSLINK Fixed Plate (optional) |
| | N/A | N/A | 8115531 | 8116431 | 8105531 | 8106431 | 31mm X10 CROSSLINK Fixed Plate (optional) |
| | 8115528 | 8116428 | 8116428 | 8105528 | 8106428 | 28-30mm X10 CROSSLINK Multi-Span Plate |
| | 8115530 | 8116430 | 8116430 | 8105530 | 8106430 | 30-34mm X10 CROSSLINK Multi-Span Plate |
| | 8115534 | 8116434 | 8116434 | 8105534 | 8106434 | 34-36mm X10 CROSSLINK Multi-Span Plate |
| | 8115536 | 8116436 | 8116436 | 8105536 | 8106436 | 36-39mm X10 CROSSLINK Multi-Span Plate |
| | 8115539 | 8116439 | 8116439 | 8105539 | 8106439 | 39-45mm X10 CROSSLINK Multi-Span Plate |
| | 8115545 | 8116445 | 8116445 | 8105545 | 8106445 | 45-57mm X10 CROSSLINK Multi-Span Plate |
| | 8115558 | 8116458 | 8116458 | 8105558 | 8106458 | 58-81mm X10 CROSSLINK Multi-Span Plate |
| | 8110855 | 8110855 | 8110855 | 8100855 | 8100855 | X10 CROSSLINK Plate Break-off Set Screw |

| **Instruments** | 8110501 | 8110502 | 8110501 | 8110501 | 8110501 | 8110501 | Measuring Credit Card |
| | 8110502 | 8110502 | 8110502 | 8110502 | 8110502 | 8110502 | Measuring Caliper |
| | 8110510 | 8110510 | 8110510 | 8110510 | 8110510 | 8110510 | Forceps Plate Holder (optional) |
| | 8110511 | 8110511 | 8110511 | 8110511 | 8110511 | 8110511 | 45° In Line Plate Holder |
| | 8110525 | 8110525 | 8110525 | 8110525 | 8110525 | 8110525 | Plate Bender |
| | 8110530 | 8110530 | 8110530 | 8110530 | 8110530 | 8110530 | 3.0mm Hex Head Shaft, Removal Driver |
| | 8110535 | 8110535 | 8110535 | 8110535 | 8110535 | 8110535 | 7/32" Torque-Limiting Set Screwdriver |
| | 8110540 | 8110540 | 8110540 | 8110540 | 8110540 | 8110540 | Counter Torque |
SURGICAL TECHNIQUE

Important Information on the CD HORIZON® Spinal System

PURPOSE:
The CD HORIZON® Spinal System is designed to help position, stabilize, and maintain or achieve spinal alignment in an effort to reduce the incidence of chronic pain and improve function.

DESCRIPTION:
The CD HORIZON® Spinal System is a surgical device used to perform spinal fusion procedures. It consists of a pedicle screw system and a vertebral body reconstruction system. The pedicle screw system includes screws, rods, and connectors, while the vertebral body reconstruction system includes cages and other components.

INDICATIONS:
These systems are indicated for use in the treatment of various spinal conditions, including degenerative disk disease, spondylolisthesis, and post-lumbar discectomy. They are also used to achieve spinal alignment and provide support for the spinal column.

CONTRAINDICATIONS:

1. Infections
2. Trauma
3. Bone abnormalities
4. Poor bone quality
5. Intercorporeal screw insertion

WARNING AND PRECAUTIONS:

1. Use preoperatively to prepare the patient for any post-operative care.
2. Use with other surgical instruments, including drills, saws, and drills.
3. Use with caution in patients with a history of severe osteoporosis.

SUMMARY:
The CD HORIZON® Spinal System is a surgical device designed to help position, stabilize, and maintain or achieve spinal alignment in an effort to reduce the incidence of chronic pain and improve function. It is indicated for use in the treatment of various spinal conditions, including degenerative disk disease, spondylolisthesis, and post-lumbar discectomy. It is contraindicated in patients with infections, trauma, bone abnormalities, poor bone quality, and intercorporeal screw insertion. Use with caution in patients with a history of severe osteoporosis.
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.

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 device 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. Different metal types should never be used together.

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 neurologic functions.

2. Breakage, slipping, or misuse of instruments or implant components may cause injury to the patient or personnel.

3. The rods should not be repeatedly or excessively bent. The rods should not be reversed bent in the same location. Use great care to ensure that the implant surfaces are not scratched or notched, 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 assure a smooth, non-sharp surface and be smooth to the feel of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.

4. Whenever possible or necessary, an imaging system should be utilized 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 can cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures. Do not overlap or use a screw that is either too long or too large. Overtapping or using an incorrectly sized screw may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert.

6. Bone graft must be placed in the areas to be fused and graft material must stand from the upper to the lower vertebrae being fused.

7. To assure maximum stability, two or more CROSSLI® plates or DTT Transverse Links on two bilaterally placed, continuous rods, should be used whenever possible.

8. Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal uses, and this material will make removal of the components difficult or impossible.

The heat generated from the curing process may also cause neurologic damage and bone necrosis.

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 accomplished go back and firmly tighten all of the screws and nuts. Retighten 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 required or recommended prior to firm bony union, the patient must be warned that bending, loading and/or breakage of the device(s) are 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 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, and the patient should avoid the maximum degree for a successful surgical result, the patient or device 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 tobacco or utilize nicotine products, or to consume alcohol or non-steroidal anti-inflammatory medications such as aspirin during the bone graft healing process.

3. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and 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. It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by neuroradiographic 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 ensure cooperation until bony union is confirmed.

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.

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, it is most prudent to remove the implants to prevent future support for those same purposes. 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, 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 delayed by adequate postoperative management to avoid fracture, refracture 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 loosen or corrosion 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 disinfected (if applicable) and sterilized using a method of sterilization with a known sterilization efficacy rate prior to implantation. If the device(s) were sterilized using the equipment and should personally assemble the device 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. Different metal types should never be used together.

An adequate inventory of implants 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 neurologic functions.

2. Breakage, slipping, or misuse of instruments or implant components may cause injury to the patient or personnel.

3. The rods should not be repeatedly or excessively bent. The rods should not be reversed bent in the same location. Use great care to ensure that the implant surfaces are not scratched or notched, 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 assure a smooth, non-sharp surface and be smooth to the feel of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.

4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.

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8. Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal uses, and this material will make removal of the components difficult or impossible.

The heat generated from the curing process may also cause neurologic damage and bone necrosis.

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 accomplished go back and firmly tighten all of the screws and nuts. Retighten 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.

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g., temperature, time) used for their equipment. * For outside the United States, some non-U.S. Health Care Authorities require sterilization according to these parameters so as to minimize the potential risk of transmission of Germs/other diseases, especially of surgical instruments that could come into contact with the central nervous system. Remove all packaging materials prior to sterilization. Use only sterile implants in the operative field.

PRODUCT COMPLAINTS:

Any Health Care Professional (i.e., customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or MEDTRONIC SOFAMOR DANEK. Further, if any of the implanted CD HORIZON Spinal System component(s) reveal “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 “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, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

FURTHER INSTRUCTIONS:

In case of complaint, or for supplementary information, or further directions for use of this system, please see the address listed below.
For product availability and/or more information on any MEDTRONIC SOFAMOR DANEK USA, INC. products, contact your MEDTRONIC SOFAMOR DANEK USA, INC. Sales Associate, or call MEDTRONIC SOFAMOR DANEK USA, INC. Customer Service toll free: 800-933-2635.

MEDTRONIC SOFAMOR DANEK USA, INC.
1800 Pyramid Place Memphis, TN 38132
(901) 396-3133 (800) 876-3133
Customer Service: (800) 933-2635

www.sofamordanek.com