as described by:

**William A. Phillips, M.D.**
Chief, Pediatric Orthopedic Surgery
Professor, Department of Orthopedic Surgery
Baylor College of Medicine
Houston, Texas

**Frank T. Gerow, M.D.**
Pediatric Orthopedic Surgery
Baylor College of Medicine
Houston, Texas
# Table of Contents

**Introduction** .................................................................................. 2

**Implants and Instruments** ...................................................... 3

**Surgical Technique Steps**

Patient Position ................................................................................. 7

Incision and Exposure ..................................................................... 8

Hook Site Preparation ..................................................................... 9

Hook Options and Placement

  Pedicle Hooks ............................................................................. 10

  Supralaminar Hooks .......................................................... 11

  Infra-laminar Hooks ......................................................... 11

  Transverse Process Hooks ........................................... 12

  Reduction Hooks ............................................................ 12

Correction Rod

  Rod Contouring ........................................................................ 13

  Rod Insertion ......................................................................... 14

  Rod Reduction ....................................................................... 15

  Rod Rotation ......................................................................... 23

  Compression/Distraction .................................................. 24

Reduction Hook Tab Removal ..................................................... 25

Stabilizing/Holding Rod Placement ........................................... 26

CROSSLINK® Plate Placement ................................................ 27

Final Tightening and Closure ..................................................... 28

**Basic Hook Information** .......................................................... 29

**Product Ordering Information** .................................................. 30
Since the introduction of the Cotrel-Dubousset instrumentation system in the 1980s, the use of segmental hook constructs has become the standard of care worldwide for the treatment of scoliosis and other spinal deformities. The ability to place multiple hooks on the same rod oriented in compression and/or distraction modes was revolutionary to the segmental correction of idiopathic scoliosis.

A variety of hooks are available with the CD HORIZON® System to fit the unique anatomic regions of the posterior elements on a variety of patients. The reduction hook, with its unique design, can be quite helpful in capturing the apical hooks in a large scoliosis. In addition, the reduction hook allows rod capture in a more dorsal and lateral position than that allowed by a normal hook, along with spine translation beneath the rod by means of plug tightening.

This CD HORIZON Hooks and Reduction Hooks Spinal System Surgical Technique features the implementation of reduction hooks and other situation-specific hooks within a segmental hook construct for the instrumentation and correction of a right thoracic idiopathic scoliosis.
Implants

**Pediatric Hooks**
Available in 5.5mm only, Titanium or Stainless Steel.

- Small Pedicle
- Small Wide Blade
- Small Narrow Blade
- Small Narrow Blade Ramped
- Small Extended Body
- Small Angled Blade

**Standard Hooks**
Available in 5.5mm and 6.35mm, Titanium or Stainless Steel.

- Pedicle
- Wide Blade, Small Groove
- Narrow Blade, Small Groove
- Angled, Left
- Standard Blade, Ramped
- Wide Blade
- Narrow Blade
- Angled, Right
- Narrow Blade, Ramped
- Extended Body
- Angled Blade
- Offset Right
- Offset Left

**Large Hooks**
Available in 6.35mm, Titanium or Stainless Steel. 5.5mm available in Stainless Steel only.

- Large Pedicle
- Extended Body, Large Groove
- Wide Blade, Large Groove
- Large Groove

**Reduction Hooks**
Available in 5.5mm and 6.35mm, Titanium or Stainless Steel.

- Pedicle
- Narrow Blade
- Standard Ramped Blade
- Narrow Ramped Blade
- Wide Blade
# Implants and Instruments

## Implants

*Available in 5.5mm and 6.35mm, Titanium or Stainless Steel.*

- Domino Connector
- Axial Connector
- Break Off Set Screw
- Reduction Break Off Set Screw
- Fixed Angle Screw
- Hex End Rod

## Rod Reduction Instruments

- Rod Pusher
- Cork Screw
- Rod Reducer and Lever Arm
- Rocker

## Reduction Hook Instruments

- Beale Rod Reducer
- Tab Breaker
- Rod Reducer Sleeve
  *Available in 7mm and 14mm*
- Ring Counter Torque
- Extended Rocker
- Split T25 Driver

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**Surgical Technique**

**CD HORIZON®**

**HOOKS AND REDUCTION HOOKS**

**SPINAL SYSTEM**
Instruments

Hook Instruments

- Captive Hook Pusher
- Pedicle Elevator Finder
- Transverse Process Elevator
- Laminar Elevator

Compression/Distraction Instruments

- Curved Compressor
- Curved Spreader

Dual Purpose Hook Pusher

Straight Implant Holder

Curved Implant Holder

Lateral Implant Holder
Set Screw/Connector Instruments

- Tapered Hex Shaft
- TORX 20
- TORX 25
- Plug/Set Screw Starter
- Plug/DTT Starter
- Provisional Plug Driver
- Counter Torque

General Instruments

- French Bender
- Power Grip
- Rod Holder
- Right/Left In-situ Benders
- Fixed Angle Screwdriver
- Quick Connect Ratcheting Universal Handle
- Quick Connect Handle
The patient is placed in the prone position following the induction of anesthesia, intubation and placement of monitors. Care should be taken in positioning the patient to avoid pressure areas and compromise of the abdomen (Figure 1). The patient is then prepped and draped in the usual manner.

Figure 1
Incision and Exposure

Following a skin incision that extends above and below the planned instrumentation site, a meticulous dissection is carried out to allow full exposure of the fusion bed and spine. A subperiosteal dissection is carried out to the tips of the transverse processes, allowing for full exposure of the posterior elements (Figure 2). The exposure and dissection are carried out with a Cobb Elevator and electrocautery unit.

Once the posterior elements are fully exposed, bilateral partial facetectomies of the thoracic spine are carried out using an osteotome and mallet or curette (Figure 3). The intervening cartilage is denuded to allow exposure of the subchondral bone assisting in bone fusion. A great deal of care should be taken while performing the dissection to avoid penetration of the spine. In addition, homeostasis should be maintained throughout the dissection.
After completing the bilateral partial facetectomies, the bone is prepared for the hook blades. The up-going hook sites are prepared by osteotomizing the inferior facet parallel to the lamina, allowing appropriate hook placement. Laminotomies are performed with a Leksell and Kerrison Rongeur to prepare the down-going hook sites. The laminotomies are carried out almost to the pedicles. In addition, a small portion of the spinous process may need to be removed to accommodate the head of the hooks.

Sometimes in the lumbar spine, the facets are hypertrophied or will block the ability to place a hook; therefore, partial facetectomies of the inferior facets are carried out to remove the bone and allow proper placement of the hook (Figure 4).
Hook Options and Placement

The CD HORIZON Spinal System offers a number of top-loading hooks of different anatomic shapes and sizes. At the same time, any CD HORIZON hook may be treated as a closed hook by simply placing the break-off set screw into the hook prior to insertion of the rod. The surgeon must choose the appropriate hook based on the individual patient’s anatomy, deformity degree and type, method of correction chosen, and amount of compression/distraction that will be needed to provide proper and stable purchase of the implants.

Pedicle Hooks

The pedicle hook may be applied from T1 to T10. The hook blade direction is always cephalad (an up-going hook) and is in the infralaminar position. The facet capsule is divided, and a portion of the inferior facet process may be removed to facilitate insertion of the hook (Figure 5). Once the pedicle has been clearly identified, the hook may be inserted with a hook holder, a hook pusher, or with the hook holder, captive hook pusher, and mallet combined (Figure 6). It is important that pedicle hooks are placed under the pedicle and not splitting the pedicle.
Supralaminar Hooks
The direction of this hook is always caudal (a down-going hook). A small laminotomy and division of the ligamentum flavum is carried out on the superior lamina. The laminar elevator (Figure 7) may be used to dissect the ligamentum flavum from the lamina. The amount of bone removed from the lamina may vary depending on the size of the hook blade and throat angle chosen. The inferior edge of the lamina above may be removed to ease the placement of this hook. An implant holder is typically used to insert the hook. While inserting the hook, a small lamina spreader may be used to enlarge the opening.

Infrafaminar Hooks
This hook is always inserted in the cephalad direction (up-going) and is generally used at T11 or below. With this hook type, the ligamentum flavum is separated from the inferior surface of the lamina, keeping the bone intact, if possible. Use of the laminar elevator and/or the hook holder with the hook pusher may facilitate the placement and insertion of this hook.
Transverse Process Hooks
This is generally a wide blade hook and is typically used in a claw construct. It may be used as a cephalad (up-going) or caudal (down-going) hook. Most often, this hook is placed in the caudal direction. The transverse process elevator (Figure 8) may be used to separate the ligamentous attachment of the undersurface of the transverse process and the upper aspect of the rib prior to placing the hook. An implant holder is used to insert this hook.

Reduction Hooks
This type of hook is typically placed at the base of the apex of the thoracic curve on the correcting side. The reduction hooks facilitate rod placement in very large curves that are offset and curves that have a significant amount of lordosis to them. The reduction hooks are available in the following styles: pedicle hook, infralaminar, supralaminar and transverse process.

NOTE: All hooks should be continuously checked throughout the procedure to ensure proper position is maintained.
Once the hooks on the correction side of the deformity are tested for fit and placement (Figure 9), the correction rod is measured, cut, and contoured. It is important to maintain same plane orientation of the rod in order to prevent a spiral type bend down the rod. The rod is contoured using a French bender (Figure 10). The rod is bent to essentially fit into the hooks, and then the rod will be rotated into its final position maintaining thoracic kyphosis and lumbar lordosis. The rod is placed along the spine to check for proper correction, hook fit, and contouring.

NOTE: After completion of the rod bend, the spine may be decorticated to carry out the bone fusion. Morselized cancellous bone is placed along the decorticated spine, extending out over the transverse processes.
The contoured rod is placed into the top-loading implants beginning from either the cephalad or caudal direction (Figure 11). A rod holder may be used to assist in placing the rod. Break-off set screws (hereafter interchanged with “plug”) are placed into each implant to assist in holding the rod in place. Another option would be to place one plug in the first implant (becoming a closed implant) to hold the rod while it is placed in the other implants. The plugs are placed using a plug starter. To facilitate proper threading of the plug, turn the plug starter counter-clockwise until an audible “click” occurs and then proceed clockwise. A rod pusher may be used to push the rod down in order to place a plug. In addition, the implants can be stabilized and controlled with a lateral or curved implant holder while placing the plugs (Figure 12). Finally, a provisional driver is used to hand tighten the plugs.

NOTE: It is essential for the double-threaded set screws to be used with the reduction hooks and not a standard plug. The Split-T 25 is used to start the M8 reduction set screws as a standard plug starter will not fit these plugs. And, the TORX 25 is used to provisionally tighten the M8 reduction plugs. The M10 reduction plugs use the standard plug starter and provisional driver.
There are several methods and instruments that may be used to achieve rod reduction and fully seat the rod in the saddle of the implants. **NOTE: Care should be taken with any of the following rod reduction methods. Improper instrument use may dislodge implants or damage the inferior facets and other bony anatomy.**

**Method 1 (Rocker)**

Use of the rocker is an effective method for reducing (or seating) the rod in the implant when only a slight height difference exists between the rod and the implant saddle. To use the rocker, grasp the sides of the implant with the rocker cam above the rod (Figure 13a) and then lever backwards over the rod (Figure 13b). The levering action allows the rod to be fully seated in the saddle of the implant. The plug starter is then used to place the plug.
Method 2 (Corkscrew)

Corkscrews and implant holders may also be used to reduce (or seat) the rod into the implants. Using lateral implant holders, place the implant holder onto the implant walls, and then attach a corkscrew to each finger loop of the lateral implant holder. The rod is seated by turning the T-handle on the corkscrew (Figure 14). Once the rod is seated, a plug can be placed using a plug starter. When using the curved implant holder, place the holder on the implant walls and then connect the corkscrew to the ratcheting mechanism of the curved implant holder (Figure 15). Again, turning the T-handle of the corkscrew will advance the rod, allowing for a plug to be placed.
Rod Reduction (continued)

Method 3 (Rod Reducer and Lever Arm)

If the rod lies medial or lateral to the implant, the rod reducer and lever arm provide translational capabilities, allowing the rod to be reduced into the saddle of the implant. Attach the tines of the rod reducer to the side of the implant by holding the coupling sleeve and stabilizing bar and sliding the tines down over the implant. The rod reducer attaches to the implant parallel to the rod and with the open portion facing the rod (Figure 16). Once the tines are in position, hold the stabilizing bar and slide the coupling sleeve downward until the implant is properly engaged. Once the implant is engaged, turn the threaded knob at least one full clockwise revolution, locking the rod reducer into position.
Rod Reduction (continued)

Method 3 (continued)
To translate a rod, attach the lever arm to the coupling sleeve axles. While turning the threaded knob, rotate the lever arm downward in a sweeping motion to capture the rod (Figure 17a). Continue to use the lever arm to manually translate the rod until it is over the head of the implant (Figure 17b).
Rod Reduction (continued)

Method 3 (continued)
With the rod over the implant, turn the threaded knob clockwise until the rod is captured in the head of the implant. Remove the lever arm and continue turning the threaded knob until the rod is fully seated in the saddle of the implant. Using a plug starter or provisional driver, slide a set screw down the center of the rod reducer and into the implant (Figure 18). The provisional plug driver is then used to provisionally tighten the plug.

NOTE: If the rod is above the implant, the rod reducer may be used without the lever arm.
Rod Reduction (continued)

Method 4 (Beale Rod Reducer)

In situations where the rod rests at the top of the implant, the Beale rod reducer may be used to seat the rod. The reducer is placed over the implant with the ratchet portion parallel to the rod (Figure 19). The reducer is then slowly closed allowing the attached sleeve to slide down and seat the rod into the saddle of the implant. A plug is then placed through the plug tube with a plug starter and provisionally tightened with the provisional plug driver.
Method 5 (Reduction Implants)

With the reduction implants, any of the following methods may be used to reduce the rod:

- Using the TORX 25 for M8 or the provisional plug driver for M10, place the appropriate ring counter torque on the implant head and advance the double-threaded break-off set screw until the rod is fully seated in the implant saddle (Figure 20).

- The extended rocker may be used in the same manner as the standard rocker to seat the rod in the reduction implants and then advance the double-threaded set screw (refer to Method 1).

- Depending on where the rod is seated within the reduction implants, the Beale rod reducer may be used in the same manner as described in Method 4 and/or with the modular reduction sleeves. If the rod is toward the bottom of the implant, but needs assistance to achieve full reduction, add the 14+ sleeve to the reducer. Place the reducer, with the modular sleeve, on the reduction implant head with the ratchet parallel to the rod (Figure 21). Slowly close the reducer and then advance the double-threaded set screw to the rod, fully seating the rod.

NOTE: The TORX 25 is used to provisionally tighten the M8 reduction set screw, and the provisional plug driver is used for the M10 reduction set screw.
**Method 5 (continued)**

If the rod is toward the middle of the implant head, add the 7+ sleeve to the reducer, place the reducer and sleeve on the implant head and slowly close (Figure 22). Again, advance the set screw to the rod. To achieve full reduction, the 14+ sleeve will then be used as described above. Finally, if the rod is seated high in the implant head, use the rod reducer in the same manner as described in Method 4 and then advance the double-threaded set screw to the rod (Figure 23). In order to achieve full rod reduction, the 7+ sleeve and then the 14+ sleeve will need to be applied in sequential order and used in the same manner as described above.

**NOTE:** The Beale rod reducer alone provides 7mm of rod reduction. The 7+ sleeve provides an additional 7mm and the 14+ sleeve another 7mm for a maximum of 21mm of rod reduction. The use of modular sleeves to reduce the rod allows for slow and gradual reduction and the ability to monitor neurological functions while reducing the rod.
Rod Rotation

Once the contoured rod and all break-off set screws have been placed, the rod is ready to be rotated into its final position. The rotation is done at the level of the interval hooks, typically located at the base of the apex of the curve, using two rod grippers and a hook pusher. The hook pusher helps to stabilize the hook (Figure 24). It is important to monitor the interval hooks, which tend to back out during rod rotation. The rotation must be done slowly in order to prevent rapid neurological changes and/or injury to the spinal cord. Once the rotation of the rod is complete and the position of the hooks is verified, the reduction and interval hooks’ set screws are provisionally tightened to prevent rod derotation. The hooks should be checked following all rotation maneuvers and the necessary adjustments made to ensure that proper placement is maintained. At this point, the rod should be fully seated in the saddle of all the implants. If further rod reduction is required, any of the previously mentioned reduction methods may be applied to complete rod reduction. In-situ benders may also be used for final adjustment of the rod and to facilitate rod placement in the implants.
Once the rod is secured in the implants, sequential tightening, distraction, and/or compression are performed to place the hooks in their final position. The compressor, spreader, provisional driver, and rod gripper are used to carry out these maneuvers. One foot of the compressor or spreader should be placed against the side of the hook and the other foot against the rod gripper as compression and distraction are carried out (Figure 25). Care should be taken to ensure that the foot of either instrument is placed against the implant body and not against the plug. Failure to do this may cause the implant to slip or the plug head to break prematurely. The provisional driver is used to maintain temporary locking and unlocking of the rod/implant construct. Temporary fixation of the construct may be done numerous times without damage to either the plug or the implant threads. However, if a plug is cross-threaded, it must be removed and replaced with a new plug.
Reduction Hook Tab Removal

Once the rod is fully seated along the construct and correction is complete, the extended tabs are broken off the reduction hooks. The tab breaker and ring counter torque are needed to remove the tabs. Place the appropriate size ring counter torque over the head of the reduction implant and slide it down to the rod. Slide the tab breaker over the tab and then lever the tab breaker away from the rod (Figure 26). The tabs typically break off away from the rod. If the lateral tab is difficult to break off due to tissue and/or muscle:

- Break off the medial tab medially (or away from the rod).
- Then break off the double-threaded set screw. (Refer to Step 13 if necessary to break off the set screw head at this point.)
- Finally, break off the lateral tab medially (or toward the rod).

**NOTE:** At least one of the extension tabs must be removed from the implant before the double-threaded set screw can be broken off.
With the completion of the deformity correction and the seating of the correction rod, the stabilizing side of the construct is prepared. Measure the stabilizing rod for length, then cut. Using the French bender (shown on page 13), contour the rod to accommodate the curvature that the patient now has. Place the contoured rod into the hooks and temporarily secure the rod with plugs. Then, provisionally tighten the plugs (Figure 27). Once the rod is secured to the implants, sequential tightening, distraction, and/or compression are performed to place the hooks in their final position. Refer to Step 9 to ensure that the appropriate steps are followed.

NOTE: After completion of the rod bend, the stabilizing side of the spine may be decorticated to carry out the bone fusion and morselized cancellous bone placed along the decorticated spine, extending out over the transverse processes (the same process as was done on the correcting side of the spine).
Once all the plugs are provisionally tightened, the construct is measured for placement of the Low Profile CROSSLINK Plate and/or CROSSLINK® Multi-Span™ Plate. In long constructs, a CROSSLINK Plate should be placed in the upper one-third of the construct and another one in the lower one-third of the construct. The appropriate size CROSSLINK Plate is determined by placing the plate template from rod to rod, measuring the distance between the rods (Figure 28). The number on the plate template corresponds to the appropriate size CROSSLINK Plate or CROSSLINK Multi-Span Plate. A plate holder is then used to place the CROSSLINK Plate on the rods (Figure 29). The rods may be compressed or distracted to assist with placement. The set screws are advanced using the screwdriver to a torque of approximately 60 in-lbs., alternating from side-to-side to ensure uniform closure. Two screwdrivers may be used to advance the set screws simultaneously for uniform closure. When using the CROSSLINK Multi-Span Plate, the center set screw should be tightened 

If the CROSSLINK Plate needs contouring, the plate benders should be used. When contouring the CROSSLINK Multi-Span Plate:

- Shorten the telescopic mechanism slightly less than the span between the rods, and provisionally tighten the center set screw.
- Take care not to exceed a 20° bend in any one plane.
- Loosen the center set screw, and apply the CROSSLINK Multi-Span Plate as described above.

NOTE: CROSSLINK Plates may be placed before or after breaking off the set screw heads.
When all implants are securely in place and the rod fully seated, final tightening and break off of the plug heads is done.

**Standard Plug** – The appropriate size counter torque instrument is placed over the implant and rod (Figure 30). The tapered hex shaft and quick connect T-handle are then placed through the cannulation of the counter torque. The quick connect T-handle provides adequate leverage for the breaking off of the plug heads (between 10-12 N-m for M8 and 11-14 N-m for M10). The handle of the counter torque device should be held firmly to prevent torquing of the construct while the plug is secured and sheared off (Figure 31). If necessary, the plug may be removed after final tightening using the TORX 25 and quick connect T-handle (Figure 32). Once a plug has been removed, it must be discarded and replaced with a new one.

**Reduction Plug** – The appropriate size ring counter torque or standard counter torque may be used when shearing the heads off the reduction plugs. Follow the same steps as listed above to shear the heads off of the reduction plugs.

Wound closure is performed in the customary manner.
Basic Hook Information

CD HORIZON HOOKS – 5.5mm and 6.35mm

PEDICLE HOOK, SMALL
Catalog # M8: 859-020 – M8 SS
Catalog # M10: 859-020 – M10 SS
Placement and Purpose:
Notes:• used as supra-laminar hook
• infra or supra-laminar hook

NARROW BLADE RAMPED HOOK
Catalog # M8: 859-102 – M8 SS
Catalog # M10: 8693102 – M10 SS
Placement and Purpose:
Notes:• designed for smaller patients
• narrow canal, or high thoracic
• ramp above blade tip draws up against lamina when fully engaged
• ramp reduces intra-canal intrusion
• effective at the apex of kyphosis

WIDE BLADE HOOK
Catalog # M8: 859-010 – M8 SS
Catalog # M10: 859-010 – M10 SS
Placement and Purpose:
Notes:• used as transverse process hook
• used as infra or supra-laminar

EXTENDED BODY HOOK, SMALL
Catalog # M8: 859-010 – M8 SS
Catalog # M10: 859-010 – M10 SS
Placement and Purpose:
Notes:• reduces the need for rod contouring in the sagittal plane
• infra or supra-laminar position
• used in the lumbar spine when there is a discrepancy in the height of adjacent hooks

NARROW BLADE HOOK, SMALL
Catalog # M8: 859-020 – M8 SS
Catalog # M10: 859-020 – M10 SS
Placement and Purpose:
Notes:• narrow blade hook
• designed for narrow canal, or high thoracic
• small throat opening than wide blade hook
• can be used in lieu of thoracic hook

WIDE BLADE, LARGE GROOVE HOOK
Catalog # M8: 859-102 – M8 SS
Catalog # M10: 8693102 – M10 SS
Placement and Purpose:
Notes:• same use as standard hook
• larger anatomy

LARGE GROOVE HOOK
Catalog # M8: 859-112 – M8 SS
Catalog # M10: 8693112 – M10 SS
Placement and Purpose:
Notes:• same as angled hook, right

ANGLLED BLADE HOOK
Catalog # M8: 859-112 – M8 SS
Catalog # M10: 8693112 – M10 SS
Placement and Purpose:
Notes:• same as angled hook, right

PEDICICLE HOOK
Catalog # M8: 859-102 – M8 SS
Catalog # M10: 859-102 – M10 SS
Placement and Purpose:
Notes:• used as infra or supra-laminar hook
• used as infra-laminar hook in lower thoracic and lumbar

NARROW BLADE HOOK
Catalog # M8: 859-112 – M8 SS
Catalog # M10: 8693112 – M10 SS
Placement and Purpose:
Notes:• designed for adult use or large boned adolescents
• supra-laminar hook
• wide blade for increased metal/bone contact
• effective at the apex of kyphosis

STANDARD BLADE RAMPED HOOK
Catalog # M8: 859-112 – M8 SS
Catalog # M10: 8693112 – M10 SS
Placement and Purpose:
Notes:• designed for adult use or large boned adolescents
• supra-laminar hook
• wide blade for increased metal/bone contact
• effective at the apex of kyphosis

OFFSET HOOK, LEFT
Catalog # M8: 8693112 – M8 SS
Catalog # M10: 8693112 – M10 SS
Placement and Purpose:
Notes:• same as offset hook, right

EXTENDED BODY, LARGE GROOVE HOOK
Catalog # M8: 859-112 – M8 SS
Catalog # M10: 8693112 – M10 SS
Placement and Purpose:
Notes:• generally implanted in the lower lumbar spine
• rarely used above L3

LARGE GROOVE HOOK
Catalog # M8: 859-112 – M8 SS
Catalog # M10: 8693112 – M10 SS
Placement and Purpose:
Notes:• same as angled hook, right

ANGLED HOOK, RIGHT
Catalog # M8: 859-112 – M8 SS
Catalog # M10: 8693112 – M10 SS
Placement and Purpose:
Notes:• same as angled hook, right

WIDE BLADE HOOK
Catalog # M8: 859-010 – M8 SS
Catalog # M10: 859-010 – M10 SS
Placement and Purpose:
Notes:• wider blade

ANGLED BLADE HOOK
Catalog # M8: 859-112 – M8 SS
Catalog # M10: 8693112 – M10 SS
Placement and Purpose:
Notes:• same as angled hook, right
Basic Hook Information (continued)

EXTENDED BODY HOOK
Catalog # M8:
859-130 – M8 SS
859-130 – M8 Ti
Catalog # M10:
9698130 – M10 SS
9698130 – M10 Ti
Placement and Purpose Notes:
• reduces the need for rod contouring in the sagittal plane
• infra or supra-laminar position
• effective if the lumbar spine is ankylosed

NARROW BLADE, SMALL GROOVE HOOK
Catalog # M8:
859-122 – M8 SS
859-122 – M8 Ti
Catalog # M10:
9698122 – M10 SS
9698122 – M10 Ti
Placement and Purpose Notes:
• smaller throat opening than wide blade hook
• used as infra or supra-laminar hook

EXTENDED BODY HOOK
Catalog # M8:
859-130 – M8 SS
859-130 – M8 Ti
Catalog # M10:
9698130 – M10 SS
9698130 – M10 Ti
Placement and Purpose Notes:
• reduces the need for rod contouring in the sagittal plane
• infra or supra-laminar position
• effective if the lumbar spine is ankylosed

OFFSET HOOK, RIGHT
Catalog # M8:
859-140 – M8 SS
859-140 – M8 Ti
Catalog # M10:
9698140 – M10 SS
9698140 – M10 Ti
Placement and Purpose Notes:
• used in the lumbar spine when offset is required
• can be used as a transverse process hook
• reduces the need to bend the rod in the coronal plane

ANGLED BLADE HOOK, SMALL
Catalog # M8:
859-024 – M8 SS
859-024 – M8 Ti
Catalog # M10:
9698024 – M10 SS
9698024 – M10 Ti
Placement and Purpose Notes:
• generally implanted in the lower lumbar spine
• implanted as infra-laminar hook

PEDICLE HOOK, LARGE
Catalog # M8:
859-042 – M8 SS
859-042 – M8 Ti
Catalog # M10:
9698042 – M10 SS
9698042 – M10 Ti
Placement and Purpose Notes:
• same use as standard hook option
• larger anatomy

Product Ordering Information

M8 SETS

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<td>148</td>
<td>Titanium CD HORIZON M10 Standard Hooks</td>
</tr>
<tr>
<td>147</td>
<td>Stainless Steel CD HORIZON M10 Standard Hooks</td>
</tr>
<tr>
<td>208</td>
<td>Titanium CD HORIZON M10 Reduction Hooks</td>
</tr>
<tr>
<td>209</td>
<td>Stainless Steel CD HORIZON M10 Reduction Hooks</td>
</tr>
<tr>
<td>189</td>
<td>Titanium CD HORIZON M10 Fixed Angle Screws</td>
</tr>
<tr>
<td>186</td>
<td>Stainless Steel CD HORIZON M10 Fixed Angle Screws</td>
</tr>
<tr>
<td>211</td>
<td>CD HORIZON M10 Instrument Set</td>
</tr>
</tbody>
</table>
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 SPINA® 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 SPINA® Spinal systems can be used with the CD HORIZON® Spinal System. These components include TSH®-P rods, hooks, plates, CROSSLINK® plates, connectors, staples and washers. GOLD® rods, hooks, connectors and CROSSLINK® bar and connectors; LIBERTY® rods and screws; DYNALOK® PLUS® bolts. 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 ø5.5mm rods and ø6.35mm 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 described by such standards as ASTM F138 or ASTM F583-1 or ASTM F583-9. Alternatively, the entire system may be made out of medical grade titanium or titanium alloy described by such standards as ASTM F138 or ASTM F136 or ASTM F583-3 or SS-02-2. MEDTRONIC SPINA® DURABLE expressly warrants that these devices are fabricated from one of the foregoing material specifications. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MSD Catalog for further information about warranties and limitations of liability. Never use stainless steel and titanium implant components in the same construct.

The CD HORIZON® Spinal System also includes anterior staples made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium implants only. Do not use with stainless steel.

To achieve best results, do not use any of the CD HORIZON® Spinal System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another MEDTRONIC SPINA® DURABLE document. As with all orthopedic and neurological implants, none of the CD HORIZON® Spinal System components should ever be reused under any circumstances.

Indications, contraindications and possible adverse events:

Indications:
The CD HORIZON® system is intended for the following indications:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the CD HORIZON® Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) spondylosis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, (8) bone loss or decrease in bone density, possibly caused by stresses shielding, (9) graft donor site complications including pain, fracture, or wound healing problems.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the CD HORIZON® Spinal System is intended for the following indications: (1) degenerative disc disease as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies, (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

When used in a percutaneous posterior approach with the SEQUENCE® instrumentation, the CD HORIZON® Cannulated Multi-Axial Screw components are intended for the following indications:

When used as a pedicle screw fixation system the CD HORIZON® Cannulated Multi-Axial Screw components are also indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the CD HORIZON® Spinal System is intended for the following indications: (1) degenerative disc disease as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies, (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

The CD HORIZON® ECLIPSE® components are intended for the following indications:

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 benefits of implant surgery, and 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. Osteoporosis or osteopenic relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical correction.
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 case that requires the mixing of metals from two different components or systems.
14. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
15. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
16. Any patient unwilling to follow postoperative instructions.
17. Any case not described in the indications.

possible adverse events:
All of the possible adverse events associated with spinal surgical instrumentation 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 diseases.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or burn. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
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 paralysis (complete or incomplete)), dysesthesias, hypotension, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neurama, spema, sensory loss, tingling sensation, and/or visual defects.
9. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, anachorditis, and/or muscle loss.
10. Urinary retention or loss of bladder control or other types of urological system complication.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bore graft or bone graft harvest site at, and/or below the level of surgery. Retrograded graft.
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 stresses 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, sepsis, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
22. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
23. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
24. Change in mental status.
25. Death.

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

WARNING AND PRECAUTIONS:

WARNING: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant morphological 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 neurological 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.

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 extenuating circumstances may compromise the result. This device system is not intended to be the sole means of spinal support. Use of this product without a well-considered surgical plan that develops into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loss of alignment, disc space narrowing, and/or loosening of the device(s) will eventually occur.

Preparative and operating procedures, including knowledge of surgical techniques, good judgment, 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 may have been shown to have a history of significant 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 paralyzation 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.

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

CAUTION: FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

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 SOFAMOR DANEK CD HORIZON® Spinal System instrumentation contains 4.5 mm, 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-ADJUSTING THE PLUG 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 predispositions 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 present, 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. Different metal types should never be used together.
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 operative 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. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
5. To insert a screw properly, a guidewire should first be used, followed by a sharp tap.

**Caution:** Be careful that the guidewire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the guidewire 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. Do not overtight or use a screw that is either too long or too large. Overlapping or using an incorrectly sized screw may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert.

6. Bony graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebra being fused.

7. To achieve maximum stability, two or more CROSSLINK® plates or DTT Transverse Links on two bilateral 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 completed go back and firmly tighten all of the screws or nuts. Rethread 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.

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 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 disabiled or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.

To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical impacts 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 or anti-inflammatory medications such as aspirin during the bone graft healing process.

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.

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.

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 implant systems 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 stress or the other possible adverse events listed elsewhere in this package insert.

**FURTHER INFORMATION:**
In case of complaint, or for supplementary information, or further directions for use of this system, please see the address below.

**In the USA:**
MEDTRONIC SOFAMOR DANEK International® 1800 Pyramid Place Memphis, Tennessee 38132 USA Telephone: 800-876-3133 or 901-396-3133

**IN EUROPE:**
Customer Service Division Telephone: (33) 3.21.89.50.00 MEDTRONIC SOFAMOR DANEK 1800 Pyramid Place or (31) 4.93.89.80.00 **authorized EC representative** Memphis, Tennessee 38132 USA Telephone: (33) 3.21.89.50.00 **Customer Service Division**

MEDTRONIC SOFAMOR DANEK International** 13, rue de la Paix Telephone: 800-876-3133 93290 TREMBLAY EN FRANCE or 901-396-3133 MEDTRONIC SOFAMOR DANEK France ** see the address 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*, see the appropriate Non-U.S. Health Care Facilities 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 complaint or who feels that any medical device belongs to the system should contact the manufacturer, should be available in case of an unexpected need. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. For a 10th Sterility Assurance Level, these products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below.

**METHODOLOGY:**

<table>
<thead>
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<th>METHOD</th>
<th>CYCLE</th>
<th>TEMPERATURE</th>
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<td>Gravure</td>
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<td>Steam*</td>
<td>Gravure*</td>
<td>275°F (134°C)</td>
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**NOTE:**

The CD HORIZON® Spinal System implant components 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 stress or the other possible adverse events listed elsewhere in this package insert.
For product availability, labeling limitations, 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