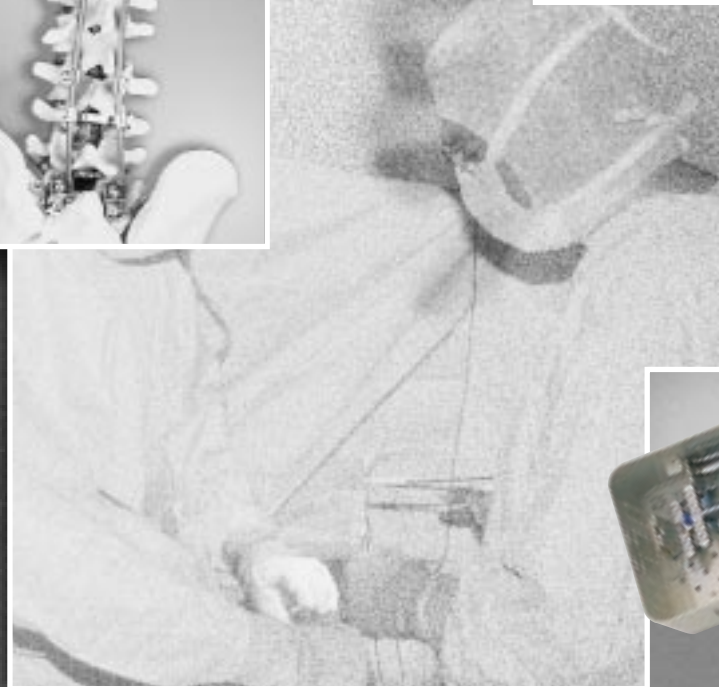
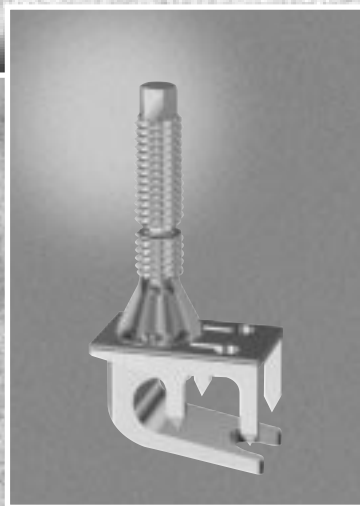


# Colorado<sup>TM</sup>

THE NEW REVOLUTION

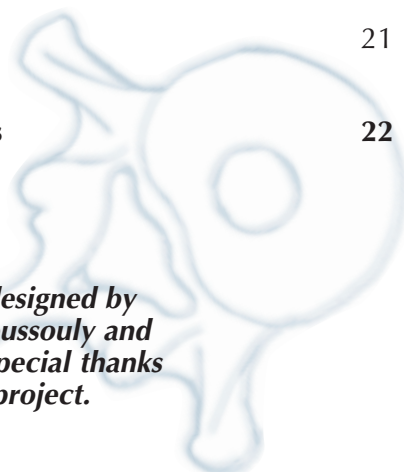


**Surgical Technique**

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*This spinal system has been designed by Dr Chopin, Dr Grosse, Dr Roussouly and Dr Taglang who all deserve special thanks for their involvement in this project.*



## Main Indications:

This system is intended to provide stabilization until a solid spinal fusion mass develops. The main indications for the COLORADO 2<sup>TM</sup> Spinal System are the following:

- Degenerative disc disease
- Pseudoarthrosis
- Stenosis
- Spondylolisthesis
- Spinal deformities such as scoliosis, kyphosis, and lordosis
- Fracture
- Revision surgery
- Tumor resection

## Main Contraindications:

This device is not intended for cervical spine use. Other contraindications include, but are not limited to:

- Infection, local to the operative site
- Signs of local inflammation

*For further information please refer to the package insert.*



## ***SPECIFICATIONS THAT MEET THE SURGEONS EXPECTATIONS AND NEEDS.***

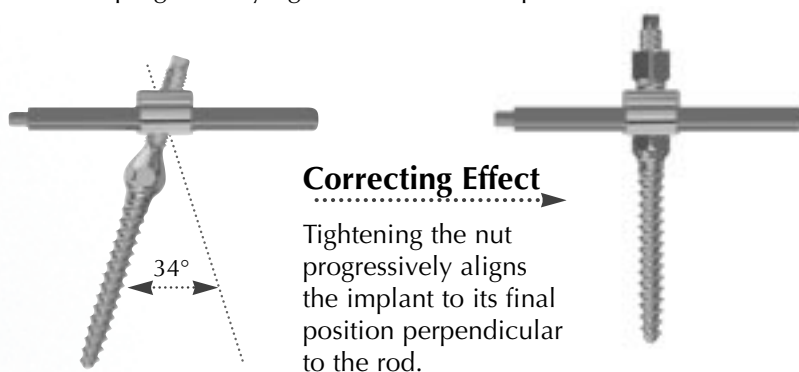
### **BECAUSE OF:**

- Flexible rods with excellent fatigue resistance
- Ease of connection due to the open clamp
- A low profile with superior mechanical properties
- Excellent sacral and sacroiliac fixation
- Three dimensional correction
- Functional and ergonomic instrumentation

### **EASE OF CONNECTION**

Because of the variable angulation of the implant/clamp interface (34°), the correcting effect of the clamp realigns the vertebra perpendicular to the rod.

Three dimensional correction occurs simultaneously as the nut is progressively tightened onto the implant.



### **Ease of connection**

34° of angulation is possible when introducing the clamp.

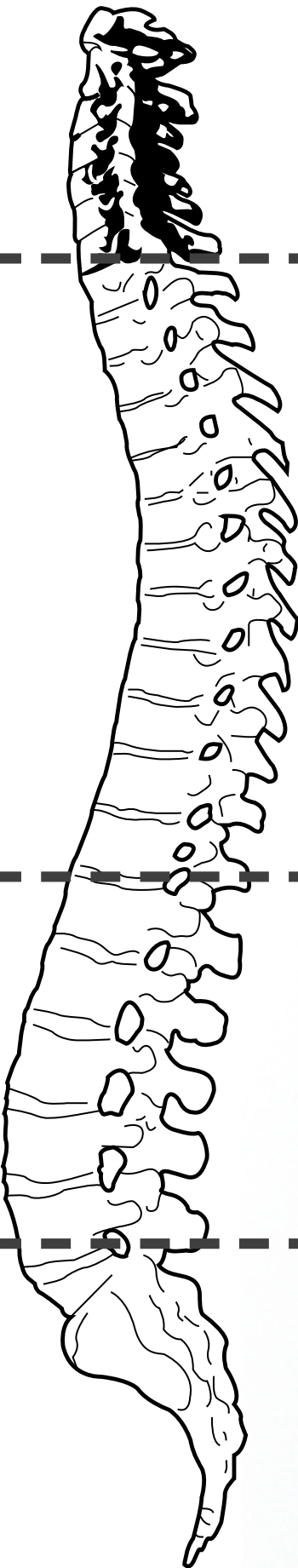


# STABLE FIXATION CONCEPT

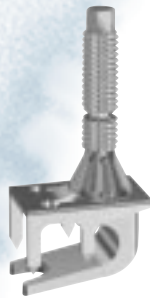
THORACIC

LUMBAR

SACRAL



PEDICULAR HOOKS & STAPLE



PEDICULAR SCREWS & INTERPEDICULAR PLATES

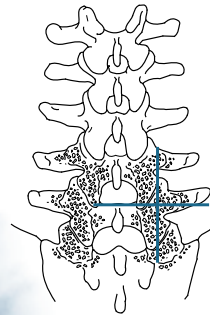
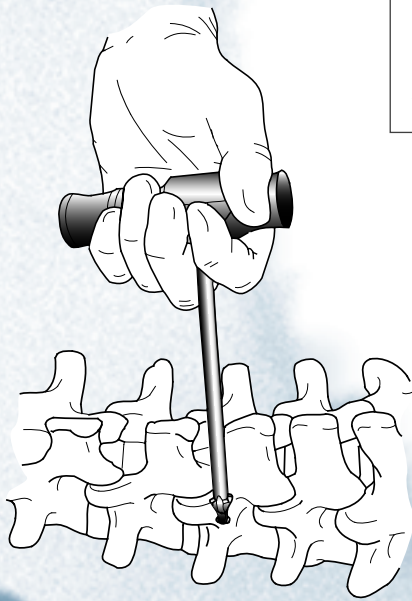


SACRAL PLATES & SACRAL SCREWS





1

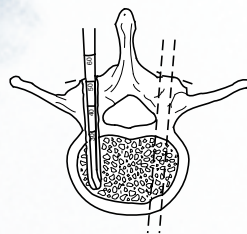
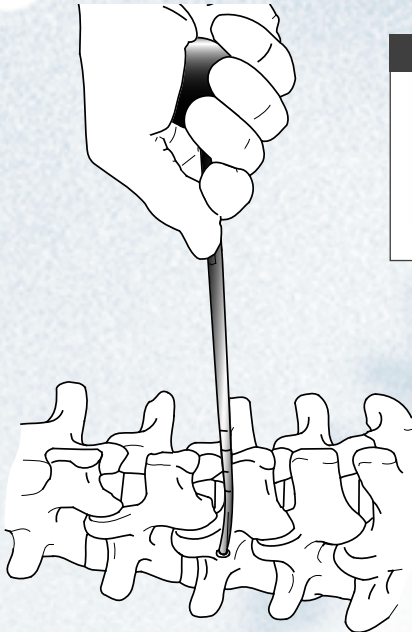


## IDENTIFICATION AND PREPARATION OF THE PEDICLES

The square awl shaft and the dual purpose handle can be used to locate an opening on the pedicle. The handle can be used in the axial or T-position.

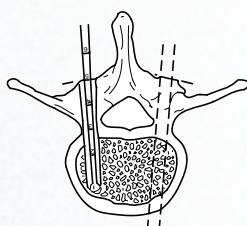
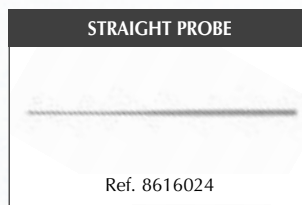
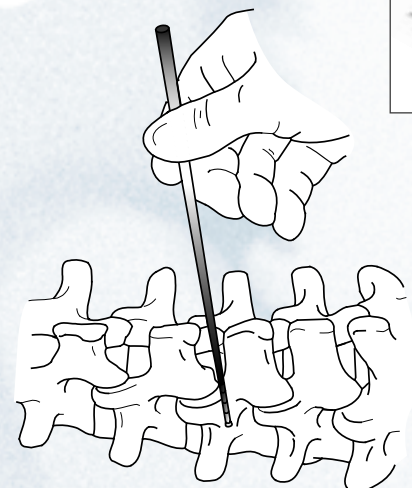
The location of the pedicular entry point should be at the convergence of the middle of the transverse process, the superior facet, and the pars interarticularis convergence over the dorsal portion of the pedicle. This starting point can also be determined at the intersection of two lines drawn through the middle of the transverse process and the lateral border of the superior facet. A burr or rongeur may be used to clear away the hard cortical bone to reveal the cancellous portion of the pedicle.

2



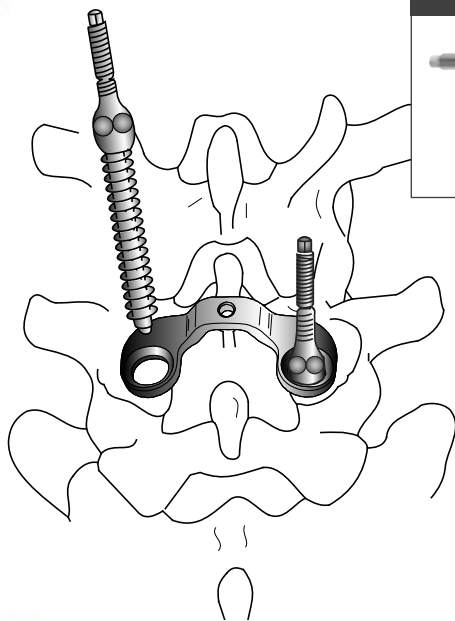
The pedicle spatula is inserted through the pedicle and into the vertebral body. The spatula should be in permanent contact with the bone. The spatula should pass through the pedicle without excessive force. The curvature of the spatula is designed to follow the shape of the vertebra. A curette can also be used in place of the spatula, if preferred.

3



Palpate the pedicle with the straight probe to help ensure the walls of the bony channel are intact.

4



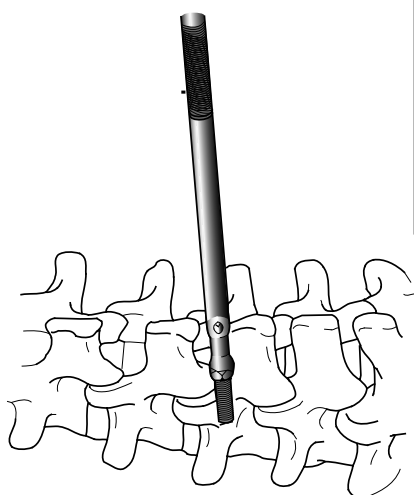
PEDICULAR SCREWS & INTERPEDICULAR PLATES



## INTERPEDICULAR PLATE

To increase the bone fixation an interpedicular plate can be used, this must be placed first ; the pedicular screws are inserted through the plate. Any necessary bone debridement must be achieved to seat the plate in its final position. The plate **CANNOT** be fitted after pedicular screws have been implanted. It is recommended to place bone graft under the interpedicular plate, before final attachment.

5



SCREWDRIVER SHAFTS & HANDLE



Short: Ref. 8616019  
Long: Ref. 8616004



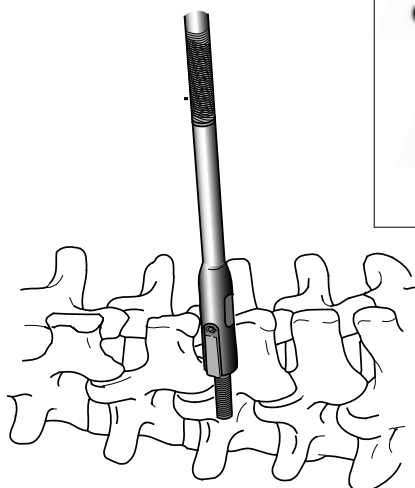
Ref. 8616014

## SCREW PLACEMENT

The ratcheting handle adapts to several screwdriver shafts.

This shaft (long or short) fits onto the small hexagon of the threaded end post, providing excellent vision of the screw head during introduction into the pedicle.

6



NUT & SCREW DRIVER SHAFT



Ref. 8616021



Ref. 8616014

The second shaft grasps the large hexagonal head of the screw.

Its use is recommended for the final tightening during the placement of interpedicular plates to prevent the risk of premature breakage of the self-breaking threaded post.

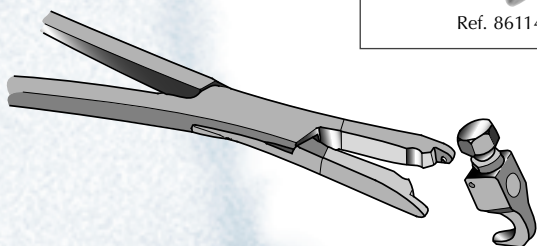
This shaft is also used in the case of screw removal.

The insertion limit of the screw is achieved when the end-part of the bone thread is completely inserted. Contact between screw head and bone should be avoided to allow room for the clamp/rod interface.

7

**CLOSED LAMINAR THORACIC HOOK**

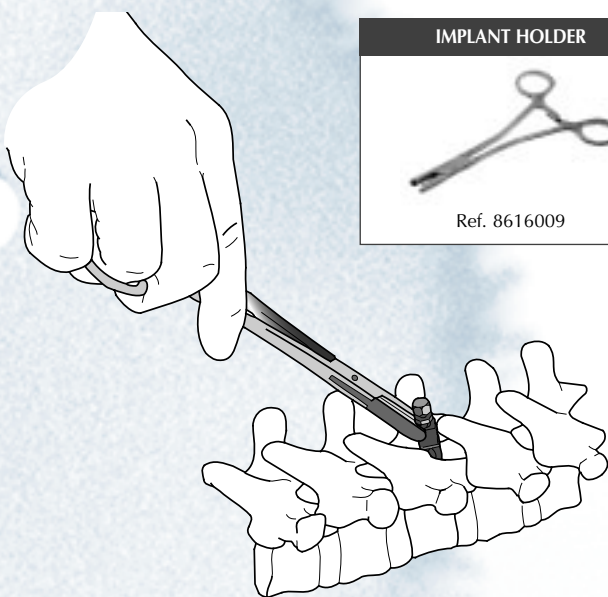
Ref. 8611402



8

**IMPLANT HOLDER**

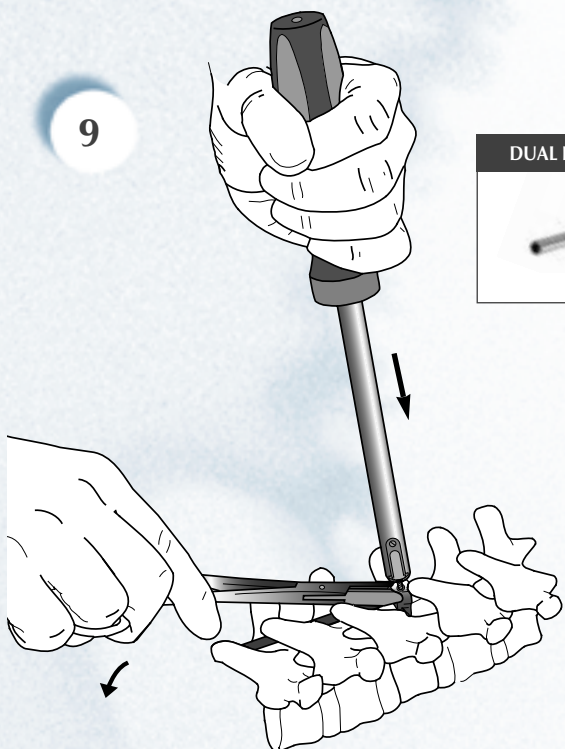
Ref. 8616009



9

**DUAL PURPOSE NUT DRIVER**

Ref. 8616001

**CLOSED LAMINAR THORACIC HOOK**

The universal implant holder acts as a closed hook holder and introducer. Two pins at the tip of the instrument fit into the dimples on the lateral sides of the closed hook to secure the implant for insertion. The small break-off locking screw must be untightened to permit the introduction of the rod.

The closed laminar thoracic hook is inserted after a careful opening of the canal.

The rod is connected to the hook. The hook holder is then pushed down to allow the tightening of the locking screw onto the rod with the nut driver.



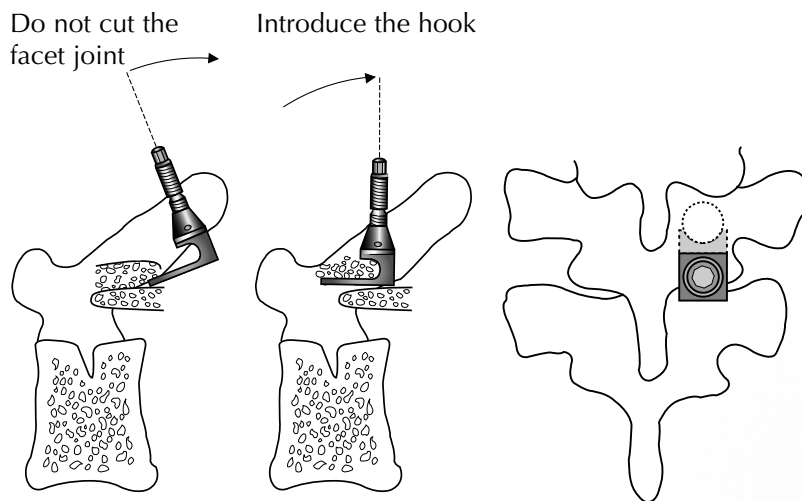
10



## PEDICULAR AND LAMINAR HOOK PLACEMENT

This hook holder instrument acts both as a holder and impactor. The metallic cap is pushed open with the thumb. The pins at the top of the hook holder ensure a good grasp onto the hook. The instrument is used as a laminar or pedicular hook holder.

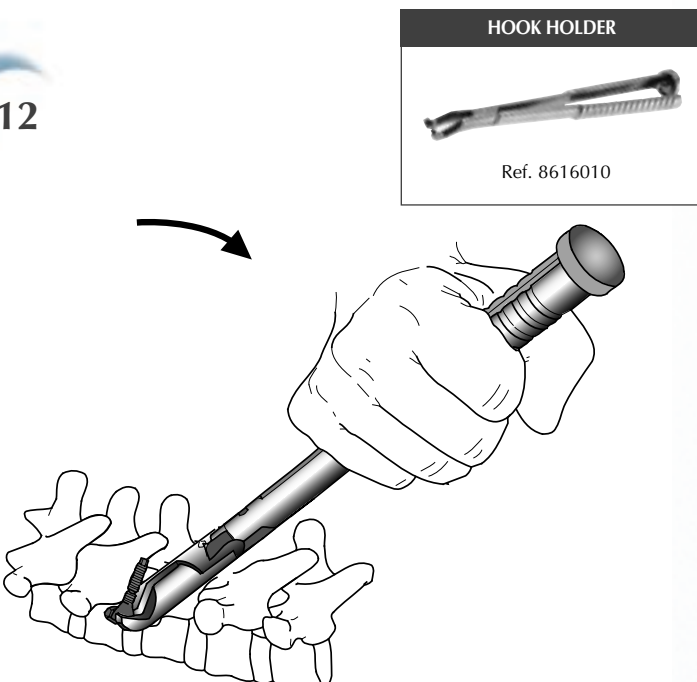
11



For correct positioning of the pedicular hook in the horizontal plane, there should be a partial resection of the transverse process and of the lamina of the vertebra below with a rongeur.

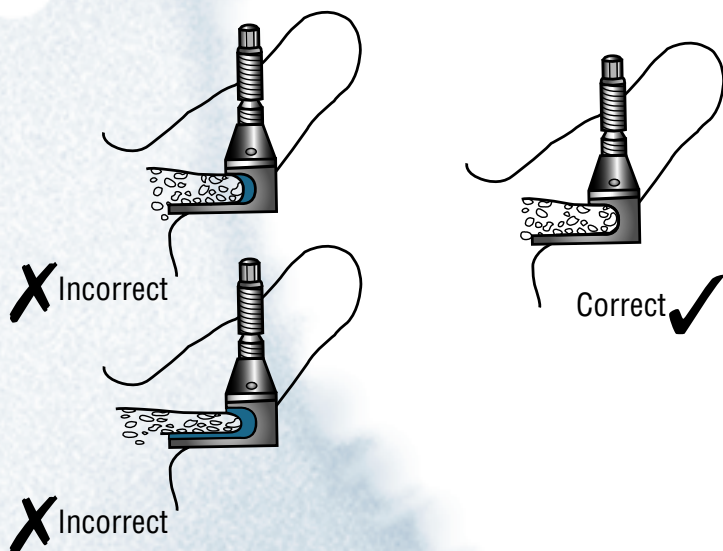
This way the pedicular hook can be inserted within the two articular facets, in optimal conditions.

12



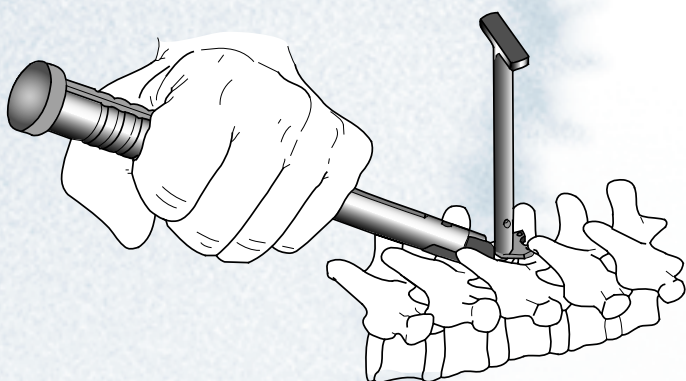
The pedicular hook is inserted under the facet and impacted. The two sizes of pedicular hooks are designed to match the thickness of the lamina.

13



Correct sizing of the pedicular hook has to be checked. If the stability of the pedicular hook is not sufficient, it is recommended to use the smaller size. Using the large hook first allows the option to change to the small pedicular hook and increase the stability. A stable position of the pedicular hook is necessary to get optimal setting of the pedicular staple.

14



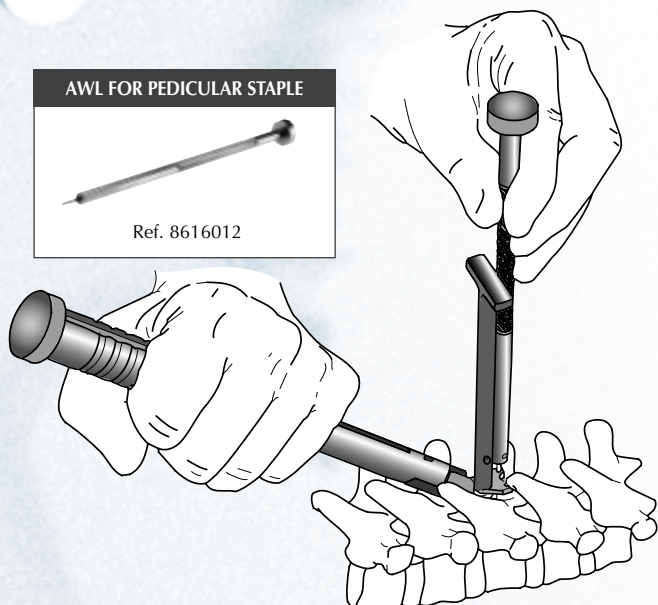
## STAPLE PLACEMENT

The pedicular hook can be stabilized by a locking staple that attaches to the inferior facet which gives an excellent fixation to the vertebra.

A template is used to target the two upper points of the staple into the lamina. The hook is maintained in position during this step by the hook holder.

The internal hexagon of the template fits on the end post of the hooks. This helps to avoid rotation of the template.

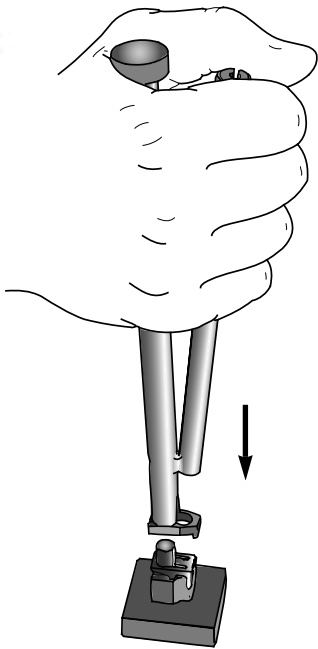
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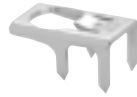
Holes are made with a depth-limiting awl. The mallet is used to drive the awl into the bone, until contact with the template.

It is important to note that no matter which size of pedicular hook is used, at no time is the point of the awl able to go beyond the blade of the hook.

16



SUPPORT FOR PEDICULAR STAPLE



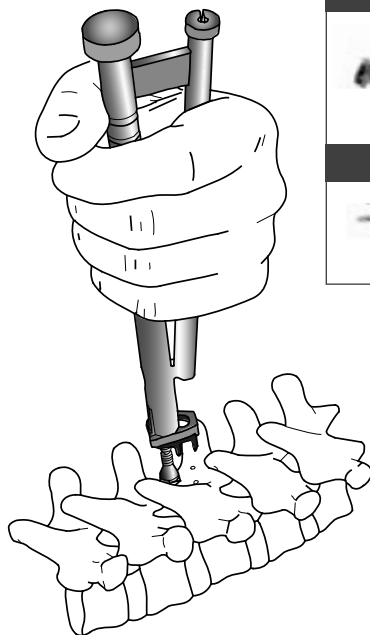
Ref. 8611300



Ref. 8616018

After removal of the hook holder the staple is mounted on the impactor using the staple support.

17



STAPLE IMPACTOR



Ref. 8616013

TONGUE IMPACTOR



Ref. 8616013

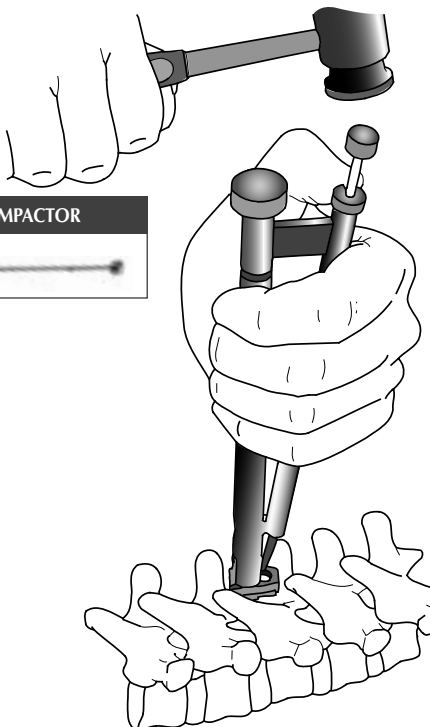
The impactor must be aligned with the threaded end post.

The two superior prongs of the staple have to be introduced into the prepared sites first.

The staple, on the instrument, is impacted into the lamina until it is firmly seated.

18

TONGUE IMPACTOR

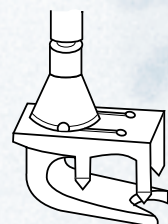


The tongue impactor is then introduced, locking the staple into place by impacting the tongue UP TO THE STOP.

Only one type of staple is used for both sizes of pedicular hooks. It is important to note that no matter which size of pedicular hook is used, at no time are the prongs of the staple able to go beyond the blade of the hook.



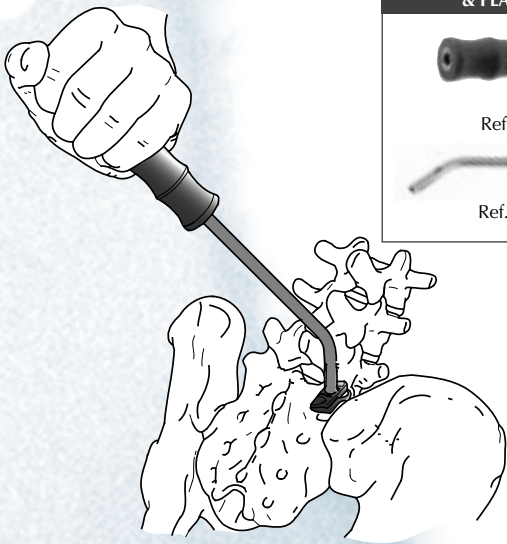
Before locking



Locked



19

DUAL PURPOSE HANDLE  
& PLATE HOLDER

Ref. 8616015



Ref. 8616007

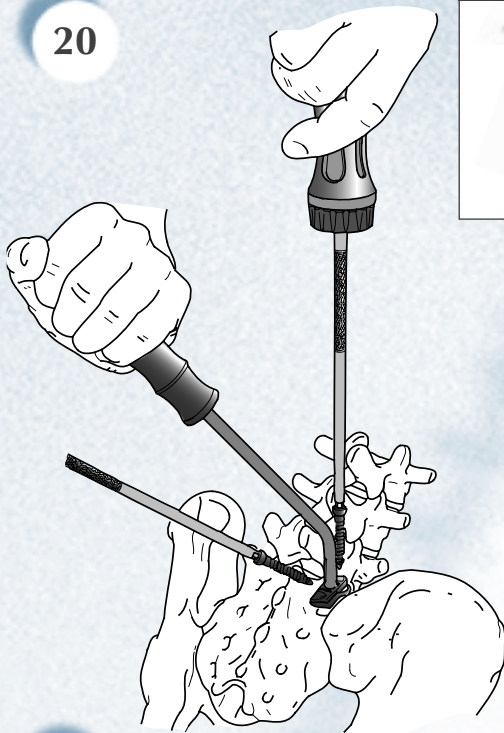
## SACRAL FIXATION

When a very stable sacral fixation is required, the use of a sacral plate with two screws is recommended instead of a single pedicular screw.

After resection of the inferior facet of L5, the S1 pedicles are targeted and prepared as close as possible to the sacral plateau. Preparation of the pedicle should be slightly convergent (5 - 10 degrees).

An anatomically designed sacral plate is positioned with the plate holder.

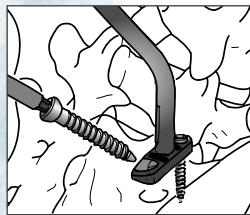
20

SCREWDRIVER SHAFT FOR  
SACRAL & ILIAC SCREWS

Ref. 8616006



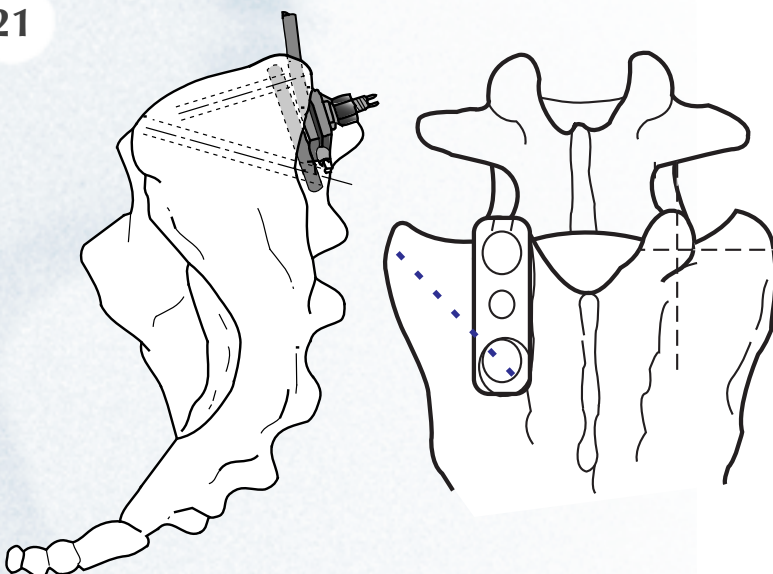
Ref. 8616014



The S1 screw is placed first, but not completely tightened to prevent plate tilting.

The second screw is placed cephalad and angled laterally. Then final tightening of both screws is completed.

21



The triangulation of the screws provides optimal pullout resistance. The first screw is inserted into the cortical bone of the promontory. The second cephalad screw should be placed with bi-cortical fixation, to increase its anchorage. Careful preparation is mandatory in order to respect the anterior structures.

22



#### SACROILIAC PLATE & ILIAC SCREW



Left: Ref. 8619280  
Right: Ref. 8619210



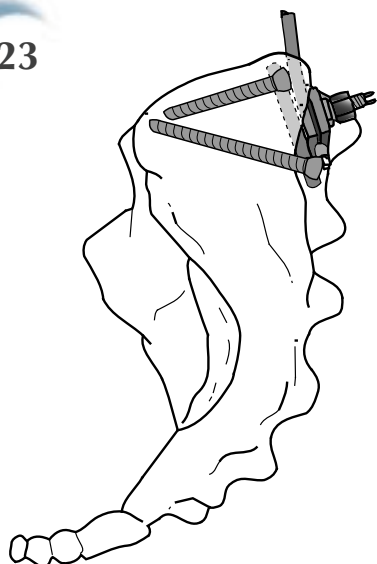
## SACROILIAC FIXATION

To improve the anchorage in case of pelvic obliquity or revision, the use of the sacroiliac plate is recommended.

Identical positioning of both sacral screws is applied. The third iliac screw is placed within the two iliac cortices using the same screwdriver shaft as the sacral screws.

In many cases a notch must be made with a rongeur in the posterior iliac wing to insert the extension of the sacroiliac plate.

23



#### LOCKING SCREW



Ref. 8619300

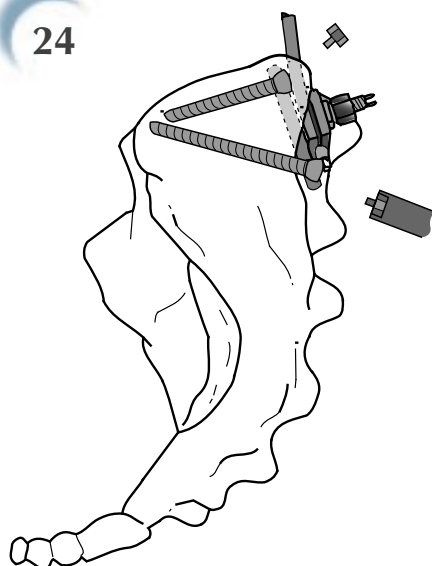
## LOCKING SCREWS

Break off locking screws can be added to help secure the sacral screws.

To tighten them, the nut and screwdriver shaft (8616021) and handle (8616014) or the dual purpose nut driver (8616001) are used.



24



#### NUT BREAKING WRENCH

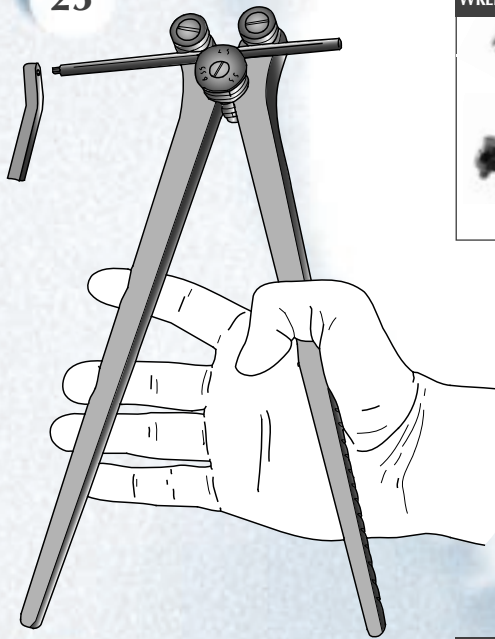


Ref. 8616002



Final break off is done using the nut breaking wrench, retaining the break off part.

25



## WRENCH FOR ROD &amp; FRENCH BENDER

Ref. 8616025



Ref. 94625H

## ROD BENDING

A large choice of rod lengths is available and all the rods have a hexagonal end to facilitate movements of the rod. This hexagonal end must be 5mm beyond the edge of the last clamp. Marked lines along the rod ensure orientation for bending in a given plane. Rods are bent according to the desired sagittal profile.

When using sacral or sacroiliac plates, rods **MUST NOT** be bent at their distal extremity for ease of insertion into the closed connector.

26

## CLAMP



Ref. 8614100

## ROD CONNECTION

Clamps are slid onto the rod (Figure 1) and connected to the threaded post.

Clamps can also be loaded into place by nut tightening after the rod has been positioned. (Figure 2).

The rod may be placed laterally or medially to the fixation points. The connection to the implants is easy to perform due to the 34° of freedom along the post and 360° around it in the coronal plane.

It is recommended to start the rod connection from top to the bottom. For some cases, the distal connection can be done with the help of the counter torque using the elasticity of the rod.

FIGURE 1

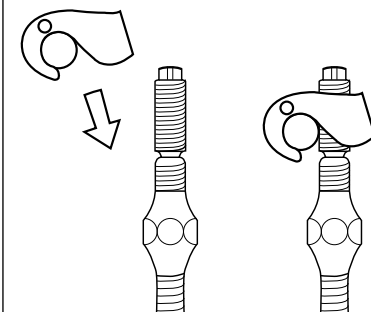
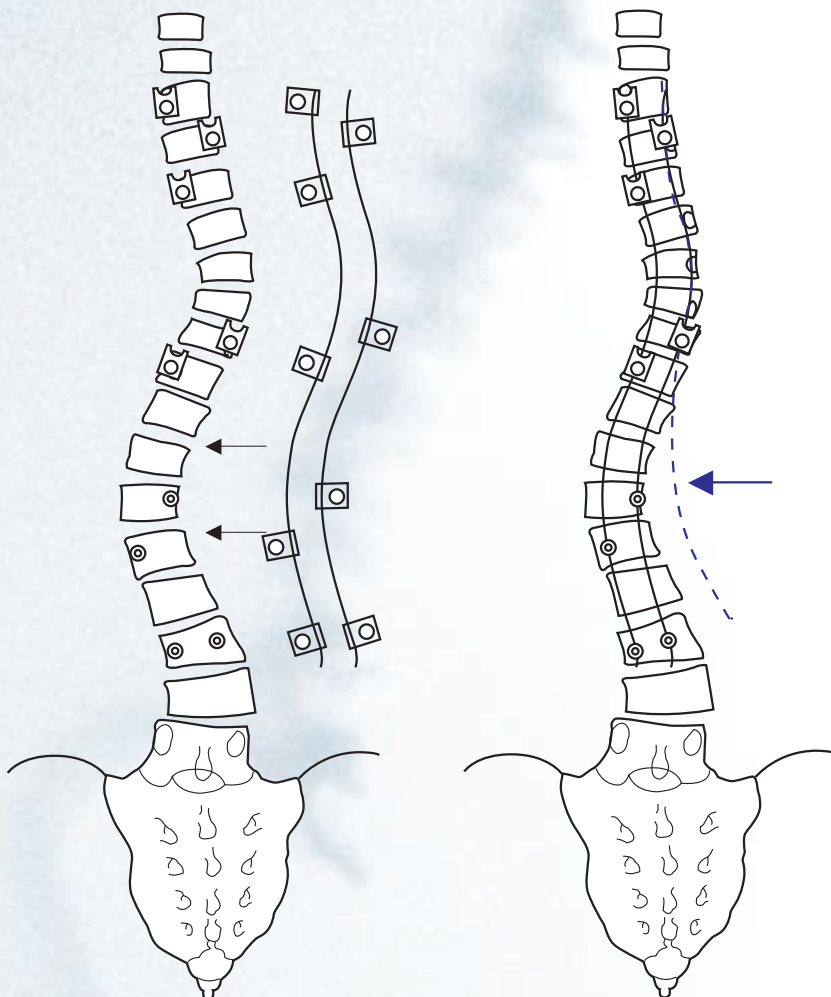
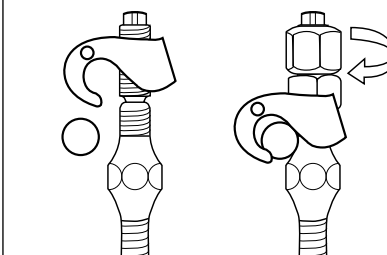
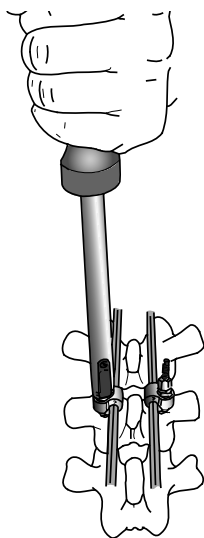


FIGURE 2





27



## DUAL PURPOSE NUT DRIVER



Ref. 8616001

## PROVISIONAL NUT TIGHTENING

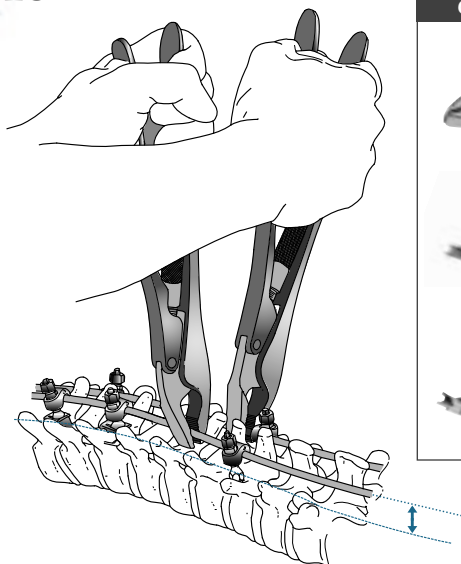
The nuts are lightly tightened using the dual purpose nut driver.

The nut is loaded, hex first, in the dual purpose nut driver. (Figure 1).

FIGURE 1



28

ROD GRIPPER,  
COMPRESSOR & SPREADER

Rod gripper Ref 84642



Compressor Ref 94632



Spreader Ref 94633

## ROD POSITIONING

In scoliosis correction, the sagittal positioning of both rods is performed first. The rods are at a variable distance from the spine. Gently adjusting the rods allows each of the segments to find its natural position in the frontal plane.

## Stage 1:

The rods are still at a distance from the spine, because of the long threaded posts on each implant.

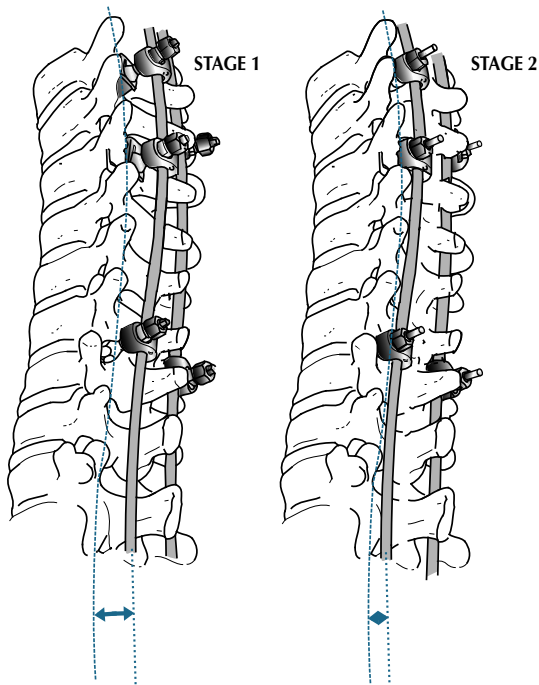
The implants are not yet perpendicular to the rods.

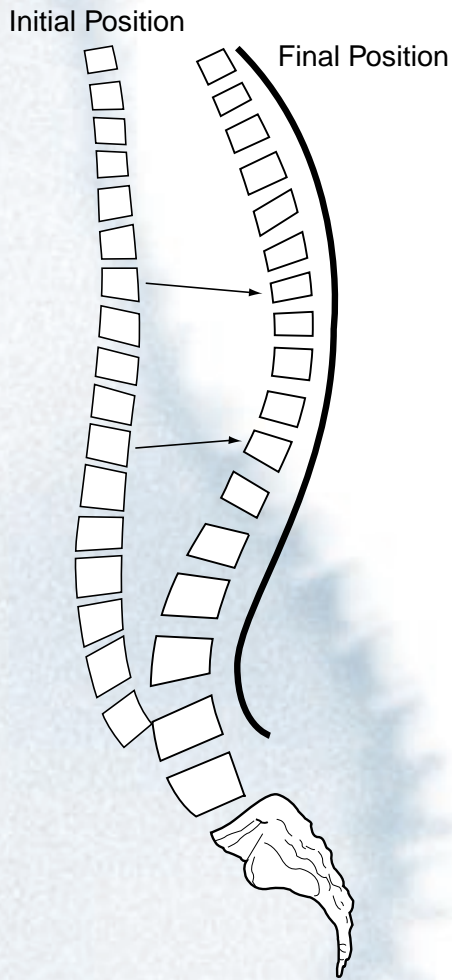
## Stage 2:

Progressive tightening of the nuts on the threaded posts approximates the spine to the rods with the possibility to work alternatively from one point to the other. During this maneuver, the nuts can be partially tightened in any sequence, allowing the spine to move gently into its final position.

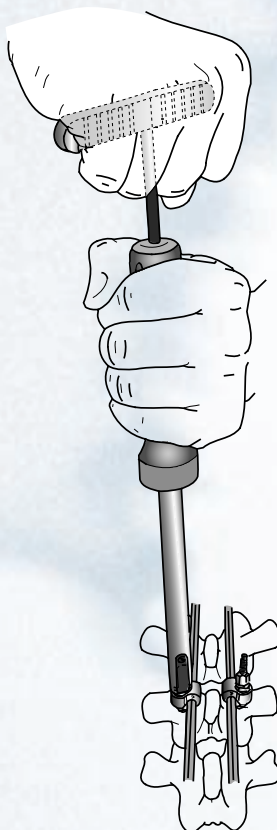
The implants are now perpendicular to the rods and the vertebrae have been corrected in 3 dimensions.

29





Tightening of the nuts on the threaded posts brings the spine to the rod, producing appropriate sagittal contouring.



T-HANDLE & NUT DRIVER



Ref. 8616001

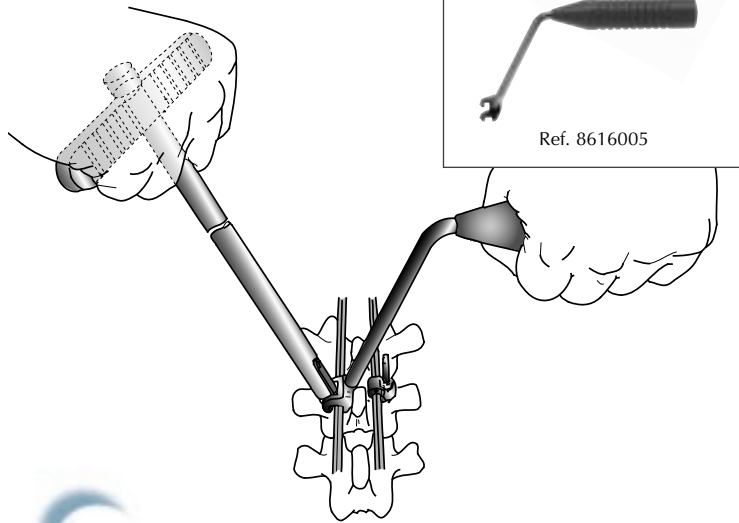
## FINAL NUT LOCKING

The T-handle stabilizes the implants by blocking the small hexagon of the threaded post. The final tightening of the nut achieves reduction of the spine deformity toward the pre-bent rod, resulting in the best compromise in 3D correction with regard to the stiffness of the deformity.

The implants are now perpendicular to the rod.

It is imperative to have complete contact between the clamp and the rod. It is recommended to check the clamp to rod interface. If required, untighten the nut to allow the possibility to reposition the clamp with the help of the implant holder (8616009) or the rod gripper (84642).

32

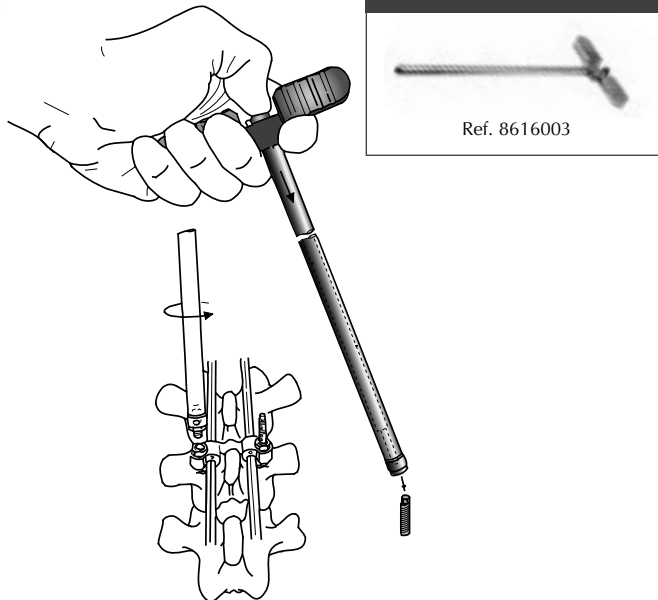


## NUT BREAKAGE

Final locking of the system is performed by using the break-off nut, this provides an excellent locking method to achieve appropriate torque tightening. As soon as the nuts are secured, they are broken off with the nut breaking wrench. A counter torque prevents forces from being transferred to the rod.

The breaking wrench retains the hexagonal parts of the nut inside its tube. The pieces can be released by unscrewing the blue cap on the handle and emptying the shaft.

33



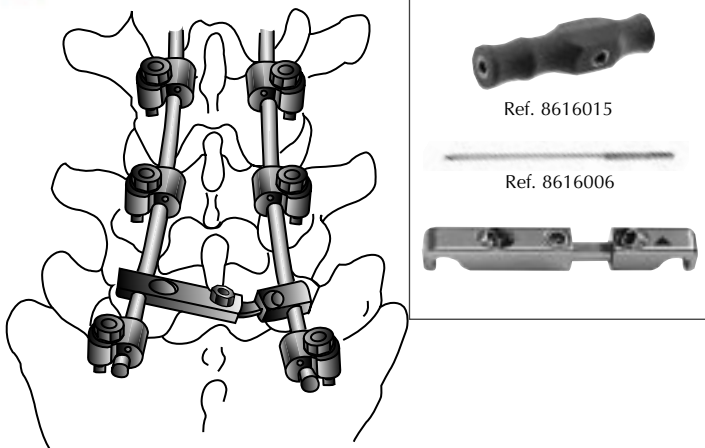
## THREADED END BREAKAGE

The threaded posts are then broken off on each implant by using the threaded end breaker. This is connected to the small hexagonal head and turned in a counter-clockwise direction.

The broken portion is held within the tube of the instrument. It is ejected by pressing the button on top of the handle.

The implant has a very low profile, after both the nuts and threaded ends are broken off.

34



## LOW PROFILE CROSSLINK®

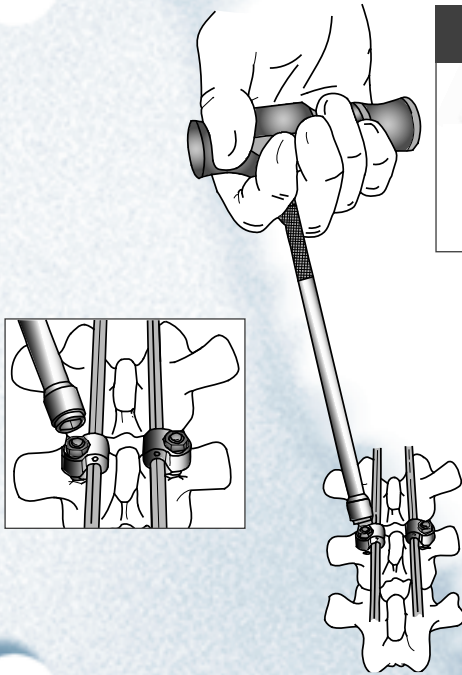
At this point in the procedure a fixed or adjustable Low Profile Crosslink can be added.

Following the final locking of the construct, the appropriate size of Low Profile Crosslink is determined. Rods may be distracted or compressed if necessary.

The LPC is connected to the rods by tightening the lock-nuts using the screwdriver shaft and the dual-purpose T-handle.



35



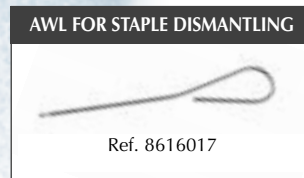
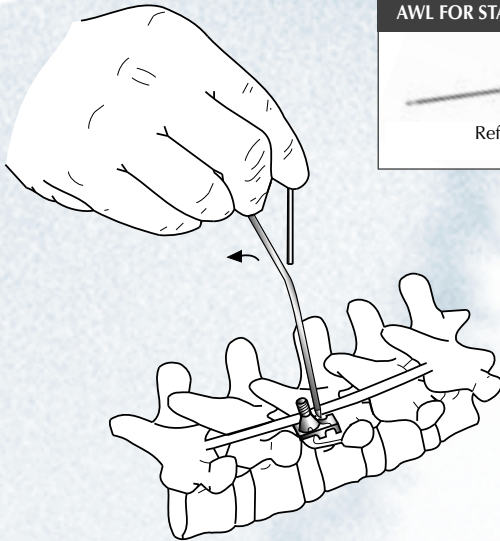
## REVISION

To revise the locking nuts, the dismantling shaft **MUST** be used.

Use the same procedure for removal of the locking screw of the closed laminar hook.

Implants cannot be re-used after revision.

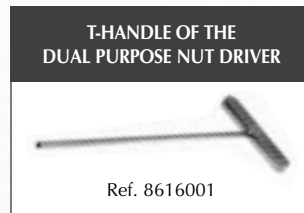
36



To unlock the pedicular staple, it is recommended to use the dismantling awl. The awl has to be inserted in one of the grooves laterally to the tongue and levered down in order to eject the tongue.

The staple cannot be re-used after removal.

37



## REMOVAL OF SACRAL LOCKING SCREW

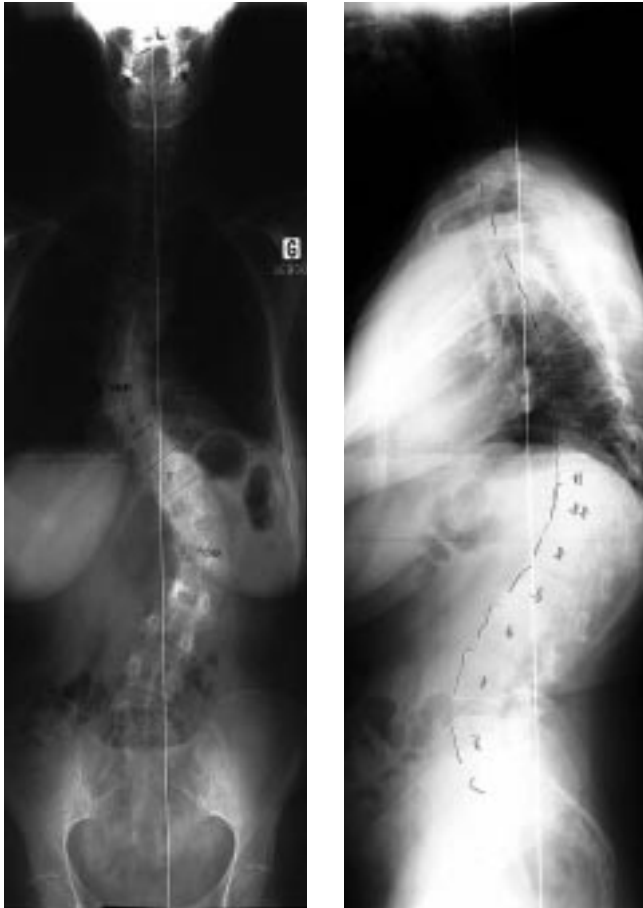
To untighten the sacral screws it is necessary to remove the small locking screws first.

For that, use the T-handle instrument which adapts to the small hexagon of the locking screw.

## CLINICAL CASE - DEFORMITY

### Idiopathic Scoliosis

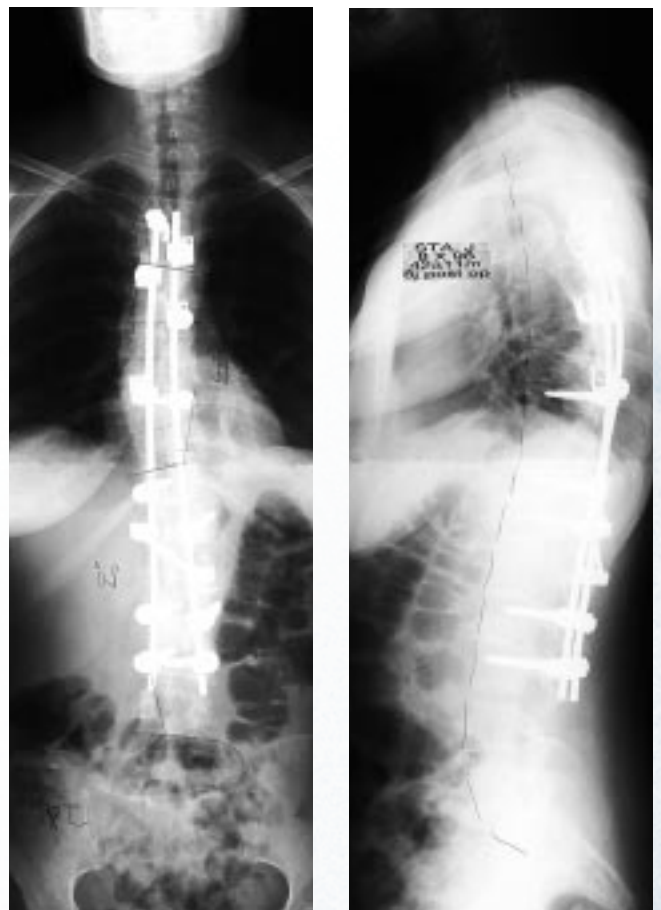
A 43-year-old patient with idiopathic kypho-thoracolumbar scoliosis ( $65^\circ$ ) and compensatory structural thoracic curve ( $45^\circ$ ).



Pain plus angular progression at the thoracolumbar level (from  $56^\circ$  in 1993 to  $65^\circ$  in 1998) with increasing thoracolumbar kyphosis and rotatory dislocation at L2-L3.

**Phase one :** anterior discectomy from T10 to L3 and grafting without instrumentation

**Phase two :** posterior COLORADO 2™ from T4 to L3



**Note:** Horizontal repositioning of the lowest vertebra of the construct and restoration of the sagittal profile.

## CLINICAL CASE - DEGENERATIVE

### Displasic spondylolisthesis

A 15-year-old female patient with displasic spondylolisthesis L5-S1 grade IV



L4-S1 COLORADO 2™ osteosynthesis with posterolateral grafting. Total reduction of the slipping and rotation of L5. Noticeable improvement of the sagittal profile.



## CLINICAL CASE - TRAUMA

### Trauma

A 48-year-old patient.

L1 Burst fracture due to a fall.

Surgery in emergency.

Patient positioned on orthopaedic table in traction position.



Use of a construct T11 to L2.

Placement of T11, T12, and L2 pedicular screws plus sub-laminar hooks to protect L2 screws.

Rods and pre-loaded clamps are connected to the anchorage points. The corrective effect of the clamp achieves the reduction of the kyphosis.

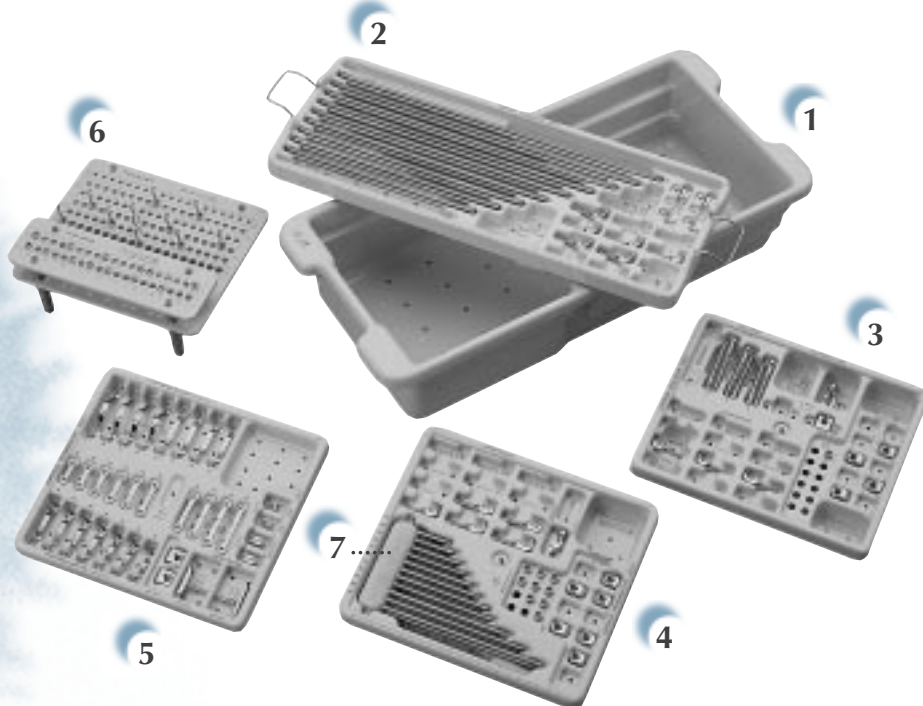
Immediate weight bearing is permitted.

Rods are placed medially to the threaded posts to facilitate the positioning of the sub-laminar hooks.

*Colorado* <sup>2</sup>™  
THE NEW REV

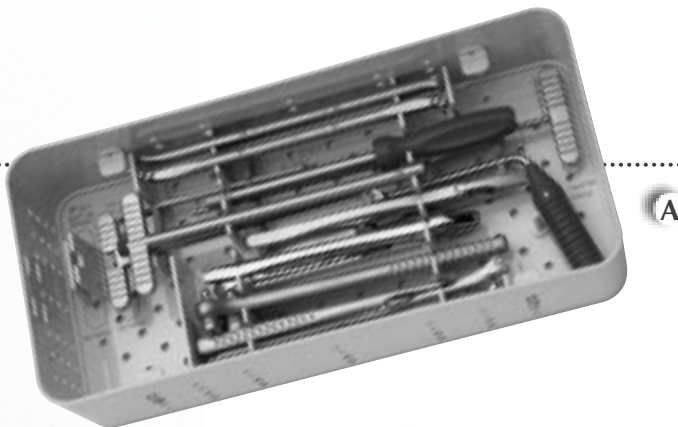
## IMPLANTS SET

- |                |  |          |
|----------------|--|----------|
| <b>8617110</b> | Implants base                                      | <b>1</b> |
| <b>8617115</b> | Lid for implants base<br>8617110 (not illustrated) |          |
| <b>8617120</b> | Inferior scoliosis tray<br>and its lid             | <b>2</b> |
| <b>8617125</b> | Superior scoliosis tray<br>and its lid             | <b>3</b> |
| <b>8617130</b> | Inferior degenerative<br>tray and its lid          | <b>4</b> |
| <b>8617135</b> | Superior degenerative<br>tray and its lid          | <b>5</b> |
| <b>8617140</b> | Screw rack   | <b>6</b> |
| <b>8617145</b> | Support for rods                                   | <b>7</b> |

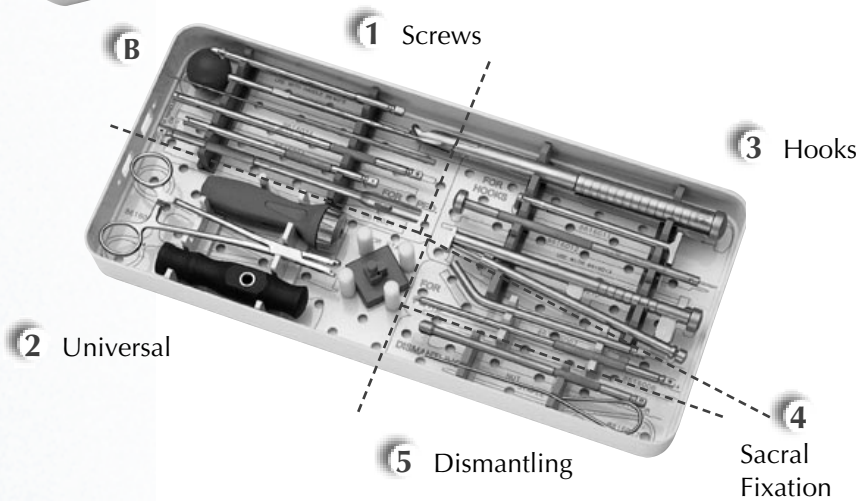


## INSTRUMENTS SET

- 8617150** Instruments base **(A)**
- 8617160** Instruments tray **(B)**
- 8617170** Lid for instruments base (not illustrated)



- Pedicular Screws 1
- Universal 2
- Hooks 3
- Sacral Fixation 4
- Dismantling 5







## PURPOSE

The COLORADO 2™ 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 COLORADO 2™ Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors, and connecting components. COLORADO 2™ implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. COLORADO 2™ Spinal System implant components are fabricated from medical grade stainless steel described by such standards as ASTM F138 or ISO 5832-1 or ISO 5832-9. Alternatively, the entire system may be made out of medical grade titanium or titanium alloy described by such standards as ASTM F67 or ASTM F136 or ISO 5832-3 or 5832-2.

The titanium version of the COLORADO 2™ Spinal System is used in conjunction with GDLH® f5.5 rods, TSRH® Spinal System rods and TENOR® Spinal System rods.

Never use stainless steel and titanium implant components in the same construct.

Medtronic Sofamor Danek expressly warrants that these devices are fabricated from 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.

To achieve best results, do not use any of the COLORADO 2™ Spinal System implant components with components from any other system. As with all orthopaedic and neurosurgical implants, none of the COLORADO 2™ Spinal System components should ever be reused under any circumstances.

## INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EVENTS:

### Indications:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the COLORADO 2™ Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the COLORADO 2™ Spinal System is 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 (4) 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 COLORADO 2™ 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 as an anterolateral thoracic/lumbar system, the COLORADO 2™ 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.

### 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 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. Osteoporosis or osteopenia is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
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. Screws with a 4.5mm diameter thread are limited to use in the thoracic spine.
18. Any case not described in the indications.

## POTENTIAL ADVERSE EVENTS

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis, and/or pain. Bursitis. 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, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
8. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
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 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 bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
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, 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 mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown.

**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 results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

**PHYSICIAN NOTE:** Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document must 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.

## 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 component. 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 COLORADO 20 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. The instructions given in the surgical technique, if available, should be followed.
2. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. 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, pre-cut rods of the length needed.
5. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
6. To insert a screw properly, a guide wire should first be used, followed by a sharp tap. Caution: Do not overlap 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. If screws are being inserted into spinal pedicles, use as large a screw 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 on two bilaterally placed, continuous rods should be used whenever possible.
9. 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.
10. Before closing the soft tissues, all of the nuts or screws should be tightened firmly. Recheck the tightness of all nuts or screws after finishing to make sure that none loosened during the tightening of the other nuts or screws. Failure to do so may cause loosening of the other components.

## POSTOPERATIVE:

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

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of 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 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-steroidals or 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 taught to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.



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

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and disinfecting of instruments can be performed with alkali aldehyde-free solvents at higher temperatures.

Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

Also, certain instruments may require dismantling before cleaning.

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

#### STERILIZATION:

Unless marked sterile and clearly labeled as such, the COLORADO 2™ Spinal System components described in this insert are provided non-sterile and must be sterilized prior to use.

If the Medtronic Sofamor Danek components described in this insert are sterilized by the hospital in a tray or case, they should be sterilized in the tray or case provided by Medtronic Sofamor Danek. These products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

NOTE: The following note applies to the process parameter identified with the \*\* below: For use of this product and instruments 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.

#### METHOD CYCLE TEMPERATURE EXPOSURE TIME

Steam Gravity 250° F (121° C) 30 Minutes

Steam Gravity 273°F (134°C) 20 Minutes\*\*

Steam Pre-Vacuum 270° F (132° C) 4 Minutes

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

#### PRODUCT COMPLAINTS:

Any Health Care Professional (e.g. 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 at the addresses below. Further, if any of the implanted COLORADO 2™ 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, 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 INFORMATION:

If further directions for use of this system are needed, please check with Medtronic Sofamor Danek Customer Service. If further information is needed or required, please contact:

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**CE 0123**

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