Medtronic
SOFAMOR DANEK

ZEPHIR™ Anterior Cervical Plate System
Surgical Technique

as described by:

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New York, New York

INTRODUCTION

Dear Fellow Colleague:

Anterior cervical plating has become widely accepted when anterior spinal fusion surgery is performed. Through our surgical experience over the past years, we have found the need for a simple to use, low profile plate, which maintains the existing standards of strength for anterior cervical fixation.

The ZEPHIR Anterior Cervical Plate System, developed in Lille, France, represents an advance in cervical plate fixation. For the surgeon, the ZEPHIR System's minimized height and narrow transverse width enhance visualization and plate manipulation for precise plate placement while reducing the amount of traction on the trachea and esophagus. The rotating drill guides, self-tapping screws and integrated antimigration cap simplify plate fixation and reduce operative time. Finally, the flexibility of the ZEPHIR System through variable angulation of screw trajectory, multiple screw lengths and revision screws allows the surgeon to individually tailor the construct to each patient's anatomy. We believe that these design features make implanting the ZEPHIR System plate a nearly seamless component of the anterior cervical decompression and stabilization procedure.

The ZEPHIR System has been tested following the ASTM testing standards and was found to perform equal to or better than other clinically available systems. Prior to its launch, the ZEPHIR System was used worldwide by a group of surgeons to enhance the instrumentation and the implants and to measure its clinical efficacy.

The following monograph describes the ZEPHIR System as well as some of our personal thoughts reflecting our current operative techniques.

Sincerely,

Richard Assaker, M.D.
Lille University Hospital
Lille, France

Paul McCormick, M.D.
Columbia Presbyterian Hospital
New York, New York

PATIENT POSITIONING/ANTERIOR APPROACH

The patient is placed in the supine position with the head in slight extension. The posterior cervical spine is supported to establish and maintain normal cervical lordosis. The surgeon must then choose a right- or left-sided approach to the cervical column.

After exposing the cervical spine, the self-retaining retractor is placed to provide optimal visualization (Figure 1). A vertebral body distractor may be used. The distraction pins are positioned midline in the vertebral bodies adjacent to the level to be treated. The distractor is placed over the pins and the appropriate amount of distraction is applied.

Pituitary forceps, curettes, and kerrisons may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament. Bone graft is then positioned between the vertebrae.

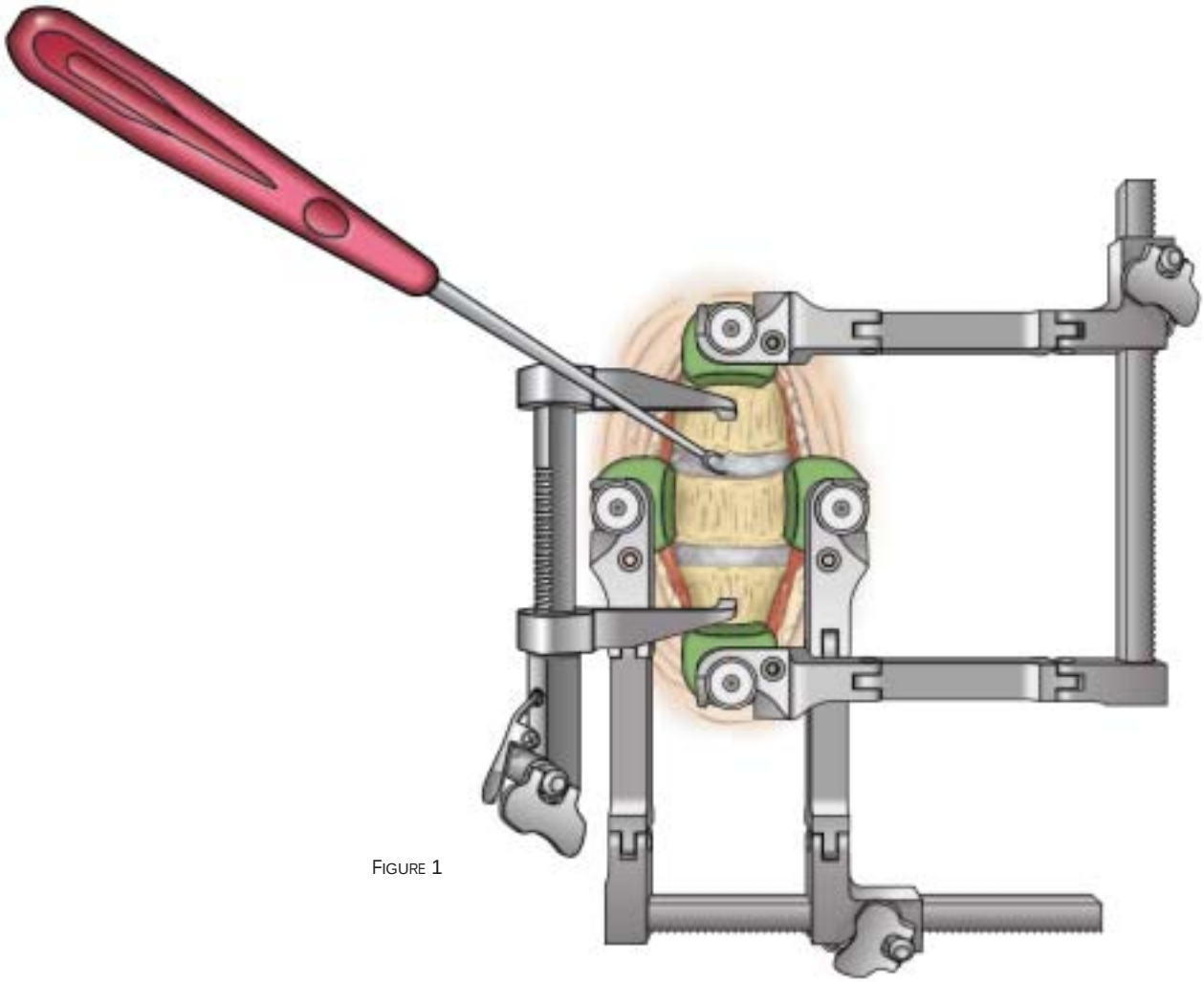


FIGURE 1

STEP 1

PLATE SELECTION & CONTOURING

Plate Selection

Anterior osteophytes are removed from the exposed vertebrae so that the plate may sit flush/evenly on the anterior cortex. The plate length should be defined according to the chosen screw length and angulation so that it does not interfere with the adjacent unfused disc spaces.

Plate Contouring

The plate is machined into a lordotic curve. However, the Plate Bender can be used to increase or decrease lordosis as necessary (Figures 2 and 3). Bending at the extremities of the plate is not recommended as it could damage the antimigration cap mechanism.

FIGURE 2

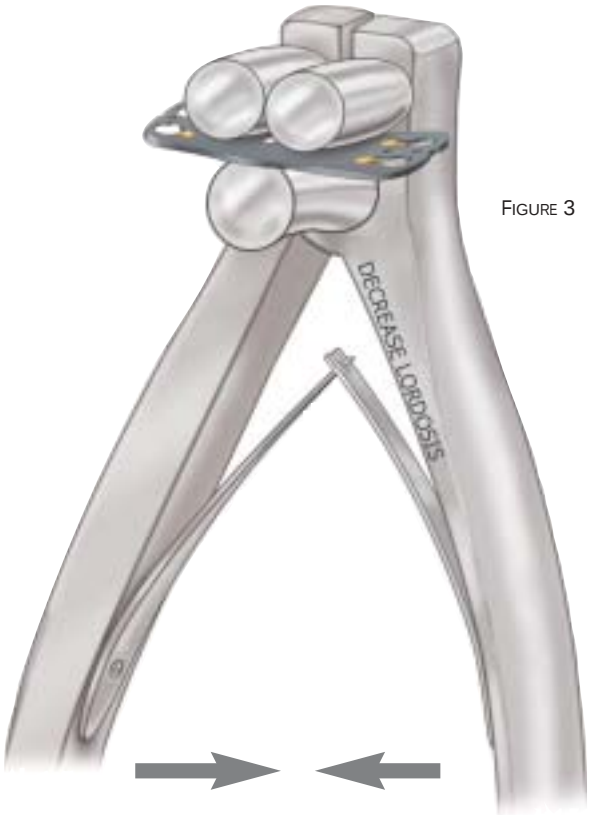


FIGURE 3

"For C2 fixation it is always necessary to contour the superior aspect of the plate. I bend the plate just caudally with respect to the antimigration cap."

–R. Assaker, M.D.

STEP 2

PLATE POSITIONING

To pick up a plate with the Plate Holder, push the button on the proximal end of the Plate Holder and insert the tip into any screw hole or central slot in the plate. Release the button to engage the plate (Figure 4).

Prefixation Pins can be used to assist positioning and to stabilize the plate in the midline prior to screw insertion. To open the jaws of the Prefixation Pin Holder, pull the flange on the shaft toward the handle. Place it over a Prefixation Pin in the sterilization case and release the flange to engage the pin. Insert the pin through one of the four small holes along the midline of the plate (Figure 5). Do not insert the pin through the bone screw holes. Slide the jaws of the instrument to the side and then lift it up to clear the pin. Next, pick up a second Prefixation Pin from the sterilization case and insert it into one of the small holes at the other end of the plate.

An alternative use for the Prefixation Pins is to assist in placing the plate along the midline. First, place the superior pin in the midline of the superior body (Figure 6). Insert the needle portion of the pin only. Next, place the notch in the end of the plate against the bulb portion of the pin. Once the plate is precisely positioned, insert the inferior pin through the plate in one of the small midline holes at the other end of the plate (Figure 7).

"Alternatively, a screw distraction post can be utilized to buttress either end of the plate."

–P. McCormick, M.D.

"Plate prefixation allows me to precisely check the positioning and the length selection of the plate."

–R. Asssaker, M.D.

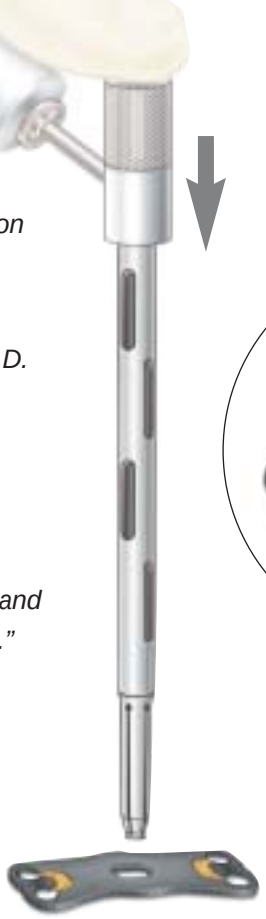


FIGURE 4

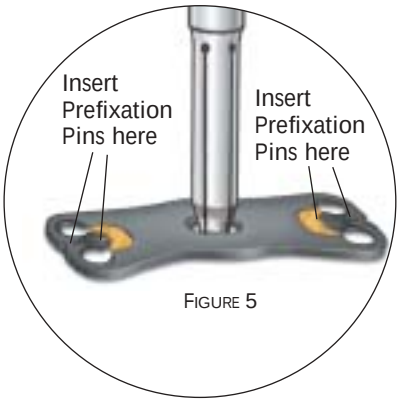


FIGURE 5

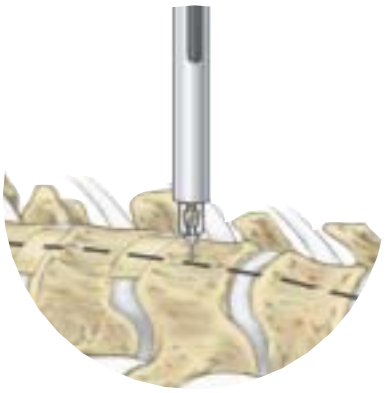


FIGURE 6

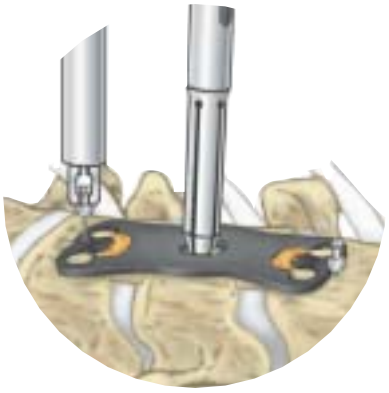


FIGURE 7

STEP 3

DRILLING

Option 1: Mono Drilling Guide

First, position the Mono Drilling Guide into the bone screw hole in the plate.

Then apply slight downward pressure until the leg support of the Drilling Guide comes into contact with the plate (Figure 8).

The Mono Drilling Guide is designed to provide a maximum of 16° of angulation during the drilling step. To achieve less angulation, pivot the guide toward the end of the plate. The range of cephalad/caudal angulation is from 0° to 16° (Figures 8a and 8b).

Loosen the nut with the Universal Handle and insert the tri-flat drill bit into the handle. Tighten the nut to securely hold the drill bit. If using power to drill, the tri-flat or the circular tip drill bit can be used. The drilling depth is fixed to 13mm, (Figure 8b) with a 0.3mm off-center drill hole for graft compression (Figure 8c), which will be achieved as the bone screw is inserted.

The handle of the Mono Drilling Guide rotates for optimal handle positioning.

"The Mono Drilling Guide is most frequently used. First, I drill two diagonally opposite screw holes and then I partially insert the screws."

–R. Assaker, M.D.

"The 180° rotation of the drill guide enhances the stability and control of drilling by allowing me to comfortably drill both superior and inferior holes with my dominant hand."

–P. McCormick, M.D.

"I prefer to angle the rostral screws 5° to 10° superiorly to optimize load sharing and permit some graft settling allowed by this semi-constrained system. I place the caudal screws perpendicular to the plate (i.e. 0° angulation)."

–P. McCormick, M.D.

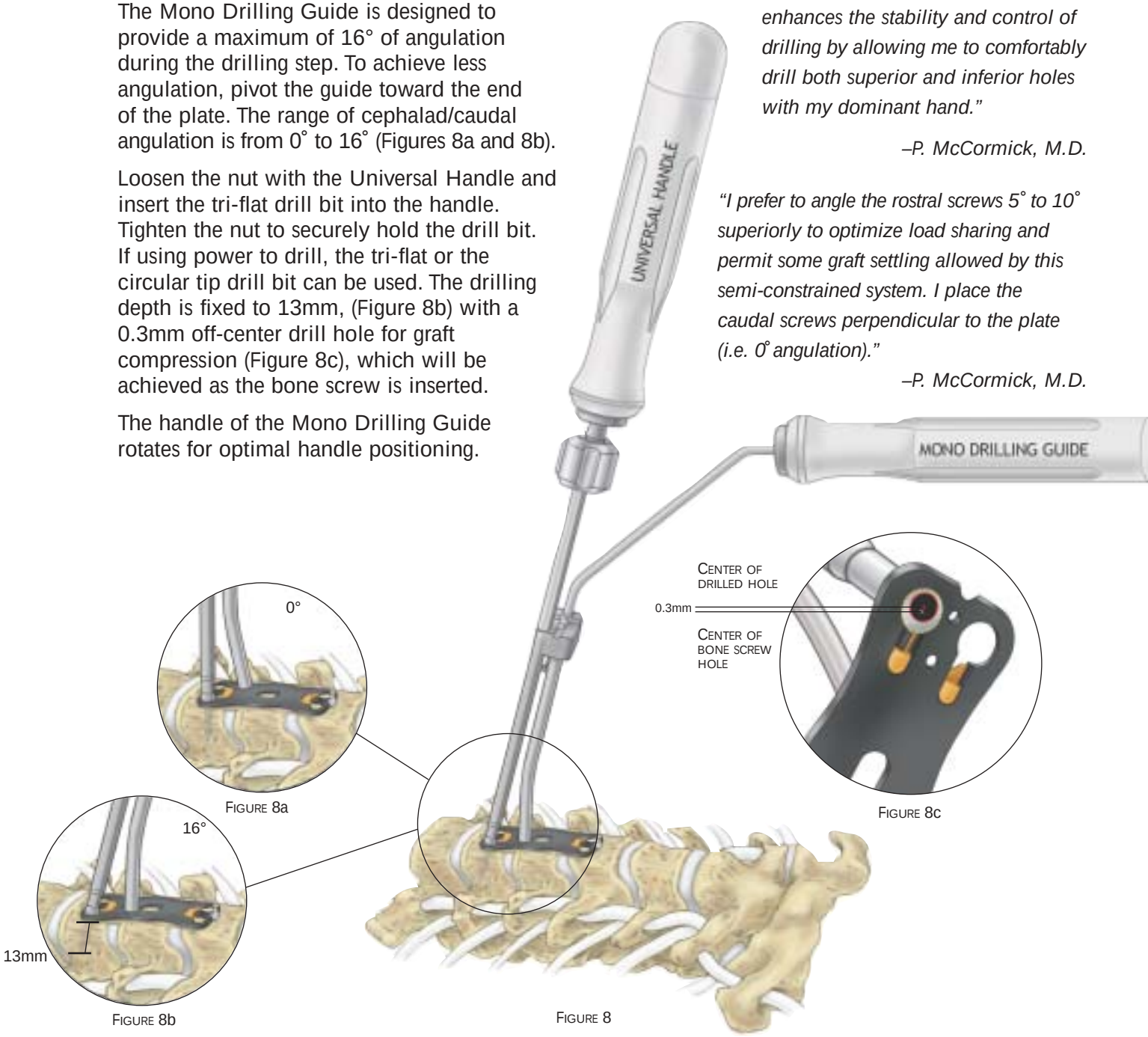


FIGURE 8a

FIGURE 8b

FIGURE 8c

FIGURE 8

ZEPHIR™ ANTERIOR CERVICAL PLATE SYSTEM

STEP 3

DRILLING

Option 2: Dual Drilling Guide

The angulation is first determined by adjusting the leg support of the Dual Drilling Guide (Figure 9). Two marks are engraved on the leg support. If the leg support's upper mark is set to the top of the platform, the drilling angulation is 0° (Figure 9a). The lower mark yields a 16° drilling angulation (Figure 9b). Angulation of the Dual Drilling Guide should not exceed 16°.

Place the double barrel of the Dual Drilling Guide into the bone screw holes of the plate and slightly lower the guide until the leg support sits on the plate. Drill both holes successively through the Drilling Guide. The drilling depth is fixed to 13mm, with an offset of 0.3mm for graft compression. (See Figure 8c, Page 5) Once the drilling is performed, remove the Drilling Guide. The handle of the Dual Drilling Guide rotates for optimal handle positioning.

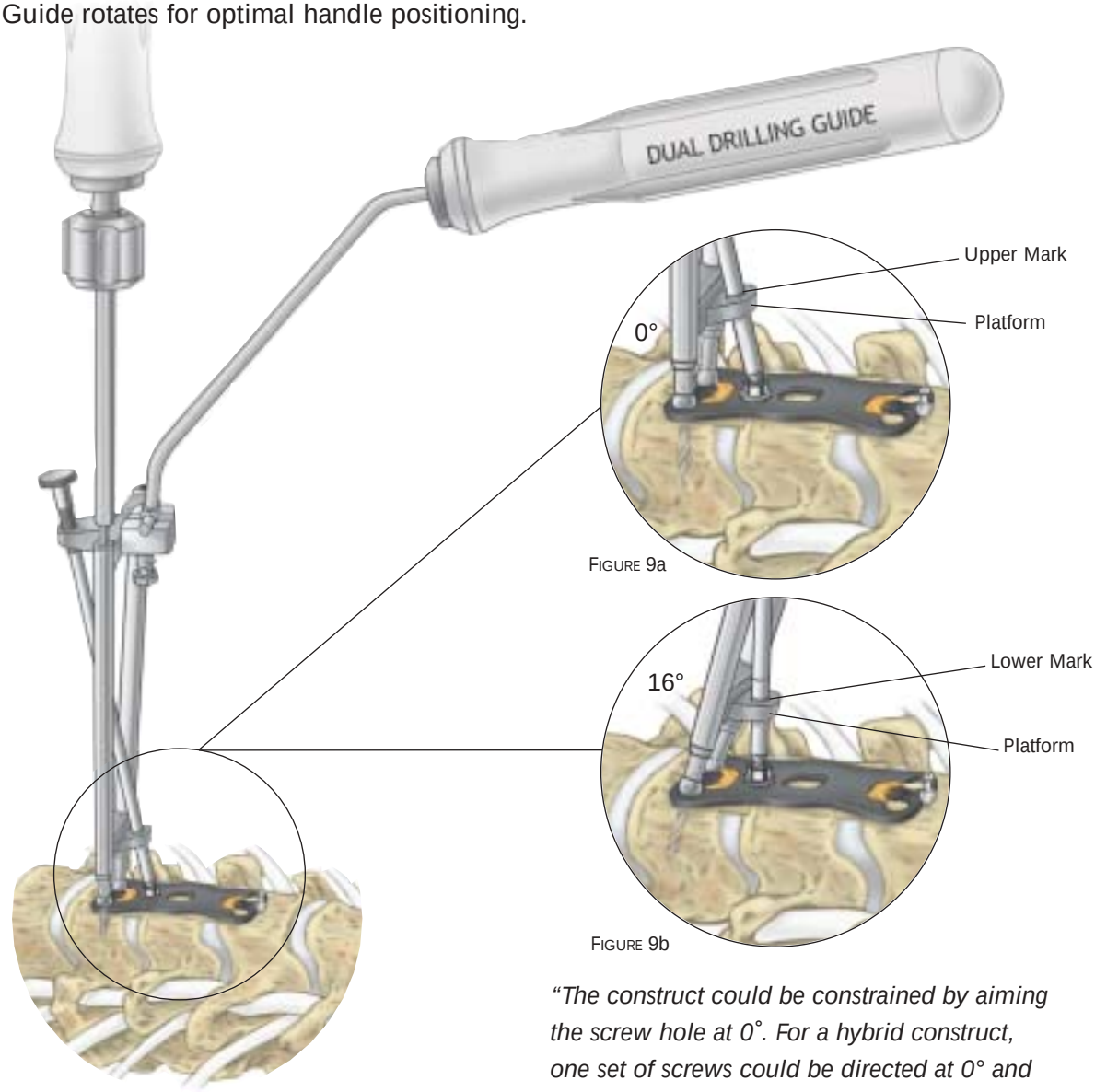


FIGURE 9a

FIGURE 9b

FIGURE 9

"The construct could be constrained by aiming the screw hole at 0˚. For a hybrid construct, one set of screws could be directed at 0° and the other set between 0° and 16°."

–R. Assaker, M.D.

STEP 4

BONE SCREW SELECTION

The standard bone screw diameter is 3.5mm and the revision/central slot bone screw diameter is 4.0mm. These bone screws are self-tapping and come in 11, 13, 15, and 17mm lengths. The Screwdriver consists of two pieces, the Sleeve and the Shaft.

Separate the Sleeve from the Shaft and use the Sleeve to pick up the appropriate diameter and length bone screw (Figure 10). Then place the Shaft through the center of the Sleeve to engage the cruciate drive in the screw (Figure 11).

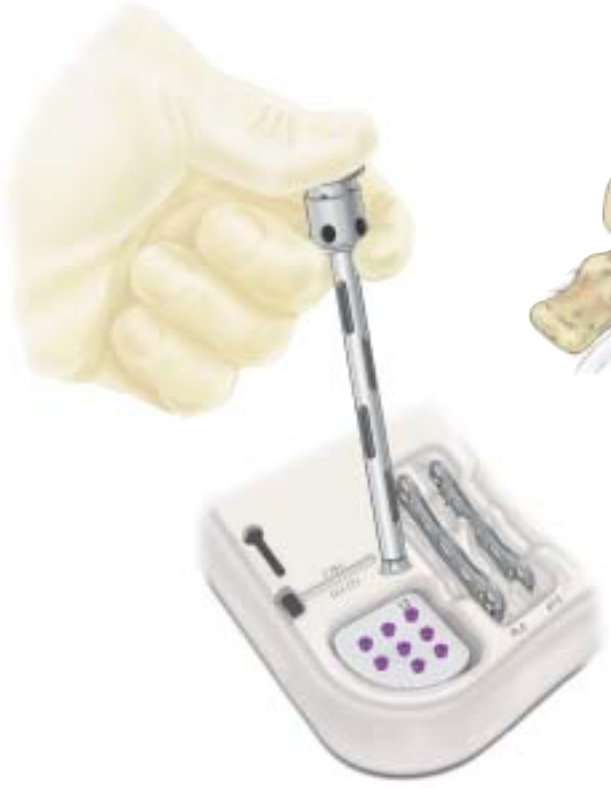


FIGURE 10

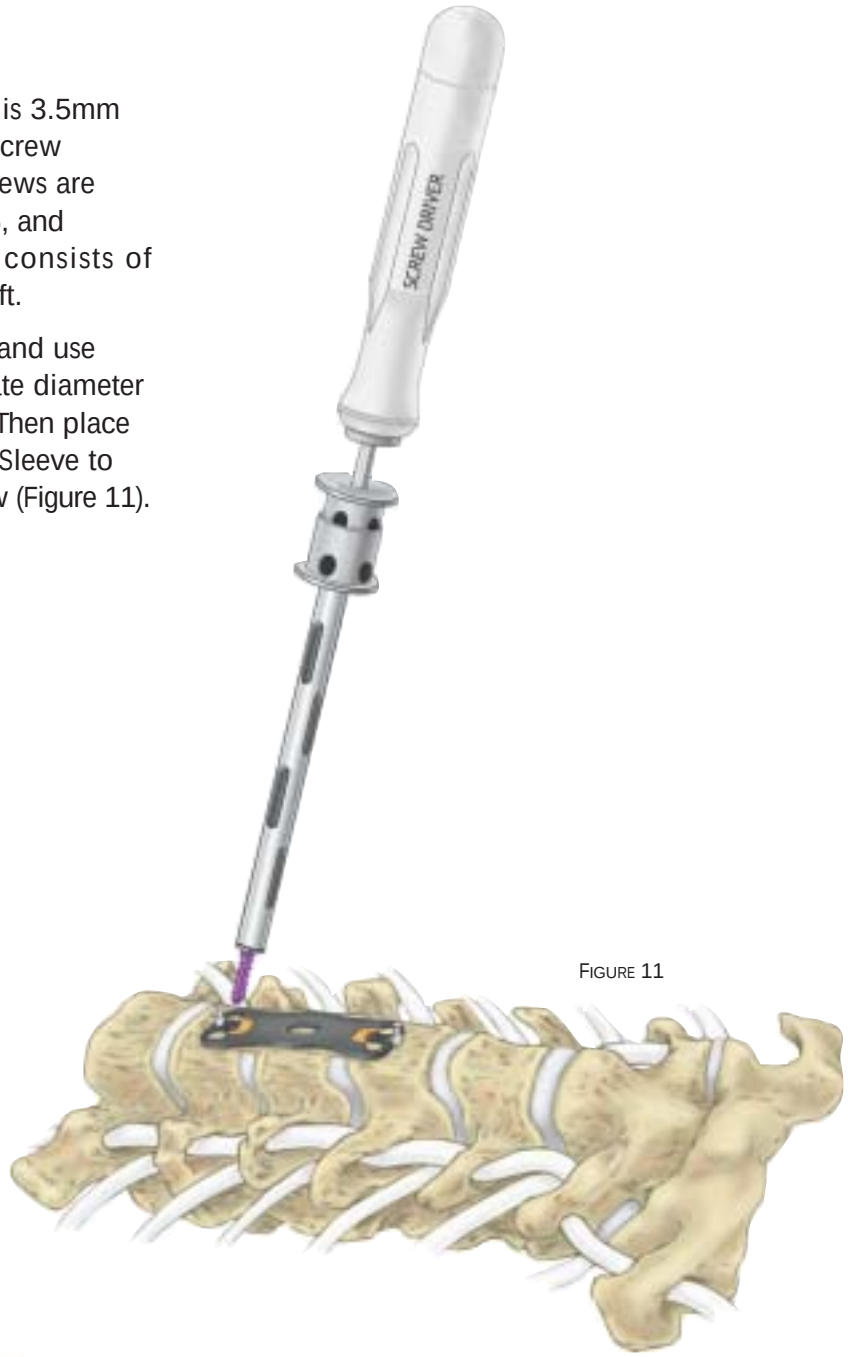


FIGURE 11

"To increase efficiency of the plate insertion, the scrub nurse loads the screws while the surgeon drills the screw holes. The surgeon's eyes do not leave the operative field at any time during plate insertion."

–P. McCormick, M.D.

STEP 5

BONE SCREW INSERTION

Partially insert two bone screws diagonally positioned in the plate (Figure 12). Remove the Prefixation Pins with the Pin Holder. Fully insert the two remaining screws (Figure 13). Complete final tightening of the first two screws.

The compression of the graft is achieved by the combination of the offset drilling (0.3mm) and the screw head interference with the plate screw holes (Figure 14). The red dot in the illustration represents the drilled hole; the black dot represents the center of the bone screw hole. The drilled holes are off center by 0.3mm per hole. As the screw heads are seated in the plate, they pull the vertebral bodies toward each other, resulting in 0.3mm of graft compression on each end of the plate, or 0.6mm of total compression.

When performing a multi-level procedure and intermediate vertebral body or graft fixation is desired, the 4.0mm diameter screws must be used in the central slot (Figure 15). These screws are designed to self-lock in the central slots via an interference between the minor diameter of the screw and the sides of the slot. It is recommended that the pilot hole be drilled perpendicular to the slot.

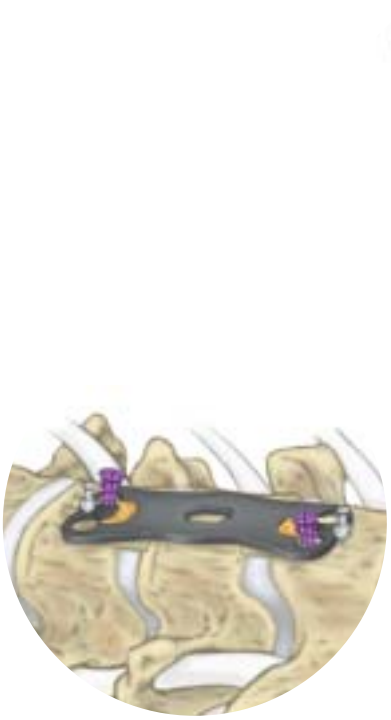


FIGURE 12

FIGURE 13

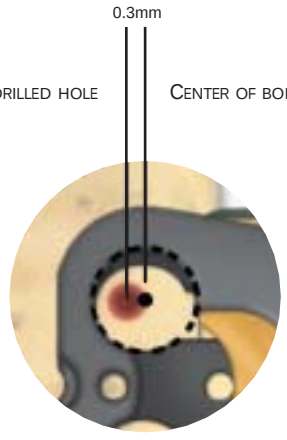


FIGURE 14

FIGURE 15

"Retraction of the Screwdriver Sleeve once the screw is firmly engaged in the bone improves visualization and facilitates final screw tightening."

–P. McCormick, M.D.

"Remove Prefixation Pins prior to final tightening of the bone screws to maximize the compression capabilities."

–R. Assaker, M.D.

STEP 6

ANTIMIGRATION CAP LOCKING

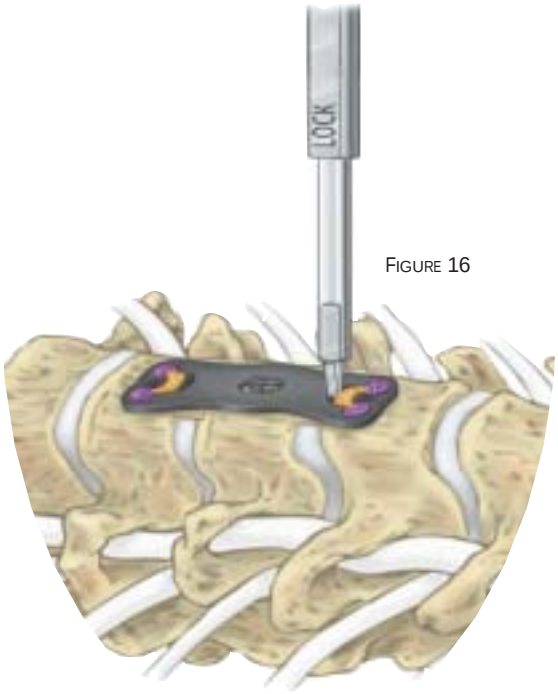


FIGURE 16

The Antimigration Cap Pusher is assembled onto the Universal Handle by inserting the "UNLOCK" tip into the handle and tightening the nut on the handle.

The translation of both antimigration caps is obtained by inserting the "LOCK" tip into the gap between the plate and the cap and giving the instrument a quarter turn (Figure 16). When properly advanced, the tips of the antimigration caps will partially cover the bone screw heads, thus preventing screw migration. The cap locks in place via a hemisphere on the undersurface of the cap that rests in the midline hole (Figure 17) when the cap is advanced. Proper seating of the screws ensures easy locking of the antimigration caps.

If unlocking is needed, place the "UNLOCK" tip between the end of the plate and the cap and give it a quarter turn (Figure 18).

FIGURE 17

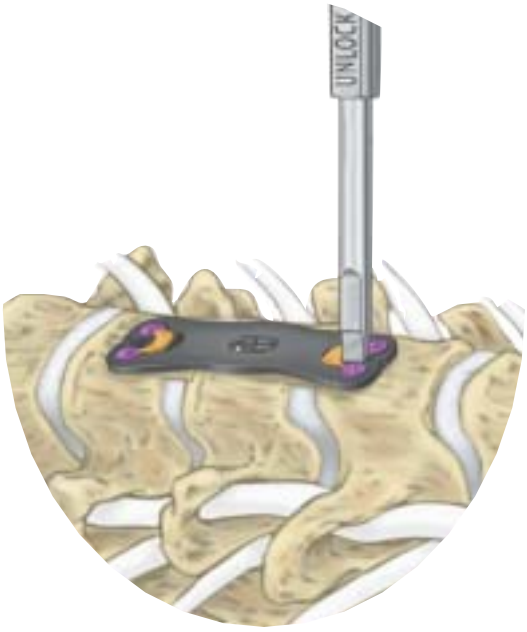
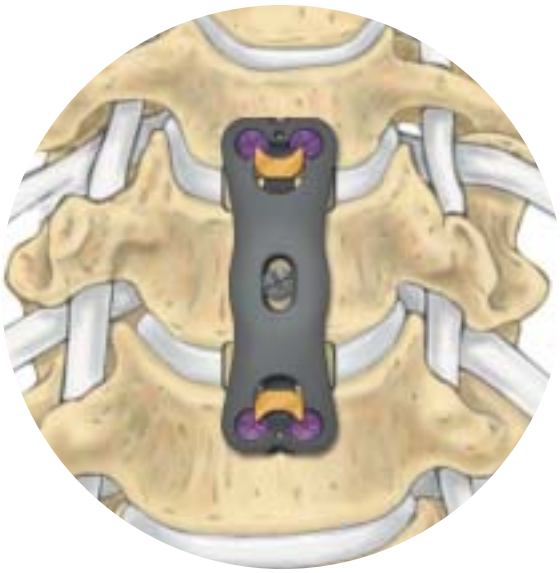


FIGURE 18

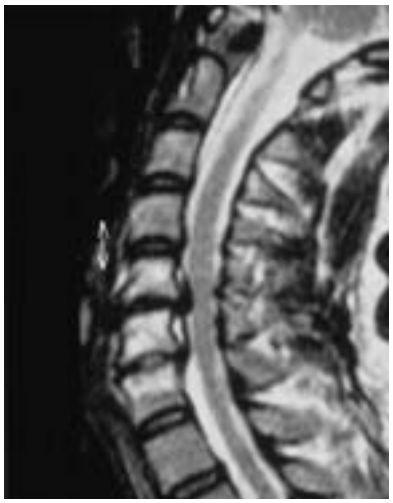


FINAL CONSTRUCT

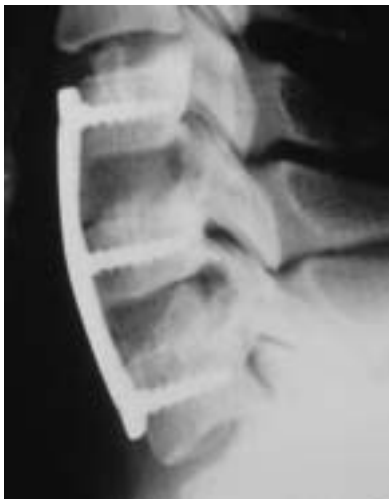
CLINICAL CASES

CASE 1

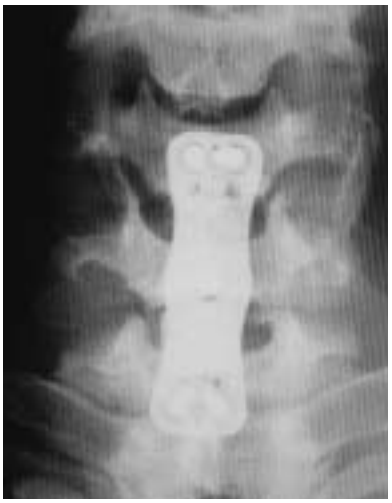
PRE-OP



POST-OP LATERAL



POST-OP A/P

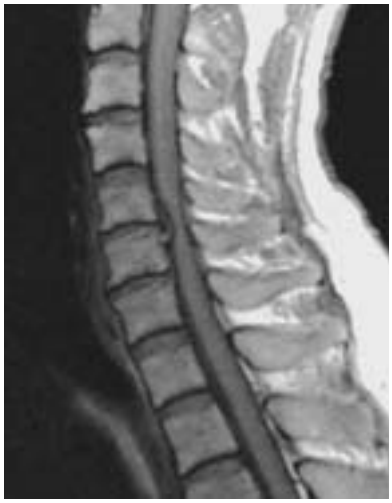


42-year-old female, C5-6 and C6-7 disc herniations with significant compression of the spinal cord.

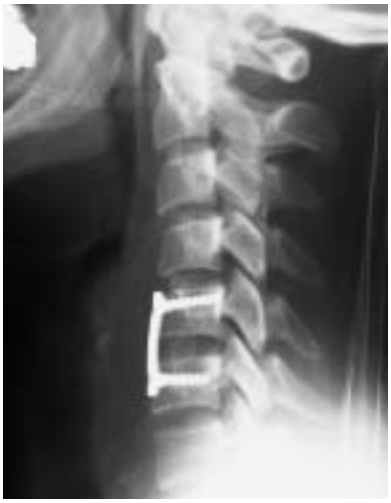
Post-op: C5-6 and C6-7 discectomies with ventral decompression and fixation using a 47.5mm ZEPHIR plate and 5 screws.

CASE 2

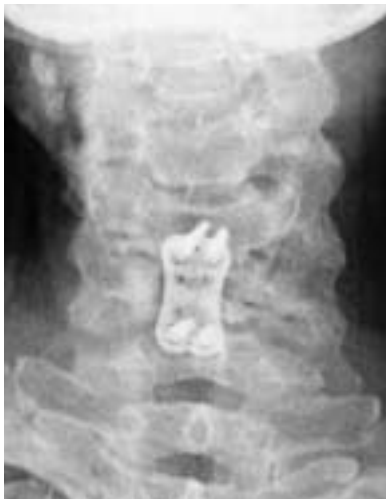
PRE-OP



POST-OP LATERAL



POST-OP A/P



37-year-old female with C6 radiculopathy from a left C5-6 disc herniation.

Post-op: C5-6 discectomy and decompression were performed. A/P and lateral cervical spine films show excellent fixation using a 25mm ZEPHIR plate and 13mm screws.

PRODUCT INFORMATION

ANTERIOR CERVICAL PLATES

ITEM	DESCRIPTION	ITEM	DESCRIPTION
8799022	22.5mm Plate, Ti	8799147	47.5mm Plate, Ti
8799025	25mm Plate, Ti	8799150	50mm Plate, Ti
8799027	27.5mm Plate, Ti	8799152	52.5mm Plate, Ti
8799130	30mm Plate, Ti	8799155	55mm Plate, Ti
8799132	32.5mm Plate, Ti	8799157	57.5mm Plate, Ti
8799135	35mm Plate, Ti	8799160	60mm Plate, Ti
8799137	37.5mm Plate, Ti	8799162	62.5mm Plate, Ti
8799140	40mm Plate, Ti	8799165	65mm Plate, Ti
8799142	42.5mm Plate, Ti	8799167	67.5mm Plate, Ti
8799145	45mm Plate, Ti	8799170	70mm Plate, Ti

SELF-TAPPING CANCELLOUS SCREWS

ITEM	DESCRIPTION	ITEM	DESCRIPTION
8792111	3.5 x 11mm Self-Tapping Cancellous Screw	8792711	4.0 x 11mm Self-Tapping Cancellous Screw
8792113	3.5 x 13mm Self-Tapping Cancellous Screw	8792713	4.0 x 13mm Self-Tapping Cancellous Screw
8792115	3.5 x 15mm Self-Tapping Cancellous Screw	8792715	4.0 x 15mm Self-Tapping Cancellous Screw
8792117	3.5 x 17mm Self-Tapping Cancellous Screw	8792717	4.0 x 17mm Self-Tapping Cancellous Screw

INSTRUMENTS

ITEM	DESCRIPTION	ITEM	DESCRIPTION
8796001	Plate Holder	8796036	Lock Screwdriver
8796002	Pin Holder	8796071	Plate Bender
8796003	Prefixation Pin	8796321	Screwdriver Shaft
8796006	Dual Drilling Guide	8796322	Screwdriver Sleeve
8796007	Mono Drilling Guide	8796912	13mm Drill Bit, Tri-Flat (Sterile)
8796008	Mono Drilling Guide Without Kickstand	8796913	13mm Drill Bit, Circular (Sterile)
8796011	Universal Handle	8797000	Sterilization Case
8796033	Central Slot Screw Removal Tool	8796084	11mm Screw Caddy

PRODUCT INFORMATION

TrimLine™

ANTERIOR CERVICAL DISCECTOMY & FUSION INSTRUMENT SET

HAND-HELD RETRACTORS

Catalog #	Description
875-050	Hand-Held Retractor, Straight, 18mm
875-051	Small Hand-Held Retractor, Straight, 18mm
875-052	Hand-Held Retractor, Back Lip, 20mm
875-053	Hand-Held Retractor, Curved, 23mm

SELF-RETAINING RETRACTORS AND BLADES

Catalog #	Description
875-110	Transverse Self-Retaining Retractor Frame
875-115	Longitudinal Self-Retaining Retractor Frame
875-149	Retractor Blade Handle

Catalog #	Description
875-150	23x30mm Discectomy Blade
875-152	23x40mm Discectomy Blade
875-154	23x50mm Discectomy Blade
875-156	23x60mm Discectomy Blade
875-158	23x70mm Discectomy Blade

Catalog #	Description
875-160	20x30mm Longitudinal Blade
875-162	20x40mm Longitudinal Blade
875-164	20x50mm Longitudinal Blade
875-166	20x60mm Longitudinal Blade
875-168	20x70mm Longitudinal Blade

CURETTES

Catalog #	Description
875-300	Curette Straight 6-0
875-302	Curette Straight 4-0
875-303	Curette Straight 3-0
875-304	Curette Straight 2-0
875-305	Curette Straight 1-0
875-307	Curette Straight 2

Catalog #	Description
875-310	Curette Angled 6-0
875-312	Curette Angled 4-0
875-313	Curette Angled 3-0
875-314	Curette Angled 2-0
875-315	Curette Angled 1-0

MICRO CURETTES

Catalog #	Description
875-370	Micro Curette Straight 6-0
875-372	Micro Curette Straight 4-0
875-373	Micro Curette Straight 3-0
875-374	Micro Curette Straight 2-0

Catalog #	Description
875-380	Micro Curette Angled 6-0
875-382	Micro Curette Angled 4-0
875-383	Micro Curette Angled 3-0
875-384	Micro Curette Angled 2-0

KERRISONS

Catalog #	Size
875-251	1mm Kerrison
875-252	2mm Kerrison
875-253	3mm Kerrison

GRAFT HARVEST/PLACEMENT INSTRUMENTS

Catalog #	Description
875-701	Graft Holder/Introducer
875-708	8mm Tapper
875-712	6x12mm Tapper
875-715	Mallet, 8”

Important Information on the ZEPHIR™ Anterior Cervical System

PURPOSE:
The ZEPHIR™ Anterior Cervical System implant components are temporary implants that are intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion. The implantation of the ZEPHIR™ Anterior Cervical System is via an anterior surgical approach.

DESCRIPTION:
The ZEPHIR™ Anterior Cervical System consists of a variety of bone plates and screws. Fixation is achieved by inserting bone screws through the openings in the plate into the vertebral bodies of the cervical spine. The ZEPHIR™ Plates include anti-migration caps that cover the heads of the bone screws to reduce the potential for screw back-out. The anti-migration caps come preassembled to the plate. Associated instruments are available to facilitate the implantation of the device.

The ZEPHIR™ Anterior Cervical System implant components are made from titanium alloy such as described by ASTM F136 or ISO 5832-3. This material is not compatible with other metal alloys. Do not use any of the ZEPHIR™ Anterior Cervical System components with the components from any other system or manufacturer. 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.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EFFECTS.

INDICATIONS:
Properly used, this system is intended for anterior interbody screw/plate fixation of the cervical spine. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis), 5) pseudarthrosis, and/or 6) failed previous fusions.

NOTA BENE:
This device system is intended for anterior cervical intervertebral body fusions only.

WARNING:
This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

CONTRAINDICATIONS:
Contraindications include, but are not limited to:
1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion or where fracture healing is not required.
11. Any case requiring the mixing of metals from different components.
12. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
13. Any case not described in the Indications.
14. Any patient unwilling to cooperate with the post-operative instructions.
15. Any time implant utilization would interfere with anatomical structures or expected physiological performance.

POTENTIAL ADVERSE EVENTS:
All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible 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, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis. Tissue 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, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
9. Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
10. Loss of bowel and/or bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
13. Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
14. Non-union (or pseud-arthrosis). Delayed union. Mal-union.
15. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
16. Bone loss or decrease in bone density, possibly caused by stress shielding.
17. Graft donor site complications including pain, fracture, or wound healing problems.
18. Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
19. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
20. Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
21. Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
22. Change in mental status
23. Death.

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

WARNINGS AND PRECAUTIONS:
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. The ZEPHIR™ Anterior Cervical System is only a temporary implant used for the correction and stabilization of the spine. This system is also intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the ZEPHIR™ Anterior Cervical System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot 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 planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the ZEPHIR™ Anterior Cervical 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 and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion.

PHYSICIAN NOTE:
Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions 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 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 components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those 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 ZEPHIR™ Anterior Cervical System components are not to be combined with the components from another manufacturer. Different metal types should not 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. Any available instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
3. When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary. The components should not be reverse bent at the same location.
4. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
5. Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
6. Bone cement should not be used since 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.
7. Before closing the soft tissues, all of the screws should be seated onto the plate. Recheck the tightness of all screws after finishing to make sure that none has loosened during the tightening of the other screws. Lock the anti-migration caps over the heads of the bone screws. Failure to do so may result in screw loosening. Caution: Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.

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 or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive 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, demented or otherwise unable to use crutches or other such weight supporting devices. 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 device should not be exposed to mechanical vibrations 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 or consume alcohol during the bone graft healing process.
3. The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. 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 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. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. The ZEPHIR™ Anterior Cervical 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. 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/or 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, and (7) Bone loss due to stress shielding.

While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal, should be followed by adequate postoperative management to avoid fracture.
6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the ZEPHIR™ Anterior Cervical System components should ever 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 should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to MEDTRONIC SOFAMOR DANEK.

DECONTAMINATION AND CLEANING:
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 surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by deionized water rinse.
Note: Certain cleaning solutions such as those containing caustic soda, 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 noted otherwise on the package labeling, the ZEPHIR™ Anterior Cervical System components are provided non-sterile. These products need to be steam sterilized by the hospital using one of the following methods:

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 onto contact with the central nervous system.

Method	Cycle	Temperature	Exposure Time
Steam	Gravity	250°F (121°C)	30 Min.
Steam**	Gravity	273°F (134°C)	18 Min.
Steam	Pre-Vacuum	270°F (132°C)	5 Min.

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. After surgery, immediately decontaminate, clean, and resterilize before handling or (if applicable) return to MEDTRONIC SOFAMOR DANEK.

PRODUCT COMPLAINTS:
Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, MEDTRONIC SOFAMOR DANEK. Further, if any of the implanted ZEPHIR™ Anterior Cervical System component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any MEDTRONIC SOFAMOR DANEK product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION:
Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact:

IN USA
1800 Pyramid Place
Memphis, TN 38132 USA
Telephone
800 876 3133 (In USA)
901 396 3133 (Outside USA)

IN EUROPE*
13, Rue de la Perdrix
95940 TREMBLAY EN FRANCE
800 933 2635 (In USA) FRANCE
SOFAMOR, SNC au capital de 33418000 Francs
RCS Bobigny B 617 320 486
Telephone (33) 1.49.38.80.00
*Authorized EC Representative

For product availability, labeling limitations, and/or more information on any Medtronic Sofamor Danek products, contact your MEDTRONIC SOFAMOR DANEK USA Sales Associate, or call MEDTRONIC SOFAMOR DANEK USA Customer Service toll free: 800-933-2635.

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