Medtronic

VERTEX MAX®

Cannulated Reconstruction System

Surgical Technique

The VERTEX MAX® Cannulated Reconstruction System features cannulated multi-axial screws that can be used with cannulated instruments to allow for screw placement over a guidewire. Used in conjunction with the VERTEX MAX® System, the VERTEX MAX® Cannulated Reconstruction System allows surgeons to treat degenerative conditions, spinal stenosis, fracture, dislocation, failed previous fusions, and tumors.

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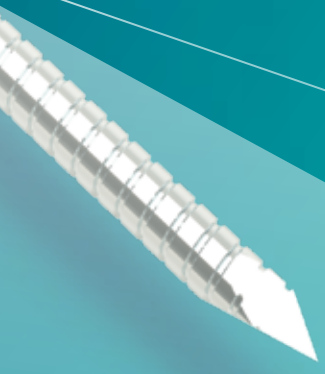


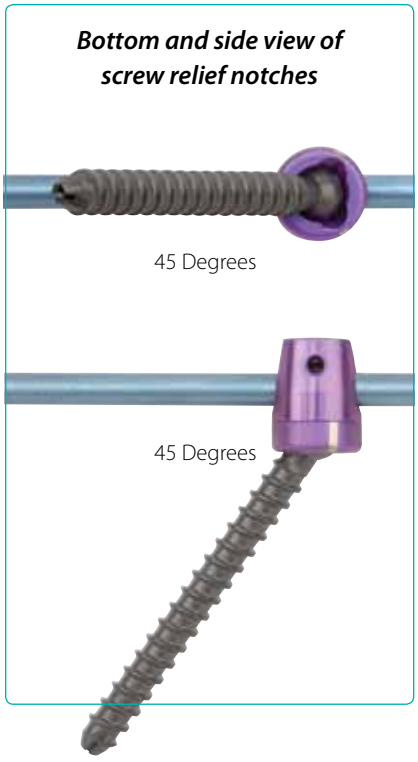
Overview

With the market introduction of the VERTEX MAX® Reconstruction System in 2001, this system has proven to be the system of choice for fixation techniques of the occipitocervical and upper thoracic spine. To continue to meet the demands of spinal surgeons and the needs of their patients, we introduce a modular system to supplement the market leading VERTEX MAX® System: the VERTEX MAX® Cannulated Reconstruction System. The system features cannulated multi-axial screws that can be used with cannulated instruments to allow screw placement over a guidewire.

Used in conjunction with the VERTEX MAX® System, the VERTEX MAX® Cannulated Reconstruction System allows surgeons to treat degenerative conditions, spinal stenosis, fracture, dislocation, failed previous fusions, and tumors. The improved versatility of these combined systems will further allow spinal surgeons to address more patients' unique anatomical requirements.The following monograph introduces the VERTEX MAX® Cannulated Reconstruction System and provides valuable information pertaining to the implants within this system, along with a step-by-step guide to using the instrument set. As an additional reference to support the technique described in this monograph, you will find a thorough guide to using the VERTEX MAX® System in the VERTEX MAX® System Surgical Technique.

VERTEX SELECT™ Cannulated Multi-Axial Screws

- Cannulated screw design allows for screw insertion over the Guidewire
- Compatible with 3.2mm and 3.5mm rods
- Up to 45 degrees of angulation
- Three angle-relief notches to allow for greater flexibility in screw placement
- Index markers on saddle to easily identify 45-degree relief notches
- Self-tapping bone screws
- Top loading for independent screw placement
- Rotating saddle reduces rod contouring
- Multi-axial screw (MAS) available in 4.0mm and 4.5mm diameters
- Partially threaded multi-axial screw (MAS) available in 4.0mm diameter
- Color-coded internal washers help appropriately match screw size to corresponding tap
- Compatible with the VERTEX MAX® Reconstruction System




Seafoam


Bronze


Seafoam


4.0mm Multi-Axial Screw

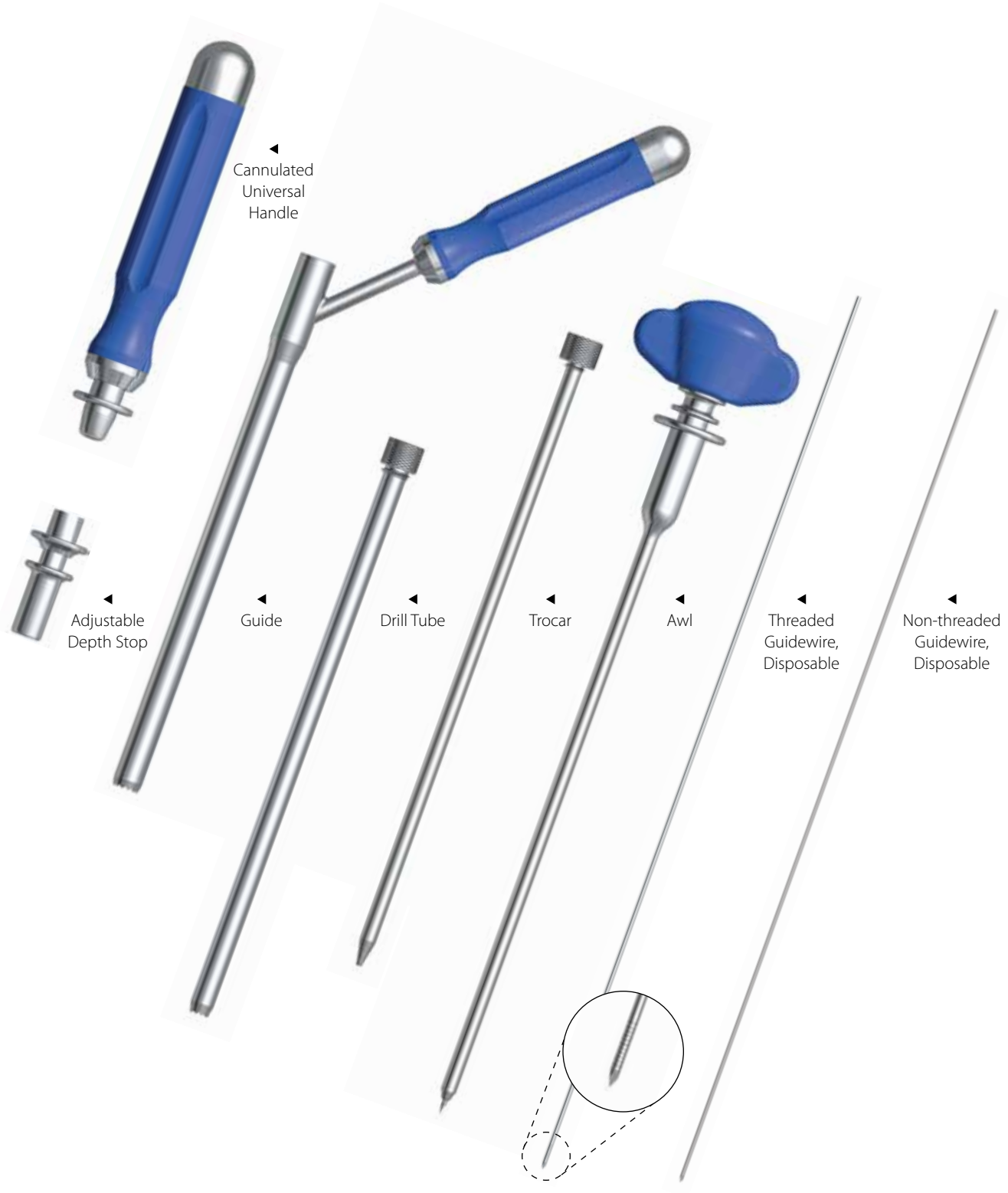

4.5mm Multi-Axial Screw


4.0mm Partially Threaded Multi-Axial Screw

Color-coding Reference

	Screw Size	Color	Tap	Drill Bit
VERTEX SELECT™ Cannulated MAS	4.0mm × 30mm to 50mm	Seafoam	VERTEX MAX® Cannulated Tap, 4.0mm	3.0mm
	4.5mm × 30mm to 50mm	Bronze	VERTEX MAX® Cannulated Tap, 4.5mm	3.0mm
VERTEX SELECT™ Cannulated Partially Threaded MAS	4.0mm × 26mm to 40mm	Seafoam	VERTEX MAX® Cannulated Tap, 4.0mm	3.0mm

Instrument Set



Instrument Set *continued*

Penetration through Soft Tissue

This surgical technique represents a limited subset of the original surgical technique for the VERTEX MAX® Reconstruction System.

Assembly and Insertion of Guide, Drill Tube, and Trocar

- Insert the Drill Tube into the Guide and tighten the components by rotating the knurled portion on the Drill Tube clockwise **(Figure 1)**.
- Insert the Trocar into the Drill Tube and tighten using the same motion as above. The Trocar will facilitate penetration through the soft tissue **(Figure 1)**.
- Position the Guide, Drill Tube, and Trocar assembly through the soft tissue to the correct position for desired screw trajectory.

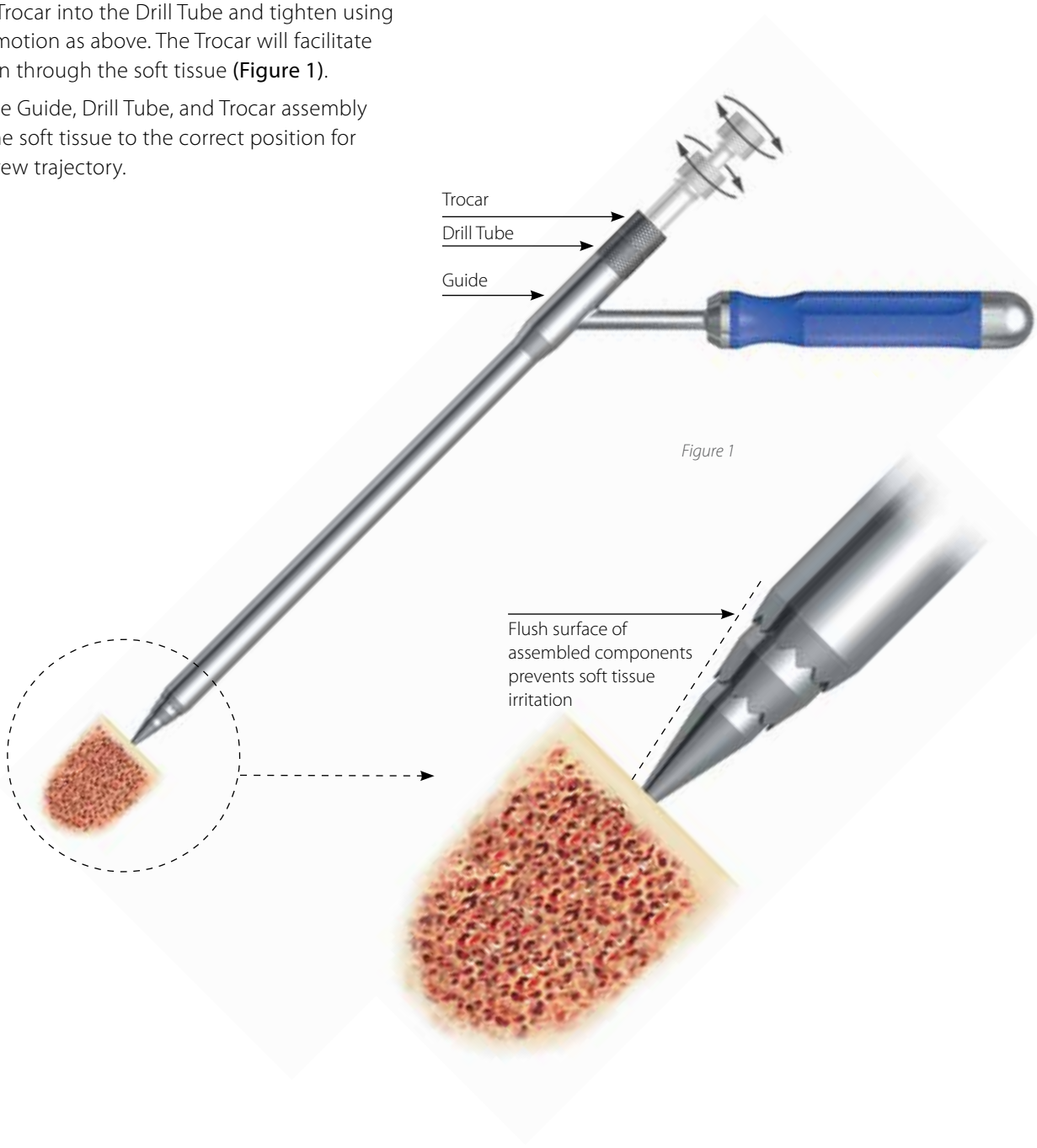


Figure 1

Preparation of Screw Hole

Insertion of Awl

» An entry hole is made in the cortical bone using the Awl. To use the Awl, first remove the Trocar and then insert the Awl through the Drill Tube **(Figure 2)**.

» Make an indentation in the bone at the desired location. The tip of the Awl is revealed when the spring-loaded shaft is retracted.

Figure 2

Preparation of Screw Hole *continued*

Insertion of Guidewire

- After removing the Awl, reinsert the Trocar in the Drill Tube. Load the Guidewire, threaded or non-threaded, onto a cannulated power drill and insert the Guidewire through the Trocar. Advance the Guidewire into the bone to the desired depth **(Figure 3)**.
- Remove the cannulated power drill from the Guidewire.
- Remove the Trocar from the Drill Tube, leaving the Guidewire in place. The Guidewire will remain positioned in the bone throughout the remainder of the procedure.

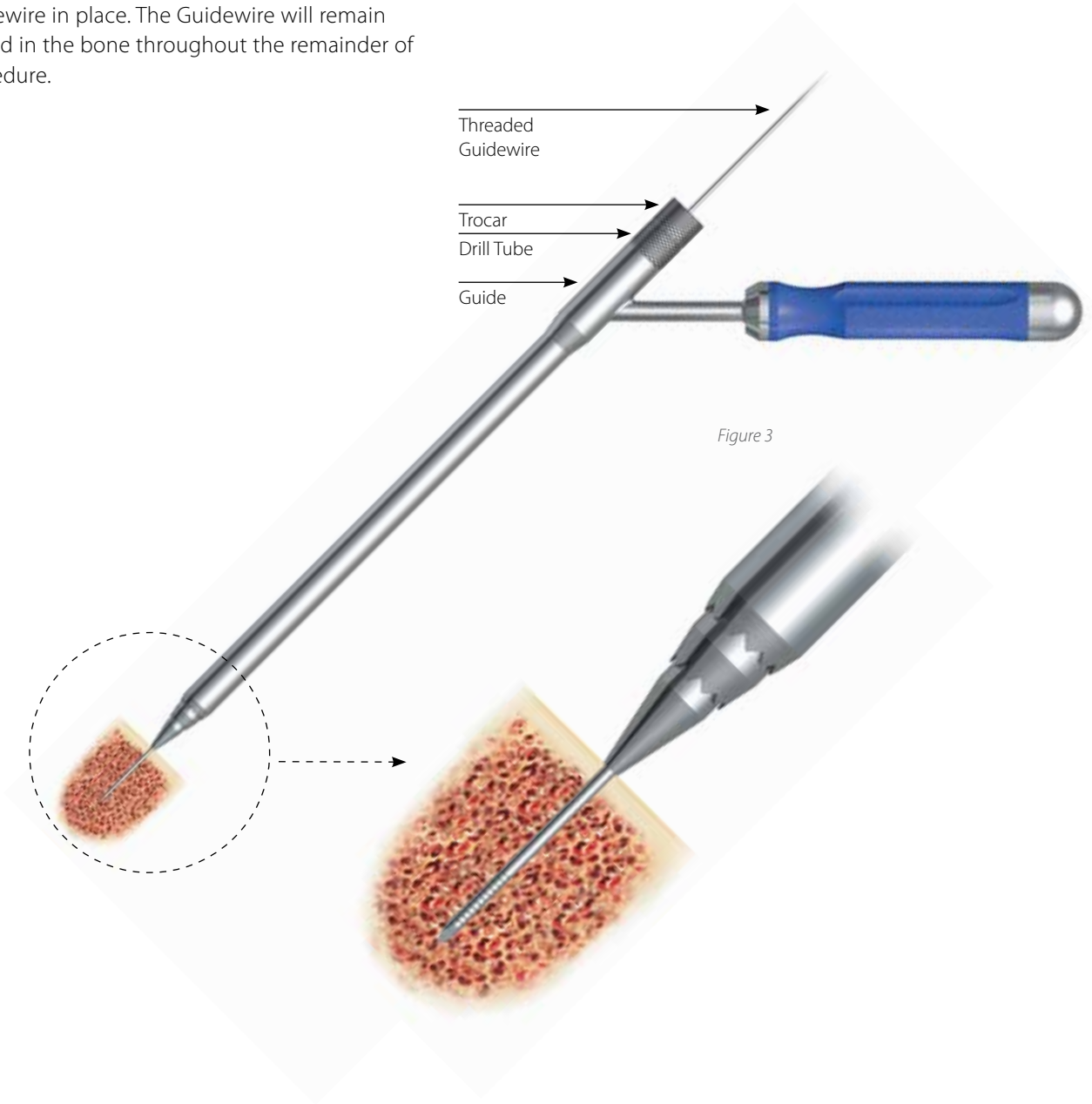


Figure 3

Preparation of Screw Hole *continued*

Determination of Guidewire Depth

- Position the Cannulated Depth Gauge over the Guidewire and insert the Depth Gauge into the Drill Tube to measure the depth of the Guidewire. To ensure an accurate depth reading, make certain the Depth Gauge is seated flush with the bone **(Figure 4)**.
- The laser marking on the Guidewire, which correlates with the scale on the Depth Gauge, indicates the appropriate choice of screw length **(Figure 5)**. After noting the depth of the Guidewire, remove the Depth Gauge.

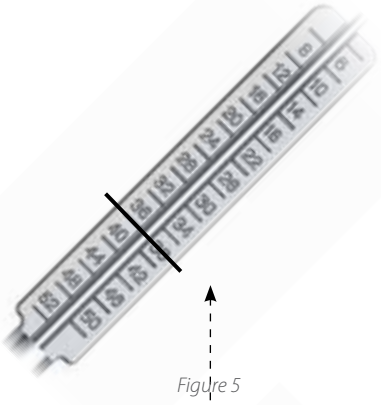


Figure 5

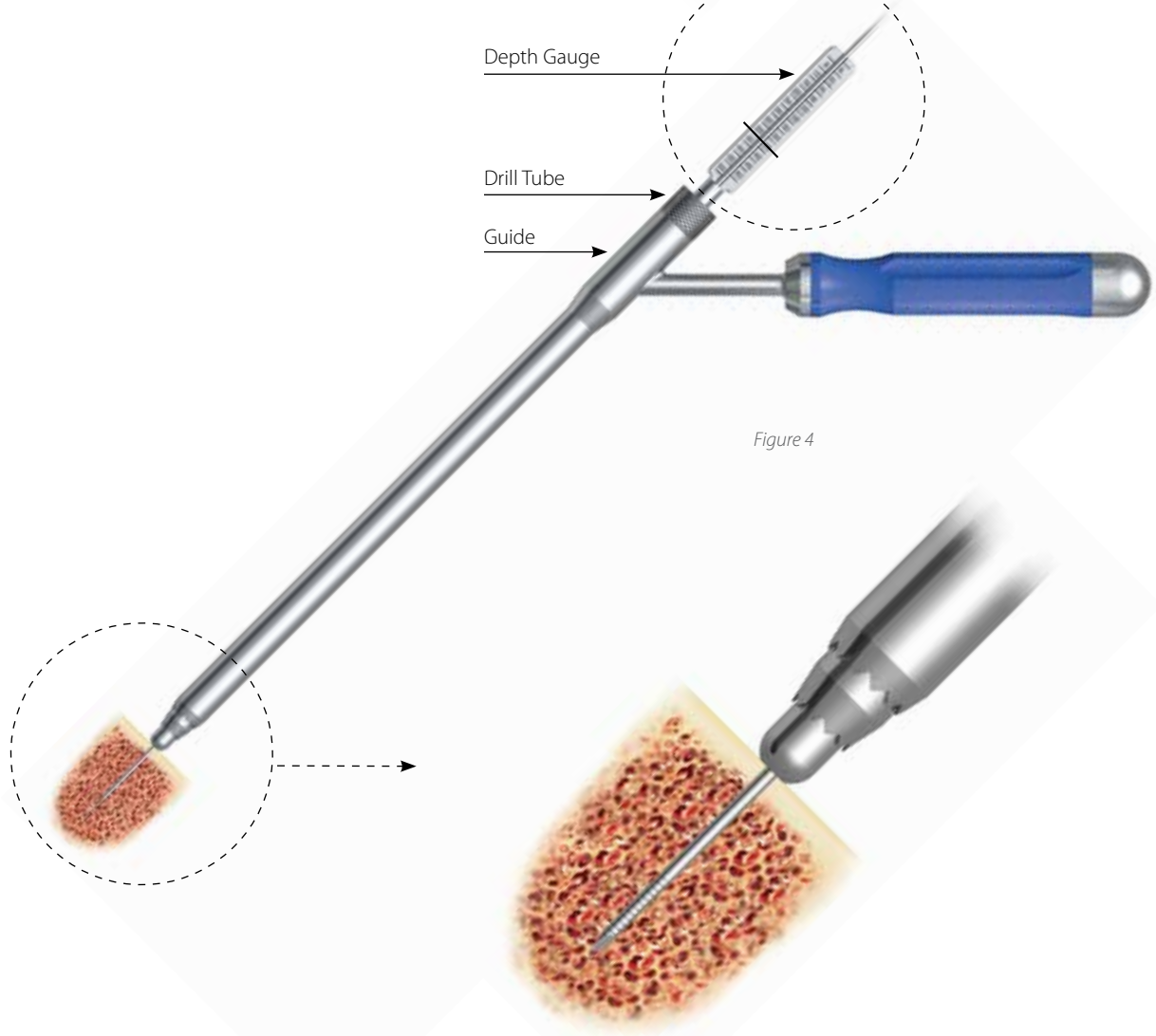


Figure 4

Preparation of Screw Hole *continued*

Drilling

- Assemble the Cannulated Drill Bit with the Adjustable Depth Stop, setting the Adjustable Depth Stop to the appropriate depth marking on the Cannulated Drill Bit **(Figure 6)**.
- Attach the Cannulated Drill Bit to either the Cannulated Universal Handle or a cannulated power drill and position the drill bit over the Guidewire **(Figure 7)**.
- Advance the Cannulated Drill Bit in the Drill Tube and drill through the bone to the appropriate depth. Remove the Cannulated Drill Bit.

Figure 6

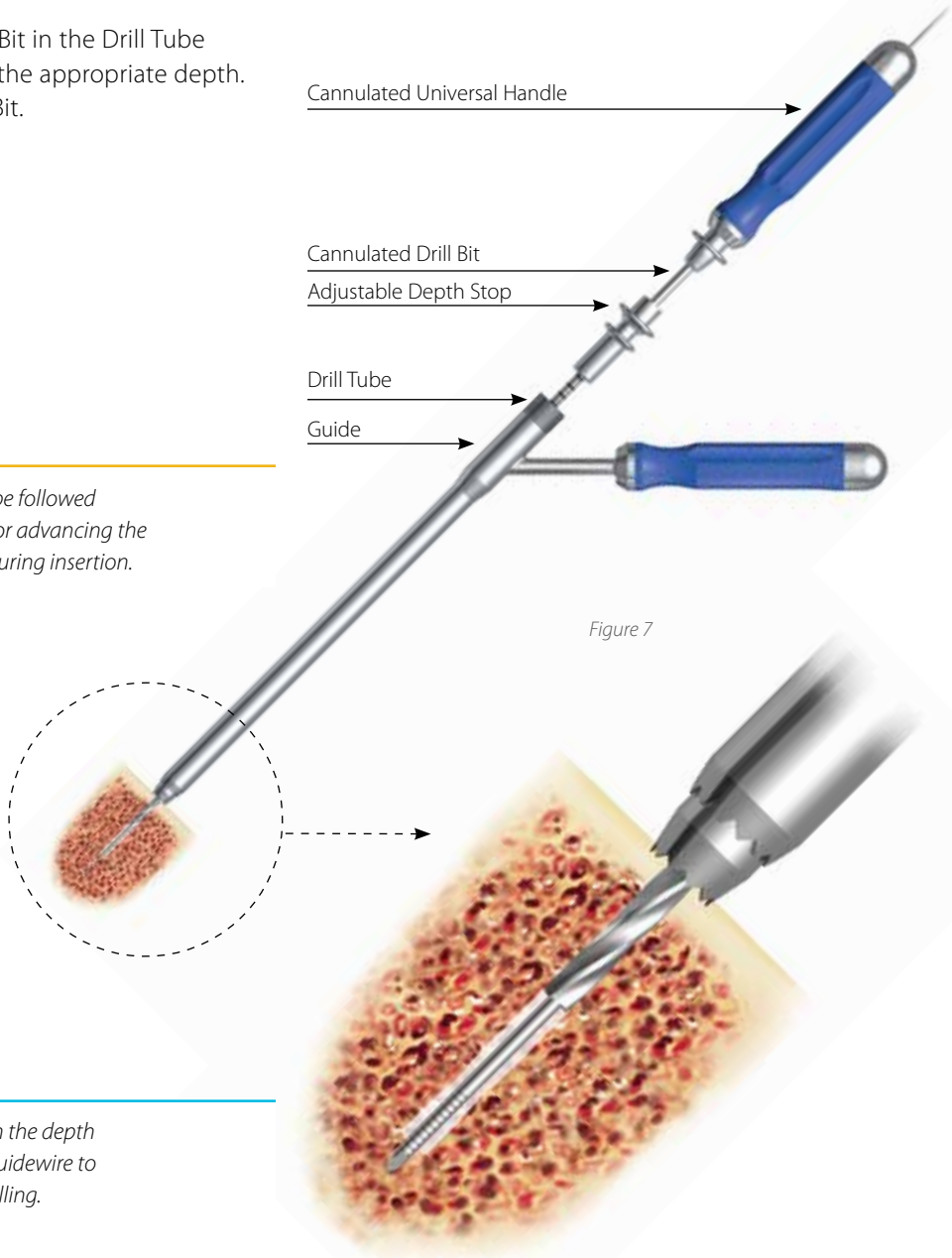


Figure 7

Important

The trajectory of the Guidewire must be followed precisely to avoid bending, breaking, or advancing the Guidewire while drilling, tapping, or during insertion.

Helpful Hint

It is beneficial to drill 2-3mm less than the depth of the Guidewire. This will allow the Guidewire to remain anchored in the bone after drilling.

Preparation of Screw Hole *continued*

Tapping

- Assemble the appropriate Cannulated Tap with the Cannulated Universal Handle. The Cannulated Taps are color coded to help choose the appropriate tap to match the corresponding screw size.
- Position the Cannulated Tap over the Guidewire and advance the tap in the Drill Tube. Tap to the appropriate depth using the scale on the tap shaft, indicated by the top of the Drill Tube **(Figure 8)**.
- Remove the Cannulated Tap.

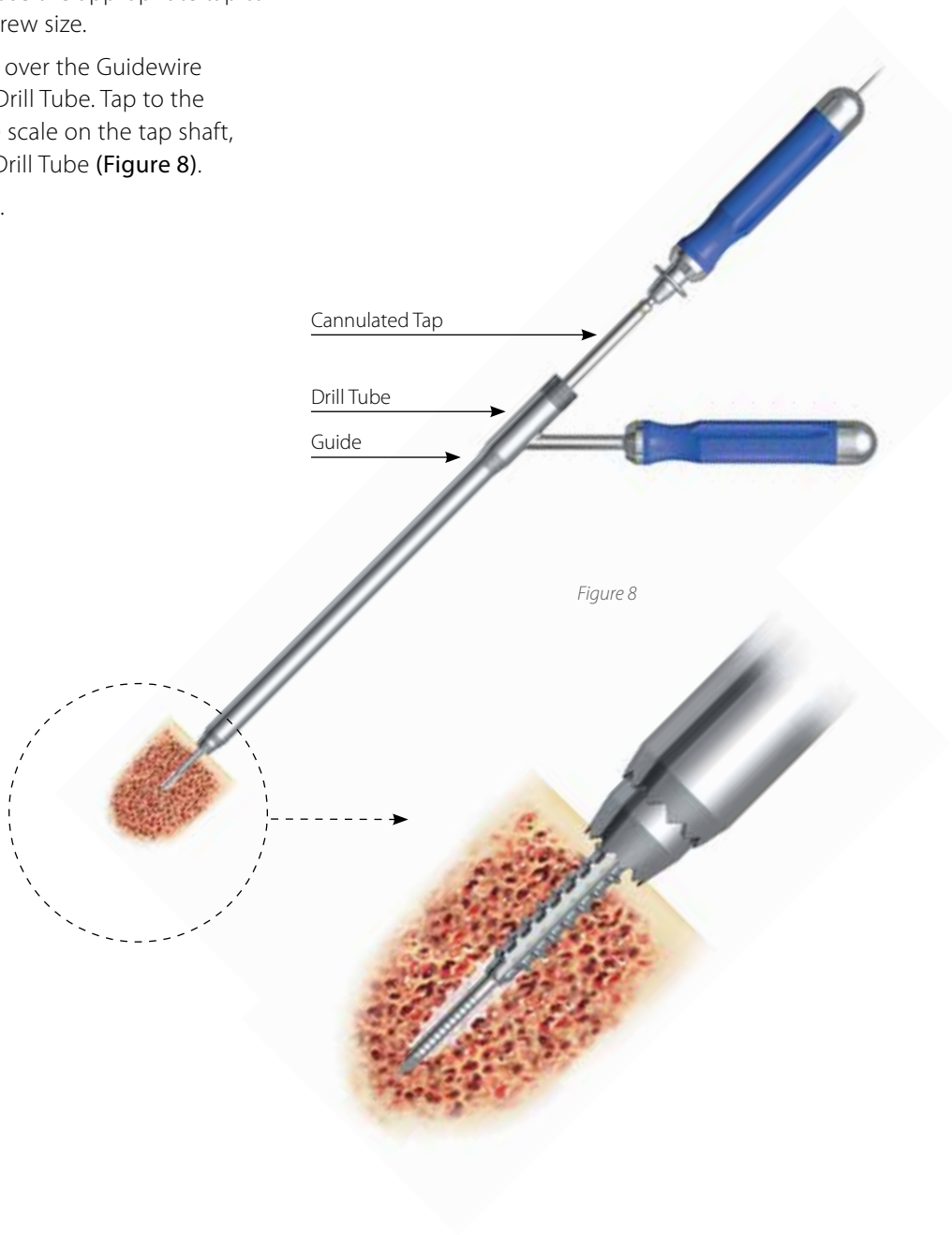


Figure 8

Screw Insertion

- Assemble the Cannulated Threaded Screwdriver and the Cannulated Universal Handle.
- Engage the appropriate size VERTEX SELECT™ Cannulated Multi-Axial Screw using the Cannulated Threaded Screwdriver. Hold the multi-axial screw by the screw shaft to align and engage the hex of the driver in the head of the screw. Thread the sleeve of the driver into the threads on the saddle of the screw until firmly attached **(Figure 9)**.
- Remove the Drill Tube.
- Position the Cannulated Threaded Screwdriver over the Guidewire and advance the screwdriver into the Guide. Advance the screw to the desired depth **(Figure 10)**.
- Release the Cannulated Threaded Driver from the screw by holding the Handle and turning the sleeve of the driver counterclockwise.
- Remove the Cannulated Threaded Screwdriver.

Figure 9

Figure 10

Removal of the Guidewire

» Re-attach the cannulated power drill to the Guidewire and in reverse rotation, remove the Guidewire (**Figure 11**).

» Remove the Guide.

Figure 11

Explantation

To remove any of the VERTEX SELECT™ Multi-Axial Screws described throughout this technique, engage the screw with the Cannulated Screwdriver and turn counterclockwise until the bone screw is disengaged from the bone.

Product Ordering Information

VERTEX SELECT™ Cannulated Multi-Axial Screws

Item Number	Description
6959430	4.0mm × 30mm
6959432	4.0mm × 32mm
6959434	4.0mm × 34mm
6959436	4.0mm × 36mm
6959438	4.0mm × 38mm
6959440	4.0mm × 40mm
6959442	4.0mm × 42mm
6959444	4.0mm × 44mm
6959446	4.0mm × 46mm
6959448	4.0mm × 48mm
6959450	4.0mm × 50mm
6959530	4.5mm × 30mm
6959532	4.5mm × 32mm
6959534	4.5mm × 34mm
6959536	4.5mm × 36mm
6959538	4.5mm × 38mm
6959540	4.5mm × 40mm
6959542	4.5mm × 42mm
6959544	4.5mm × 44mm
6959546	4.5mm × 46mm
6959548	4.5mm × 48mm
6959550	4.5mm × 50mm

Partially Threaded Cannulated Multi-Axial Screw

Item Number	Description
6959426PT	4.0mm × 26mm
6959428PT	4.0mm × 28mm
6959430PT	4.0mm × 30mm
6959432PT	4.0mm × 32mm
6959434PT	4.0mm × 34mm
6959436PT	4.0mm × 36mm
6959438PT	4.0mm × 38mm
6959440PT	4.0mm × 40mm

Instrument Set

Item Number	Description
6957300	Guide
6957301	Trocar
6957303	Awl
6957302	Drill Tube
6957306	3.0mm Cannulated Drill Bit, Sterile
6957308	4.0mm Cannulated Tap for Multi-Axial Screws
6957309	4.5mm Cannulated Tap for Multi-Axial Screws
6957312	Cannulated Self-Holding Screwdriver
6957313	Cannulated Threaded Screwdriver
6957305	Cannulated Universal Handle
6957304	Cannulated Depth Gauge
873-010	T-Bar
6905712	Adjustable Depth Stop
6957314	Threaded Guidewire, Disposable
6957315	Non-threaded Guidewire, Disposable

Important Information on the VERTEX® Reconstruction System

PURPOSE

The VERTEX® Reconstruction System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the occipital, cervical and/or upper thoracic spine.

DESCRIPTION

The VERTEX® Reconstruction System is a posterior system, which consists of a variety of shapes and sizes of plates, rods, hooks, screws, multi-axial screws, and connecting components, which can be rigidly locked to the rod in a variety of configurations, with each construct being tailor-made for the individual case. Titanium ATLAS® cable may be used with this system at the surgeon's discretion. See the package inserts of both of those systems for labeling limitations.

The VERTEX® Reconstruction System is fabricated from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium. Medical grade titanium, medical grade titanium alloy, and/or medical grade cobalt chromium may be used together. Never use titanium, titanium alloy, and or/cobalt chromium with stainless steel in the same construct. The VERTEX® Reconstruction System includes a retaining ring for the multi-axial screw made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium, titanium alloy, and cobalt chromium implants only. The posted screw connectors and some multi-axial screws contain elastomeric stakes made of silicone adhesive commonly used in implantable medical devices. Do not use with stainless steel. No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog or price list for further information about warranties and limitations of liability.

To achieve best results, do not use any of the VERTEX® Reconstruction System implant components with components from any other system or manufacturer unless specifically labeled to do so in this or another MEDTRONIC document. As with all orthopedic and neurosurgical implants, none of the VERTEX® Reconstruction System components should ever be reused under any circumstances.

INDICATIONS

When intended as an adjunct to fusion of the occipitocervical spine, cervical spine, and the thoracic spine, (Occiput-T3), the VERTEX® Reconstruction System is indicated for skeletally mature patients using allograft and/or autograft for the following:

DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

Occipitocervical Components: Plate Rod/Plates/Rods/Occipital Screws/Hooks

The occipitocervical plate rods, plates, rods, occipital screws, and hooks are intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the occipitocervical junction and the cervical spine. When used to treat these occipitocervical and cervical conditions, these screws are limited to occipital fixation only. The screws are not intended to be placed in the cervical spine.

Occipitocervical constructs require bilateral fixation to C2 and below.

Note: Segmental fixation is recommended for these constructs.

Hooks and Rods

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Multi-axial Screws/Connectors

The use of multi-axial screws are limited to placement in T1-T3. The screws are not intended to be placed in the cervical spine.

Titanium ATLAS® Cable System to be used with the VERTEX® Reconstruction System allows for cable attachment to the posterior cervical or thoracic spine.

In order to achieve additional levels of fixation, the VERTEX® Reconstruction System may be connected to the CD HORIZON® Spinal System rods with the VERTEX® rod connectors. Refer to the CD HORIZON® Spinal System package insert for a list of the CD HORIZON® Spinal System indications of use.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Active infectious process or significant risk of infection (immunocompromise).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion.
11. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
12. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
13. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
14. Any patient unwilling to follow postoperative instructions.
15. Any case not described in the indications.

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

1. **Severe bone resorption.**
2. **Osteomalacia**
3. **Severe osteoporosis.**

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, necrosis, 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. 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. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Bone loss or decrease in bone density, possibly caused by stresses shielding.
18. Graft donor site complications including pain, fracture, or wound healing problems.
19. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
20. 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.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Death.

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

WARNINGS AND PRECAUTION

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 also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

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 severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices 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.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

!USA FOR US AUDIENCES ONLY

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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.

Important Information on the VERTEX® Reconstruction System *continued*

PREOPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre-dispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The VERTEX® RECONSTRUCTION SYSTEM components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer. Different metal types should never be used together.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
5. To insert a screw properly, drill a pilot hole corresponding to selected screw size and prepare screw site with a sharp tap.
6. Caution: Do not overtap or use a screw that is either too long or too large. Overtapping or using an incorrectly sized screw may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert.
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. Before closing the soft tissues, all of the screws or set screws should be tightened firmly. Recheck the tightness of all screws or set screws after finishing to make sure that none loosened during the tightening of the other screws or set 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. The VERTEX® Reconstruction 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 should 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 VERTEX® Reconstruction 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.

CLEANING AND DECONTAMINATION

Unless just removed from an unopened MEDTRONIC package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to MEDTRONIC. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must 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, many instruments require disassembly before cleaning.

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

STERILIZATION

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes
Steam*	Pre-Vacuum *	273°F (134°C)*	20 Minutes*
Steam*	Gravity*	273°F (134°C)*	20 Minutes*

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

*For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

PRODUCT COMPLAINTS

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or MEDTRONIC. Further, if any of the implanted spinal system component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any MEDTRONIC 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 MEDTRONIC.

EC REP

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Contact Customer Service or your Sales Representative for the most up-to-date revision of the package insert.

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

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.