Duet™ Spinal Fixation System

Instructions for Use

IMPORTANT: Read all instructions, cautions and warnings prior to use, including the Duet™ Spinal Fixation System Surgical Technique Guide. These instructions provide guidance to the experienced physician using the Duet™ Spinal System for the treatment of symptomatic degenerative disc disease. This is not a reference to spine surgery technique. **Failure to properly follow the instructions or to heed any warnings or precautions could result in patient injury. Do not attempt to use the Duet™ Spinal System prior to receiving training.**

SYSTEM DESCRIPTION: The Duet™ Spinal Fixation System is a spinal fixation device intended to immobilize and stabilize spinal segments as an adjunct to fusion in the lumbar and sacral regions of the spine. The Duet™ Spinal Fixation System is a dual screw system that eliminates the need for standard pedicle system rods. All components of the Duet™ Spinal Fixation System are manufactured from titanium (Ti-6Al-4V ELI per ASTM F136). The Duet™ Spinal Fixation System construct of three components: halo-screw, sphere screw, and set screw. Both screws are offered in various lengths to accommodate individual patient anatomy. The Duet™ Spinal Fixation System is intended to be used at 1-level of the spinal segment to provide supplemental fixation. The Duet™ Spinal Fixation System implants and single use instruments are supplied sterile.

INDICATIONS: The Duet™ spinal fixation construct is intended to provide immobilization and stabilization of a single spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of lumbar and sacral spine from L1-S1: degenerative disk disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spinal stenosis; pseudoarthrosis; and failed previous fusion.

CONTRAINDICATIONS: Contraindications include but are not limited to:

- Active systemic or local infection in the proposed area of surgery.
- Involved level is a revision of a previous intervertebral fusion procedure(s) or failed PLF.
- Known allergy to the materials in the medical devices (titanium alloy)
- Severe osteoporosis, osteopenia, and/or osteomalacia.
- A medical condition that interferes with postoperative management program.
- Active malignancy.
- Morbid obesity.
- Grade II or greater spondylolisthesis or retrolisthesis at involved spine level.
- DDD that requires surgical intervention at three or more spine motion segments.
- Abnormal anticoagulation status.
- Any condition not described in the Indications for Use.

WARNINGS: Failure to follow any instructions or failure to heed any warnings or cautions could result in serious patient injury.

IMPLANT SELECTION: The selection of the proper length of the implant construct for each patient is crucial to the success of the procedure. Unless care is taken in patient selection, proper implant placement and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage, bending or loosening of the device before the healing process is complete. The Duet™ Devices are available in multiple lengths. Device length is measured during drilling with ruler markings on the 3.75mm Drill shaft using the bone surface for reference.

SURGICAL STEPS (Refer to Duet™ Spinal Fixation Surgical Technique Guide for full details)

1. Patient Preparation: Place patient in prone position and use a midline incision open approach.
2. Place guide wire - Using Jamshidi needle and A/P fluoroscopy to target the pedicle.
3. Remove the inner stylet of the Jamshidi needle and place the guide wire through.
4. Drill over the guide wire and tap if desired.
5. Place Halo Device using Device driver and insert to desired depth taking care to align the head in the correct orientation to place the Sphere Device.
6. Using the angle guide placed in the head of the Halo Device, a Jamshidi, and fluoroscopy, target the adjacent level pedicle and insert the Jamshidi into it.
7. Remove the inner stylet of the Jamshidi needle and place the guide wire through.
8. Drill over the guide wire and tap if desired.
9. Place the Sphere Device through the head of the Halo Device and insert until the Sphere head is fully seated in the head of the Halo Device.
10. Place the counter torque over the head of the Halo Device and insert the locking cap into the Halo Device head through the counter torque.
11. Use the torque limiting driver to fully tighten the Locking Cap.
12. Remove all instruments and close the incision site using standard procedure.

MRI SAFETY INFORMATION



The Duet™ Spinal Fixation System has not been evaluated for safety and compatibility in the MR environment. The Duet™ Spinal Fixation System implant has not been tested for heating or migration in the MR environment.

The Duet™ Spinal Fixation System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Duet™ Spinal Fixation System in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury.

GENERAL PRECAUTIONS

- Do not use the sterile, single use device if the packaging appears to be damaged or if there is evidence of tampering.
- The single-use devices are intended for single-use only. Do not re-sterilize or reuse. Reuse of the device could result in infection, cross-contamination, and failure to perform in a safe manner as intended.
- Surgeons should be familiar with the implant, instruments, and surgical technique before implanting this device.
- It is important to read the Instructions for Use and these precautions prior to device operation.
- The user should inspect the device for damage prior to use. If the device appears to be damaged, do not use. Discard or return to the manufacturer.
- Use the Jamshidi Needle prior to the expiration date noted on the package.
- Implants and single use instruments are provided sterile.
- The physician should be familiar with the anatomy and pathology being treated with this device.
- The correct choice of implant angle and device length for each patient is crucial to the success of the procedure.
- Always perform final tightening of the Duet™ Devices with the torque limiting driver. Failure to do so may risk damaging the implant.
- This device must be inserted using fluoroscopic guidance. Failure to use fluoroscopic guidance could result in serious patient injury.
- Implants must never be re-used or re-implanted.
- Failure to observe recommendations may contribute to serious patient injury.
- Physician's postoperative directions and warning to the patient and the corresponding patient compliance are extremely important. Detailed instructions on the use and limitations of the device should be given to the patient. The patient must be warned that loosening, and/or breakage of the device(s) are complications which may occur as a result of early or excessive weight-bearing, muscular activity or sudden jolts or shock to the spine.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Preoperative

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the aforementioned contradictions should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Components of the system should be protected during storage, especially from corrosive environments.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment.

Intraoperative

- The instructions in the Duet™ Spinal Fixation System Surgical Technique Guide should be carefully followed.
- Extreme caution should be used around the spinal cord and nerve root. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- Use great care to ensure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct.

Postoperative

- The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.
- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
- To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical 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 or utilize nicotine products, or to consume alcohol or non-steroidal or anti-inflammatory medications such as aspirin during the bone healing process.
- The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction of body motion.
- Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures) prophylactic antibiotics may be considered, especially for high-risk patients.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. The Duet™ Implant components should never be reused under any circumstances.

POSSIBLE ADVERSE EFFECTS: The following are potential adverse events or complications associated with spinal fusion surgery with supplemental fixation. Possible adverse events with use of the Duet™ Spinal Fixation System include, but are not limited to:

- Infection, early or late
- Implant migration, breakage, or subsidence
- Hemorrhage of blood vessels and/or hematomas
- Damage to the surrounding soft tissue
- Decrease in bone density due to stress shielding
- Nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis, or cerebral spinal fluid leakage
- Gastrointestinal, urological, and/or reproductive system compromise, including sterility, impotency and/or loss of consortium
- Malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height
- Failure to relieve back pain or increased back pain
- Non-union (or pseudoarthrosis), delayed union
- Death

Standard medical practice and procedures should be followed prior to use and following the use of the Duet™ Spinal Fixation System. These practices are not within the scope of this document.

HOW SUPPLIED: The Duet™ Implants and Accessory Instruments are supplied in single use sterile packaging and should not be re-sterilized. Do not use device if package is damaged, opened, accidentally contaminated, or past the expiration date listed on the package.

DISPOSAL: No unique requirements. Dispose of in accordance with hospital clinic requirements.

LIMITATION OF LIABILITY: IN NO EVENT SHALL DUET SPINE BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR EXEMPLARY DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE DUET™ SPINAL FIXATION SYSTEM, BASED UPON BREACH OF CONTRACT (INCLUDING BREACH OF WARRANTY).

SERVICE REPRESENTATIVES AND REQUESTS FOR INFORMATION: For service, technical support, requests for information or reorder information, contact, in the United States:

DUET SPINE HOLDINGS LLC
P.O. BOX 420
WINONA LAKE, IN 46590
855 948 6848
www.duetspine.com

Any device-related-incident or problem which is believed to represent a safety issue should be immediately reported to Duet Spine.

PRODUCT RETURNS: To return Duet Spine Product, contact Duet Spine.

SYMBOL DEFINITIONS:

Symbol Title / Description	Symbol
Do not reuse / Indicates a medical device that is intended for one single use only	
Do not use if package damaged and consult instructions for use / Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	
Lot Number / Indicates the manufacturer's batch code so that the batch or lot can be identified	LOT
Catalog Number / Indicates the manufacturer's catalogue number so that the medical device can be identified	REF
MR Unsafe / The implant has not been tested for heating or migration in the MR environment.	MR
Caution / Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	
Manufacturer / Indicates the medical device manufacturer	
Non-Sterile / Indicates a medical device that has not been subjected to a sterilization process	NON STERILE
Use-By Date / Indicates the date after which the medical device is not to be used	
Keep Dry / Indicates a medical device that needs to be protected from moisture	
Consult instructions for use or consult electronic instructions for use / Indicates the need for the user to consult the instructions for use	
By Prescription Only / Product is a prescription device restricted by U.S. FDA regulations to sale, distribution, or use by a licensed healthcare practitioner	Rx ONLY
Sterile using Irradiation / Indicates a medical device that has been sterilized using irradiation	STERILE R
Do Not Re-sterilize / Indicates a medical device that is not to be re-sterilized	
Single sterile barrier system with protective packaging inside / Indicates a single sterile barrier system with protective packaging inside	
Double sterile barrier system / Indicates two sterile barrier systems	