STRYKER SPINE
ES2® AUGMENTABLE SPINAL SYSTEM

STERILE PRODUCT

The Stryker Spine ES2® Augmentable Spinal System is comprised of devices for the posterior pedicle fixation of the noncervical spine via either an open or a percutaneous surgical approach. The system consists of polyaxial and monoaxial screws that can be used in conjunction with implant components from Xia® 3, and ES2® Spinal Fixation Systems, such as blockers, rods, and cross connectors.

The ES2® Augmentable screws are polyaxial and monoaxial cannulated screws that contain a series of fenestrations (lateral side holes) which allows CORTOSS® Bone Augmentation Material to be injected into the treated area. The CORTOSS® Bone Augmentation Material is used to augment screw fixation in the pedicle in patients with diminished bone quality such as osteoporosis. CORTOSS® Bone Augmentation Material and the ES2® Augmentable screws are provided sterile, for single use only. Refer to Stryker CORTOSS® Bone Augmentation Material package insert for information regarding the use of the bone augmentation material.

Refer to Stryker Spine ES2®, and Xia® 3 Spinal Fixation Systems package inserts for information regarding the implant components used in conjunction with the ES2® Augmentable screws. Care should be taken so that the correct components are used in the spinal construct.

MATERIALS
ES2® Augmentable Screws:
Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136

Blockers, Rods, and Cross Connectors:
Refer to Stryker Spine ES2®, and Xia® 3 Spinal Fixation Systems package inserts for information regarding the material specifications.

CORTOSS® Bone Augmentation Material:

Refer to Stryker CORTOSS® Bone Augmentation Material package insert for information regarding the bone augmentation material specifications.

MATERIALS IDENTIFICATION
Titanium: symbol **T**

INDICATIONS
When used with Stryker CORTOSS®, bone augmentation material, the ES2® Augmentable screws are intended for posterior, non-cervical pedicle fixation as an adjunct to fusion in patients with diminished bone quality such as osteoporosis for the following indications: degenerative disc disease (define as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

CONTRAINDICATIONS

The contraindications listed below may be relative or absolute and must be taken into account by the physician when making his decision. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Fever or leukocytosis
- Patients with clotting disorders
- Patients with severe cardiac and/or pulmonary insufficiency
- Pregnancy
- Any patient with known hypersensitivity or allergy to any of the components in Stryker CORTOSS® bone augmentation material.
- Patients with any contra-indication to Stryker CORTOSS® Bone Augmentation Material.
- Pedicular /vertebra posterior wall defects, damage or fracture
- Any case not needing a bone graft and fusion
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any patient having inadequate tissue coverage over the operative site
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- Any patient unwilling to follow postoperative instructions
- Any case not described in the indications
- Fractures and tumors with loss of anterior support and primary or metastatic tumors involving the spine
- Osteoporosis when used without bone augmentation material
- Severe Osteoporosis
- Previous history of infection or active infection
- Excessive local inflammation
- Open wounds
- Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spine which can lead to failure of the fixation of the device or to failure of the device itself.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery such as the presence of tumors, 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

Contraindications related to Stryker CORTOSS® Bone Augmentation Material:

Refer to Stryker CORTOSS® Bone Augmentation Material package insert for information regarding Contraindications, Warnings and Precautions associated to the use of this material.

GENERAL CONDITIONS OF USE

The implantation of the ES2® Augmentable pedicle screw spinal system must be performed only by experienced spinal surgeons having undergone the necessary specific training in the use of such

system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
The information contained in the Package Insert is necessary but not sufficient for the use of this system. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

INFORMATION FOR PATIENTS
The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion must be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up.
The surgeon must warn the patient of the surgical risks and made aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advise the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warn of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.

INFECTION
Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it is advisable to use antibiotic prophylaxis before and after such procedures.

INSTRUMENTS
Specialized instruments are provided by Stryker Spine and must be used to help assure accurate implantation of the device. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or extensive force are more susceptible to fracture depending on the operative precaution, number of procedures, disposal attention. Instruments must be examined for wear or damage prior to surgery.

REUSE
Re-sterilization of the implants is strictly forbidden, regardless of the method that might be employed. Never reuse or re-implant spinal surgical implants. These could become contaminated resulting in infection. In addition, even though the device appears undamaged, it may have small defects which could compromise structural integrity reducing its service life and/or leading to patient injury.

HANDLING
Correct handling of the implant is extremely important. The operating surgeon should avoid notching or scratching the device.

ALLERGY AND HYPERSENSITIVITY TO FOREIGN BODIES

When hypersensitivity is suspected or proven, it is recommended that the tolerance of the skin to the materials that make up the implants be checked before they are implanted.

IMPLANT SELECTION AND USE

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice which depends on each patient.
Patients who are overweight may be responsible for additional stresses and strains on the device which can speed up metal fatigue and/or lead to deformation or failure of the implants.

The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants should be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

Improper selection, placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. Contouring or bending of rods or plates is recommended only if necessary according to the surgical technique of each system. Rods should only be contoured with the proper contouring instruments. Incorrectly contoured rods, or rods which have been repeatedly or excessively contoured must not be implanted. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Refer to the Stryker Spine surgical protocols for additional procedural information. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

METAL COMPONENTS

Some of the alloys utilized to produce orthopaedic implants contain metallic elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomena.

SYSTEM COMPATIBILITY

While some degree of corrosion occurs on all implanted metal and alloys, contact of dissimilar metals may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system may also increase. Internal fixation devices, such as rods, screws, connectors, etc., which come into contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of the system should not be used in conjunction with components from any other manufacturer’s spinal system. Any such use will negate the responsibility of Stryker Spine for the performance of the resulting mixed component implant.

POSTOPERATIVE CARE

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation

and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician should closely monitor the patient if a change at the site has been detected.

ADVERSE EFFECTS

- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Bending, disassembly or fracture of any or all implant components.
- Fatigue fracture of spinal fixation devices, including screws and rods, has occurred.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin.
- Dural leak requiring surgical repair.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) should be revised or removed immediately before serious injury occurs.
- Loosening of spinal fixation implants can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, migration and/or pain.
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Serious complications may be associated with any spinal surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Decrease in bone density due to stress shielding.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft, the intervertebral body, pedicle, and/or sacrum above and/or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision.

Refer to Stryker CORTOSS® Bone Augmentation Material package insert for information regarding the adverse effects associated to the use of this material.

REMOVAL OF IMPLANTS

These implants are temporary internal fixation devices designed to stabilize the operative site during the

normal healing process. After healing occurs, these devices serve no functional purpose and can be removed. Removal may also be recommended in other cases, such as:

- Corrosion with a painful reaction
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions
- Pain or abnormal sensations due to the presence of the implants
- Infection or inflammatory reactions
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains
- Failure or mobilization of the implant

Standard ancillaries provided by Stryker Spine can be used to remove the implants. Any decision by a physician to remove the internal fixation device must take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically. Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture. Removal of the implant after fracture healing is recommended. Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

PACKAGING, STORAGE AND RECOMMENDATIONS FOR STERILE IMPLANTS

- The implants are single use devices that are provided sterile. Implants sold sterile are always presented in individual packaging and are clearly labeled as "sterile" on the package label. Implants that are not labeled as such are not sterile. Packaged sterile product must be stored in a clean, dry, and temperate place. Sterile products may be stored at room temperature.
- The sterilization method applied is indicated on the product label. The implants have been exposed to a minimum of 25 kGy of gamma radiation.
- The packaging of sterile product must be intact at the time of receipt. The packaging is expected to withstand normal transportation conditions. However, the integrity of the original packaging must be verified before use. Sterility is ensured only if there is no trace of damage to the packaging. If damage to the sterile packaging is detected, the product must not be used.
- Do not use if the packaging is opened or damaged or after the "Use by" date on the label has expired. Stryker is not responsible for the use of products presenting package deterioration or expiration shelf-life.
- Care must be taken to prevent contamination of implant after opening of the packaging prior to use.

FURTHER INFORMATION

A surgical technique brochure is available on request through your Stryker agent or directly from Stryker Spine. Users with brochures that are over two years old at the time of surgery are advised to ask for an updated version.

PRE-OPERATIVE PRECAUTIONS

Anyone using Stryker Spine products can obtain a Surgical Technique brochure by requesting one from a distributor or from Stryker Spine directly. Those using brochures published more than two years before the surgical intervention are advised to get an updated version.

Stryker Spine devices can only be used by doctors who are fully familiar with the surgical technique required and who have been trained to this end. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by Stryker Spine. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to causes injury to the patient.

To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable Stryker Spine Surgical Technique.

Extreme care must be taken when the instruments are used near vital organs, nerves or vessels.

Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization. Refer to Stryker Spine Instruments package insert for the decontamination, cleaning, and sterilization parameters. The Instruments package insert can be by requested from a distributor or from Stryker Spine directly.

COMPLAINTS

Any health professional having a complaint or grounds for dissatisfaction relating to the identity, quality, durability, reliability, safety, effectiveness or performance of a device should notify Stryker Spine or its representative. Moreover, if a device has malfunctioned, or is suspected of having malfunctioned, Stryker Spine or its representative must be advised immediately.
If a Stryker Spine product has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or Stryker Spine must be informed as soon as possible by telephone, fax or in writing.

For all complaints, please give the name and reference along with the batch number of the component(s), your name and address and an exhaustive description of the event to help Stryker Spine understand the causes of the complaint.

For further information or complaints, please contact:

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