Reflex® Zero Profile
Surgical Technique

Anterior Cervical Plating System
Anterior cervical discectomy and fusion remains one of the most successful surgical procedures, and the application of a plate to provide temporary postoperative stability has gained widespread acceptance as the “gold standard” of care. Anterior cervical plating systems continue to evolve and incorporate contemporary biomechanical understanding of the demands placed on these devices.

Currently available anterior cervical instrumentation includes constrained systems, in which the screws are rigidly locked to the plate, and semi-constrained systems, which allow motion of the screws with respect to the plate. Combining these two fixation philosophies allows the surgeon to use the most applicable technique when treating a variety of traumatic and non-traumatic cervical spine pathologies.

The Reflex® Zero Profile Anterior Cervical Plate system offers optimized versatility along with an easy, reproducible implantation technique. In addition to accommodating both constrained and semi-constrained constructs, this next generation system offers recessed cross bars which aid in aligning the plate in the coronal plane. The unique “H-Plate” design minimizes contact with soft tissue, while maintaining the biomechanical integrity of a traditional anterior cervical plate.

Acknowledgements

Stryker® Spine would like to thank Alfred Rhyne, MD, Charlotte, NC, for his contribution.
System Overview

The Reflex® Zero Profile ACP System offers a selection of one- and two-level low profile anterior cervical plates. Used in conjunction with Reflex® Hybrid bone screws, the system can accommodate both semi-constrained and rigid bone screw fixation philosophies.

The Ti-6Al-4V alloy plate has minimal material running sagittally through its center, thereby minimizing contact with soft tissue. The contoured undersurface creates isolated points of contact between the plate and the bone at each screw hole, thus allowing the plate to sit more flush against the vertebral body, regardless of bone morphology.

The recessed cross bars increase the strength and torsional stability of the construct, in addition to aligning the plate in the A/P view.*

The one-step locking ring expands upon screw insertion, and then contracts over the screw head to hold each screw securely in place. The screw hole geometry accommodates both fixed and variable angle screws.

**Note:** The Reflex® Zero Profile ACP System is intended to be used in conjunction with the Reflex® Hybrid bone screws and instrumentation.

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* Data on file at Stryker Spine.
The neutral axis of the end-hole bone screws is defined as 8° cephalad or 8° caudal from perpendicular to the plate in the sagittal plane as well as 8° of medial convergence in the axial plane. All types of screws have the same degree of medial convergence.

**Reflex® Hybrid fixed angle bone screws**, which are used if a rigid construct is desired, are inserted into the plate in the neutral position as described above, and they remain in this position under loading. Fixed bone screws in the middle holes are inserted perpendicularly to the plate (at 0 degrees angulation).

**Reflex® Hybrid variable angle bone screws**, which allow sagittal angulation of the screw within a certain range measured from the neutral axis, follow the philosophy of load sharing through the bone graft as a prerequisite for a successful fusion. In the sagittal plane, the end-hole variable angle screws can move +/- 6° from the neutral axis, resulting in an actual range of angulation of 2 up to 14 degrees from perpendicular to the plate. Middle-hole screws also allow for +/- 6 degrees of angulation.

If desired, both types of bone screws can be combined into a hybrid construct, which includes fixed angle bone screws at one level and variable angle bone screws at the remaining levels.
Both fixed and variable screws are offered as **self-tapping**, which feature a cutting flute and a less aggressive screw tip, and **self-drilling**, which have been designed with a sharp tip for insertion without prior drilling.

The individual screw families have been **color coded** for easy identification:

<table>
<thead>
<tr>
<th>Screw Type</th>
<th>Variable Angle</th>
<th>Fixed Angle</th>
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<tbody>
<tr>
<td>4.0mm Self-Tapping</td>
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The Reflex® Zero Profile plates and Reflex® Hybrid screws represent a complete system, which is separate and **not interchangeable with the original Reflex™ ACP system implants**.

Refer to the indications and limitations of the Reflex® Hybrid ACP System and the Reflex® Zero Profile System provided in the Packaging Insert/Instructions for Use.
Patient Positioning and Exposure

The patient is placed in a supine position with the head turned slightly away from the side of the approach. For one- or two-level procedures, a transverse incision parallel to the skin creases of the neck is recommended. The left side is preferred, as the more constant course of the recurrent laryngeal nerve on this side potentially minimizes the risk of its injury. After blunt dissection through the various tissue layers, the anterior cervical spine is gently exposed.

The implantation of the anterior cervical plate follows a discectomy or a corpectomy, including an appropriate bone graft insertion. Care should be taken to remove any bony anatomy or osteophytes which would inhibit the Reflex® Zero Profile plate from sitting flat against the bone.

**Note:** Osteophytes may need to be taken more laterally to allow for placement of the plate.

The crossbars of the Reflex® Zero Profile Plate are intended to be positioned within the disc space, and will be recessed 1.25mm below the surface of the bone. Because of this, both the curved and the flat graft impactor have been designed with a 2mm stop to ensure that the crossbars do not make contact with the bone graft within the disc space. After bone graft insertion, place the end of the curved or flat graft impactor (depending upon the shape of the bone graft) against the graft device and, using a mallet, gently tap the bone graft into the disc space until the 2mm stop touches the vertebral end plates.

**Note:** The crossbars should be recessed into the disc space to ensure a solid construct.
Implant Selection and Preparation

The sizing of the Reflex® Zero Profile plates is measured from the center of the cephalad hole to the center of the caudal hole. Using the caliper, measure the distance between the center points of the appropriate vertebrae and select the corresponding plate. In cases, in which the measured distance falls between two sizes, it is usually recommended that the smaller size be used as a plate that is too long may interfere with the disc space above or below the implanted construct. Regardless of the plate size selected, the screws must be inserted with the correct amount of screw angulation. A plate holder is available to hold the plate next to the vertebral column to confirm size selection.

The Reflex® Zero Profile plate has been designed with a slight sagittal and axial bend for optimal matching of a patient’s anatomy. If additional sagittal plate contouring is necessary, use the plate bender as follows:

Depending on whether lordosis needs to be added or reduced, position the removable bending block to face up with the correct side (laser marking indicates + or − lordosis). The bending hammer should be positioned so that the + or − match the position of the bending block.

Slide the plate between the block and the bending hammer in such a way that the plate is bent in the area between screw holes. To avoid damage to the plate, it is key that the plate is positioned so that the curved portion of the hammer mates with the same curve in the crossbar, and so that the plate is straight within the block for even contouring.
Do not bend the plate in a vicinity of a screw hole, as it may compromise the locking ring mechanism. Due to the notch sensitivity of titanium, the plate should never be reverted to its original shape once it has been contoured.

**Caution:** The Reflex® Zero Profile Plate should only be contoured using the Reflex® Zero Profile Plate Bender. Do not use the Reflex Hybrid Plate Bender.

Temporary fixation pins are available to hold the plate during screw hole preparation. The threaded pins – short or long – are loaded onto the quick-release pin inserter and threaded through one of the holes of the plate. Placement of two pins diagonally from each other is recommended for stabilization of the plate on the anterior vertebral column.

**Note:** The point of the pins dull with repeated use, and should be treated as a disposable or inspected on a regular basis. Additionally, while inserting or removing the pins, caution should be used with angulating the pins within the bone to avoid potential breakage.
Depending on the type of a screw selected for a particular procedure, the following options are available for screw hole preparation.

In all procedures, optional tapping would precede screw insertion, if desired.

**Note:** To ensure proper locking of the bone screws, freehand insertion of the bone screws is not allowed.

**Note:** The Reflex Hybrid Double Barrel Drill Guides and the Reflex Hybrid All-In-One Guides are NOT compatible with the Reflex® Zero Profile plate.
While certain instruments – such as the awl, drills, tap, and the screwdriver – are used for all types of bone screws, the drill guides and punch awl must correspond to whether fixed or variable angle bone screws will be implanted. The variable and fixed angle guides can be identified by their blue and purple handles, respectively. The punch awl handle is not screw-specific; however, the fixed and variable angle awl sleeves can be identified by the appropriate laser marking.

Both the fixed and the variable angle guide instruments direct the screw trajectory within the range that ensures optimal functioning of the locking ring. The fixed guide is rigidly attached to the plate at 8 degrees of sagittal angulation in the end holes (neutral axis) and 0 degrees of sagittal angulation in the middle holes. The tip design of the variable guide allows for a range of sagittal angulation from +/- 6 degrees in all screw holes. Positioning the bone screws within the allowed range of angulation will ensure secure locking of the screws within the plate.

**Note:** Both the fixed and variable guides must be engaged securely to the plate prior to screw hole preparation. Additionally, they will disengage from the plate if they are positioned outside the optimal range of angulation.

Drill bits, which are available in 2.5mm diameter and six sizes corresponding to the screw lengths (10, 12, 14, 16, 18, and 20mm), provide a positive stop for accurate drilling depth in combination with any of the guides. The tap is available in one pre-set depth (10mm).
The **single-barrel drill guide** (fixed or variable) directs the drill bit to prepare the screw pathway. The guide provides a positive “lock” when inserted into the screw hole in the plate. The guide needs to be removed for tapping and/or screw insertion. A slight rocking motion facilitates assembly and disassembly; forcing the guide straight into or out of the screw hole should be avoided.

The fixed guide attaches rigidly to the plate when positioned in the neutral axis as described above (8 degrees of sagittal angulation on the end holes, and perpendicular to the plate in the center holes). Outside of this position, the fixed guide does not provide the optimal trajectory and may result in an inaccurate screw position. The proper angulation of the fixed guide can be confirmed by releasing the handle, as the instrument will “stand up” on its own in this location.
As an alternative to the single-barrel drill guide, the punch awl may be used to center and direct the pathway of the self-drilling screws. Interchangeable fixed or variable sleeves (identified by the appropriate laser marking) are threaded onto the punch awl shaft, and are designed to lock into the screw hole in the plate. As with the drill guide, the punch awl should rigidly attach to the plate for the fixed screws, and should provide the correct range of angulation for the variable screws when the awl is properly locked to the plate.

Select the appropriate punch awl sleeve and thread it onto the punch awl shaft. The awl should be in the “closed” position before attaching it to the plate, so as to avoid prematurely engaging the awl tip into the bone. Once the awl is attached to the plate, the awl may then be turned to the “open” position, and the handle depressed so as to engage the awl tip into the bone. A slight rocking motion facilitates disassembly. The punch awl is strongly recommended when self-drilling screws are used, as it provides an optimal screw trajectory.

Note: Each screw hole should use the technique as described above. The punch awl should be returned to the “closed” position before engaging the next screw hole.
Following screw hole preparation, select the appropriate screw and confirm its length using the **screw depth gauge** in the screw tray. The screw size indicates the actual amount of screw purchase in the bone below the bottom surface of the plate (i.e. a 14mm screw is protruding 14mm below the plate, while the screw head is contained within the screw hole).

Bone screws are placed using the **retaining screwdriver**, which features a self-centering pin and a sleeve to hold the screw head securely. Using the screw tray to load the screws, insert the screwdriver pin into the cannulated head of the bone screw. Ensure that the tip of the screwdriver is aligned with the cruciform design of the bone screw. Once the screwdriver is seated into the bone screw, lower the sleeve until it is locked onto the head of the screw. There should be a tactile and audible confirmation that the screwdriver sleeve is locked. Pull up on the sleeve to disengage the screwdriver from the bone screw. **The retaining screwdriver must not be used for final tightening.**

**Note:** Once the loaded assembly is pulled out of the screw caddy, touching the screwdriver sleeve must be avoided. Sliding the sleeve forward will cause the bone screw to become disengaged from the screwdriver. If this occurs, the screw should be placed back into the screw caddy to reload it onto the screwdriver.
Bone screws may also be placed using the insertion screwdriver, which features a tapered tip in combination with a small nitinol holding pin for a secure hold of the screw head.

Screws should be inserted to the point where they are just above the ring. Inserting the screws sequentially at opposite corners of the plate – and working toward the center of the plate – helps keep the plate flat against the bone.

Once all bone screws have been inserted, the final tightening screwdriver should be used to lock the screws into the ring. The final tightening screwdriver, which features a protruding center pin to facilitate placement into the screw head, has been designed for optimal strength as to minimize the risk of stripping. To facilitate identification, the shaft of the final tightening screwdriver has been anodized gold.

**Note:** The amount of torque required to complete final tightening can be done with a single hand, and must not exceed one quarter turn once the screw is underneath the ring.

In addition to the tactile sensation of the locking ring closing over the bone screw head, final screw locking should also be confirmed visually with the ring being clearly visible over the bone screw head. It is possible that the entire ring may not be visible if the screws have been implanted at their extreme angulation; however, two-thirds of the ring provides sufficient coverage for safe locking of the bone screw to the plate.
Bone Screw Removal

The **screw extractor** allows for removal of bone screws that have been locked into the plate. While the larger tip of the screwdriver spreads the locking ring, the threaded inner shaft allows for rigid attachment of the screw to the screwdriver. In addition, the instrument utilizes an outer sleeve to provide counter force against the plate during screw removal. **Do not pull the screw out with only the draw rod.**

To begin removal of the screw, the outer sleeve should be pulled up and threaded onto the upper ring of threads just below the handle, so as to keep the sleeve from impeding visibility when seating the driver. The screwdriver should then be **fully seated** into the cruciform head of the bone screw. Insert and tighten the threaded inner shaft until the knob will no longer turn (approximately 10-12 rotations). Before removing the screw, release the outer sleeve from the upper ring of threads, and allow it to drop onto the plate. **While holding the outer sleeve stationary, unthread the bone screw from the plate.**

**Note:** While the screw extractor is attached to the screw, pivoting or angulation of the instrument must be avoided, as it can cause bending or breakage of the inner shaft.

**Note:** The screw extractor must be axially aligned with the screw trajectory and fully seated in the screw head before inserting or tightening the inner shaft.

The locking mechanism of the Reflex® Zero Profile ACP System has been tested to ensure that a screw inserted into a previously used screw hole will be securely locked*. The locking ring can be re-used for the implantation of a rescue screw. However, repeated screw insertion through the locking ring should be avoided as its function may have been compromised. A maximum of two bone screw insertions is recommended for any screw hole within a plate.

* Data on file at Stryker Spine.
# Implants

## Reflex® Hybrid Implants

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<th>Description</th>
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## Reflex® Hybrid Instruments

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## Reflex® Zero Profile Instruments

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DESCRIPTION
The Stryker Spine Reflex® Zero Profile ACP system consists of bone plates that are available in a variety of sizes in order to accommodate individual patient physiology and pathology and to facilitate anterior stabilization of the cervical spine. The Reflex® Zero Profile ACP plates are intended to be used with the Reflex Hybrid ACP bone screws. The Reflex® Zero Profile ACP system is intended for unilateral fixation.

MATERIAL
The components of the Reflex® Zero Profile ACP system are manufactured out of Titanium alloy as defined in the ISO 5832-3 and ASTM F136 standards.

INDICATIONS
The Reflex® Zero Profile Anterior Cervical Plating (ACP) System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:
- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Decompression of the spinal cord following total or partial cervical vertebrectomy
- Spondylolisthesis
- Spinal stenosis

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

CAUTION
Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

GENERAL CONDITIONS OF USE
Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the spinal device. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome. Consult the medical literature for information regarding proper surgical techniques, precautions, and potential adverse effects associated with spinal fixation surgery.

Do not substitute another manufacturer’s device for any component of the Reflex® Zero Profile ACP System. Any such use will negate the responsibility of Stryker Spine for the performance of the resulting mixed component implant.

Do not mix metals (i.e. Titanium based devices with stainless steel items). Some corrosion occurs on all implanted metals and alloys. Contact of dissimilar metals, however, may accelerate corrosion. Corrosion may accelerate fatigue fracture of implants, and cause metal compounds to be released into the body.

ANATOMICAL LIMITATIONS
- Stryker Spine implants may be implanted in children on condition that the overall size of the assembly and the size of the implants are checked beforehand to verify whether they are suited to the height and the size of the bone structures of the child outside USA only. In the USA, implants are not to be used in children.
- The Reflex Zero Profile ACP System is intended for use in the cervical spine only. However, as with any orthopaedic implant, even when an implant's design does not expressly contraindicate its placement in a particular area, the surgeon may encounter certain patient pathologies which impose their own unique anatomic limitations.
- Anterior cervical plates are for use in the cervical region of the spine only and must not be used below T1.

CONTRA-INDICATIONS
- Marked local inflammation.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the devices.
- Bony abnormalities preventing safe screw fixation.
- Open wounds.
- Rapid joint disease, bone absorption, osteopenia, osteomalacia, and/or osteoporosis. Osteoporosis or osteopenia are relative contraindications, since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
- Metal sensitivity, documented or suspected.
- Pregnancy.
- Anytime implant utilization would interfere with anatomical structures or physiological performance.
- Inadequate tissue coverage over the operative site.

Other medical or surgical conditions which would preclude the potential benefit of surgery, such as congenital abnormalities, immunosuppressive disease, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or marked left shift in the WBC differential count.

These contra-indications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.

INFORMATION FOR PATIENT
The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. The rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weightbearing, 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) they may be at increased risk for failure of the fusion and/or the device.

PRE-OPERATIVE PRECAUTIONS
The surgical indication and the choice of implants must take into account certain important criteria such as:
- Patients involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.
- Surgeons should instruct patients in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected with a normal, healthy spine, and surgeons should counsel patient not to have unrealistic functional expectations.
- A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.
- Foreign body sensitivity. Where material sensitivity is suspected appropriate tests should be made prior to material implantation.
- Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned 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.

THE CHOICE OF IMPLANTS
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.

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.

INTRA-OPERATIVE PRECAUTIONS
- The insertion of the implants must be carried out using instruments designed and provided for this purpose and in accordance with the specific implantation instructions for each implant.
- Those detailed instructions are provided in the surgical technique brochure supplied by Stryker Spine.
• Discard all damaged or mishandled implants.
• Stryker Spine implants must not be reshaped, unless otherwise indicated in the surgical technique instructions. When implants need to be bent, the bending must be carried out gradually using the appropriate instruments, provided by Stryker Spine. The use of inappropriate instruments may result in scratches, notches, and sharp bending, causing the breakage of the implants. Improper seating of the implant may result in implant failure.
• Never reuse an implant, even though it may appear undamaged.
• Do not mix metals.

POST-OPERATIVE PRECAUTIONS
Physician instructions regarding full weight-bearing activities must be complied with until maturation of the fusion mass is confirmed. Failure to comply with physician instructions may result in failure of the implant, the fusion, or both.

SIDE EFFECTS
Include but are not limited to:
• Late bone fusion or no visible fusion mass and pseudarthrosis;
• Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis;
• Superficial or deep-set infection and inflammatory phenomena;
• Allergic reactions to the implanted materials although uncommon can occur;
• Metal sensitivity of allergic reactions to a foreign body have been reported, possibly leading to tumor formation;
• Decrease in bone density due to stress shielding;
• Neurological and spinal dura mater lesions from surgical trauma;
• Dural leak requiring surgical repair;
• Asymptomatic presence of microparticles may be observed around the implants as a result of interaction between the components as well as between the component and bone (i.e. wear).
• Cessation of growth of the fused portion of the spine;
• Loss of proper spinal curvature, correction, height and/or reduction;
• Pain, discomfort, or abnormal sensations due to the presence of the device;
• Early loosening may result from inadequate initial fixation, latent infection, premature loading of the device or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, or pain.
• Serious complications may occur with any spinal surgery. These complications include, but are not limited to, genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including embol; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
• 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.
• Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft or the intervertebral body above or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock. Adverse effects may necessitate reoperation.

REMOVAL
• Stryker Spine devices are indicated for treatment of fracture or stabilisation of a surgical site during the normal bone consolidation process. After this period, the presence of the device is no longer strictly required and its removal can be planned. Removal may also be necessary as a result of the above mentioned adverse effects.
• Removal of an ACP System may require special instruments to disengage the implant from the vertebral. Appropriate recommendations are provided in the Surgical Technique brochure.
• Any decision by a physician to remove the internal fixation device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.

PACKAGING
• The implants are delivered in packages; these must be intact at the time of receipt.
• The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.

PRE-CLEANING / CLEANING AND STERILIZATION

PROCEDURE RECOMMENDED FOR NON STERILE MEDICAL DEVICE
For safety reasons, non-sterile devices must be pre-cleaned, cleaned and sterilized prior to use. Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery.

WARNING: SPECIAL DECONTAMINATION PROCEDURE FOR NCTA (CREUTZFELDT-JAKOB DISEASE) FOLLOWING FRENCH GUIDELINE DGS/DHOS N°138:
If, for any reason, a device is suspected to have been contaminated with NCTA (Creutzfeldt-Jakob disease), the following procedure must be followed depending on the device material:

1- If the device is made of titanium or titanium alloy, immerse totally in a 2% sodium hypochlorite solution for 1 hour.

2- The device must be autoclaved at 137°C (278°F) for 18 minutes in a porous-load autoclave.

After this process, devices are considered decontaminated against NCTA and sterile (a Sterility Assurance Level (SAL) of 10-6 is obtained).

Devices made of titanium or titanium alloy are identified by a laser marking.

Plastic materials used by Stryker Spine withstand both treatments described above.

If the device material is not identified, please contact your local Stryker Spine representative.

Determinations made will be documented and a list of instruments potentially used - or intended to be used - in high contamination risk procedures can be obtained by contacting a Stryker Spine representative.

STERILIZATION PROCEDURE RECOMMENDED FOR NON-STERILE MEDICAL DEVICES INCLUDING IMPLANTS
Medical Devices should be sterilized in their container with water vapor in an autoclave in accordance with standard hospital procedure. The sterilization method suggested has been validated according to the AAMI TIR 12 in order to obtain a Sterility Assurance Level (SAL) of 10-6.

STERILIZATION CONDITIONS: 2 sets of low parameters have been validated on wrapped items:
• Prevacuum steam sterilization (Porous load autoclave): TEMPERATURE: 132°C (270°F), EXPOSURE TIME: 4 minutes, DRY TIME: 45min.
• Gravity-displacement steam sterilization: TEMPERATURE: 132°C (270°F), EXPOSURE TIME: 10 minutes, PRESSURE: 2.5 Bars/36-PSIG, DRY TIME: 45min.

STRYKER Spine recommends using higher parameters:
TEMPERATURE: 137°C (278°F), EXPOSURE TIME: 18 minutes, PRESSURE: 2.5 Bars/36-PSIG, DRY TIME: 45min.

All intermediary sets of parameters can be used.

The autoclave must be validated by the hospital and regularly checked to guarantee the recommended sterilization temperature is reached for the entire exposure time.

If sterilization containers with paper filters are used, it is advisable to use a new filter for each sterilization. If after having followed this sterilization method there is still water in the sterilization containers or on/inside the device, the device must be dried and sterilization repeated.

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.

CAUTION

Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

COMPLAINTS

Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and/or its performance, 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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The information presented in this brochure is intended to demonstrate the breadth of Stryker product offerings. Always refer to the package insert, product label and/or user instructions before using any Stryker product. Surgeons must rely on their own clinical judgement when deciding which product and treatments to use with their patients. Products may not be available in all markets. Product availability is subject to the regulatory or medical practices that govern individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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