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This package leaflet applies to

Spinal implants of the system
VERTICALE® POSTERIOR SPINAL FIXATION SYSTEM
VERTICALE® MIS

Separate package leaflets are available: for the reprocessing of the instruments (D60007) and instrumentation guides VERTICALE (D60000) and VERTICALE MIS (D60005), needed for implantation.

Table of Content

1. Description

The VERTICALE® POSTERIOR SPINAL FIXATION SYSTEM consists of longitudinal rods, monoaxial screws, polyaxial screws, uniplanar screws, reduction screws, iliac screws, hooks and different connectors. All implants are available in various sizes to suit the individual pathology and anatomical conditions of the patient.

The VERTICALE® POSTERIOR SPINAL FIXATION SYSTEM implant components are compatible with VERTICALE MIS system as described in instrumentation guide (D60005) VERTICALE MIS.

The VERTICALE® MIS System comprises instrumentation that can be used for all VERTICALE® POSTERIOR SPINAL FIXATION SYSTEM pedicle screws. The VERTICALE® MIS System requires special rods for minimally-invasive use.

The Silony Medical VERTICALE® POSTERIOR SPINAL FIXATION SYSTEM and VERTICALE® MIS components are available in commercially titanium alloy conforming to ASTM F 136 specifications as well as rods in cobalt-chromium-molybdenum alloy conforming to ASTM F 1537.

Cobalt-chromium-molybdenum alloy rods are intended for use with components of titanium alloy.

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

2. Indications for use

The VERTICALE® System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The VERTICALE® system is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined 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 in skeletally mature patients.

When used in a posterior percutaneous approach with MIS instrumentation, the VERTICALE® MIS System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined 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 in skeletally mature patients.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the VERTICALE® and VERTICALE® MIS metallic implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach.

3. Contraindications

Under certain circumstances, implantation is prohibited or associated with substantial risks, even though there may be an indication for it.

These include in particular:

- Anticipated or documented allergy or intolerance to composite materials (e.g, titanium or cobalt chromium)
- Any case in which the chosen implants would be too large or too small to achieve a successful outcome
- Any patient for whom the use of the implant would conflict with anatomical structures
- Active systemic infection or infections localized to the site of the proposed implantation are contraindications to implantation.
- Osteoporosis is a relative contraindication because the missing bone structures that render good anchoring of the implant impossible and thus preclude the use of this or any other spinal instrumentation system.
- Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is a relative contraindication.
- Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.
- Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity.

In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.

4. Potential adverse events and complications

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional surgeries include: early and late infection, cross infection, damage to blood vessels, damage to spinal cord or peripheral nerves, epidural hematoma, pulmonary emboli, loss of sensory and motor function and permanent pain and deformity. Rarely some complications may be fatal.

Potential risks identified with the use of this system, which may require additional surgery, include:

- bending, fracture or loosening of the device, loss of fixation
- non or delayed union
- epidural hematoma, neurological, vascular or visceral injury
- metal sensitivity or allergic reaction to a foreign body
- decrease in bone density due to stress shielding
- discomfort or abnormal sensations due to the presence of the device
- nerve damage due to surgical trauma, neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia
- bursitis
- dural leak
- paralysis
- death
- vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period

- Screw back out, possibly leading to implant loosening, and or reoperation for device removal
- Damage to lymphatic vessels and/or lymphatic fluid exudation
- Spinal cord impingement or damage
- Fracture of bone structures
- Degenerative changes or instability in segments adjacent to fused vertebral levels

5. Warnings, Cautions and Precautions

General warnings and precaution

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 neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Warning: The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g, osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.

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.

Specific warnings and precautions

Following are specific warnings and precautions that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

The VERTICALE and VERTICALE MIS are intended for use only as indicated.

Single Use! Surgical implants must never be reused. The VERTICALE and VERTICALE MIS implants are delivered sterile and must not be reprocessed again. If the package is damaged or the expiry date is exceeded, the implant is unusable. Implants are for single use only and must not be reused and reprocessed after use in a patient and contamination with blood or tissue. An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage. Reuse of single use devices can also cause cross-contamination leading to patient infection.

Correct Handling of the implant is extremely important. Contouring of metal implants should only be done with proper equipment. Notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.

Correct selection of the implant is extremely important. The potential success depends directly on the right selection of the proper size of implant. While the right selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. An implant cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone.

Magnetic Resonance Imaging (MRI) Safety Information: The VERTICALE and VERTICALE MIS implants have 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 the VERTICALE and VERTICALE MIS implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Patient selection: following factors may be of importance to the potential success of the procedure:

- The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.
- The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
- A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
- Certain degenerative diseases. In some cases, the progression of a degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
- Foreign body sensitivity. The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
- Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

Caution must also be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials. These devices can break when subjected to the increased load associated with delayed union or nonunion.

Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

Patient Education: Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

Compatibility: Do not use the VERTICALE and VERTICALE MIS Systems with components of other systems. All implants should be used only with the appropriately designated instrument (reference instrumentation guides). All components should be final tightened per the specifications in the instrumentation guide.

Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices which are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

6. Preoperative Warnings

- Only patients that meet the criteria described in the indications should be selected.
- Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage, and from corrosive environments.
- Instruments are delivered non-sterile and should be cleaned and sterilized before use.
- Inspect all components for damage before use.
- Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

7. Post-operative warnings

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments. Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration as well as to other complications. To ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING.

If the device is not removed after the completion of its intended use, any of the following complications may occur:

- Corrosion, with localized tissue reaction or pain,
- Migration of implant position resulting in injury,
- Risk of additional injury from postoperative trauma,
- Bending, loosening, and/or breakage, which could make removal impractical or difficult,
- Pain, discomfort, or abnormal sensations due to the presence of the device,
- Possible increased risk of infection and
- Bone loss due to stress shielding.

The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low physical activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

8. Method of Use

The VERTICALE and VERTICALE MIS implants are for implantation. The VERTICALE and VERTICALE MIS implants should be used only with the appropriately designated instruments as referred in the instrumentation guides D60000 "VERTICALE® POSTERIOR SPINAL FIXATION SYSTEM" and D60005 "VERTICALE® MIS". The surgery must be precisely planned based on the X-ray findings. The X-ray images provide information about the suitable type of implant, its size and about possible combinations. For the surgical procedure, all possibly required implant types and components in the combination recommended by the manufacturer as well as the instruments needed for implantation must be available for the event that a different size or a different implant is required.

Prior to the surgery it must also be clarified whether that patient has an allergy to the implant material. Failure to perform adequate preoperative planning can lead to errors (e.g, with regard to misalignment, the choice of implant, and its size).

For the procedure of implantation of the device please refer to the Instrumentation guide for VERTICALE® POSTERIOR SPINAL FIXATION SYSTEM (D60000) and VERTICALE® MIS (D60005).

Cannulated screws can be implanted by use of guide wires with a diameter of 1.5 mm. During the surgical procedure, the rods may be cut to size and shaped to provide correction and maintain proper anatomic lordotic and kyphotic alignment. Protruding tabs of the head profile of the reduction screws are broken off by gently tilting them using the VERTICALE Break-Off Tool.

After solid fusion occurs, these devices serve no functional purpose and may be removed. In some cases, removal is indicated because the implants do not intend to transfer or to support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

9. Postoperative Mobilization

Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended. Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

10. Packaging

Packages for each of the components should be intact upon receipt. Implants are delivered sterile and should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to Silony.

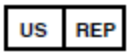
The contents are sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. Remove implants from packaging, using aseptic technique, only after the correct size has been determined.

11. Cleaning, Decontamination and Sterilization

VERTICALE implants are delivered sterile (gamma radiation sterilization, ISO 11137-2 VDmax 25) and must not be reprocessed.

All instruments of the VERTICALE and VERTICALE MIS system must first be thoroughly cleaned using the validated methods prescribed in the Silony Reprocessing guideline for VERTICALE instruments (D60007) before introduction into a sterile surgical field.

12. Glossary of Symbols

Symbol	Title of Symbol /Explanatory Text	Standard Reference
	Catalogue Number	ISO 15223-1, Clause 5.1.6
	Batch number	ISO 15223-1, Clause 5.1.5
	Use-by date	ISO 15223-1, Clause 5.1.4
	Manufacturer	ISO 15223-1, Clause 5.1.1
	U.S. Representative	ISO 15223-1, Clause 5.1.2
	Follow instructions for use	ISO 15223-1, Clause 5.4.3
	Attention – read instruction for use	ISO 15223-1, Clause 5.4.4
	Sterilized using irradiation	ISO 15223-1, Clause 5.2.4
	Do not re-use	ISO 15223-1. Clause 5.4.2
	Do not resterilize	ISO 15223-1, Clause 5.2.6
	Do not use if packaging is damaged	ISO 15223-1, Clause 5.2.8
	Keep dry / Keep away from rain	ISO 15223-1, Clause 5.3.4
	Keep away from sunlight	ISO 15223-1, Clause 5.3.2
CE 0483	The device complies with European Directive MDD 93/42/EEC	MDD 93/42/EEC
Rx only	Prescription Use Only	21 CFR 801.109