CENTRAFIX® MIDLINE FIXATION SYSTEM

IMPORTANT NOTE: The user of this system must read and acknowledge the conditions of this insert prior to use.

Consult the product electronic instructions for use for all current languages and latest document revision at corelinksurgical.com/ifu or by scanning the barcode on the product labeling.

DESCRIPTION

The CentraFix Midline Fixation System is an implant system used to provide temporary immobilization and stabilization of the thoracolumbar spine while fusion occurs. The CentraFix Midline Fixation System consists of screw shanks, tulip heads, rods, set screws and cross-connectors in various configurations which can be assembled to create a construct that meets the need of the patient. It can be used for single or multiple level fixation. Spinal rods may be contoured intraoperatively to meet specific anatomical requirements.

Implants in the CentraFix Midline Fixation System are manufactured from the following materials:

- Medical grade titanium alloy (Ti6Al4V as per ASTM F136).
- Medical grade cobalt-chromium-molybdenum alloy per (CoCr as per ASTM F1537).
- Medical grade nickel-titanium alloy (Nitinol as per ASTM F2063)

The screw shanks are anodized to facilitate size selection. Changes or variation in color during use or preparation do not affect implant quality.

Do not use any of the CentraFix Midline Fixation System components with components from any other manufacturer or system unless specifically allowed to do so in this or other CoreLink document. Implants in this system must never be reused under any circumstance. The CentraFix Midline Fixation System is provided with surgical instruments specifically for the implantation of the associated implants.

The CentraFix Midline Fixation System includes a variety of manual surgical instruments manufactured from surgical grade stainless steel as per ASTM F899.

The CentraFix Midline Fixation System Navigated Instruments are nonsterile manual surgical instruments that are intended to be used with the Medtronic StealthStation® System to assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures for preparation and placement of pedicle screw system implants. This surgical imaging technology provides surgeons visualization for complex and MIS procedures and confirms the accuracy of advanced surgical procedures. Use of these navigation systems provides the surgeon access to real-time, multi-plane 3D images (and 2D images) providing confirmation of hardware placement.

The CentraFix Midline Fixation System Navigated Instruments are comprised of Taps and Screwdrivers. The CentraFix Midline Fixation System Navigated Instruments were tested for compatibility utilizing the Medtronic Navigation StealthStation S8 with software version 1.2.0 (1.2.0-20), Violet, Orange, Green, and Gray Navlock Trackers (Part Numbers 9734682, 9734683, 9734734, and 9734590), Medtronic Navigation Instrument Drivers (Part Numbers 9735023, and NAV2019K) and the Navlock Small Passive Reference Frame (Part Number (9731478).

Use of the CentraFix Midline Fixation System Navigated Instruments are limited to Taps ranging in sizes of 4.5mm to 10.5mm and bone screws ranging from 4.5mm to 10.5mm with lengths ranging from 25mm to 110mm. For a complete listing of compatible implants and navigation instruments, please refer to the navigation instrument and implant compatibility table in the surgical technique guide.

INDICATIONS

The CentraFix Midline Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1 – S1/Ilium): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used for posterior non-cervical screw fixation in pediatric patients, the CentraFix Midline Fixation System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the CentraFix Midline Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, and fracture caused by tumor and/or trauma. Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

CoreLink Navigation Instruments are intended to be used during the preparation and placement of CoreLink screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System S8 (V1.2.0), which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

CONTRAINDICATIONS

Do not use the CentraFix Midline Fixation System in the presence of an active systemic infection or infections localized to the site of the proposed implantation. Other relative contraindications include:

- Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices.
- Severe osteoporosis as it may prevent adequate fixation of spinal anchors 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, osteopenia).
- Obesity.
- Certain degenerative diseases.
- Foreign body sensitivity.
- A 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, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.

COMPLICATIONS AND ADVERSE EFFECTS

Use and/or misuse of this system may result in the following list of complications and potential adverse effects:

- Loosening of any or all components.
- Disassembly, bending and/or breakage of any or all components.
- Inadequate fixation.
- Non-union, delayed union or mal-union.
- Allergic reaction to implant material, debris, corrosion products including metallosis, staining, tumor formation, and/or autoimmune disease.
- Infection.
- Wound healing disorders or hematomas.
- Fracture, damage, or penetration of any spinal bone.
- Post-operative change in normal spinal curvature, loss of correction, height.
- Pain, skin penetration, irritation, fibrosis caused by skin pressure by implant components.
- Bursitis.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone at, above, and/or below the level of surgery.
- Herniated nucleus pulposus, disc disruption or disc degeneration at, above or below the level of surgery.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of sensory and/or motor function including paralysis (complete/incomplete), dysesthesia, hyperesthesia, paresthesia, radiculopathy, pain, numbness, spasms, sensory loss, tingling sensation and/or visual deficit.
- Neuropathy, paraplegia, paraparesis, reflex deficit, irritation, neurological deficit (transient or permanent) and/or muscle loss.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Damage to the urological, gastrointestinal, and/or reproductive systems resulting in compromises including urinary retention, loss of bladder control, gastritis, bowel obstruction, loss of bowel control, sterility, consumption, sexual dysfunction etc.
- Decrease in bone density potentially caused by stress shielding.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Limited ability to perform daily activities.
- Continuation of symptoms that were to be treated for by the implantation.
- Change in mental status.
- Development of respiratory problems, e.g., pulmonary embolism, bronchitis, pneumonia, etc.
- Death.

Additional surgery may be required to correct these potential adverse effects and/or outcomes.

USE OF IMPLANT COMPONENTS

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.

Patients must be informed that implants cannot be made to last indefinitely, and the purpose of the implant is to provide temporary internal support while the fusion mass about the implant is developing. Without solid biological support provided by sufficient fusion mass, the implant components will fail in any of several modes. These modes may include bone-metal interface failure, implant fracture, or bone failure. Spinal implants of this type are more likely to fail if no bone graft is used, if a pseudarthrosis develops, or if patients have severe or multiple preoperative curves.

Spinal implants, like other implants or temporary internal fixation devices, have a limited life. The life of the implant is directly impacted by the level of activity of the patient. Inform the patient that any activity increases the risk that the implant components may become loose, bend, or break. Instruct patients about restrictions to their activity levels in the postoperative period. Examine patients postoperatively to evaluate the condition of implant components and the development of the fusion mass about the implant components. Instruct the patient that implant components may bend, break, or loosen even though restrictions in activity are followed and even if fusion mass about the implant component sufficiently develops.

This device is not intended or expected to be the only mechanism of support of the spine. Regardless of the spinal pathology for which implantation of this device was chosen, solid biological support is anticipated but is not always obtained. Without solid biological support

provided by bony fusion, the device cannot be expected to support the spine indefinitely and will lose effectiveness in any of several modes. These modes include, but are not limited to, bone-metal interface failure, rod fracture or deformation, and/or bone failure.

Spinal implants of this type may be removed after sufficient bone fusion develops. However, please inform the patient that a second surgical procedure may be necessary and that there are risks associated with a second surgical procedure. The decision to remove a broken implant must be made by the physician who must consider the risks associated with the presence of the broken implant and the condition of the patient.

Potential risks associated with the use of this system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, vascular or visceral injury, neurological complications, over-distraction, trauma to nerve root or dura, incorrect implant positioning, implant migration, pseudarthrosis, disc height loss, adjacent level disc degeneration, allergy or inflammation, general adverse effects related to surgical procedures (e.g. anesthesia, infection), subsidence, and expulsion. Risks and potential benefits must be provided to patients for whom this treatment modality is suggested.

This device must not be reused. Reuse may result in patient injury or other complications including but not limited to component fracture and/or deformation, breakage, difficulty with implantation, incompatibility with mating components and infection. It is the physician's responsibility to discard all damaged or mishandled implants.

Contouring or bending of an implant may reduce its strength from fatigue and cause its fracture or deformation. If spinal implants (including rods) are excessively bent, bent forward and then backward or otherwise damaged during insertion or adjustment, they may not be implanted and must be replaced. Rods must be contoured with the proper contouring instruments. Incorrectly contoured rods or rods which have been repeatedly or excessively contoured must not be implanted and are to be discarded. Refer to the CentraFix Midline Fixation System surgical technique manual for descriptions of appropriate bending instruments to be used with rods.

Internal fixation devices cannot withstand activity and loads equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant fracture or deformation may result.

Failure to verify a modular tulip head is secured onto a modular screw shank could compromise the mechanical stability of the construct. To prevent implant damage, do not mallet on the tulip head inserter to seat a tulip head onto a screw shank. Failure to reset the tulip head inserter indicator prior to tulip attachment will result in the inability to visually assess attachment and may result in an unstable construct.

This device contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy or hypersensitivity to these materials.

In addition to the warnings and precautions discussed above, the patient must be informed about general surgical risks prior to surgery.

PRECAUTIONS: The implantation of pedicle screw spinal systems is a technically demanding procedure that presents a risk of serious injury to the patient. Accordingly, such a procedure must be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system. The surgeon must be thoroughly knowledgeable in the medical and surgical aspects of the implant procedure, and the surgeon must be thoroughly knowledgeable of the mechanical and metallurgical limitations of the implant components. It is the surgeon's responsibility to ensure that the operating procedure is performed correctly. The Surgical Technique can be requested from CoreLink by calling the phone number at the end of this document. No manufacturer can be responsible for complications resulting from erroneous indication, wrong choice of implant size, incorrect operating procedure, and incorrect implant component combination. Internal fixation devices such as the CentraFix Midline Fixation System rely upon individual patient physiological response, and proper use of the device does not guarantee any result.

Use of the system off-label is forbidden by CoreLink.

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

USE OF NAVIGATION INSTRUMENTS

CAUTION: CoreLink is not a navigation provider. The navigation system must be set up per the manufacturer's instructions. The CentraFix Midline Fixation System Navigated Instruments have been validated for use with the third-party Medtronic StealthStation navigation system and software version 1.2.0 (1.2.0-20). Instructions for use and handling of third-party navigation systems are the responsibility of the hospital and navigation company. Refer to the navigation company's software and user guides for calibration and navigation guidance. Compatible third-party navigation clamps, reference frames, and arrays are listed in the Surgical Technique Guide. Ensure the hospital has the appropriate third-party navigation equipment prior to the surgical case. It is recommended to setup the operating room and instrument arrays such that camera view of all arrays remain uninterrupted at all times. A field assessment should be performed by positioning the navigation instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system. If the inputs result in the correct and anticipated outputs, functional verification is confirmed.
WARNING: Navigation instruments are highly accurate and sensitive medical devices that must be handled with extreme care. If you drop or otherwise damage it, do not use it in a surgical case. Any instrument that is suspected of being damaged, inaccurate, or cannot be registered or verified must not be used in a surgical case and must be returned to CoreLink immediately. Failure to do so may lead to serious injury to the patient. Additionally, all navigation instruments and StealthStation tracking instruments must be continuously verified for correct registration with the Stealth Station software. Positional accuracy must be continuously monitored intraoperatively. Immediately discontinue use of the navigation instruments if an inaccuracy is detected. Inaccuracy may also occur if bending or other alteration of the instruments occurs.

Only surgeons and medical personnel trained in the use of StealthStation navigation are to use the CentraFix Midline Fixation System Navigated Instruments when used with the StealthStation System.
Only the identified tool card is to be selected for each instrument to prevent patient injury from inaccurate navigation.
Only use the CentraFix Midline Fixation System Navigated Instruments with the software version of StealthStation System for which the instrument accuracy was validated to prevent patient injury from inaccurate navigation.
Note: For information on use of disposable reflective marker spheres, refer to navigation manufacturers' user guide.

PREPARATION AT THE POINT OF USE

The implants and instruments of the CentraFix Midline Fixation System are supplied non-sterile and must be thoroughly decontaminated, cleaned, and sterilized prior to surgical use. Instruments must be cleaned using the following validated methods before sterilization and introduction into the surgical field. Instrument sets are provided with a system specific tray suitable for transportation and steam sterilization. Remove all packaging that individual devices may be provided in prior to cleaning. Clean instruments may be placed in the supplied instrument tray, then into an approved sterilization wrap or container.

All instruments that are partially dismantlable must be disassembled prior to cleaning. This includes the following:

- Removal of all detachable handles from each instrument
- Removal of the inner sleeve from the drill guide
- De-coupling of the modular legs from the screw-to-screw distractor
- Implants disconnected from mating instruments

Failure to disassemble a soiled device may lead to inadequate reprocessing, which poses a risk of infection to patients. Instruments must be placed into their respective locations in the sterilization tray to ensure proper steam sterilization. Prior to use, instruments must be inspected for signs of wear, damage, corrosion, and proper function. This includes inspecting drills, taps and decorticators for wear and cutting flute damage, inspection of drivers and inserters to ensure correct and full engagement of implants, and inspection of lumens to ensure functional movement to allow for passage of set screw drivers and final locking drivers.

Do not use potentially defective instruments. If an instrument is suspected to be damaged it must not be used and CoreLink should be contacted for a replacement.

All instruments should be reassembled following cleaning, prior to sterilization. This includes the following:

- Reassemble the inner drill guide sleeve into the drill guide.

Follow the *Cleaning and Sterilization* procedures below.

CLEANING AND STERILIZATION

Instruments exposed to tissue must be thoroughly cleaned after use. Dried residues from surgery will make the cleaning process more difficult and/or ineffective. Maximum recommended time between use and cleaning is 4 hours. Instruments should not be exposed to elevated air temperatures (>100 °F). Certain cleaning solutions such as those containing fixatives, alcohols, aldehydes, chlorides, and/or excessive amounts of basic detergents can cause degradation of stainless-steel surfaces and laser marking. Use a cleaning and disinfecting agent that is compatible with aluminum, stainless steel, plastics, and silicone according to the manufacturer's instructions.

Manual Cleaning Instructions:

1. Completely submerge the instrument in a lukewarm neutral pH enzyme solution and allow it to soak for a minimum of 10 minutes. Use a soft-bristled brush to gently clean the instrument (particular attention must be given to crevices, cannulations, hinges, mated surfaces and other hard-to clean areas) until all visible soil has been removed. Brushing steps should be performed while submerged to prevent aerosols. A lumen brush must be used to clean cannulations. The enzyme solution should be changed on a regular basis in order to ensure its effectiveness.
2. Remove the instrument from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled). Thoroughly flush cannulations, holes, and other difficult to reach areas with a syringe or equivalent tool.
3. Prepare a neutral pH cleaning solution according to the manufacturer's instructions and place in an ultrasonic cleaning unit at 45-50 kHz to aid in thorough cleaning of devices
4. Completely submerge device in cleaning solution and sonicate for minimum of 14 minutes.
5. Rinse instrument in running purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least one minute. There must be no sign of detergent, blood, or soil in the rinse stream.
6. Dry the instrument with a clean, disposable, absorbent, lint-free wipe. Instruments that require reassembly should be done so after drying.
7. Visually inspect instruments to ensure they are clean and in working order. If the device is found to not be visually clean, the previous cleaning steps must be repeated. **NOTE:** Instrument cases, trays, and caddies must be thoroughly cleaned according to the above instructions. Inspect the containment devices and if found to not be visually clean, repeat the previous cleaning steps.

Automated Cleaning Instructions:

1. Rinse devices under running tap to remove gross soils. Particular attention must be given to crevices, lumens, mated surfaces and other hard-to-clean areas. Use a syringe or jetted water to flush difficult to reach areas.
2. Place instruments in a suitable washer basket and process through a standard instrument washer. The table below represents the minimum parameters required for proper cleaning and disinfection.

Typical Automated Washer Cycle for Surgical Instruments

Step	Description
1	2-minute prewash with cold tap water
2	1-minute enzyme spray with hot tap water
3	2-minute detergent wash with hot tap water (64-66°C/146-150°F)
4	15-second hot tap water rinse
5	2-minute thermal rinse (80-93°C/176-200°F)
6	10-second purified water rinse (64-66°C/146-150°F)
7	7 to 30-minute heated air dry (116°C/240°F)

Notes:
- The washer manufacturer's instructions should be strictly adhered to.
- Avoid impact, scratching, bending or surface contact with any material that might affect the implant surface or configuration.
- Pay particular attention to recesses as chemicals and rinse water may be entrapped in the recess after rinsing.
- Visually inspect all devices after cleaning to ensure cleanliness and function.

Sterilization Instructions
Implants and instruments of the CentraFix Midline Fixation System are provided non-sterile. The non-sterile condition is conspicuously set forth on the product label. Implants supplied non-sterile are clean. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components.

Sterilization: In a properly functioning calibrated steam sterilizer, testing has shown that effective sterilization to a 10^{-6} sterility assurance level (SAL) may be achieved as follows:

Sterilizer type:	Pre-vacuum
Temperature:	132°C (270°F)
Full Cycle Time:	4 Minutes
Minimum Dry Time:	30 Minutes (allow for cool-down)

Instruments and implants should be sterilized in the steam sterilization cases provided by CoreLink. Instrument and implant sets must be wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554 or similar wrap) using sequential envelope techniques. Only wraps validated to maintain sterility after processing are to be used. Saturated steam with a quality of 97-100% must be used.

REUSABLE RIGID STERILIZATION CONTAINERS

The CentraFix Midline Fixation System provided in a perforated steam sterilization case may be placed directly into Aesculap™ SterilContainers™. Testing has demonstrated the system, when processed in Aesculap SterilContainer systems JK440, JK442, JK444, JK446 rigid containers (with corresponding JK series lid and re-usable JK series filter assembly), can be sterilized to a 10^{-6} sterility assurance level (SAL) in a Dynamic Air Removal (pre-vacuum) steam sterilization cycle when processed using the required sterilization cycle.

Required Sterilization Cycle

Sterilizer type:	Pre-vacuum
Temperature:	132°C (270°F)
Exposure Time:	4 Minutes
Minimum Dry Time:	30 Minutes (allow for cool-down)

CoreLink does not recommend the use of gravity displacement steam cycles for sterilization in Aesculap rigid container systems. Ensure that the supplied reusable rigid sterilization container is in proper working order prior to sterilization. Aesculap SterilContainer System has been validated ONLY with Aesculap reusable filters. For more information on the use of the Rigid Sterilization Containers please consult the Instructions for Use of the Manufacturer (https://www.aesculapusa.com/products/instructions-for-use).

THE STERILIZATION PARAMETERS PROVIDED IN THIS INSTRUCTIONS FOR USE SUPERCEDE THOSE LISTED IN THE AESCULAP INSTRUCTIONS FOR USE. ALL OTHER USAGE, CARE AND MAINTENANCE INSTRUCTIONS SPECIFIED IN AESCULAP DOCUMENTATION REMAIN APPLICABLE.

It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the US FDA for the selected sterilization cycle.

Flash sterilization of the CentraFix Midline Fixation System is not recommended.

MAINTENANCE OF TORQUE WRENCH

Calibration: Regular calibration ensures the torque wrench performs according to its specifications. To ensure that the torque wrench operates properly and safely at all times, CoreLink recommends that the torque wrench be calibrated every six (6) months, after 200 autoclaves cycles, or approximately 3000 actuations (clicks), whichever comes first. Heavy use applications may require more frequent calibration. If at any time a device seems to be malfunctioning, remove it from service and return to CoreLink immediately for replacement or calibration.

IMPORTANT CONSIDERATIONS AND WARNINGS

1. **Corrosion from Mixed Metals.** Damage from corrosion may occur following surgical implantation of metals. All implanted metals and alloys display general or uniform corrosion, and the rate of corrosion implanted metals and alloys is typically low due to the presence of passive surface films on the implanted metals and alloys. The CentraFix Midline Fixation System implants are available in titanium alloy and cobalt chrome alloy. It is imperative that the CentraFix Midline Fixation System implants do not come into contact in-vivo with other dissimilar metals. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment. Corrosion may accelerate failure of implants. Corrosion also causes metal compounds to be released into the body.
2. **Failure of Implants Due to Excessive Demands in Connection with Delayed Union or Nonunion.** Implants of this type are temporary devices that are used to obtain alignment until normal healing occurs and bone fusion mass is developed. If healing is delayed, or does not occur, the implant may fail over time due to metal fatigue. The useful life of the implant will be in part affected by the degree or success of implant to bone union, loads produced by weight bearing, and activity levels. The useful life of the implant will be also in part affected by notches, scratches or bending of the implant which may occur during the surgical procedure. Please inform patients of the risks of implant failure.
3. **Implant Selection.** Appropriate implant selection, placement, and fixation are critical factors that affect implant life. Strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to maximize implant longevity. Implants cannot withstand activity levels equal to those placed on normal healthy bone. As mentioned above, implants of this type are temporary and should not be expected to withstand indefinitely the unsupported stress of full weight bearing. Care must be taken to protect the components from being marred, nicked, or notched. Alterations will product defects which may become the point for eventual implant breakage. Inspection and trial assembly are recommended to determine proper working order of the system. If any components are damaged in any way, do not use them and return them to CoreLink.
4. **Patient Considerations.** The following must be considered when evaluating whether a patient is a candidate for such a procedure.
   - **Weight.** An overweight or obese patient can produce loads on the device that may lead to failure of the implant component.
   - **Lifestyle 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 after the bone is fully healed, the patient may not be able to resume these activities.
   - **Alcoholism, Drug Abuse or Mental Conditions.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions leading to implant failure or other complications.
   - **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 implant component. In these cases, the use of the implant may only postpone potential outcomes and/or be of a temporary nature.
   - **Implant Sensitivity.** No preoperative test can completely exclude the possibility of sensitivity or allergic reaction. A patient may develop sensitivity or allergy after implants have been in the body for a period of time.
   - **Smoking.** Smoking has been linked to a higher rate of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Smoking can also lead to progressive degeneration of adjacent segments and late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

ADDITIONAL PRECAUTIONS

- **Patient Instructions.** Instructions for the patient's postoperative care, and the patient's ability and willingness to follow such instructions are extremely important for successful bone healing. In addition to the instructions described previously, instruct the patient on the limitations of the implant, and to limit and restrict physical activities, especially lifting and twisting motions and sports-related activities. Inform the patient that an implant is not as strong as normal healthy bone, and that the implant could loosen, bend, and/or break if excessive demands are placed on the implant, especially in the absence of complete bone mass fusion. Inform the patient that improper activities may cause the implants to become displaced or damaged and cause the implant to migrate and damage nerves or blood vessels. As mentioned above, a patient having certain conditions, such as alcoholism, drug abuse, or other mental conditions may not properly use weight-supporting devices and may be particularly at risk during postoperative rehabilitation.
- **Implant Location.** Because vascular and neurological structures are located near to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage during and after implantation procedure. Serious or fatal hemorrhage may occur if: (i) the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage or migration of implants; or (ii) pulsatile erosion of the vessels occurs due to the placement of the implants adjacent to the vessels.
- **Implant Removal.** Spinal implants of this type may be removed after sufficient bone fusion develops. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. When the implant is removed, the surgeon should provide postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery. If the device is not removed after sufficient bone fusion develops the following may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Possible increased risk of infection; (3) Bone loss due to stress shielding (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Migration of implant position resulting in injury ; and (7) Risk of additional injury from postoperative trauma.
- **Do Not Reuse Implants.** An implant previously implanted must never be reused. An implant previously implanted may have small defects that are not readily visible that may lead to early breakage, and compromise device performance and patient safety. Reuse may also lead to cross contamination and patient infection.

POSTOPERATIVE IMMOBILIZATION
Until X-rays confirm the development of a fusion mass, external immobilization (such as bracing or casting) is recommended.

Please inform the patient to reduce stress on the implants in order to reduce the risk of complications from fixation failure.

CAUTION: Under federal law, this device may only be sold by or on the order of a physician.

LIMITED WARRANTY AND DISCLAIMER

CORELINK PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION OF THIS INSERT AND THE DATE OF CONSULTATION, CONTACT CORELINK CUSTOMER SERVICE FOR CURRENT INFORMATION AT 888-349-7808.

The Aesculap SterilContainer System is FDA 510(k) cleared under K792558, K053389, K040865, K093493, K093649, K041623, and K073168. All third-party trademarks used herein are the trademarks of their respective owners. Aesculap and SterilContainer are trademarks of Aesculap, Inc., a B. Braun Company. StealthStation and NavLock are registered trademarks of Medtronic Navigation, Inc.

For further information contact:

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SYMBOLS GLOSSARY

Symbol	Description	ISO 15223 Reference
	Prescription Required – Federal Law restricts this device to sale by or on the order of a licensed practitioner.	N/A
	Reference Number – Indicates manufacture's catalogue number so that the medical device can be identified	5.1.6
	Lot Number – Indicates the manufacture's batch code so that the batch or lot can be identified.	5.1.5
	Non-Sterile – Indicates a medical device that has not been subject to a sterilization process.	5.2.7
	Do not re-use - Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
	Consult instructions for use - Indicates the need for the user to consult the instructions for use.	5.4.3
	Caution – Indications the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4