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GII spinal fixation system – Instruction For Use

US GII spinal fixation system IFU 2020-05-20

Symbols used in coLigne labeling

Symbol	Standard	Ref no	Title	Meaning
	ISO 15223-1:2016 - Symbols to be used with medical device labeling and information to be supplied – Part1: General requirements	5.4.4	Caution	Attention, see instructions for use
		5.4.2	Do not re-use	Single use
		5.1.6	Catalogue number	Reference number
		5.1.5	Batch code	Lot number
		5.2.7	Non-sterile	Non-sterile
		5.1.1	Manufacturer	Manufacturer
			Prescription	Physician's prescription required

Caution

Federal law (USA) restricts these devices to sale by or on the order of a physician. These devices should be implanted only by a physician who is fully trained with the devices, intended use, instrumentation and with knowledge of the surgical techniques required. Contact your coLigne representative for surgical technique.

Important note to operating surgeon

The coLigne GII spinal fixation system is designed to aid in the surgical correction and stabilization of the spine during the development of a solid fusion mass. The system is intended to be used only in the thoracic, lumbar and sacral levels of the posterior spine.

Pedicle fixation should only be undertaken after the surgeon has had hands on training in this method of pedicle fixation and has become thoroughly knowledgeable about spinal anatomy and biomechanics.

Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential adverse effects of the sur- gery. The patient should be instructed to limit postop- erative activity, as this will reduce the risk of bending, breaking or loosening the implant components.

The patient must be made aware that implant compo- nents may bend, break or loosen even though restrictions in activity are followed.

Postoperative evaluation of the fusion and implant sta- tus is necessary. The surgeon should consider removing the implant once a solid fusion is obtained. The patient must be informed of the potential of this secondary surgical procedure and the associated risks.

Description

The coLigne GII spinal fixation system consists of a variety of plates, connectors, screws, optional washers, hooks, nuts, rods and transverse connectors.

Special self-breaking nuts are provided for plate or rod/connector/screw fixation. Always tighten until the upper part of the nut breaks off to leave the assembly at optimum fixation security. The head part should not remain in the patient. After the upper part of the self- breaking nut or screw has been sheared off, further re-tightening is not advised. The fixation nut must be removed and totally replaced if any subsequent re-adjustment is necessary.

The coLigne GII spinal fixation system contains components which are intended to be used only with coLigne system parts. They should not be mixed with any other instrumentation, since other fixation systems may not be compatible nor guaranteed.

Device specific instruments should be used during implantation. Instruments required to retrieve the device are also available. The system components are temporary devices and should be considered for removal following fusion..

Implant materials

The implants are made of ostaPek® (Long Carbon Fiber Reinforced Polymer, LCFRP) with radiographic markers in gold, or titanium forging alloy (ISO 5832-3). Improper combinations of implant components and materials can have detrimental effect on the mechanical function and longevity of the implant. It is important that mechanical fit and metallurgical compatibility be considered in selecting mating components. Further information on the chemical composition and the mechanical properties of the materials is contained in the corresponding material catalogue sheet or in the corresponding product information, which may be obtained from the local representatives.

Indications for use

The GII spinal fixation system when used as a pedicle screw system in the non-cervical posterior spine, the GII spinal fixation system is to be used in skeletally mature patients as an adjunct to fusion using autograft and/or allograft for one or more of the following:

(1) Degenerative or severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar/first sacral (L5-S1) joint with objective evidence of neurologic impairment,

(2) Fracture,

(3) Dislocation,

(4) Scoliosis,

(5) Kyphosis,

(6) Spinal tumor, and/or

(7) Failed previous fusion (pseudoarthrosis).

The GII spinal fixation system when used as a hook and sacral/iliac screw fixation system in the non-cervical posterior spine, the GII spinal fixation system is to be used in skeletally mature patients as an adjunct to fusion using autograft and/or allograft for one or more of the following:

(1) Degenerative spondylolisthesis with objective evi- dence of neurologic impairment,

(2) Fracture,

(3) Dislocation,

(4) Scoliosis,

(5) Kyphosis,

(7) Spinal tumor, and/or

(8) Failed previous fusion (pseudoarthrosis).

Contraindications

This device is not intended for cervical spine use. Other contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of malignant tumors or severe congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC), or a marked left shift in the WBC differential count.
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and the amount of mechanical fixation.
9. Suspected or documented metal allergy or intoler- ance.
10. Any case not needing a bone graft and fusion.
11. For pedicle screw cases, missing or deformed lumbar pedicles.
12. Any case requiring the mixing of metals from two different components.
13. Any patient having inadequate tissue coverage over the operative site.
14. Any case not described in the indications.
15. Any patient unwilling to cooperate with the post- operative instructions.
16. Use of this type of surgical implant surgery in children or pediatric patients presents particular risks because of bone growth or physical movement. Subse- quent re-intervention may be required.
17. Infants with a known hereditary or acquired bone friability or calcification problem, or those with a very short life expectancy, should not be considered for this type of surgery.
18. Any patient in which implant utilization would inter- fere with anatomical structures or expected physiological performance.

Contraindications of this device are consistent with those of other spinal rod systems. This spinal implant system is not designed, intended, or sold for uses other than those indicated.
See also the warnings, precautions and possible adverse affects sections of this insert.

Warnings

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

- Device component fracture,
- Metallosis,
- Loss of fixation,
- Non-union,
- Fracture of the vertebra,
- Neurologic injury, and
- Vascular or visceral injury.

See the warnings, precautions, and potential adverse events sections of the package insert for a complete list of potential risks.

Precautions

1.Implant selection. The coLigne GII spinal fixation system is available in a variety of sizes to insure proper sizing of implanted components. The potential for the success of the fusion is increased by selecting the correct size and shape of the implant. Undersiz- ing of implants can lead to premature failure of the component. These devices are not intended to be used as the sole support for the spine.

2. Delayed union or nonunion. The coLigne GII spinal fixa- tion system is designed to assist in providing an ad- equate biomechanical environment for fusion. It is not intended to and must not be used as the sole support for the spine. If a delayed union or nonunion occurs the implant may fail due to metal fatigue. Patients should be fully informed of the risk of implant failure.

3. Mixed metals. The coLigne GII spinal fixation system is available in titanium alloy and ostaPek®. It is imperative that this metal materail does 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.

4. Patient selection. Proper patient selection is critical to the success of the procedure. Only patients who satisfy the criteria set forth under the indications section of this document and who do not have any of the condi- tions set forth under the contraindications section of this document should be considered for pedicle fixation surgery using the coLigne GII spinal fixation system.
The benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines. In addition, patients who smoke have been shown to have an increased incidence of pseudarthrosis.

5. Single use only. These devices are provided as single use only implants and are not to be reused or reim- planted regardless of an apparent undamaged condition.

6. Patient education. Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential adverse effects 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 restriction in activity are followed.

Possible adverse events

Potential risks identified with the use of this system, which may require additional surgery, include but are not limited to:

1. Early or late bending, fracture or loosening of implant component(s).
2. Nonunion, delayed union (or pseudoarthrosis).
3. Implant migration.
4. Disassembly, bending, loosening, slippage, and/or breakage of any or all of the components or instru- ments.
5. Decrease in bone density or fracture of the vertebra due to, for example, stress shielding.
6. Metal sensitivity, allergic reaction and/or foreign body reaction to the implants including possible tumor formation, autoimmune disease, metallosis, and/or scarring.
7. Infection.
8. Pressure on the skin possibly resulting in skin breakdown from component parts where there is inadequate tissue coverage over the implant. Implant or graft extrusion through the skin. Wound complications.
9. Loss of proper spinal curvature, correction, height, and/or reduction.
10. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis or other types of serious injury. Cerebral fluid leakage.
11. Gastrointestinal, urological, and/or reproductive system compromise, including sterility. Impotency.
12. Hemorrhage of blood vessels and/or hematomae. 13. Cessation of growth of the fused portion of the spine.
14. Discitis, arachnoiditis, and/or other types of inflam- mation.
15. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
16. Bone graft donor site complications.
17. Inability to resume activities of normal daily living.
18. Death.

Storage and handling of implants and instruments

Implants are extremely sensitive to damages. Every small scratch or mark of impact on the surfaces can cause excessive wear and can give rise to complications. Extremely careful handling is strongly recom- mended. Implants must be stored in the original packaging, unopened. If a loaner or consignement set is used it should be checked for completeness. All items should be checked to ensure functionality and maintenance status prior to use. Damaged, expired of non functioning implants should not be used and must be return to the responsible local representative for repair or replacement. For additional information refer to the coLigne guidelines for maintenance, cleaning and sterilization of implants and instruments.

The instruments are subject to a certain degree of wear and have to be considered non-durable materials. Before use, they must be checked for correct functioning, and, if necessary, they must be returned to the responsible local representative for repair or replacement.

Limited warranty

coLigne AG products are sold with a limited warranty to the original purchaser against defects in work- manship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

MRI compatibility
GII spinal fixation system has not been evaluated for safety and compatibility in the MR environment. GII spinal fixation system has not been tested for heating, migration, or image artifact in the MR environment. The safety of the GII spinal fixation system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

See also the warnings, precautions and possible adverse affects sections of this insert.

Note
Additional surgery may be necessary to correct some of these anticipated adverse reactions.

Reprocessing (Cleaning, Decontamination and Sterilization)

The GII spinal fixation system implant is supplied clean and not sterile. All implants and instruments should be cleaned and sterilized prior to surgery according to the method described in this instruction for use:

Warnings on reprocessing	Coligne has validated this method but equipment, operators, cleaning agents and procedures all contribute to the efficacy of the processing. The hospital or health care facility should ensure that the selected processing steps are safe and effective. Alternative methods of processing outside the scope of this document may be suitable for reprocessing; however, the end user must validate them. In case of inability to follow these instructions the effectiveness and the potential adverse consequences should be evaluated. For all instruments a manual pre-cleaning prior to automated cleaning is required. During cleaning pay close attention to devices with tubes, hinges, retractable features, matted surfaces, and textured surfaces and finishes. Hypochlorite solutions should not be used in order to avoid corrosion. The quality of the water used should be carefully considered. Mineral residues from hard water, as well as higher contamination with microorganisms and endotoxins can result in staining of the device or prevent effective cleaning and decontamination. New devices or items received not directly from surgery must be removed from their packaging where applicable and processed starting from reprocessing step: *3- Preparation for cleaning* before use. Coligne does not recommend reprocessing of soiled implants as they are single use. The temperature must not exceed 140°C in any of the reprocessing steps.
Limitations on reprocessing	End of life of a device is normally determined by wear and damage due to use and not reprocessing. To minimize risks to the end user, Coligne devices must be inspected carefully. Evidence of damage and wear (corrosion, discoloration, excessive scratches), improperly functioning devices and devices with unrecognizable markings should not be used and returned to Coligne AG for repair or refurbishment.

Reprocessing instructions

Step	General instructions	Specific instructions for Instruments	Specific instructions for Implants
1 - Point of use	Keep unused implants and instruments separated from equipment in use.	Wipe blood and/or debris from instruments throughout surgical procedure to prevent it from drying onto the surface. Instruments should be cleaned as soon as possible after use. If cleaning is to be delayed, instruments should be covered with a towel dampened with sterile or purified water to prevent blood and/or debris from drying. Excessive soil on the instruments should be removed with a disposable wipe. To minimize the chance of corrosion; keep instruments away from prolonged exposure to saline solutions.	Implants are single use. Unused implants can be repeatedly reprocessed, but Coligne does not recommend reprocessing of soiled implants.
2 - Transportation	Soiled devices should be transported separately from non-contaminated devices in closed or covered containers to prevent and avoid contamination.	Pay particular attention to cutting edges, both to avoid personal injury and prevent damage to the Instrument.	No specific instructions for Implants
3 - Preparation for cleaning	no general instructions	All used instruments must be unloaded from the dedicated spots in the tray. Multi-component instruments shall be disassembled for appropriate cleaning. The disassembly is generally self-evident to trained personnel or Coligne AG provides specific instructions.	Implants can be kept in the dedicated fixtures throughout the reprocessing cycle, where applicable.

Step	General instructions	Specific instructions for Instruments	Specific instructions for Implants
4 - Precleaning	no general intructions	Delicate instruments must be cleaned separately from other instruments. Rinse the devices carefully with cold tap water. Soak the instruments for at least 10 minutes in an enzymatic cleaner or neutral detergent with a pH between 7 and 9 prepared according to the manufacturer instructions. Use a soft bristle brush to remove all traces of blood and debris; special attention should be given to textured surfaces, any hard to reach areas, or crevices. If the instrument belongs to any instrument category specified below (A or/and B) follow those additional steps. Rinse the devices carefully with warm (30° C. to 40° C.) tap water until no visible contamination remains.with a minimum rinse time of 30 seconds. Visually inspect devices. Repeat the pre-cleaning procedure until no visible soil remains on device **Category A - Instruments with cannulations or lumens (i.e. tubes), or holes** Use a tight-fitting, soft, non-metallic cleaning brush or pipe cleaner to scrub the cannula, lumen, or hole. Adapt the size of the brush to the cannula/lumen of the diameter instrument. Push out, using a twisting motion to remove debris. To reach internal areas, use a syringe filled with enzymatic cleaning solution. Pay specific attention to flush the cannulations, lumens, or holes with warm tap water when rinsing. **Category B - Articulating instruments (with moveable parts)** Actuate any moveable mechanism, such as hinged joints, box locks, or spring-loaded features, to free trapped blood and debris. Retract or open part of the instruments that can be retracted, while cleaning the area. Pay specific attention to internal areas and moveable parts when rinsing. Actuate moveable parts while rinsing. Retract or open any part of the instruments that can be retracted, while rinsing the area. Use a syringe or water jet for to reach and difficult areas.	Precleaning is not required for implants.
5 - Automated cleaning and disinfection	A validated, calibrated and properly maintained Washer-Desinfector in accordance with ISO 15883-1 or FDA approval with a thermal disinfecion program with A0 value > 3000 and drying program must be used. Follow the Washer/disinfector manufacturer's instructions for loading the devices and for the cleaning agent intended for use in washer-disinfector. Do not exceed the concentration and temperature recommended by the detergent manufacturer.	Instruments should be loaded disassembled in such a way that cannulations and holes can drain and hinges are open. Avoid contact between devices as movement could cause damage/washing action obstructed. Heavier instruments should be placed on the bottom of containers and should never be placed on top of delicate instruments. To facilitate draining, place instrument with the concave surface facing downward where applicable.	Implants can be kept in the dedicated fixtures throughout the reprocessing cycle, where applicable.

Step	General instructions	Specific instructions for Instruments	Specific instructions for Implants
6 - Inspection and functionality check	All devices should be visually inspected before sterilization to ensure the complete removal of soil. Re-clean the devices if soil is still present.	For difcult to view design features, such as cannulation, apply 3% hydrogen peroxide. Bubbling is indicative of the presence of blood. Note: Rinse the instruments thoroughly with warm water following hydrogen peroxide testing. Repeat cleaning if not visibly clean and re-inspect. Inspect the instruments for functionalty, damage and wear:. Pay special attention to inspection of instrument features described in **category A** or **B** above, and ensure that: – Jaws and teeth should align properly . – Moveable parts should have smooth movement without excessive play. – Cutting edges should have a continuous edge, no distortion and be free of nicks. – Locking mechanisms should fasten securely and close easily. – Long, thin instruments should be free of bends and distortion. – Mating parts should fit together witout complications. – Hammering surfaces should be free of burrs and large nicks. – Metal surfaces should be free of corrotion and major deformation – Plastic ends should be free of cracks and large nicks. Devices should not be used if they are damaged, worn, improperly functioning, with unrecognizable markings, or with missing part numbers. If any such devices are found, contact Coligne or local representative for further instructions. Medical grade lubricating oil suitable for steam sterilization should be applied on movable parts to ensure smooth operation. Follow manufacturers instructions.	no specific instructions for Implants
7 - packaging	Arrange all devices in their dedicated trays to allow maximum access of steam to all surfaces, where applicable. The trays should be double wrapped according to technique described in AAMI ST79. Single devices may be package in an approved medical grade sterilization pouch. The packaging and wrapping for terminally sterilized devices should meet the following requirements: – Suitable for steam sterilization – ISO 11607-1 – FDA clearance for the cycle proposed below. – Grade appropriate for weight of instrument case.	Re-assemble multi-component instruments. Instruments can be sterilized in a general tray if no dedicated tray is available.	Implants should be sterilized in their dedicated trays, where applicable. If no dedicated trays are available implants should be sterilized individually in approved medical grade sterilization pouches.

Step	General instructions	Specific instructions for Instruments	Specific instructions for Implants
8 - Sterilization	A validated, calibrated and properly maintained steam sterilizer in accordance with ISO 17665 or AAMI ST79 must be used. Use the following cycles for effective steam sterilization: Cycle type: Pre-vaccum Minimum temperature: 270°F (132°C) Minimum exposure time: 4 min Minimum drying time: 30 min Do not stack device cases in the sterilizer. When sterilizing multiple sets in one autoclave cycle ensure the maximum load stated by the equipment manufacturer is not exceeded.	no specific instructions for Instruments	no specific instructions for Implants
9 - Storage	Store and transport sterile medical devices in a way to maintain sterility integrity. Protect the wrapped devices from contamination by additional covering. Do not use the devices if the sterilization wrap is open, damaged or wet. Sterile packaged instruments must be stored in a way that provides protection from dust, moisture, insects, vermin, and extremes of temperature and humidity.	no specific instructions for Instruments	no specific instructions for Implants

Manufactured by

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