Coligne AG, Utoquai 43, CH-8008 Zurich, Switzerland
Tel +41 43 343 80 00, Fax +41 43 343 80 09, info@coligne.com, www.coligne.com

ACIF – Instruction For Use

US ACIF IFU 2017-09


Attention, see instructions for use


Single use

Reference number

Lot number

Non-Sterile


Manufacturer

Symbols used in coLigne labeling

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 ACIF system are designed to assist in providing an adequate biomechanical environment for fusion and must be used in association with a complementary bone graft. Without a complementary graft its use may not be successful, as the cage serves as a mechanical strut for a temporary period while the surrounding bone heals and carries the spinal load. ACIF surgical procedure should only be undertaken after the surgeon has had hands on training in this method, 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 surgery. The patient should be instructed to limit post-operative activities as this will reduce the risk of bent, broken or loose implants. The patient must be made aware that implants may bend, break or loosen even though restrictions in activity are followed. Postoperative evaluation of the fusion and implant status is necessary. After the fusion, implant has not to be removed.

Description

The coLigne ACIF system consists of one and/or more ostaPek® cage(s) in a variety of sizes and is available for anterior cervical approach. Instruments required to implant the device are also part of the system. The system implants should not 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.

Indications for use

The ACIF system is indicated for use as an intervertebral body fusion device in skeletally mature patients at one or two contiguous levels of the cervical spine (C2-T1) to facilitate fusion in case of degenerative disc disease (DDD) defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The ACIF implants are placed via an anterior approach using autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft. The ACIF implants are to be used with supplemental fixation. Patients should have at least six weeks of non-operative treatment prior to surgery.

Contraindications

Any condition that precludes the possibility of fusion is relative contraindication for the use of the coLigne ACIF system. This includes but is not limited to:

1. Active infections or high risk of infection,
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 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 and osteopenia are a relative contraindication: they may limit the degree of obtainable correction and the amount of mechanical fixation.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion.
11. Any case in which a wrong selection of the implants size to use is performed.
12. Any case of mixing implants belonging to systems not cleared by coLigne.
13. Any patient having inadequate tissue coverage over the operative site.
14. Any patient unwilling to cooperate with the post-operative instructions.
15. Use of this type of surgical implant surgery in children or pediatric patients presents particular risks because of bone growth or physical movement. Subsequent re-intervention may be required.
16. 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.
17. Substance abuse or senility that precludes the patient from following post operative precautions to prevent implant failure.
18. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
19. This spinal implant system is not designed, intended, or sold for uses other than those indicated.
20. Spondylolisthesis unable to be reduced to Grade 1

The following are specific warnings, precautions, and adverse effects, which should be understood by the surgeon and explained to the patient. General surgical risks should be explained to the patient prior to surgery.

Warnings

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

1. System components fracture,
2. Loss of fixation,
3. Non-union,
4. Fracture of the vertebra,
5. Neurologic injury, and
6. Vascular or visceral injury.
7. The risk of device expulsion and migration is higher without the use of supplemental fixation.

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

Precautions

1. Implant selection. The coLigne ACIF implants are 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. Undersizing of implants can lead to premature failure or migration of the implant.

2. Delayed union or nonunion. The coLigne ACIF system is designed to assist in providing an adequate biomechanical environment for fusion. If a delayed union or nonunion occurs the implant may fail due to fatigue. Patients should be fully informed of the risk of implant failure.

3. 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 conditions set forth under the contra-indications section of this document should be considered for surgery using the coLigne ACIF system. The benefit of spinal fusions 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. Patients should be advice and informed about the possible consequences.

4. Single use only. Implants are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.

5. Handling. Implant components should be handled and stored appropriately to protect them from unintentional damage. The surgeon should avoid introducing notches or scratches into the cage surface as these may induce premature failure of the component. Care must be taken when placing a cage to avoid damage.

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 implants. The patient must be made aware that implants may bend, break or loosen even though restrictions 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. Bending, fracture or migration of implant(s).
2. Nonunion or delayed union (or pseudoarthrosis).
3. Fracture of the vertebra.
4. Disassembly, bending, loosening, slippage, and/or breakage of instruments peroperatively.
5. Scar formation leading to neurological compromise, nerve compression, or pain
6. Decrease in bone density, resorption,fracture of the vertebra and/or of the bone graft, at, above or below the treated level, due to, for example, stress shielding. Retropulsed graft.
7. Hernia or any disc diseases at, above or below the treated level.
8. Infection.
9. Wound complications.

10. Loss of proper spinal curvature, correction, height, and/or reduction.
11. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular deficits (temporar or permanent) including paralysis or other types of serious injury. Cerebral fluid leakage, meningitis.
12. Gastrointestinal, urological, and/or reproductive system compromise, including sterility. Impotency.
13. Hemorrhage of blood vessels and/or hematomae.
14. Cessation of growth of the fused portion of the spine.
15. Discitis, arachnoiditis, and/or other types of inflammation.
16. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus. Respiratory complications.
17. Bone graft donor site complications.
18. Inability to resume activities of normal daily living. Loss or increase of mobility or function.
19. Change in psychological status.
20. 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 recommended. 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 workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

MRI compatibility

The coLigne ACIF system has not been evaluated for safety and compatibility in the MR environment. The coLigne ACIF system has not been tested for heating, migration, or image artifact in the MR environment. The safety of coLigne ACIF 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 coLigne ostaPek® interbody fusion cage 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. Coligne equipment is not normally used in surgical procedures where they contact TSE infective tissue (Transmissible Spongiform Encephalophaties). The parameters recommended in this document are not intended and may not be suitable for inactivation of prions. Under specific classifications of risk, consult the World Health Organization (WHO) or local authorities for recommendations regarding special CJD inactivation processing procedures. 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

Step	General instructions	Specific instructions for Instruments	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.
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	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.	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
	exceed the concentration and temperature recommended by the detergent manufacturer.	To facilitate draining, place instrument with the concave surface facing downward where applicable.	
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 for terminally sterilized devices should meet the following requirements: – Suitable for steam sterilization – ISO 11607-1 – FDA clearance for the cycle 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

coLigne AG, Utoquai 43, CH-8008 Zurich

Phone +41 43 343 8000, Fax +41 43 343 8009
info@coligne.com, www.coligne.com

US representative

coLigne USA, 1951. 33rd Street, 80 301 Boulder (CO)
Phone +1 303 444 59 72, Fax +1 303 541 94 24