COVISION
ORTHOPAEDICS

IMPORTANT MEDICAL INFORMATION
COVISION KNEE SYSTEMS

IMPORTANT NOTE:

The COVISION Knee system (Superica;St. Leger Neo; Reflecto Revision Knee, Ancale) is a reconstructive knee system intended for patients in Adult / skeletally mature patients suffering from pain and/or deformity of the knee joint.

DESCRIPTION OF THE SYSTEMS:

COVISION manufactures these Knee Systems in a variety of sizes to accommodate differing surgeon and patient requirements.
Description of the component material is provided on the labels
Each Knee Component is designed as part of a system and does not allow the substitution of components from other systems or manufacturers. All implantable devices are designed for Single-Use only.

Indications:

St.Leger neo Knee System is indicated for use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:
1) Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) inflammatory degenerative joint disease including rheumatoid arthritis;
3) correction of functional deformity;
Superica Knee System is indicated for use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:
1) Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) inflammatory degenerative joint disease including rheumatoid arthritis;
3) correction of functional deformity;
Ancale Knee System is indicated for use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:
1) Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) inflammatory degenerative joint disease including rheumatoid arthritis;
3) correction of functional deformity;
Refecto Revision Knee System indicated for use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:
1) Failed osteotomies, unicompartmental replacement, or Primer total knee replacement.
2)Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
3) inflammatory degenerative joint disease including rheumatoid arthritis;

POSSIBLE ADVERSE EFECTS:

The general principles of good patient selection and sound surgical judgment apply to the total knee procedure. Preoperative planning and meticulous surgical technique are essential to achieve optimum results. Considerations of anatomic loading, soft-tissue condition, and component placement are critical to minimize a variety of postoperative complications.

1. Osteolysis (progressive bone resorption). Osteolysis can be asymptomatic, and therefore, routine periodic radiographic examination is vital to prevent any serious future complication
2. Particulate generation leading to increased wear rates necessitating early revision. Soft tissue imbalance leading to excessive wear;
3. Allergic reactions to materials; metal sensitivity that may lead to histological reactions;
4. Delayed wound healing; deep wound infection (early or late) which may necessitate removal of the prosthesis. On rare occasions, arthrodesis of the involved joint or amputation of the limb may be required;
5. A sudden drop in blood pressure intra-operatively due to the use of bone cement;
6. Damage to blood vessels or hematoma;
7. Temporary or permanent nerve damage, peripheral neuropathies and subclinical nerve damage as possible result of surgical trauma resulting in pain or numbness of the affected limb;
8. Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
9. Dislocation, migration and/or subluxation of prosthetic components from improper positioning, trauma, loss of fixation and/or muscle and fibrous tissue laxity;
10. Periarticular calcification or ossification, with or without impediment to joint mobility;
11. Varus-valgus deformity;
12. Traumatic arthrosis of the knee from intraoperative positioning of the extremity;
13. Inadequate range of motion due to improper selection or positioning of components,periarticular calcification, flexion contracture;
14. Femoral, tibial or patellar bone or component fracture intraoperatively or postoperatively; fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
15. Undesirable shortening or lengthening of the limb;
16. Aggravated problems of the affected limb or contralateral extremity by leg length discrepancy, excess femoral medialization, or muscle deficiency;
17. Pain.

Contraindications:

1. Tibia, femur or patella fractures.
2. Blood circulatory constriction such as arteriostenosis
3. Known allergic reaction to CoCr and titanium
4. Infection
5. Skeletally immature patients
6. Tumors, cysts in the distal femur, proximal tibia

WARNINGS AND PRECAUTIONS :

The patient should be warned of surgical risks and made aware of possible adverse effects. The patient should be warned that the devices do not replace normal healthy bone, and that the implant can break or become damaged as a result of strenuous activity or trauma and has a finite expected service life and may need to be replaced in the future. Higher rates of wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to early revision surgery to replace the worn prosthetic components.

Loosening, bending, cracking, or fracture of implant components; fracture of the implant can occur as a result of trauma, strenuous activity.

The potential long-term biological effects of metal wear debris and metal ion production are not known. Questions regarding carcinogenicity have been raised in literature; no studies have conclusive evidence that metal wear debris or metal ions are carcinogenic.

Preoperative:

1. Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's weight, activity level, occupation and lifestyle.
2. The patient should be warned of surgical risks and made aware of possible adverse effects. The patient should be warned that the prosthesis does not replace normal healthy bone, that the prosthesis can break or become damaged as a result of certain activity or trauma, has a finite expected service life, and may need to be replaced at some time in the future. The patient should also be advised of other risks that the surgeon believes should be disclosed. The patient should be advised that any noise or unusual sensation should be reported to the surgeon as it may indicate implant malfunction.
3. Use care in handling and storing of implant components. Cutting, bending, or scratching the surfaces of components can significantly reduce the strength, fatigue resistance and/or wear characteristics of the implant system. These in turn may induce internal stresses that are not obvious to the eye and may lead to fracture of the component.
4. Surgical information is available upon request. The surgeon should be familiar with the technique.
5. An adequate inventory of implant sizes should be available at the time of surgery.
6. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear and damage prior to surgery.

Intraoperative:

1. The correct selection of the implant is extremely important. The appropriate type and size should be selected for patients with consideration of anatomical and biomechanical factors such as patient age and activity levels, weight, bone and muscle conditions, etc. Generally, the largest cross-section component which will allow adequate bone support to be maintained is preferred. Failure to use the optimum size component may result in loosening, bending, cracking, or fracture of the component and/or bone.
2. Modular components must be assembled securely to prevent disassociation. Avoid repeated assembly and disassembly of the modular components which may compromise a critical locking action of the components. Surgical debris must be cleaned from components before assembly. Debris may inhibit the proper fit and locking of modular components leading to early failure of the procedure.
3. Prior to closure, the surgical site should be thoroughly cleaned of bone chips, extraneous cement, etc.; foreign particles at the metal and/or plastic interface may cause excessive wear and/or friction.
4. An implant should never be reused. While it may appear undamaged, imperfection may exist which would reduce the service life of the implant.

Postoperative:

1. The patient must be advised of the limitations of the reconstruction and the need for protection of the prosthesis from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma
   affecting the joint replacement have been implicated with failure of the reconstruction by loosening, fracture and/or wear of the prosthetic components. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.
2. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.
3. Periodic postoperative x-rays are recommended for close comparison with early post-op conditions to detect long term evidence of changes in position, loosening, bending, or cracking of components
4. COVISION Knee Systems have not been evaluated for safety in the Magnetic Resonance Imaging environment. The COVISION Knee Systems have not been tested for heating or migration in the MRI environment.

PACKAGING AND LABELING:

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact.

STERILIZATION / RESTERILIZATION:

Most implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to a minimum of 25 kiloGrays of gamma radiation. Inspect packages for punctures or other damage prior to surgery, If the sterile barrier has been broken, return the components to your local distributor.

SYMBOLS:

LOT	Batch code		Use by	STERILE EO	Sterilized using ethylene oxide
REF	Catalog number		Keep dry	STERILE R	Sterilized using radiation
	Do not re-use		Keep away from sunlight		contents packed without sterilization

	Consult Instruction For Use		Date of manufacture		Manufacturer
EC REP	Authorized representative in the European Community				

INFORMATION:
Should any incident occur with implantable device, call the phone number given below.
For further information, please contact Customer Service
Tel: +44 (0) 1909 733 737

CE 2195

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