Before using a product introduced in to the market by COVISION, the operating surgeon is asked to carefully study the following recommendations, warnings, and instructions.
This user instruction applies to surgical instruments (hereinafter called "instruments") of COVISION that are needed for the implantation of prostheses, for the use of joint replacement and internal/external fixation.

1) Safety Instructions

1.1 General Instructions

The products of COVISION may only be used by surgeons who are qualified to carry out joint replacement and internal/external fixation surgery and who are trained in the product-specific surgical techniques.
The instruments are to be stored either in their original unopened packaging, in the appropriate instrument tray or in suitable packaging that protects the instruments from damage. Before they are used they must be examined for possible damage and it must be ensured that they are in good working order.
Any complications or other effects that may occur for reasons such as incorrect indication or surgical technique, unsuitable choice of implant or treatment, inappropriate use or handling of the instruments etc., fall under the responsibility of the operating surgeon and are not the liability of the manufacturer or the distributor.
The Manufacturer does not accept liability in the case of non-compliance with the requirements of this user instruction.

Important instructions:

- The instruments of COVISION form part of a system (set) and must only be used with original parts belonging to the same system (set).
- Instruments must not be mechanically worked or altered in any way,
- The general risks involved in the use of instruments are; allergic reaction to the material used in their manufacture, loosening, wear, corrosion, ageing and fracture of the instrument or its components. The instruments must be inspected for these features prior to use.
- The use of the instruments for other purposes is prohibited.

Warnings:

- Instruments that are contaminated, unsterile, damaged, have been improperly handled, or have been altered without authorization, must not be used under any circumstances.
- If instruments are subjected to excessive loading or are handled improperly, they may fracture, become loose, exhibit excessive wear and/or their functionality may be impaired.
- With the use of reamers, drills and other cutting instruments, frictional heat can be generated, which may lead to cell damage.
- Instruments may sometimes have sharp edges or pointed tips. Consequently, if plastic gloves are used there is a danger that these may become damaged. Therefore please pay attention to the risk of puncture and/or infection.
- Articulating or assembled instruments or their components must be thoroughly cleaned before they are assembled or used as contamination can lead to wear, impairment of function or fracture of the instruments.
- Torque wrench accuracy is ± 10% of set value over the life of the instrument, as long as it is recalibrated every 6 months by authorized Covision personnel. The torque wrench mechanism will relax, whether it is sitting on a shelf or being used in daily procedures. Covision therefore requires that each torque wrench be returned every six (6) months for a review of all components for wear and recalibration to maintain device accuracy.

1.2 Cleaning and Maintenance

Instruments must not come into contact with substances containing chlorine or fluorine. Instruments that are made wholly of plastic must not come into contact with strong acids or organic or ammonia-containing solvents, aromatic and/or halogen hydrocarbons or oxidising chemicals. Aluminium and materials containing aluminium must never come into contact with substances containing mercury. Even the smallest traces of mercury can lead to considerable corrosion. Instruments made from materials containing aluminium must be wiped and cleaned with, or placed in detergents and disinfectants that have a pH value between 4.5 and 8.5. Higher or lower pH value cleaning agents will dissolve the protective neutral coating of materials containing aluminium leading to corrosion. Detergents containing a caustic substance may cause surface corrosion and/or discoloration on anodized aluminium instruments therefore detergents containing caustic should not be used during the cleaning process for those parts.
Multiple-use instruments must be cleaned and sterilized after use (also see instructions under point 1.3) contaminants must not be allowed to dry on the instruments, as cleaning may be difficult.
Instruments should not be placed in a physiological saline solution, as prolonged contact with this medium can lead to corrosion and changes to the surface of the instruments.
Freshly prepared cleaning and sterilizing materials must always be used. Neither metal brushes nor scouring agents may be used for the cleaning of instruments. In order to avoid water stains, a final rinsing with desalinated water is recommended. The instruments must then be dried immediately.
It is the end user's responsibility to validate the cleaning process recommended here.

1.3 Sterilization

Sterilization must be carried out with equipment and under conditions that meet the requirements of applicable standards. The user is responsible for the regular maintenance and checking of the cleaning and sterilization equipment and for the appropriate validation.

The components are supplied non-sterile and must be sterilized prior to use by a hospital's validated steam autoclaving process, in appropriate protective wrapping when necessary. If necessary components must be cleaned prior to sterilization in compliance with the hospital's validated cleaning process or cleaning equipment manufacturers' user instructions and recommendations for chemical detergents. All instruments must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.
The following process parameters are validated by Covision and recommended for sterilization.

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prevacuum 273°F (134°C)	Exposure Temperature	273°F (134°C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

These recommendations have been developed and validated using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment.

Important instruction:

- **The validation of the cleaning, sterilization and re-sterilization procedures and the correct setting of the corresponding equipment must be checked ~~out~~ regularly.**
- **The recommendations set out under points 1.2 and 1.3 serve only for information. No liability is accepted for instruments that are cleaned and sterilized by the purchaser or the user, or for re-sterilised instruments.**

2-) Symbols:

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

LOT	Batch code		Date of manufacture		Consult Instruction For Use	EC REP	Authorized representative in the European Community
REF	Catalog number	NON STERILE	contents packed without sterilization		Manufacturer		

Information:

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

CE

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