CURVY INSTRUMENTATION SYSTEM

Reusable instrument set for anterior lumbar spinal surgery

Important Medical Information

Caution
Carefully read all instructions and be familiar with the surgical technique(s) prior to use of the system. Review the instructions for use associated with any implant and instrument to be used in conjunction with the system. Use universal precautions when handling contaminated or biohazard components.

Description

The Curvy system is a set of reusable orthopaedic surgical instruments. The system is used with the Curvy screw, which is packaged sterile separately.

Indications

The device is to be used for anterior lumbar surgical procedures. The device is a reusable instrument set that is used to retract soft tissues to provide exposure during anterior lumbar surgical procedures. The proper use of the instrument set is defined in the surgical technique.

Contraindications

The instrument should only be used in skeletally mature patients without osteoporosis or other conditions that might weaken bone.

Instruments should not be used for anything other than their intended use. Any patient undergoing a surgical procedure has a risk of intra-operative and post-operative complications. Every patient's tolerance to surgical procedures, medication, and implantation of a foreign object may be different.

Possible risks, adverse reactions, and complications associated with surgery and the use of this surgical technique should be discussed with and understood by the patient prior to surgery.

It is the responsibility of the surgeon to provide the patient with information prior to surgery.

Adverse reactions or side-effects

Side effects may include but are not limited to:

- Infection, both acute post-operative wound infection and late deep wound sepsis.
- Temporary or permanent nerve damage, resulting in pain or numbness of the affected area, may occur.
- Wound hematoma, thromboembolic disease including venous thrombosis, pulmonary embolus, or myocardial infarction.
- Damage to blood vessels.
- Damage to nerves
- Delayed wound healing.
- Pain, discomfort, or abnormal sensations
- Risk of additional injury from post-operative trauma

Adverse effects may necessitate re-operation.

Preoperative

Each patient must be evaluated by the surgeon to determine the specific risk/benefit relationship in light of the patient's condition and the surgeon's practice, training, experience, and knowledge of the related medical literature.

Use care in handling and storage of instrument components as per manufacturer's guidelines.

Allergies and other reactions to instrument materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.

Surgical technique information for use of the device is available upon request. Appropriate training and knowledge of surgical techniques, and post-operative patient management are considerations essential to a successful outcome. Refer to medical or manufacturer literature for specific product information.

Labelling

The set is provided in a case. The lot number for the set and individual part numbers are found printed on the case.

Use of the instrument

The surgeon must use the instrumentation supplied in accordance with the operative technique available from *Signature Orthopaedics Europe Ltd.* Do not attempt a surgical procedure with faulty, damaged or suspect instruments. Inspect all components preoperatively to assure utility. Opening of the instrument set must be done according to aseptic condition.

When handling the instrument, avoid any contact with other material or tools which may damage the instrument surface. Under no circumstances should the instrument be modified.

The Curvy is designed to work with most ring and table mounted systems. If a mounting device other than the Curvy ring is used, verify proper function of system prior to use.

Materials

Curvy components are stainless steel, Radel or aluminium. These materials are not approved for long term implantation and should not be left in the patient post-operatively.

Re-use of the instrument

The Curvy system can be reused after appropriate reprocessing. The recommended reprocessing procedure is included in this insert.

Warnings
The health care facility is responsible for verifying that their facility can adequately perform the reprocessing procedure. Since Signature Orthopaedics is not familiar with individual hospital handling and cleaning methods, Signature Orthopaedics cannot assume responsibility for sterility even though the guideline is followed.

It is the user's responsibility to validate sterilization and cleaning procedures other than those specified.

Long narrow cannulations and blind holes require particular attention during cleaning.

Enzymatic or other cleaning agents with neutral pH are recommended. Prepare the cleaner to manufacturer specifications. Use of highly acidic or alkaline cleaning agents will quickly corrode the instruments.

Cleaning at Point of Use
Remove excess soil with disposable non-shedding wipes. The part should not be allowed to sit for more than 30 minutes after use.

If cleaning must be delayed, immerse instruments in a compatible detergent solution or water to prevent drying and encrustation of surgical soil. Avoid prolonged exposure to saline to minimize the chance of corrosion.

Preparation for Cleaning
Disassemble instruments prior to cleaning.

Instruments should be cleaned separately from the case. The case undergoes the same cleaning procedure as the instruments.

Cleaning: Automated
A washer/disinfector with an enzymatic cleaner (e.g. Enzol) are required. It is important that the cleaner has a neutral pH and is compatible for use with aluminium.

Warning
Automated cleaning of the instruments and case is not recommended in isolation. A combination of manual and automated cleaning is recommended. Automated cleaning cycles should be validated to equal or exceed the cleaning process as specified in the Manual cleaning section below.

1) Load the case and instruments in such a way as to promote drainage. Ensure hinges are open and cannulations and holes can drain.

2) Prepare an enzymatic cleaning solution in a sonication unit per manufacturer's specifications. Load the case and instruments in such a way as to promote drainage. Ensure hinges are open and cannulations and holes can drain. Sonicate for a minimum of 9 minutes.

3) Inspect that there is no visible contaminant left. If an area of the part cannot be visually inspected, immerse the area in a 3% hydrogen peroxide solution. If bubbles form then there is blood present. Rinse the hydrogen peroxide off the instrument thoroughly after the inspection. If necessary, repeat cleaning or perform manual cleaning.

Cleaning: Manual
A brush, running water and a washer/disinfector with an enzymatic cleaner (e.g. Enzol) are required. It is important that the cleaner has a neutral pH and is compatible for use with aluminium.

Warnings
Soft bristled nylon brushes and pipe cleaners should be used to avoid damaging the surface and finish of the instrument.

Low foaming cleaning agents should be used to ensure the parts are visible during cleaning.

The instrument should be held below the surface of the cleaning solution to prevent the formation of aerosols or splashing which can spread contamination.

1) Soaks the case and parts in enzymatic cleaner prepared per manufacturers recommendations for a minimum of 5 minutes.

2) Rinse excess soil from the case and instruments.

3) Using brush, brush all surfaces ensuring that hinged instruments are cleaned in both open and closed positions. A sterile syringe and pipe cleaner may be used to flush hard to reach areas.

Note: If the solution becomes bloody or turbid, prepare a new solution

Note: Clean cannulations and holes using an appropriate brush ensuring that full depth of the feature is reached.

4) Prepare a fresh enzymatic cleaning solution in a sonication unit per manufacturer's specifications. Fully immerse the device in the solution and sonicate for a minimum of 9 minutes.

5) Rinse under clean running water for 1 minute. Ensure that running water passes through cannulations, and that blind holes are repeatedly filled and emptied. Rinsing should remove all evidence of detergent.

6) Inspect that there is no visible contaminant left. If an area of the part cannot be visually inspected, immerse the area in a 3% hydrogen peroxide solution. If bubbles form then there is blood present. Rinse the hydrogen peroxide off the instrument thoroughly after the inspection. Repeat cleaning if necessary.

Disinfection
Disinfection is only to be performed in addition to sterilization.

Warning
Soaking in disinfectants may be required for protection against certain viruses. Disinfectants may corrode instruments or make further decontamination more difficult. Where possible, soaking in disinfectants should be avoided.

Drying
Manual drying should be done with clean soft dry cloth and filtered pressurized air (no greater than 40psi).

Warning
When drying is achieved as part of a washer/disinfector cycle ensure the temperature does not exceed 120°C.

Packaging

In sets, instruments may be loaded into dedicated instrument trays, or general purpose sterilization trays. Pack the dedicated instrument trays only as intended. Ensure that cutting edges are protected. Wrap the trays using disposable surgical instrument wrap following AAMI double wrap method (ANSI/AAMI ST46-1993).

Warning
Unwrapped cases do not maintain sterility.

Sterilization

The following sterilization procedure has been validated for surgical instruments manufactured by *Signature Orthopaedics*. This procedure should be followed as a minimum.

Warnings
Sterilizer manufacturer recommendations should always be followed.

Polymer components may be damaged if the sterilization temperature exceeds 141°C, or if moprholine is used.

Perform a pre-vacuum sterilization, with 3 preconditioning pulses and a minimum temperature of 132°C for a minimum 4 minutes. Allow 70 minutes of drying time.

Note: Drying time is subject to variation depending on machine load.

Re-sterilization of unused instrument parts

Unused instrument parts should be reprocessed following the same procedure as used instrument parts.

Storage

Cases are stored in accordance with AS4187:2003. Items shall be stored in a clean environment that is insect, vermin and dust-free. A dedicated container/drawer should be used to protect instruments from environmental contamination. Avoid storage at extreme temperatures or humidity. It may be necessary to reprocess the items prior to use.

Warning
Healthcare facilities should establish a shelf life for wrapped cases based on the wrap used and the wrap manufacturer specifications.

Inspection

Repeated processing of the device following the procedure outlined in this insert has a minimal effect on the device. End of life is typically determined by damage or excessive wear due to use.

Parts should be inspected before and after use.

- All parts of the set should be accounted for.
- Moving parts should have smooth movement without excessive "play".
- Locking or ratcheting mechanisms should fasten securely and easily.
- Cutting edges should be free of nicks and present a continuous edge.
- Long slender features should be undistorted.
- Jaws and teeth should align properly.
- Assemblies should be checked for fit.
- Polymer components should not appear "chalky"
- Instruments should be free of damage or visible wear.
- Case should not be warped or corroded.

Note: Particular attention should be paid to areas surrounding laser marking because these areas are likely to corrode first.

Maintenance

Return blunt or damaged instruments to *Signature Orthopaedics* for repair.

Apply a small quantity of surgical grade lubrication oil to hinges.

Warning
Mineral oil or silicone lubricants should not be used because they: 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove.

Limited warranty/Liability

Signature Orthopaedics Europe. Ltd. products are sold with a limited warranty to the original purchaser against defects in workmanship and materials.

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact *Signature Orthopaedics Europe Ltd*. for current information.

For product information or questions pertaining to sales and service, please contact your local sales representative in European Union countries or ***Signature Orthopaedics Europe Limited, Ireland*** **customer service** by calling **+353 (0) 906400539.**

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