ENGLISH

CLARIANCE

Spinal instruments

1. PURPOSE

The reusable manual surgical instruments are intended for scraping, cutting, gripping, holding, removing or manipulating structural tissues, components of spinal devices associated with these instruments.

2. DESCRIPTION

Manual surgical instruments are designed to be used in a wide variety of spinal procedures. They are non- powered devices, or devices that are not connected to a power source, which are used manually, are reusable and are intended for various spinal surgical procedures.

The reusable manual surgical instrument for spinal surgery is made of medical quality stainless steel according to the ASTM F899 standard, or of a titanium alloy according to the ASTM F136 standard, or of a polymer material.

Choice of the appropriate instrument and trial is the responsibility of the surgical team.

The instruments may be used when preparing and approaching spinal structures and when placing spinal implants. It may be used in combination with other instruments which are specifically dedicated to a CLARIANCE product (e.g. quick-connect removable handle). These instructions do not apply to instruments with an electric motor or compressed air drive. However, they may be applied to connected devices (e.g. reamers and drills) which are linked to motorized equipment when used. These manual instruments for spinal surgery may only be used with CLARIANCE products. Please refer to the surgical technique relating to the product for detailed information. Detailed information about the surgical technique for using CLARIANCE products is available on request. Please get in touch with CLARIANCE or its local representative.

3. INDICATIONS

Instruments are used in surgery with one or more CLARIANCE implants. The indications of these implants therefore apply to the surgical instruments. Please refer to the instructions for use for CLARIANCE's implants associated with the instruments.

4. CONTRA-INDICATIONS

None known.

5. SECONDARY AND POSSIBLE SIDE EFFECTS

The following side effects or possible effects may occur during spinal surgery. A list of potential incidents associated with these instruments includes:

- Breakage of the instrument during surgery.
- Damage done to neurological tissues and elements due to poor positioning and placement of implants or instruments.
- Infection.

Comment: Drugs and/or additional surgery may be necessary to correct some of these side effects.

6. WARNINGS

- Do not use these instruments for purposes other than those for which they are intended.
- The reuse of single-use devices can have irreversible consequences on the security and the health of the patients (risk of contamination, risk of failure of the device, etc.). It is therefore strongly prohibited to reuse single use devices.
- Do not bend or raise them or use any excessive force, as this may lead to the instrument and trial breaking or failing, causing possible harm to the patient or the user.
- Pay very careful attention when handling and cleaning delicate or sharp instruments and trials so as to avoid injuries or damage.
- Use appropriate personal protective equipment when handling contaminated instruments.
- Check the assembly and functionality of all instruments and trials before use.
- Because the materials, tolerances, manufacturing characteristics, components and design parameters of spinal device manufacturers are different, components of the spinal surgery instruments and trials must not be combined with another manufacturer's components. CLARIANCE cannot accept any liability for the performance of the implant resulting from this combination of components.
- Evaluate the allergic background of the patient before using the device.
- CLARIANCE surgical instrumentation may include handles. The verification of the torque limited handles must be done once a year. Contact CLARIANCE or its representative for performing this verification.
- The life expectancy of CLARIANCE's instruments depends on many factors including the method and duration of each use, and the handling between uses. Careful inspection and functional test of the devices before use is the best method of determining the end of serviceable life for the medical device. Do not use instruments and trials that show evidence of damage and/or wear. Evidence of damage and wear on an instrument or trial may include, but is not limited to, corrosion, discoloration, excessive scratches, flaking, wear, and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed part numbers, damaged and excessively worn devices should not be used.

7. CAUTION OF USE

- **PREOPERATIVE**

- Do not reuse single-use instruments.
- Only sterilize clean instruments; sterilization is only effective on clean instruments.
- All the instruments supplied non-sterile by CLARIANCE must be cleaned and sterilized before use.
- If surgery requires devices that are supplied sterile by CLARIANCE, additional sterile instruments should be available in the event of any unexpected need.
- Given that mechanical parts are involved, the surgeon must be trained in the use of these instruments and trials before employing them and must personally check that all the required components and instruments are present before surgery starts.

- **INTRAOPERATIVE**

- Breakage, slipping or incorrect use of instruments, trials or implants may injure the patient or damage the device.
- Always take care when handling instruments and trials and putting them away.
- Do not drop the instruments, otherwise they may get damaged. Do not use a damaged instrument or trial.

- **POSTOPERATIVE**

- Disassemble the instruments before immersing them in decontamination tanks.
- Avoid any body fluids drying on the instruments and trials, immerse them in decontamination tanks as soon as possible.
- Avoid covering the instruments and trials with a wet field or one soaked with tap water - do not use a saline solution after usage and before decontamination.

8. PACKAGING HANDLING AND STORAGE

Packaging for each of the components must be intact on receipt. If using a loan or consignment system, all sets of instruments must be carefully inspected and all components carefully checked to make sure there has been no deterioration before using them. Any products with damaged packaging must not be used and must be returned to CLARIANCE.

Manual spinal surgery instruments must be handled as seldom as possible and always with the greatest possible care. The instruments (in their original packaging) must be carefully stored in a clean, dry place. Do not expose the instruments and trials to extreme temperatures.

In the event of these requirements not being adhered to, the mechanical properties may be reduced and in some cases, this could lead to the implant failing.

9. CLEANING – DECONTAMINATION – STERILISATION

All the instruments are delivered non-sterile. They must be cleaned using alkaline cleaning agents and then rinsed in deionized water before sterilization. Please note that it is necessary to disassemble some instruments in order to ensure proper cleaning. Refer to document 99REPINS « Non-sterile Instruments and Implants: Instructions For Care, Cleaning, Maintenance, Sterilization" to obtain detailed instructions. All products must be sterilized before they are introduced into a sterile surgical site, or (if applicable) when the product is returned to CLARIANCE.

Method	Cycle	Temperature	Exposure time	Drying time[1]
Steam	Dynamic air removal	132°C (270°F)	4 Minutes	20 Minutes
Steam	Gravity	132°C (270°F)	15 Minutes	30 Minutes
Steam	Dynamic air removal	134°C (273°F)	18 Minutes	30 Minutes

[1]The minimum dry times were validated using sterilizers having vacuum drying capabilities. Drying cycles using ambient atmospheric pressure may require longer dry times. Refer to the sterilizer manufacturer's recommendations.

Instruments have been validated up to 200 reprocessing cycles. These operating instructions are valid for the standard surgical instruments of the production of the manufacturer.

The devices must always be verified before use: any devices presenting signs of weakness or any damages must not be used (Surface damage such as scratches, cracks, nicks, dents, bent parts, tightening torque deviations indicate that the instrument must not be used). Return to the manufacturer or distributor any instruments showing deterioration.

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

10. INTENDED USERS

Instruments should be used only by an orthopedic surgeon or neurosurgeon who is knowledgeable in the surgical aspects and who has been trained as to device mechanical and material applications and limitations.

11. PATIENT TARGET GROUPS

The instrumentation should be used in skeletally mature patients. The target population depends on type of implant used in combination. Please refer to the instructions for use of the implant for further information.

12. CLINICAL BENEFITS

The clinical benefits of the instruments: successful completion of the implant surgery and safe completion of the implant surgery with no harm for the patient.

13. PRODUCT COMPLAINTS

Any health care professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identification, durability, reliability, safety, effectiveness and/or performance, should notify CLARIANCE. Further, if any of the instruments do not meet any of its performance specifications or otherwise does not perform as intended, or is suspected of doing so, CLARIANCE should be notified immediately.

If any CLARIANCE product may have caused or contributed to the death or serious injury of a patient, CLARIANCE and the National Competent Authority where the incident has occurred should be notified as soon as possible by telephone or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report is requested from CLARIANCE.

FOR ALL INFORMATION OR COMPLAINTS, CONTACT:

In Europe	In USA
CLARIANCE  18 rue Robespierre 62217 Beaurains, FRANCE Tel: +33 3 21 16 12 15 Email: contact@clariance-spinevision.com	CLARIANCE Inc. 2547 Farrington Street Dallas, TX 75207 – USA Tel: +1 773-832-7554 Email: contact@clariance-spinevision.com

14. DISPOSAL

Disposal of all infectious wastes must be in accordance with applicable national and local regulations and the medical waste protocol of the medical center, and not endanger the security or the health of patient, user, or another person until its complete disposal (including cleaning, decontamination and

waste).

Symbol	Significance	Symbol	Significance
	Manufacturer		Lot number or batch code
	Catalog Number		Date of manufacture
	Attention: See package insert		Non-sterile
	Consult instructions for use available online (e-IFU)		Do not use if packaging is damaged
	Medical device		Packaging is sensitive to humidity
	The device complies with Regulation (EU) 2017/745		

CE 2460