ENGLISH

Instruments

SOCORE, DIVA, MATRIS, Universal Removal Kit, Universal Retractor Kit, Universal Discectomy Kit

Instructions For Use - READ ATTENTIVELY BEFORE USE

1) INTENDED USE

The range includes instruments to use in associations with implantable devices of SOCORE, DIVA and MATRIS ranges, and additional generic instruments for spinal surgery.

The SOCORE, DIVA, and MATRIS instruments are intended for the implantation of the corresponding NovaSpine implants (specific implant IFU shall be consulted for more details).

The Universal Removal Kit, Universal Retractor Kit and Universal Discectomy Kit are generic instruments, which can be used for the preparation of the surgical site during spinal surgery, and the removal of implants during revision surgery.

All instruments can be used in adults. Universal Removal Kit and SOCORE instruments can be used in pediatrics, when the anatomy is favorable.

NovaSpine transport containers, although not medical devices, are specifically and only designed for the transport of NovaSpine devices. They are not specifically intended for the cleaning, disinfection or sterilization of devices. They must not be considered as sterilization containers or sterile barriers.

2) DESCRIPTION AND MATERIALS

The SOCORE, DIVA and MATRIS instruments are reusable surgical devices used for implantation of devices manufactured by NovaSpine during spinal surgeries.

All instruments are delivered non-sterile and must be cleaned and sterilized by the hospital prior to use.

The surgical instruments are mainly made from medical grade stainless steel and may include silicone, titanium alloy (TA6V ELI) or Radel.

3) INDICATIONS

For specific indications of SOCORE, DIVA and MATRIS instruments, please refer to associated specific implants IFU.

Universal Removal Kit is intended for removal of various types of spinal implants. Universal Retractor Kit is intended for tissues retraction to allow surgical access to the spine and Universal Discectomy Kit is intended for bone and disc removal to prepare the surgical site before implant placement.

4) COMBINATION OF MEDICAL DEVICES

The SOCORE, DIVA and MATRIS reusable surgical instruments can only be used in association with the corresponding NovaSpine devices. Universal Removal Kit, Universal Retractor Kit and Universal Discectomy Kit are to be used alone, without combined devices. NovaSpine has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

5) PERFORMANCE CHARACTERISTICS OF THE DEVICE AND EXPECTED CLINICAL BENEFITS

The performance of instruments is the correct realization of their intended use according to the surgical technique and the correct achievement of performance of associated devices. For benefits, please refer to the IFU of the specific implant that may be used with these surgical instruments. Based on the clinical evaluation, all residual risks are deemed acceptable when weighed against the benefits to the patient base on current knowledge/the state of the art.

6) CONTRA-INDICATIONS

For contra-indications, please refer to the IFU of the specific implants that may be used with surgical instruments. With any surgery, the following contraindications exist:

- Infection in or around the operative site
- Allergy or sensitivity to instrument materials
- Any condition that would preclude the correct of progress of the surgery
- Any case not described in the indications

7) POTENTIAL ADVERSE EFFECTS, COMPLICATIONS AND RESIDUAL RISKS

The residual risks, adverse effects and complications that may occur with the use of NovaSpine instruments are listed below may lead to a new operation or to the extension of the operation time:

- Injury to the patient or operator
- Instrument breakage / risk of debris remaining in the patient. Damaged or broken instruments can be dangerous for the user, the patient or a third party.
- Tissue or vascular injury
- Infection
- Biological / allergic reaction
- Disassembly of components
- Premature wear / deterioration of instruments due to misuse

8) INSTRUMENTS HANDLING

The hospital is responsible for pre-cleaning, cleaning and sterilization of instruments prior to use, in accordance with validated methods. The following recommendations do not substitute for the sanitary rules in force: standards, guides, government notices, ministerial texts, etc. A cleaning process done without respecting qualification ranges can lead to sterility or toxicity risks.

Before any operation, it is necessary to remove wedging foam in the metal containers as well as plastic bags if the instrument is delivered individually. Instruments made up of removable components must be dismantled before pre-cleaning processing and cleaning.

From a functional perspective, an inspection must be carried out prior to use to check for any burrs or debris that could damage tissue or personal protective equipment. Furthermore, the integrity of tools must be verified. Any device deemed to be dull or non-functional in any manner should be returned to NovaSpine for maintenance or exchange. The instructions hereafter must be followed in order to maintain optimal efficiency and safety of instruments:

- Chemicals or cleaning substance based on chlorine, aldehyde, alcohol, acid or abrasives which are likely to damage the instruments must not be used.
- Phosphoric acid must not be used for the neutralization of alkaline residues after the cycle of automated machine cleaning on instrumentation packaging trays and on instruments made up of polymer pieces (example: handles).
- The pre-disinfection temperature should be < 45°C to avoid the risk of fixing residues.:

It is imperative that the instructions for use, such as temperature, concentration, action time, etc., are strictly respected. Otherwise, problems may occur with the instruments, such as visual changes in the material (colour change).

If rust forms on one instrument, it can contaminate others, so rusty instruments should not be mixed with intact instruments to avoid contacts that could be hazardous to sterilization.

All personnel in contact with soiled instruments should observe good hygiene and use appropriate protective equipment (gloves, mask, apron, etc.).

Sharp or pointed devices must be handled with the utmost care.

a. Greasing and lubrication

After use and cleaning, it is sometimes necessary to lubricate articulated parts or any moving parts of instruments. Use only sterilizable maintenance oil and permeable to water vapor.

b. Control, maintenance and verification

After each use and cleaning:

- Let the instrument cool down to ambient temperature after cleaning.
- check the instrument for cleanliness, functionality and damage, and isolate instruments that are twisted, deformed, worn, bent, broken, cracked, or instruments with dismantled parts.
- Check compatibility with associated instruments.
- Immediately remove a damaged instrument.

c. Packaging

- Protect instruments with thin tips.
- Place the instrument in its storage compartment or in the appropriate tray. Make sure cutting blades are protected.
- Package the trays according to the sterilization process (make sure that the packaging prevents any further contamination of the instrument between the final phase of its treatment and its next use).
- Package the instruments in suitable sterilization packages allowing the maintenance of the sterile state until the next use.

9) PRE-CLEANING TREATMENT

Dried surgical residues may complicate the cleaning process making it inefficient or accelerate corrosion of stainless steel. Pre-disinfection processing aims to make subsequent cleaning easier. It is also intended to protect staff while handling instruments and avoid contamination of the environment. All reusable devices must undergo immediate pre-disinfection processing or be immediately treated in a washer-disinfector after use. If immediate pre-disinfection is impossible, instruments may be preserved in demineralized water until pre-disinfection.

- Pre-disinfection processing is achieved by dipping instruments, for a minimum of 15 minutes, in a neutral or alkaline solution that does not contain aldehyde nor ethanol. Preferably use a solution that does not fix proteins. Strictly follow the manufacturer's instructions for use and ensure that the products used are compatible with the instruments.
- Use suitable cleaning and disinfection products. If there is a delay between pre-disinfection and washing, rinse the instrument thoroughly with running water before cleaning and disinfection with washer-disinfector (WD).
- If necessary, clean the instrument with ultrasound, see Cleaning section.
- Remove all visible organic residues (blood, bone, etc.), special attention will be paid to grooved or hollow devices.
- The use of metallic brushes, scrub pads and other articles likely to damage the instruments must be avoided. The use of soft-bristled brushes and swabs with dimensions adapted to the devices to be treated is preferred to clean the parts from all biological residues (blood, bone, …) that can potentially alter the action of detergents and decontaminants. Pay special attention to cannulated devices.
- The use of a mechanical action through manual or ultra-sonic means is recommended 10)a.
- Devices that can be disassembled should be disassembled prior to pre-disinfection processing. Additionally, devices with movable components that do not facilitate disassembly should be manually articulated during the pre-disinfection processing step in order to evacuate additional residues.
- Preferably immerse instruments in a solution of combined enzymatic-type cleaner and disinfectant which does not bind proteins. Avoid the use of disinfectants containing aldehydes which have a binding effect. Follow the conditions of use recommended by the manufacturer and ensure the compatibility of the product with the instruments.
- The instruments should then be carefully rinsed in a controlled water to avoid interference between the cleaning solutions. It is important to refer to the instructions supplied by the manufacturer of these products.
- Long waiting times for treatment should be avoided - e.g. overnight or at weekends - because of the risk of corrosion and the effectiveness of the cleaning. Immersion in demineralized water prevents residues from drying out and facilitates subsequent washing.
- In case of long waiting periods between pre-disinfection and cleaning, wash the instruments with controlled water before cleaning and disinfection with a washer-disinfector.

CAUTION: Packaging trays and baskets must not be in contact with decontaminating solutions for a long time. Clean dirty areas and rinse immediately.

10) CLEANING

The instruments must be thoroughly cleaned individually outside of the container (the efficiency of parts cleaned inside their loading container is not ensured), after disassembly if assembly/disassembly is possible. We recommend the exclusive use of mechanized pre-disinfection and cleaning methods with a WD compliant with the requirements of ISO 15883 series. Refer to the manufacturers' instructions on how to use the washer-disinfector. The detergent shall be compatible with medical applications, instruments materials and present no known residual toxicity for the patient. In case the process cannot be done automatically, a manual process shall be used by reproducing the conditions described in the cleaning recommendations. The cleaning cycle must include a final rinse with a controlled water. Time, water flow and rinsing volumes shall be sufficient to reduce as much as possible the level of cleaning agent residues left on the product surface. Instruments should be carefully dried to avoid recontamination.

a. Ultrasonic cleaning

This cleaning method is particularly suitable for threading tools or instruments with deep grooves. The equipment must be validated by the user and used with products adapted to the materials of the instruments. Perform ultrasonic cleaning for 10 to 20 minutes to preclean instruments with dried residues or as an effective mechanical support before cleaning and disinfection in WD.

b. Automated washing

Ensure that the WD is conform (EC marking), maintained and qualified according to the applicable standards. Use only products compatible with the implants, aldehydes-free, and complying with the Standard Prion Protocol (SPP) if necessary. Follow the instructions for concentration, temperature and duration of action.

Use neutral or alkaline pH detergents.

Follow the washing procedures to ensure proper protection of the implants. After cleaning and disinfection in WD, check that all residues have been removed. If necessary, repeat the cleaning process with brushing until all visible residues are removed. Failure to properly clean the devices could lead to inadequate sterilization.

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Table 1 - Recommended automated washing protocol

Cycle Step	Minimum time	Recommended temperature	Type of Water / Detergent
Pre-Cleaning	2 minutes	Cold, 20°C	Water
Cleaning	5 minutes	Heated, 55°C minimum	Neutral or Alkaline detergent solution
Neutralization	2 minutes	Cold, 20°C	Water
Rinse	2 minutes	Cold, 20°C	Water
Thermal Rinse	5 minutes	Heated, 93°C minimum	Water
Drying	30 minutes	Air at 99°C minimum	Not applicable (Air)

As appropriate, dry residual moisture by means of a complementary drying cycle in the machine or lint-free wiping squares and compressed air.

Nota: In the case of patients with suspected or confirmed transmissible spongiform encephalopathies (TSE), the cleaning procedure for the washer-disinfector shall be done after a decontamination process conform to the instruction DGS/RI3/2011/449. Three inactivation processes, none of which is an absolute guarantee, are possible:
- Steam sterilization at 134°C for 18 minutes,
- Immersion in 1N sodium hydroxide for 1 hour at room temperature,
- Immersion in sodium hypochlorite 20,000 ppm, for 1 hour at room temperature.

The use of sodium hypochlorite is not recommended as it causes corrosion of the instruments. None of the three methods is an absolute guarantee. In accordance with the World Health Organization's guidance, the safest and most unambiguous method of avoiding residual infectivity on contaminated instruments and other materials is to discard and destroy them by incineration

11) STERILIZATION

Instruments, containers and storage trays must be sterilized before use. They must be compatible with water steam sterilization at a temperature not exceeding 140°C. In accordance with the government instructions on the non-transmission of unconventional transmissible agents and the standards in force (specially ISO 17665-1), we recommend to use a water steam sterilization (in compliance with the requirements of the ISO 17665 series) with a **validated cycle** including a period of **18 minutes minimum at 134°C (-0 / +5°C)** and followed by a vacuum drying cycle of 30 minutes minimum with heated air at 80°C minimum. NovaSpine transport containers are compatible with steam sterilization and can be used to hold the instruments during sterilization, as long as products specifically designed for sterilization are used to guarantee maintenance of sterile state of the instruments. They can either be wrapped into two sterilization wraps, or inserted into a sterilization container, which includes two filters in its lid. The packaging used must be CE marked for a use as sterile barrier for autoclave sterilization. Use absorbent paper between the package and the container and check the absence of moisture inside the container and the package before using the products. Each container and its contents must not exceed 10kg. The cycle of sterilization and drying must be validated by the end user according to the sterilizer manufacturer's recommendations.

The instruments must be packaged in suitable packaging allowing the maintenance of the sterile state.

Any other methods of sterilization (ethylene oxide or oxygen peroxide at low temperature) are not recommended and are the sole responsibility of the user.

Instruments must be prepared in such a way that all surfaces are in direct contact with water vapor: hinged instruments and sliding instruments must be slightly open. Complex instruments manually dismantlable must be dismantled, and all parts must be wedged in the sterilization box. Hospitals shall validate and qualify, using appropriate techniques, their equipment and methods used for autoclave sterilization, in accordance with the current standards for sterilization of medical devices using moist heat. The hospital assumes final responsibility for the validity of the sterilization of the products and their maintenance in this state.

Sterilization recommendations are given for information purposes only. The user/processor must comply with the laws and regulations of the country in which it is established. Under no circumstances can the manufacturer be held responsible for the sterility of sterilized devices within the hospital.

12) REUSE OF DEVICES

The instruments are intended to be reused. The number of reuses depends on the integrity of each instrument. There is no theoretical limit to its reuse as long as it fulfills the claimed performance and providing that it does not show signs of wear, distortion, damage or loss of performance.

Prior to reuse, the devices must be pre-disinfected, cleaned and sterilized (as described in previous sections.

13) STORAGE, HANDLING AND TRANSPORT

Surgical instrumentation must be handled with care and should be stored carefully in a clean room under normal temperature and humidity conditions. Instruments must be protected from UV rays and all corrosive environments. Instruments must not be stored in contact with or near products that may have a corrosive effect.

When transporting sterilized instruments to the site of use (operating room), the sterile state must be maintained. Use sterile packaging to maintain the sterile state of the instruments. Be aware of the risk of falls and/or injury.

Used instruments should be transported to the supply department in closed or covered containers to avoid unnecessary contamination.

Dropping may result in breakage or damage to the instrument and/or injury to the operator. Use rigid trays or containers.

14) RETURN, ELIMINATION AND NON-FUNCTIONAL INSTRUMENTS

After each use and before returning to NovaSpine, the loan instrumentation (entire box or isolated instrument) must be pre-disinfected, cleaned and sterilized according to the aforementioned recommendations. Instruments that appear to be non-functional must not be used and must be sent to NovaSpine for maintenance or exchange. The nature of dysfunction must be clearly indicated. The instrumentation must be correctly packaged before being returned, and the original positioning of the components in corresponding containers should be respected.

After pre-disinfection and cleaning, and unless otherwise specified, the devices to be eliminated shall be eliminated in accordance with the applicable procedures of the hospital in accordance with the regulations in force or, if they do not present a potential toxic hazard, sterilized for a possible return to the manufacturer for analysis or expertise.

Lifetime of device

The end of life for each device is determined when the device's characteristics or performance indicate that the health or safety of the patient or user may be compromised. The device's lifetime depends on many factors, including but not limited to, method and duration of use and level of reprocessing. Hence NovaSpine does not define the maximum number of uses. Careful inspection and functional testing should be completed. Examine the cutting edges, flutes, tips, shafts, handles, and features of the working end, as applicable, for dulling, chipping, warping, cracking, or other indications of material degradation or compromised structural integrity. The laser marking should remain readable. If the device displays any of these signs of wear or other indications of malfunction, it is recommended to discontinue use and replace the device. Per the surgical technique, actuate moving parts and assemble devices to test for sticking or obstruction. If moving or assembled parts have limited functionality, replace the device(s).

15) WARNING

- The manufacturer recommends that all personnel responsible for handling and using the devices read and understand this information before use. The use of surgical instrumentation requires knowledge of anatomy, biomechanics, and reconstructive surgery of the musculo-skeletal system. Surgical instrumentation must be used only by a qualified surgeon operating in accordance with current information on the state of scientific progress and state the art of spinal surgery.
- Care and maintenance are essential to preserve the life and efficiency of the instruments.
- The SOCORE, DIVA and MATRIS instruments have been designed to be used only with the corresponding NovaSpine implants. The Universal Removal Kit, Universal Retractor Kit and Universal Discectomy Kit instruments are generic instruments, which can be used for the preparation of the surgical site during spinal surgery, and the removal of implants during revision surgery.
- Do not bend or apply severe stresses on instruments, as this may cause breakage or failure, resulting in injury to the patient or operator.
- Do not attempt to modify the instrument.
- The user should ensure that the equipment is in good condition and working properly before use.
- Visually inspect each instrument before use to detect and isolate worn, deformed, twisted, damaged or defective instrument. Such instruments must be replaced immediately with new instruments.
- All instruments, if used frequently, are subject to natural wear and tear. Replace the most frequently used and fragile instruments regularly, especially if they tend to twist or deform and wear out (hexagonal screwdrivers, probes, taps, etc.).
- If an instrument is broken during surgery, all broken fragments and debris should be removed from the patient.
- Ensure that no moisture remains on the laser marking area. If a brownish stain forms, strongly wipe the stain away with a soft rag.
- It is important to refer to the technical documentation prior to use, for a more detailed description on the use of instrumentation. Under no circumstance should an instrument be implanted.
- During the surgery, devices may experience a variety of forces which cannot be fully anticipated. Even with proper reprocessing, maintenance, and inspection, devices may reach the end of their lifetime during surgery. A replacement or alternative should be available to the surgeon.

Note: The instructions provided in this manual have been validated by NovaSpine to prepare NovaSpine reusable surgical instruments for reuse. It is the responsibility of the user/treatment manager to ensure that the treatment, as actually performed using treatment equipment, materials and personnel, achieves the desired result. This requires routine verification and/or validation and monitoring of the process.

It is the surgeon's responsibility to provide the patient with all necessary information prior to the operation, including adverse events related to the operation, implants and instruments.

16) SERIOUS INCIDENT

"Serious incident" means any incident that directly or indirectly led, might have led or might lead to any of the following: the death of a patient, user or other person; the temporary or permanent serious deterioration of a patient's, user's or other person's state of health; a serious public health threat.

Any serious incident that has occurred in relation to NovaSpine instruments should be reported to NovaSpine and the competent authority of the Member State in which the user and/or patient is established.

Year of initial MDR 2017/745 EC certification: 2024

CE 0476 Conformity to European regulation

Medical device

Unique device identifier


Read the Instructions


Consult instructions for use

Non-sterile


Keep away from sunlight


Keep dry


Single protective packaging

Lot number


Do not use if package is damaged

Catalogue number


Date of manufacture

Quantity


Manufacturer

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