ENGLISH

DIVA

Spinal Interbody Stabilization Range

Instructions For Use - READ ATTENTIVELY BEFORE USE

1) INTENDED USE

The DIVA range is a range of medical devices used for the surgical treatment of pathologies in cervical and lumbar spine.

The DIVA implants are intended to stabilize spinal segments by replacing intervertebral discs to promote interbody fusion.

DIVA implants are used for skeletally mature patients by an anterior approach in the cervical spine (C2-C7), and several approaches in the lumbar spine (L1-S1), depending on the cage used. PLIF cages are inserted from a posterior approach, TLIF cages from a transforaminal approach, LLIF cages from a direct lateral or oblique lateral approach, and ALIF cages from an anterior approach.

2) DESCRIPTION AND MATERIALS

DIVA range includes the following implantable medical device: interbody fusion implants (cages) of Class III and screws and plate of Class IIb.

Titanium 3D printed cages, plates and screws of DIVA range are all made of Titanium Alloy TA6V ELI conforming to standard ISO 5832-3 and ASTM F136 (Titanium – 6% Aluminum – 4% Vanadium – Extra Low Interstitial compounds). PEEK cages are made of Polyetheretherketone conforming to ASTM F2026 and are assembled to Titanium Alloy TA6V ELI parts (ISO 5832-3 and ASTM F136) or Tantalum X-Ray markers conforming to ASTM F560.

All devices of the DIVA range are available sterile. PEEK cages, metallic plates and screws are also available in non-sterile version. Non-sterile devices are intended to be sterilized by the user prior to use. Sterile devices are ready to use devices, sterilized by gamma radiation.

The DIVA range includes cervical and lumbar implants. Cervical implants include cervical cages (standard and blocked), screws and plates, corpectomy cages. Lumbar implants include lumbar cages (PLIF, TLIF, ALIF standard and blocked, LLIF standard and blocked), screws and plates. Blocked cages are fixed to both adjacent vertebrae using screws. In cervical area, plates are assembled to the cage with a screw and the assembly is fixed to adjacent vertebra with screws. In lumbar area, plates prevent cage migration and are fixed to vertebrae with screws, without interface with the cage.

3) INDICATIONS

The DIVA range is intended for use in skeletally mature patients following discectomy for temporary internal stabilization of the spine as an adjunct to fusion.

Except for corpectomy devices, the DIVA range is used as an adjunct to fusion for degenerative pathologies (e.g. Degenerative Disc Disease – DDD with or without disc herniation, Loss of discal height, Cervical spondylotic myelopathy, Spondylolisthesis).

Cervical corpectomy devices of the DIVA range are used as an adjunct to fusion for corpectomy procedures, mainly due to fractures caused by tumor and/or trauma.

4) COMBINATION OF MEDICAL DEVICES

The DIVA range implants are applied using the associated DIVA instrumentation. The following medical devices or substances can be used in association with DIVA implants:

- Autograft and/or allograft and/or bone substitute
- Cervical plate

NovaSpine has tested DIVA range compatibility with its own cervical plate MATRIS. Other devices provided by other manufacturers have not been tested for compatibility with DIVA range and no liability is assumed in such instances.

5) PERFORMANCE CHARACTERISTICS OF THE DEVICE AND EXPECTED CLINICAL BENEFITS

The performance of the DIVA range is the achievement of spinal stabilization as an adjunct to fusion. The clinical benefits expected are pain reduction and disability reduction.

The clinical benefits can be expected for patients adequately selected according to indications and contraindication, and if all warnings and precautions are respected to the extent possible.

A summary of safety and clinical performance of the DIVA range is available on the European Database on Medical Devices (EUDAMED): https://ec.europa.eu/tools/eudamed/ (upon activation).

6) CONTRA-INDICATIONS

Contraindications include:

- Patient not needing bone graft and fusion
- Local or systemic infection or significant risk of infection (immunocompromise)
- Suspected or documented allergy or intolerance to the materials used, foreign body sensitivity
- Mental illness
- Patients with inadequate bone quality or quantity (e.g. severe osteoporosis, osteopenia, osteomalacia)
- Active smoking, alcoholism, drug abuse
- Morbid obesity
- Pregnancy
- Elderly, severe comorbidity
- Any patient unwilling to follow postoperative instructions
- Any case where the implant components selected for use would be too large or too small or would interfere with anatomical structure and compromise the successful result
- Signs of local inflammation, fever or leukocytosis
- Any entity or condition that totally precludes the possibility of fusion or the potential benefit of spinal implant surgery (i.e., cancer, kidney dialysis, presence of congenital abnormalities, unexplained elevation of sedimentation rate, white blood count elevation or left shift)
- Vertebral tumor (excluding corpectomy if corpectomy procedure is required)
- Fracture caused by trauma and/or tumor (excluding corpectomy)
- Poor vascular conformation (ALIF)
- Pediatric patients
- Any case not described in the indications

7) POTENTIAL ADVERSE EFFECTS, COMPLICATIONS AND RESIDUAL RISKS

Potential adverse effects and complications constitute the residual risks of the device. Adverse effects and complications associated with the DIVA range are similar to those encountered with other spinal ranges and may require additional or revision surgery:

- Tissue, bone, vessel or nerve damage due to surgical trauma, malposition or mishandling of implants or instruments.
- Early or late loosening, disassembly, migration of any or all implants or graft.
- Breakage of the implants due to stresses or fatigue or malposition.
- Post-operative change in spinal curvature, loss of correction, height, or reduction.
- Subsidence into vertebral body or retropulsion of cages.
- Delayed union, non-union or pseudarthrosis.
- Persistence of pain and pre surgical signs.
- Infection (superficial or deep), Inflammation.
- Fracture, microfracture, resorption, damage, or collapse of any spinal bone (including the pelvis, pedicles, or vertebral body) or bone graft or bone graft harvest site at, above, or below the level of surgery.
- Pressure on the surrounding tissues or organs due to presence of the device or heterotopic ossification.
- Bursitis.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Loss of neurological function including paralysis (complete or incomplete), reflex deficit, muscle loss, pain, dizziness, numbness, spasms, sensory loss, or visual deficit.
- Dural tears possibly resulting in persistent CSF leakage, pseudomeningocele, fistula, possible meningitis.
- Sensitivity or allergic reaction to implants, materials used, scattered wear debris, corrosion, including metallosis, necrosis, staining, tumor formation, or autoimmune disease.
- Hemorrhage, hematoma, seroma, edema, embolism, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood or lymphatic vessels, occlusion or other types of cardiovascular system compromise or injury.
- Respiratory disorders (e.g. pulmonary embolism, pneumonia, pneumothorax, bronchitis, etc.).
- Bladder dysfunction or reproductive system compromise (urinary retention or loss of bladder control, retrograde ejaculation, sterility or sexual dysfunction).
- Inability to perform the activities of daily living, impotence.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Ileus, gastritis, bowel obstruction or loss of bowel control, or other types of gastrointestinal system compromise.
- Discomfort, abnormal sensations, vascular or neurological damage, pain, dysphagia and/or perforation of the esophagus, dysphonia, hoarseness due to the presence or prominence of the device or scar formation.
- Change in mental status.
- Bone loss or decrease in bone density, possibly caused by stresses shielding.
- Death.

8) RISK OF INTERFERENCE WITH MEDICAL IMAGING

MRI / CT: The patient must systematically mention the implants to the clinician in charge of the imaging.

The surgeon must also indicate to the patient that in case of investigation and / or treatment (e.g. MRI), he must warn in advance the person responsible of the investigation and / or treatment the presence of the medical device in order to limit the reciprocal negative influences.

Non-clinical testing has demonstrated that the DIVA range of products is MR Conditional in accordance with the ASTM F2503-20 standard definitions. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Cylindrical-bore
- Horizontal magnetic field (B_0) of 3.0 T
- Maximum spatial field gradient 30.52 T/m (=3052 G/cm)
- Radiofrequency (RF) field exposure:
  - RF excitation: Circularly Polarized (CP)
  - RF transmit coil: whole-body transmit coil
  - RF receive coil type: whole-body receive coil
  - Maximum permitted whole-body averaged specific absorption rate (SAR): Normal Operating Mode, 2 W/kg

  Note: During non-clinical testing, the device SOCORE produced a maximal temperature rise of 3.9 ±0.4°C at 3 T for a WB-SAR of 2 W/kg after 15 minutes of continuous scanning.
- Scan duration: 15 minutes of continuous scanning
- Patients with compromised or uncompromised thermoregulation and under controlled conditions.
- Patients with uncompromised thermoregulation and under uncontrolled conditions
- The presence of DIVA implants may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.

Alternative imaging systems may be used to avoid artifacts, such as radiculography, to identify prolapsed intervertebral discs of nerve roots compression.

9) PACKAGING

Devices may be supplied in a sterile or non-sterile form. Packages for each of the components should be intact upon receipt. Once the seal on the sterile package has been broken, the product should not be re-sterilized. If a loaner or consignment set is used, all sets should be carefully checked for completeness and all components should be carefully checked to ensure there is no damage prior to use. Damaged packages or products should not be used, and should be returned to NovaSpine.

10) PRE-CLEANING / CLEANING

Unless marked "sterile" with a specific pictogram and clearly labeled as such in an unopened sterile package provided by the company, all implants used in surgery must be cleaned and sterilized by the hospital prior to use. The implants must be removed from their original packaging, after checking the integrity of this packaging, and checked up to guarantee that they have not been damaged. They must undergo pre-disinfection and cleaning operations with appropriate and compatible products, used in hospitals for this type of implants, before their sterilization. Any cleaning, disinfection and decontamination solution based on aldehyde, alcohol, chlorine, acid or abrasive should be proscribed. The user must validate its pre-disinfection and cleaning procedures according to the applicable standards.

We recommend the exclusive use of mechanized pre-disinfection and cleaning methods with a washer-disinfector (WD) compliant with the requirements of ISO 15883 series.

Automated washing:

Ensure that the WD is in conformity (CE 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.

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)

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

11) STERILIZATION

Unless marked "sterile" with a specific pictogram and clearly labeled as such in an unopened sterile package provided by the company, all implants used in surgery must be sterilized by the hospital prior to use. It is recommended to use a water steam sterilization (in compliance with the requirements of the ISO 17665 series) with a **validated cycle** according to parameters mentioned Table 2.

Table 2 - Recommended sterilization protocol

Cycle Step	Method	Temperature	Minimum exposure time
Sterilization	Steam, pre-vacuum	134°C (-0 / +5°C)	18 minutes
Drying	vacuum	Heated air, 80°C minimum	30 minutes

Implants should be prepared so that all surfaces are in direct contact with water steam. The containers supplied by NovaSpine and used to transport devices must be packaged in a way allowing to maintain the sterility of the container. It 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 implants must be packaged in suitable packaging, handled, stored and transported carefully to guarantee the maintenance of the sterile state until the surgery.

The equipment and cycle of sterilization and drying must be validated and monitored by hospitals with appropriate laboratory techniques and according to the sterilizer manufacturer's recommendations and current standards for moist heat sterilization of medical devices. The validation should cover all possible configurations of loads and wrapping/packaging of devices. The sterilization process parameters and the autoclave settings must be monitored regularly. Periodic maintenance must be defined and followed (e.g. calibration, verification of process: time, temperature, …).

The end user assumes final responsibility for the validity of sterilization of products and their maintenance in this state.

Any other method of sterilization (ethylene oxide or oxygen peroxide at low temperature) must not be used and is the sole responsibility of the user.

Sterilization recommendations are given for informative purposes only. Under no circumstances can the manufacturer be held responsible for the sterility of sterilized devices within the hospital.

All users using these instructions should be qualified with documented expertise and training. Users should be trained on hospital policies and procedures along with current applicable guidelines and standards.

12) REUSE OF DEVICES

All implants of the DIVA range are single use devices. An implant is used when it has been implanted in a patient or in contact with tissues or body fluid of a patient.

Surgical implants must never be reused. A device that has been implanted or in contact with human tissue or body fluid should never be reprocessed or reused under any circumstances. Reprocessing or reuse of used devices may create a risk of contamination of the implants which could result in patient infection or death.

Sterile packaged devices should also never be resterilized. Used device shall be eliminated (see §15)g).

Non-sterile implants, clearly labeled as such, that were made available during the surgery but that were not used by the surgeon, or any other authorized person during the procedure, can be cleaned and sterilized for further use, in the absence of signs of wear, damage and loss of performance. The number of cleaning and sterilization cycles of unused devices depends on the material of the implants:

For titanium alloy (ISO 5832-3 and ASTM F136) or PEEK (ASTM F2026 and ASTM F560) materials, there is no theoretical limit to their reprocessing with the exception of use, damage, wear, or loss of performance. In such cases, cleaning and sterilization and subsequent use compromise the claimed performances and safety of the implant.

Non-sterile devices must always be cleaned and sterilized (see §10) and §11)) prior to their use.

13) STORAGE

Implants should be stored carefully in a clean room under normal temperature and humidity conditions. Implants must be protected from UV rays and all corrosive environments.

14) WARNING

Following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. All information is common to the whole range unless otherwise specified. This information does not include all adverse effects that can occur with surgery in general, but are important considerations particular to temporary metallic internal fixation devices.

Although the physician is the learned intermediary between the manufacturer and the patient, the important medical information given in this document should be conveyed to the patient. General surgical risks should be explained to the patient prior to surgery.

The safety and effectiveness of the ranges have been established only for spinal conditions with degeneration or fracture requiring fusion with instrumentation. These conditions are detailed in the indications. The safety and effectiveness of these devices for any other conditions are unknown. Despite the care brought by the surgeon to the indications and to the technique of use of the implants, there is a risk of non-union and absence of fusion. The implants are not prostheses. In case of pseudarthrosis or absence of fusion, the instrumentation and/or one or more of its components can be expected to pull out, bend, or fracture as a result of exposure to every day mechanical stresses, and pain may persist. In such a case, a revision surgery may be necessary and can be performed with the DIVA range, to revise and/or remove devices before a serious injury occurs.

DIVA range components must not be used with components from other manufacturers unless otherwise specified. NovaSpine assumes no responsibility and cannot be held responsible for any combination of DIVA implants with those from another manufacturer. Combining metallic DIVA implants with stainless steel material may accelerate the corrosion of devices and increase risks of breakage or failure of the device.

Surgical implants must never be reused. A device that has been implanted or in contact with human tissue or body fluid should never be reprocessed or reused under any circumstances. Reprocessing or reuse of used devices may create a risk of contamination of the implants which could result in patient infection or death.

Sterile packaged devices should also never be resterilized.

15) PRECAUTIONS

a. General

The implantation of the DIVA range must only be performed by qualified and experienced spinal surgeons with specific training in the use of spinal cages and strong knowledge of the procedure through the scientific publications related to spine surgery, because the procedure is technically demanding and may cause serious injury to the patient.

Implanting surgeons must be thoroughly knowledgeable with all aspects of the surgical techniques of the DIVA range, through the careful reading and understanding of the provided documentation, and must also be aware of the mechanical and metallurgical limitations of PEEK and metallic surgical implants. We recommend that the surgeon undergo training with a surgeon already experienced with the DIVA range before using the DIVA device for the first time.

b. Patient selection

The adequate selection of patients, according to the indications provided, and their respect of pre- and postoperative instructions are crucial elements to the success of the procedure. Patients who smoke have been shown to have an increased incidence of non-unions.

Obese, malnourished, or alcohol abuse patients are also poor candidates for spine fusion.

Overweight or obese patients can produce loads on the device that can lead to failure of the implants.

If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully fused. Even with full fusion, the patient may not be able to return to these activities successfully.

Conditions of senility, mental illness, alcoholism, or drug abuse, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the device, leading to implant failure or other complications.

No preoperative test can completely exclude the possibility of sensitivity or allergic reaction.

c. Implant selection

The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage, bending, or loosening of the device before the fusion process is complete which may result in further injury or the need to remove the device prematurely.

d. Use

The successful result of the operation is based on the reduction of pain and disability and the achievement of the bone fusion, within the expected lifetime of one year. The DIVA range is not intended to be the sole means of spinal support. Use of this product without a bone graft, or in cases that develop into a non-union, may not be successful. 3D printed titanium cages designs do not always allow the insertion of graft inside the cage. The porous structure of the cage is defined to promote bone fusion without the addition of graft in the cage, but the use of bone graft around cages at each level treated remains essential for the success of the operation. No spinal implant can withstand indefinitely body loads without solid biological support provided by spinal bone fusion. In this event, device(s) will fail in any of several modes. These modes may include bone-metal interface failure, implant failure (bending, loosening and/or fracture), subsidence in the vertebra or bone failure. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure.

Proper patient selection, according to the indications provided, proper implants selection, the respect of pre- and postoperative instructions by patients and an adequate surgical technique, according to documentation provided and intended use, are also essential requirements for the success of the operation. Implied warranties of merchantability and fitness for a purpose different than what is recommended in this IFU are excluded.

Postoperative care is extremely important. The patient must be instructed in the limitations of PEEK and metallic implant and be warned regarding weight bearing and body stresses on the device, and limitation of daily activities, prior to firm bone fusion. The patient should be warned that compliance with postoperative instructions is an important consideration for the success of the surgery. Non compliance with instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device.

e. Preoperative precautions

- The surgeon must be completely familiar with all aspects of the device, the instruments, the surgical procedure/technique, and device limitations. Refer to the individual surgical technique manuals for additional important information.
- An adequate and sufficient inventory of implants (shapes, sizes) should be available before surgery and before sterilization for non-sterile devices. It is advised to have a larger inventory than what is expected to be used.
- All instruments required for the surgery must be available, not worn or distorted and functional. If an instrument is worn or distorted or unfunctional it must be returned to the manufacturer.
- Care should be used in the handling of the implant components. The implants should not be scratched or otherwise damaged. If an implant is damaged, it must be returned to the manufacturer.
- Validity of sterilization must be verified before surgery.
- Unless sterile packaged, all devices should be sterilized before use. Additional sterile components should be available in case of an unexpected need.
- Only patients that meet the criteria described in the indications should be selected. Patient conditions and pre dispositions such as those addressed in the aforementioned contraindications should be avoided.

f. Intraoperative precautions

- Strictly follow the operating steps detailed in the surgical procedure(s)/technique(s) provided by the manufacturer.
- The surgeon must be extremely careful when placing the implants and must pay particular attention to neurological and vascular elements to prevent permanent damage, loss of neurological functions or death.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- The correct selection of the type and size of the implants adapted to each other and to the patient as well as their proper use and correct positioning and implantation are extremely important for the success of the operation
- Avoid strong impaction of cages, especially small sizes of cages and PEEK cages, to avoid their breakage

- DIVA Non-blocked cages must be used in association with pedicle screws or plates and screws in lumbar use. It is recommended to use plates and screws with non-blocked cervical cages.
- Cervical corpectomy cages must be associated with the use of a cervical plate with screws.
- Before closing the soft tissues, verify the adequate position of all implants and tightening of all devices to tighten. All locking sets of lumbar plates and blocked cages must cover screws to prevent their back-out and migration.
- In revision surgery, all implants have to be replaced with new ones, even if their appearance is correct and do not show signs of damage, wear or fatigue
- Only usable and STERILE implants should be used during the surgical procedure
- During implants manipulation, check their proper surface appearance (absence of scratches, shock, etc.) avoid mechanical stresses during implantation
- Clean and dissect the vertebral endplates and use when possible, bone graft inside and around the cages to promote bone fusion
- The DIVA range components must not be combined with any components from a different manufacturer, unless otherwise specified
- Cement injection must never be used in the interbody zone
- Implantation and eventual removal of implants must be done exclusively with the specific instruments provided by NovaSpine
- Implants must not be modified or reworked by the user, except if it complies with the surgical procedure provided
- When cervical plate contouring is absolutely necessary to fit the cervical spine, it is recommended that such contouring be gradual using the appropriate instruments with great care to avoid notching or scratching the surface of the plate. The use of inappropriate instruments may result in scratches, notches, and sharp bending, causing the breakage of the implants. Improper seating, excessive bending, repetitive bending or reverse bending of the plates may result in implant failure.

g. Postoperative precautions

- Elimination of retrieved devices: Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the DIVA range components should never be reused under any circumstances. After pre-disinfection and cleaning, the devices to be eliminated will be eliminated according to the methods applied by the hospital while respecting regulations in force, or, if they do not present potential risk, will be sterilized for eventual return to the manufacturer for analysis or expertise.
- Detailed instructions on the use and limitations of the device should be given to the patient, especially regarding activities after surgery before fusion. The patient must be warned and should understand that bending, loosening, and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity, and that strict compliance with these instructions is essential to favor the survival of the assembly. Surgeon should warn patient to respect the following non-exhaustive list of restrictions:
- Avoid extreme forced positions (flexion-compression, rotation), avoid intense physical activities, avoid carrying heavy loads, avoid excessive body weight, avoid stresses on implants, avoid falls, avoid exposition to vibrations or shocks. Patient should also avoid bending and rotation at the spine fusion point, and compensate body motion accordingly.
- The physician's postoperative recommendations and warnings to the patient, and patient compliance to recommendations and warnings are essential for the success of the operation, especially for the reductions of stresses on the implants. The patient should be advised not to smoke tobacco, utilize nicotine products, or consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process, in order to favor bone healing and fusion.
- Risk of postoperative complications is increased if the patient is mentally ill or unwilling to comply with precautions or warnings.
- The surgeon should prescribe to the patient an appropriate program of physiotherapy
- Urgently treat any postoperative infection
- It is recommended to make regular postoperative follow-ups to check patient and device condition and adapt daily life limitation as appropriate, or prevent damage due to failure of the device or of the surgery. Until imaging confirms the spinal bone fusion, external immobilization (such as bracing) is recommended. Patient should be closely supervised until spinal fusion is confirmed.
- Failure to immobilize spine or a delayed union will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by examination. If a state of non-union persists or if the components loosen, bend, or break, the device(s) should be revised or removed immediately before serious injury occurs.
- The DIVA range implants are temporary internal fixation devices, intended to stabilize the operative site during the normal healing process and achievement of the fusion. After fusion of the spine, these implants serve no functional and cannot be removed. After the completion of its intended use, potential long-term complications or adverse effects as listed in section POTENTIAL ADVERSE EFFECTS, COMPLICATIONS AND RESIDUAL RISKS may still occur.
- After surgery, even with full bone healing and fusion, the patient should avoid as much as possible extreme lifestyle: excessive weight-bearing or muscular activity, intense physical activities, avoid excessive body weight, avoid falls, avoid shocks. These precautions are essential to avoid fracture or other complications.

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 DIVA device 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

MD	Medical device	UDI	Unique device identifier
	Read the Instructions		Consult instructions for use
	Do not re-use		Keep away from sunlight
	Do not resterilize	STERILE R	Sterilized using irradiation
	Keep dry	NON STERILE	Non-sterile
LOT	Lot number		Double sterile barrier system
REF	Catalogue number		Single protective packaging
QTY	Quantity		Do not use if package is damaged
	Manufacturer		Date of manufacture
	Use-by date		

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