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IMPORTANT INFORMATION
about:
INITIAL COMPLETE SPINE INSTRUMENTATION
Rods, Screws, Crosslink kit, Instrumentation

1 – DESCRIPTION
This instruction leaflet applies to the following ATF spine fixation system components:
- Polyaxial pedicle screws Ø4.5, Ø5, Ø5.5, Ø6, Ø6.5 et Ø7.5
- Monoaxial pedicle screws Ø4.5, Ø5, Ø5.5, Ø6, Ø6.5 et Ø7.5
- Set screws
- Scoliosis hooks
- Sacral plates
- Crosslink kit
- Posterior rods
- Product-specific instrumentation (forceps, rod bender, rod pusher, screwdriver, etc.)

These components must always be implanted and/or used together. This will ensure that the various component sizes and materials are compatible.
These products are for **single use** and are sold **non-sterile** or **sterile**.
Warning: The Ø5.5 PEEK posterior rods must ONLY be assembled with the Ø5.5 monoaxial pedicle screws.

2 – INDICATIONS
This medical device is intended for the posterior fixation of the thoracic, lumbar and sacral spine. It is indicated for the treatment of deformities (any etiology), trauma, tumors, and the degenerative spine (spondylolisthesis, degenerative disc disease, spinal fractures, spinal stenosis, non-union).

3 – CONTRAINDICATIONS
The following is a non-exhaustive list of contraindications:
- Acute or chronic, local or systemic infection
- Allergy or intolerance
- Any concurrent disease that could affect implant function
This medical device is designed, intended and sold only for the uses indicated.

4 – SIDE EFFECTS
- The side effects are the same as those encountered during any spine surgery procedure: infection, pain, hematoma, neuropathy, etc.
- Intraoperative neurological complications may require temporary or permanent removal of the fixation hardware.
- Secondary neurological complications may require a revision procedure for partial or complete, temporary or permanent removal of the fixation hardware.
- Over time, the components may loosen or disassemble, thus an additional surgical procedure may be needed.
Warning: Patients receiving the INITIAL system should be advised that implant longevity may be affected by their weight, age and activity level, and that premature or inappropriate physical activity could also reduce its longevity.

5 - WARNING
- The postoperative instructions provided by the surgeon are based on the length of the fixation hardware, involved levels and type of pathology. It is extremely important for the patient to follow these instructions.
- A second procedure may be needed for anterior spine fixation after the posterior fixation: either planned beforehand as a part of a two-stage procedure or because of the patient's anatomy and/or pathology.

6 – PRODUCT USE
These medical devices must only be implanted and/or used by a person who is well-trained in spine surgery. Implantation must be performed using appropriate instrumentation provided by the manufacturer.
Warning:
- Never reuse a component of the INITIAL system that has previously been implanted. Reuse of the device is prohibited because of the chemical, biological (allergy, toxicity, contamination, infection) and mechanical (deterioration, implant wear, etc.) risks.
-If removing the cage, appropriate extraction instrumentation must be used to avoid damaging bone, dura mater and/or nerve roots that could be hidden under fibrous tissue.

7 - MATERIALS
The implants are made of TA6V titanium alloy (ISO 5832-3) or PEEK-OPTIMA® LT1-6BA (ASTM F2026).
Use of these components with devices other than those recommended by ATF is prohibited. The instrumentation is made of non-implantable stainless steel.

8 – PACKAGING
Upon receipt, make sure the packaging of each component is still intact. If using a loaned or purchased system, carefully inspect every device prior to use. Make sure the device has all its components and that none of these components are damaged. If the packaging or the component itself is damaged, do not use it, return it to ATF.
Remove the packaging material before sterilization. Only use sterile implants and components during surgery. Any implant or component that was used in the operating room must be cleaned and resterilized before it is used again.

9 – CLEANING AND DECONTAMINATION
All devices, including those that may have been provided and/or loaned, or that were previously used in an operating room, must be decontaminated and cleaned before being sterilized.
Inspect the devices before using them – do not use devices that appear to be damaged or scratched.

10 – STERILIZATION
Non-sterile products:
Because of the risk of Creutzfeldt Jakob disease transmission, medical authorities recommend using the sterilization parameters shown below, particularly for surgical instruments that could come into contact with the nervous system.
This medical device must be sterilized in an autoclave according to the following parameters:

Method	Cycle	Temperature	Exposure time
Steam	Atmospheric pressure	134 °C	18 min.

Sterile products:
Products are packaged in protective boxes or tube and sterilized at a minimum dose of 25 kGy. The expiry date is listed on a label on the outer packaging.

11- RESTERILIZATION
Resterilization is forbidden. The manufacturer is not responsible for implants resterilized by the customer.

11 - PRODUCT-RELATED COMPLAINTS
Any health professional who is not satisfied with or who has a complaint regarding product quality, identification, reliability, safety, effectiveness or performance must notify the distributor and/or ATF. In addition, if a part did not work properly and/or could have caused and/or contributed to a patient's death or serious injury, the distributor or ATF must be notified immediately.

12 – INSTRUMENT RETURNS (for maintenance, etc.)
Any component sent to the manufacturer/vendor for repair, service or maintenance must be accompanied by a traceability form proving that the processing procedure described in French circular DGS/RI3/2011/449 dated 1st December 2011 has been applied in its entirety.

IMPLANTATION TECHNIQUE

Preoperative management:
- Patients must meet the criteria described in the indications.
- Implants must be handled and stored very carefully. They must not be scratched or damaged.

Preoperative planning:
- For the procedure to be successful, selecting the proper rod length and diameter, screw length and diameter and hook type is crucial. Use 30 x 90 cm plain X-ray films to view any deformities and determine which levels should be instrumented.
- After implantation, the implants are subjected to repeated loading. Their strength is limited by how well their geometry fits to the size and shape of the human pelvis and vertebrae and by the need to not interfere with muscles and cutaneous tissues.
- Carefully select patients based on the above indications, make sure the implant is placed correctly, and outline appropriate post-operative care to minimize the loads applied to the implant.

Intraoperative management:
- When treating spinal deformities, SEPs should be monitored during the procedure and the intraoperative wake-up test performed if needed.
- Use a posterior midline approach.
- Prepare the vertebral arches until the targeted transverse processes are reached.
- If needed, decompress the spinal cord and/or nerve roots.
- If a posterior osteotomy is needed, use a microsurgery burr to avoid spinal cord concussion.
- Hook placement: To make sure the implants are well-positioned and do not penetrate the spinal canal, only use product-specific instrumentation to prepare the site and insert the implants.
- Screw placement: Once the pedicle entry points have been determined, use intraoperative X-rays or fluoroscopy to verify screw orientation.
- Rod bending: Bend the rods to provide the desired spinal correction. The crosslinks will be easier to insert onto the rod and more stable if there are no sharp bends on the rod.
- Rod placement: Slip all the needed crosslinks onto the rods, bring the entire assembly to the operative field, then move the connectors along the rods to the desired location on the implants.
- Correction of deformities: Very gradually approximate the vertebrae to the rods to avoid damaging the bone fixation sites.

Year CE mark was received: 2008

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