IMPORTANT INFORMATION
about:

IDEAL PLATE

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CE 0459

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1 – DESCRIPTION

This instruction leaflet applies to the following ATF products:

- IDEAL Plate made of TA6V titanium alloy
- IDEAL Ø5 and Ø6 screws made of TA6V titanium alloy

These products are sold **non-sterile** or **sterile**.

2 – PRODUCT USE

These devices can only be implanted by a person who is well-trained in orthopedic surgery.Device implantation must be performed using appropriate instrumentation provided by the manufacturer.
Warning: Never reuse a plate that has previously been implanted.Reuse of the implant is prohibited because of the chemical, biological (allergy, toxicity, contamination, infection) and mechanical (deterioration, implant wear, etc.) risks. In case of system ablation is necessary to have an adapted instrument to remove devices without damage bone stock, the dura or nerves roots that may be hidden under fibrous nervous.

3 – INDICATIONS

This medical device can only be used to treat disc diseases such as spondylolisthesis, spinal fractures, stenosis and non-union.The IDEAL plate is an anatomically designed plate for the posterior lumbar spine.It helps to restore disc height and the normal lordotic curvature through the use of screws.

4 – CONTRAINDICATIONS

The following is a non-exhaustive list of contraindications:
* Acute or chronic, local or systemic infection
* Severe muscular, neurological, or vascular deficiency in the involved limb
* Bone damage or poor bone quality
* Any concurrent disease that could affect implant function
* Known or suspected metal allergy or intolerance

The contraindications for these devices are similar to those for other spine devices.This medical device is designed, intended and sold only for the uses indicated.

5 – SIDE EFFECTS

The side effects are the same as those encountered during any surgical procedure:infection, pain, hematoma, and in very rare cases, reaction to the anesthesia, pulmonary embolism, infarction.
One of the screws could potentially loosen.If this occurs, an additional surgical procedure may be needed.
Warning: Patients receiving IDEAL Plates 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.

6 - MATERIALS

The plates are made of TA6V titanium alloy, a material with proven biocompatibility.
Use of these components with devices other than those recommended by ATF is prohibited.The instrumentation is made of non-implantable stainless steel or RADEL®.

7 – PACKAGING AND STERILITY

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.

9 – HANDLING AND STORAGE

Implants should be stored away from humidity or external conditions that could lead to deterioration of the packaging and/or medical device.
When handling the product, protect packaging and medical device from damage.

10 - IMPLANTATION TECHNIQUE

Implant selection:
For the procedure to be successful, selecting the proper implant type, shape and size for each patient is crucial. 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 human bones.To minimize implant loads, carefully select patients based on the above indications, make sure the implant is placed correctly, and communicate appropriate postoperative care.

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.

Further information on the use of this system is available upon request.

Intraoperative management:
Step 1
Posterior midline approach
Prepare the vertebral arches until the targeted transverse processes are reached.
Step 2
If needed, perform a medullary or radicular decompression.
If a posterior osteotomy is needed, use a microsurgery burr to avoid spinal cord concussion.
Step 3
Put K-wires into the pedicle entry points.These will be used to guide the placement of the pedicle screws.
Step 4
Determine the best plate length and then installthe screws to attach the entire unit.
Step 5
Remove the K-wires from the vertebral bodies.
Step 6
Close the incision.

Postoperative management:
It is extremely important for the patient to follow the postoperative instructions and warnings provided by the surgeon.
Detailed instructions on the use and limitations of the device must be provided to the patient.The patient should be advised to limit and restrict his/her physical activities, avoid smoking and excessive alcohol consumption during the healing of the bone graft.
Poor bone healing will, over time, result in excessive and repeated loads on the implant.In this case, immobilize the fusion level and monitor healing with X-rays.If fusion does not occur, the device must be immediately revised and/or removed before a serious injury occurs.

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.