IMPORTANT INFORMATION
about:

DUAL PLATE

ATF
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ZI des Prés Paris
74970 MARIGNIER
FRANCE
Tél.: 04-50-34-57-10
Fax. : 04-50-89-21-20

CE 0459

Year CE mark was received: 2008

1 – DESCRIPTION

This instruction leaflet applies to the following ATF products:
- DUAL Plate made of TA6V titanium alloy
- Revision screw

These products are for **single use** and are sold **sterile** or **non sterile.**

2 – PRODUCT USE

These devices can only be implanted by a person who is well-trained in spine surgery.Device implantation must be performed using appropriate instrumentation provided by the manufacturer.
Before using the device, inspect the packaging to ensure thatplate sterility has not been compromised.Remove the implant from its packaging using aseptic technique.Make sure the plate does not contact objects that could alter its surface finish.
Warning:
-Never reuse a plate or screws that have 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 plate, appropriate extraction instrumentation must be used to avoid damaging bone, dura mater and/or nerve roots that could be hidden under fibrous tissue.

3 – INDICATIONS

This medical device can be used only to treat cervical disc diseases such as refractory radiculopathy (radiating pain) and/or myelopathy (weakness) with a herniated disc and/or osteophyte formation and/or spinal cord compression.
The DUAL plate is an anatomically designed plate for the anterior cervical spine.It helps to restore disc height and the normal lordotic curvature.The plate is used at levels C2-C3 to C7-T1 with an anterior approach.

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, osteoporosis, necrosis
* Bone tumor at the implantation site
* Any concurrent disease that could affect implant function
* Pregnancy
* Morbid obesity
* Known or suspected metal allergy or intolerance
* Mental illness, alcoholism or drug dependency
* Inadequate activity

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, bleeding, thrombosis and in very rare cases, reaction to the anesthesia, pulmonary embolism, infarction.Because an anterior cervical surgical approach is used, the following effects can occur:hoarseness or difficulty swallowing, non-union, disease of the adjacent segment, nerve damage.
One of the screws could potentially loosen.If this occurs, an additional surgical procedure may be needed.
Warning: Patients receiving DUAL 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.

8- RESTERILIZATION

Resterilization is forbidden. Only expired **metal** components that have never been implanted can be resterilized.They must be returned to ATF for resterilization.**Do not resterilize them yourself.**
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
Anterior cervical approach,discectomy and decompression
Step 2
Prepare the vertebral endplates.Implant a trial cervical cage to verify the flatness of the endplates, ensure maximum contact area and confirm the exact size of the final implant.
Step 3
Thread the selected cervical cage onto the impactor handle and place the cage into the packing block.Use the compactor to compact the cancellous bone into the graft compartment of the implant.
Warning:Do not damage the threads when screwing the cage onto the handle; any damage could lead to particles being releasedwhen the instrumentation is removed.
Step 4
Apply a slight distraction and then carefully impact the cervical cage into the intervertebral space.
Step 5
Release the distraction.
Step 6
Position the plate and use the awl to mark the screw holes.
Step 7
Use the provided screwdriver to screw in the cervical screws to hold the plate in place.
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 healingwill, over time, result in excessive, 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.

IMPORTANT INFORMATION
about:

SCREWS FOR CERVICAL PLATES

ATF
520 Avenue de l'industrie
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74970 MARIGNIER
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CE 0459

Year CE mark was received: 2009

1 – DESCRIPTION

This instruction leaflet applies to the following ATF products:
Anchoring screw for use with TRIAL, PAL, POSTAL plates.
Revision screw for use with DUAL, TRIAL, PAL, and POSTAL plates.
Device are packaged sterile by two, **sterile by two with one plate, sterile unit** or **non** sterile by two with one plate. They are for **single use** only.

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.
Before use, inspect the packaging to ensure that implant sterility and cleanliness have not been compromised. Remove the implant from its packaging using aseptic technique. Make sure the screws do not contact objects that could alter their surface finish.

Warning : Never reuse screws that have 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.

3 – INDICATIONS

Refer to section 3 of the instruction leaflet of the plate in question.

4 – CONTRAINDICATIONS

Refer to section 4 of the package insert of the plate in question.

5 – SIDE EFFECTS

Refer to section 5 of the package insert of the plate in question.

6 - MATERIALS

The screws 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 tubes and sterilized at a minimum dose of 25 kGy. The expiry date is listed on a label on the outer packaging.

8 - 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

Refer to section 10 of the instruction leaflet for the plate being used.

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.