INNOV'spine
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# CERVICAL PLATE ANCEPLATE

CE 0459

## 1 – DESCRIPTION

This instruction leaflet applies to the following INNOV'SPINE products:

- ANCEPLATE plate made of TA6V titanium non sterile
- ANCEPLATE plate made of TA6V titanium sterile
- ANCEPLATE plate 4 holes + 4 screws made of TA6V titanium steriles
- Sterile screws

These devices are for **single use** and can either be sold **sterile** or in pouches suitable for **autoclave sterilization**.

| Non sterile plate | Sterile plate | Sterile plate + 4 screws |
|---|---|---|
| ACP-4-21 | ACP-4-21-S | ACP-4-21-40-14-S |
| ACP-4-26 | ACP-4-26-S | ACP-4-21-40-16-S |
| ACP-4-31 | ACP-4-31-S | ACP-4-21-40-18-S |
| ACP-6-36 | ACP-6-36-S | ACP-4-21-40-20-S |
| ACP-6-41 | ACP-6-41-S | ACP-4-26-40-14-S |
| ACP-6-46 | ACP-6-46-S | ACP-4-26-40-16-S |
| ACP-6-51 | ACP-6-51-S | ACP-4-26-40-18-S |
| ACP-8-56 | ACP-8-56-S | ACP-4-26-40-20-S |
| ACP-8-61 | ACP-8-61-S | ACP-4-31-40-14-S |
| ACP-8-66 | ACP-8-66-S | ACP-4-31-40-16-S |
| ACP-8-71 | ACP-8-71-S | ACP-4-31-40-18-S |
| ACP-8-76 | ACP-8-76-S | ACP-4-31-40-20-S |
| ACP-8-81 | ACP-8-81-S | |

## 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 using the device, inspect the packaging (plastic-wrapped box sealed with a red "STERILE" sticker for the screws and double pouches for the plate) to ensure that sterility and cleanliness have not been compromised. Remove the implant from its packaging using aseptic technique. Make sure the plate and screws do not contact objects that could alter their surface finish.

**Warning:**

-Never reuse a plate or screws that have 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.

-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.

## 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 resulting in symptomatic spinal cord or nerve root compression. The ANCELPLATE plate is an anatomically designed plate for the anterior cervical spine. It helps to restore disc height and the normal lordotic curvature. It is available in multiple lengths to provide the best fit and with multiple holes to treat multilevel disease. The plate is used at levels C2-C3 to C7-T1 with an anterior approach.

ANCEPLATE plate can be implanted in conjunction with an INNOV'SPINE cervical cage.

## 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, and thrombosis and in very rare cases, reaction to the anesthesia, pulmonary embolism, and 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 ANCELPLATE 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 INNOV'SPINE is prohibited. The instrumentation is made of non-implantable stainless steel or RADEL®.

## 7 – PACKAGING AND STERILITY

Non sterile devices:

They are individually packaged in double pouches (for autoclave sterilization).

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 | Temp. | Time |
|---|---|---|---|
| Steam | Atmospheric pressure | 134 °C | 18 min. |

Sterile devices :

They are individually packaged in sterile protective boxes or tubes (gamma sterilized at min. 25 kGy).

The expiry date is listed on a label on the outer packaging.

## 8 – RESTERILIZATION

Only expired **metal** components that have never been implanted can be resterilized. They must be returned to INNOV'SPINE 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 an ANCELPLATE 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 released when 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 healing will, over time, result in excessive, repeated loads on the implant. In this case, the fusion level should be immobilized and the healing verified 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 INNOV'SPINE. 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 INNOV'SPINE must be notified immediately.

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Manufacturer | REF | Catalog number | LOT | Batch code | | Use by | STERILE R | Sterilized using irradiation | | Keep away from sunlight |
| | Do not resterilize | | Do not reuse | | Caution, consult accompanying documents | | Consult instructions for use | | Do not use if package is damaged | | Keep dry |

Last revised on 01/2015

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CE 0459

# Cervical Screw

## 1 – DESCRIPTION

This instruction leaflet applies to the following INNOV'SPINE products:
- Anchoring screws
- Revision screw

These screws are used for fastening the following plates : ANCEPLATE, ACIFBOX PL et POCEPLATE.
The devices are for **single use** and sold **sterile.** They can be packaged by 2 if sold with a plate or or single.

## 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 (plastic-wrapped box sealed with a red "STERILE" sticker) 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 INNOV'SPINE is prohibited. The instrumentation is made of non-implantable stainless steel or RADEL®.

## 7 – PACKAGING AND STERILITY

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 INNOV'SPINE. 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 INNOV'SPINE must be notified immediately.

Year of the CE certification obtention : 2009

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | Manufacturer | REF | Catalog number | LOT | Batch code | | Use by | STERILE R | Sterilized using irradiation | | Keep away from sunlight |
| | Do not resterilize | | Do not reuse | | Caution, consult accompanying documents | | Consult instructions for use | | Do not use if package is damaged | | Keep dry |

Date de dernière révision : 08/2012