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CE 0459

CERVICAL PLATE POCEPLATE

1 – DESCRIPTION

This instruction leaflet applies to the following products:

Référence
PCP-2-25
PCP-3-38
PCP-4-51
PCP-5-64
PCP-6-81

These products are for **single use** and are sold **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 (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 device is prohibited because of the chemical, biological (allergy, toxicity, contamination, infection) and mechanical (deterioration, implant wear, etc.) risks.

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 POCEPLATE plate is an anatomically designed plate for the posterior 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 a posterior 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, and thrombosis and in very rare cases, reaction to the anesthesia, pulmonary embolism, and infarction. One of the screws could potentially loosen. If this occurs, an additional surgical procedure may be needed.

Warning: Patients receiving POCEPLATE 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

Plates: All the plates 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.

Screws: All screws are individually packaged in sterile protective boxes (gamma sterilized at min. 25 kGy).The expiry date is shown 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

Reduce the deformity by placing the patient on the surgical table in ventral decubitus.

Step 2

Posterior cervical approach

Step 3

Use the Roy-Camille posterior fixation technique to relieve the compression.

Step 4

Perform a laminectomy of the involved vertebrae.

Step 5

After performing the decompression, position the plate and use the awl to mark the screw holes.

Step 6

Use the provided screwdriver to screw the cervical screws into the facet joints to hold the plate in place.

Step 7

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, 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 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: 08/2012