SOFEMED

CE
2803

1. PRODUCT

Thoraco-lumbar fixation device

2. MATIERIALS
Alloyed titanium medical grade ISO 5832-3/ ASTM F136

3. DESCRIPTIONS AND GENERAL INFORMATION ON THE PRODUCT
The thoraco-lumbar fixation device is composed by a set of rod of connections, components of connections as well as monoaxial or/ and polyaxial screws of reduction of various diameters. Monoaxial or polyaxial Pedicle screws are available in various diameters and lengths to re-hang best on the treatment of every surgical case.
The components of thoraco-lumbar fixation device are made from titanium or alloyed titanium such as defined in the paragraph 2. Components made from other metallic alloys must not be used in the same structure.
SOFEMED international recommends strongly the use of the components of spinal fixation of the same mark during an assembly

4. INDICATIONS
The components of Thoraco-lumbar fixation device are used for:
1- The treatment of the diverse cases of disease of the lumbar spine such as:
*Stenosis,
*Spondylolisthesis,
*backache requiring an intervention,
* Thoraco-lumbar vertebra fracture and dislocation of the vertebral bodies,
*Deviation of the lumbar vertebra as the scoliosis or the cyphosis.

2- Trauma of the lumbar spine.
Warning: The components of thoraco-lumbar fixation device are not for cervical use. They are designed for adult patient treatment.

5. CONTRAINDICATION
The use of the thoraco-lumbar fixation device is against indicated in the following cases (not exhaustive):
*Patient suffering from an Infection located in the operating zone or presenting signs of local inflammation.
*Patient suffering from fever or leucocytosis.
*Patient suffering from a sick obesity.
*Patient having a bad muscular and osseous quality.
*Patient suffering from a nervous paralysis.
*Patient suffering from diseases of articulations with fast evolution, osseous absorption, osteopeny or osteoporosis, or presenting an insufficient tissular cover at the level of the operating site.
*Pregnant patient whether it is at the beginning of pregnancy or in delivery.
*Patient presenting mental disorders.
*Patient presenting an allergy / intolerance and/or an hypersensitivity reaction in one of component of the material.
*Patient presenting a congenital abnormal anatomy or with not adapted anatomy.
*Patient not wanting to conform to the post-operative instructions.

6. COMPLICATIONS AND POSSIBLE UNDESIRABLE EFFECTS
Possible complications exist during any surgical operation. The risks and the complications associated to those implants include:
-Premature complications such as:
*Postoperative Hematoma.
*Dural wound.
*Infection (abscess of mild parts, epiduritis, arachnoïdite, meningitis, spondylitis and arthritis inter-apophysary posterior)
*Root Deficit .
- Late complications such as :
* Destabilization of the operated floor
* Remove of the knickknack of the osteosynthesis equipment
* Lack of consolidation or pseudarthrosis
* Failure of the surgical operation
* Migration of the implant

Other undesirable effects:
* Allergic reaction due to the presence of implants.
* Break of the equipment translating a pseudarthrosis.
* Compression by the equipment translating neurological disorders.
* Pains further to the badly positioned equipment.
* Hurts translating leaks of the cerebrospinal fluid, disorders and/or loss of the neurological functions or the paralysis.
* Incapacity to take back the activities of the normal everyday life.
* Death.

7. WARNINGS AND PRECAUTIONS
1-The appeal to the surgical operations must be envisaged only after the failure of preservatives treatments except for the cases requiring an emergency intervention: pains judged unbearable, fracture of the rachis lumbar vertebra. Only the surgeon is authorized and responsible for the decision to pass in the surgical act.
2- As all the surgical operations, the competence of the doctor plays an important role in the success of its intervention. However, an additional surgical operation can be necessary to correct some of these anticipated unwanted effects
3- The assembly type must be determined before any intervention
4- The follow-up by imaging: MRI, scanner, radiology or other one is a main factor for success intervention. This is applicable in pre- per-post-operative.
5- Before any intervention, verify that implants are not damaged, lined or presenting signs of wear. Make sure that all the necessary instruments are available and functional.
6- Do not mix the components of SOFEMED international with components of other brands.
7- The fixation system for the lumbar vertebra is not the only means of support of the spine. No spinal implant can support of physical load without osseous support.
8- It is imperative to respect the post-operative instructions. Failing that, the system can deform, remove of the knickknack and finally break under the influence of the mechanisms of fatigue.
9- Use screws and locking screws of correct size. A too long or too wide screw and/or a badly selected locking screw can damage nerves, cause a bleeding and/or a removal of the knickknack.
10- In the case of use of mono or polyaxial reduction screws, use the adequate instruments for the break of the reduction part.
11- The instructions defined at the level of this note must be correctly respected.

8. PRECAUTIONS PEROPERATIVES
* During the intervention, it will be necessary to show an extreme caution around the spinal cord and the nervous roots.
* Proceed to the identification and to the preparation of the pedicular channel before any insertion of screws.
* Insert the polyaxial screw in the chosen pedicle and screw until the maximal depth allowing maintaining the polyaxiality of the head.
* Insert the monoaxial screw into the chosen pedicle until the body of the screw gets in touch with the bone at the level of the site of insertion of the screw.
* Stalks have to exceed 5 mm the heads of screw situated in the extremities of the assembly.
Use the adequate instruments for the bending of stalks. The latter must not be arched in a repeated or excessive way beyond what is absolutely necessary. A correctly arched stalk normally has to fit at the bottom of every body of polyaxial screw.
* Use a sterile and adequate tap for screw. Do not tap too much. An excessive tapping can damage nerves or cause a bleeding.
* The follow-up by imaging: MRI, scanner or radiology is important for the success of the intervention.

9. INFORMATION TO BE SUPPLIED TO THE PATIENT
The patient should be informed about the post-operative instructions, we quote in a not exhaustive way:
* Implants have no properties of an alive bone. They are planned to supply a stability of the rachis until the cure.
* Implants are metallic devices attached to bones allowing the osseous consolidation. It is important to avoid the curvature of the back at the level of the operating site.
* The limitation of the activities to those recommended by the surgeon.
The work requiring an effort, the sports activities, the distant journeys and requiring an effort should be avoided.
* The use of crutches to support partially or totally the body of the patient allows optimizing the results of the intervention.
* The respect of the post-operative instructions allows avoiding the risks of lesion and/or additional surgical operation.

10. REMOVE OF THE DEVICE:
The spinal implants are not intended to remain in position infinitely. They must be removed from the human body after having performed their role because they are not planned to resist the strengths developed during the normal activities.
However, the period of implantation remains to define by the surgeon. The osseous consolidation success is a determining factor for ablation of implants.
A premature ablation of implants can be envisaged in the following circumstances:
- Development of an allergy in one of the components of the material,
- Pain due to implants,
- Infection,
- Break of the implant.

Warning :
If an implant remains implanted after complete healing, the implant may cause the following complications:
-corrosion
- Migration of the implant ending in a lesion
- Risk of additional lesion further to the post-operative trauma.
- Remove of the knickknack of the osteosynthesis equipment, distortion and/or break which make impossible the ablation of the implant.
- Bone lyse.
- Pain or discomfort due to the presence of the implant.

11. PACKAGING
The implants of SOFEMED international are supplied not sterile; all the components must be cleaned, disinfected and sterilized before use. Any component with damaged packaging must be eliminated.

12. MANIPULATION AND STERILIZATION
Implants are exclusively single-use. Never re-use a device having been put in touch with tissues or organic liquids.

13. CLEANING
The cleaning and the disinfection of implants can be made with solvents free from aldehydes. The cleaning and the decontamination must be realized by using neutral cleaners and by rinsing with some demineralized water.
Do not use alkaline cleaners.
Inspect visually to verify the cleanliness. All the internal and external visible surfaces must be visually inspected. If necessary, clean and disinfect again the implant until it is apparently clean.

14. STERILIZATION
SOFEMED International recommends the technique and the following parameters:

Cycle	Temperature	Exposure time
Steam	134°C (273°F)	20 min

However, every establishment of health has to validate the technique as well as the used parameters of sterilization. Respect the regulations of your country if a text of law requires the parameters of sterilization and the technique to be adopted.
There is no limit regarding sterilization of instruments. However, it is necessary to verify the state of the material before any use. Any damaged material must be eliminated immediately.
Do not sterilize an implant in case it has been in touch with human tissues or organic liquids. Proceed to his elimination immediately to avoid its deliberate use.

15. COMPLAINTS:
Any professional who wishes to claim for a reason of dissatisfaction with the quality of the product, its identity, its durability, its reliability, its effectiveness, and / or its performance, should contact SOFEMED International or its supplier by indicating at least the product number, the name and address of the complainant and the reason for the said claim. SOFEMED International does not engage in a complaint handling process if the product information (such as essentially the batch number) is not provided by the complainant.

Symboles and signification :

Manufacturer	Do not re-use	Batch number
Date of manufacture	Caution, consult accompanying documents	Reference of the product
Expiry date	Consult instructions for use	Authorized representative in EU

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