



DPZ Pedicular Fixation System

Instructions for Use



Fundamentals of Operation and Action

The DPZ Pedicular Fixation System was developed to promote the fixation and stabilization of vertebral spine, however, built only to assist the bone regeneration and not to substitute the structures of human skeleton.

To provide biomechanical stability, the implants provide a natural way to the regeneration of bone tissues.

The system is implanted by posterior way.

As the posterior structure of column work physiologically in compression, the DPZ Pedicular Fixation System is an implant for resist the force of compression. The best place to posterior anchor is the pedicular region.

The surgical treatment is been used for traumatic injuries of the spine. This approach, more aggressive, ensure immediate stability restoration of the injured segment, allowing early rehabilitation programs, making easier the nursing care and minimizing possible complications resulting from immobility of the patients.

Indications/Purposes

The purpose of DPZ Pedicular Fixation System is fixing the column by Posterior way. Is used to stabilization mono and multi segment in the thoracic, lumbar and thoracic-lumbar, indicated to the pathologies:

- **Deformities:** Scoliosis; Neuromuscular deformities; Kyphosis; Lordosis.
- **Degenerative diseases:** Pseudoarthrosis; Intervertebral Disc degeneration; Spondylolisthesis; Stenosis.
- **Fractures and Tumors.**

Criterion of Selection

The correctly choose of the shape, size and design of the implantable device for each patient is essential for the surgery success. The surgeon is the responsible for choose, and depend of each patient. The excess weight of the patient can be responsible for pressures and deformation over the implants that can accelerate the material fatigue and/or can produce a deformation or fail of the implants.

The size and the shape of bone structure determine the size, the form and the type of implant. Once implanted, they will be exposed to loads and deformation. Those loads applied repeatedly should be considered by the surgeon over the choice of implant, its implantation and during the follow-up pos-surgery. The action of these loads could cause fatigue in the implant, leading to rupture of the material before the bone graft is totally consolidated.

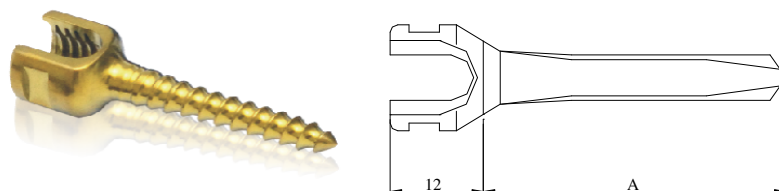
System Description

The DPZ Pedicular Fixation System is a system of medical device compound by pedicle screw, union rods, locking device and a crosslink system.

Pedicle Screws – Based in Titanium alloy (Ti-6Al-4V – ISO 5832-3):

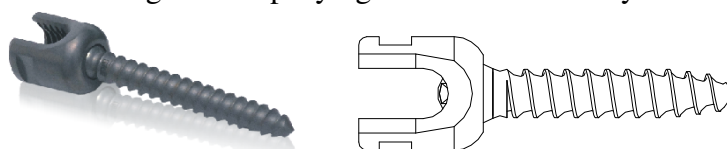
The DPZ Pedicular Fixation System has three different screws models:

Monoaxial (DPZ Pedicular Screw – Fixed Head) – is a pedicle screw for cancellous bone tissues.

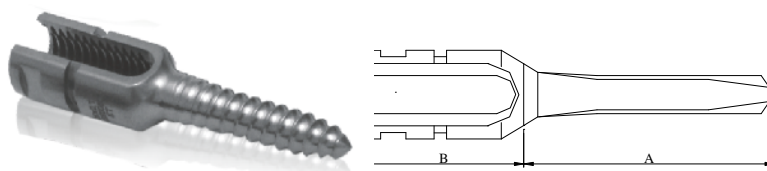


Diameter (D) mm	Length (A) mm
4,0	25 / 30 / 35 / 40
5,0	30 / 35 / 40 / 45 / 50 / 55
6,0	30 / 35 / 40 / 45 / 50 / 55 / 60
7,0	35 / 40 / 45 / 50 / 55
8,0	40 / 45 / 50 / 55

- **Polyaxial (DPZ Pedicular Screw – Moving Head)** – is a pedicle screw with a mobile head. This device is a dynamic system used to variations in the spinal anatomy, reducing the need for precision coronal rod bending and simplifying constructs assembly.



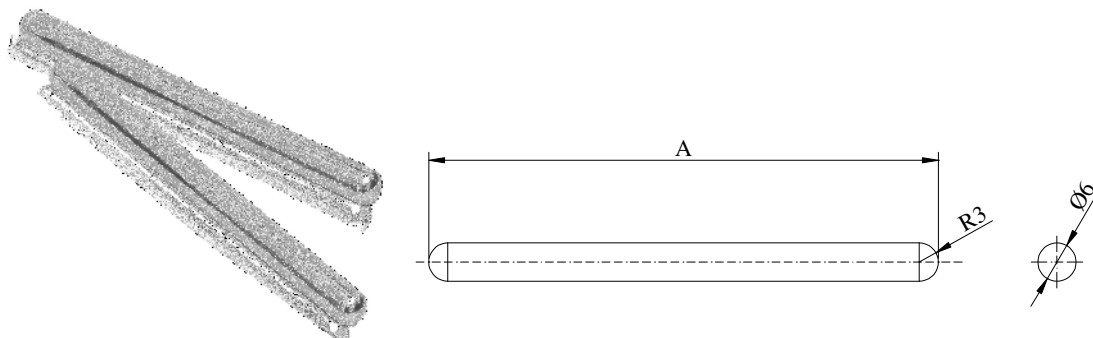
- **Reduction (DPZ Pedicular Screw – Long Head)** – is a pedicle screw with an extra extension on his head. It is used in correction of spondylolisthesis.



Diameter (D) mm	Length (A) mm	Length (B) mm
5,0	35 / 40 / 45 / 50 / 55	7,93
6,0	40 / 45 / 50 / 55	7,93
7,0	40 / 45 / 50 / 55	7,93
8,0	40 / 45 / 50 / 55	7,93

Union Rod (DPZ Pedicular Union Rod) – Based in Titanium (Ti – ISO 5832-2):

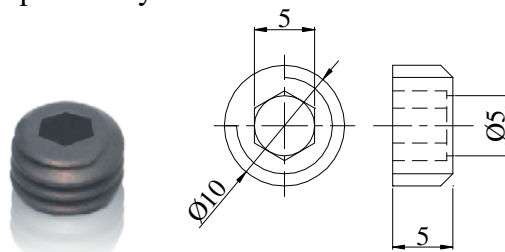
The union rod (DPZ Pedicular Union Rod) is a rod that connects the pedicle screws fixed in the vertebrae bones stabilizing the system and helping to partially support the load in the column and the spine column.



Length (A): 35, 40, 45, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200, 220, 250, 300, 350, 400, 450, 500 mm

Locking Device (DPZ Pedicular Locking Device) – Based in Titanium alloy (Ti-6Al-4V – ISO 5832-3):

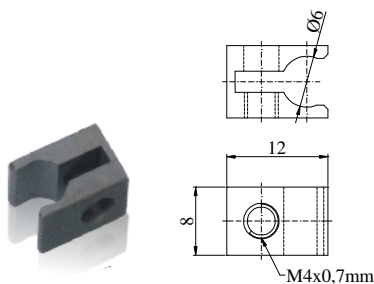
The locking device (DPZ Pedicular Locking Device) is used to lock the union rod inside the pedicle screw head, prevent the slip of the system.



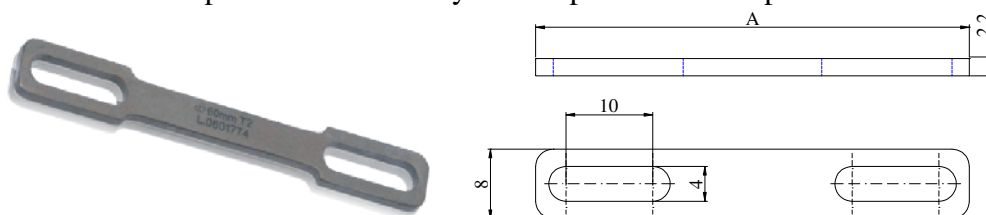
Crosslink System:

The crosslink system is a construction used to stabilize and lock the DPZ Pedicular Fixation System implanted in both side of spinal column, improving the strength of the structure. The crosslink system has three parts:

- **Hook (DPZ Pedicular Hook DTT) – Based in Titanium alloy (Ti-6Al-4V – ISO 5832-3):** is the device used to fix the crosslink system in the union rod.

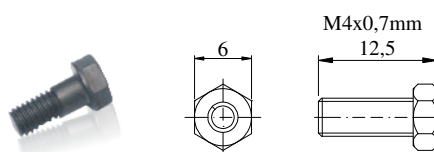


- **Bar (DPZ Pedicular Bar DTT) – Based in Titanium (Ti – ISO 5832-2):** is the device used to link both sides of the pedicular fixation system implanted in the spinal column.



Length (A): 35, 40, 45, 60 and 75 mm

- **Screw (DPZ Pedicular Screw DTT) – Based in Titanium alloy (Ti-6Al-4V – ISO 5832-3):** is the device used to fasten the bar DTT to the hook DTT, and also, lock the hook DTT in the union rod.

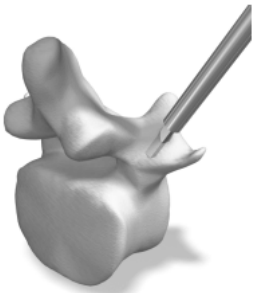

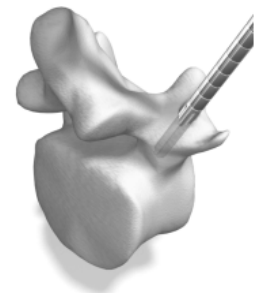

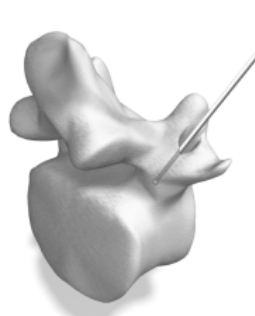

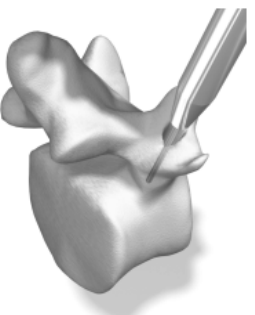

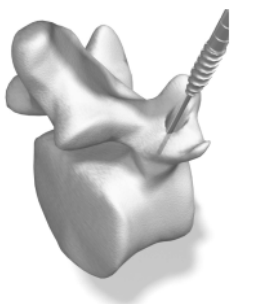



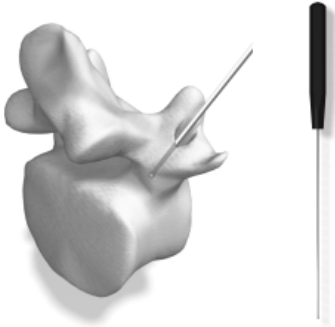
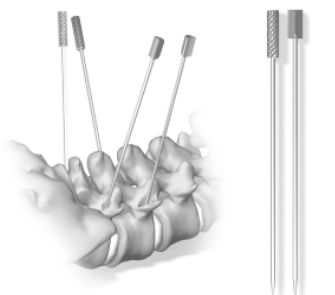
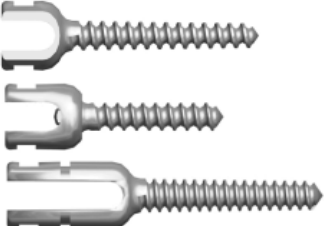
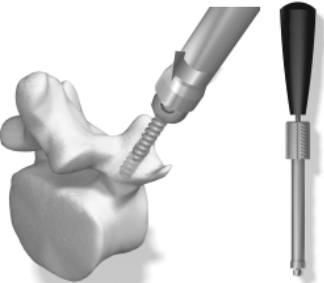
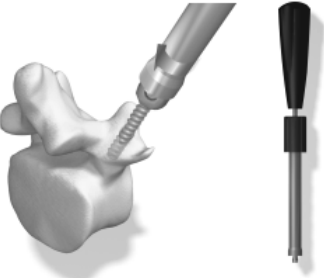


After assemble all parts of DPZ Pedicular Fixation System, the construct will assume the appearance below:



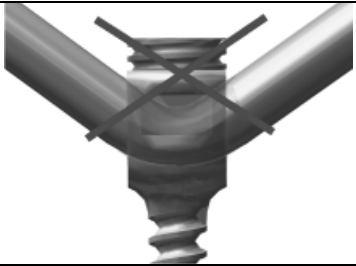
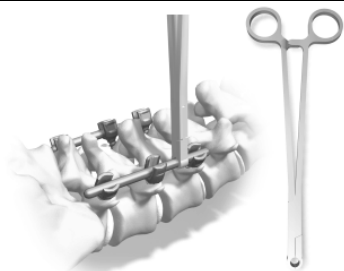
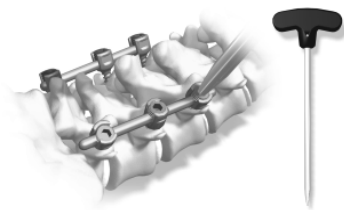
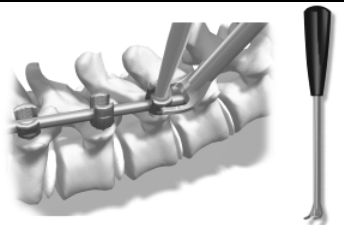



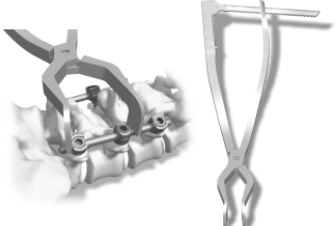

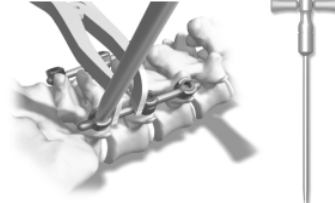

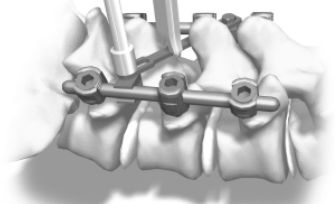
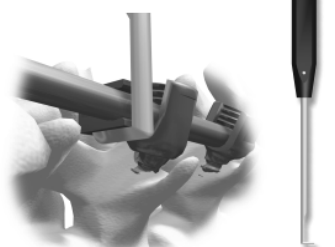
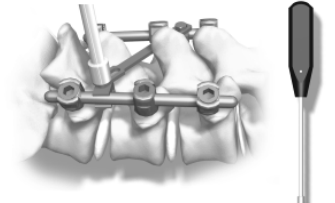
Procedure to use the DPZ Pedicular Fixation System

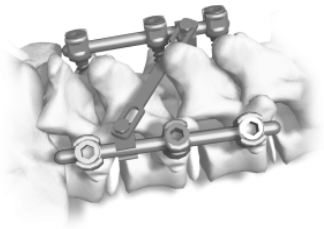

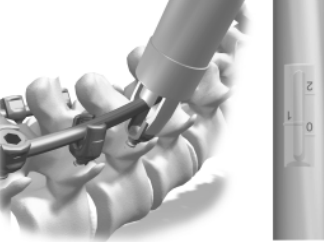
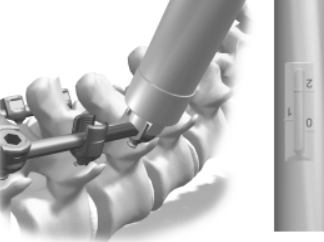
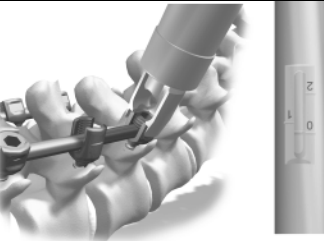
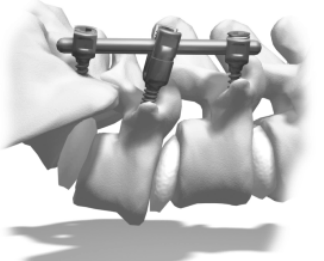
This procedure is only an illustrative technical to use the implants and instruments. Only surgeons totally familiarized with the surgical technique, instrumental and implants must apply this system in patients. The instrumental isn't the target of this technical file.

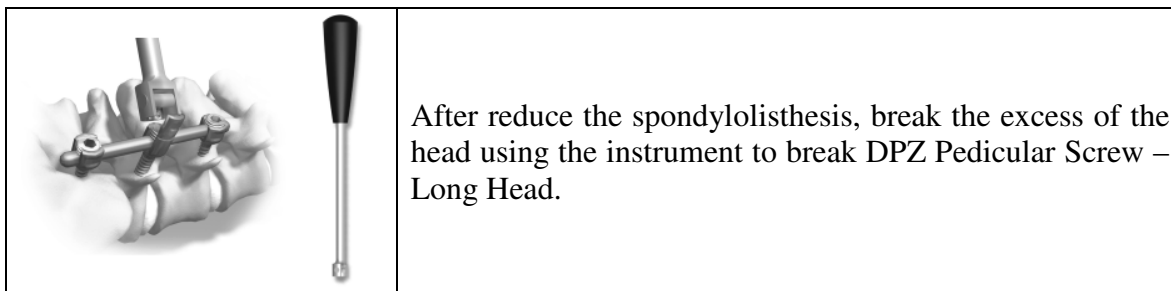
 	<p>Start drilling using the perforator of cortical.</p>
 	<p>Drilling the pedicle and the vertebral body using the graded perforator according to diameter of the screw to be used. Observe that length of the screw already can be selected.</p>
 	<p>Use the feeler of pedicle to verify the integrity of the hole walls.</p>
 	<p>Put the wire guide for measurer of depth in the hole and use the measurer to choose the length of screw.</p>
 	<p>If the impaction of cancellous bones is necessary, use the cannulated taper thread according to the diameter of the screw chosen.</p>

	<p>Use the feeler to pedicle to verify the integrity of the hole walls.</p>
	<p>If the use of X-ray is needed, the localization needles must be used to analyze the position of the holes. The needles have two shapes of head: rounded and triangular. This distinguish is used to identify the right side from left side in the X-ray.</p>
	<p>Select the type of applicable screw. In the case of spondylolisthesis, use the DPZ Pedicular Screw – Long Head. In the other cases, select between DPZ Pedicular Screw – Fixed Head or DPZ Pedicular Screw – Moving Head.</p>
	<p>If the screw chosen is a DPZ Pedicular Screw – Fixed Head, use the introducer of fixed head to introduce the screw.</p>
	<p>If the screw chosen is a DPZ Pedicular Screw – Moving Head, use the introducer of moving head to introduce the screw.</p>
	<p>Final assemble of screws.</p>
	<p>DPZ Pedicular Union Rod.</p>

	<p>DPZ Pedicular Locking Device.</p>
	<p>If necessary modeling of the union rod, use the rod bender. Don't do model in acute angles, because it can interfere in the sliding over the accommodation canal of the rod.</p>
	<p>The rod should never be put in the DPZ Pedicular Screw if it has a sharp bend at the point of linkage.</p>
	<p>Put the rods on the screws to evaluate the bends are enough to a perfect fit in the system. Use the rod holder tong to execute this step.</p>
	<p>Introduce the locking device using the hexagonal tightener of 5,0 mm</p>
	<p>If the rod don't lean the bottom of accommodation canal, use the rod fork to fit it and settle it with the locking device.</p>
	<p>Final locking.</p> <p>Start with the attach of a locking device using the torque meter with the contra-torque wrench to avoid the spin of the system during tightness.</p>

	<p>If necessary, compress the system using the compressor.</p>
	<p>If necessary, separate the system using the distractor.</p>
	<p>After the Compression or distraction of the system, tightening the locking device to avoid the sliding, nullify the process of compression or distraction.</p>
	<p>Assemble of the crosslink device.</p> <p>Use the hook holder tong to put the DPZ Pedicular Hook DTT in the union bar. Put it such a way that the side with the ribbed stay turned up.</p>
	<p>After the selection of the size of DTT bar, station it on the DTT hooks using the bar holder tong.</p>
	<p>Use the hook guide to assist the introduction of the DPZ Pedicular Screw DTT.</p>
	<p>After introduce all screws in the hooks, finish the tightening using the wrench to DPZ Pedicular Screw DTT.</p>

	<p>Assembled System</p>
	<p>Reduction of Spondylolisthesis. Use the rod approacher to reduce the spondylolisthesis. In position “0”, connect the rod approacher to the head of the DPZ Pedicular Screw.</p>
	<p>Turn the head of the rod approacher until the indicator line moves to position “1”. Now the rod approacher is locked to the screw. From this position, the spondylolisthesis can be reduced.</p>
	<p>Turn the head of the rod approacher until the indicator line moves to position “2”. The rod is totally accommodated in the screw allowing the insertion of the locking device. Put the locking device with hexagonal wrench through the rod approacher.</p>
	<p>Remove the rod approacher by turning the head of the instrument back to initial position, and rotating the complete instrument.</p>
	<p>A option to reduce the spondylolisthesis is DPZ Pedicular Screw – Long Head. To introduce and fix the screw, use the same instrument used to DPZ Pedicular Screw – Fixed Head.</p>



Device Classification

The DPZ Pedicular Fixation System is a Long term device because is normally intended for continuous use for more than 30 days. Also is a surgically invasive device because penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

The DPZ Pedicular Fixation System is an implantable device, to be totally introduced into the human body, by surgical intervention which is intended to remain in place after the procedure. Also may contact the central nervous system at meninges and spinal cord.

Therefore the PDZ Pedicular Fixation System is classified by Rule 8, as implantable devices and long-term surgically invasive devices, in which case they are in Class IIB.

Result:

Rule 8 - Class IIB

Advertence

The implant is commercialized in a non sterile way. The sterilization process must be done in hospital, using Auto Clave before use, following the hospital process. The implants mustn't be re-used.

The orthopedist or neurosurgeon must warn the patient about the limitation over the implant and the risks about an overload create by the human body over the implant until the bone consolidation occurs.

In according to ASTM F 1717-12: "The fatigue testing in these test methods establish the maximum run out load where all of the tested constructs have withstood 5 000 000 cycles without a failure. 5 000 000 cycles represents the number of loading cycles a specimen might experience within two years based on moderate activity (;7000 cycles per day)". After this consolidation time, the implant will remain in place, however, it will not be subjected to mechanical loads anymore.

Points to be considered before the surgery:

- The physical activities – excessive physical activities can lead the implant to failure.
- The weight – heavy patient can produce overload in the implants.
- Alcoholism or mental problems – the patient could not respect the limits of the implants.
- Degenerative diseases – can make the osteointegration slower or even stop it.
- Foreign body sensibility – observe the biocompatibility of the implant's materials and the patient's bone tissue. The implants can cause pain, discomfort or weird sensations.
- Implants must be used once – is not possible determine the fatigue stage of an implant already used.

- Is prohibited use of different types of implants together from different manufacturer.
- The code number and lot number of each implant must be maintained.
- If the osteointegration don't occur, the implant can fail.

Special care

- The implants are commercialized as **non sterile** medical devices.
- Before utilization, all implants must be cleaned and sterilized.
- Before sterilization, remove the implant from the package.
- The cleaning must be manual, or by ultra-sonic device, according with the manufacturer's instruction of the equipment.
- Must be avoiding abrasive instruments or products (abrasive sponge and metallic brush).
- Should be verified the integrity of the instruments and their functionalities before each surgery.
- Sterilize the implants using the steam autoclave procedure, most common in the hospitals: steam, temperature 134°C for 20 minutes.
- Others cycles of sterilization can be used either. However, the methods that differ from the indicated must be validated by suitable laboratory techniques.

Contraindications

The contraindications could be partial or total and must be considered by surgeon to take a decision.

The choose of device must be carefully studied front the evaluation of patient. The situations below must be avoided to lead to a better chance of successfully results.

- Any abnormality that interfere the normal process of bone remodeling as: severe osteoporosis in the column, bone absorption, osteopenia, tumors, infections active in loco or certain metabolic disturbs that affect the osteogenesis.
- Quality or quantity of bone tissue not enough to promote a rigid fixation of implant.
- Previous infection historic.
- Patient with systemic infection.
- Inflammation in the bone site.
- If the patient shows suspect or confirm an allergic or intolerance reaction against the material.
- Presence of neural/vascular deficits or associated pathologies that after could be harm by the implant use.
- Obesity. Weight excess could lead to a faster fail of the implant or his fixation. The patient must not have more than 120 kg (surgeon criterion).
- Pregnancy.
- The screws must be placed in intact bones (pedicle).
- Patients with another medic, surgical or psychological conditions that can interfere the benefits of the fixation surgery as: tumors, congenital anomalies, growth of sedimentation tax without reasons, increase of leucocytes or significant deviation in the differential counting of leucocytes.

The cases cited above can lead to an early screw loosening by excessive solicitation, fracture by fatigue, infection or strained.

Information to the Patients

The surgeon must discuss with the patient all physical and psychological limitations inherent to the use of implant, including the rehabilitation stage, physiotherapy and the use of orthopedic devices, according to medical prescription. The surgeon must warn about the risk of physical activities.

Patient with vigorous work or activities (lift weight, run, jump, or any excessive muscular work) that require a compressive resistance in the spine must be warned about the necessity of a substitution in future, to avoid the risks of fail. Smokers show a tendency of fail in the bone fusion and must be warned about this condition. Patient with degenerative disease in advanced stage can be susceptible to a smaller life time of the fixation system so this surgical technique is faced as a palliative technique.

The Titanium and Titanium alloy are materials non ferromagnetic and don't offers any restriction about environment or equipment (X-ray, computerized axial tomography and magnetic resonance).

Cautions in Case of Explantation

- Preserve the adjacent tissues with minimal damages in the implants.
- Radiologic Monitoring.
- Clinical Historic of patient/implant.
- Verifying the functionality of the implant before removing procedure.
- Removing registry (X-ray, computerized axial tomography).
- Microbiological study over the tissue around the implant.
- Sample of fluid and tissue for historic exam.
- Identification of the removed implant.
- Labeling of the implant for future identification.

The discard procedure is described in the item **Product Security/Discard.**

Product's Clarification

The DPZ Fixation System is designed to orthopedic and traumatologic surgery, existing specifics methods for each case. The surgeon must choose the most appropriate device according to the disease and dimension after complete exams for each patient.

All cares and precautions must be reviewed before any procedure.

The domain and knowledge of all technique about manipulation and setting of implants is extremely important. They mustn't be modified, scratched or crooked because these situations can lead to a fracture or fail of implants.

All the support staff (instrument manager, nurse, etc) must be familiarized with the product, as well the procedures adopted.

Storage / Transport



The storage must be in a place clean, dry and protect from solar radiation, with moderate temperature.

Do not use if package is damaged.

Be careful during transporting, avoiding shocks or damages in the original package.

Keep the medical device inside their pack until the use, inside the medical area.

The device must be keeping in a place with temperature between 15°C - 40°C, free of moisture.

In case of package or label damage, the device must be sent back to Osteomed or authorized representative in the European community and will be replaced.

Package

The implants are package individually in a primary pack made of plastic tubes sealed by heat. It's transparent, made of low density polyethylene non toxic, printed in red with the logo and the name of Osteomed. The second pack is card box, containing the primary pack.

If the pack or the implant is damage, the device must be sent back to Osteomed or authorized representative in the European community.

Verifying before use

The pack and label mustn't show any damage and the device must have its identification printed on his own body.

The device must be free of damages, without any mark or crack. The surface must be clean and polished.

The device must be handled with care, the minimum as possible. The device must be removed from the pack immediately before the sterilization.

If the device has suffered a fall and is suspect to have suffered damage must be sent back to Osteomed or authorized representative in the European community. However the final judgment about the functionality of the device must be decided by the surgeon.

Traceability

All devices receive identification printed on their own body. This print contains information necessary to realize the traceability: trademark and lot number.

In the invoice, the lot number is registered with the customer data, emission date and description and quantity of product.

With the invoice is annexed a traceability report. The fields of name and code of distributor and the invoice number must be filled by the seller, and the others data must be filled by the customer. All fields must be filled.

The traceability report must be kept for at least 2 years after the sale date or expire date of the implant. Where necessary, the Osteomed can require this report back at any moment without any previous notice.

Product Security

The DPZ Pedicular Fixation System is compound by devices classified as class IIB according to rule 8, therefore is a long term implantable device and is susceptible to the following risks: biological risk, biocompatible risk, mechanical and anatomic risk.

The decisions taken by Osteomed to prevent such risk are:

- **Design:**

The design of the devices are made to fit along the bone structure, allowing the perfect placing and ensuring the functionality considering the biomechanical loads applied in the place of action.

- **Material Selection:**

The materials selected to produce the medical devices are Titanium (Ti) and alloy. These materials were selected according to standards ISO (ISO 5832-2 and ISO 5832-3). Therefore these materials are according to ISO 10993-1 and all biological evaluations have been shown positive. Titanium – Aluminum – Vanadium (Ti-6Al-4V).

- **Mechanical Test:**

The medical devices are tested according to ASTM standards: F 1798 and F 1717.
Result of tests:

- Maximum Torque: 9,5 Nm (DPZ Pedicular Screw)
- Maximum Torque: 3,5 Nm (DPZ Pedicular Screw DTT)
- Maximum Torque: 10,0 Nm (DPZ Pedicular Locking Device)
- Maximum Load applied: 1294,9 N (system DPZ Pedicular Screw – Fixed Head)
- Maximum Load applied: 647,5 N (system DPZ Pedicular Screw – Moving Head)
- Slip Load: 1697,1 N (DPZ Pedicular Screw – Fixed Head)
- Slip Load: 1883,5 N (DPZ Pedicular Screw – Moving Head)

The maximum load applied in the system (rod, pedicular screw, locking device, and crosslink system) was 1294,9 N. Considering the biomechanical of the system, its indicated to be used in the lumbar, thoracic and sacral region, under action of compressive forces, therefore is indicated to patient with maximum weight of 120 kg (1177,2 N).

However, another information must be considered, like bone structure, diseases (ex: osteoporosis or bone tumor), and the patient conditions. The surgeon is responsible about indication and implantation of medical devices.

According to the mechanical tests, is indicated the priority use of DPZ Pedicular Screw – Fixed Head, because shown better compressive resistance. The use unique of DPZ Pedicular Screw –

Moving Head must be avoided. The decision about the indication for assembly of the system belongs to the surgeon responsible.

- **Biological Risk:**

After the manufacture process, all medical devices are cleaned by detergent and ultra sonic cleaner to remove oils and grease.

All devices are cleaned with alcohol (70% concentration) before package, and sealed after. This procedure ensures the cleaning of devices during the handling and transporting, free of residual organic material.

Before the surgery, all devices must be sterilized by autoclave. The parameter to execute the autoclave sterilization is shown in the next table:

Sterilization Parameters – Steam Autoclave	
Temperature	134°C ± 0,5 °C
Pre-vacuum	5 minutes
Sterilization Time	20 minutes
Drying Time	10 minutes
Internal Chamber Pressure	2,5 kgf/cm ² ± 0,2 Kgf/cm ²
External Chamber Pressure	2,5 kgf/cm ² ± 0,2 Kgf/cm ²

Therefore the autoclave procedures indicated by the manufacturer must be followed.

- **Chemical Risk:**

Titanium and Titanium alloy are materials extremely stable at human body temperature, don't spreading any dangerous material in the circulatory system. The colors are given by anodic treatment, without additional material, and the resulting oxides are inert in the human body.

The potential difference between Titanium and Titanium alloy are closer, and thus the galvanic corrosion hasn't an expressive interference in the mechanical properties along the bone restoration.

- **Discard:**











In case of discard, all devices must have their functional characteristic disenabled using a hammer, saw or pliers.

If the devices are explanted from a patient, some cares must be taken: immersion in NaOH solution bath for one hour; sterilization in a gravity autoclave at 132°C for 1 hour.

Those devices must be placed in plastic double bags, white, impermeable, identified as biohazard garbage.

- **Symbols:**

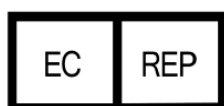
The symbols used in the label are in according with the EN 980:2008. Below are presented the definitions.

	Non sterile product
	Do not use if package is damaged
	Do not reuse
	Consult instructions for use
	Keep away from sunlight
	Caution
	Authorised representative in the european community
	Manufacturer
	Manufacture Date
	Use by

CE 1023



Sharp or pointed materials must be placed in waterproof container with cover.



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