CAUTIONARY NOTE:

The Ti-TaMED Spinal System comprises a number of different types of spinal implants and only surgeons adequately trained in the use of specific spinal implant are authorized to use these. The types referred to include: pedicle screws, spinal hooks and spinal wiring
It is essential to use adequate amounts of bone graft to achieve fusion.

Ti-TaMED Pty LTD will not accept liability for complications from adequate bone grafting or due to either the incorrect use of a specific implant, e.g.:

1. Use of Mobile screw heads over one motion segment (two screws in sequence) in unstable fractures, spondylolisthesis or bilateral foraminectomies. There is a risk of translational displacement which is obviated by using Poly Axial, locking or three Mobile screws in a row.
2. Use of Locking and Mobile screws, or Rigid and Mobile head screws in the same construct. There would be disproportionate loading on the Rigid or Locking screw, resulting in a greater chance of breaking. You may use Locking and Poly Axial screws in the same construct.

Ti-TaMED PTY LTD will not accept liability for complications. In the event that its implants and/or other implant tools are used in combination with the implants and/or implant tools of another manufacturer.

**Intended Purpose:**

The Ti-TaMED Spinal System is intended for the immobilization and stabilization of the spine as an adjunct to fusion for use in the anterior, anterolateral, or posterior non cervical, pedicle and non-pedicle fixation, for spinal conditions with significant mechanical instability or deformity requiring fusion of the thoracic, lumbar or sacral spine secondary to the following conditions:

- Degenerative disc disease
- Spondylolisthesis
- Fracture
- Dislocation
- Spinal Stenosis
- Scoliosis
- Kyphosis
- Lordosis
- Spinal Tumor
- Failed previous fusion.

**General:**

For posterior instrumentation place the patient in a prone position with an obstructed abdomen and the desired amount of lumbar lordosis if applicable.

Make an incision of appropriate length and expose the spine to the tips of the transverse processes and the ala of the sacrum if necessary.

**Pedicle Screw insertion:**

**Awl:** Used to start the hole in the desired position

**Pedicle burr:** This is advanced down the pedicle by means of alternating clockwise and anti-clockwise movements whilst exerting only a moderate longitudinal force. Proceed to the desired depth, utilizing the circumferential markings on the Pedicle Burr.

**Pedicle Probe:** Used to test all four walls of the pedicle hole for continuity.

**Screw head seater:** Used to clear away bone that may obstruct the screw head and pipe tool.

**Hole markers:** Are provided to allow radiographic verification of the position of the pedicle holes prior to inserting the screws.

**Tap:** In very hard bone it is recommended to tap the hole. The Tap is used in the following way: for every two clockwise turns use one anti-clockwise turn to loosen the bone fragments in the flues of the Tap. As the different types of screws (Rigid/Uni Axial/Poly Axial, 6mm & 7mm) require different taps, please ensure the correct tap used.
Cautionary note: It is essential to tap the pedicle hole in hard bone if Mobile/Locking Poly Axial Head screws are to be used.

Grafting markers: To facilitate optimal bone graft placement, it is recommended to place some of the bone graft to the adequately decorticated bone bed before inserting the screws, thereby allowing screws to rest on top of bone graft. The Grafting Markers are placed into the pedicle holes to allow location of these holes once the bone graft has been applied. Based on the patients size, pathology and bone quality select a suitable screw diameter, length and type, namely Rigid, Locking, Mobile and Poly Axial.

Screw Insert tools: Please note there are two different types of insert tools: Poly Axial and Rigid screws – black handle, Uni-Axial and Locking screws – white handles. Hold the screw and screw the tool into the screw head.

Screw Head forceps: Used to lightly tighten the Locking and Mobile screws onto the Screw Insert Tool and for holding the screw when removing the Insert Tool.

Rod Insertion:
Select the type of rod required based on the procedure i.e.:
Round Rods: used when no rod rotation is required
Hex Rods: used when the rod needs to rotated to provide deformity correction
Flat Rods: are used when the rod needs to be locked, preventing any rotation of the rod when rotational forces are exerted through wiring or equivalent techniques.
If only 2 Mobile, Locking or Poly Axial screw are used, the rod may fit without requiring bending.
If more than 2 Mobile, Locking, Rigid or Poly Axial screws are used, use the Rod Bender to contour the rod for a flush fit within the screw head.

Cautionary note: To make sure the Grub Screw/Cap application easier, avoid sharp bends of the rod that will fall within the screw head.
Avoid very sharp bends or re-bending as this can weaken the rod.
Hex Rod Spanner: If Hex Rods are used, this tool can be used to rotate the rod into a suitable orientation.
Depending on the particular circumstances the following tools may be required to facilitate easy rod insertion.:

Screw T-Tool: Used to rotate the screw into alignment relative to adjacent screws. It can also be used to turn Mobile, Locking and Rigid screws further in or out of the pedicle, or for removing these screws.
Poly Axial Adjustor: Used to turn the Poly Axial screws further in or out of the pedicle
Poly Axial Removal: used to remove the Poly Axial screws when the screws have been in position for a number of years and have bone fused around them.
Persuader: Used when the rod needs to be reduced into the screw head. Also allows complete 180° alignment with the screw head for application of the screw head. Individual training is required for effective use of this tool.
Mini Persuaders Used when the rod needs to be reduced into the screw head. More than one Mini Persuader can be used at a time, to achieve reduction over the whole length of the rod. Use the Extension if extra length is needed on the Mini Persuader. Individual training is required for effective use of this tool.
Rod Pusher: Used to encourage a rod into position, allowing application of the cap/grub screw

Spreader and Compressor: Used if the alignment of the spine is to be corrected, ad after final tightening of the caps/grub screws to check that no cross threading has occurred.
Pipe Tool: This is fitted over the screw head once the rod is properly in place. Ensure that the Pipe Tool is pushed onto the screw head to at least 2mm from the bottom of the head. If the Pipe tool cannot be pushed onto the screw head by hand, there must be some obstruction that needs to be removed. Do not hammer the pipe tool into position – it is only an alignment guide for the application of the cap/grub
screw. Fit the Cap/Grub Screw onto the Hex tightener and insert into the pipe. Lightly tighten the Cap/Grub Screw onto the screw head. Loosen by half turn before removing the Pipe Tool.

**Anti-Torque Pipe Tool:** Final tightening of the screw cap/grub screw is done by placing this tool over the rod and screw head assembly, and while applying a counter torque use the **Torque Hex Tightener** to tighten the Cap/Grub screw. Tighten until the 2 lines are aligned that indicate a torque of 18Nm. Do not perform final tightening without using an Anti-Torque Tool.

**Muscle Retractors** – Used to keep soft tissue out of the field when applying caps/grub screws. The locator hooks under the screw head. The Muscle Retractor without a locator can be used at S1.

**Warnings:**

1. **Correct selection of implant is extremely important.**
   The potential for satisfactory fusion is increased by the selection of the proper size, shape and design of the implant. Internal fixation devices that are made from metal cannot withstand activity levels equal to this placed on normal healthy bone. No implant can withstand, indefinitely, the unsupported stress of full weight bearing.

2. **Implants can break when subjected to the increased load associated with delayed union or nonunion.**
   Pedicle screws are load sharing devices which are used to obtain alignment until normal healing (bony fusion) occurs. If this fusion is delayed or does not occur the implant may eventually break due to metal fatigue.

3. **Mixing metals may cause corrosion.**
   It is strongly recommended that Ti-TaMED implants are not used in conjunction with those of other spinal systems, as this may lead to corrosion and therefore faster metal fatigue.

4. **Patient selection.**
   In selecting patients for internal fixation, the following favors can be of extreme importance to the eventual success of the procedure:
   - The patient's weight: An overweight or obese patient can produce loads on the device that can lead to failure of the implants and therefore the operation.
   - The patient’s occupation: If the patient is involved in an occupation that may include heavy lifting, muscle strain, repetitive bending or manual labor, he/she should not return to these activities until the fusion is complete. Even with full healing the patient may not be able to return to these activities successfully.
   - A condition of senility, mental illness, alcoholism or drug abuse. These conditions may cause the patient to ignore certain postoperative advice and orders leading to implant failure and other complication.
   - Foreign body sensitivity: The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reactions. Patients can develop allergy after the implants have been in the body for a period of time.
   - Smoking: Patience who smoke experience higher rates of pseudoarthrosis (nonunion) following procedures where bone graft is used. Additionally smoking has been shown to cause degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

**Contraindications:**

- Disease conditions that have shown to be managed without the use of internal fixation are relative contraindications for the use of these devices, e.g. laminectomies that will not cause instability, fusions that are normally successful without fixation.
• Active system infection, or infection localized to the site of proposed implantation
• Sever osteoporosis, is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this and any other spinal instrumentation
• Any entity that totally precludes the possibility of fusion e.g. cancer, kidney dialysis, or osteopenia.
• Other relative contraindications include:
  - Obesity
  - Foreign body sensitivity
  - The patient’s occupation or activity level or mental capacity may be relative contraindications.

**Precautions:**
The implantation of pedicle screws spinal systems should be performed only by experienced spinal surgeons with specific training the use of this pedicle screw spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but must also be aware of the mechanics and metallurgical limitations of metallic implants. Post-operative care is very important. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device.

- Correct handling of the implant is extremely important. The surgeon should avoid scratching, notching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish that may become the focal point for eventual breakage of the implant.
- Considerations for the removal of the implant after healing. If the device is not removed after the completion of its intended use (to achieve stability over 2 motion segments, while waiting for fusion to occur) any one of the following may occur:
  - Metal corrosion
  - Migration of implant position
  - Risk of additional injury from postoperative trauma
  - Bending/loosening and or breakage which could make removal impractical or difficult.
  - Pain, discomfort or abdominal sensations due to the presence of the device.
  - Possible increased risk of infection
  - Bone loss due to stress shielding

The surgeon should carefully weigh risks versus benefit when deciding to remove the implant. Implant removal should be followed by adequate postoperative management. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involves with second surgery.

- Adequately instruct the patient. Post-operative care and the patient’s willingness and ability to follow instructions are amongst the most important aspects of successful bone activity. The patient needs to be made aware of his limitations and restrict physical activity, especially lifting and twisting motions. The patient needs to be informed that a metallic implant is not as strong as bone and could loosen, bend or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels.
- Correct placement of Anterior spinal implants. Due to the proximity of vascular and neurological structures to the implantation site, there are serious risks of fatal hemorrhage and risks of
neurological damage with the use of this product. Serious or fatal hemorrhage may occur if the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage of implants, migration of implants or possible erosion of vessels can occur because of close apposition of the implants.

Possible adverse effects:

1. Bending or breaking of the implant or construct
2. Loosening of the implant in the bone, or loosening of the caps or grubscrews keeping the construct together
3. Metal sensitivity
4. Infection, early or late
5. Nonunion (pseudoarthrosis)
6. Decrease in bone density
7. Pain, discomfort or abdominal sensations due to the presence of implants
8. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and or bladder dysfunction, impotence, retrograde ejaculation and parathesia.
9. Bursitis
10. Paralysis
11. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak and/or possible meningitis
12. Death
13. Vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Mal-positioned implants adjacent to large vessels could erode vessels and cause catastrophic bleeding.
14. Damage to the lymphatic vessels
15. Spinal cord damage or impingement
16. Fracture of bony structures
17. Degenerative changes or instability in segments adjacent to fused vertebral levels

Surgical implants should never be reused. AN explanted implant should never be re implanted. Even though it may appear to be undamaged, it may have small defects and internal stress patterns which may lead to early breakages.
Sterilization and Cleaning:

Spinal implant trays can be put through an automated washing cycle after use, before sterilizing.
The cleaning instructions below are specific to tools.

Devices: All reusable surgical instruments supplied by Ti-TaMED comprising fixed assemblies and those with moving parts.

<table>
<thead>
<tr>
<th>WARNINGS:</th>
<th>Aluminum based instruments are damaged by alkaline detergents and solutions. Ensure that all crevices, sharp bends and joins are thoroughly cleaned with the appropriate size brush. Do not use Stainless steel renovating solutions without first consulting your Ti-TaMED agent. Check all tools for damage and replace as necessary.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limitations on processing:</td>
<td>Repeated processing has minimal effect on these instruments. There may be some discoloration of handles and tools, but end of life is normally determined by wear and damage due to use.</td>
</tr>
<tr>
<td>INSTRUCTIONS:</td>
<td></td>
</tr>
<tr>
<td>Point of use:</td>
<td>Remove excess soil with a damp disposable cloth/paper wipe</td>
</tr>
<tr>
<td>Containment and Transportation:</td>
<td>No particular requirements. It is recommended that the instruments are resterilized as soon as possible. Please follow hospital specific protocol.</td>
</tr>
<tr>
<td>Preparation for cleaning:</td>
<td>No particular requirements. Please follow hospital specific protocol. Disassembly required for certain instruments. Please see cleaning instructions with photos to see which instruments need to be disassembled, and how.</td>
</tr>
<tr>
<td>Cleaning Automated:</td>
<td>Equipment: Washer/disinfector, Detergent: Bacteriostatic/Enzymatic cleaner. Method: Load instruments such that all hinges, crevices &amp; joins get maximum exposure. Run cycle: minimum 20 minutes wash and 10 minutes rinse. When unloading the washer check that all hinges, crevices and joins have no visible soil on them. If need repeat the cycle or use manual washing.</td>
</tr>
<tr>
<td>Cleaning Manual:</td>
<td>Equipment: Detergent: Bacteriostatic/Enzymatic cleaner. Brushes and running water. Method: Rinse excess soil from instruments. Using the brush apply the detergent to all surfaces, ensuring that all hinges, cervices, joins and bends are covered. Please ensure that all instruments that have moving parts in all positions. Please see cleaning instructions with photos for more detail. Rinse under clean running water for 10 minutes. Ensure that running water passes through all hinges,</td>
</tr>
</tbody>
</table>
crevices, joins, sharp bends & cannulations.

**Drying:**
When drying is achieved as part of a washer cycle, do not exceed 120° C. When manual washing is used, instruments can be air dried. Instruments that have crevices, joins, sharp bends and hinges should be dried with compressed air. All parts of an instrument should be completely dry before assembly. Please do not pack instruments when they are still wet.

**Maintenance:**
Please refer to the relevant Maintenance instructions with photos for detail on which instruments need specific maintenance. If you have any queries, please contact your Ti-TaMED agent.

**Inspection & function Testing:**
Hinged instruments: check for smooth movement of hinge without excessive play. All instruments: check for damage and wear, cutting edges should be free of nicks and present a continuous edge. Check all instruments with long slender features for distortion. Please Maintenance Instructions for details of specific instruments to check. A Lubricant/Rust inhibitor can be used on all instruments with moving parts. If there are any queries or problems please contact your Ti-TaMED agent.

**Packaging:**
Instruments should be loaded into dedicated instrument trays, in general purpose sterilization trays. Ensure that the cutting edges are protected. Wrap the trays in the appropriate method. Please follow hospital specific protocol.

**Sterilization:**
Autoclave: These products need to be steam autoclaved at at least 135° C for at least 10 minutes, in a validated autoclave that reaches pressure of at least 245 KPA.

**Storage:**
If stored unsterile, please store in a closed container to prevent contamination with dust etc. Preferable to store sterile as per hospital protocol on storage of sterilized devices/packs.

**Additional Information:**
When sterilizing multiple packs in one autoclave cycle ensure that the sterilizers maximum load is not exceeded.

**Manufacturer contact:**
See brochure for telephone number of local representative or contact the Head Office at +27 (0) 21 510 8382

The instructions provided have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure the processing as actually performed, using equipment, materials and personnel in the processing facility achieve the desired result. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.