Posterior Spinal Fixation System
Teslake, Inc.
Please Read the Instruction for Use carefully before using the product.

1. System Description
The Posterior Spinal Fixation System is intended to be marketed as part of a system. The Posterior Spinal Fixation System is available as two separate sets:

Teslake Reach LEGEND (designed for open surgery)
Teslake Reach LONG (designed for minimally invasive surgery (MISS))

Each set comprises of different rods, screws, set screws, and accessory parts, including various lengths and diameters of reduction screws. Both sets are designed for internal posterior thoracolumbar fixation of the spine. Patient diagnosis and individual conditions should be taken into consideration when selecting the surgical option.

The Teslake Reach LEGEND and Teslake Reach LONG have separate sets of surgical instruments provided with the spinal fixation device.

2. Indications for Use
The Posterior Spinal Fixation System is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); Spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

3. Contraindications
Contraindications include but are not limited to:
1) Obvious risks for infections
2) Local inflammation
3) Fever or leukocytosis
4) Morbid obesity
5) Pregnancy or lactation
6) Mental illness
7) Excessive anatomical distortion caused by congenital anomalies
8) Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital malformations, of indications of ongoing infection or inflammation, such as acceleration of sedimentation rate and leukocytosis

9) Acute joint diseases, bone resorption, decrease bone density, chondropathy and/or osteoporosis. (Decreased bone density and osteoporosis are relative contraindications thatr educe the stability, correction efficacy and mechanical strength.)
10) Suspected or documented allergy or intolerance to the composite materials or bone cement.
11) Any case not needing spinal fixation or spinal fusion
12) Any case where the implant components selected for use would be too large or too small to achieve a beneficial result
13) Any case that requires the combined use of different devices or systems from more than one company.
14) Any patients without adequate tissue coverage of the operative site or adequate bone stock or bone quality
15) Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
16) Any patient unwilling to cooperate with postoperative instructions by the doctors
17) Any case not described in the indications

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

Severe bone resorption
Osteomalacia
Severe osteoporosis

4. Warnings & precautions

4.1 General

1) The devices should only be used for patients between 12 and 80 years old. The device is not intended for the treatment of children below 12 years.
2) Spinal fusion surgery should be performed only by trained orthopaedic surgeons and neurosurgeons, as it requires both, specialized skills and experience. Correct preoperative and postoperative measures are critical for the success of spinal fusion.
3) The implant and related specialized instruments cannot be used in combination with other products of different manufacturers. Titanium alloy components must not be used in combination with stainless steel components.
4) The Teslake Reach LEGEND and Teslake Reach LONG systems are for single use only. Never reuse the implants because the risks of infection, breakage and possibly other adverse events may increase. Used implants include any implant that has had contact with blood, bone, tissue and/or other body fluids. After removal from the patient, it shall be disposed and cannot be used again.
5) Proper selection of the size of the implant for each individual patient is important. Implants of different dimensions should be prepared for the surgery, because a correct choice of the device may increase the rate of success. The inappropriate selection, installation and position of the implant will greatly reduce its longevity.

6) During any stage of the surgery, minimizing the stress on the implant and optimizing the circumstances for fusion is crucial. High or repeated stress cycles can loosen, move, exhaust or break the implant before fusion is complete.

4.2 Preoperative

1) Only patients who meet the criteria described in the indication´s section should be chosen.
2) Patient should be carefully examined regarding contraindications. The user should also inform the patient about the potential risks and adverse events.
3) The implants should be handled and stored carefully. Collision, bending, scratching may greatly reduce the strength and lifetime of the implants. Implants and instruments should be protected from corrosive environments.
4) All non-sterile parts should be cleaned and sterilized before use.
5) Devices should be inspected for damage and integrity before use.
6) Care should be taken to avoid damage to the device(s) and injury to the patient.

4.3 Intraoperative

1) The user should follow the instructions in the surgical technique manual.
2) Breakage, slippage and misuse of instruments or implants may cause injury to the patient or operative personnel.
3) The user should be extremely careful when using implants or instruments around the spinal cord and nerve roots. Damage to nerves will cause severe injuries to the patient.
4) To avoid over-reduction or over-extension, it is advised to operate under X-ray or spinal cord monitoring.
5) If bone cement is deemed necessary by the user for more robust screw fixation, its injection should be carefully monitored and maximum 3 mL bone cement is allowed per screw.
6) Attention to be paid on cement working time. When the working time is almost over, remaining cement should not be used to avoid solidification during injection.

4.4 Postoperative

1) The patient should be aware of the postoperative limitations, such as weight-bearing, excessive muscle activity and sudden movements. The patient should also be informed about the fact that implants are not as strong and reliable as healthy bones. Until fusion is finished, implants cannot restore the spine to its normal flexibility, strength and durability. Noncompliance with the postoperative limitations will increase the risk of breakage, migration or loosening of the implant and other complications. Smoking may result in delay or failure of graft fusion, so smoking patients should be made aware of this postoperative limitation.
2) During the first 12 month following the surgery, the devices must be checked periodically to ensure the earliest possible detection of loosening, migration or breakage, using appropriate radiographic

techniques. If any of the mentioned complications occur, the risk of deterioration should be evaluated. Measures, such as further lowering activity level and/or early revision should be considered.

3) It is advised to wear external support for 3-6 months as auxiliary tension reliever.
4) Even after fusion is achieved, implants may still loosen, break and corrode. If the implant stays in the body for too long（e.g.more than 1.5 years）,complications may occur, including functional failure of the implants, corrosion, soft tissue response and pain, harm to soft tissues, nerves and joints due to migration, difficulty in removing the implants, pain and discomfort caused by the implants, increasing risk of infection and reduction of load- bearing capacity of normal bones.Therefore, Removal of the implant is recommended in the following situations:

- Corrosion with a painful reaction.
- Migration of the implant,with subsequent pain and/or neurological,artilular or soft tissue lesions.
- Pain or abnormal sensations due to the presence of the implants
- Infection or inflammatory reactions.
- Reduction in bone density due to the different distribution of mechanical and physiological
- stresses and strains.
- Failure or mobilization of the implant.

5) When removing the implants, the risk of a second surgery should be taken into consideration. Care should be taken to avoid bone fracture.

5. Potential adverse events

It is important to understand that not using the specific instruments provided with the device may lead to adverse events. With proper equipment, potential adverse events include, but are not limited to:

1) Early or late loosening of any or all of the components
2) Changes in spine curvature, loss of intervertebral height
3) Infection
4) The implant may affect the skin and lead to penetration of skin, irritation, fibrosis, necrosis and/or pain and bursitis. Inappropriate implantation or position of implants may lead to muscle and neurological damage.
5) Dural tears, pseudo encephalomyelitis, spinal dural fistula, persistent cerebrospinal fluid leakage and meningitis.
6) Loss of neurological function (e.g. sensory and/or motoric function), including paralysis (total or partial), loss of sensitivity, hyperalgesia, numbness, paresthesia, nerve root disease symptoms, persistent and/or aggravating pain, neuroma, convulsion, tinnitus, and/or visual decline.
7) Cauda equina syndrome, neurological disease, neurologic decline (temporary or permanent), paraplegia, paresis, reflection decline, stimulation, arachnoid inflammation, and/or muscle loss.
8) Urinary retention, bladder control problems, or other types of urinary tract complications.
9) Scar formation that may lead to neurological degeneration or nerve pressure and/or pain.
10) Bone fractures, micro fractures, resorption, damage or penetration on the horizontal level or up-down positions in any spine bone (including sacrum, pedicle, and/or vertebral body)

11) Disc hernia, debacle or penetration at the surgery site and its surrounding places.
12) Bone nonunion (or pseudoarthrosis). Delayed or insufficient bone healing.
13) Spinal motor function loss or increase.
14) Inability of the patient to perform the activities of daily living.
15) Loss of bone or bone mineral density caused by stress sheltering.
16) Difficulties at the implant site, including pain, fracture and healing of the injury.
17) Intestinal obstruction, gastritis, intestinal occlusion or bowel disorders, or other types of gastrointestinal system diseases.
18) Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, thrombosis and stroke, excessive bleeding, phlebitis, wound necrosis, torn wound, blood vessel damage.
19) Cardiovascular system failure complications.
20) Reproductive complications, including sexual dysfunction, pain, fracture, or wound healing problems.
21) Respiratory complications, such as pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
22) Changes in mental status.
23) Death.

Additional surgery may be necessary to correct some of these potential adverse events.

6. Packaging

Package for each of the components should be intact upon receipt. All sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used and should be returned to local agent or contact Teslake, Inc.

7. Storage

- The devices are packed in protective packaging that is labeled to its contents.
- Always store the implants and single-use instruments in the original protective packaging, store the re-use instruments in their provided sterilization cases and trays.
- Do not remove the implant from the packaging until immediately before use
- Store the devices in a dry and dust-free place (standard hospital environment).

8. Device Functionality Assessment

1) Users must visually inspect all implants and surgical instruments before use in the surgical procedure.
2) If the surgical instrument show signs of breakage or deterioration (e.g. worn down tips, corrosion, pitting, cracking, cuts, gouges, separation) on any part of the surgical instrument, then the surgical instrument must not be used.
3) Unusable implants or surgical instruments must be handled with the local regulations.. Please contact your local agent or Teslake, Inc.

9. Cleaning, Sterilization, and Reprocessing of the reusable Instruments

Posterior Spinal Fixation Systems are provided sterile and the surgical instruments are provided both sterile and non-sterile.

The sterile implants and instruments are s packaged according to standard sterilization protocols and are single use only.

Do not re-sterilize or reuse. Do not use if package is open or damaged. This is a single-use device. Re-use of single-use sterile devices can result in the transfer of materials not limited to bone, tissue, blood or infectious disease. This device is provided sterile, and re-sterilization of the device has not been validated. Sterile packaging includes implant identification including lot number and expiration date.

9.1 Cleaning procedure for reusable surgical instruments

9.1.1 Pre-Cleaning

1. Remove all packaging materials prior to cleaning and sterilization.
2. Prepare enzymatic detergent (e.g., Enzol®) according to manufacturer's recommendations.
3. Immerse device in prepared detergent solution. Ensure that air is not trapped within features of the device when immersing in the solution. Soak for 5 minutes.
4. After soaking, use suitable soft bristle brushes to thoroughly clean the device for 1 minute. Thoroughly clean rough surfaces and features where soil may accumulate or be shielded from the cleaning process.
5. Rinse in running RO water for 1 minute.

9.1.2 Ultrasonic Cleaning

1. Prepare enzymatic detergent (e.g., Enzol®) in a container used in the field of medical devices that will be placed inside of an ultrasonic bath large enough to allow complete immersion of the device.
2. Fully immerse the device in the prepared detergent. Activate ultrasonic bath and soak device for 10 minutes.
3. Following the soak time, while the device is still immersed, use a soft-bristled brush to thoroughly clean all areas of the device for 1 minute. Thoroughly clean all holes, lumens, threads, knurls, grooves, and other hard to clean areas.
4. Remove the device from the ultrasonic tank.
5. Thoroughly rinse device under Critical water (RO or Distilled water) for 1 minute. Thoroughly clean all holes, lumens, threads, knurls, grooves, and other hard to clean areas.
6. Dry devices using a clean, soft non-linting cloth.
7. Visually inspect the device after cleaning. If visible soil is still observed, repeat the Pre-Cleaning and Ultrasonic Cleaning instructions.

9.2 Sterilization

1. Follow the cleaning instructions above for surgical instruments before sterilization.
2. Individually double-pouch cleaned surgical instruments using FDA-cleared pouches.
3. Place double-pouched items in the autoclave in a single layer.
4. Use the sterilization parameters in the table below to achieve a sterility assurance level (SAL) of 10^{-6}:

Cycle	Exposure	Temperature(ºC)	Time(min)	Dry Time(min)
Dynamic air removal cycle	Full cycle exposure	132	4	20
Dynamic air removal cycle	Full cycle exposure	134	3	20

9.3 Reprocessing

Implants are intended for single use only and are not intended to be reprocessed. Therefore, the following reprocessing instructions are intended for reusable surgical instruments only.

9.3.1 Point-of-Use Processing

1. Prompt, initial cleaning steps and/or measures to prevent the drying of soil on the reusable surgical instrument surface prior to reprocessing should be conducted to facilitate subsequent cleaning and re-sterilization of the surgical instruments.
2. The instruments should be wiped with sterile surgical sponges moistened with sterile water after the surgical procedure to remove soil.
3. Do not use saline to wipe instrument surfaces.
4. Irrigate instruments with lumens with sterile water as needed to maintain clear channels throughout the surgical procedure. Immediately after use, wipe the surgical instruments until theyare visually clean, and subsequently keep them moist.
5. Do not place heavy or sharp surgical instruments on top of delicate or easily damaged surgical instruments. Segregate surgical instruments into separate containers as needed to prevent damage.

9.3.2 Reprocessing

1. Once the surgical procedure is complete, users must visually inspect all surgical instruments before reprocessing the surgical instruments for further use.
2. If a surgical instrument shows signs of breakage or deterioration (e.g. worn down tips, corrosion, pitting, cracking, cuts, gouges, separation) on the handles or any part of the surgical instrument, then the surgical instrument must not be reused and must be discarded.
3. If a surgical instrument does not show signs of breakage or deterioration then the users may reprocess the surgical instruments by following the Cleaning, Sterilization, and Reprocessing steps provided above.

10. Surgical Technique Guides

To obtain copies of the surgical technique guides contact Teslake, Inc. customer service or your local sales representative.

11. Product Complaints

Any healthcare professional (e.g. a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any product should notify Teslake, Inc., or, where applicable, their distributor. In the event of an incident, or risk of an incident, having resulted in, or that may potentially result in, the death or severe deterioration in the state of health of a patient or user, Teslake, Inc. or the distributor must be notified as soon as possible. When filing a complaint, please provide the component(s) reference number, type and specification(s), manufacturing lot number(s), your name and address, and the nature of the complaint in full detail, as well as notification of whether a written report is requested.

12. Symbols

Note: Not all of these symbols will appear on the labels you see, you may see them on labels in different regions/countries and understand what they mean.

	Catalogue Number		Sterilized using irradiation
	Batch Code		Consult instructions for use
	Do not reuse		Do not use if package is damaged
	Date of Manufacture		MR Unsafe
	Caution	Rx only	Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

	Use-by date		Keep away from sunlight
	Keep dry		Medical device
	Unique device identifier		Non-sterile
	Sterilized using ethylene oxide		Manufactured by

13. MRI Safety Information

The Sterile Posterior Spinal Fixation Device has not been evaluated for safety and compatibility in the MR environment, and is therefore considered MR Unsafe. It has not been tested for heating, migration, or image artifact in the MR environment. This person is implanted with a Posterior Spinal Fixation device and poses a risk of RF induced tissue injury. Scan conditions for safe use have not been determined.

14. Further information

For further information, please contact:

Teslake, Inc.

17150 Via Del Campo

Suite 308

San Diego, CA. 92127

Manufactured for Teslake, Inc. by:

Shanghai REACH Medical Instrument Co.,Ltd.

13th Building, No.999 Jiangyue Road, Minhang District,

201114 Shanghai,China