Mariner Cap System – English

Rx Only Caution: Federal Law restricts this device to sale by or on the order of physician

Manufacturer:
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Single Use Only		Expiration date (YYYY-MM-DD)	
Sterilized Using Irradiation		Do Not Re-Sterilize	
Lot Number (Batch Code)		Catalog Number	
Non-Sterile		Consult Instructions for Use www.seaspine.com/eIFU	
Do Not Use if Damaged		Caution, Consult Accompanying Documents	
Manufacturer		Material	

DESCRIPTION

The Mariner Cap is composed of three components, the Mariner Cap SP Connector, the Mariner Cap SP Locking Base SP, and the Locking Insert. The cap is designed to mate with the Mariner Pedicle Screw System screws. The Mariner Cap is added to the proximal end of the Mariner Screw and provides for an alternate method to attach the JAZZ Band and JAZZ Passer Band to skeletal structures as compared to the current method using a JAZZ connector.

The Mariner Cap System also consists of instrumentation to assist in the placement of the Mariner Cap on the SeaSpine Mariner Pedicle Screw System. The instrumentation is designed to facilitate the placement, adjustment, securement, and removal, if necessary, of the system implants. The instruments are supplied non-sterile and are reusable. They must be cleaned and sterilized prior to each use.

INDICATIONS FOR USE

The Mariner Cap System is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as adolescent idiopathic scoliosis, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The Mariner Cap System shall be used in conjunction with the SeaSpine Mariner Pedicle Screw System whenever "wiring" may help secure the attachment of other implants.

IMPLANT MATERIALS

Titanium Alloy Ti-6Al-4V per ISO 5832-3 and PEEK-OPTIMA LT1 per ASTM F2026.

CONTRAINDICATIONS

- Bone metabolism disorders that potentially compromise the mechanical support expected for this type of implant (any abnormality affecting the normal functioning of bone tissue including, but not limited to, bone resorption, primary or metastatic tumors of the spine, active infection at the site, and some metabolic disorders that affect osteogenesis. Insufficient quality and quantity of bone which would limit the efficacy of osteosynthesis. Severe fractures such that segments may not be maintained in satisfactory proximate reduction).
- Active local or systemic infections, or recent history of local or systemic infections that may jeopardize the outcome of the operation.
- Major local inflammation.
- Open wounds.
- Immunosuppressive diseases. Any other medical or surgical condition that might limit the potential benefits of the procedure such as the presence of a tumor, congenital anomalies, an elevated sedimentation rate not explained by other diseases, and leukocytosis or marked abnormalities of the white blood cell differential.
- Pregnancy.
- Sensitivity to implant materials or foreign bodies. If there is any suspected sensitivity to the materials used, the patient should have the appropriate tests before selection and implantation of the material.
- In any situation where implant utilization would interfere with anatomical structures or expected physiological performance, such as impinging on vital structures.
- Any other relative contraindication including:
  - Obesity. A person who is overweight or obese can overload the system leading to failure of fixation or breakage of the material.
  - Excessive physical activity. Intense occupational level or activity level of the patient or a state of senility, mental illness, or other use of psychoactive substances. These conditions, along with others, may lead the patient to neglect surgeon recommendations, in turn leading to failure of the fixation or rupture of the material.
  - Any neuromuscular deficit that would result in an unusual overload of the system during the consolidation period. Patients with insufficient muscle or tissue coverage of the operative site.

POSSIBLE ADVERSE EVENTS

Like other spinal system implants, the following adverse events are possible. This list is not exhaustive:

- Deformation, disassembly, or breakage of one or more components of the device.
- Fatigue fracture of spinal fixation device.
- Pains, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on the skin by implants if there is inadequate tissue coverage over the implant, with extrusion from the skin.
- Dural breach requiring surgical repair.
- Disorders and instability of adjacent segments.
- Loss of spinal curvature, loss of correction (height or reduction of listhesis).
- Non-fusion, delayed fusion or pseudoarthrosis. Spinal fixation devices are intended to stabilize the spinal column and to bear loads applied to the spine until fusion or consolidation is achieved. In the case of delayed or failed consolidation or fusion, in the case of inability to immobilize the components of the pseudoarthrosis, implants will be subjected to excessive and repeated stresses that can result in disassembly, deformation, and fatigue fracture of the material. The success of the fusion and the load produced by lifting and other physical activities influence implant longevity. If there is pseudoarthrosis or if the implants disassemble, deform, or break, replace or remove the device(s) immediately before lesions occur.
- There can be disassembly of the components of the internal spinal fixation. Premature disassembly can occur if the initial fixation is defective or if there is a latent infection, premature overload on the internal fixation, or trauma. Late disassembly can occur if there is trauma, infection, biological complications, or mechanical problems, and it can cause bone erosion, migration, and/or pain.
- Peripheral neuropathy, nerve injury, heterotopic bone formation, or neurovascular injury can occur including paralysis, loss of the functions of the center, or a steppage gait.
- Any surgical procedure on the spine involves risks of severe complications including particularly genitourinary, reproductive, gastrointestinal, cardiovascular, and pulmonary disorders including bronchopulmonary thrombus as well as embolism, bursitis, hemorrhage, myocardial infarction, infection, paralysis, and death.
- Neurologic, vascular, or soft tissue injury directly related to the unstable nature of the fracture or to surgical trauma.
- Incorrect or inappropriate surgical implantation of this device can result in a reduction of load on the graft or the bone graft or stress shielding, which can disrupt bone fusion.
- Reduction of bone fusion due to stress shielding.
- There is an intraoperative risk of injury, crack, and spine fracture caused by implants. A postoperative fracture of the bone graft, the intervertebral area, the pedicle, or the sacrum that is above and/or below the operative level can occur as a result of trauma, the presence of bone defects, or insufficient bone mass.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Inability to perform the activities of daily living.
- Bone forming around the implant making removal difficult or impossible.
- Cessation of bone growth in the operated portion of bone.

Note: These adverse reactions can necessitate a second operation or revision.

WARNINGS

- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery. The safety and effectiveness of spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion

with instrumentation. These conditions are significant mechanical instability or deformity of the spine secondary to severe spondylolisthesis, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other condition is unknown.

- Additional fixation is required at the cephalad and caudal ends of the construct in scoliosis surgery, especially in case of obesity, extreme kyphosis or muscular weakness, except where additional fixation would increase the risk to the patient.
- Depending on the resistance of the patient's bone, do not apply an excessive strength on the braid that could lead to crack the lamina and/or transverse process.
- Do not use if package is opened or damaged or if expiration date has passed.
- Do not use damaged implants.
- Never reuse an implant. Even if it seems to be intact, a previously used implant can have imperfections or defects that could reduce its lifetime.
- Resterilization of this implant is strictly prohibited. If a single-use product is reused, the performance, cleaning and sterility of the device are no longer assured. This can in particular result in failure of the procedure or risks of infection that can lead to death of the patient.
- It is essential to adhere to aseptic conditions when opening the protective packaging and extracting the implant.
- It is extremely important to handle implants carefully. The surgeon and the surgeon's assistants should avoid nicking or scratching the components.
- All implants should be used in the original form unless specifically stated. If applicable, any modification of the implant is exclusively the surgeon's responsibility.
- Only proper use of the specific accessory equipment for the implant ensures satisfactory implant placement. Before use, check that the instruments are intact and functioning completely properly.
- The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

PRECAUTIONS

- The implantation of this type of implant should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- The information in these instructions is necessary but not sufficient for using this system. This information in no way takes the place of the professional judgment, expertise, and experience of the surgeon in patient selection, preoperative planning and the choice of implant size, knowledge of the anatomy and biomechanics of the spine, knowledge of the materials and understanding of the mechanical characteristics of the implants used, training and expertise in spinal orthopedic surgery, the use of accessory instruments for implantation, and patient commitment to follow an appropriate postoperative plan and having the expected postoperative exams.
- Brochures on the surgical technique are available from Customer Service of SeaSpine or its distributors. Before a surgical procedure, it is suggested that users with brochures more than two years old should check for the availability of updates.
- A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. The device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.
- Before using the implant, it is absolutely essential to check the integrity of the packaging and to check the expiration date on the label, which guarantees that sterility has been maintained.
- Only physicians who are familiar with and trained on the techniques for using the instruments for this system are authorized to use them.
- Instruments must be checked before the procedure to be sure that they are not worn or damaged.
- Before use, it is advisable to check that the instruments are intact and functioning completely properly.
- Surgeons should ensure that they are not using instruments that could cause inappropriate tension on the spinal column or on the implants and must scrupulously follow the operative protocol described in the surgical technique that is available. This means, for example, that surgeons must avoid injuring the patient from pressure exerted during in-situ repositioning of the instrument.
- To reduce the risk of breaking, the implants should not be bent, folded, struck, or scratched with instruments unless the system specific surgical technique specifies otherwise.
- Instruments should be used with extreme caution near vital organs, nerves, and blood vessels.
- The instruments can be reused after decontamination, cleaning, and sterilization unless particularly specified.
- When hypersensitivity is known or suspected, it is recommended to check the skin tolerance of the implant's materials before implantation.
- The waste resulting from the operation (packaging, explants, etc) must be dealt with in the same way as the health facility deals with any other medical waste.

MRI SAFETY

The device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CLEANING AND DECONTAMINATION

All instruments that have been previously taken into a sterile surgical field must be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into the sterile surgical field. The following recommendations are for the manual cleaning and decontamination of surgical instruments. These recommendations are considered guidelines with the ultimate responsibility for verifying adequate cleaning remaining with the user. Automated cleaning systems differ between hospitals and therefore must be qualified by the hospital.

Manual Cleaning Procedure

1	Remove all gross visible soil with a damp gauze pad or wipe.
2	Prepare an enzymatic cleaning solution (such as Prolystica® 2X Enzymatic) per manufacturer's instructions.
3	Immerse the instruments in the cleaning solution and actuate all features so the enzymatic cleaner contacts all mated surfaces and soak for 15 minutes.
4	Transfer the instruments to fresh cleaning solution (such as Prolystica® 2X Enzymatic). Thoroughly scrub all instruments with a soft bristle cleaning brush while immersed in the enzymatic cleaning solution. Be sure that thorough scrubbing also includes any lumens with an appropriate size brush. Actuate device to allow access to hard to reach areas.
5	Thoroughly rinse all instruments with warm running water and dry with a clean cloth and/or allow to air dry.

Automated Cleaning Procedure

1	Remove all gross visible soil with a damp gauze pad or wipe. Special attention will be required to examine products with tight crevices, voids, and lumens. Lumens may require pre-cleaning with dampened soft bristle brushes and tight crevices, voids, lumens should be flushed with a syringe.
2	Prepare an enzymatic cleaning solution (such as Prolystica® 2X) per manufacturer's instructions. Immerse the instruments in the cleaning solution and actuate all features so the enzymatic cleaner contacts all mated surfaces and soak for a minimum of 15 minutes.
3	Transfer items to a washer and run a cycle with the parameters listed in the following steps.
4	PRE-WASH: Cold tap water for a minimum of 2 minutes.
5	ENZYME WASH: Enzyme wash using cleaner (such as Prolystica® 2X Enzymatic) per manufacturer's recommendations, hot tap water for a minimum of 4 minutes.
6	DETERGENT WASH: Detergent wash using detergent (such as Prolystica® 2X Alkaline) per manufacturer's recommendations, hot tap water (minimum temp of 66°C/150°F) for a minimum of 2 minutes.
7	RINSE 1: Rinse, hot tap water for a minimum of 2 minutes.
8	RINSE 2: Purified water rinse (minimum temp of 66°C/150°F) for a minimum of 15 seconds.
9	DRYING: Hot air dry (minimum temp of 82°C/180°F) for a minimum of 12 minutes.
10	Remove items from the washer and remove any residual moisture with a lint-free, clean cloth.

STERILIZATION

The Mariner Cap instruments are to be sterilized by the hospital prior to surgery.

Precaution: The Mariner Cap implant is offered sterile and should not be re-sterilized. The implant was sterilized by gamma irradiation.

Double wrap trays using FDA-cleared sterilization wraps (2 wraps). For a fully loaded tray, the recommended sterilization parameters below will provide a Sterility Assurance Level (SAL) of 10^{-6}:

Method	Steam	Steam
Cycle	Pre-vacuum	Gravity Displacement
Exposure Temperature and Time	270°F (132°C) for 4 minutes	270°F (132°C) for 15 minutes
Drying Time	30 minutes	30 minutes

STORAGE CONDITIONS AND EXPIRATION

Storage and handling conditions must ensure the integrity of the implant and its packaging.

Before using the implant, it is absolutely essential to check the integrity of the packaging and to check the expiration date on the label, which guarantee that sterility has been maintained.

Any deterioration of this specific packaging could permanently compromise product sterility.

INSTRUCTIONS TO BE GIVEN TO PATIENTS BY THE SURGEON

The surgeon must inform the patient of all restrictions and physical and psychological consequences involved in the use of this material and particularly the program of rehabilitation, physical therapy, and wearing of an appropriate orthosis prescribed by the physician. It is particularly important to address the issue of premature weight-bearing, physical activities, and the need for regular medical follow up.

The patient must be informed of the surgical risks and the potential adverse reactions. The patient must be aware that the system cannot and does not reproduce the flexibility, strength, or durability of normal healthy bone, that the implant can be broken or damaged by strenuous exercise or trauma, and that the system can require replacement in the future. If the patient's job or leisure activities involve excessive stress on the implant (for example, a lot of walking, running, lifting, or significant muscle exertion), the resulting forces can cause the material to break. It has been proven that non-fusion is more common in patients who smoke. These patients must be informed of it and warned about the potential consequences. For patients with degenerative disease, the degenerative disease may be advanced enough at the time of the implantation to reduce the expected life of the device. If so, internal fixation can be used only as a delaying technique or to provide temporary relief.

During any treatment or test near the implant (injection, CT scan, MRI, etc.), the patient must report that he/she has a prosthesis. The surgeon should advise the patient to have another consultation for any symptoms that seem abnormal.

SURGICAL TECHNIQUE

This package insert is designed to assist in using the product and is not intended to provide information on surgical technique. Contact a SeaSpine Representative, customerservice@seaspine.com or +1-760-727-8399 for a Surgical Technique Guide.

IMPLANT SELECTION

Verify that all parts and necessary instruments are present prior to surgery, including sizes larger and smaller than those that are expected for use. The construct should be assembled prior to surgery.

REMOVAL OF IMPLANTS

These implants are temporary internal fixation systems intended to stabilize the operative site during the consolidation process. After consolidation, the devices have no further functional utility and may be removed. Removal may also be recommended in other cases such as:

- Failure of fusion.
- Implant migration with pain and/or neurologic, joint, or tissue injury.
- Pain and abnormal sensations due to the presence of the device.
- Infection, inflammatory reaction, corrosion with reactive pain.
- Reduction of bone density due to different distributions of mechanical and physiological stresses.
- Failure or poor fixation of the implant.
- Restrictions of bone growth due to the presence of implants (in pediatric use).

Implants can be removed with the instruments provided by this system. Surgeons who decide to remove the internal fixation device should consider factors such as the risk of another procedure on the patient and difficulty with removal. Specific instruments can be essential. This technique may require prior training. Implant removal should have appropriate postoperative follow-up to avoid fracture or repeat fracture. Implant removal is recommended after fracture consolidation. Implants can disassemble, deform, break, corrode, or migrate leading to pain or stress shielding.

COMPLAINTS

Immediately notify SeaSpine or a SeaSpine representative by phone, fax or email regarding complaints, malfunctions or adverse events associated with this product. When possible, retain the product involved in the complaint and return to SeaSpine as instructed by SeaSpine Customer Service.

PRODUCT INFORMATION DISCLOSURE

This warranty ("**Warranty**") applies to the Products (defined below) purchased on or following the date set forth above SeaSpine provides this Warranty only to the entity that purchases the Product directly from SeaSpine, (the "**Purchaser**").

"**Products**" means the following products of SeaSpine Orthopedics Corporation or its affiliates including SeaSpine Sales LLC, IsoTis OrthoBiologics, Inc., and SeaSpine, Inc. (collectively referred to herein as "SeaSpine"):

(i) Medical devices or accessories used to perform actions during surgery, but not intended to be implanted in the patient, provided in non-sterile condition and sterilized by the end-user prior to use ("**Instruments**");

(ii) Medical devices intended for implantation provided in non-sterile condition and sterilized by the end-user prior to use ("**Non-Sterile Implants**"); and

(iii) Medical devices or biologics intended for implantation delivered in sterile condition ("**Sterile Implants**").

1. **Warranty**.

Instruments. SeaSpine warrants to the Purchaser only that the Instrument is free from manufacturing defects in material and workmanship under normal use and service (i) with respect to new Instruments, for a period of two (2) years commencing on the date of delivery by SeaSpine to the Purchaser, and (ii) with respect to used Instruments, for a period of one (1) year commencing on the date of delivery by SeaSpine to the Purchaser.

Non-Sterile Implants. SeaSpine warrants to the Purchaser only that the Non-Sterile Implant is free from manufacturing defects in material and workmanship under normal use and service for a period of commencing on the date of delivery by SeaSpine to the Purchaser and ending one hundred eighty (180) days after the date of such delivery.

Sterile Products. SeaSpine warrants to the Purchaser only that the Sterile Product is free from manufacturing defects in material and workmanship under normal use and service for a period commencing on the date of delivery by SeaSpine to the Purchaser and ending on the earlier of (i) one hundred eighty (180) after such delivery date, or (ii) the expiration date stated on the Product's labeling.

2. **Warranty Conditions**.

This Warranty shall not apply (i) if the Product is not used or stored in accordance with the Product's instructions for use supplied by SeaSpine and/or included in the product packaging, (ii) to any Product that has been repaired by anyone other than an authorized SeaSpine service representative or altered in any way so as, in SeaSpine's judgment, to affect its stability or reliability, or (iii) to any Product which has been subject to misuse, negligence or accident.

If the Purchaser seeks to invoke the terms of the Warranty, the Purchaser must notify the SeaSpine customer service department at the address set forth in the product labeling, which can be found at www.seaspine.com, of the covered defect during the warranty period, and the Product must be returned as directed by SeaSpine. The defective Product should be returned promptly, properly packaged and postage prepaid. Loss or damage in return shipment to SeaSpine shall be at sender's risk.

SEASPINE'S SOLE RESPONSIBILITY AND LIABILITY UNDER THIS WARRANTY SHALL BE, AT SEASPINE'S SOLE DISCRETION, REPAIR OR REPLACEMENT OF THE DEFECTIVE PRODUCT, OR REFUND OR CREDIT OF THE PRICE PAID FOR THE DEFECTIVE PRODUCT, SUBJECT TO THE TERMS OF THIS WARRANTY AND APPLICABLE AGREEMENTS. SEASPINE DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION OR WARRANTY OF QUALITY. No warranty or guarantee may be created by any act or statement nor may this warranty be modified in any way, except as a result of a writing signed by an officer of SeaSpine. These limitations on the creation or modification of this warranty may not be waived or modified orally or by any conduct.

3. **Liability Limitations**.

TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAWS, IN NO EVENT, REGARDLESS OF THE FAILURE OF THE SOLE AND EXCLUSIVE REMEDY SET FORTH HEREIN, SHALL SEASPINE BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY SEASPINE PRODUCT.