Instruction for Use

PLAGE™ ANTERIOR CERVICAL FUSION SYSTEM

DESCRIPTION
The Rhausler PLAGE Anterior Cervical Fusion System consists of the PLAGE and locking bone screw implants, and instrumentation. The PLAGE attaches to the anterior portion of the cervical spine during the development of cervical spine fusion.

Rhausler PLAGEs come in heights from 5mm to 10mm and in widths of 14mm and 16mm. Each PLAGE has an attached cage that comes in widths of 14mm and 16mm, and depths of 13mm,15mm and 17mm. All PLAGEs have a 1mm taper from the proximal and distal portion of the cages. PLAGEs have one cephalad screw slot and one caudal screw slot to receive bone screws. Bone screws are 4.0mm diameter and come in lengths of 10mm to 16mm. Bone screws are available in self-tapping, and self-tapping self-drilling styles. Oversized self-tapping 4.5mm diameter bone screws are also available in lengths of 10mm to 16mm. The PLAGE and bone screw implants are manufactured from medical grade titanium alloy Ti6 Al 4V.

INDICATIONS

The Rhausler PLAGE Anterior Cervical Fusion System is intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone. This device is to be used in patients who have had at least 6 weeks of non-operative treatment.

CONTRAINDICATIONS
1. Patients with a systemic infection, with a local inflammation at the bone site or with readily progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis.
2. Patients with known allergies to metals.
3. Patients with mental illness or who are resistant to following post-operative activity restrictions.
4. Patients where the available implant sizes are unsuitable for their anatomy.
5. Other medical conditions that would preclude or outweigh the potential benefits of spinal surgery.

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WARNINGS
1. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
2. US Federal law restricts this device to sale by or on the order of a physician.
3. If needed, all metal implants and instruments or fragments thereof can be located by means of an X-Ray.
4. This device may not be used with components from other manufacturers.
5. Do not use implants made from dissimilar metals in contact with the titanium alloy Ti6 Al 4V PLAGE implant components; otherwise, galvanic corrosion may occur.
6. Implants and instruments are provided non-sterile and must be sterilized prior to use.
7. This device provides temporary stabilization during the development of spinal fusion. It is not intended to be the sole means of spinal support. No spinal implant can withstand body loads without the support of bone. In this event, Implant bending, loosening, disassembly, or breakage(s) will occur.
8. Use without a bone graft or in cases that develop into a non-union will not be successful.
9. Testing has not been performed to assess the safety and compatibility of PLAGE Implants in a Magnetic Resonance Environment. The PLAGE implants have not been tested for heating or migration in the MR environment.

POTENTIAL ADVERSE EVENTS
1. Infection.
2. Nonunion, delayed union, or malunion, which can lead to loosening or breakage of the implants.
3. Loss of fixation.
4. Metal sensitivity or allergic reaction to a foreign body.
5. Pain, discomfort, or abnormal sensation due to the presence of the device.
6. Fracture of the vertebral bodies.
7. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
8. Dural tears, persistent CSF leakage, meningitis.
9. Loss of bladder control or other types of urological system compromise.
10. Nerve damage due to surgical trauma.
11. Spinal bone fracture, resorption, damage, or necrosis.
12. Loss of or increase in spinal mobility or function.
13. Scar formation.
14. Vascular damage, including possible paralysis.
15. Inability to perform daily activities.
16. Death.

Re-operation may be needed to treat some of the potential adverse events. General surgical risks should also be explained to the patient.

⚠ **PRECAUTIONS**

Device Performance. Metallic supplemental fixation systems are internal splints, which align the vertebral bodies during the fusion process. If there is delayed fusion or non-fusion, the implant can eventually break due to metal fatigue. Based on fatigue testing results, the physicians/surgeon should consider the levels of implantation, patient, weight, patient activity level, and other patient conditions, which may impact performance of the system. Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.
Surgical implants must never be re-used. Even though the device appears undamaged, it may have small defects and internal stress patterns, which could lead to breakage. Re-use also presents biological hazards associated with disease transmission and immune/allergy issues, some of which could cause severe illness or be fatal.

Single Use Only

Correct handling of the implant is extremely important. Contouring of metallic implants must be avoided. Caution should be taken not to over-tighten threaded components, including implants, instruments, and implant/instrument interfaces.

Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful fracture healing. The patient must be made aware of the limitations of the implant and that physical activity and full load bearing have been implicated in premature loosening, bending or fracture of supplemental fixation devices. The patient should understand that a metallic implant is not as strong as a normal, healthy bone and will fracture under weight-bearing or load bearing in the absences of complete boney healing (fusion). Mental or physical impairment, which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of the consequences. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spinal fusion, as are patients with poor muscle and bone quality and/or nerve paralysis. Use of allograft material may not give as good a result as pure autograft.

SURGICAL INSTRUCTIONS

Patients should be selected in accordance with the indications for use. Correct selection of the implant is extremely important. The potential for success of fracture fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of the human bones may present limitations on the size and strength of implants. Metallic supplemental fixation devices cannot withstand activity levels and/or loads not designed to withstand the unsupported stress of full weight bearing or load bearing.

The use of these surgical implants gives the surgeon a means of providing internal fixation during fusion of the vertebra. However, the implants are intended for use in accordance with techniques developed in surgical procedure. It is recommended that surgeons utilizing these instruments and implants attend one of the various instructional courses offered periodically.

A surgical technique guide is available with more detailed use information. It may be obtained by contacting Rhausler at 650-200-3466.

INSTRUMENT CLEANING

1. Rinse instruments immediately after surgery under running water. This should remove most of blood, body fluids, and tissue. Clear any corners or recesses of all debris. Extra care should be taken to clean out any cannulated areas by using an appropriate cleaning stylet and rinsing immediately.
2. Take apart the following instruments to clean:
   C-7052 Universal Drill Guide – Remove the knurled depth screw. Clean the tube that it was removed from and the inner diameter of the screw.
   C-7025 One Step Locking Screwdriver or C-7026 Clocked Screwdriver - Remove the outer locking shaft. Clean the inner diameter.
3. Sonicate for 10 minutes in a pH neutral enzymatic cleaner (Prolystica® manufactured by Steris or equivalent) prepared in accordance with the manufacturer's instructions.
4. Remove instruments from the sonicator and place into a container with the enzymatic cleaner being used. Manually clean the instruments with a soft bristled brush while immersed in the cleaning solution. Pay particular attention to crevices and hard to clean areas. Never use steel brushes or abrasive pads, as these, rupture the passive layer of the instrument surface which can lead to corrosion.
5. Remove instruments from the cleaning solution and thoroughly rinse in demineralized water for a minimum of three minutes and until no sign of soil is seen in the rinse stream. Flush all hard-to-reach areas. Be sure to remove all residual cleaning solution before sterilization.
6. Dry instruments immediately after cleaning with a clean, soft cloth.
7. Visually examine devices to ensure all visible soil has been removed. Repeat cleaning steps 3-7 if necessary. Dispose of device in accordance with approved hospital biohazard disposal procedures if unable to remove all visible soil.
8. After instruments pass visual inspection, reassemble the C-7052 Universal Drill Guide, C-7025 One Step Locking Screwdriver or C-7026 Clocked Screwdriver.
9. Lubricate the moving parts of the C-7052 Universal Drill Guide, the C-7025 One Step Locking Screwdriver or the C-7026 Clocked Screwdriver, and the C-7028 Handle for AO Shafts using a hospital approved surgical instrument lubricant prior to sterilization.

INSTRUMENT INSPECTION AND FUNCTION TESTING

Carefully inspect reusable instruments prior to each use for functionality and damage. Damaged instruments should not be used and should be returned to Rhausler immediately and replaced. Kits are serialized and are inspected for function and wear by the manufacturer every 12 months.

Rhausler screwdrivers are serialized and inspected for function and wear by the manufacturer every 12 months.

STERILIZATION

The Rhausler PLAGE Anterior Cervical Fusion System implants and all instruments are provided non-sterile and must be sterilized before use. Instruments must be free of biocontaminants prior to sterilization. Non-sterile implants and instruments should be autoclave sterilized using one of the following validated cycle parameters. Sterilization should be conducted using FDA-cleared wraps/containers or wraps/containers approved by applicable national regulatory authorities.

Method	Cycle Type	Sterilization Temperature	Exposure Time	Dry Time
Steam	Gravity Displacement	250° F (121° C)	30 minutes	150 minutes
Steam	Pre-vacuum	270° F (132° C)	4 minutes	30 minutes

These parameters are qualified to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and the user must establish new cycle parameters. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

STORAGE

After sterilization, kit should remain in sterilization wrap and be stored in clean dry cabinet or storage case.

GRAPHIC SYMBOL KEY:

Symbol	Title of Symbol	Description of Symbol
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Manufacturer	Indicates the medical device manufacturer, as defined in EU directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Do not re-use	Indicates the medical device is intended for single patient use only and not for re-use.
	MR Unsafe	The implant has not been evaluated for use in an MR Environment. MR Unsafe devices should not enter the MRI scanner room. Patients with MR Unsafe devices should not be scanned as this would result in harm to patients.
	Used by Prescription Only	Federal Laws (USA) restricts this device to sale by or on the order of a physician

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Manufactured for:
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