Instructions for Use
ANTERIOR CERVICAL VERTEBRAE PLATE SYSTEM

DESCRIPTION
The Rhausler Anterior Cervical Vertebrae Plate System consists of plate and locking screw implants, and instrumentation for use. Plates attach to the anterior portion of the vertebral body of the cervical spine (levels C2-C7).

The Rhausler Dynamic, Semiconstrained and Quick Plate Plates each come in lengths ranging from 21mm to 109mm. All of the plates, regardless of the length, are 16mm wide at the cephalad end and 19mm wide at the caudal end. The Quick Plate Cervical Plates come in sizes from 21mm to 78mm. The Quick Plate regardless of the length, are 15mm wide at the cephalad and caudal ends. The Dynamic Plates have slots to receive the screws and the Semi-constrained Plates have round holes to receive the screws. All other plate dimensions are the same. Both plates have tack holes and drill guide holes at the cephalad and caudal ends of the plate. Both plates are curved in the longitudinal and lateral planes. The plate and screw implants are manufactured from medical grade titanium alloy Ti6 Al4 V.

INDICATIONS
The Rhausler Anterior Cervical Vertebrae Plate System is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (neck pain of discogenic origin with degeneration of the disc, confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis and tumors (primary and metastatic), deformities or curvatures (i.e., scoliosis, kyphosis, and lordosis), psuedoarthrosis and failed previous fusions.

CONTRAINDICATIONS
The Rhausler Anterior Cervical Vertebrae Plate System is contraindicated in patients with a system 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. The devices should not be implanted in patients with known allergies to metals.

⚠ WARNINGS
- This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- US Federal law restricts this device to sale by or on the order of a physician.
- If needed, all metal implants and instruments or fragments thereof can be located by means of an X-Ray.
- This device is not intended to be used in conjunction with plate systems from other manufacturers.

POTENTIAL ADVERSE EVENTS
1. Infection
2. Non-union or delayed union which can lead to loosening or breakage of the implant
3. Metal sensitivity, or allergic reaction to a foreign body
4. Pain, discomfort, or abnormal sensation due to the presence of the device
5. Fracture of the vertebral bodies
6. Post-operative changes in spinal curvature
7. Nerve damage due to surgical trauma
8. Necrosis of bone
9. Vascular damage, including possible paralysis

Re-operation may be needed to treat some of the 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.
Correct handling of the implant is extremely important. Contouring of metallic implants should be avoided where possible. If contouring is necessary, the surgeon should avoid sharp bends, reverse bends, or bending the device at the screw hole. Avoid notching or scratching of the device when contouring. These factors may produce internal stress or stress concentrations, which may lead to breakage of the implant.
Removal after fracture healing. Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even following fusion of the vertebra. While the surgeon must make the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, supplement fixation devices should be removed once their aid to healing is accomplished. Used implants are biohazards and should be disposed of in accordance with national regulations and approved hospital practices.

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.

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.

INSTRUMENT CLEANING

1. Rinse instruments immediately after surgery under warm running water. This should remove most of blood, body fluids, and tissue. Clear any corners or recesses of all debris. (Note: extra care should be taken to clean out any cannulated areas by using an appropriate cleaning stylet and rinsing immediately.)
2. Sonicate for 10 minutes in a pH neutral enzymatic cleaner (ENZOL™ manufactured by Johnson and Johnson or equivalent) prepared in accordance with the manufacturer's instructions.
3. 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.
4. Thoroughly rinse instruments in demineralized water. Be sure to remove all residual cleaning solution before sterilization as it can cause stains.
5. Dry instruments immediately after cleaning with a clean, soft cloth.

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 screw drivers C-7025 are serialized and inspected for function and wear by the manufacturer every 6 months.

STERILIZATION

Kit:
These devices are supplied NONSTERILE. Sterilization is must be performed prior to use. Instruments must be free of bio-contaminants prior to sterilization. Non-sterile implants and instruments should be steam 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	Temperature	Exposure Time
Steam	Gravity	132°- 135°C	30 Minutes
	Displacement	(270°- 275°F)	
	(Wrapped Tray)		
Steam	Pre-Vacuum	132° 135°C	15 Minutes
	(Wrapped Tray)	(270°- 275°F)	

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. 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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