

DI131B-EN (Rev G)	CORRIDOR™ FIXATION SYSTEM	
05/2025  GLOBUS M E D I C A L  GLOBUS MEDICAL, INC. Valley Forge Business Center 2560 General Armistead Avenue Audubon, PA 19403 USA Customer Service: Phone 1-866-GLOBUS1 (OR) 1-866-456-2871 Fax 1-866-GLOBUS3 (OR) 1-866-456-2873	IMPORTANT INFORMATION ON THE CORRIDOR™ FIXATION SYSTEM [EC REP:] AJW Technology Consulting GmbH Breite Straße 3 40213 Düsseldorf, Germany [CH REP:] AJW Technology Consulting GmbH Kreuzplatz 2, 8032 Zurich, Switzerland AUSTRALIA SPONSOR: GLOBUS MEDICAL AUSTRALIA PTY LIMITED, Unit 9/5-7 Inglewood Place Baulkham Hills NSW 2153, Australia  0297 	

For symbols glossary, please refer to www.globusmedical.com/eIFU

ENGLISH

OUTSIDE THE UNITED STATES ONLY

IMPORTANT INFORMATION THE CORRIDOR™ FIXATION SYSTEM

DESCRIPTION

The CORRIDOR™ Fixation System consists of screws as well as washers designed to compress bone grafts. The screws are available partially threaded or fully threaded, cannulated or non-cannulated, and in various diameters and lengths to accommodate patient anatomy. The CORRIDOR™ Fixation System is fabricated from medical grade titanium alloy as specified in ASTM F136 and F1295. Due to the risk of galvanic corrosion following implantation, titanium alloy implants should not be used in the same construct as stainless steel implants.

INDICATIONS

The CORRIDOR™ Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from T1 to S1, and to stabilize Type II odontoid fractures. For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. Screws may be placed alone or with a transarticular washer which can be filled with autogeneous graft to promote fusion. For translaminal facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle. For Type II odontoid fixation, one or two screws are inserted anteriorly through the C2 vertebral body and into the odontoid process.

The CORRIDOR™ Fixation System is indicated for treatment of any or all of the following: pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity; spondylolisthesis; spondylolysis; degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies; degeneration of the facets with instability and trauma including spinal fractures and/or dislocations.

CONTRAINDICATIONS

The contraindications include, but are not limited to: Active infectious process or significant risk of infection (immunocompromise); local inflammation, fever, or leukocytosis, morbid obesity; pregnancy; mental illness; distorted anatomy caused by congenital abnormalities; any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities; rapid joint disease, bone absorption osteopenia, and/or osteoporosis; suspected or documented metal allergy or intolerance; any case where metals must be mixed from different components; any case where the implant components selected for use would be too large or too small to achieve a successful result; any case where fracture healing is not required; any patient in which implant utilization would interfere with anatomical structures or expected physiological performance; any patient unwilling to follow post-operative instructions; any case not described in the indications.

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.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

WARNINGS

Possible adverse effects which may occur include, but are not limited to: failed fusion or pseudoarthrosis leading to implant breakage; allergic reaction to implant materials including metallosis, staining, tumor formation and/or autoimmune disease; infection; device fracture or failure; device migration or loosening; decrease in bone density; loss of spinal mobility or

function; inability to perform activities of daily living; fracture of any spinal bone including the pedicles, spinous process, pars interarticularis, vertebral body, or sacrum; change in spinal curvature or disc height; herniated nucleus pulposus, disc degeneration or disruption; graft donor site complications including pain, fracture and wound healing problems; tissue damage, pain, discomfort, or abnormal sensations due to the presence of the device or implantation surgery; scar formation causing neurologic compromise or pain; injury to nerves including loss or decrease of neurologic function, paralysis, dural tears, development of radiculopathy, numbness or tingling; cauda equina syndrome; injury to vessels, hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, or other types of cardiovascular system compromise; injury to organs including urinary retention, loss of bladder control, or other types of urologic system compromise; gastrointestinal system compromise; reproductive system compromise including sterility, sexual dysfunction; development of respiratory problems including pulmonary embolism; venous thrombosis, lung embolism and cardiac arrest; and death. Additional surgery may be necessary to correct some of these effects.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

The components of this system are manufactured from titanium alloy. Mixing of implant components with different materials is not recommended, for metallurgical, mechanical and functional reasons.

PRECAUTIONS

Implantation of these devices should be performed only by experienced spinal surgeons with specific training in the use of the system due to a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implants.

Surgical implants must never be reused. An explanted metal implant must never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery. To insert a cannulated screw, a guide wire may be used, followed by a sharp tap. Ensure that the guide wire, if used, is not inserted too deep, becomes bent, and/or breaks. Also ensure that the guide wire does not advance during tapping or screw insertion. Remove the guide wire and confirm that it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.

Correct handling of the implant is extremely important. Contouring of metal implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends, or bending the device at a screw hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.

Correct selection of the implant is extremely important. The potential for success on fracture fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can minimize risks, size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load-bearing. A higher risk of device loosening, bending, or breaking exists with fractures involving severe comminution, displacement or other difficult fracture management situations.

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to constantly changing environment of salts, acids and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn can enhance fatigue fractures of implants. Thus every effort should be made to use compatible metals and alloys in conjunction with each other.

CLEANING

Cleaning instruments by hand, when properly carried out, causes less damage than mechanical cleaning. When cleaning instruments by hand, the following should be observed:

1. 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. Remove all traces of blood and other such residues immediately. Do not allow these to dry.
3. The instruments should be submerged (if applicable) and cleaned with a commercially available manual cleaner (i.e. Instraclean from Calgon or Medline High Suds Detergent) prepared according to the manufacturer's recommendation.
4. A soft nylon bristled brush is then used to manually clean the devices while immersed in the cleaning solution. Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
5. The instruments should be thoroughly rinsed after cleaning. Distilled water should be used.
6. Dry instruments immediately after cleaning.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-456-2871. A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

The CORRIDOR™ implants are provided non-sterile and the CORRIDOR™ surgical instruments are provided sterile or non-sterile.

Sterile CORRIDOR™ instruments are sterilized by gamma radiation using a standard medical device sterilization dose of 25-40kGy. This dose was validated using the VD_{max} method according to ANSI/AAMI/ISO 11137-2:2006 Sterilization of Healthcare Products – Radiation. Sterilization validation was performed to assure a Sterility Assurance Level (SAL) of 10⁻⁶. Sterile instruments are packaged in a heat sealed, double foil pouch. Product packaging was validated according to ANSI/AAMI/ISO 11607-1:2006 Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems. Shelf life was determined to be 5 years. The expiration date is provided on the package label. Do not use if expired. These instruments are considered sterile unless the packaging has been opened or damaged.

Non-sterile CORRIDOR™ implants and instruments have been validated following ANSI/AAMI/ISO 17665-1:2006 Sterilization of Health Care Products – Moist Heat to assure a Sterility Assurance Level (SAL) of 10⁻⁶. The use of FDA cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*.

Implants:

These devices are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132°C (270°F)	28 minutes	30 minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	132°C (270°F)	4 minutes	30 minutes

Instruments:

These devices may be supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132°C (270°F)	25 minutes	30 minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	132°C (270°F)	15 minutes	30 minutes

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.