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BioBridge® Resorbable Chest Wall Stabilization Plate

Instructions for Use

DESCRIPTION	The BioBridge® Resorbable Chest Wall Stabilization Plate is a sterile packed bioabsorbable plate.
MATERIAL	The BioBridge® Resorbable Chest Wall Stabilization Plate is made from the biodegradable copolymer 70:30 poly (L-lactide-co-D,L-lactide).
INDICATIONS	General indications: In the presence of appropriate additional immobilization or fixation, indicated for maintaining the alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts, and, maintenance of relative position of weak bony tissue (e.g., bone grafts, bone graft substitutes, or bone fragments from comminuted fractures), in trauma and reconstructive procedures. Specific indications: 1) Metacarpus, proximal and middle phalangeal bones, 2) Long bones, flat bones, short bones, irregular bones, appendicular skeleton, and thorax.
CONTRAINDICATIONS	• Contraindications for this system are active or latent infection, sepsis, osteoporosis, insufficient quantity or quality of bone/soft tissue, and material sensitivity. • If sensitivity is suspected, tests should be performed prior to implantation. • Patients who are unwilling or incapable of following postoperative care instructions are contraindicated for this device. • This device is not intended for attachment or fixation to the posterior elements (pedicles) of the cervical, or lumbar spine.
WARNINGS	• For safe effective use of this implant, the surgeon must be thoroughly familiar with the implant, the methods of application, instruments, and the recommended surgical technique for this device. • The device is not designed to withstand the stress of weight bearing, load bearing, or excessive activity. This device can break or be damaged due to excessive activity or trauma which could result in an additional surgery for removal. • Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing. • Improper insertion and/or inadequate fixation of the device during implantation in a single or stacked configuration can increase the possibility of loosening or migration. • Do not use in procedures where a permanent implant is needed. • The patient must be cautioned, preferably in writing, about the use, limitations, and possible adverse effects of this implant including the possibility of the device or treatment failing due to aforementioned causes. The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail. • In addition, because of the thermal sensitivity of bioabsorbable materials, the device shall not be utilized if the dot in the middle of the temperature sticker has turned black. A black dot on the sensor signifies that the environmental temperature may have exceeded the softening temperature of the bioabsorbable material during storage and/or transit. Exceeding the softening temperature of the material can lead to degradation of the mechanical properties and/or warping. • An implant shall never be reused or resterilized.

PRECAUTIONS	• Protect implants from nicks and scratches during handling, because they can cause stress concentrations and may lead to a device failure. Instruments shall be inspected for wear or damage prior to usage. • Choose a suture that provides effective support throughout typical bone healing time.
ADVERSE EFFECTS	• Sterile inflammation as a result of a body reaction to the degradation products of the absorbable material; pain, discomfort, or abnormal sensations due to the presence of an implant. • Implant fracture, migration and/or loosening may occur due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. • Histological or allergic reaction resulting from implantation of a foreign material may occur. • Nerve or soft tissue damage, necrosis of bone or bone resorption, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.
STERILITY	This product is provided sterile. It was sterilized with a minimum of 25 kGy of gamma radiation. The product must never be resterilized. Do not use past expiration date.
MR COMPATIBILITY	The BioBridge® Plating System has not been evaluated for safety and compatibility in the MR environment. The BioBridge® Plating System has not been tested for heating or migration in the MR environment
STORAGE INSTRUCTIONS:	Store in a cool dry place and keep away from direct sunlight. The product should be stored in a place with a temperature below 110°F. Prior to use, inspect packaging for signs of tampering or water contamination. Check the expiration date on the box to ensure that the shelf life of the product has not been exceeded. Also, please inspect the center dot of the temperature sticker on the box to ensure that it has not turned black. If the temperature of the packaging exceeds the softening temperature of the material, the center of the temperature sensor sticker, located on the outside of the box, will turn black and this device must not be implanted (Figure1). If the temperature sensor stickers is partially darkened or gray this indicates that the product was exposed to temperatures close to but not exceeding 110°F (Figure 2). Use the oldest unexpired lots first because the bioabsorbable material has a finite shelf life. **Figure 1** **Figure 2**  **Do not implant if the temperature sensor on the label is black, or if the date on the package has past the expiration date.**
INSTALLATION RECOMMENDATIONS	Choose a suture that provides support throughout typical bone healing time of 6 to 8 weeks. When selecting suture, a polyester or nylon braided suture (U.S.P. 2,3,4, or 5) is recommended.

MANUFACTURER CONTACT:		Acumed Headquarters 5885 NE Cornelius Pass Road Hillsboro, OR 97124 USA Office: +1.888.627.9957 Office: +1.503.627.9957 Fax: +1.503.520.9618	These materials contain information about products that may or may not be available in any particular country or may be available under different trademarks in different countries. The products may be approved or cleared by governmental regulatory organizations for sale or use with different indications or restrictions in different countries. Products may not be approved for use in all countries. Nothing contained in these materials should be construed as a promotion or solicitation for any product or for the use of any product in a particular way that is not authorized under the laws and regulations of the country where the reader is located. Nothing in these materials should be construed as a representation or warranty as to the efficacy or quality of any product, nor the appropriateness of any product to treat any specific condition. Physicians may direct questions about the availability and use of the products described in these materials to their authorized Acumed distributor. Specific questions patients may have about the use of the products described in these materials or the appropriateness for their own conditions should be directed to their own physician.

REF	Part Number		Caution, consult instructions for use.		MANUFACTURER
LOT	Lot Number		Use-by date	STERILE R	Sterilized using irradiation
	Consult the electronic instructions for use (eIFU) at www.acumed.net/ifu		Do not use if package is damaged	Rx Only	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
	Upper limit of temperature		Do not re-use		Do not resterilize
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