



MIIG® INJECTABLE Graft 150816-0

The following languages are included in this packet:

English (en)

Deutsch (de)

Nederlands (nl)

Français (fr)

Español (es)

Italiano (it)

Português (pt)

中文- Chinese (sch)

Türkçe (tr)

For additional languages, visit our website www.wmt.com
Then click on the **Prescribing Information** option.

For additional information and translations please contact the manufacturer or local distributor.



CE 0086*

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117
U.S.A.

EC REP

Wright Medical UK Ltd
3rd Avenue
Letchworth
Herts, SG6 2JF
UK

*** The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.**



R ONLY

October 2013
Printed in U.S.A.

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

WRIGHT MEDICAL

MIIG® INJECTABLE Graft

(150816-0)

OUTLINE:

DEFINITIONS

I. GENERAL PRODUCT INFORMATION

- A. INDICATIONS
- B. CONTRAINDICATIONS
- C. POTENTIAL COMPLICATIONS
- D. PRECAUTIONS
- E. ADVERSE REACTIONS
- F. HANDLING & STERILIZATION
- G. STORAGE CONDITIONS
- H. DIRECTIONS FOR USE/MIXING INSTRUCTIONS

DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Storage temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
	Sterilized using radiation
	For prescription use only

I. GENERAL PRODUCT INFORMATION

MIIG[®] graft products consists of pre-measured surgical grade calcium sulfate, pre-measured mixing solution, and the tools necessary to mix the components into a paste and inject the material into the defect site. These products are provided sterile for single patient use. When mixed and injected according to directions, MIIG[®] paste will harden in situ and provide temporary intra-operative support.

The mini MIIG[®] 115 kit contains a vial of calcium sulfate, a vial of sterile saline, a syringe, two delivery needles, a spatula, and a funnel.

The MIIG[®] 115 kit contains a vial of calcium sulfate, a vial of sterile saline, a syringe, two delivery needles, and a spatula.

The micro MIIG® HV kit contains a vial of calcium sulfate, a vial of sterile water, a syringe, two delivery needles and four k-wires, a spatula, and a funnel.

The MIIG® X3 HiVisc kit contains a vial of calcium sulfate, a vial of sterile water, a syringe, two delivery needles, a spatula, five transfer syringes, and a vacuum mixing bowl

All other MIIG® X3 kits contain a vial of calcium sulfate, a vial of sterile water, a syringe, two delivery needles, a spatula, and a vacuum mixing bowl.

A. INDICATIONS

The MIIG® paste is intended to be injected into open bone voids/gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities, spine, and pelvis) and to cure *in situ*. These open bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The MIIG® paste provides a bone void filler that resorbs and is replaced with bone during the healing process.

The MIIG® paste cured *in situ* provides an open void/gap filler that can augment provisional hardware (e.g., K-Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

B. CONTRAINDICATIONS

The MIIG® paste is contraindicated where the device is intended as structural support in load-bearing bone and in articulating surfaces. Conditions representing relative contraindications include:

- Severe vascular or neurological disease
- Uncontrolled diabetes
- Severe degenerative bone disease
- Closed bone void/gap filler
- Pregnancy
- Uncooperative patients who will not or cannot follow postoperative instructions, including individuals who abuse drugs and/or alcohol
- Hypercalcemia
- Renal compromised patients
- Patients with a history of or active Pott's disease
- When intra-operative soft tissue coverage is not planned or possible

C. POTENTIAL COMPLICATIONS

Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the procedure used based on personal medical training and experience. Although Wright Medical cannot recommend a particular surgical technique suitable for all patients, a detailed surgical technique is available for surgeon reference.

D. PRECAUTIONS

As with any surgical procedure, care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure. This includes individuals with bleeding disorders of any etiology, long-term steroidal therapy, immunosuppressive therapy, or high dosage radiation therapy.

Avoid **overfilling** the bone void or **pressurizing** the treatment site.

The provided K-wires (where supplied) are not intended for implantation.

Use MIIG® graft products as supplied and according to the **Handling and Use** information provided.

This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

Warning: Do not use kit if glass vial is cracked or broken.

Intra-Operative Precautions

Use medical devices in accordance with their labeled indications and Wright Medical Technology's instructions for use, especially during insertion and removal.

- Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
- If the device is damaged, retain it to assist with Wright Medical Technology's analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
 - a. The material composition of the fragment (if known);
 - b. The size of the fragment (if known);
 - c. The location of the fragment;
 - d. The potential mechanisms for injury, e.g., migration, infection;
 - e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

E. ADVERSE EFFECTS

Possible adverse effects include but are not limited to:

- Wound complications including hematoma, site drainage, bone fracture, infection, and other complications that are possible with any surgery
- Fracture or extrusion of the bone void filler, with or without particulate debris generation
- Deformity of the bone at the site
- Incomplete, or lack of, osseous ingrowth into bone void, as is possible with any bone void filler.
- Transient hypercalcemia
- Potential to pressurize material in a closed void, which could result in fat embolization and/or embolization of the device material into the blood stream.

F. HANDLING AND STERILIZATION

MIIG® injectable graft products are provided sterile and should be considered sterile unless the inner packaging has been opened or damaged. This product should not be resterilized. The kits are for single patient use and should never be reused. Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

G. STORAGE CONDITIONS

All kits must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature. MIIG® graft products should be stored at 15-30°C or 59-86°F.

H. DIRECTIONS FOR USE/MIXING INSTRUCTIONS

MIIG® graft products are supplied in a kit that contains the components and tools required to mix and inject the resultant paste. Detailed mixing and handling instructions are included on the Mixing Instructions Card.