

Amendia Inc.
ICBGH
Iliac Crest Bone Graft Harvesting System

CAUTION: Federal law restricts this device to sale by or on the order of a licensed physician.

DESCRIPTION:

The Iliac Crest Bone Graft Harvesting System is a multi-component system of instrumentation used to harvest autologous bone graft cylinders from the posterior iliac crest through a minimally invasive approach. The system is comprised of a sterile single-use kit. The Iliac Crest Bone Graft Harvesting System is comprised of instruments made from biocompatible materials such as stainless steel and polycarbonate.

INDICATIONS:

The Iliac Crest Bone Graft Harvesting System is indicated for minimally invasive access to the posterior iliac crest and for harvesting of autologous bone graft through the established access.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

- Pregnancy due to radiation exposure
- Active infection or suppressed immune system
- Coagulopathy
- Abnormal anatomy which prevents access to the posterior iliac crest

INTENDED USE:

The Iliac Crest Bone Graft Harvesting System is intended to harvest autologous bone graft from the posterior iliac crest.

GENERAL PRECAUTIONS:

The Iliac Crest Bone Graft Harvesting System is intended for use only by a licensed physician familiar with the contraindications of harvesting bone graft from the iliac crest. This instrument kit requires the physician's judgment to consider the patient's risk factors prior to harvesting bone graft. Single use risk is limited to the utilization of all instrumentation labeled and marked single use, but used multiple times. Single use instrumentation is clearly labeled as such and should be used in the manner consistent to its labeling. Re-cleaning and re-use of single use instrumentation is not recommended. The re-use of single use devices has not been evaluated and therefore the manufacturer does not recommend reuse of items labeled for single use. Some single use devices contain areas that will be difficult to clean after use, which may inhibit re-sterilization. In addition, the function and integrity of single use devices may degrade after multiple uses and cannot be guaranteed to perform as intended.

CONTENTS:

Single-Use Instrument Kit (Sterile): Tissue Dilator Sheath, Tissue Dilator Shaft, 8mm Trephine Saw, and Trephine Plunger.

INSPECTION PRIOR TO USE: Carefully examine for defects. Verify package integrity prior to use.

Single-Use Sterile Instrument Kit Sterilization: The single-use instruments corresponding to this document are packaged as a group and sterilized by Gamma irradiation.

IMPORTANT NOTE:









Adhering to proper surgical techniques is the responsibility of the medical professional. The technique guidelines are furnished only as recommended techniques. The physician must evaluate the appropriateness of the techniques based on his or her own medical training and expertise, and consider patient-specific variations, including vascular and neural elements.


USE OF THE ILIAC CREST BONE GRAFT HARVESTING SYSTEM

**ALL Steps Must Be Completed Using Fluoroscopic Guidance:
See Surgical Technique For Detailed Instructions**

Note: If additional autologous bone graft volume is required, an additional bone graft plug may be harvested from ipsilateral side of the iliac crest dependent upon anatomy, or from the contralateral side of the iliac crest.

Package Symbol Definitions:

-  : Manufacturer
-  : Lot Number
-  : Expiration date
-  : Additional Information Enclosed
-  : Single use. Do not reuse
-  : Sterilized by Gamma Irradiation
-  : Sterilized using ethylene oxide
- Rx Only** : Prescription only. Federal law restricts this device to sale by or on the order of a licensed physician
-  : Reference/Catalog number

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