

Acumed Bone Graft Harvesting System 2

US Instructions for use2



Instructions for Use

Bone Graft Harvesting System 2



These instructions are intended for the Operating Surgeon and supporting Healthcare Professionals. The US instructions are intended for users in the United States and its territories.

Rx only

DESCRIPTION

Acumed Bone Graft Harvesting System 2 instruments facilitate harvest of morselized autogenous cancellous graft from various sites of the body through a small skin incision.

INDICATIONS FOR USE

The Acumed Bone Graft Harvesting System 2 is sterile, single use, bone graft harvesting device that is intended to harvest cancellous bone from various sites in the body, including the calcaneus, distal radius and iliac crest.

CONTRAINDICATIONS

- Active or latent infection
- Sepsis
- Insufficient quantity or quality of bone, osteoporosis
- Soft tissue or material sensitivity
- Patients who are unwilling or incapable of following post-operative care instructions

WARNINGS & PRECAUTIONS

Warning:

- Acumed Bone Graft Harvesting System 2 has not been evaluated for use in dental or spinal procedures or for use in skeletally immature patients.
- Instrument breakage or damage, as well as tissue damage, may occur when an instrument is subjected to excessive loads, excessive speeds, dense bone, improper use or unintended use.
- Improper insertion of the device can lead to soft tissue and/or bony complications.
- The instrument must be used at rpm's which are generated either by hand or with a drill.

Caution:

- The instruments are intended only for professional use by a licensed physician.
- Do not use the sterile product past the use-by date. Refer to the device label.
- Do not reuse single use surgical instruments. The instrument may suddenly fail as a result of previous stresses.
- Do not resharpen drill bits or reamers as these devices have critical dimensions and geometries that cannot be restored once the instrument has been consumed.
- Do not use chemical disinfection methods as chemical residues may affect steam sterilization.

- Screws, tacks, Kirschner wires, guidewires, cutting instruments, and similar devices may be sharp. Observe hospital procedures, practice guidelines, and/or government regulations for the proper handling and disposal of sharps.

ADVERSE EFFECTS

Possible adverse effects include:

- Pain, discomfort, or abnormal sensations, nerve or soft tissue damage, necrosis of bone or tissue, bone resorption, or inadequate healing due to surgical trauma.
- Metal sensitivity, histological, allergic or adverse foreign body reaction resulting from implantation of a foreign material. Consult our document "Metal Sensitivity Statement" at www.acumed.net/ifu.

SURGICAL TECHNIQUE

Acumed offers one or more Surgical Techniques to promote the safe and effective use of this system. Consult our Surgical Techniques at www.acumed.net.

Important: Surgical techniques may contain important safety information.

Important: The instruments in this system are intended to be used by suitably trained and qualified surgeons in a hospital operating room setting. Before treatment, the surgeon is advised to read and fully understand all instructions and communicate to the patient any relevant medical information provided therein, including the use, limitations, risks (safety communications), and possible adverse effects of the proposed treatment.

Consult the most recent versions of the Instructions for Use and Surgical Techniques as they are subject to change. Contact Acumed or an authorized agent to request any additional information.

STERILITY

- Instruments are provided sterile as indicated on the label.
- Devices purchased and received sterile were exposed to a minimum dose of 25.0 kGy gamma radiation to obtain a minimum sterility assurance level of 10^{-6} .

"In accordance with the State of California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):

WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov."

INSTRUMENTS

MATERIALS

The instruments are manufactured from 17-4 stainless steel per ASTM A564 and ASTM F899.

MULTIPLE USE and SINGLE USE

- Instruments are intended for single use as identified on the label for single use only.
- Single use instruments are intended to be disposed after use on a single patient during a single procedure.
- Do not reuse single use instruments as this may increase the risks of failure and cross-contamination.

IMPORTANT















- The bone graft trephines are available in various sizes, and it is important to choose the bone graft trephines that meets both the size of the patient and the harvesting site.
- Protect instruments against scratching and nicking to prevent stress concentrations, which can lead to instrument failure.
- Avoid prolonged instrument contact with iodine and saline.

STORAGE CONDITIONS

STORAGE OF PACKAGED STERILE PRODUCT

Final packaged product should be stored at room temperature (59-77°F or 15-25°C) and protected from direct sunlight, pests, and high humidity.

Symbols Glossary

Symbol	Description	ISO 15223-1
	Consult the electronic instructions for use (eIFU) at www.acumed.net/ifu	5.4.3
	Caution	5.4.4
	Sterilized using irradiation	5.2.4
	Double sterile barrier system	5.2.12
	Use-by date	5.1.4
	Catalogue number	5.1.6
	Batch code	5.1.5
	Medical device	5.7.7
	Manufacturer	5.1.1
	Date of manufacture	5.1.3
	Do not re-sterilize	5.2.6
	Do not re-use	5.4.2
	Do not use if package is damaged and consult instructions for use / do not use if the product sterile barrier system or its packaging is compromised	5.2.8
Rx Only	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.	U.S. 21 CFR 801.109
	The reticle is a registered trademark of Acumed. It may appear alone or with the Acumed name.	



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