Manufactured By:
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FastGrafter® Autograft Harvesting System
Instructions for Use

Description
The FastGrafter® Autograft Harvesting System instruments are designed to harvest autogenous cancellous bone. The system includes a cannula with a cutting tip and an extrusion device to remove the cancellous bone from the cannula.

Indications
The FastGrafter® Autograft Harvesting System is intended for use in harvesting cancellous autograft bone.

Contraindications
The FastGrafter® Autograft Harvesting System does not have product specific contraindications. General surgical contraindications include:

1. Infection.
2. Patient conditions including blood supply limitations, obesity, and insufficient quantity or quality of bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

Warnings
For safe and effective use of this system, the surgeon should be familiar with the recommended surgical technique for this device (recommended surgical technique can be accessed at www.treace.com). In every case, accepted surgical practices should be followed in postoperative care. Patient sensitivity to instrument materials should be considered and assessed prior to surgery.

Precautions
This is a single use only device and should not be reused. Protect instrument against scratching or nicking. Such stress concentration can lead to failure.

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

Potential Adverse Events
The following are specific adverse effects, which should be understood by the surgeon and explained to the patient:

- Infection or adverse reactions to material or a foreign body;
- Pain or discomfort;
- Nerve or soft tissue damage;
- Necrosis, resorption, or fracture of the bone;
- Necrosis of the tissue or inadequate healing

These do not include all adverse effects, which can occur with surgery in general. General surgical risks should be explained to the patient prior to surgery.

Packaging, Cleaning, Sterilization
This product has been sterilized via gamma irradiation and should be considered sterile unless the inner package has been opened or damaged. If the inner package integrity has been compromised, contact the manufacturer for instructions. Remove the product from package using aseptic OR technique. Always handle the product with powder-free gloves and avoid contact with objects that may damage the product.

All components of this product are for single use only and should never be re-sterilized after contact with body tissues or fluids.

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.

WARNING: All packaging materials MUST be removed from the devices prior to surgical use.

This product must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

For product experience feedback, call 904-373-5940 or email pe@treace.net.