CAPITAL™ BONE GRAFT HARVESTER

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

DESCRIPTION: The TranS1® Capital™ Bone Graft Harvester 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 non-sterile, single-use instrument kit.

INDICATIONS: The TranS1® Capital™ Bone Graft Harvester is indicated for minimally invasive access to the posterior iliac crest 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 TranS1® Capital™ Bone Graft Harvester is intended to harvest autologous bone graft from the posterior iliac crest.

GENERAL PRECAUTIONS: The TranS1® Capital™ Bone Graft Harvester 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 reuse 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 (Non-Sterile): Tissue Dilator Sheath, Tissue Dilator Shaft, Trephine Saw, and Trephine Plunger.

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

STERILIZATION:

Note: Do NOT reuse the Single-Use Instruments

The TranS1® Capital™ Bone Graft Harvester Instruments described within this document are provided in a non-sterile single-use kit and clearly packaged and labeled as such.

Single-Use Non-Sterile Instruments: The single-use TranS1® instruments corresponding to this document are each individually packaged and are sterilized by the hospital in a tray or case. These products are recommended to be steam sterilized by the hospital using the process parameters below:

STERILIZATION INSTRUCTIONS (STEAM)	
Type/Cycle	Pre-Vac / Full Cycle
Exposure Time	Four (4) minutes
Temperature	132°C
Dry Time	Twenty (20) minutes

IMPORTANT NOTE: Adhering to proper surgical techniques is the responsibility of the medical professional. The surgical technique (MKT-50586) is 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.

ALL Steps Must Be Completed Using Fluoroscopic Guidance:
See Surgical Technique (MKT-50586) 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.

PRODUCT COMPLAINTS: Any user of this product, who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or TranS1. If any of the devices ever "malfunctions", or is suspected of doing so and/or may have caused or contributed to death or serious injury of a patient, the distributor or TranS1 should be notified immediately by telephone, or written/email correspondence. When filing a complaint please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

Package symbol definitions:	
	Manufacturer
REF	Reference/Catalog Number
LOT	Lot Number
	Non-Sterile
	Additional information enclosed
	Single use. Do not reuse.
Rx Only	Prescription only. Federal law restricts this device to sale by or on the order of a licensed physician.

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