# Instructions for Use: OSSEO-TIP™ BONE GRAFTER

#### **DENTAL INSTRUMENTS**

OTA Dental Instruments may only be used for its intended purpose according to the general rules for dental/surgical treatment, occupational safety and accident prevention. The instruments must only be used by dentists and surgeons with training and experience in oral surgery, prosthetics as well as diagnosis and pre-operative planning. OTA or its partners, collectively as the manufacturer, the importer, and the distributor are not liable for damages resulting from treatment outside of our control. The responsibility rests with the provider.

#### DESCRIPTION:

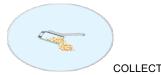
OTA930, Osseo-Tip™ Bone Grafter is manufactured from surgical steel. The instrument has a 3.0mm diameter and is delivered non-sterile and must be cleaned, disinfected and sterilized according to standard sterilization procedures.

#### **INDICATIONS FOR USE:**

The Osseo-Tip™ is designed to collect all the bone chips into a removable cup that would otherwise have been wasted during the drilling procedure. After drilling, the user can simply empty the cup and autogenous bone is ready for immediate use. The Osseo-Tip™ is an effective and efficient tool to harvest large quantities of autogenous bone without creating a secondary surgical site and avoiding hand fatigue or use of a bone mill. It is designed to fit in any standard handpiece.







DRILL

**CAUTION:** Federal (U.S.A.) law restricts this device to sale on or by the order of a physician.

WARNINGS: Re-use of this device without proper cleaning and sterilization may result in serious cross infection or be harmful to the patient.

All components that are used intra-orally must be secured to prevent aspiration or swallowing.

After use, this product may be a potential biohazard. Handle in accordance with accepted medical practice and applicable laws and regulations.

**PRECAUTIONS:** OTA dental instruments must only be used if they are in good condition. Surgical instruments are susceptible to damage and wear and should be inspected before use. If inspection reveals signs of wear, damage, or unrecognizable color or label identification, replace the instrument(s) accordingly.

### **CLEANING/STERILIZATION INFORMATION:**

Disinfection and sterilization procedures should conform to OSHA or local guidelines for blood borne pathogens.

#### **CLEANING INFORMATION:**

Use the following guidelines for cleaning instruments:

Rinse with cool-to-lukewarm tap water for 2.5 minutes. Use a soft bristle brush to clean the instruments until all visible soil is removed. Place in an ultrasonic cleaner with an enzymatic detergent diluted with tap water per the manufacture's guidelines. Sonicate for 10 minutes. Rinse with tap water for 3 minutes. Dry the instruments with a clean cloth.

# STERILIZATION INFORMATION:

These tools are provided non-sterile. Sterilize non-sterile product and components prior to use in patients.

Individual parts should be placed in appropriate autoclave pouches prior to sterilization. The following sterilization parameters (method, time and temperature) are required to achieve a 10<sup>-6</sup> sterility assurance level (SAL). Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table. Verify the calibration of your unit to ensure recommended temperatures are not being exceeded. To ensure autoclave is performing effectively, periodic use of biological indicators should be considered. Chemclave sterilization is NOT recommended. Excessive and long term exposure to water or moisture in the atmosphere could result in discoloration of metals and in some instances rust.

## **Sterilization Parameters For Individual Instruments**

Cycle Type	Temperature	Exposure Time
<sup>1</sup> Pre-vacuum(steam)	132°C/270°F	3 minutes
<sup>1</sup> Gravity (steam)	121°C/250°F	40 minutes

1. Minimum validated sterilization time and temperature required to achieve a 10-6 sterility assurance level (SAL). **DISPOSAL:** 

After use, this product may be a potential biohazard. Handle in accordance with accepted medical practice and applicable laws and regulations.

Distributed By:

Osseous Technologies of America

A Division of A. Titan

10 Centre Drive Orchard Park, NY 14127 L-027 Rev. B Issued: 04/2012