

mx-grafter® Bone Harvester Technique Guide

INTENDED USE

The **mx-grafter™ Bone Grafting System** is intended for the removal, harvest, and grafting of autogenous bone in surgical applications.

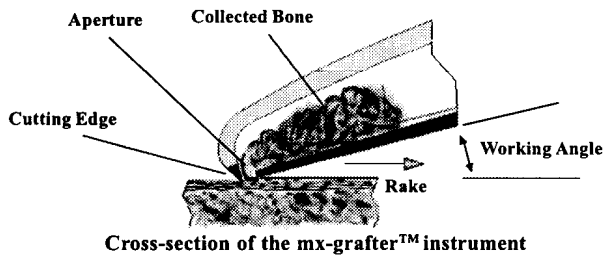
FEATURES

The **mx-grafter™** system is a manual, self-contained instrument that provides a rapid and cost-effective method to easily graft autogenous bone. Designed as a *Bone Grafting System*, it incorporates several features including:

- A high technology blade that effortlessly cuts and removes bone shavings from cortical surfaces.
- A streamlined, transparent handle that efficiently collects the bone into a storage chamber as it is harvested.
- A plunger to consolidate and advance the collected bone.
- A chamber for mixing the harvested bone with other constituents and safely delivering the materials to the recipient site.

Blade

The curved, hollow ground blade cuts cortical bone over a wide range of working angles (5-50 degrees). With light downward pressure and a gentle raking motion, bone can be harvested from flat, concave, or convex surfaces. For difficult to access areas, the curved blade also cuts with a lateral drawing motion.



Cross-section of the mx-grafter™ instrument

Handle

The streamline nose and ergonomically shaped body of the **mx-grafter™** instrument enables controlled handling and greater access to constricted anatomic locations. Visual feedback through the optically clear handle gages cutting efficiency and the quantity of bone collected.

The chamber also provides a protected, temporary storage area for about 2cc of the collected bone. With the blade partially retracted, the handle provides a channel for mixing or to safely deliver the harvested bone to the recipient site.

Plunger

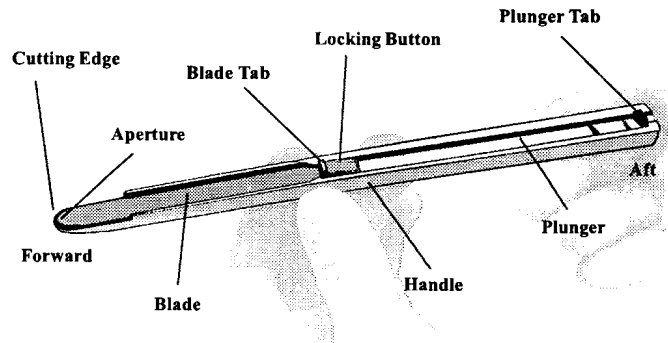
The plunger advances collected bone to the forward aspect of the instrument and also serves to lock the blade in the cutting position. With the chamber closed, the plunger consolidates the bone in the storage chamber.

Bone graft

Acquired in the form of thin shavings, the harvested autogenous bone combines with blood to form an osseous coagulum. This porous matrix provides a high surface area to volume ratio in comparison to the block form of cortical bone.

The bone is acquired manually to minimize heat and promote bone cell survival. And without the need for suction, minimal saliva and/or soft tissue contaminants are incorporated into the graft.

Moderate amounts of bone (about 2-4 cc) can be rapidly harvested from cortical surfaces with minimal patient morbidity and donor site defects.



INSTRUCTIONS FOR USE

Remove from package

The instrument is packaged in a sterile and ready to use condition. The inner surface of the tray and lid, and the instrument are sterile. To remove the instrument from the tray, face the printed lid upright and carefully peel the lid from the "PEEL HERE" tray corner. Deliver the grafter to the surgical field by either gently inverting the tray over the sterile field, or else remove it directly with a sterile gloved-hand or instrument.

Handling

The device is held with the blade forward and down in the hand either like a pencil, or by gripping the body of the instrument in the palm of the hand with index finger placed on the forward, flat section of the handle.

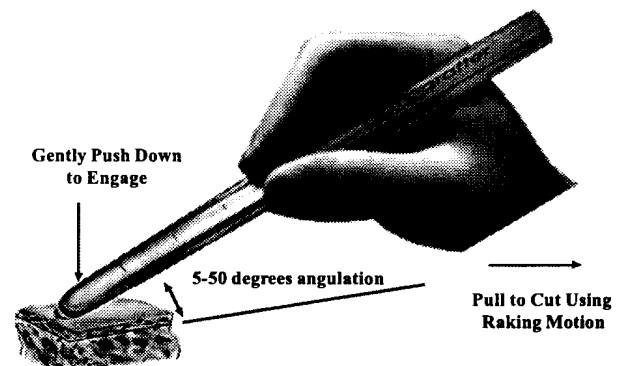
Cut and Collect bone

Moisten and lubricate the forward chamber of the grafter by dipping it into sterile saline or water. This facilitates movement of the bone shavings into the instrument.

To collect bone, lightly push the edge of the blade down into the bone surface. Use a raking motion to remove bone and collect it into the handle. The instrument cuts when held at an angle between 5-50 degrees to the bone surface. The curved blade will cut bone when drawn directly backward and also with lateral drawing motions.

Caution: The blade edge is sharp and will cut gloves and soft tissues!

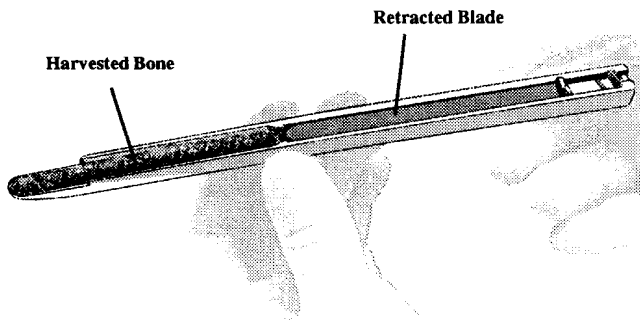
The bone can be safely stored in the handle until needed. If more than 2 cc of bone is required, the contents can be emptied into a sterile bowl, and another load of bone can be harvested.



Mixing/Preparation

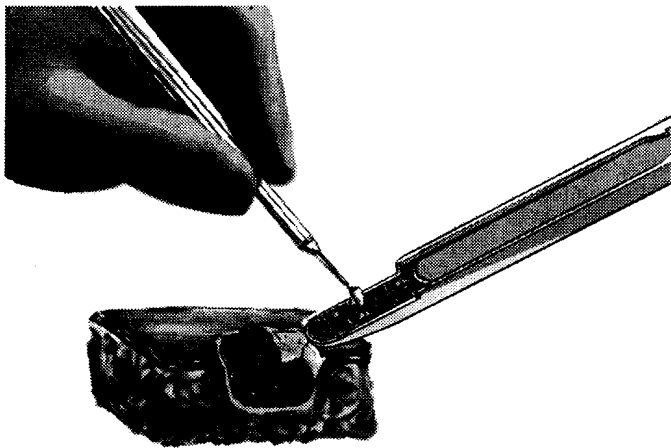
For access to the collected bone, turn the grafter with the blade facing upright, depress the plastic locking button adjacent to the blade and slide the plunger forward slightly. Now the blade is unlocked and can be carefully drawn back with the blade tab.

Optional materials i.e. additional blood, can be added to the bone as desired when the blade is fully retracted. With the blade fully closed, the plunger can be advanced forward to compact/consolidate the bone.



Delivery

To deliver bone to the recipient site, position the blade facing upright and drawn back about 25 mm from its closed position. Gradually advance the contents forward with the plunger tab. The forward section of the handle provides a carrier to deliver the bone safely to the recipient site. Any curette-like instrument can be used to move and pack the bone into position.



TROUBLESHOOTING

Clogging- Occasionally during use, the collected bone and blood coagulum may tend to clump in the chamber above the blade and thereby reduce the effectiveness of collection. To clear this site, either gently tap the aft end of the instrument on a firm surface, or partially retract the blade and with a curette-like instrument, push the bone into the rear of the chamber. Dip the tip of the instrument in saline to re-lubricate the surfaces.

Poor cutting- Be sure that the instrument angle (working angle) to the bone surface is in the range of 5-50 degrees. If the blade seems to catch and not slide, decrease the working angle and use less downward pressure.

If the instrument does not engage and slides over the surface of the bone,

either 1) slightly increase downward pressure and/or increase the working angle of the instrument to the bone, or 2) Try rolling the instrument and cutting slightly off the curved blade's center. If this is not effective, the blade has been dulled and a new instrument is required.

Cutting efficiency can vary based on several parameters, including: 1) variability of the patient's apparent bone hardness, 2) bone lamellar direction-cutting is most efficient when parallel to the fiber direction, 3) depth into cortical surface- the deeper cortical bone typically has greater hardness than the superficial layers. Increase the working angle to enhance cutting.

HOW SUPPLIED

Reference No.	Item	Quantity
GFR-0702	mx-grafter™ Bone Grafting System	1 unit

STERILE

The mx-grafter™ instrument is packaged in a sterile and ready to use condition. The inner surface of the tray and lid, and the instrument are sterile.

Warning: Please check packaging.
Contents sterile as noted unless lid and/or tray has been opened, torn, pierced or damaged.

SINGLE USE ONLY

The device has been designed for single use only. This insures that the blade is sharp for maximum performance and that no residual contaminants are present that could effect clinical outcome.

Warning: Instrument cannot be adequately cleaned for reuse.

Bioburden can not be adequately removed from the instrument interstices using standard cleaning or ultrasonic techniques. Chemical sterilization residues remain on instrument surfaces and are toxic to the graft materials. If the instrument is heat autoclaved, the handle will deform and the blade edge will corrode.

Warning: Please properly dispose of the instrument as a "sharp contaminated device".

STORAGE

This product should be stored at room temperature. Avoid excessive heat or humidity.

CONTRAINDICATIONS

The clinician must determine the suitability of the patient for a bone grafting procedure. Contraindications may include and are not limited to:

- Vascular impairment of the recipient site
- High dose therapy with corticosteroids or current use of anticoagulants
- Acute infection or contamination at the surgical sites
- Uncontrolled metabolic disturbances
- Severe renal dysfunction, severe liver disease

PRECAUTIONS

The clinician should take precautions to minimize the known risks of infection and complications associated with bone grafting procedures. Antibiotic coverage may be required in intraoral applications.

CAUTION

Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician, dentist, or licensed practitioner.

Manufactured For
maxilon Maxilon Laboratories, Inc.
Hollis, NH 03049 USA
...ON THE CUTTING EDGE

Reorder # MX-GRAFTER