

BONE GRAFT™

HARVEST SYSTEM



SURGICAL TECHNIQUE GUIDE
Bone Graft™ Harvester System

Exclusively foot & ankle
Paragon[®] 20

System Overview - Bone Graft™ Harvester System



This surgical technique guide pertains to the redesigned Bone Graft™ Harvester System, consisting of single-use trephines and plungers. For technique instructions pertaining to the original system, consisting of trephines with detachable doors, please refer to P99-STG-0001 at Paragon28.com/resources/surgical-technical-guides/

SYSTEM OVERVIEW:

Autogenous bone graft can be used in primary and revision foot and ankle surgery. Autogenous bone provides osteogenic, osteoinductive and osteoconductive properties to the surgical site to aid in healing. Common harvest sites in the foot and ankle include the calcaneus and distal tibia. Paragon 28® has developed a Bone Graft Harvester to allow for harvest of cancellous bone to augment foot and ankle surgical procedures. The Bone Graft Harvester is available in two diameters (8mm and 10mm) to allow the surgeon versatility in size depending on amount of bone graft needed and harvest site selected.

The Paragon 28® Bone Graft Harvester is designed for quick retrieval of morselized autogenous bone. A graft pusher is used to push graft material into the back of the trephine and then out of the retrieval window for simple recovery.

To increase bone volume, the harvested autogenous bone can be combined with demineralized bone matrix (DBM), allogenic cancellous bone chips, PRESERVE™ structural bone wedges or other sources of allogenic bone.

INSTRUMENTATION HIGHLIGHTS:

Bone Graft Harvester

- ▶ Bone Graft Harvester available in two sizes developed for common foot and ankle surgical applications
- ▶ Depth markings present on trephine
- ▶ Retrieval window at the back of the trephine to facilitate efficient graft recovery

Ø8 mm

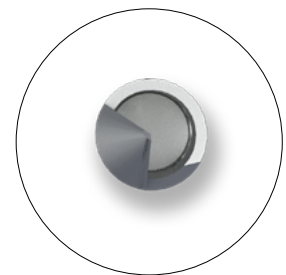
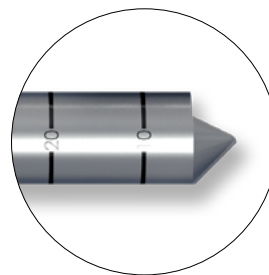


Ø10 mm



Trephine

- ▶ The single-use trephine provides a sharp cutting surface as well as an AO connection for attaching to power equipment



Plunger

- ▶ Used to push morselized bone captured in trephine to the back, then out through the retrieval window

Ø8 mm



Ø10 mm



OPTIONAL (NOT PROVIDED):

≥Ø0.9 mm K-wire



- ▶ Used to create an optional pilot hole for Bone Graft Harvester entry

INCISION EXPOSURE:

The patient is placed supine with an ipsilateral hip bump or in a lateral decubitus position. Fluoroscopy can be used to facilitate incision placement. A small incision is made over the lateral aspect of the calcaneus, posterior and inferior to the peroneal tendons and sural nerve. Incision length should be slightly longer than the diameter of bone graft harvester to be used.

The incision is continued to the lateral wall of the calcaneus using blunt dissection. Care should be taken to protect branches of the sural nerve.



CANCELLOUS BONE HARVEST:

Retraction is recommended during bone graft harvesting to avoid injury to the nearby structures and obtain visualization of the lateral wall of the calcaneus.



OPTIONAL: A K-wire ($\geq \emptyset 0.9$ mm, not provided) can be used to create a pilot hole at the desired entry point, driving it past the near cortex.



Place the tip of the bone graft harvester into the pilot hole or at the desired starting point for bone graft harvester entry. For calcaneus harvest, an 8mm (shown) harvester is recommended.

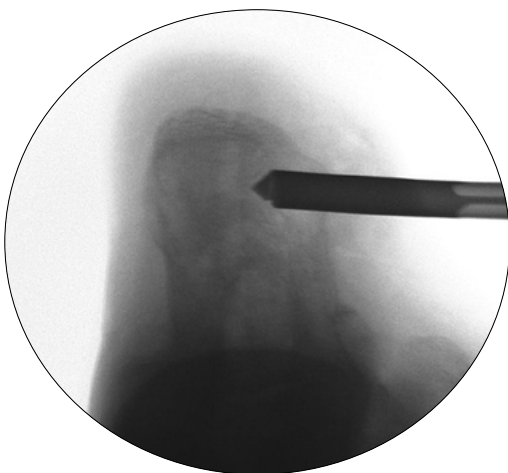
CANCELLOUS BONE HARVEST:



Contact the tip of the bone graft harvester to bone prior to applying power to the device. Under power, begin advancing the bone graft harvester into the cortical bone entry point. Advance the instrument to the desired depth and remove through the entry point.



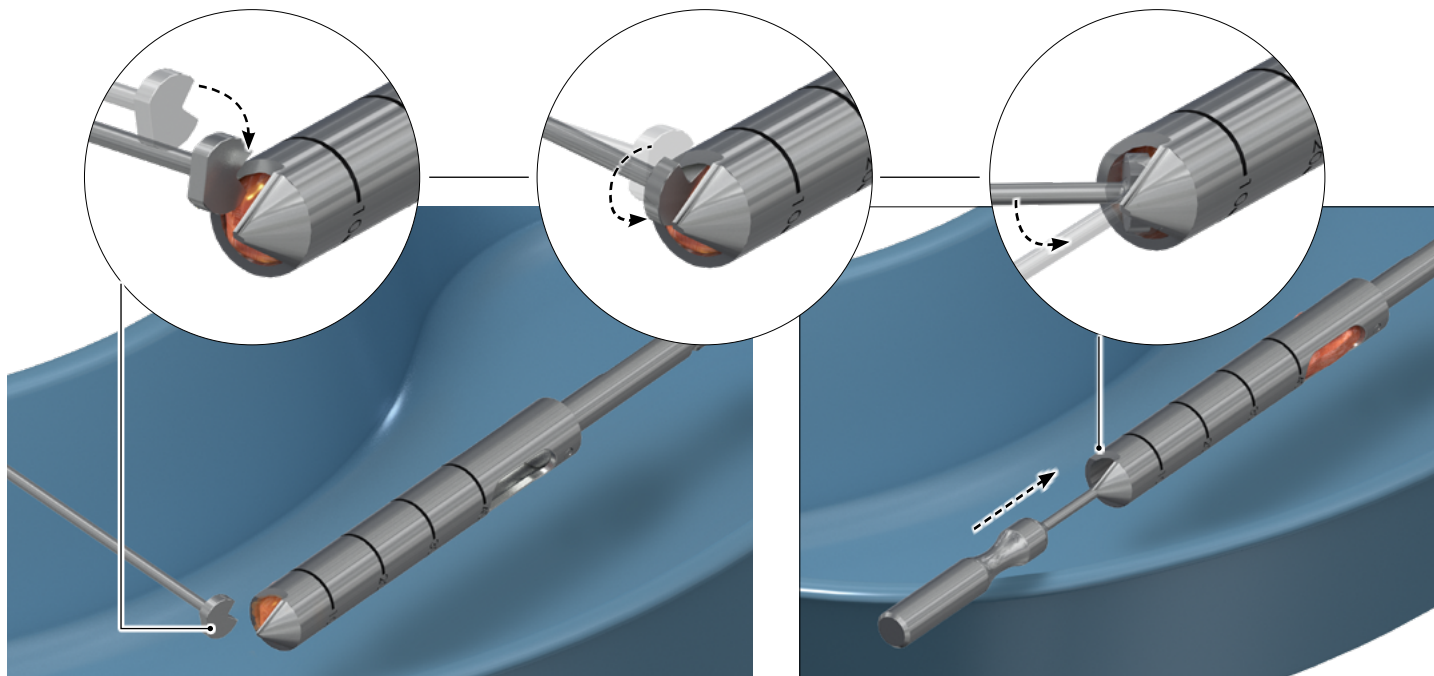
NOTE: Additional bone graft may be harvested from the original bone graft harvester hole by re-directing the trephine 45° outward in a circular pattern. Graft should be removed once it is visible in the window, past the 40mm depth mark.



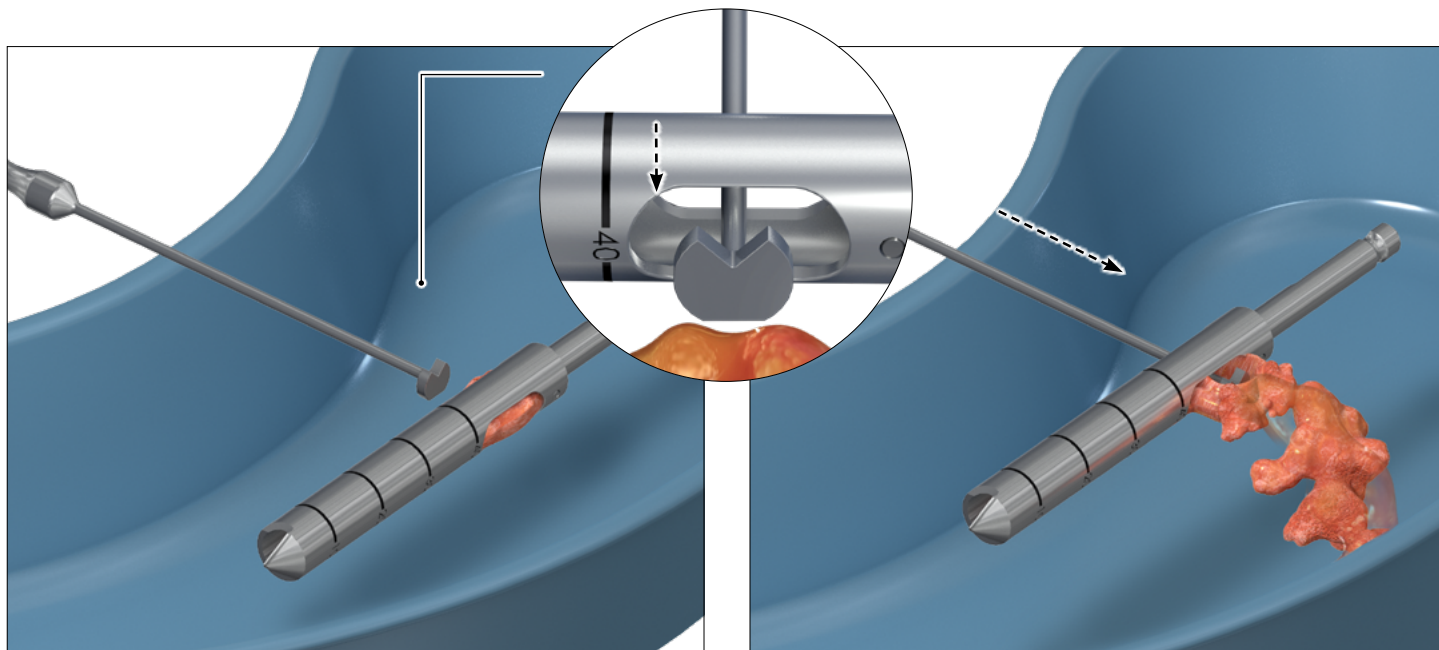
In cases of poor quality bone, it is recommended to perform calcaneal harvest under fluoroscopy to avoid breaching the far cortical wall.

REMOVAL OF MORSELIZED BONE GRAFT FROM THE BONE GRAFT HARVESTER:

Over a sterile basin, insert the tip of the appropriately-sized graft pusher through the front of the trephine, by placing the notched section of the pusher against the flat wall of the harvester end and “rolling” it into the trephine tunnel. Once inserted, use the pusher to push the graft material to the back of the harvester.



After the bone graft has been pushed to the back of the trephine, insert the Graft Pusher through the retrieval window, using multiple passes if needed, to push out all of the graft into the basin.



OPTIONAL: The donor site in the calcaneus can be back-filled with allograft, per surgeon preference.

CLOSURE:

Proceed to incision closure or concomitant procedures at this time.

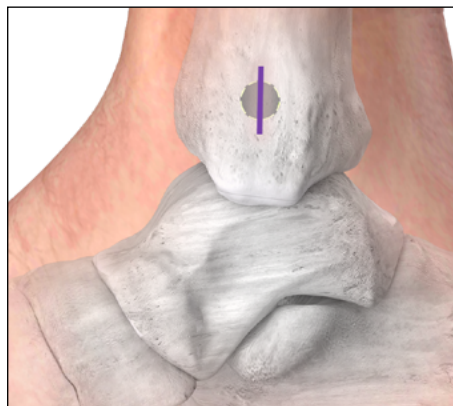
OTHER HARVEST SITES:



Distal Tibia

The design and size options for the Paragon 28® Bone Graft Harvester lends itself to other locations for bone graft harvesting. The same technique can be followed as described above to yield morselized cancellous autograft.

Another example of use is presented below, but surgeons are not limited to these options.



Location:

- Medial distal tibia, midline over the metaphyseal flare

STERILE KIT CONTENTS:

- The Bone Graft™ Harvester System components are single-use and provided in sterile kits.
- Each sterile kit consists of one (1) Bone Graft Harvester trephine (either Ø8mm or Ø10mm) and a matching sized plunger
- Optional ≥ Ø0.9 mm K-wires are not provided.



INSTRUCTIONS FOR USE: GORILLA®/BABY GORILLA® PLATING SYSTEM

Indications, Contraindications, Warnings and Precautions relevant to the Bone Graft™ Harvester System are contained in the Instructions for Use document of the Gorilla® Plating System P51-IFU-0001.

MR SAFETY INFORMATION

The Gorilla® Plating System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Gorilla® Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.”

Refer to www.paragon28.com/ifus for the complete and most current Instructions for Use document.

BONETM GRAFT

H A R V E S T S Y S T E M

SURGICAL TECHNIQUE GUIDE

Bone GraftTM Harvester System

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Disclaimer:

The purpose of the Bone GraftTM Harvester Surgical Technique Guide is to demonstrate the optionality and functionality of the Bone GraftTM Harvester System instrumentation. Although various methods can be employed for these procedures, the procedure demonstrated was chosen for simplicity of explanation and demonstration of the unique features of our device. Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.