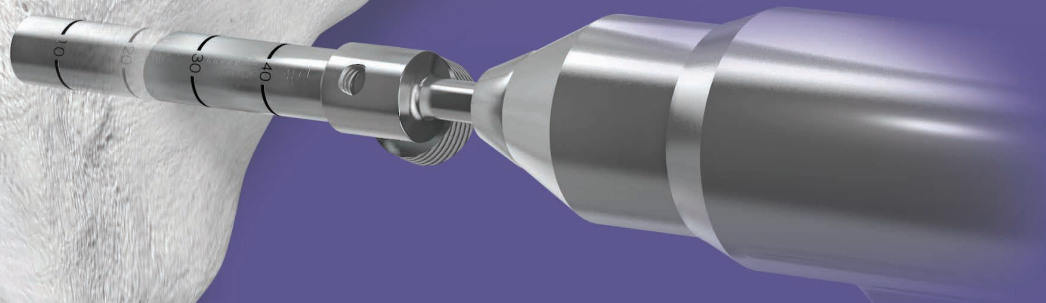


SURGICAL TECHNIQUE GUIDE:

BONE GRAFT HARVESTING

Exclusively foot & ankle **20**
Paragon[®]

BONE  **GRAFT**[™]
HARVEST SYSTEM



GORILLA[®]
R3CON PLATING SYSTEM

SYSTEM OVERVIEW

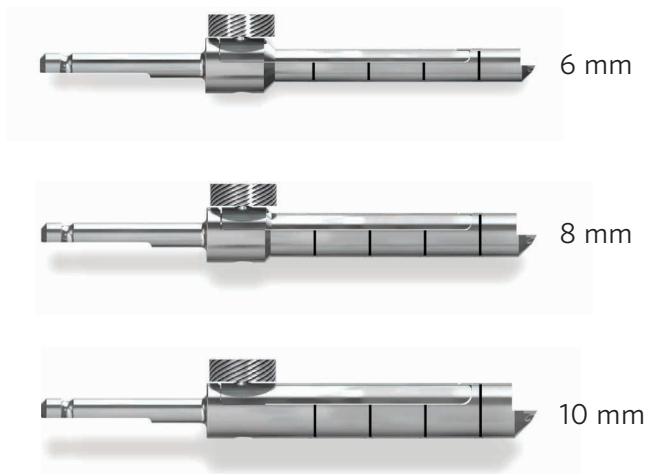
Autogenous bone graft can be used in primary and revision foot and ankle surgery. Autogenous bone provides osteogenic, osteoinductive and osteoconductive properties to the surgical site to aid in healing. Common harvest sites in the foot and ankle include the calcaneus, distal tibia and proximal tibia. 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 three diameters (6 mm, 8 mm and 10 mm) 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 removable, reusable door attaches to the trephine to provide access to the harvested bone to facilitate 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

Bone Graft Harvester



- Bone Graft Harvester available in three sizes developed for common foot and ankle surgical applications
- Comprised of a trephine and door
- Depth markings present on trephine

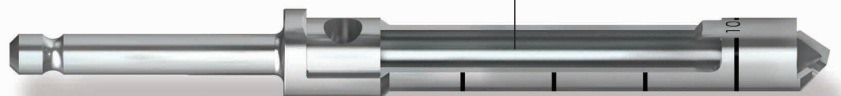
Door

- The reusable door is designed for easy access to morselized bone graft via the twist knob



Trephine

- The single-use trephine interfaces with the door to provide a sharp cutting surface as well as an AO connection for attaching to power equipment



2.3 mm x 150 mm K-wire



- Available for use if a pilot hole is desired prior to using the Bone Graft Harvester

SURGICAL TECHNIQUE GUIDE:

BONE GRAFT HARVESTING - CALCANEUS

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.

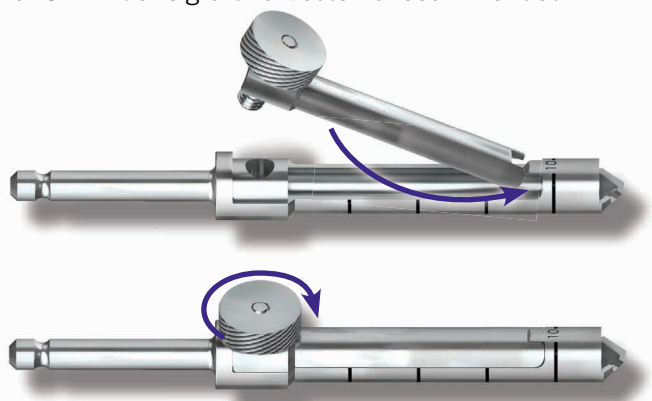
The incision is continued to the lateral wall of the calcaneus using blunt dissection. Care should be taken to protect branches of the sural nerve.



BONE GRAFT HARVESTER SELECTION & ASSEMBLY

Retrieve the selected bone graft harvester. For the calcaneus, a 6 mm or 8 mm bone graft harvester is recommended.

Assemble the bone graft harvester by retrieving the trephine portion of the bone graft harvester. The door size corresponding to the trephine size of the bone graft harvester is retrieved. Connect the door of the bone graft harvester to the trephine by inserting the female portion of the door under the "tab" male portion of the trephine.



Insert the thumb screw into the hole in the trephine and turn in a clockwise direction until the door is secured to the trephine.

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 2.3 mm K-wire is provided to create a pilot hole at the desired entry point for the bone graft harvester. Drive the 2.3 mm K-wire past the near cortex to create the pilot hole.



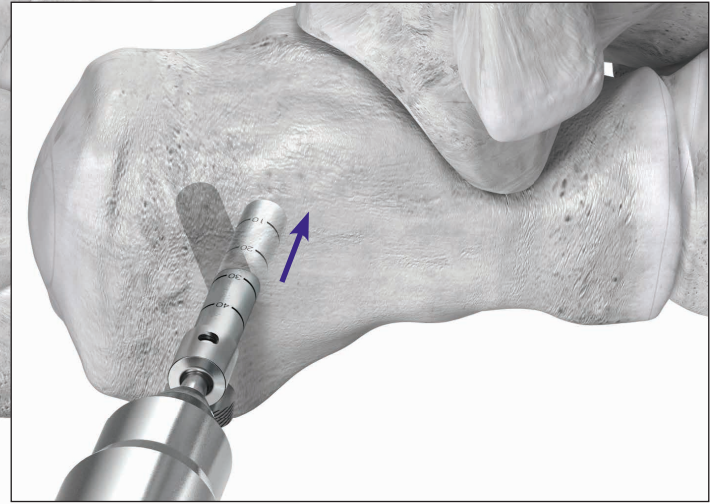
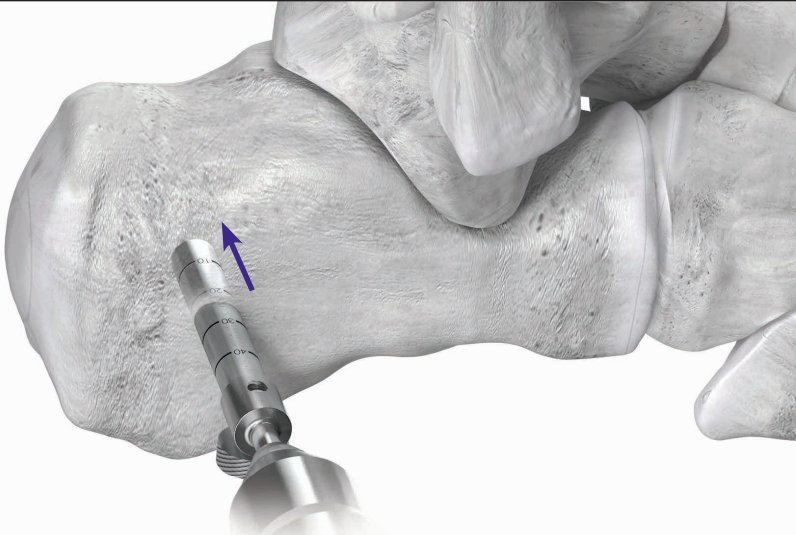
Place the tip of the bone graft harvester into the pilot hole or at the desired starting point for bone graft harvester entry.



SURGICAL TECHNIQUE GUIDE:

BONE GRAFT HARVESTING - CALCANEUS

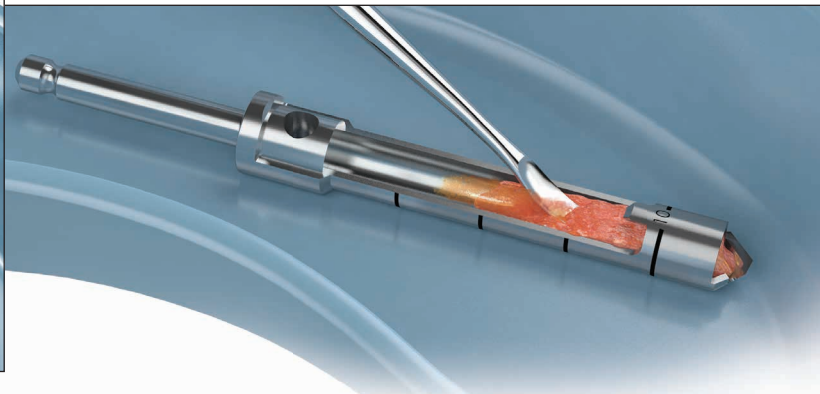
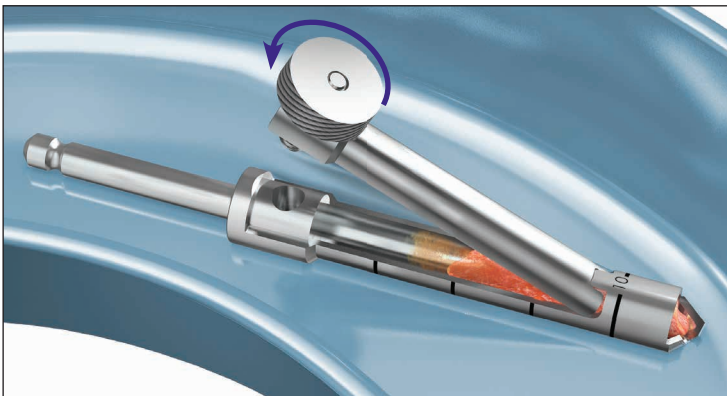
CANCELLOUS BONE HARVEST



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. Approximately 3 passes of the bone graft harvester can be made before removal of morselized bone from the bone graft harvester is necessary.

REMOVAL OF MORSELIZED BONE GRAFT FROM BONE GRAFT HARVESTER



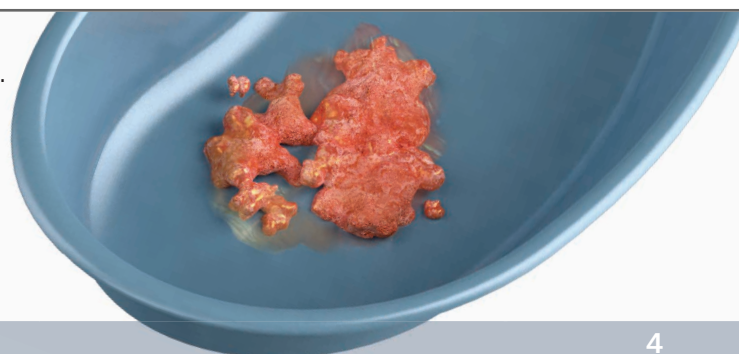
Over a sterile basin, twist the thumbscrew on the door in a counterclockwise direction. When disengaged from the trephine, pull the door off by separating the female portion of the door from the male portion of the trephine. Set the door aside for re-processing.

Using a freer elevator or a K-wire, remove the morselized bone graft from trephine and collect in a basin for later use or for mixing with allograft, if necessary.

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.

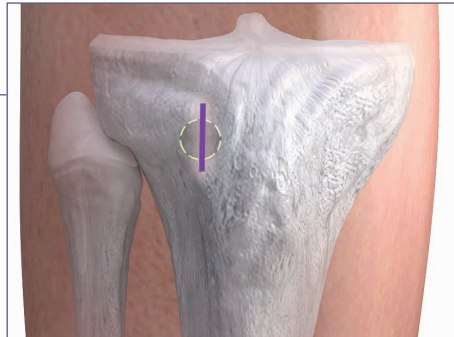
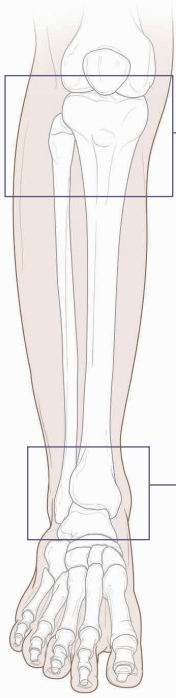


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BONE GRAFT HARVESTING

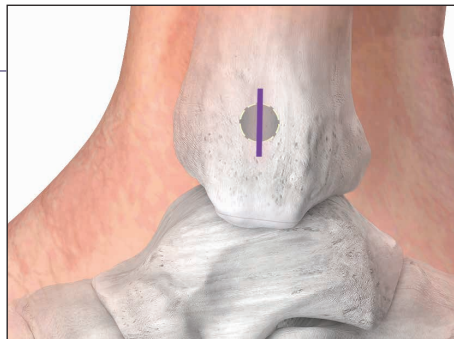
OTHER HARVEST SITES

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. Other examples of use are presented below, but are not limited to these options.



Proximal Tibia

- **Location:**
Lateral to the tibial tuberosity, centered over Gerdy's tubercle
- **Recommended bone graft harvester sizes:**
8 mm, 10 mm
(depending on bone quantity needed)



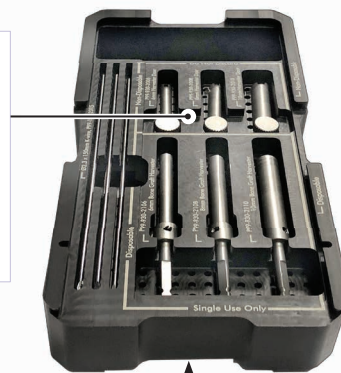
Distal Tibia

- **Location:**
Medial distal tibia, midline over the metaphyseal flare
- **Recommended bone graft harvester sizes:**
6 mm, 8 mm, 10 mm
(depending on bone quantity needed)

CADDY OFFERING

Gorilla® Bone Graft Harvester Caddy

The Gorilla® Bone Graft Harvester Caddy contains the 6 mm, 8 mm and 10 mm single-use Bone Graft Harvester trephines with the corresponding reusable doors, and the 2.3 mm K-wires. This caddy can be provided standalone or can be delivered in the Gorilla® R3CON Plating System Case.



BONE GRAFT™ HARVEST SYSTEM



PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle **28**
Paragon®

www.paragon28.com


For the contraindications, potential complications and adverse reactions, warnings and precautions associated with this device, please refer to the device-specific instructions for use at <http://www.paragon28.com/ifus>

P99-STG-0001 RevD

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DISCLAIMER

The purpose of the Bone Graft Harvester Surgical Technique Guide is to demonstrate the optionality and functionality of the Bone Graft 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.