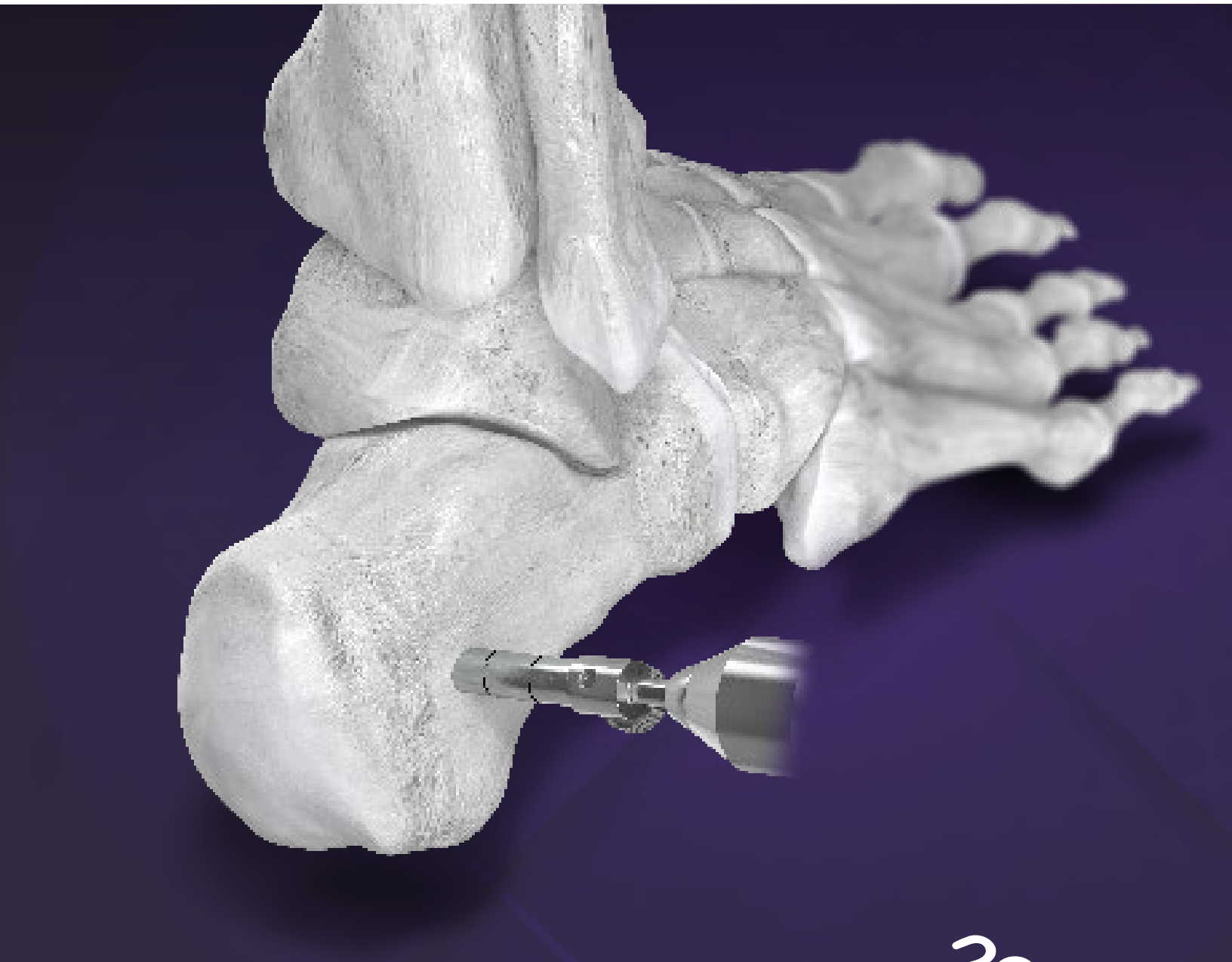
BONE GRAFT™ HARVEST SYSTEM

SURGICAL TECHNIQUE GUIDE

Bone Graft Harvesting



GORILLA® R3CON PLATING SYSTEM

Paragon 28®

a ZIMMER BIOMET company

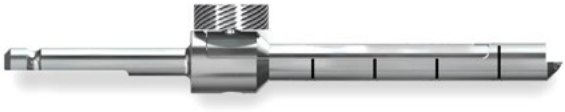
SYSTEM OVERVIEW

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



6 mm

8 mm

10 mm

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

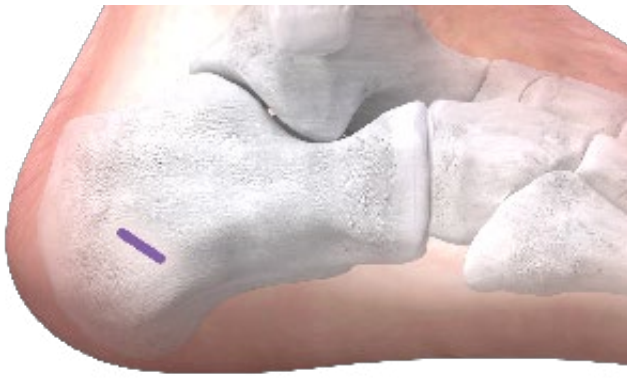
- The single-use trephine interfaces with the door to provide a sharp cutting surface as well as an AO connection for attaching to power equipment

2.3 MM X 150 MM K-WIRE

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

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.

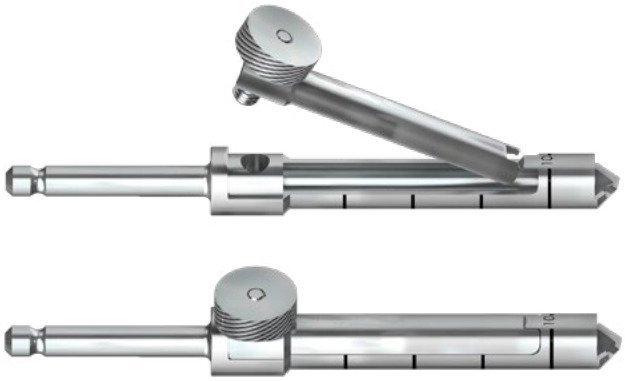


The incision is continued to the lateral wall of the calcaneus using blunt dissection. Care should be taken to protect branches of the sural nerve.

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.

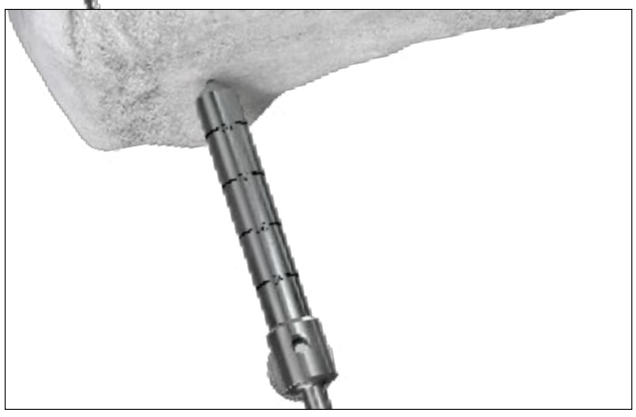


Insert the thumb screw into the hole in the trephine and turn in a clockwise direction until the door is secured to the trephine.

CANCELLOUS BONE HARVEST

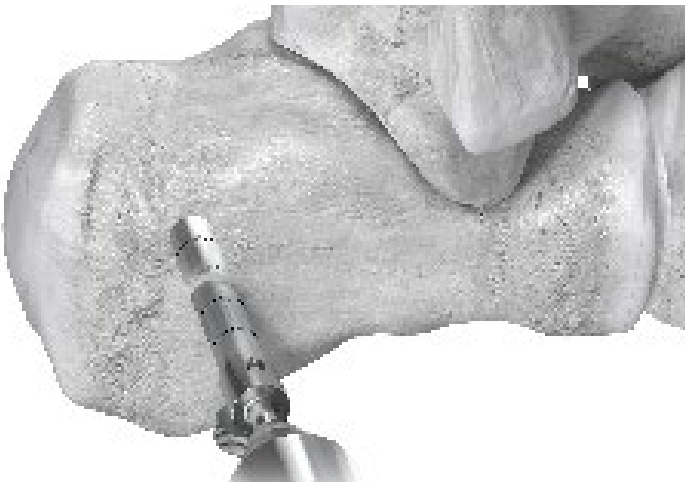
Retraction is recommended during bone graft harvesting to avoid injury to the nearby structures and obtain visualization of the lateral wall of the calcaneus.

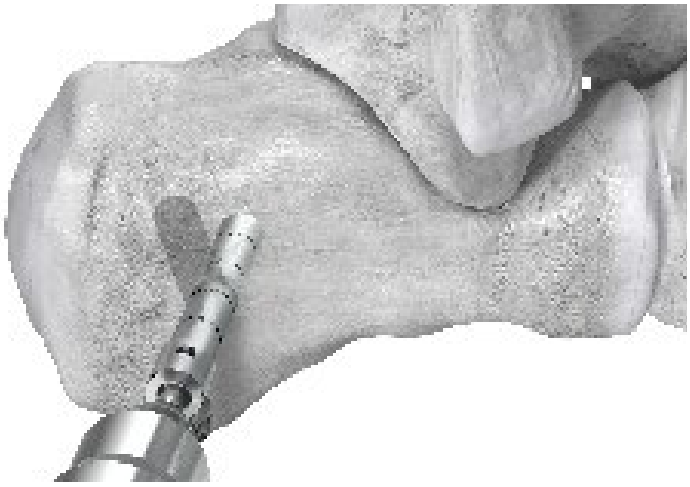
OPTIONAL: *A 2.3 mm K-wire is provided to create a pilot hole at the desired entry point for the bone graft harvester. Drive the 2.3 mm K-wire past the near cortex to create the pilot hole.*



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

CANCELLOUS BONE HARVEST

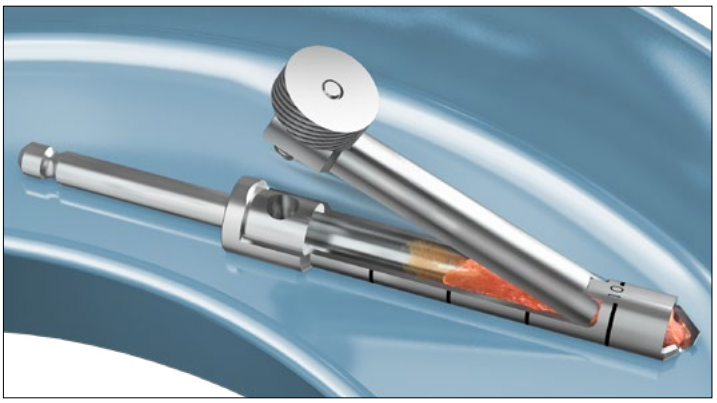


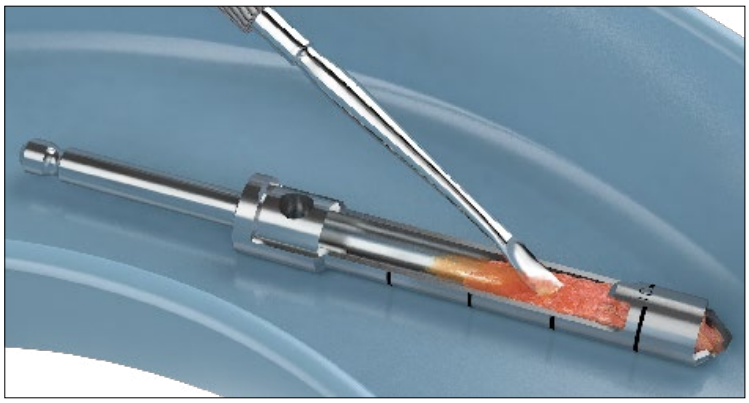


Contact the tip of the bone graft harvester to bone prior to applying power to the device. Under power, begin advancing the bone graft harvester into the cortical bone entry point. Advance the instrument to the desired depth and remove through the entry point.

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





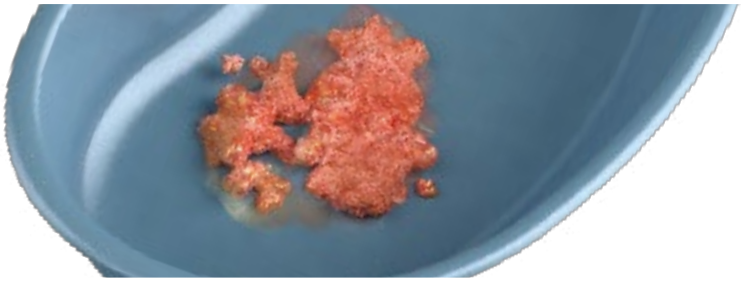
Over a sterile basin, twist the thumbscrew on the door in a counterclockwise direction. When disengaged from the trephine, pull the door off by separating the female portion of the door from the male portion of the trephine. Set the door aside for re-processing.

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.*

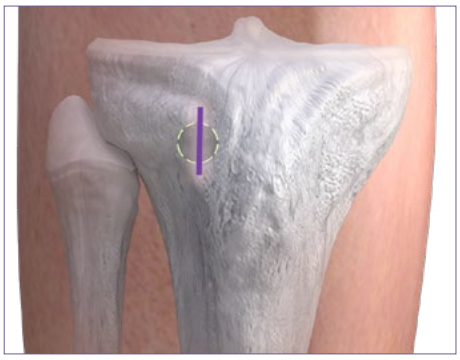
CLOSURE

Proceed to incision closure or concomitant procedures at this time.



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.



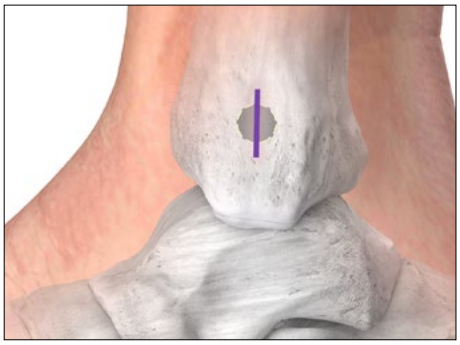
PROXIMAL TIBIA

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.

GORILLA BONE GRAFT HARVESTER SYSTEM

Part #	Description	Use
P99-930-2006	Morselizing Bone Graft Harvester, Door, 6mm	Reusable
P99-930-2008	Morselizing Bone Graft Harvester, Door, 8mm	Reusable
P99-930-2010	Morselizing Bone Graft Harvester, Door, 10mm	Reusable
P99-930-2106	Morselizing Bone Graft Harvester, AO, 6mm	Single-use
P99-930-2108	Morselizing Bone Graft Harvester, AO, 8mm	Single-use
P99-930-2110	Morselizing Bone Graft Harvester, AO, 10mm	Single-use
P99-192-2315	ø2.30mm X 15cm Kirschner Wire, 316 LVM	Single-use

*See the complete Gorilla Plating Surgical Technique Guide (P51-STG-0001) for general instrument information

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

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

Indications, Contraindications, Warnings and Precautions relevant to the Baby Gorilla®/Gorilla® Plating System are contained in the Instructions for Use document of the Baby Gorilla®/Gorilla® Plating System P51-IFU-3001.

A patient with the Paragon 28® Baby Gorilla®/Gorilla® Plating System may be safely scanned under the following conditions.
Failure to follow these conditions may result in injury to the patient.

Name/Identification of Device	Paragon 28® Baby Gorilla®/Gorilla® Plating System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spacial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact

If information about a specific parameter is not included, there are no conditions associated with that parameter.

GORILLA®
R3CON PLATING SYSTEM

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