



COREX™

MINIMALLY INVASIVE BONE HARVESTER

Hospital Overview & Technical Assessment

The COREX™ Bone Harvester is a manually operated single-use trephine supplied sterile for minimally invasive harvesting of autogenous cancellous bone from various skeletal sites.

- » Suitable for harvesting from the iliac crest, proximal tibia, distal tibia and calcaneus
- » Designed to reduce operative time, blood loss and donor site morbidity
- » 7mm & 9mm sizes

Technology Overview

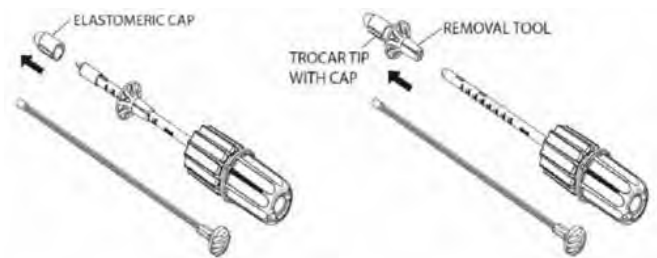
The COREX™ Bone Harvester is a minimally invasive device used to recover living cells from the patient to be used alone or combined with bone graft extenders and bone void fillers in arthrodesis procedures.



Technology Application

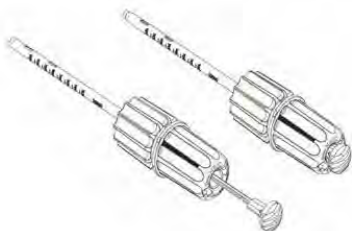
PREPARATION FOR USE

The COREX® Bone Harvester is supplied with a removable trocar tip, for the purpose of creating a cortical aperture/bore. The tip is associated with the distal shaft of the harvester. Carefully remove the protective elastomer cap, then apply the sharp, trocar tip to cortical bone surface, beneath which one intends to remove cancellous bone. While applying sufficient but not excessive pressure against the cortical bone, rotate the COREX™ device by gripping the proximal handle and rotating clockwise and then counter clockwise beyond 45 degrees in either direction. Adjust pressure as needed to control depth of penetration. Avoid plunging trocar beyond proximal collared surface (immediately proximal to sharp trocar edges). Once the cortical hole is developed, remove the trocar tip from the COREX™ device, by replacing the elastomer cap, and either depressing the tab engagement while pulling it off, or pushing the trocar tip off with the supplied removal tool. In the event that the trocar tip is not used, or is insufficient in developing a cortical defect, use an Osteotome, Capner gauge, drill, etc. Make a cortical window large enough to allow the COREX™ Bone Harvester to be redirected along various axes upon successive passes.



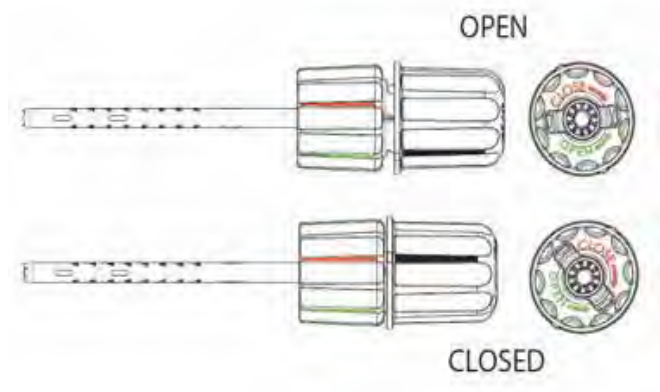
PRIOR TO HARVEST

A plastic extrusion tamp is provided in the bubble pack. **DO NOT DISCARD TAMP**- tamp will be used to extrude cancellous bone from device.



TO HARVEST CANCELLOUS BONE

1. Prior to harvest ensure that the upper handle is rotated fully counter-clockwise to the lower handle.
2. An audible click will indicate the harvester is locked in the open position and ready for harvesting.



3. Rotate the COREX™ Bone Harvester in an oscillating clockwise-counter-clockwise manner while simultaneously applying advancing pressure to the harvest bed, by pushing on the proximal handle.
4. When full depth of harvest has been achieved, fully lock the device by turning the upper handle clockwise relative to the stabilized lower handle (locked position).
5. Rotate the locked the COREX™ Bone Harvester in a clock-wise manner while gradually withdrawing from harvest site.
6. After withdrawing from the harvest site:
 - » Open the COREX™ Bone Harvester by completely turning the upper handle in a counter-clockwise direction relative to the stabilized lower handle to the open the locked position (see "Prior To Harvest" instruction #1).
 - » Extrude cancellous bone from the COREX™ Bone Harvester into a sterilized dish using a plastic tamp.
 - » Extrude after each pass to prevent cylindrical graft material from binding inside the retaining harvesting cylinder.

RECOMMENDED SPINE USE

The COREX™ device can be used to harvest bone from the Anterior and Posterior Iliac Crest.

SUGGESTIONS FOR ILIAC CREST HARVESTING

Posterior Approach [Suggested Size - 9mm]

Harvest from the large dilated area of PSIS (Posterior Superior Iliac Spinous Process).

Anterior Approach [Suggested Size - 7mm]

Stay between the inner and outer tables of the ASIS (Anterior Superior Iliac Spinous Process) as you direct the harvester under the rim of the Iliac crest.

SUGGESTIONS FOR PROXIMAL TIBIAL METAPHYSEAL HARVESTING

1. Make a small (2-3 cm) linear skin incision either just medial (preferred) or lateral to the tibial tubercle.
2. While retracting the skin with a small self-retaining retractor, create a cortical defect.
3. Palpate the joint line and direct the COREX™ harvester within the metaphysis, remaining 1 to 2 cm below the joint line and closely monitoring the depth of penetration to avoid opposite cortical breach. Bovie coagulate all subcutaneous bleeders and suture the skin.
4. Apply a compressive dressing during the early post-op period.

Coding and Payment

INPATIENT

ICD-9-CM Procedure Codes

Hospitals use ICD-9-CM procedure codes to report inpatient services. The following codes may be appropriate for the excision of bone for graft with the COREX™ Device.

77.75 Excision of bone for graft, femur

77.77 Excision of bone for graft, tibia and fibula

77.79 Excision of bone for graft, other

Medicare Severity-Diagnosis Related Groups (MS-DRG)

Individual patient diagnosis(es) and the reporting of any surgical procedures performed will determine the appropriate MS-DRG. Potential MS-DRG assignment varies due to the product's various indications.

OUTPATIENT

CPT Code

When using the COREX™ Device to harvest autogenous bone in a spinal application, report code 20937. Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision). (List separately in addition to code for primary procedure).

CPT Codes for obtaining autogenous bone through separate skin/fascial incisions should be reported separately unless the code description references the harvesting of the graft or implant (eg, includes obtaining graft). 20900 - Bone graft, any donor area; minor or small (eg, dowel or button). 20937 has a status indicator of C for Inpatient procedure.

PAYER ADVOCACY

Refer to payer policies and guidelines for specific coverage criteria.

Summary of Indications, Contraindications, and Warnings

INDICATIONS

The COREX™ Bone Harvester (Corex) is a supplied sterile, single patient use, manually operated trephine intended for harvesting cancellous bone from various skeletal sites.

CONTRAINDICATIONS

Osteopenic/Osteoporotic patients may have insufficient density of bone to facilitate use of the COREX™ Bone Harvester. This device has sharp cutting surfaces and potentially represents a hazard to the user, patient, and disposer. All appropriate cautious handling should be exercised.

CAUTION

Device is a single patient use item reuse may result in failure of proper actuation and or biologic contamination. These consequences could result in adverse patient effects.

Extreme caution should be utilized when placing the sharp tip of the device near vulnerable, "at risk" structures.

PRECAUTIONS

Once the trocar tip is removed, the COREX™ trephine (hollow tube) section is not intended to further penetrate cortical bone. There are circumstances of use when cortical penetration might occur, or is even likely to occur.

The surgeon must be keenly aware of this potential hazard, as serious or life threatening injuries to nerves, vessels, or other soft tissue structures external to the bone's cortical margins may result.

The surgeon should understand the orientation and depth of penetration associated with the COREX™ cutting tip, relative to the skeletal anatomy within which it is being applied.

Every effort to ensure that the cutting tip remains within the cancellous portion of the bone should be exercised. If there is any doubt, the device's depth of entry and axial orientation should be measured and noted and, if appropriate, the device should immediately be withdrawn from the bone entry site.

Additional Information

Is the product Implantable?

No

How was the Product Cleared?

Class 1 General Instrument

Does the product require additional instruments?

No

Does the product need to be checked by Biomed?

No

Does the product contain Mercury?

No

Does the product contain Latex?

No

Product Ordering Information

Part Number	Description
300-070	7mm COREX™ Bone Harvester
300-090	9mm COREX™ Bone Harvester

www.trinityorthodevice.com



Trinity Orthopedics, LLC

8817 Production Avenue
San Diego, CA 92121

Customer Service: (858) 689-4113

Consult instructions for use at this
website www.trinityorthodevice.com

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.