

INNOVASIS

TECHNIQUE GUIDE

Innovasis is expanding its base business with the introduction of CranioFuse™; a unique product that, when hydrated, compresses like a sponge and is designed to fill the “Kerf” (the craniotomy line or the place in the cranium where a drill has removed bone to create the flap), burr holes, or other voids left in the cranium after craniotomy.

CranioFuse™ brand Allograft was conceived by Dr. Peter Nakaji, of the Barrow Neurological Institute, who had an idea to create a bone allograft product that precisely fills the defects made in fashioning a craniotomy.

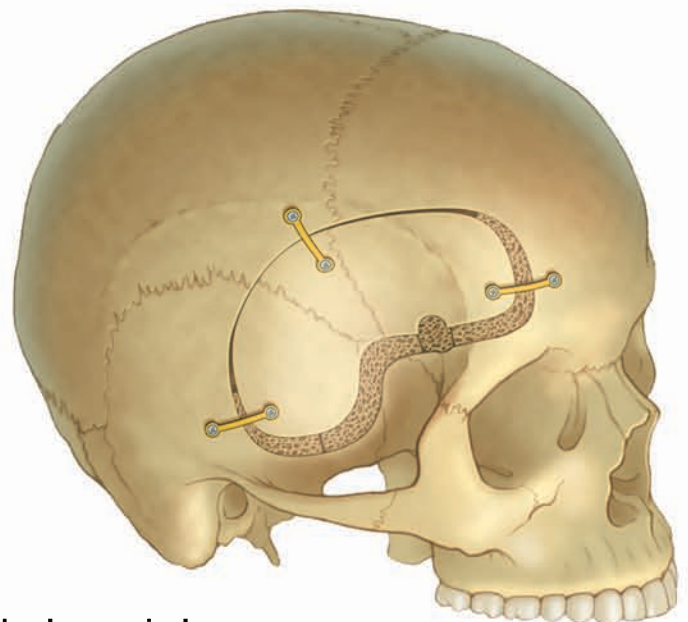
CranioFuse™ is a flexible, cancellous bone allograft that contains no carrier agent that can inhibit or dilute the BMP activity of the graft. CranioFuse™ compresses like a sponge, springs back to its original shape and conforms to any shape. CranioFuse™ is processed in AATB accredited and FDA inspected tissue banks and receives post packaging terminal sterilization by gamma irradiation. It can be easily stored, having a shelf life of five years.

HOW IT'S SUPPLIED

The fillers are made of spongy allograft bone and when rehydrated become soft and flexible. These grafts are tailored for craniotomy gap or burr hole filling. They may be placed easily by hand into the craniotomy defect in order to obtain immediate reconstruction of the cranial contour.

HOW IT'S PACKAGED

| Part Code | Description | Size |
|-----------|-------------------------------------|------------------|
| 63015012 | CranioFuse™ Dowel, Parallel, 1 pkg. | 12mm |
| 63015015 | CranioFuse™ Dowel, Parallel, 1 pkg. | 15mm |
| 63115256 | CranioFuse™ Strip, V-Shape, 1 pkg. | 25mm x 6mm x 4mm |



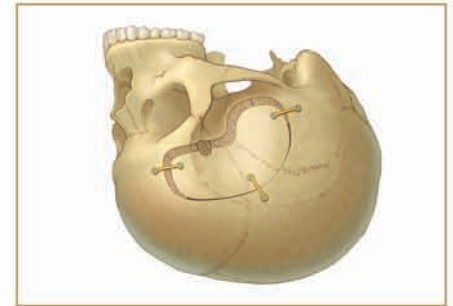
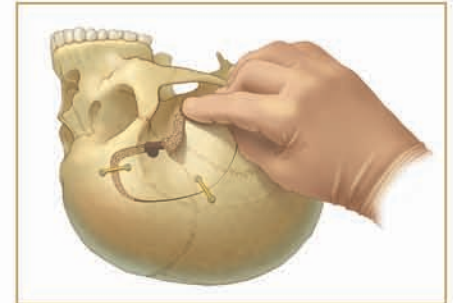
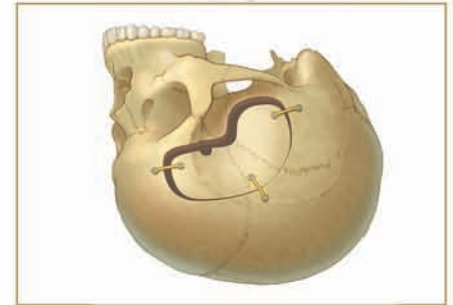
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CRANIOFUSE™

CRANIOFUSE™ BURR HOLE FILLER - GUIDE FOR USE

- (a) The CranioFuse™ burr hole graft is stored dried and dehydrated at room temperature in packs of a single burr hole filler.
- (b) The dried graft is hard and inflexible. When rehydrated in sterile water or sterile saline it will become soft and flexible.
- (c) The graft will become malleable after 5 minutes of soaking, but should be soaked a minimum of 30 minutes. Therefore it is recommended to open and soak the grafts at the time the craniotomy is fashioned.
- (d) The burr hole fillers are positioned over the burr hole and introduced by pinching them together between a thumb and forefinger; the rest of the implant is then pressed into the burr hole until it lies flush with the outer table of the skull.
 - (i) Care must be taken that the implant is not placed too deeply in areas where the bone is thin. A burr hole filler should not be used in bone which is not at least 2mm thicker than the depth of the implant.
 - (ii) Best results are obtained if the burr hole filler is the proper diameter to fill the selected burr hole, so that the filler will fit snugly.
 - (iii) The burr hole should be filled until the graft lies flush with the outer table. It is not necessary and not recommended to fill the burr hole all the way to the inner table.



CRANIOFUSE™ CRANIAL KERF FILLING STRIPS - GUIDE FOR USE

- (a) The CranioFuse™ cranial kerf filling graft is stored dried and dehydrated at room temperature in packs of a single strip.
- (b) The dried graft is hard and inflexible. When rehydrated in sterile water or sterile saline it will become soft and flexible.
- (c) The graft will become malleable after 5 minutes of soaking, but should be soaked a minimum of 30 minutes. Therefore it is recommended to open and soak the grafts at the time the craniotomy is fashioned.
- (d) Placing the graft: the strip filler is positioned over the craniotomy gap and introduced by pinching it together between a thumb and forefinger at one end; the rest of the implant is then pressed into the gap by running a finger along it until it lies flush with the outer table of the skull.
 - (i) Care must be taken that the implant is not placed too deeply in areas where the bone is thin. A craniotomy gap filler should not be used in bone which is not at least 2mm thicker than the depth of the implant.
 - (ii) Best results are obtained if the strip fits snugly in compression most of the length of the gap. Areas too narrow to accommodate the graft may not need to be filled.
 - (iii) The craniotomy gap should be filled until the graft lies flush with the outer table. It is not necessary and not recommended to fill the burr hole all the way to the inner table.