



Packaging™
Engineered
for Life

CranioLoc®

Autologous Cranial Bone Flap Storage



CranioLoc®

Autologous cranial bone flap (CBF) storage kits

Single-use, sterile, protective packaging for musculoskeletal (CBF) tissue.

STANDARD & PLUS SIZE KITS

CranioLoc® autologous cranial bone flap storage kits comes in two sizes. The standard kit (CBF 90-135) accommodates CBFs up to 6" (152 mm) in diameter. For larger CBFs a Plus sized kit (CBF 90-140) is also available. Plus sized CBF kits can accommodate CBFs up to 7.5" (190 mm).

SEALED TIGHT, NOT ZIPPED UP

Each **CranioLoc®** (CBF) storage kit includes an peel-able inner primary pouch, a peel-able outer overwrap bag and a single-use sterility cover which protects the sterility of the primary peel pouch during the sealing process. Sealing the CBF ensures tamper evident, permanent, air-tight protection during the storage term.

DESIGNED FOR CBF STORAGE

CranioLoc® cranial bone flap (CBF) storage kits are designed specifically for short to intermediate term storage of CBF during a Craniotomy. **CranioLoc®** is manufactured using medical grade, high performance virgin film that remains stable at temperatures as low as **-80 °C**.

Product Details

CranioLoc® autologous cranial bone flap (CBF) storage kits are engineered to protect cranial bone flaps during the processing and storage between Craniotomy procedures.

Produced in an ISO 6 clean room the

CranioLoc® system meets or exceeds industry standards. All **CranioLoc®** systems undergo a 3x-inspection protocol:

- pre-process
- in process
- final inspection

Each **CranioLoc®** system consists of two high-strength film pouches, an inner protective tissue peel-able pouch and outer peel-able overwrap. This 2-pouch configuration provides redundant protection and enables aseptic presentation into surgical environments.

- Complete sterile system
- Biologically and chemically inert
- Films conform to USP Class VI
- No plasticizers, leachables or extractables
- Clear design for visual inspection
- **Temperature to -80 °C**

How To Use

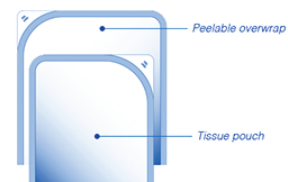
IMPORTANT: **CranioLoc®** autologous cranial bone flap storage (CBF) kits should only be used by professionals operating under facility protocols on hygiene and gowning.

- Insert the bone tissue into the smaller, tissue pouch.
- Place the non-stick, square-cornered, sealing sleeve over the opening of the tissue pouch.
- Align the sleeved end of the tissue pouch with the heating element of the bag sealer.
- Follow your sealer's instruction to secure the open-end of the tissue pouch. (see **CranioLoc®** Sealer systems for securing instructions)
- After securing the tissue pouch, remove the non-stick sealing sleeve and discard.
- Insert the sealed tissue pouch into the peel-able overwrap pouch.
- Align the peel-able overwrap pouch with the heating element on bag sealer.
- Follow sealer instruction to secure the open-end of the peel-able overwrap pouch. (do not use non-stick sleeve)
- Place filled **CranioLoc®** system into storage and follow surgical protocols.

System and Options

- CBF 90-135 - Standard (10 units)
- Tissue pouch - 7.5" x 9"
- Peel-able overwrap - 9" x 10"
- Sterile, single use, heat sealer covers

- CBF 90-140 - Oversized (1 unit)
- Peel-able overwrap - 10.5" x 12"
- Sterile, single use, heat sealer cover



- CBF 60-077 - **CranioLoc®** Sealer System
Magnetic release, table top heat sealer

For more information:

Instant Systems, Inc
965 Denison Ave STE 101
Norfolk, VA 23513

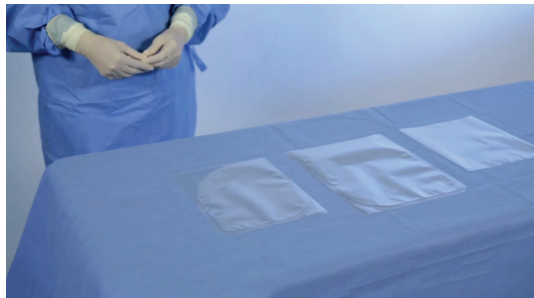
info@InstantSystems.com
800.706.5808

STANDARD INSTRUCTIONS SHEET

CranioLoc® cranial bone flap storage kit



CBF 90-135 **Standard kit** *instructions*



Autologous cranial bone flap [CBF 90-135] storage kit video instructions can be found Online at: <http://InstantSystems.com/cranioLoc.html>

STEP 1. - TAKE INVENTORY

Open and layout the **CranioLoc®** CBF storage kit to inspect the components: 1 peel-able CBF tissue pouch, 1 peel-able overwrap bag and 1 sterility sealing sleeve.

NOTE: **CranioLoc®** CBF kits require a medical impulse sealer. Verify a sealer is available before opening the **CranioLoc®** kit.

STEP 2. - INSERT CBF AND SEAL TISSUE POUCH

Insert the cranial bone flap into the opening of the smaller, primary peel-able pouch.

Place the non-stick, square-cornered, sealing sleeve over the opening of the CBF tissue pouch.

Align the sleeved end of the tissue pouch with the heating element of the impulse bag sealer.

Follow your sealer's instruction to secure the open-end of the tissue pouch. Discard the sterility sleeve once primary tissue pouch is sealed.

STEP 3. - SEAL TISSUE POUCH IN OVERWRAP BAG

Insert the sealed tissue pouch into the peel-able overwrap bag.

Align the peel-able overwrap pouch with the heating element on bag sealer.

Follow sealer instruction to secure the open-end of the peel-able overwrap pouch.

IMPORTANT: do not use non-stick sleeve.

Place filled **CranioLoc®** CBF 90-135 kit into storage and follow hospital chain-of-custody procedures and protocols.

IMPORTANT: **CranioLoc®** Autologous Cranial Bone Flap Storage (CBF) Systems should only be used by professionals operating under facility protocols on hygiene and gowning. A comprehensive training video is available Online at InstantSystems.com.

The following instructions are guidance on how to use the **CranioLoc®** cranial bone flap (CBF 90-135) storage kit. When using **CranioLoc®** it is important to follow hospital procedures as well as state and federal guidelines.

