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Figure 9
Remove Opteform™ from foil pouch using sterile gloves that are free from bodily fluids, but not dry.

Remove excess debris and body fluids from gloves. Dampen gloves using sterile saline before handling Opteform.

Allograft does not require gentle handling.

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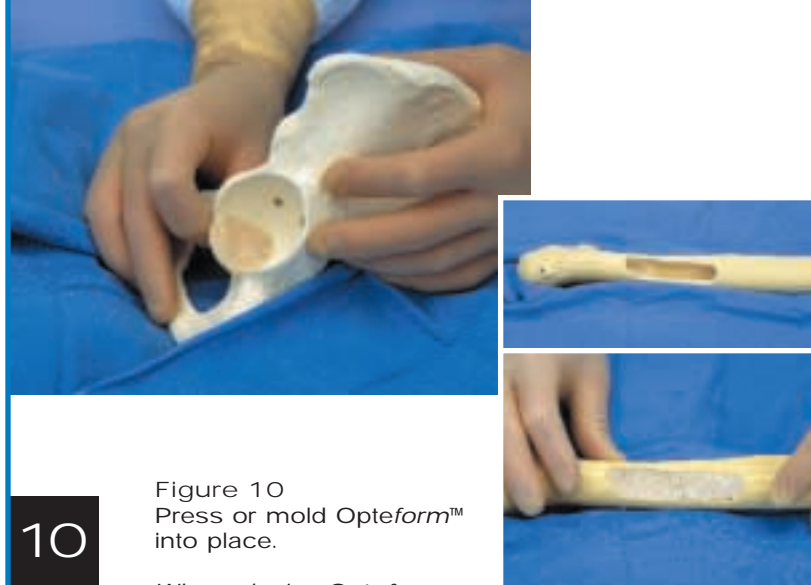


Figure 10
Press or mold Opteform™ into place.

When placing Opteform into a surgical site:

Mixing Opteform with blood or body fluids will reduce its capacity to cool to a resilient solid. Hold tissue until it begins to cool. Place tissue into the surgical site, and form immediately.

- Opteform can be implanted at room temperature.
- Opteform can be cut with scissors to desired shape and implanted.
- Opteform can be shaped as desired, cooled to a resilient solid then implanted.
- Cooling time is variable depending upon volume of tissue and ambient temperature.
- Opteform can be shaped using trial components/implants.



Opteform™

Allograft

Preparation
and Handling
Technique

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Figure 11
Re-warm as necessary. Prepare for re-warming by returning Opteform™ to foil pouch, rolling top down and closing securely with hemostats.

When re-warming Opteform, close pouch securely and prop against warmer or basin side to prevent direct contact with water. Assure that blood or water does not infiltrate the sterile pouch.

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Figure 12
Place securely closed foil pouch in warm water to re-warm Opteform™. Avoid leakage of water into pouch.

Placing hemostats on both sides of the pouch closure allows for the pouch to be propped on the side of the warming vessel.

Opteform can be rewarmed as necessary during a single surgical event but cannot be saved for use in future surgeries.

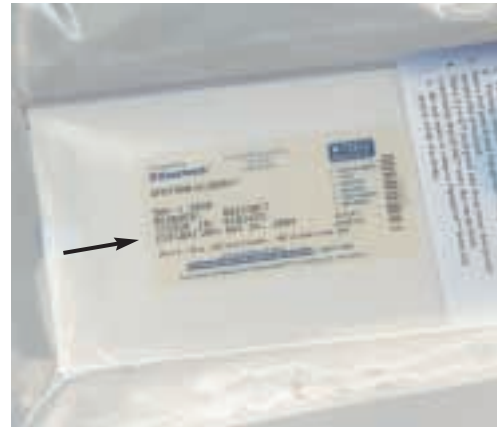


Figure 1
Verify expiration date prior to opening.

Shelf life information:

- 5 years @ -40°C or colder
- 6 months @ -20°C to -39°C
- 3 months @ -7°C to -19°C

Figure 2
Open non-sterile dustcover and remove box.

Open box and remove contents which include:

- 1) Patient labels
- 2) Package insert
- 3) Tissue Utilization Record
- 4) Double pouch containing Opteform



Figure 3
Open outer peel pouch and deliver inner foil pouch containing Opteform™ to sterile field.

Tissue must be warmed inside the inner foil pouch. Allograft contained in the inner foil pouch is aseptically processed. Handle the same as other aseptically processed fresh-frozen human tissue.

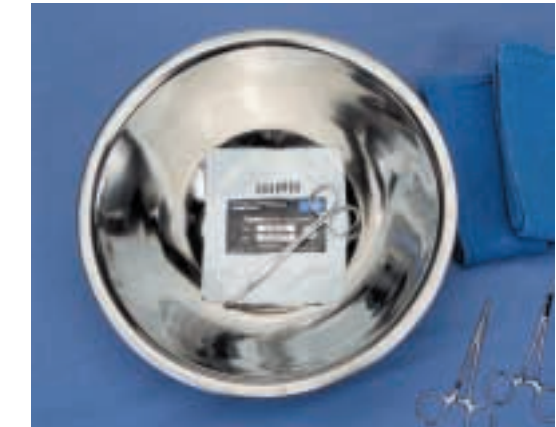


Figure 4
Place inner foil pouch into sterile basin.

Sterile basin method: Unopened foil pouch should be placed in the sterile basin.

- Use sterile instruments to weight pouch to the bottom of sterile basin.
- Ensure temperature strip is visible.
- Temperature strip will change color to indicate temperature of the pouch.

Figure 5
Obtain sterile water/saline from blanket warmer and pour over foil pouch.

- Sterile water/saline heated to 140°F (60°C) may initially be used, but should be cooled to 110-120°F (43-49°C) within 10 minutes.
- Maintain temperature at 110-120°F (43-49°C).
- The Temperature strip should be monitored for indication that rewarming is necessary.



WARMING METHOD B



Figure 6
Sterile drape the water bath and fill with sterile water/saline, using a minimum of two liters. Turn ON and set temperature to 120°F (49°C).

Notes regarding the warmer directions:

- The temperature can be set prior to surgery.
- Two liters is the minimum quantity of water/saline to be used.
- Analog, secondary thermostat (black knob on front) must be turned to the 9 o'clock position.
- Ensure that drape is flat against the inside tray of the warmer. The drape may melt if the above precautions are not followed.
- Opteform can be kept at 120°F for up to 6 hrs.



Figure 7
Place inner foil pouch containing Opteform™ into warm water bath.

Water bath method: Unopened foil pouch should be submerged in the water bath.

- Use sterile instruments to weight pouch to the bottom of water bath.
- Ensure temperature strip is visible.
- Temperature strip will change color to indicate temperature of the pouch.



Figure 8
Remove foil pouch from water.

Using sterile scissors, cut the foil pouch open just below the seal, leaving space to re-close the pouch if re-warming becomes necessary.