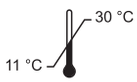
Explanation of Symbols

	Do not use if package is damaged
	Sterilized using irradiation
	Single use only
	Consult Instructions for Use
	Use By Date
	Prescription Only
	Temperature Limit
	Do not re-sterilize
	Lot Symbol
	Manufacturer

This product is to be handled by trained qualified persons having read these Instructions for Use.

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Part Number: 10-0307 Rev. C

Date of Approval: 2024-06-25

osteoamp®

Flowable Access Cannula

OFAC-C	Contents: 1 Allograft Delivery Device (Cannula and Push Rod), Curved

Instructions for Use

IMPORTANT PRODUCT INFORMATION

Please read before use

Bioventus LLC
4721 Emperor Blvd. Suite 100
Durham, NC 27703

A. MATERIALS & DEVICE DESCRIPTION

The Allograft Delivery Device consists of a cannula and push rod made of biocompatible polypropylene. The device is provided sterile and is intended to be used with hydrated allograft to facilitate delivery into bony defects in orthopedic surgical sites.

B. INDICATIONS FOR USE

The Allograft Delivery Device is intended to be used for the delivery of hydrated allograft to an orthopedic surgical site.

C. WARNINGS & PRECAUTIONS

- Do not use if package is opened or damaged. Contents are provided sterile.
- Read expiration date before use. Do not use if expiration date has been exceeded.
- Do not attempt to re-sterilize or reuse. The device is for single use only.
- The device is intended for use by surgeons familiar with bone grafting procedures.
- The system components are not intended for use outside of orthopedic surgical sites.
- Do not overfill or pressurize the bony defect site, to prevent graft material extrusion and damage to surronding tissues.
- **A minimum 6.5 mm opening** is recommended for use of the device.
- Do not use a mallet, hammer or any other power source with the Allograft Delivery Device. Only use manual expression when using the device.

D. INSTRUCTIONS FOR USE

1. Peel open outer pouch and transfer inner pouch to the sterile field.
2. Peel open inner pouch and remove the cannula and push rod.
3. Secure the proximal luer end of the cannula onto the syringe containing the hydrated allograft.
4. Place cannula into application site and visually confirm correct location.
5. Express the hydrated allograft through the cannula into the application site. Resistance will be felt when the disk space has filled up.
6. Use the supplied push rod to express the remaining hydrated allograft in the cannula barrel, as needed. To do this:
    - Disconnect the syringe
    - Visually re-confirm correct location
    - Insert the push rod into the cannula
    - Advance the push rod in small increments. Resistance will be felt when the disk space has filled up
7. Once completed, remove the cannula from the surgical site.
8. Observe the area around the application site and **remove any excess allograft to prevent bone overgrowth**.
9. After use, dispose of the cannula and push rod in biohazardous waste per hospital protocol.

E. STORAGE CONDITIONS AND DISPOSAL

The Allograft Delivery Device must be stored and maintained 11 – 30 °C (51.8 – 86 °F).

The expiration date is printed on the label. **DO NOT** use after the expiration date.

The contents of the pouch are sterile unless opened or damaged.

After use, dispose of as biohazard waste.