5. ADVERSE EVENTS AND REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as related to the AlloSert Uveo System must be reported to Iantrek.

Iantrek, Inc.
Attention: Medical Safety Officer
216 Weybosset Street
Providence, RI 02903
T: 866.426.8735

6. HOW SUPPLIED

- The AlloSert Uveo Handpiece and Carriers are supplied sterile in a pouch.
- The AlloSert Uveo Handpiece and Carriers are intended for single use only.
- The safety and effectiveness of cleaning, re-sterilization and/or reuse of these instruments has not been evaluated and may adversely impact device integrity and patient safety.
- The AlloSert Uveo system components and manufacturing processes do not contain latex.
- Used AlloSert Uveo instruments should only be discarded in a suitable, biohazardous sharps container.

7. STORAGE REQUIREMENTS

Product should be stored in a dry location at room temperature.

8. EXPIRATION DATE

The functional expiration date (year and month) is clearly indicated on product packaging. Functionality is assured until the expiration date unless packaging is punctured or damaged. Neither the AlloSert Uveo Handpiece nor the AlloFlo Uveo Pre-Loaded Sclera should be used past the date indicated.

9. MR SAFETY INFORMATION

The AlloSert Uveo System is not safe for use in magnetic resonance (MR) environment.

10. RETURNED GOODS POLICY

In the United States, returned product which has been found to be faulty may be replaced or a credit may be issued at the sole discretion of Iantrek. All returns must be accompanied by an Iantrek Returned Goods Number (RGN) and be shipped via traceable means. A Returned Goods Number is obtained by contacting Iantrek's Customer Service Department. Issuance of this number does not constitute final acceptance of the returned products. For detailed policy guidelines including product exchange, please contact your Sales or Customer Service Representative.

11. MANUFACTURER

Iantrek, Inc.
216 Weybosset St, 2nd Floor Providence, RI 02903 USA

Customer Service:
866-IANTREK (866.426.8735)
CustomerService@IantrekMed.com
www.iantrekmed.com

12. GLOSSARY OF SYMBOLS

Symbol	English definition
	Caution, consult accompanying documents
	Consult instructions for use
REF	Catalog number
LOT	Batch code
SN	Serial number
QTY	Quantity
	Date of manufacture (YYYY-MM-DD:Year-Month-Day)
	Manufacturer

Symbol	English definition
	Use by last day of (YYYY-MM-DD:Year-Month-Day)
NON STERILE	Instrument must be sterilized prior to use.
2	Do not reuse
STERILE R	Sterilized using irradiation
	Do not use if package is crushed or damaged
Rx	Caution: Federal law restricts this device to sale by or on the order of a physician
	Store at room temperature (68° to 75° F [22± 2°C])
	Keep dry

PN: 900105, Revision F

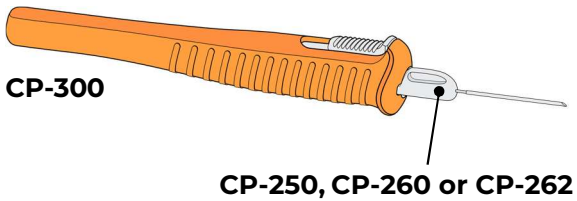
This IFU corresponds to the following product codes:

CP-300 – AlloSert Uveo™ Handpiece w Slider, Sterile
CP-250 – Cyclodialysis Carrier Tip (CCT), Sterile
CP-260 – AlloFlo Uveo™ Sterile Pre-Loaded Sclera (1 Carrier)
CP-262 – AlloFlo Uveo™ Sterile Pre-Loaded Sclera (2 Carriers)

Caution: Federal law restricts this device to sale by or on the order of a physician.

allosert uveo
INSTRUCTIONS FOR USE

AlloSert Uveo™ Microinterventional Cyclodialysis System



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1. DEVICE DESCRIPTION AND INTENDED USE

The AlloSert Uveo™ Microinterventional Cyclodialysis System is a manual surgical instrument used for the ab-interno construction or modification of a cyclodialysis, followed by delivery of viscous materials, bio-tissue/allograft, or other materials to reinforce and maintain the cleft. The AlloSert Uveo System includes a Handpiece (CP-300) and a Cyclodialysis Carrier Tip (versions CP-250, CP-260 or CP-262) which is attached to the Handpiece prior to use.

The following Cyclodialysis Carrier Tips (CCTs) are available:

- CP-250 – one sterile, single-use disposable CCT. Can be manually loaded on site.
- CP-260 – one sterile, single-use disposable CCT, pre-loaded with a scleral AlloFlo Uveo™ allograft.
- CP-262 – two sterile, single-use disposable CCTs, pre-loaded with a scleral AlloFlo Uveo™ allograft.

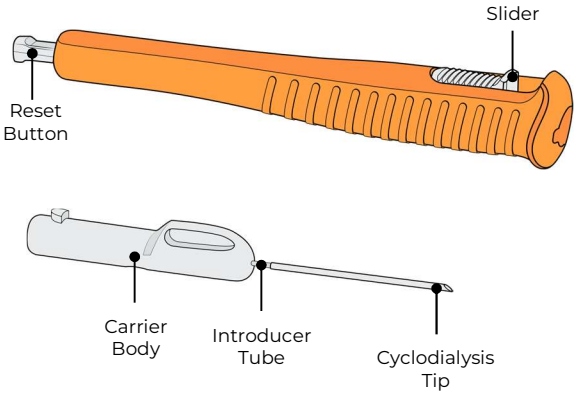
The internal lumen dimensions of the CP-250, CP-260 and CP-262 are 600 microns and the external outer diameter is 800 microns.

The AlloSert Uveo System should be used by surgeons trained in anterior segment intraocular surgery.

2. CONTRAINDICATIONS AND WARNINGS

- Use the AlloSert Uveo System only in a sterile environment.
- The AlloSert Uveo System is contraindicated for multiple patient use.
- The AlloSert Uveo System should not be used in cases with poor gonio-visualization of the iridocorneal angle anatomy.

3. INSTRUMENT CONTROLS

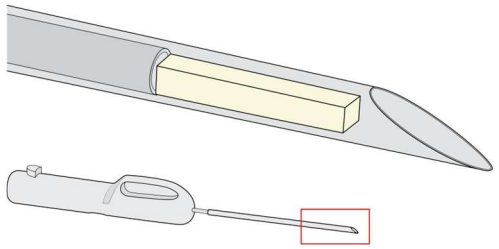


4. DIRECTIONS FOR USE

Remove the AlloSert Uveo Handpiece and Carrier(s) from packaging and place in the sterile field.

CP-250 tip can be used empty and coupled directly to the handpiece for the creation of a cyclodialysis without delivery of viscous or non-viscous material. CP-250 can also be loaded during surgery. Viscous or non-viscous material (e.g., allograft) materials can either be front-loaded or loaded with suction when attached to a standard 5 or 10-ml syringe.

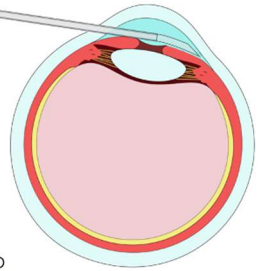
CP-260 and CP-262 Cyclodialysis Carrier Tips are pre-loaded with allograft. Before use, confirm the bio-tissue is fully loaded into the tip of Carrier. If bio-tissue extends beyond the tip of the CCT, lightly tap the tissue to push back into the cannula such that no part of the tissue is protruding outside of the bevel.



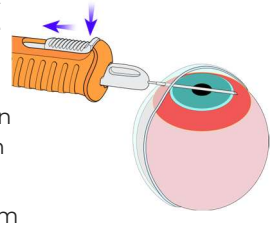
To prepare the Handpiece for use with the Carrier, push the Reset Button until it clicks in place.

Connect the Carrier to the proximal end of the Handpiece. Rotate Carrier to lock in place.

- Inflate the anterior chamber with viscoelastic.
- Enter the eye through a ≥ 1 mm corneal or scleral incision approximately 180 degrees from site of intended gonio-intervention, taking care to avoid iris or corneal endothelial touch.



- Advance the cyclodialysis tip above the iris plane to create a cyclodialysis.
- When the tip is inserted to the desired depth in the cleft, press down on the Slider to deploy CCT contents, while controlling the retraction speed with the finger on the slider.



- Withdraw the CCT from the cyclodialysis cleft and the anterior chamber.
- Confirm material positioning in cleft is flush with the iris root and no protruding allograft eminence into the anterior chamber.

Dispose of the AlloSert Uveo assembly per facility procedures

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