

Symbols Used on Labeling

	Catalog Number		Authorized Representative in the EU
	Lot Number		Authorized Representative in the UK
	CE Mark & Notified Body No.		To identify a Type B Applied Part
	Caution		Sterilized using ethylene oxide
	Do not use if the product sterile barrier system or its packaging is compromised and consult instructions for use.		Single sterile barrier system with protective packaging inside
	Do not resterilize		Temperature limit
	Keep away from sunlight		Do not reuse
	Date of Manufacture (YYYY-MM-DD) & Country of Manufacture		Use-by Date (YYYY-MM-DD)
	Medical Device		Manufacturer
	Fragmentation		Ocular Irrigation
	Keep Dry		For use by, or on the order of, a physician
	Unique device identifier		Consult instructions for Use

Part Number 900-2881-008
Release Date: 8/19/2025

Product Warranty and Limitations of Liability

MED-LOGICS warrants that CataPulse® Lens Removal Handpiece Set will conform to MED-LOGICS' then current version of the product specifications for such disposable items in all material respects and shall be free from defects in material and/or workmanship for a period equal to the disposables expiration date. MED-LOGICS exclusive all other warranties, whether expressed, implied or by operation of law, including but not limited to any implied warranties of merchantability or fitness. MED-LOGICS shall not be liable for any incidental, consequential or exemplary loss, damage or expenses, directly or indirectly resulting from the use of the CataPulse® Lens Removal Handpiece Set or accessories even if MED-LOGICS has been advised of the possibility of such loss, damage, or expense.

Storage Conditions:

- The CataPulse® disposable products have no special storage conditions, but should be stored under normal warehouse conditions, which includes protection from moisture, extreme cold (less than 5°C), and excessive heat (greater than 40°C).



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CATAPULSE®



CP2100

CataPulse® Lens Removal Handpiece Set



U.S. and Foreign Patents Pending

Intended Use: The MED-LOGICS CP2100 CataPulse® Lens Removal Handpiece Set is a component of the CataPulse® System and intended to be used in the removal of the crystalline lens and cortical tissue.



Product Description: The instrument set consists of an irrigation and aspiration handpiece. Each handpiece features an ergonomically designed handle with male luer connectors at the distal end for attachment of CataPulse cannulas. The opposite end of the irrigation set contains a spiker for attachment to BSS irrigation solution bags/bottles. The opposite end of the aspiration handpiece is the lens removal cassette, which inserts into the CataPulse console for collection of lens fragmentation material conveyed from the eye. The devices are provided sterile (terminally sterilized by ethylene oxide) and are intended for single use only. A rigid, clear terminal tray protects the devices inside the Tyvek pouch (single sterile barrier) and can be used to facilitate aseptic transfer to the sterile field.

Indication for Use / Intended User: The devices are used in cataract surgery when removal of the natural crystalline lens is indicated. The devices are intended to be used by ophthalmic surgeons.

Contraindications and undesirable side-effects: No contraindications and no undesirable side-effects are known when used as intended.

Clinical Benefits: The clinical benefits of the CataPulse® Lens Removal Handpiece Set includes the fragmentation and extraction of crystalline lens tissue during cataract surgery.

Precautions:

- Good clinical practice dictates testing for adequate irrigation and aspiration flow prior to entering the eye. If stream of fluid is weak or absent, good fluidics response will be jeopardized.
- Use appropriate flow parameters to maintain fluidic balance.
- Prior to use, the instruments must be thoroughly inspected for correct function and to detect possible damage.
- This product is intended for use by experienced ophthalmic surgeons who have received proper training on the use of the CataPulse® System.
- Instructions for Use (IfU) are not intended to substitute the need to read and understand the CataPulse Operator's Manual (200-1142).
- U.S. Federal law restricts sale and use to or on the order of a physician.

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Warnings:

- This product is not intended for purposes other than removal of the crystalline lens and cortical tissue removal.
- Do not use after the expiration date.
- Do not use if the Tyvek pouch (single sterile barrier) is damaged, compromised, or if the seal is broken in any way.
- Do not open the pouch until immediately before use.
- The CataPulse® Lens Removal & Irrigation Handpiece Set are sterile disposable medical devices and labeled as "Single-Use". The components have been designed for one time use only. Do not try and clean, re-sterilize, or reuse any components of the CataPulse® System that have been labeled as "Single-Use".
- Potential risks from using the devices beyond the expiration date, reprocessing, and /or reuse include: a) loss of instrument functionality potentially leading to loss of components in the eye, b) introduction of residues into the eye, c) cross-contamination / inadequate sterility of the instrument.
- Mismatch of consumable components not related to the CataPulse® System and the use of settings not specially adjusted for a particular combination of consumable components may cause patient injury due to fluidic imbalance.
- Never intentionally modify the handpiece or tips (e.g. Do not bend, cut, or engrave) as this could cause them to break or malfunction.
- Only use the Irrigation Set provided.
- The CataPulse® Console must remain above the patient's eye level to avoid fluidic imbalance and potential patient injury
- Do not manually modify or force a change in the CataPulse® Cart IV Pole height because this could cause incorrect indications of bottle height and subsequent patient injury due to fluidic imbalance.

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NOTICE:
Any serious incident that has occurred in relation to the CataPulse® System should be reported to MED-LOGICS and the competent authority of the Member State in which the user and/or patient is established.

Instruction For Use

1. Cover the CataPulse® Cart Arm or Medical Tray with the sterile cover.
2. Open the Lens Removal Handpiece Set and aseptically transfer to the surgical technician along with the cannulas to be used. The sterile clear terminal tray can be used to store the handpieces in the sterile field when they are not in use.
3. Find the strip of double sided tape on the bottom of the clear thermal tray and identify the one inch tab.
 - 3.1 Peel the protective cover off of the double sided tape and place the clear thermal tray in a convenient location on the sterile cover.
4. Install the sterile Screen Cover. This allows the surgical technician to utilize the features on the Consoles touchscreen under sterile conditions.
 - 4.1. Hold the two tabs of the Screen Cover and pull the tabs apart from each other.
 - 4.2. If necessary, lightly shake to unfold the Screen Cover. Slip the Screen Cover over the Console so that the narrow strip is behind the Console screen and the longer strip covers the screen.
5. Install the Irrigation Set.
 - 5.1. Carefully position the Irrigation Line so that each hand is holding an end of the six inch clear pinch tubing.
 - 5.2. Place the pinch tubing section in the pinch valve located above and behind the Cassette Receiver. This can be done by holding the six inch soft section of the Irrigation Set tubing and pulling it into the Console Pinch Valve until it is against the inner wall of the Pinch Valve.

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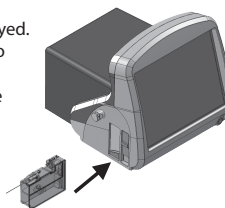
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- NOTE:** Make sure that the spiker is connected to the end that will be positioned out of the top of the pinch valve and the handpiece is connected to the end that will be positioned out of the bottom of the pinch valve.
- 5.3. The circulating nurse can now spike the irrigation bag/bottle with the irrigation line spiker.
 - 5.4. Hang the irrigation bag/bottle on the IV Pole.
- WARNING:** Do not manually modify or force a change in the CataPulse Cart Pole height because this could cause incorrect indication of bottle height and patient injury.
- 5.5 Repeat steps 1 - 5.4 for each new patient or eye.

Irrigation Flow Test:

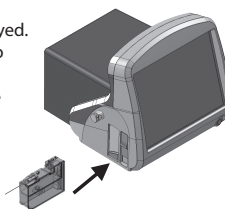
6. The BSS bottle/bag should be attached to the Irrigation Set with the Irrigation Set properly and securely placed in the Irrigation Pinch Valve.
 7. A sterile Irrigation Cannula can now be attached to the plastic Irrigation Handpiece.
 8. Insert the correct Lens Removal Handpiece Cassette and verify that the correct operating screen is displayed.
 9. If using the Cart, activate that the irrigation switch to the 'ON' position (Irrigation Section of the Screen) and verify that irrigation fluid flows out the tip of the cannula and that there are no leaks in the fluid path from the BSS bag/bottle to the tip of the irrigation cannula. If using a manual IV pole activate irrigation.
- NOTE:** Sterile BSS solution for this test can be drained into the sterile disposable tray for the Lens Removal Handpiece.
- a. If BSS does not flow out of the cannula or flows at a reduced rate, check for obstructions in the irrigation line.
 - b. If a leak is found in the irrigation line at one of the connections and cannot be corrected by pressing those connections together, discard the irrigation line and install another irrigation line
10. Place the cannula or cutter tip in the sterile BSS that was drained in the tray, or other containment vessel.



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- NOTE:** When testing the Lens Removal Handpiece Set, securely attach the intended cannula for operation. The handpiece does not need to be primed before testing or before use.
11. Press the linear pedal on the Footswitch and verify that fluid is being aspirated through the blue tube of the six foot twin bore tubing and is drained into the Cassette.
 - a. If the fluid is not aspirated or an obstruction in the fluid path is observed, discard the disposable set and install another.
 - b. If a leak is found in the disposable set at one of the connections or the containment vessel, and cannot be corrected by pressing those connections together, discard the disposable set and install another.

Procedure

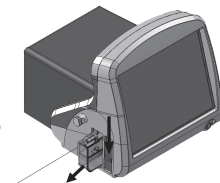
Refer to the CataPulse® Operator's Manual to understand the surgical approach and technique.

WARNING: The operator should be aware of and ensure sufficient volume of irrigation solution for and during the procedure.

After Use

1. Take off the Cortical Removal Cannula from the handpiece and carefully place any and all sharp items into the medical waste sharps bin.
2. Remove the Balanced Salt Solution bag/bottle from irrigation pole and turn right side up. Remove the spiker and carefully dispose of the Irrigation Set into a medical waste bin.
3. Eject cassette and carefully dispose of the Lens Removal Handpiece Set into a medical waste bin.

WARNING: The CataPulse® Handpiece Set and accessories are sterile disposable medical devices and labeled as "Single-Use". The components have been designed for one time use only. Do not try and clean, re-sterilize, or reuse any components of the CataPulse® System that have been labeled as "Single-Use".



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