MYNOSYS ZEPTO™ SYSTEM INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The Mynosys Zepto™ System is comprised of (1) a disposable Zepto™ Handpiece with integral power cord, tubing set, capsulotomy tip and attached Roller Dispenser, (2) the reusable Zepto™ Power Console (with integral power supply and controls), and (3) Zepto™ Fluid Isolator. The capsulotomy tip at the distal end of the Zepto™ Handpiece consists of a circular, collapsible, micro-molded silicone suction cup, approximately 1.18mm in height and 6.10mm in diameter. This silicone suction cup contains an embedded nitinol ring (approximately 4.4mm in diameter) cutting element to deliver highly focused capsulotomy energy. The disposable Zepto™ Handpiece is connected to the Zepto™ Power Console, which contains vacuum controls, electronic timing circuits, and safety diagnostics.

PHYSICAL OPERATING PRINCIPLES

The Mynosys Zepto™ cutting technology utilizes a very low mass, micro-fabricated nitinol cutting element, which is placed against the lens capsule that undergoes rapid heating and cooling on a microsecond time scale without significant heat propagation to surrounding tissues only microns away. Capsulotomy energy is efficiently transferred to water molecules immediately under the edge of the cutting element, converting them into microscale steam, that rapidly expands to mechanically cut the underlying lens capsule. Suction is provided by the Zepto™ Power Console to hold the silicone suction cup and cutting element in close contact with the anterior lens capsule. Microscale steam conversion occurs only in the sub-micron area adjacent to the cutting element and does not affect any other ocular tissues.

QUALIFIED OPERATOR PROFILE

Licensed Ophthalmic Surgeon with training for the Mynosys Zepto™ System.

Contact your Mynosys representative for training for the Mynosys Zepto™ System.

CONTENTS

REF	Contents
12684	One reusable Mynosys Zepto™ Power Console
Z1000	One disposable Zepto™ Handpiece
E1000	One disposable Zepto™ Fluid Isolator

INDICATIONS FOR USE

The Zepto™ System is indicated for use in performing anterior capsulotomy during cataract surgery.

CONTRAINDICATIONS

Contraindications for Zepto™ anterior capsulotomy include the following:

- Pediatrics (at this time)

Any contraindications to cataract surgery, including:

- Microphthalmos
- Buphthalmos

WARNINGS for disposable Zepto™ Handpiece:

- Contents sterile unless package is opened or damaged.
- The disposable Zepto™ Handpiece is single use only. Do not re-sterilize, autoclave or reuse. Discard opened unused product.
- Do not use past expiration date.
- Do not use in oxygen rich environment.
- Read the instructions for use completely prior to using the disposable Zepto™ Handpiece.
- Prior to use, inspect the packaging for any signs of damage or tampering. Use only devices that are packaged in unopened and undamaged containers. Discard and DO NOT USE damaged or previously opened devices.
- Never modify the Zepto™ Handpiece or tip.
- Moving the disposable Zepto™ Handpiece or patient movement while suction is applied to lens capsule may lead to patient injury or poor procedure outcome.
- Do not re-extend the push rod to remove the Zepto™ Handpiece from the eye, doing so may damage the Zepto™ Handpiece tip, or cause injury to the patient.
- Use a Thornton fixation ring during insertion and removal of the Zepto™ Handpiece tip from the eye, doing so will provide stability for ease of insertion and extraction.
- The tip of the Zepto™ Handpiece should not be touched by the operator as damage to the tip can occur.
- Zepto™ capsulotomy procedure may be completed with saline medium and with the use of cohesive or dispersive Ophthalmic Viscoelastic Devices (OVD). Note: OVDs with a zero shear viscosity exceeding 5,000,000 mPa-s may affect the effectiveness of suction and may cause an incomplete capsulotomy.
- If a Zepto™ Handpiece malfunctions creating a partial capsulotomy, remove from the eye and complete using manual capsulorhexis technique.
- If a Zepto™ Handpiece malfunctions during deployment, remove from the eye and use a second Zepto™ Handpiece or perform a manual capsulorhexis.
- If a malfunction occurs resulting in the suction cup being stuck to the eye, or if improper centration has occurred and the Zepto™ is in suction mode, do not attempt to relocate the device while suction is still present. In order to safely release the device from the eye, the emergency stop button must first be pushed in, which turns off the console and releases suction. The Roller Dispenser is then deployed to fully release the suction cup from the capsule of the eye, at which point the device can be safely removed from the eye. To reset the console, the emergency stop button must be pulled out to its reset position, and the power switch on the back of the console toggled OFF and then ON again. The Zepto™ Handpiece should not be reinserted into the eye, a new Handpiece must be used.

WARNINGS for disposable Zepto™ Fluid Isolator:

- The disposable Zepto™ Fluid Isolator is non-sterile.
- The disposable Zepto™ Fluid Isolator is single use only.
- Inspect the packaging prior to use for any signs of damage or tampering. Use only devices that are packaged in unopened and undamaged containers. Discard and DO NOT USE damaged or previously opened devices.

WARNINGS for Console:

- To avoid risk of electric shock, this equipment must only be connected to electrical supply mains with protective earth.
- This equipment complies with International Standard IEC 60601-1-2:2007 for ElectroMagnetic Compatibility (EMC) for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful electrical interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified below.
- The Zepto™ Power Console is not to be used within 8 inches of uncontained liquids.

PRECAUTIONS

- US Federal law restricts this Mynosys Zepto™ System to sale, distribution, or use by or on the order of a physician.
- It is the surgeon's responsibility to become familiar with appropriate surgical techniques prior to using the Mynosys Zepto™ System.
- Use caution to prevent entanglement and tripping over cables, cords and wires.

CLINICAL SUMMARY

Zepto™ was clinically evaluated in a prospective, single arm, multi-center study in which the study eye received a capsulotomy with the Zepto™. For subjects with bilateral cataracts the study eye selection was chosen randomly.

Primary Safety Endpoint: No posterior capsule rupture and vitreous loss in 100 eyes treated with Zepto™.

Primary Effectiveness Endpoint: Successful Zepto™ 360 degree capsulotomy in 98 of 100 subjects treated with Zepto™. Two eyes required manual capsulotomy, both with good visual outcome and IOL capsular fixation, and without adverse outcomes:

- 1 case was attributed to user error (simultaneous energy applied and suction release);
- 1 case with small tissue bridge observed after Zepto™ procedure was completed manually, attributed to suboptimal surgical microscope visualization, leading to application of Zepto™ energy before complete apposition of Zepto™ capsulotomy ring with the capsule was observed.

[Note: Zepto™ incomplete capsulotomy rate (per boundary of 95% confidence interval) approximates or is less than reported upper boundaries from 3 published studies for femtosecond laser capsule bridge rate.]

Additional Safety Parameters:

- **AC Tear:** 2 of 100 eyes treated with Zepto™ had anterior capsule tear, neither with vitreous loss:
    - 1 case noted at end of surgery with secondary PC tear extending during exchange of damaged IOL;
    - 1 case attributed to cataract chopping technique, did not extend to posterior capsule.

- **Corneal Touch:** No cases reported.
- **Adverse Events:** Epithelial erosion and macular edema, anterior capsule tear, anterior and posterior capsule tear without vitreous loss, IOP elevation, and ache in treated eye. Only 1 case (ac/pc tear) was noted to be device-related.

Additional Effectiveness Parameters:

- **Diameter and Circularity of Capsulotomy:** Mean anterior capsule diameter 5.14mm +/- S.D. 0.14mm (range 4.9-5.5mm). 99 cases recorded as circular without zonular damage.
- **Pre- and Post Zepto™ Corneal Incision Size:** Mean increase in incision size post-Zepto™ treatment 0.0305mm (range 0-0.2mm).
- **Ease of cortex removal:** 97/100 cases reported as similar or easier ease of cortex aspiration as compared to manual capsulorhexis.
- **Capsulotomy centration:** 96/100 reported as centered.
- **IOL centration:** 100% reported with IOL intracapsular fixation and centered.

Clinical Findings:

- Mean BCVA at 1 month was 20/20 (Snellen equivalent to ETDRS assessment).
- No capsular abnormalities reported.
- No clinically significant slit lamp exam findings reported.

Diameter of Anterior Capsulotomy:

- Mean diameter of Zepto™ capsulotomies = 5.14mm +/- S.D. 0.14mm (median = 5.2mm; range 4.9-5.5mm).

Minimum Incision Size

The minimum incision size required to accommodate the Zepto™ Handpiece tip is 2.2mm. The minimum incision size used during the clinical study was 2.4mm.

POSSIBLE ADVERSE EFFECTS

During cataract surgery, possible adverse effects associated with capsulotomy include the risk of capsulotomy decentration, incomplete or interrupted capsulotomy, capsular tears, and posterior capsule rupture.

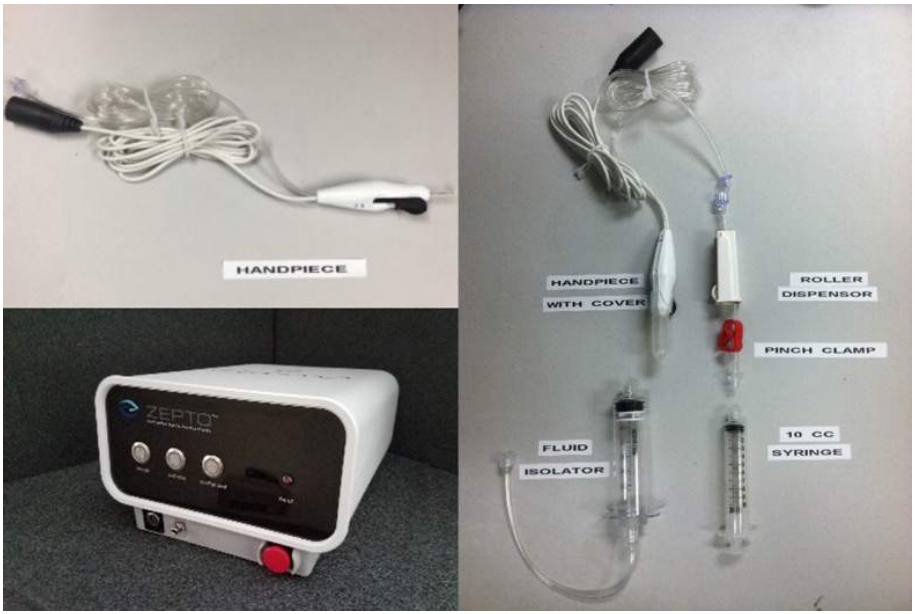


Figure 1: Mynosys Zepto™ System

Indicator Lights	
Status	Status light indicates the system status. Flashing green – Zepto™ Power Console is performing a self-check and a hand piece is not connected or is not operative. Solid green – Zepto™ System has successfully completed a self-check of the console and hand piece and the system is ready to initiate the procedure.
Fault	The red fault light indicates the system has detected a fault. To reset a fault, remove the disposable Zepto™ Handpiece, power off the Zepto™ Power Console using the rear mounted mains switch, and turn the switch back ON. Connect a new disposable Zepto™ Handpiece and the console will again perform the self-check.
Control Buttons	
Suction	Pressing the “Suction” button initiates suction between the suction cup and the lens capsule, in preparation for the capsulotomy. After pressing the “Suction” button, the “Suction” button illuminates blue, and flashes until minimum vacuum level is achieved.
Cut /Vacuum Release and manual fluid release step	Pressing the “Cut/Release” button initiates the capsulotomy. Following a momentary delay after capsulotomy, the suction is vented to atmosphere and ready for release. The “Cut/Release” button will illuminate blue after it is pressed.

Emergency Stop	Pushing this button “in” stops the Zepto™ Power Console sequence to allow the disposable Zepto™ Handpiece capsulotomy tip to be safely removed from the eye.
Handpiece Connections	
Handpiece fluid fill of the Suction line	Priming the Zepto™ Handpiece may be accomplished in two manners. The first is performed by connecting a 10cc syringe to the Roller Dispenser assembly, when the tip of the Handpiece is submerged in sterile BSS. The syringe plunger is withdrawn, thus filling the Handpiece suction line. Ensure that there are no air bubbles in the line. CLOSE the red pinch clamp, remove the syringe and connect the Zepto™ Fluid Isolator to the suction line. **CRITICAL: RE-OPEN** the red pinch clamp and the system is ready to use. After the capsulotomy is performed, the operating nurse will advance the roller of the Roller Dispenser in order to fully release the suction cup from the capsule bag. Alternatively the Zepto™ Handpiece may be primed with BSS from a phaco machine. In this method the Roller Dispenser (already attached to the tubing ot the Zepto™ Handpiece) is connected to a phaco line and BSS is advanced through the tubing to come out at the perforated cap of the Zepto™ Handpiece into a beaker. *refer to Method 1 and 2 below
Cable Connection	Connection for the Zepto™ Handpiece electrical cable connector. Connect the Handpiece to the circular connector on the front of the Zepto™ console. The connector is keyed and must be aligned with the positioning key. Push the connector in until it stops.
Rear Panel	
AC Appliance Coupler	Connection for the AC power cord. To isolate from AC supply mains, disconnect power cord from wall outlet.
On/Off Power Switch	Disengages or engages power to the Zepto™ Power Console.
Accessible Fuse	Two 250VAC 10A Fuse inside the Power Entry Module.

GENERAL

1. Pressing the Zepto™ Power Console buttons in sequence initiates each action for the procedure. The blue indicator light for each Zepto™ Power Console button illuminates after the button has been pressed.
2. Pressing the Red Emergency Stop Button on the front of the console stops the Zepto™ Power Console sequence and releases any suction. At this point the roller clamp on the dispenser can be rolled towards the Handpiece to fully release the suction cup from the capsule. After completing this action, the disposable Zepto™ Handpiece capsulotomy tip can be safely removed from the eye.
3. The red Fault indicator will light if the Zepto™ System detects a fault during self-check mode or during the procedure. If a fault is detected, the Zepto™ Power Console sequence is stopped, vacuum is automatically released and the roller on the dispenser can be rolled towards the Handpiece, thus completely releasing the suction cup. After completing this action the disposable Zepto™ Handpiece capsulotomy tip can be safely removed from the eye.

4. A fault condition can be cleared by powering off the Zepto™ Power Console using the rear mounted mains switch, and then turning the switch back ON. Connect a new disposable Zepto™ Handpiece and the console will perform the self-check.

PROCEDURE

1. **Patient Preparation**
   - 1.1. Obtain preoperative dilation per standard protocol.
   - 1.2. Obtain anaesthesia per standard protocol.
   - 1.3. Clean the subject's eyelids and ocular adnexa with disinfecting solution.
   - 1.4. Apply sterile drapes.
2. **Zepto™ System Setup**
   - 2.1. Ensure that the red 'Emergency Off' button is in the 'OUT' position.
   - 2.2. Plug the female end of the Zepto™ Power Cord into the rear of the Zepto™ Power Console, and then plug the male end of the power cord into a properly grounded electrical outlet.
   - 2.3. Make sure the area around the electrical outlet is clear and easily accessible, in case there is a need to unplug the Zepto™ Power Console from the outlet.
   - 2.4. Make sure that the electrical outlet that you use is not controlled by a light switch, and do not use an extension cord that has a switch. The Zepto™ Power Console must remain powered on at all times to work properly.
   - 2.5. Turn on power for the Zepto™ Power Console using the small switch located on the rear power entry module where the power cord plugs in. The Zepto™ Power Console will perform a self-check. A successful Zepto™ Power Console self-check will result in a flashing green Status light.
3. **Priming Zepto™ by Method 1 with 10cc Syringe – for proper function the Zepto™ Handpiece and tubing must be filled with BSS**
   - 3.1. First, the Non-sterile circulator opens the Fluid Isolator package. This package is for non-sterile personnel use only.
   - 3.2. The non-sterile person then connects the Fluid Isolator to the stainless steel luer lock connector at the front of the Zepto™ Power Console and places it on the top of the Power Console in a ready position.
   - 3.3. Next, the sterile nurse/tech removes the Zepto™ Handpiece with attached Roller Dispenser - red pinch clamp from its pouch in a sterile manner. They then pass the Black-ended electrical cord and roller assembly tubing from the sterile field to the non-sterile person. The non-sterile person now connects the Zepto™ Handpiece five prong black electrical cable connector to the circular recoupling on the front lower left of the Zepto™ Power Console. The connector is keyed and must be aligned with the Black-ended cord, with the visible positioning arrow facing up Push the connector in until it stops. After the Zepto™ Handpiece electrical cable is successfully connected to the Power Console, the flashing light will convert to a constant ON green light, indicating the system is ready.
   - 3.4. The non-sterile person then attaches a 10cc (or greater) syringe to the clear tubing end of the Roller Dispenser (this is the side with the red clamp), **ensuring the red clamp is open**.
   - 3.5. Next, with the protective cap still in place, the sterile person submerges the tip of the Zepto™ Handpiece (no more than ¾ of the way up the protective cap) in a sterile beaker containing BSS. The nonsterile person then draws the syringe plunger back filling the handpiece suction line

with BSS. Ensure that there are no air bubbles in the line as air bubble can impede the creation of capsulotomy. If air bubbles are present, the non-sterile person should clamp shut the red pinch clamp, empty the syringe of BSS, reattach – open the red clamp and repeat filling the vacuum line. Once filled, close the red pinch clamp, remove the 10cc syringe and connect the Zepto™ Fluid Isolator to the suction line. Note: be sure to **UNCLAMP** the red pinch clamp after filling the line with BSS. The system is ready to use.

4. **Priming Zepto™ by Method 2 from a Phaco Machine**
   - 4.1. As in the syringe fill method the non-sterile person opens the Fluid Isolator package, attaches the Fluid Isolator to the Power Console and places the Fluid Isolator on top of the Zepto™ Power Console in a ready position.
   - 4.2. Similarly the non-sterile person presents to the scrub nurse, using sterile technique, the pack containing the sterile Zepto™ Handpiece with attached Roller Dispenser. The sterile person then places the Black-ended electrical cord on the sterile table for later use and attaches the Roller Dispenser free tubing end to the BSS fill line of the phaco machine. The sterile person pushes the appropriate screen button on the phaco machine to initiate the flow of BSS through the Zepto™ Handpiece tubing and watches for BSS to emerge from the perforated cap of the Zepto™ Handpiece into a catch beaker.
   - 4.3. When BSS is freely flowing from the Zepto™ Handpiece perforated cap, the sterile person pushes the off button on the phaco fill line, closes the red pinch clamp to close the tubing and disconnects the fill line (returning the fill line to original position). **CRITICAL**: the red clamp must be reopened on the Roller Dispenser. The system is now, as in Method 1 Syringe Priming, ready to use.
   - 4.4. The sterile person now picks up the Black-ended electrical cord and passes it, along with the clamped Roller Dispenser tubing out of the sterile field to the non-sterile person. The circulator now connects the clamped Roller Dispenser to the Fluid Isolator which has been in a ready position. The black electrical connector is coupled to the five prong connector as before, located on the lower left of the Power Console. The green indicator light now glows a steady green.

5. **Surgical Procedure**
   - 5.1. Create a clear corneal incision of 2.2mm or greater.
   - 5.2. Use an Ophthalmic Viscosurgical Device to stabilize the anterior chamber.
   - 5.3. The surgeon or sterile nurse gently removes the protective tip cover off the end of the disposable Zepto™ Handpiece, being careful not to hit the Zepto™ tip.
   - 5.4. The surgeon examines the Zepto™ to ensure there are no defects (such as push rod is not attached to the nitinol ring). If any defects are noted the Zepto™ should not be utilized for surgery. Save the defective unit and return it to Mynosys for no charge replacement.
   - 5.5. Firmly slide the finger slider distally (forward) on the disposable Zepto™ Handpiece until it fully stops in order to elongate the Zepto™ capsulotomy tip for insertion into the corneal incision (Do not pull back on the finger slider until the Zepto™ capsulotomy tip has been inserted completely into the anterior chamber).

5.6. Stabilize the eye with a Thornton fixation ring, and insert the Zepto™ capsulotomy tip through the corneal incision.

5.7. Once the Zepto™ capsulotomy tip is fully within the anterior chamber, slide the finger slider proximally to return the capsulotomy tip to a circular state. The surgeon should ensure the pushrod is now located just “outside” the nitinol ring. This area provides the best stability for Zepto™ for apposition to the anterior capsule.

5.8. Using the surgical microscope, position the Zepto™ capsulotomy suction cup tip on the capsular bag. It is recommended to center the transparent device tip on the 1st Purkinje image. Instruct and encourage the patient to look at the microscope light. This will anchor the Zepto™ created capsulotomy, customizing it to the visual axis of the patient.

5.9. Once the surgeon determines Zepto™ is centered, stop, no further motion should occur. A steady hand is needed. The surgeon now states “Suction” to verbally instruct the assistant to press the “Suction” button on the console. The assistant repeats back “Suction” to confirm the suction button has been pressed. **CRITICAL:** as the surgeon states suction – they must simultaneously pull the push rod “back” out of the narrow lumen of the Zepto™. Failure to do so may result in an incomplete capsulotomy as full suction may not be obtained with the push rod blocking the lumen. The suction button now blinks blue. When maximum suction is reached the button will remain solid blue confirming the suction cup and nitinol ring apposition onto the lens capsule. The assistant should state “Maximum Suction”.

5.10. **CRITICAL:** The surgeon should now visually confirm the flow of OVD. Monitor the movement of bubbles in the OVD. When the OVD ceases to flow, full suction has been achieved. Bubbles **must** be observed. If bubbles are not seen do not proceed to capsulotomy. Engage the red button (stopping suction) and advance the roller clamp (to break any remaining suction). Remove the Zepto™ device and replace with a new one. Save and return the first Zepto™ device in a sterile manner to Mynosys for replacement.

5.11. With the stopping of the bubble flow the surgeon now states “Energy” to verbally instruct the assistant to press the blinking blue “Cut/Release” button on the console. The assistant repeats back “Energy” to confirm the Cut/Release button has been pressed. Once capsulotomy energy is delivered, the capsulotomy is created and the suction is automatically vented to atmosphere.

5.12. **CRITICAL:** Prior to removal of the Zepto™ device from the eye, the physician must instruct the assistant to advance the roller clamp forward a full stroke thus releasing approximately 0.2 ml of pre-loaded BSS into the suction cup. This motion gently releases the suction cup from the capsule. The surgeon states “Release” to verbally instruct the assistant to slide the “roller” of the Roller Dispenser forward in order to fully release the suction cup from the capsule bag. The assistant states back “Release” to confirm this has been done.

5.13. Stabilizing the eye with a Thornton fixation ring, the surgeon removes the Zepto™ Handpiece capsulotomy tip from the anterior chamber by manually withdrawing it through the corneal incision. The Zepto™ capsulotomy tip automatically folds and conforms to the incision as it is withdrawn from the eye.

5.14. The excised capsule “button” (circular piece of capsule tissue that has been cut) from the capsulotomy will either be free-floating within the anterior chamber (can be retrieved by forceps), attached to the suction cup, or flushed from the eye.

5.15. In the event of an incomplete capsulotomy with remaining tissue bridges, use the manual Continuous Curvilinear Capsulorhexis technique to complete the capsulotomy.

STERILITY

Mynosys disposable Zepto™ Handpiece is sterilized using ethylene oxide.

CLEANING AND MAINTENANCE

Clean the Mynosys Zepto™ Power Console with an EPA approved alcohol based disinfectant using a soft cloth. Do not use chemical or scouring agents.

If the Mynosys Zepto™ Power Console requires maintenance, contact Mynosys or your local distributor.

DISPOSAL OF CONSOLE

The symbol on the product or its packaging signifies that this product has to be disposed separately from ordinary household wastes at its end of life. Please kindly be aware that it is your responsibility to dispose of electronic equipment at recycling centers to help conserve natural resources. Each country in the European Union has its collection centers for electrical and electronic equipment recycling. For information about your recycling drop off point, please contact your local electrical and electronic equipment waste management authority or the retailer where you bought the product.

DISPOSAL OF HANDPIECE, FLUID ISOLATOR

Used Zepto™ Handpiece and Fluid Isolator should be considered as contaminated devices and must be disposed of in accordance with regulations for disposal of medical waste.

STORE AT ROOM TEMPERATURE

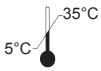
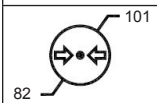
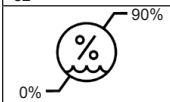
Caution: Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

Manufacturer
Mynosys Cellular Devices, Inc.
46710 Fremont Blvd
Fremont, CA 94538

EC REP EU Representative
MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany
+49 511 6262 8630

SYMBOLS

Symbols for Mynosys Zepto™ System	
	Manufacturer
	Manufacture Date
	Consult instructions for use
Rx Only	US Federal law restricts this device to sale by or on the order of a physician
	Caution
REF	Catalog number
	Keep dry
RoHS	Compliant to Restriction of Hazardous Substances
CE 0044	CE Marking on a product is a manufacturer‘s declaration that the product complies with the essential requirements of the Medical Device Directive
Symbols for Mynosys disposable Zepto™ Handpiece	
	Single use only
LOT	Lot number
STERILE EO	Sterilized by ethylene oxide
EC REP	European Representative
	Use By Date

	Do not re-sterilize
	Do not use if package is damaged
	BF symbol – Type BF equipment
Symbols for Mynosys Zepto™ Power Console	
	Operating Temperature limit
	Operating Pressure limits, kPa absolute
	Operating Relative Humidity limits
	Indoor use only
	Fuse
	Ground connection
	Dangerous voltage
	Serial number
	Direct current
	Alternating Current
	Dispose of Electrical Waste Properly
IPX1	Ingress Protection Rating

SPECIFICATIONS

- The Zepto™ Power Console complies with medical device standards EN 60601-1, EN 60601-1-2.
- The Zepto™ Power Console also complies with FCC part 15.
- Mode of operation: Continuous.
- Use only the power cord provided with the Zepto™ Power Console.
- Input: 100-240 volts AC, 200W, 50-60Hz, 1.66 amps.
- Output: 200 Volts DC, 1.4 Joules maximum
- Protection against electric shock: Class I.
- Accessible Fuse - 2 - 250VAC 10A Fast Acting Fuse (100% rating: 4 hrs. break time, 135% rating: 1 hr. break time, 200% rating: 5 sec. break time).
- Operating temperature: 5°C to 35°C.
- Operating relative humidity: less than 90% RH without condensation.
- The Zepto™ Power Console is designed for indoor use only.
- Storage and operating altitude: 0 feet to 6,000 feet (0m to 1,828m).
- Storage and operating pressures: 11.9psia to 14.7psia (82 to 101kPa absolute).
- Transportation and Storage Maximum 50°C 95% humidity, non-condensing.

APPLIED PARTS

- Mynosys Zepto™ Handpiece is an applied part. The materials that contact the patient are silicone, stainless steel and nitinol.

Manufacturer's Declaration

Table 1 - Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Zepto™ Power Console is intended for use in the electromagnetic environment specified below. The customer or the user of the Zepto™ Power Console should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Zepto™ Power Console must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected when the unit is energized.
RF emissions CISPR 11	Class B	The Zepto™ Power Console is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	The Zepto™ Power Console is suitable for use in all establishments, including domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Table 2 - Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Zepto™ Power Console is intended for use in the electromagnetic environment specified below. The customer or the user of the Zepto™ Power Console should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains ± 1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV Differential ± 2 kV Common	± 1 kV Differential ± 2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Zepto™ Power Console requires continued operation during power mains interruptions, it is recommended that the Zepto™ Power Console be powered from an uninterruptible power supply or a battery.
Power frequency (60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3 - Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Zepto™ Power Console is intended for use in the electromagnetic environment specified below. The customer or the user of the Zepto™ Power Console should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
			Portable and mobile RF communications equipment should be separated from the Zepto™ Power Console by no less than the distances calculated/listed below.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	(V1) = 3 Vrms	D=(3.5/V1)(Sqrt P) 150kHz to 80MHz
			D=(3.5/E1)(Sqrt P) 80 to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	(E1) = 3 V/m	D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz
			where P is the max power in watts and D is the recommended separation distance in meters.
			Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).
			Interference may occur in the vicinity of equipment containing a transmitter.

Table 4 - Recommended separation distances between portable and mobile RF communications equipment and the Zepto™ Power Console

The Zepto™ Power Console is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Zepto™ Power Console can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Zepto™ Power Console as recommended below, according to the maximum output power of the communications equipment.

Maximum Output Power W	**Separation (m) 150 kHz to 80 MHz** *D* = (3.5/V1)(Sqrt P)	**Separation (m) 80 MHz to 800 MHz** *D* = (3.5/E1)(Sqrt P)	**Separation (m) 800 MHz to 2.5 GHz** *D* = (7/E1)(Sqrt P)
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

CE 0044

For the English version of the manual, please go to
http://www.mynosys.com

Si desea ver la versión en español del manual, visite
https://www.mynosys.com

Die deutsche Version der Anleitung finden Sie auf
https://www.mynosys.com

Pour consulter la version française du manuel, se rendre sur le site
https://www.mynosys.com

Per la versione italiana del manuale, visitare
https://www.mynosys.com

Ga voor de Nederlandstalige versie van de handleiding naar
https://www.mynosys.com

Českou jazykovou verzi příručky naleznete na webu
https://www.mynosys.com

Slovenskú verziu príručky nájdete na adrese
https://www.mynosys.com

Kılavuzun İngilizce sürümü için lütfen
http://www.mynosys.com adresine gidin