

Intraocular Magnet

DEVICE DESCRIPTION

Intraocular Magnet comes in a stainless-steel body with very strong rare earth magnets along with set of 5 easily changeable tips: 4 Posterior Segment tips - 16G, 18G, 20G & 23G and 1 Anterior Segment tip. It comes packed in a sterilization tray with silicon mat.

INTENDED USE

This is an ophthalmic device used for atraumatic removal of magnetic foreign bodies.

CONTRAINDICATIONS

Not Known.

HOW SUPPLIED

Intraocular Magnet is supplied unsterile, packed in a sterilization tray with silicon mat. The overall packing contains Intraocular Magnet, Set of 5 changeable tips (4 Posterior Segment tips - 16G, 18G, 20G & 23G and 1 Anterior Segment tip) and IFU with external identification stickers.

CAUTIONS

For External use only.

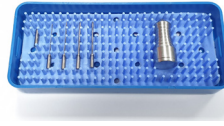
WARNING

- Read all instructions before use.
- This device is supplied in a non-sterile state and must be cleaned, disinfected and sterilized before first use and any subsequent use.
- Proper cleaning and disinfection steps need to be followed to ensure that the sterilization steps are effective.
- Using mechanical processes such as pre-cleaning and ultrasonic cleaning greatly increases the effectiveness of the cleaning process.
- For effective reprocessing, the pre-treatment should begin as soon as the surgery has been completed but not more than 30 minutes after the surgery.
- The complete cleaning process must take place within the next two (2) hours of completing the pre-cleaning.
- Follow instructions and warning as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used.
- Wherever possible avoid the use of abrasive materials for cleaning and drying.
- Incorrect handling and care or misuse can lead to premature wear of these devices.
- Inspect these devices carefully for damage, cracks or malfunctions before each use.
- Do not use damaged devices.
- Use only approved disinfectant solutions (e.g., FDA, DGHM, CE Mark).
- Ensure cleaning and disinfection solutions fully contact all device surfaces and lumens.
- Store devices in a cleaned, disinfected and dry state.
- Do not soak in Acetone or other Solvents.
- Automated cleaning is not recommended.

PRE-CLEANING STEPS

- Remove the tip from magnet handle after use.
- All components that have been used must be submerged into cold, deionized water (<40 Degree Celsius) immediately after use for removing large soiling.
- All surfaces must be cleaned with a soft bristle toothbrush to remove macroscopic contaminants. Special attention is required for uneven surfaces (such as knurled handles) to remove all macroscopic contaminants.
- Scrub the inside and outside of the device with a soft bristled nylon brush until all visible soil is removed.
- DO NOT use a fixating detergent or hot water (>40 Degree Celsius), this may cause fixation of the residue on the device causing the reprocessing steps to fail. A fixating detergent contains aldehyde solution that may cause fixation of the blood contaminants on the device.
- Soak the components in an enzymatic detergent with a pH level between 6-9 for 10 minutes at 40 Degree Celsius
- The components must be rinsed with distilled or deionized water at least 3 times.

- For all hollow parts and tubes (example: silicon tubes), use a disposable syringe (50ml or more) and rinse in normal direction of flow at least 3 times with distilled or deionized water.



ULTRASONIC CLEANING

Some devices may be heavily soiled during a surgery and require additional pre-cleaning using an ultrasonic bath. When ultrasonic cleaning is done, care must be taken that the exposure time and concentrations recommended by the manufacturers of the cleaning solution are observed, and cleaning and disinfection agents are compatible with components of the intraocular magnet.

- The devices must be placed on a silicone mat in the ultrasonic cleaner. DO NOT place devices in contact with any metal surface on the ultrasonic cleaner.
- To reduce or avoid endotoxin contamination, it is recommended to change the cleaning solution from the ultrasound cleaner after each and every use.
- If more than one device is being placed in the ultrasonic cleaner, ensure that none of the devices have any large areas of corrosion (rusted, flaky, or deep stained) before placing in the cleaner.
- When using an enzymatic detergent, care must be taken to submerge the device completely in the cleaning solution.
- Turn on the ultrasonic bath (38 KHz) for 10 minutes.
- After the ultrasonic treatment, scrub the inside and outside of the device with a suitable soft bristled nylon brush until all visible soil is removed.
- Flush the internal channels and the outside with distilled or deionized water to remove the cleaning detergent. A free flow of water through the device is required.
- Ensure that the ultrasonic bath is not contaminated before use. Contamination can increase the risk of corrosion and impairs the effective cleaning process. Criteria for contamination – visibly observe the water in the bath for contaminations, dirt, debris, or other coloration of the water. If contamination is observed, the water bath must be replaced with new distilled or deionised water.

DISINFECTION

- Disinfectant Solutions (e.g., approved by FDA, CE mark etc) may be used in accordance with label instructions of the disinfectant manufacturer. Special attention needs to be paid to disinfectant manufacturers recommended concentrations and contact durations. Ensure that disinfectant solution makes complete contact with all device surface and lumens.
- To avoid damage to the device, do not exceed recommended exposure time.
- After manual disinfection, soak and rinse in cool water for 1 min and thoroughly flush lumens. Repeat this procedure 3 times with fresh rinse water to ensure complete removal of the disinfectant solution.
- Dry the device carefully with lint free tissue or hospital grade compressed air and place it in a dry storage box.
- After the cycle is finished, the device needs to be inspected for any damage, cracks or malfunctions.

STERILIZATION

- Make sure that the devices have been cleaned and inspected before sterilization.
- Verify that the sterilizer is functioning properly on a regular basis.
- Make sure that preventive maintenance, cleaning and inspection of the sterilizer is performed on a scheduled basis, according to the manufacturer's instructions.
 - By EO (Ethylene Oxide): Kindly follow EO sterilizer manufacturer's instructions and settings for sterilization of the components. It is

recommended to pack and seal the clean and disinfected device in medical grade peel open pouches before EO sterilization.

Caution: Label the pouch with date of sterilization as per your SOP for labelling & handling in house sterilized devices.

- By Steam autoclaving: It is recommended that devices are sterilized using steam autoclaving procedure that is regularly used in hospitals and surgery center. The following table provides the suggested cycles based on recommended practices-

Steam Sterilization Cycle	Preparation	Exposure Time (Minimum Time)	Temperature	Drying Time (Minimum Time)
Gravity Displacement	Wrapped	15 Minutes	132° C /270° F	20 Minutes
Pre-Vacuum	Wrapped	4 Minutes	132° C /270° F	20 Minutes
Pre-Vacuum	Wrapped	3 Minutes	134° C /273° F	20 Minutes
Flash/ Immediate Use	Unwrapped	3 Minutes	132° C /270° F	N.A.

Note: Consult the manufacturer of your steam autoclave to confirm appropriate temperature and sterilization times. Other methods, times, and temperatures may also be used, but after validation of those methods.

PRECAUTION

- When handling the product, care should be taken to avoid damage from handling. Avoid crushing and crimping damage to the product due to application of surgical instruments.

DIRECTION FOR USE

- Open the unsterile device for sterilization before use (First time) in a controlled environment.
- Properly clean and sterilize the unsterile device.
- After sterilization, choose a tip on the basis of your application and



EXPLICATION OF SYMBOL:

Symbol	Meaning
	Caution
	Manufacturer
	Date of Manufacture
	Keep away from sunlight
	Consult Instructions for use
	Re-use
	This side up
	Do not use hook

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insert it into the Intraocular Magnet handle as shown in the image.

- Proceed with the intended surgical procedure.
- After the use, remove the tip from the Intraocular Magnet handle by holding it from the slot provided and keep it aside.
- It is recommended to keep the tips aside from the magnet handle as they tend to magnetize if kept together for a longer period of time.
- It is strongly recommended to sterilize the device after each use. Using an unsterile device may cause serious infection or other problems to the patient due to bio contaminants present on the device from the previous surgery.

RETURN OF DAMAGED PRODUCT

Return the product in its original packing identified by the batch number, purchase information, your reference and reason for return. Please contact your local distributor office regarding product return/exchange.

REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as product related and that were not previously expected in nature, severity or incidence must be report to Madhu Instruments Pvt. Ltd.

DISPOSAL OF THE USED DEVICE

The used device should be disposed off in compliance with the local regulatory requirements.

REUSE OF DEVICE

The device should undergo a detailed multi step process of cleaning and sterilization before reuse.

Symbol	Meaning
	Batch Code
	Temperature Limit
	Do not use if package is damaged
	Humidity Limitation
	Handle with care
	Maximum stacking
	Medical Device
	Non-Sterile
	Catalogue Number