



rinsada™

EN - English

Instructions for Use - rinsada™



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.



WARNING: rinsada™ is supplied sterile for single use, should be used straight from the pack and should be discarded after use. It must not be reused. One device per eye. Reuse may cause cross infection and reduce product reliability and functionality.



WARNING: Re-processing of rinsada™ intended for single use only may result in degraded performance or loss of functionality. Re-use of single use only products may result in exposure to viral, bacterial, fungal, or prionic pathogens. Validated cleaning and sterilization methods and instructions for reprocessing to original specifications are not available for this product. rinsada™ is not designed to be cleaned, disinfected, or re-sterilized.



WARNING: Read all Instructions for Use warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.

DEVICE DESCRIPTION

rinsada™ is an innovative, single use eye irrigation device. rinsada™ provides access to the palpebral and bulbar conjunctiva and conjunctival fornix for irrigation. The anatomically shaped eyelid retractor has a proximal luer lock and distal retracting lip which matches the curvature of the eyelid. The distal lip houses five ports which allow fluid to hit the palpebral conjunctiva, bulbar conjunctiva and conjunctival fornix. The proximal luer lock can be attached to a syringe of up to 15mL of fluid. As the plunger of a syringe is depressed, fluid escapes out of ports of the retracting lip. rinsada™ provides easy insertion underneath the eyelid without the need for patient cooperation. It provides a complete rinse of the ocular surface. rinsada™ is made primarily of medical grade acrylonitrile butadiene styrene (ABS) and is supplied sterile for single use only; one device per eye. It is terminally sterilized by radiation. All components are not made with natural rubber latex.

INDICATIONS FOR USE

rinsada™ is indicated for use in removal of irritants from the ocular surface. It may be used to quickly, efficiently and thoroughly rinse the ocular surface from foreign irritants or inflammation

RISK-BENEFIT INFORMATION

The benefits of irrigating with rinsada™ must be weighed against the potential risk of temporary foreign body sensation of the eye, potential blepharoptosis from repeated eyelid retraction with levator aponeurosis, conjunctival abrasions and wetting of the periocular skin.

CONTRAINDICATIONS

- Patients who have eyelid defects.
- Patients with recent eyelid surgery. Patients with a tarsorrhaphy.
- Patients with active filtering conjunctival blebs or glaucoma draining devices proceed with caution.
- Patients with recent intraocular surgery including but not limited to LASIK or LASEK.



WARNINGS

- Care should be taken in placement and removal of the device underneath the eyelid to avoid a corneal abrasion.
- The presence of a filtering bleb, glaucoma draining device, or scleral buckle is not an absolute contraindication, however special care should be taken to confirm that the device does not cause trauma to these parts. It is recommended to stain any bleb for a leak prior to rinsing with the device.
- rinsada™ may be ineffective with a single use to remove all irritants from the ocular surface and to restore pH balance of the tear film in a chemical splash injury, clinical examination and diagnostics will be warranted.
- Do not use this device if there is any lack of flow through any of the five ports.
- There is a theoretical risk of causing corneal edema or subconjunctival hemorrhage if the device is used improperly.
- Do not use rinsada™ if the device is damaged or the unit packaging is damaged or opened.
- Never over torque the device onto a syringe which can damage the device.
- It is most important that pre-use checks are carried out on the device prior to use, in order to establish whether it is safe for use. Failure of any one test indicates the device should not be used.
- Use of a sterile, preservative free eye wash solution is of importance to prevent infection. Never use tap water as this may result in an infection and vision loss.

INSTRUCTIONS

Note: Application of a topical anesthetic prior to use is preferred but not an absolute.

1. Obtain an unopened, sterile device from the box. Confirm there is no damage to the packaging.
2. Fill a luer locking syringe with sterile, preservative free, eye wash solution.
3. Open the packaging, and insert the syringe into the proximal end of rinsada™
4. Twist the syringe onto the device, depress the plunger and confirm that fluid is flowing from all 5 ports
5. To insert under the upper eyelid, first have the patient look down, manually retract the eyelid with the non-dominant hand, insert the device underneath the upper eyelid and release the eyelid with the non-dominant hand
6. Begin by depressing the plunger of the syringe and moving the device horizontally along the eyelid margin.
7. When finished, remove the device by again having the patient look down, manually retracting the upper eyelid and removing the device.
8. To insert under the lower eyelid, repeat steps 6.4-6.7 however have the patient look up during insertion and removal.
9. Dispose rinsada™ in proper biohazard waste receptacle.

INSTRUCTIONS ON ACCESSORIES

Both syringe and eyewash solution should be sterile and untampered. Please refer to their instructions for use for further information.

ADVERSE EFFECTS

There are adverse reactions associated with the use of rinsada™. Potential side effects may include temporary blurred vision, eye redness, temporary eye irritation, wetting of the periocular skin, and may have fluid enter the nasal cavity and sinuses. Theoretically, more serious adverse reactions may include corneal abrasion, corneal edema, LASIK flap dehiscence, blepharoptosis, bleb leak and conjunctival device extravasation.

DISPOSAL

Dispose of rinsada™ along with solid biohazard waste.

WARRANTY

rinsada™ is designed for a single use and warranted against manufacturing defects at the time of delivery. Warranty is applicable only if purchased from an authorized distributor.

DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.



Manufactured for
rinsada
PO Box 234
Wildwood, PA 15091

WARNING SYMBOLS

R_x Only

Prescription device

STERILE R

Sterilized using irradiation mode



Do not re-use



Do not use if package is open or damaged