

# Balanced Salt Solution

EN

Product Information

## COMPOSITION:

100 ml solution contains:	
Calcium Chloride x 2H <sub>2</sub> O	0.048 g
Magnesium Chloride x 6H <sub>2</sub> O	0.030 g
Sodium Acetate x 3H <sub>2</sub> O	0.390 g
Sodium Citrate x 2H <sub>2</sub> O	0.170 g
Sodium Chloride	0.640 g
Potassium Chloride	0.075 g

Water for injection sufficient to produce 100 ml  
Hydrochloric acid 10% (for pH adjustment)

## DESCRIPTION:

Balanced Salt Solution (BSS) is a sterile isotonic solution, used as an extraocular and/or intraocular irrigating solution during ocular surgical procedures/interventions that require eye irrigation.

## INDICATIONS:

Balanced Salt Solution (BSS) is indicated:

- for rinsing the anterior chamber of the eye during cataract and other intraocular surgery
- for rinsing out  $\alpha$ -Chymotrypsin from the anterior chamber of the eye after enzymatic zonulolysis
- for intraoperative rinsing in the anterior chamber in cases of bleeding
- for rinsing the conjunctiva after fluorescein instillation
- for rinsing the cornea during squint operations and other extraocular surgeries
- for rinsing the nasolacrimal ducts in cases of corrosive or burn injury
- for maintaining the moisture of the conjunctiva and cornea during laser treatment and
- for the irrigation the surface of the eyeball and for rinsing surgical instruments or rinsing/soaking intraocular lenses

**INTENDED USE:** Balanced Salt Solution (BSS) is a sterile isotonic solution that is used as an extraocular and/or intraocular irrigating solution during ocular surgical procedures/interventions that require eye irrigation. It is also used for rinsing surgical instruments and for rinsing/soaking intraocular lenses.

**INTENDED USERS:** Balanced Salt Solution (BSS) is intended to be used by healthcare professionals (surgeons performing ocular interventions and/or any medically trained person assisting with ocular interventions, that require eye irrigation).

**PATIENT POPULATION:** There are no restrictions in the use of Balanced Salt Solution (BSS) regarding patient population or type of intraocular surgery. BSS is used in patients of any age and gender who are eligible for cataract or any other type of intraocular surgery.

## INTENDED CLINICAL BENEFITS:

- Reduction of the risk of ocular tissue damage by minimizing the effects of intraocular surgery on corneal endothelium.
- Less corneal thickness and inflammation on the first postoperative day.
- Achievement of clear cornea on day 1 with immediate visual rehabilitation.
- Corneal transparency during ocular surgery.
- Improved visualization during surgery to help the ocular surgeon.
- Safer ocular procedures

## METHOD OF USE AND DOSAGE:

A vented administration set should be used since the bottle has no separate means of ventilation (follow the instructions for use of the relevant administration set). A syringe can also be used for aspiration/ irrigation. Fit the administration set or syringe as follows (under aseptic conditions)

1. Remove the plastic ring and disinfect the insertion points with an alcohol coated swab.
2. Push the point of the administration set/syringe straight away through the point of seal (no twist).
3. The administration set/syringe should be primed prior to surgery in order to avoid air bubbles entering the eye

## CONTRAINDICATIONS:

There are no known contraindications for the use of Balanced Salt Solution.

## ADVERSE REACTIONS:

Inflammatory reactions and incidents of corneal swelling and/or clouding have been reported post operatively. Their relationship to BSS use has not been established.

## PRECAUTIONS

- Open under aseptic conditions only.
- Do not freeze.

BSS should be left in room temperature before use.

Studies suggest that intraocular irrigating solutions which are isosmotic with normal aqueous fluids should be used with caution in diabetic patients undergoing vitrectomy since intraoperative lens changes have been observed. BSS should be used with caution and in less quantity in patients with exfoliation syndrome undergoing phacoemulsification, since intraoperative lens dislocation may occur with excessive BSS. As a rule, there is no risk from an overdose.

## WARNINGS:

BSS should not be used for injection or intravenous infusion.

BSS should not be used unless the container and seal are intact, solution is clear and free from visible particles.

BSS should not be used if product is discolored or contains a precipitate.

The content of each bottle should not be used in more than one patient. BSS contains no preservatives and unused content should be discarded.

Do not use after the expiry date stated on the label (shelf life 2 years).

The insertion points on the rubber seal are only designed to be pierced once.

## DISPOSAL:

Dispose according to national and local regulations.

## NOTICE:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the Competent Authority.

				
Consult instructions for use	Medical Device	Do not use if packaging is damaged	Batch number	Distributor
				
Use-by date	Do not re-use	Temperature limit	Sterilized using steam or dry heat	Date of manufacture
				
Low Density Polyethylene	Single sterile barrier system	Manufacturer	Unique device identifier	

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