

Instructions for use for:



*Sharp safe Intravitreal injection needle*



*English*

*Instructions for use for:  
SP.eye™ Sharp safe Intravitreal injection system*

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## I. Indications for use

SP.eye™ is intended for use as an aid for intravitreal injection with provision for sharps safety. It may be used for any medication licensed for trans pars plana injection into the eye using a 30 gauge needle.

## II. Contraindications

**DO NOT** use SP.eye™ in situations where injection at 4mm from the limbus is not safe

This may be (but is not limited to) the case in:

Short eyes

Paediatric eyes

**DO NOT** use SP.eye™ on areas of the eye where a trans-scleral injection would not be suitable

This may be (but is not limited to) the case in:

Areas of scleromalacia or scleral thinning

Conjunctivitis, Scleritis or other inflammatory or infective disease

## III. Package handling

This device should be stored and transported in a normal environment i.e away from extreme temperatures and humidity.

Store in a cool, dark, dry place

**WARNING:** Do not use if the sterile barrier is damaged and/or deteriorated and/or visibly compromised.

## IV. Technical information

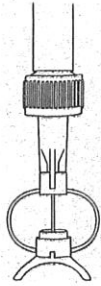
These devices are single use only. Do not reuse, re-sterilise or reprocess. Reuse, re-sterilisation or reprocessing may compromise the integrity of the device and/or lead to failure, which may lead to patient injury.

## V. Possible complications of any intravitreal injection

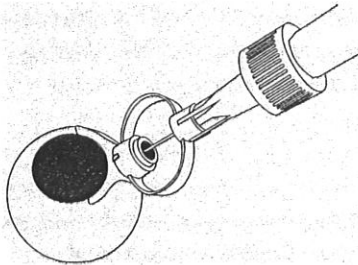
Complications which may occur with any intravitreal injection include (but are not limited to) damage to intraocular structures including the crystalline lens, retina and ciliary body which may result in temporary or permanent loss of vision, intraocular infection which may result in temporary or permanent loss of vision, vitreous haemorrhage, pain or discomfort, subconjunctival haemorrhage, scleromalacia, infection between patient and clinical staff which may lead to temporary need of medication, excessive injection force which may lead to discomfort and haemorrhage.

## VI. Operative technique

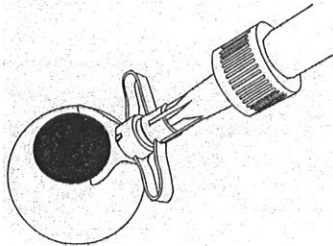
1. Open packaging and place SP.eye™ onto the sterile field
2. Hold the needle hub and connect SP.eye™ to syringe (suitable for LuerLock™ and pushfit syringes)



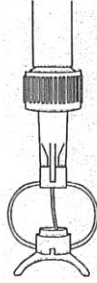
3. Prime syringe and needle
4. Prepare the eye with appropriate anaesthetic and antiseptic solution, and place a lid speculum and drape if appropriate
5. Align the inner curve of the "C caliper" of SP.needle™ with the limbus of the eye
6. Ensure the foot is fully in contact with the globe



7. Firmly push the syringe downwards until the spring is fully compressed



8. Inject the drug
9. Pull the syringe back until the SP.needle™ and needle are removed from the eye
10. To lock the needle tip safely squeeze the two spring arms together, slightly displacing either arm to the side until a click is heard, then release.
11. SP.needle™ is locked and sharps safe after the click is heard and the needle is visibly displaced to the side.



12. Dispose of SP.eye™ in an appropriate sharps container

### VII. Sterility

SP.eye™ is supplied STERILE unless the integrity of the packaging has been compromised. The sterilisation method is marked on the box and lid. Sterility will be maintained until the labeled "use by" (expiration) date marked on the packaging.

### VIII. Warranty

Andersen Caledonia Ltd warrants that this product was manufactured according to applicable standards and specifications. Patient condition, clinical treatment and product maintenance may affect the performance of this product. Use of this product should be in accordance with the instructions provided and as directed by the prescribing physician.

### IX. IP

SP.eye™ and associated designs are protected by patents pending worldwide (PCT/GB2014/053402) owned by Salar Surgical Ltd. SP.eye™ is manufactured by Andersen Caledonia Ltd under exclusive license from Salar Surgical Ltd.

Luer-Lock™ is a registered trademark of Becton-Dickinson and Company, NJ, USA

STERILE EO



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Made in the UK