

Instructions for use**TSK OptiXion™ NEEDLE****1 Intended purpose**

TSK OptiXion™ NEEDLE is intended for use with a syringe to drain intraocular substances and the administrate medications.

2 Indication

TSK OptiXion™ NEEDLE is indicated for the drainage of intraocular substances and the administration of medications.

3 Intended users

TSK OptiXion™ NEEDLE is intended to be used by doctors or other medical practitioners.

4 Target patients

TSK OptiXion™ NEEDLE is intended to be used in pediatric and adult populations who do not meet contraindications. The device should not be used in pregnant or lactating women.

5 Safety and performance objectives**Safety objectives:**

Limited complications associated with the use of the device, such as injury or bleeding at the puncture site, pain, injury of adjacent vessels or tissues, allergic reactions, or infection caused by the needle.

Performance objectives:

Provide an unobstructed channel for withdrawal and injection of liquids, or to remove fluid from a patient.

6 Clinical benefits

The needle is a simple ancillary device which is widely used in many clinical procedures; the indirect clinical benefit of the devices is to have a positive impact on patient management:

- Allow management of patients' medical conditions by providing a means of delivering essential liquid products locally or systemically in order to meet patients' medical needs.
- Allow healthcare professionals to manage medical conditions that require removal of biological fluids.

7 Undesirable side effects

Possible adverse events associated with the use of the device include:

- bleeding from the insertion site
- pain at the insertion site
- redness
- swelling
- internal bleeding
- metal allergy
- ptosis
- strabismus
- unintended eyeball perforation
- intraocular complications - pressure increase, inflammation
- blindness
- bruising
- skin irritation, itching, pruritis
- necrosis
- vasovagal reactions
- nodules
- tyndall effect

8 Contraindications

- Do not use for the heart, the central circulatory system and the central nervous system.

9 Prohibitions

- Do not reuse. [Otherwise, there is a risk of infection.]
- Do not resterilize. [Re-sterilization does not assure device sterility and could damage or degrade the device.]

10 Warnings**10.1 General precautions**

1.	Do not use the device near MRI. [Otherwise, there is a risk of MRI accidents.]
2.	Before using the device, read and follow the instructions for use.
3.	Do not use the device unless you are a medical doctor or a health care professional skilled in the procedure.
4.	If the device or patient show any abnormality, discontinue use immediately and take necessary measures.

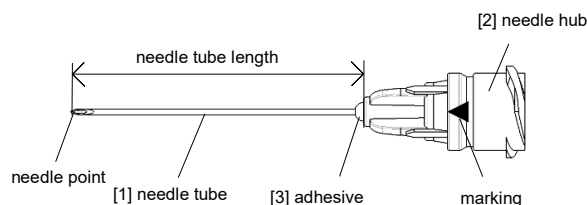
5.	Check the device's appearance before use to ensure no damage (scratches, cracks, deformation, discoloration, and others).
6.	Do not use the device if the sterile bag is opened or damaged (scratched, cracks, deformation, discoloration, and others).
7.	Refer to the associated instructions if you use the device with pharmaceuticals or other medical devices.
8.	Do not use the device for any purpose other than those described in the "instructions for use."
9.	Do not modify the device.
10.	Only use with devices that are ISO 80369-7 compliant.

10.2 Precautions for use

- Use the device immediately after opening the package. [Otherwise, bacteria could multiply and cause infection.]
- Do not touch the needle directly with your hands. [Otherwise, there is a risk of infection.]
- Check the needle gauge and length before use. [Otherwise, there is a risk that you could not perform the appropriate procedure.]
- When removing the needle tube case from the needle, be careful not to let the needle point touch the case. [Otherwise, there is a risk of needle point damage.]
- Be careful that the needle tip does not contact unintended surfaces. [Otherwise, there is a risk of needle point damage.]
- Do not connect the device to a syringe or other device without the case. [Otherwise, there is a risk of needle stick injury or needle point damage due to contact with unintended surfaces.]
- Before use, ensure that the connection to the syringe is not loose. [Otherwise, there is a risk of leakage or device dropout.]
- Do not apply excessive force when connecting to a syringe. [Otherwise, there is a risk of device damage.]
- Ensure that there is no damage, loose connections, or leaks during use.
- Ensure that pharmaceuticals, blood, and other liquids do not enter the connection. [Otherwise, the connecting could loosen.]
- Do not puncture the rubber stopper of a drug vial when using this product. [As foreign matter may remain in the needle cannula.]
- When injecting a drug solution or other substance, fill the entire needle tube with the solution before use.
- Protect the hub of the device from ethanol and organic solvents. [Otherwise, there is a risk of device damage.]
- Do not use the device together with high-pressure injectors. [Otherwise, there is a risk of damage to tissue or device.]
- Be careful to avoid needle stick injury when returning the needle to the case.

10.3 Other precautions

- The user must report all adverse events resulting from the use of the device to the manufacturer and to the competent authorities of the member state where the user or patient is.
- After use, dispose of the device safely and with care to prevent the risk of infection, following institutional, local, regional and national guidelines.
- Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

11 Device specifications**11.1 Configuration (typical diagram)****11.2 Material**

Material for parts that contact blood, body fluids, mucous membranes, and other patient tissues are:

- [1] needle tube: stainless
- [2] needle hub: hard polymer
- [3] adhesive: epoxy resin
- lubricant: silicone

The device is gamma-sterilized.

English/ENGLISH

12 Instructions for use

- 1) Open the package with proper aseptic technique and take out the product
- 2) Attach the product to the tip of the syringe.
if the product and the syringe tip are designed to luer-slip type.
 Attach by firmly pushing the tip of the syringe into the hub. Do not push with excessive force. [Otherwise, there is a risk that the device would be damaged.]
If the device and the tip of syringe are lock type
 Attach the syringe by firmly rotating the tip of the syringe into the hub. Do not apply excessive rotational load. [Otherwise, there is a risk that the device would be damaged.]
- 3) Pull the case straight to remove from the device
- 4) Puncture the injection site with the device and inject the drug solution.
- 5) Remove the needle.
- 6) Dispose of the device following standard safety protocols.

13 Storage

- Keep dry. Keep away from direct sunlight, high temperature, and humidity. Store in a clean place.

14 Expiry date

- For the useful life of the device that has been stored properly as per the storage instructions, refer to the use-by date printed on each individual package.
- Store properly and do not use the device after the expiry date.

15 Manufacturer's information

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	Date of manufacture
	Caution
	Medical device
	Single sterile barrier system
	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
	Non-pyrogenic
	Unique device identifier

Graphics and titles

	Manufacturer
	Do not re-use
	Do not resterilize
	Sterilized using irradiation
	Consult instructions for use or consult electronic instructions for use
	Do not use if package is damaged and consult instructions for use
	Keep away from sunlight
	Keep dry
	Batch code
	Use-by date
	Catalogue number