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Nam Illumination Probe with Chopper User's Manual

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Visit our website oculight.co.kr to view and download further information about the functions of the Nam Illumination Probe with Chopper, the explanation of results output, and more. OCULIGHT CO., Ltd. reserves the right to modify the appearance, specifications, and etc. of the Nam Illumination Probe with Chopper to improve the quality of the product, without prior notice for reasons of performance improvement.

Document History

Revision	Description	Date
0	Initial Release	2024.02.14

This manual is subject to change without notice according to the change of product.
Contact your distributor to receive up-to-date manual.

Nam Illumination Probe with Chopper
User's Manual

1. Intended Use
The Nam Illumination Probe with Chopper is a blunt-ended surgical instrument that is inserted inside the eyeball to illuminate and examine the surgical field. It can assist in dividing the lens materials as needed in cataract surgery.

2. Description and Characteristics of the Device
Nam Illumination Probe with Chopper is an invasive device used to convey visible light from an illuminator light source to the intraoperative field of the eyeball for use in ophthalmic procedures and provide mechanical tissue manipulation function. Name Illumination Probe with Chopper is a single-use device and is EtO sterilized.

Nam Illumination Probe with Chopper consists of a stainless-steel tube, a handle, an optical fiber for light conveyance, fiber cloth, and a proximal connector for interface with the light source, iVision.

3. Product components
Table 3-1 The Name Illumination Probe with Chopper overview

Name		Description
Nam Illumination Probe with Chopper	IC-25G	Tube outer diameter: 0.51 ±0.1 mm, Tube length: 13.0 ±2 mm, Optic fiber and Tube length: 2000 ±200 mm, Connector length: 38.0 ±1.0 mm, Total length: 2200 ±200 mm Weight: 7.5 ±3 g
	IC-27G	Tube outer diameter: 0.42 ±0.1 mm, Tube length: 15.0 ±2 mm, Optic fiber and Tube length: 2000 ±200 mm, Connector length: 38.0 ±1.0 mm, Total length: 2200 ±200 mm Weight: 10.0 ±3 g
iVision		• Dimension : 158.6(L) x 182(W) x 145(H) (mm) • Weight: 3.2kg
Power Cable		• Length: 3m

1) The Nam Illumination Probe with Chopper

- IC-25G: Tube outer diameter is 0.51mm, has a bent shaft which enhance cutting efficiency. In addition, the 90-degree bend allows better visibility and movement during the surgical procedure. Tube outer diameter of IC-25G is bigger than the IC-27G. Bigger tube outer diameter make it easier to handle rigid lens.

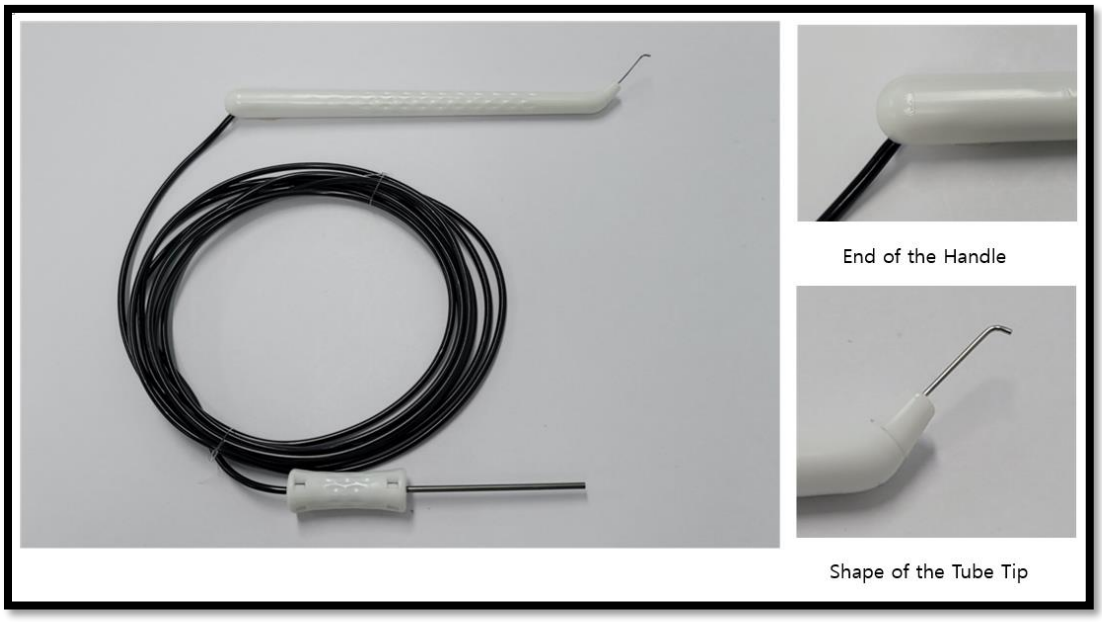


Figure 3-1. Photograph Image of IC-25G

- IC-27G: Tube outer diameter is 0.42mm, has a bent shaft which enhance cutting efficiency. In addition, the 90-degree bend allows better visibility and movement during the surgical procedure.

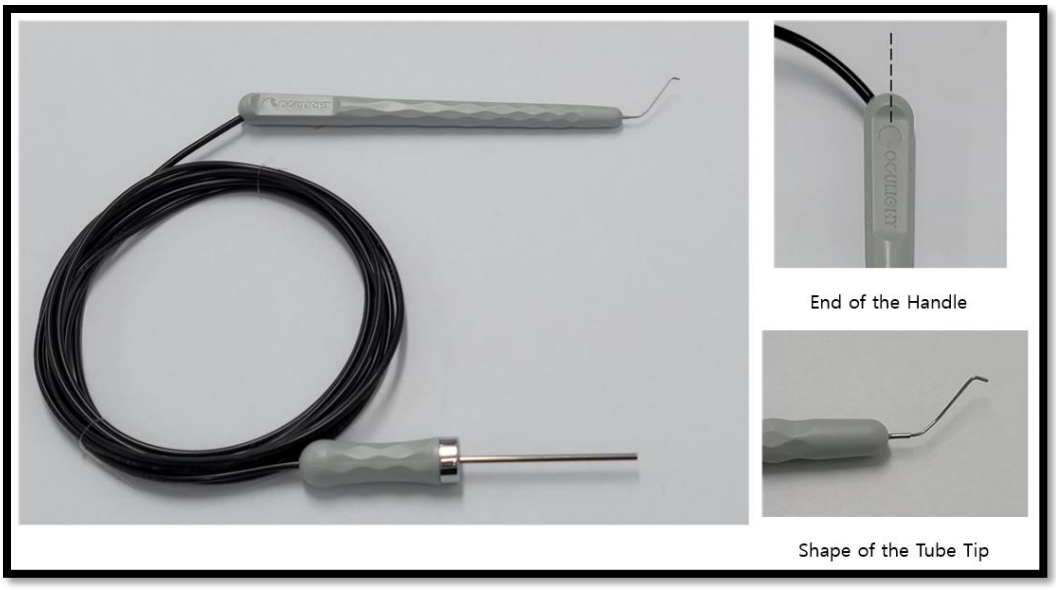


Figure 3-2. Photograph Image of IC -27G

2) iVision (1EA)

The iVision is the medical light source to illuminate the patient's surgical eye area during cataract surgery. The Nam illumination probe with Chopper connects to the iVision. In front of iVision, there is a dial to adjust the brightness of the Nam illumination probe with chopper illumination, and a probe connector. The brightness is displayed numerically on the screen and can be adjusted from a minimum of 0 to a maximum of 99. The iVision re-usable.

Front Panel of iVision

No.	Components	Function
①	Probe Connection Socket	Probe proximal connector connects to the iVision through this socket
②	Light Intensity Control Lever	Light intensity control
③	LED Display	LED light source intensity display from a minimum of 0 to a maximum of 99

Rear Panel of iVision

No.	Components	Function
①	Body Grip	Grip to carry the iVision
②	Power ON/OFF Switch	Turn the device power ON/OFF
③	Power Connector	Power supply
④	EQP-point	Electrical equalization
⑤	Cooling Fan	Dissipates heat inside the device

4. Product Specification

Device	Item	Specification
Nam Illumination Probe with Chopper	Light Performance	- Illuminance (LUX): over 2,000 - Light angle (degrees): within 50±5

Device	Item	Specification
iVision	Electrical rating and frequency	- 100-240V - 50/60Hz
	Power consumption	- Less than 200VA
	Safety device	Power fuse
	Color temperature	V1-S1: 5,700K, 5,000K

5. List of Accessories

- Power Cable (1EA) – An assembly of the iVision. The Power Cable is an electrical cable and used for transmission of electrical power.

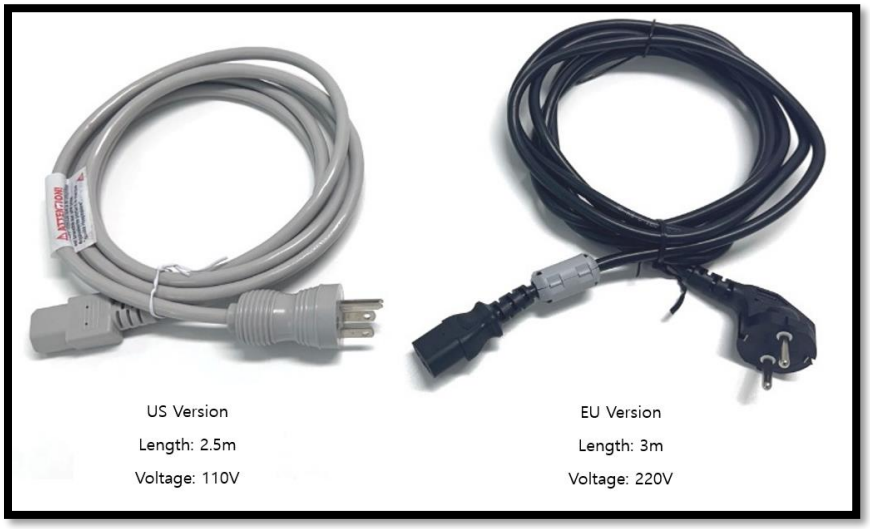


Figure 5-1 Photograph of the Power Cable

Accessory equipment connected to or used with this equipment must be certified according to the respective IEC Standard. Furthermore, all configurations shall comply with clause 16 of IEC 60601-1:2023 (as amended). Anyone connecting additional equipment or otherwise causing a different system configuration than provided by OCULIGHT is responsible for continued compliance to the requirements of clause 16 of 60601-1:2023 (as amended). If in doubt, consult the Technical Services department or your local OCULIGHT representative.

6. Contraindications / Residual risks / undesirable side-effects

1) Contraindications:
    - The patient does not desire surgery
    - Glasses or visual aids provide vision that meets the patient's needs
    - Surgery will not improve visual function
    - The patient's quality of life is not compromised
    - The patient cannot safely undergo surgery

- Informed consent cannot be obtained from patient or surrogate
- Appropriate post-operative care cannot be arranged

2) Residual risks / undesirable side-effects:
   - Blurred vision
   - Inflammation
   - Drooping eyelid
   - Corneal edema
   - Light sensitivity
   - Bleeding
   - Floaters
   - Retinal detachment
   - Bloodshot eyes
   - Secondary cataract
   - Discomfort
   - Dysphotopsia
   - Lens fragments
   - Dislocated intraocular lens
   - Cystoid macular edema
   - Posterior Capsule Opacification

7. Intended user profile

Considerations	Condition
Education	Qualified to perform eye surgery
Knowledge	Educated by the person authorized by the manufacturer
Language	- Basic language: English - Languages are supported as specified in the marketing need.
Experience	- Learned a specialized knowledge and practiced in the subject department - Fully understand how to use the device through the user manual - Ophthalmic surgeons performing cataract surgery
Permissible impairments	N/A

8. Intended patient population and user profile

Intraocular surgery patients requiring cataract surgery

9. Clinical Benefits

The clinical benefits of the Nam illumination probe with chopper include facilitating ophthalmic surgical procedure that reduce blurry vision and reduce the glare from lights.

10. Warnings / Caution

- A qualified technician must perform a visual inspection of the following components every twelve months: Warning Label, Power Cable – In case of a deficiency, do not sue the device; call OCULIGHT Technical Services.
- Route the power cable to avoid tripping.
- Avoid spilling any irrigating solution, or moisture of any kind, around the electrical probe connectors or power cable connector.
- The probe tip of the tube should not touch any solid object while in operation.
- Perform visual inspection of the probes for bent tips prior to use.
- Use of non-OCULIGHT surgical disposable probes with the ivison that do not meet OCULIGHT surgical specifications, may cause an error.
- **Presurgical check-out** must be performed as outlined in Section 11 of this manual. If there are problems, refer to the Troubleshooting section of this manual. If the problem persists, DO NOT PROCEED. Please contact the manufacturer.
- Be sure the proximal connector of the probe is dry before connecting it to the iVision.
- If required, the iVision may be wiped with alcohol-based disinfectant (e.g. 70% ethanol), mild soap and water, or any germicidal solution that is compatible with the glass and aluminum.
- The probes are designed with sharp ends, so please exercise caution when using them and also should be disposed in sharp bin.

11. Precautions

1) Do not use if the Name Illumination Probe with Chopper is received in a defective condition or has been unintentionally opened. Do not use any of the contents if the sterile package is damaged or the seal is broken in any way. In these cases, please contact the manufacturer.

By Phone:
In Korea - Tel. +82-031-8039-6177
In EU – Contact your local OCULIGHT Representative.
By Website:
www.oculight.co.kr

2) Sterile disposable medical devices should not be reused.

- Potential risk form reuse or reprocessing include: Phototoxicity from inconsistent illumination exposure caused by a damaged fiber or connector, reduced illumination output, and foreign particle introduction into the eye.

3) The Name Illumination Probe with Chopper is intended for one procedure only. Improper usage or assembly could result in a potentially hazardous condition for the patient. OCULIGHT

assumes no responsibility for complications that may result from reuse or improper usage of this device.

12. Directions for Use

The Nam Illumination Probe with Chopper transmits light through the optical fiber to the inside of the eye to illuminate the intraoperative field of the eyeball. It consists of Connector [A], Optical fiber within a fiber cloth [B], and a handle with a tip [C]. General instruction of use is as below:

① Check the sterile package before use. Do not use if the device is received in a defective condition or has been unintentionally opened.

② Aseptically remove the probe from the sterile package.

③ Hand off the connector [A] end to the circulator and insert the plug connector into the light source [E]. Make sure the connector [A] is fully inserted into the light source [E].

④ Straighten the chopper's fiber cloth [B] until it is fully untangled.

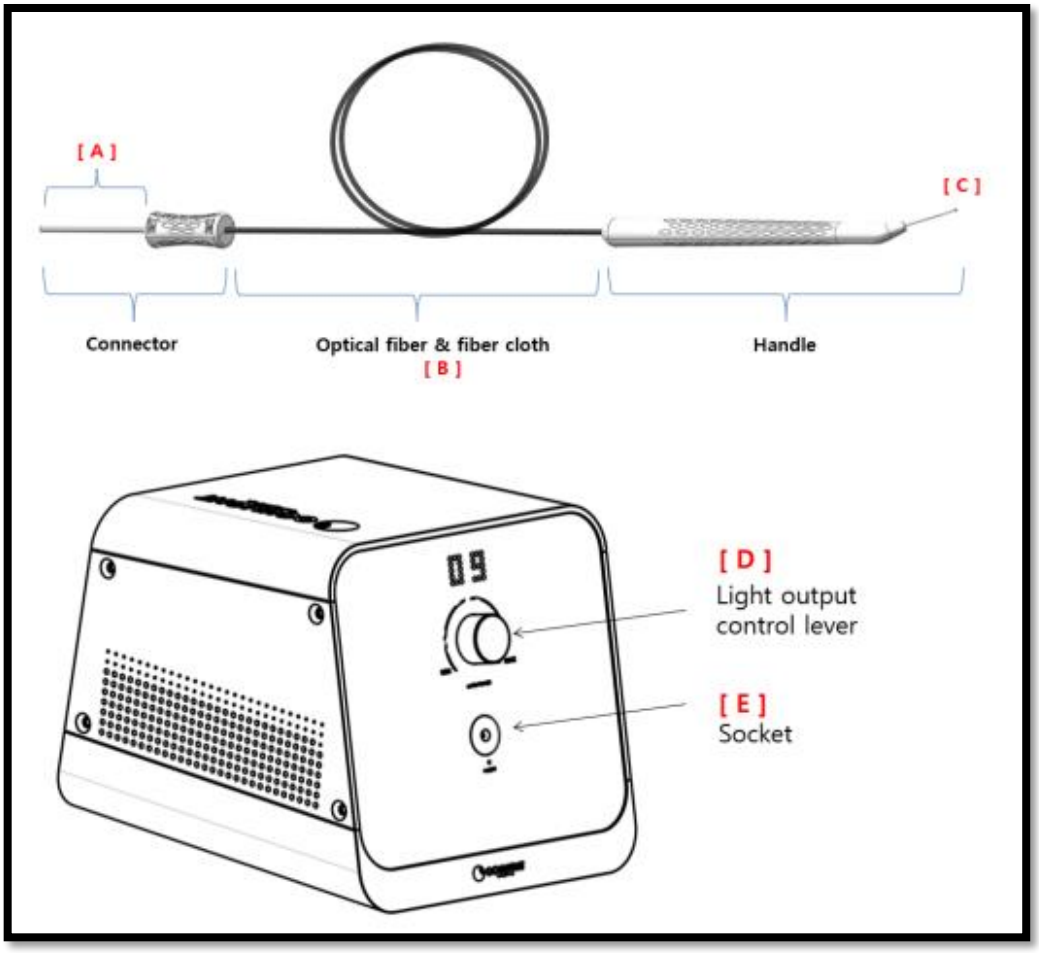
⑤ Perform **presurgical check-out test**. Turn on the light source [D] and verify light output through the fiber [C]. Check for damaged or kinked tubing.

⑥ Insert the tip of the handle [C] into the anterior chamber of the eye through an aperture made in cornea (limbus).

⑦ Illuminate the light into the anterior chamber of the eye using the Nam Illumination Probe with Chopper.

⑧ Ensure that the reflected light is within predetermined ranges and adjust the illumination parameters accordingly.

⑨ Perform the cataract surgery.



13. Operating Environment

This device is intended for use in hospitals and ambulatory surgery centers.

14. Packaging and Sterilization

Each of the Nam Illumination Probe with Chopper is packaged in a "standalone" pack configuration. The product is sealed inside Tyvek pouch and EO gas sterilized. The ship pack is comprised of 5 multiple primary packs with a single IFU insert secured in a shipping case. The ivison is a non-sterile device and packed with power cable in a separate box.

15. Conditions in Storage & Transportation

Item	Requirement
Temperature	10℃ ~ 35℃
Humidity	10 to 95% RH (non-condensing)

16. Trouble Shooting

Symptom	Probable Cause	Corrective Action
System does not power-up	1. Main power switch is in OFF position. 2. Blown power fuse.	1. Turn main power switch near power cord to ON position 2. Replace power fuse near power cord.
Probe illumination does not work	1. kinked or damaged probe 2. Faulty probe 3. loose connection with the iVision	1. Check for damaged or kinked tubing; straighten if necessary. Replace probe if visual inspection shows any damaged components. 2. Replace probe. 3. Tighten the loose connection with the iVision

17. Product Disposal

- The iVision is an electrical and electronic medical device and must be disposed of in accordance with the national waste management law.
- The Nam Illumination Probe with Chopper is designed with sharp ends. This device should be disposed in sharp bin.

18. Expiry Date

- Nam Illumination Probe with Chopper: 3years
- iVision expected service life: Approximately 7years

18. Serious Incident Reporting

Any serious incident related to the use of this medical device should be reported to OCULIGHT CO., Ltd.:

By Phone:
In Korea - Tel. +82-031-8039-6177
In EU – Contact your local OCULIGHT Representative.
By Website:
www.oculight.co.kr
By Email: oculight@oculight.co.kr

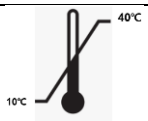
19. Definitions

Definitions for symbols that appear on product labels:

Label	Symbol	Description
1. Manual Label		

1		**Refer to instruction manual**
2		**Caution**
3		**General prohibition sign and Template for constructing a prohibition sign.**

2. Product Label

	**CONSULT INSTRUCTIONS FOR USE OR CONSULT ELECTRONIC INSTRUCTIONS FOR USE**		**BATCH CODE**
	**MEDICAL DEVICE**		**USE BY : YYYY-MM-DD**
	**STERILIZED USING ETHYLENE OXIDE**		**CATALOG NUMBER**
	**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICAIN**		**DATE OF MANUFACTURE : YYYY-MM-DD COUNTRY OF MANUFACTURE**
	**DO NOT REUSE**		**AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY**
	**DO NOT RESTERILIZE**		**DO NOT USE IF PACKAGE IS DAMAGED**
	**MANUFACTURER**		**DOES NOT CONTAIN LATEX OR DRY NATURAL RUBBER**
	**Temperature limit**		