



PRODUCT MANUAL

OCULAR LANDERS WIDE ANGLE SURGICAL VIEWING SYSTEM

AND

132D INDIRECT VITRECTOMY LENS





OCULAR LANDERS WIDE ANGLE
SURGICAL VIEWING SYSTEM (Product Code: OSVS)
Developed with: *Maurice B. Landers, III, M.D., Chapel Hill, NC*



OCULAR 132D INDIRECT VITRECTOMY LENS
(Product Code: OIV 132)

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Foreword

Ocular Instruments would like to thank you for your purchase of another fine product from our company. In choosing the **Ocular Landers Wide Angle Surgical Viewing System (OSVS)**, you have acquired a modern product using the latest technology in its field. You can be assured it has been manufactured and tested to the most stringent quality requirements.

When used with the **Ocular 132 Diopter Indirect Vitrectomy Lens (OIV 132)**, the Wide Angle Surgical Viewing System allows a clear, upright, hands-free view in the fluid or air filled eye.

Proper installation and care of the device is indispensable for accurate and safe use. For this reason, please familiarize yourself thoroughly with the contents of this instruction manual before putting the instrument into use for the first time.

If you have questions or would like additional information, please either contact us directly or the authorized Ocular distributor from whom you have purchased these products. Our service team will be most happy to assist you.

Sincerely yours,

The Management and Staff
Ocular Instruments, Inc.

System Description and Function

The OSVS is a non-contact vitrectomy system designed with a flexible arm for positioning wide angle lenses which easily swings in and out of the surgical field. The OSVS [clamps] attaches to the wrist rest or surgical bed, freeing the surgeon and assistant to perform tasks other than holding a lens.

When used with the Ocular 132 Diopter Indirect Vitrectomy Lens, the system allows the surgeon to work in the vitreous with an upright, non-reversed image under panoramic conditions.

During surgery, operative work is performed both outside and inside the globe. Use of the OIV 132 lens with the OSVS enables the surgeon to move back and forth smoothly and quickly.

**FOR BEST PERFORMANCE RESULTS,
follow "Getting Started" instructions on page 5.**

Getting Started

To get the best from your first surgical experience with the OSVS-I132, we recommend the following procedure.

- **Assemble:** Follow the assembly instructions on page 7.
- **Practice:** This is the most important step of the getting started process. Take the **non-sterile** system into the operating room. Practice setting up and adjusting the system as described in the *Operation* section on page 9. Use a member of the surgical team in place of the patient. Once all members of the surgical team are familiar with setup and adjustment, the OSVS-I132 can be prepared for surgery.
- **Sterilize:** **OIV 132 Lens** - Follow instructions on pages 12-13.
OSVS - Follow instructions on pages 14-15.
- **Operate:** The system is ready to assemble for surgery. Some helpful tips on use can be found on page 10.

System Set-up and Operation

Assembly

- Remove the OSVS from its carrying case. Please keep the carrying case available for possible storage, hand transport or shipment for servicing.
- Insert Post in Hole A or B as desired and tighten with Wrench.

| | |
|------|--|
| Note | If clamping OSVS to a wrist rest use hole A. |
|------|--|

- Slide Support Collar down onto Post about 1 inch from the top and tighten Thumb Screw.
- Slide Arm Clamp onto Post and tighten Thumb Screw.
- Attach OIV 132 Lens Holder to Slotted Arm and tighten Links with Thumb Screw.
- Slide Slotted Arm into Arm Clamp and tighten Thumb Screw.
- OSVS is now ready for use.

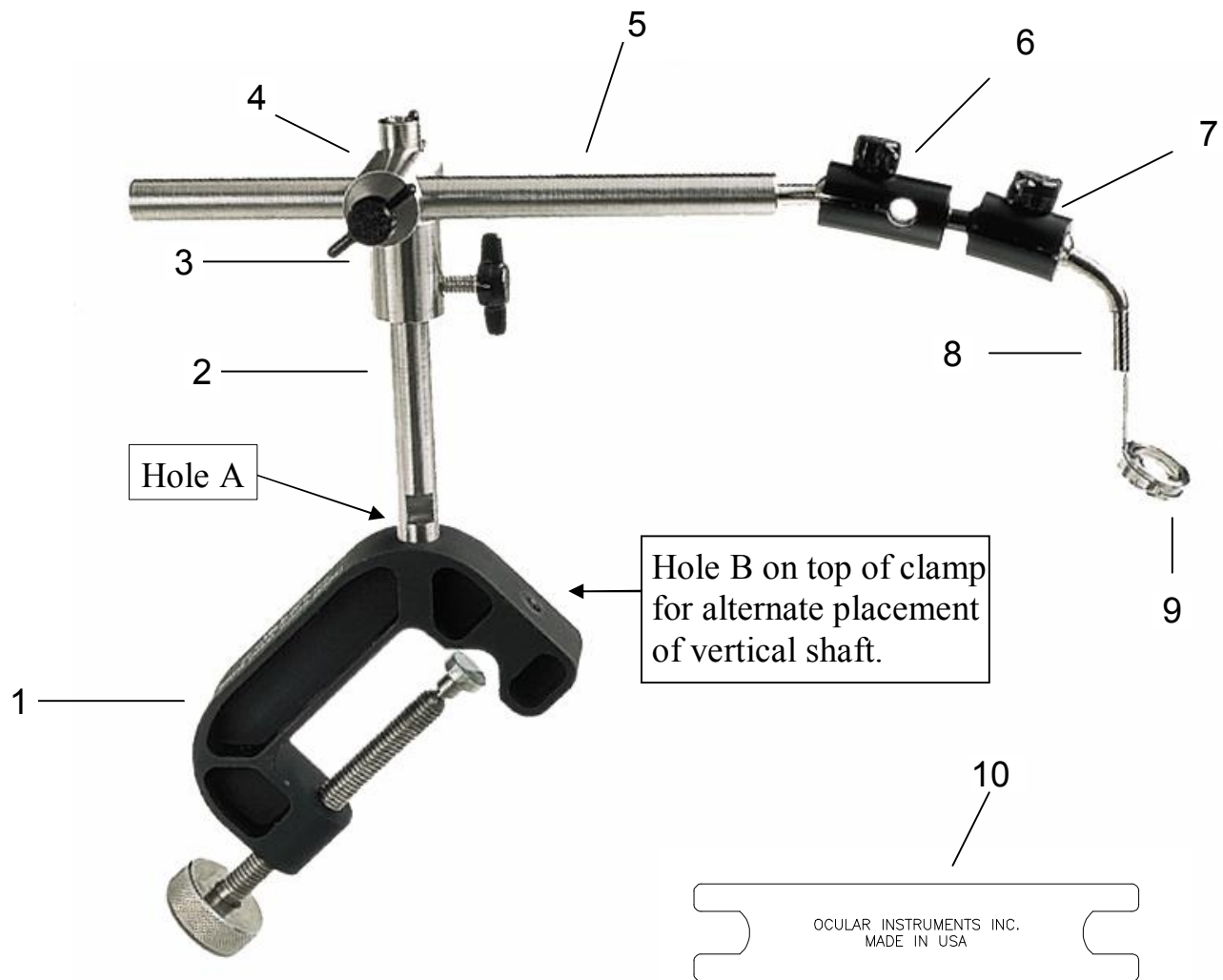


Figure 1 - The OSVS-I132 and its components

- No. 1 Frame Clamp
- No. 2 Post (shown inserted into Hole A)
- No. 3 Support Collar with Thumb Screw
- No. 4 Arm Clamp with Thumb Screw
- No. 5 Arm, Slotted
- No. 6 Link Female/Male (FM) with Thumb Screw
- No. 7 Link Female/Female (FF) with Thumb Screw
- No. 8 OIV 132 Lens Holder
- No. 9 OIV 132 Lens
- No. 10 Wrench

Operation

- Sterilize OIV 132 and OSVS following instructions on pages 12 - 15.
- Assemble OSVS, following instructions on page 7.
- Clamp OSVS on top of surgical drape with post vertical.
- Insert Lens in Lens Holder.
- Focus microscope on cornea.
- Position Lens above patient's eye and tighten Thumb Screws on Arm Clamp.
- Lift Support Collar until it touches Arm Clamp and tighten Thumb Screw.
- Top of Lens should be centered in the microscope field, bottom of Lens should be centered with patient's pupil.
- Fine position Lens manually with flexible Links. Fundus will be in focus with only minor adjustments of the microscope.
- To temporarily move lens out of surgical field, loosen Thumb Screw on Arm Clamp at Post. Slide Arm Clamp up Post and rotate Slotted Arm away from eye. Slide Arm Clamp down until it touches Support Collar.
- To re-position lens, slide Arm Clamp up Post. Rotate Slotted Arm until lens is above patient's eye. Slide Arm Clamp down until it touches Support Collar and tighten Thumb Screw. Lens should now be in previous surgical position.

Practical Tips on Using the OSVS

Before Each Use

- Be sure that unit is in good working order.
- After sterilization, tighten Post on Frame Clamp using Wrench.

During Use

- Maximum field of view is achieved with OIV 132 Lens approximately 4mm from cornea.
- Larger working distances reduce static field of view and allow greater eye rotation for viewing peripheral vitreous and retina.

After Use

- Cleaning all parts immediately after use will simplify cleaning and maximize product life.

Troubleshooting

Should a problem arise which you cannot correct by using the trouble shooting table below, please label the OSVS clearly as non-operational and call our service department or that of your local distributor from whom you purchased the OSVS.

| Problem | Possible Cause | Corrective Measures |
|------------------------------|---|--|
| Poor Image Quality | The glass surfaces of the lens are soiled. | Clean the glass surfaces with the appropriate cleaning solution. |
| OSVS wobbles | Loose Connections | Tighten the knurled screw on the OSVS clamp and tighten Post with Wrench |
| Links don't hold lens steady | Thumb Screw inserted into link incorrectly | Place Thumb Screw into non-threaded hole, then tighten |
| | Thumb Screws too loose or links have become damaged | Tighten Thumb Screws in links or replace links |

OIV 132 Lens Maintenance

- Remove lens from holder, then clean and disinfect.

Cleaning

Rinse: Immediately upon removal from patient's eye, thoroughly rinse in cool or tepid water.

Wash: Place a few drops of mild soap on a moistened cotton ball. Gently clean with a circular motion.

Rinse: Thoroughly rinse in cool or tepid water, then dry carefully with a *non-linting* tissue.

Then: Proceed with either disinfecting or sterilizing instructions.

Disinfecting

| | | | |
|----------------|---|--|--|
| Soak In: | GLUTURALDEHYDE | OR | BLEACH |
| | 2% or 3.4% aqueous solution | | 10% solution mixed at: 1 part bleach to 9 parts cool tepid water |
| | Temperature per manufacturer instructions | | Recommended exposure time = 10 minutes |
| | Minimum exposure time = 20 minutes | | |
| CAUTION | | <i>To avoid damage to the lens, do not exceed recommended exposure time.</i> | |

Then: Rinse lens *thoroughly* to remove disinfection solution. 3 cycles of 1 minute, with cool or tepid water is recommended.

Dry carefully and place in a dry storage case.

NOTE

This lens is known to be compatible with: Asepti-Wipe, Cavi-cide, Cidex, Cidex OPA, DisCide Wipe, Enviro-cide, and Opti-Cide.

- Sterilize lens.

| Sterilization - Autoclave | | | | | | | | | | | | | | | | |
|----------------------------------|--|---------------------------------|------------------|-----------------------|--|--|-------------|------|--|-------------|------|------------------|-----------------------|-----------|------------------|-----------------------|
| Prep: | Place OIV 132 on its side in sterilization case. | | | | | | | | | | | | | | | |
| Process: | <table border="1"> <thead> <tr> <th colspan="5">Standard Cycle (wrapped)</th> </tr> <tr> <th>Temperature</th> <th>Time</th> <th></th> <th>Temperature</th> <th>Time</th> </tr> </thead> <tbody> <tr> <td>270°F (134°C)</td> <td>15 minutes minimum</td> <td>OR</td> <td>250°F (121°C)</td> <td>30 minutes minimum</td> </tr> </tbody> </table> <p>Caution <i>Use only distilled water in the steam sterilizer.</i> If not distilled, mineral deposits from hard water (steam) will leave a cloudy film on the lens. The deposit can only be removed by regrinding and re-polishing the lens and repair costs approximate that of a new lens.</p> | Standard Cycle (wrapped) | | | | | Temperature | Time | | Temperature | Time | 270°F (134°C) | 15 minutes minimum | OR | 250°F (121°C) | 30 minutes minimum |
| Standard Cycle (wrapped) | | | | | | | | | | | | | | | | |
| Temperature | Time | | Temperature | Time | | | | | | | | | | | | |
| 270°F (134°C) | 15 minutes minimum | OR | 250°F (121°C) | 30 minutes minimum | | | | | | | | | | | | |
| Store: | Place in a biological barrier peel pouch to ensure sterility after the process. | | | | | | | | | | | | | | | |
| For Immediate Use Only | Flash autoclave (unwrapped) at a minimum of 270°F (134°C) for a minimum of 10 minutes. | | | | | | | | | | | | | | | |

| Sterilization - ETO | | |
|----------------------------|--------------|---------------|
| Minimum Time | Temperature | Aeration Time |
| 1 hour | 130°F (54°C) | 12 hours |

| Sterilization – Steris System 1 | Sterilization – Sterrad |
|--|--------------------------------|
| No | No |

For information on compatibility with alternative product care methods, contact Customer Service.

OSVS System Maintenance

| | |
|------------------------------|---|
| Remove the Lens First | Before proceeding with cleaning or sterilizing the OSVS, remove the Lens from the Lens Holder. See Lens maintenance instructions on page 12 for how to clean, disinfect and sterilize the OIV 132 Lens. |
|------------------------------|---|

- Remove Slotted Post from Arm Clamp.
- Loosen screws on Links.

| | |
|------|--|
| Note | If Lens Holder Links are separated, re-assembly will be difficult. |
|------|--|

| | |
|------------------|---|
| IMPORTANT | After removing accessory lens and BEFORE proceeding with cleaning or sterilizing, loosen all thumb screws on assembly to avoid distortion of the threads. |
|------------------|---|

- Remove Arm Clamp and Support Collar from Post.
- Clean all parts.

| |
|--|
| Cleaning |
| Rinse: Upon completion of surgical procedure thoroughly rinse in cool or tepid water. Wash: In mild soap. Rinse: Thoroughly rinse in cool or tepid water, then dry carefully with a <i>non-linting</i> tissue. Then: Proceed with sterilization instructions. |

- Sterilize all parts.

| | |
|------|---|
| Note | System may be sterilized after complete or partial disassembly of components. |
|------|---|

Sterilization - Autoclave

Prep: Place OSVS components in sterilizer.

Process:

| Standard Cycle (wrapped) | | | | |
|--------------------------|-----------------------|-----------|------------------|-----------------------|
| Temperature | Time | | Temperature | Time |
| 270°F (134°C) | 15 minutes minimum | OR | 250°F (121°C) | 30 minutes minimum |

Store: Place in a biological barrier peel pouch to ensure sterility after the process.

For Immediate Use Only Flash autoclave (unwrapped) at a minimum of 270°F (134°C) for a minimum of 10 minutes.

Sterilization - ETO

| Minimum Time | Temperature | Aeration Time |
|--------------|--------------|---------------|
| 1 hour | 130°F (54°C) | 12 hours |

Sterilization – Steris System 1

Follow manufacturer's instructions.

Sterilization – Sterrad

Follow manufacturer's instructions.

Note

Discoloration of the anodizing may occur using Sterrad. Functionality will not be changed.

For information on compatibility with alternative product care methods, contact Customer Service.

Guarantee

The OSVS was carefully manufactured from the highest quality materials available and with modern production techniques. To keep the OSVS in perfect working condition, it is important these operating instructions be followed.

The OSVS is unconditionally guaranteed against defects in materials and workmanship within one year of invoice date. Problems or malfunctions caused by improper handling or external causes are not covered by the warranty. The OSVS should only be serviced by a factory trained technician. Should you encounter a problem, please return it to Ocular Instruments in its carrying case.

Proof of purchase is required before services can be provided under the guarantee. Call Ocular Instruments to obtain a Return Authorization Number prior to returning the OSVS. We recommend it be insured for the purchase price prior to shipping.

All guarantee claims are cancelled if the OSVS is altered by an unauthorized person.

Please report any shipping damage immediately to your shipping company if the unit is received in a damaged condition. Many times the shipping company will not approve a claim if the damage is not reported immediately upon receipt.

Shipping the OSVS

In order to avoid unnecessary damage and costs, always ship the OSVS in its carrying case.

Service Address

Before shipping any Ocular product to Ocular Instruments, contact our customer service department to obtain a Return Authorization Number (RA#). Print this number on the outside of the shipping package to assure prompt delivery to the service department.

Ocular Instruments, Inc.
2255 116th Avenue NE
Bellevue, WA 98004-3039
USA

T: 425-455-5200 or 800-888-6616
F: 425-462-6669
E: ocular@ocular-instruments.com
I: www.ocular-instruments.com

Safety Information

The OSVS is part of a microsurgical operating system which is intended only for use as described in this instruction manual. Please keep these operating instructions in a secure place. Always follow these operating instructions when working within the surgical arena.

The OSVS is intended for use with operating microscopes in hospitals, clinics, outpatient facilities, etc. where ophthalmic surgery is performed and only by persons who have been properly trained.

Ocular Instruments assumes no responsibility for use of the OSVS for purposes other than those named in the instruction manual and/or by persons who have not been properly trained.

Use this instrument only with original manufacturer's parts and accessories in proper working condition. Do not use the OSVS if it has become damaged. Please contact Ocular Instruments or the authorized Ocular distributor from whom you have purchased these products, if you believe the unit needs repair.

Should a malfunction occur whose cause you cannot locate or eliminate with the Troubleshooting Table on page 11, please mark the unit clearly as non-operational and contact our customer service department at 800-888-6616 (toll free USA) or 425-455-5200, or email us at: ocular@ocular-instruments.com.

Standard Equipment List

| <u>Item Description</u> | <u>Product Code</u> |
|--------------------------------------|---------------------|
| 1 Viewing System assembly including: | OSVS |
| 1 Arm, Slotted | OSVS-A |
| 1 Arm Clamp | OSVS-AC |
| 1 Frame Clamp | OSVS-FC |
| 1 Post | OSVS-P |
| 1 Support Collar | OSVS-SC |
| 2 Link, Female/Male (extras) | OSVS-LFM |
| 1 Wrench | OSVS-W |
| 1 Carrying Case with foam liner | OSVS-C |
| 1 Product Manual | 7267 |

OSVS-I132 Set also includes the following:

| <u>Item Description</u> | <u>Product Code</u> |
|--|---------------------|
| 1 Ocular 132D Indirect Vitrectomy Lens | OIV 132 |
| 1 Ocular 132D Indirect Vitrectomy Lens | OIV-H132 |
| Holder assembled with: | |
| 1 Link, Female/Female | OSVS-LFF |
| 1 Link, Female/Male | OSVS-LFM |
| 1 Sterilizable Lens Case | 7071 |

We reserve the right to make technological improvements to the OSVS without prior notice.