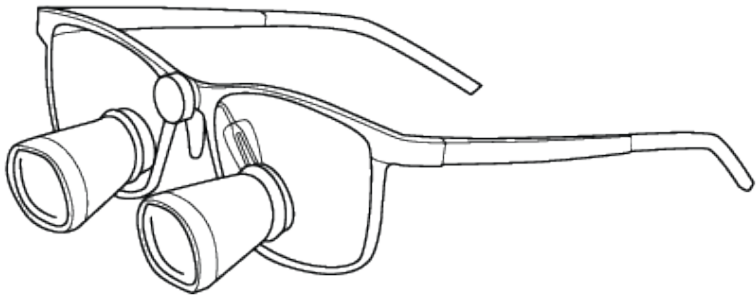




# Enova Vizix® Custom Loupes

Instructions For Use



## Introduction

This *Instructions For Use* manual is the most comprehensive source of information for the safe and effective use of your product. This manual may be used by surgeons, dentists, veterinarians, or other healthcare professionals.

Keep and consult this reference manual during the life of the product.

The following conventions are used in this manual:

- A **WARNING** highlights a safety-related issue. ALWAYS comply with this information to prevent injury to patient, user, medical personnel, and/or other persons and animals.
- A **CAUTION** highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.
- A **NOTE** supplements and/or clarifies procedural information.

If additional information, especially safety information, or in-service training is required, contact your Enova sales representative or call Enova customer service.

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## Indications for Use

Enova Loupes are designed to provide magnification during dental or minor surgical procedures. Enova loupes are fitted for your head and crafted for your eyes. Every pair is designed to consider ideal working distance, individual facial features, custom lens prescriptions, and the optimal declination angle.

## Contraindications

None known.

## Limitations of Use

None known.

## For Use With

Axis Light System, Atom Wireless Light System, Futudent microCam XS Systems, Futudent proCam XS Systems, Futudent smartCam Systems.

## Safety & Care Instructions



### WARNINGS:

Please read the instruction manual carefully before using your Enova Loupes. Damages due to disregard of the instructions within this manual are not covered under the warranty policy of Enova Illumination.

- Improper use of oculars may result in damage or failure of glue, resulting in loose or detached ocular.
- DO NOT look directly into the sun or other intense light while wearing loupes to avoid eye damage.
- Avoid vibration or shaking of loupes. This may result in loose or detached pieces.
- Proper use of the loupe and light system requires parts from Enova or licensed suppliers only.
- Avoid shock to product by keeping product in approved composite carrying case when not in use.
- Never spray disinfectant straight onto the oculars.
- Never hold your loupes by the oculars.
- Please consult local regulations for proper disposal.

**NOTE:** Proper usage of the products ensure their lifespan. Misuse, disregard for instructions, or improper care may result in breakage or deterioration of your Enova products.

## Accessories

This section describes components that may be ordered to replace original equipment that is damaged, worn, or must be replaced.



### WARNINGS:

- DO NOT modify any component or accessory, unless otherwise specified.

The following Enova-approved accessories can be sold in conjunction with the Enova Loupe System.

DESCRIPTION	REF
Classic Side Shield (L&R)	810003-001
Universal Side Shield (L&R)	810003-002
Airon Side Shield (L&R)	810003-003
Airon Radius Side Shield (L&R)	810003-004
Retainer Strap	800051-001
Chums Retainer Strap	800051-002
Enova Cleaning Cloth	810020-001
Enova Loupe Case	80034-006
Axis Light with Activ Battery Combo Case	80034-008
Axis™ Light System with Activ™ Battery	90900-001
Axis™ Light System with Hip Battery	90900-002
Axis™ Light System with Hip and Activ™ Battery	90900-003

**NOTE:** For a complete list of accessories, contact your Enova sales representative or call Enova customer service.

## Features

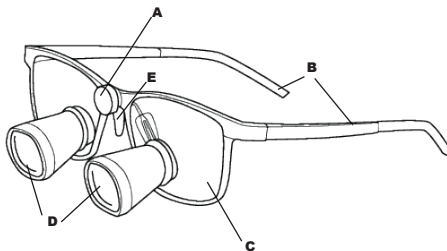


Figure 1

<b>A</b>	<b>Magnetic Adapter:</b> Every Enova loupe comes with a magnetic adapter to securely attach optional clip-on lights or cameras.
<b>B</b>	<b>Flexible Temple Arms:</b> Custom fitted to head for a comfortable and secure fit.
<b>C</b>	<b>Carrier Lens:</b> High-quality TriVex lenses provide high-resolution when not using oculars. Option to use prescription.
<b>D</b>	<b>Oculars:</b> A series of high-quality glass lenses and a custom eye-lens housed in aircraft aluminum for clear magnification and lasting durability.
<b>E</b>	<b>Nose Pads:</b> Made of comfortable materials to support the user and the frame. May be adjustable. See <i>Instructions</i> section for details.

## Instructions

1. Upon arrival, check product for damages and report immediately.
2. Check packing slip to ensure all components of your Enova Loupe System were properly packaged and delivered.
3. Put on loupes and view a 3D object at your working distance to make sure the image is sharp.
4. If applicable to frame style, adjust nose pads to desired comfort and fit.
5. To secure frames, attach included retainer strap. Pinch strap carefully to adjust.

**NOTE:** Oakley Frame nose pads are not adjustable.

## Troubleshooting



**WARNING:** DO NOT service this equipment, unless otherwise specified. If you require service, contact your Enova sales representative or call Enova customer service.

If you are experiencing issues with your new loupes, follow the matrix to help customer service determine the problem.

Issue	Additional Problem Indicators	Troubleshooting
Image is blurry	Image is clear at some point, but not the desired distance.	Yes: Adjust working distance. Contact Enova representative.
		No: Prescription is incorrect or missing. Contact Enova representative.
Image is doubled	Draw a cross. If you're seeing double lines your oculars need to be adjusted.	Contact Enova representative for help adjusting frames accordingly.
Shadowed Image	Seeing one directional shadow (top, bottom, left or right).	Your nose pads need to be adjusted opposite of the shadow appearing. Example: if your image has a left side shadow, adjust nose pads to the right.
	Seeing split shadows or double outside shadows.	Contact Enova representative.

**NOTE:** If any component must be discarded, see the *Disposal / Recycle* section.

## Cleaning



### WARNINGS:

**CAUTION:** DO NOT use solvents, lubricants, or other chemicals, unless otherwise specified. Never spray disinfectant directly onto loupes.

### To Clean Loupes

**NOTE:** Avoid scratching or striking the lenses as a reduction in visual clarity may occur.

1. To clean carrier lens, hold under running room temperature water for preliminary rinse. Apply a drop of mild soap and rub into glasses. Rinse under running water.
2. After cleaning, wipe the area with a lint-free soft cloth moistened with water to remove any residue from cleaning products.
3. To disinfect, use a small amount of non-alcohol disinfecting agents with a lint-free cloth or soft paper towel.

For further information on cleaning, care and handling of Enova surgical loupes, see Enova Loupe Customer Care Card (F20003) provided.

## Storage and Handling

**CAUTION:** ALWAYS store the equipment within the specified environmental conditions throughout its useful life.

To ensure the longevity, performance, and safety of this equipment, use of the composite carrying case or water tight packaging is recommended for storage and transport.

## Disposal / Recycle



**WARNING:** ALWAYS follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment at the end of its useful life.

# Product Specifications










## Frame Specifications

	Frame Weight (g) w/o carriers	Material	Lens Height (mm)	Frame Width (mm)	Bridge Width (mm)	Temple Length
Airon Radius	15.8	Aluminum	42.8	149.2	11.7	130.5
Airon Standard	17.9	Aluminum	43.0	149.3	12.2	142.0
Airon Small	15.1	Aluminum	40.7	137.7	8.8	136.0
Airon Sport	13.8	Aluminum	50.2	145.7	8.3	135.0
Oakley Flak 2.0 XL	16.5	Plastic	41.0	144.0	9.0	125.7
Oakley Centerboard	12.9	Plastic	43.8	138.3	8.8	138.8

## Ocular Weight Specifications (g)

	2.5x	3.0x	3.5x	4.5x	5.5x	6.5x
Galilean	28.8	34.4	36.4	-	-	-
P-Series Prism	-	-	44.6	50.4	55.8	TBD
Angled Prism	-	-	32.8	-	-	-
K-Series	-	-	42.4	47	-	-

## Symbol Definition

Symbol	Definition
	General Warning Sign (Yellow)
	Catalog Number
	Quantity
	Lot Number
	Medical Device
	Keep Dry
	Manufactured by
	Recycle of Li-Ion Battery (in Accordance with Local Laws)
	CE Mark indicating that the device complies with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

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