



ErgoDeflection™ Front-Lens-Mounted (FLM) Loupes

Instructions for Use and Care



Quick Start

www.surgitel.com/ifu-ergodeflection-flm

English

SurgiTel®, A Division of General Scientific Corp.

ErgoDeflection™ Front-Lens-Mounted (FLM) Loupes

Limited Lifetime Warranty and 45 Day Trial Period* - United States and Canada

*For more details and restrictions, please visit www.surgitel.com/support.

Warranty applies exclusively to purchases made within the United States and Canada.

General Scientific Corp. ("GSC") warrants ErgoDeflection Loupes (Product) against defects in material or workmanship as follows:

ORIGINAL PRODUCT: GSC will repair the product with new or refurbished parts, free of charge, in the event of a defect or defects in materials or workmanship from the date of original purchase for the following periods:

TELESOPES, OCULARS & ASSEMBLY PARTS:

- Crumbling ocular housing: Five (5) years
- Detached oculars: Four (4) years

FRAMES AND CASES:

- Frame Rims: Three (3) years
- Carrier Lenses: Two (2) years
- Cases: While in transit to customer

REPAIRS: GSC will repair or replace defective parts with new or refurbished parts, free of charge. The warranty of repairs is limited for a period equal to the remainder of the original limited warranty period on the original product, or for ninety (90) days after the date of the repair or replacement, whichever is longer.

WARRANTY DOES NOT INCLUDE:

- Use of non-recommended cleaning products will void warranty. Check the website for current recommended cleaning procedure.
- Any attempt to repair any SurgiTel product other than with SurgiTel will void the warranty.
- Accidents / conditions of use considered abusive by GSC, including nicks and scratches on optical surfaces.
- Normal wear and tear of the product.
- Deterioration or failure due to misuse or improperly following instructions and/or warnings found in the user manual.

This warranty does not cover products sold AS IS or WITH ALL FAULTS. THERE ARE NO EXPRESS WARRANTIES EXCEPT AS LISTED ABOVE. REPAIR OR REPLACEMENT AS PROVIDED UNDER THIS WARRANTY IS THE EXCLUSIVE REMEDY OF THE PURCHASER. GSC SHALL NOT BE LIABLE FOR LOST PROFITS, LOST SALES, LOSS OF USE OF THE PRODUCT, OR OTHER INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OF THIS PRODUCT, OR ARISING OUT OF ANY BREACH OF THIS WARRANTY. ALL EXPRESS AND IMPLIED WARRANTIES, INCLUDING THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND TITLE, ARE LIMITED TO THE APPLICABLE WARRANTY PERIOD SET FORTH ABOVE.

Some states do not allow the exclusion or limitation of incidental or consequential damages, or allow limitations on how long an implied warranty lasts, so the above exclusions or limitations may not apply to you. This warranty gives you specific legal rights and you may also have other rights which vary from state to state. If a problem with this product develops during or after the warranty period, please contact:

Customer Service Department
77 Enterprise Drive, Ann Arbor, MI 48103, USA
www.surgitel.com

Tel: 734-996-9200
Fax: 734-662-0520

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1. Introduction

Thank you for choosing SurgiTel®! Your SurgiTel® telescopes are designed to meet the demanding needs of today's clinical professionals. We recommend taking a few minutes to consult this manual before using your ErgoDeflection™ Front-Lens-Mounted (FLM) Loupes. Please note that you will experience a hand-eye coordination adjustment period of about two weeks. Ultimately, SurgiTel® telescopes will enable you to see, work, and feel your best, allowing you to fully benefit from their advanced features.

Indications for Use

Loupes are magnification devices to be worn as a visual aid. They are meant to be used exclusively by qualified professionals.

Warnings

1. The loupe must be used only for the intended purpose described.
2. Do not use the loupe if any component is damaged, loose, detached, or missing. This includes carrier lenses, oculars, frame body, temple arms, nose pad, side shields, and flip-up hinge. Parts that are broken, missing, distorted or worn should be replaced promptly. If such a repair or replacement becomes necessary, SURGITEL OR AN AUTHORIZED SERVICE DEALER SHOULD PERFORM ALL REPAIRS TO THIS PRODUCT.

New users of magnification, or those upgrading their magnification, will experience a normal adjustment period as they become accustomed to using their new loupes. This period involves adapting to hand/eye coordination within a magnified field and improving ergonomic posture. In the first week, it is recommended to begin with simple procedures for 1-2 hours in the morning. In the second week, gradually progress to more complex procedures, working both in the morning and afternoon. Additionally, remember not to walk around with your telescopes on to avoid accidental damage.

1.1. Getting Started

To properly set up your device, first remove the protection caps and adjust the nose pads for a secure fit. If you are experiencing fogging, slightly move the frames away from your face and eyes. Position the oculars against the frame lenses to maximize the field size. All SurgiTel® telescopes are shipped out set to the users specifications. If minor adjustments are needed due to a change in preference(s), follow these steps. First adjust the pupillary distance knob until the two images converge

together (see section 3.2 “Adjusting Pupillary Distance (P.D.)” for details). Next, adjust the hinge tension to a comfortable setting (see section 3.3 “Adjusting Flip-Up Tension and Declination Angle” for details), adding slightly more tension if using a clip-on light. For optimal resolution and field size, ensure the telescope oculars touch the frame lenses. The hinge tension can be fine-tuned using the bottom tension screw on the hinge.

2. Adjusting Nose Pad(s)

When the nose pads are properly adjusted to your face, they will provide excellent comfort and balance. If the nose pads do not make even contact with your nose comfortably, please follow the directions described below.

2.1 How to Adjust Nose Pad to Fit Nose

Adjusting Nose Pads for Too High Oculars

Adjust the width of the nose pads by bending the nose pad wire mounts outwards (see Figure 1). By doing so, this will reduce the height of the frame and lower the ocular position.



Figure 1

Adjusting Nose Pads for Too Low Oculars

Adjust the width of the nose pads by bending the nose pad wire mounts inwards (see Figure 2). By doing so, this will increase the height of the frame and raise the ocular position.



Figure 2

Adjusting Nose Pads for Low Nose

If the nose pads are not evenly placed on the bridge of the nose, bend the wire mounts down and away from the frame (see Figure 3) and readjust the width of the nose pads if necessary. Note that the wire mount tilt angle depends on the bridge of the nose. The less nose bridge you have, the larger the tilt becomes to fit your nose.



Figure 3

2.2 Changing Nose Pad Style, Using Ergo Fit Nose Pad Mounting Block

1. Before switching to a different nose pad style, it is recommended that you try the set choice from our engineers. If you are experiencing any slight ocular misalignment or discomfort, refer to “How to Adjust Nose Pad to Fit Nose” instructions. If you decide to change to a different nose pad style, please read and follow the steps below for help with the vertical alignment of the oculars.
2. Start by reassembling the new nose pad wire arms into the same mounting block holes, as used on previous.
3. If you see top shadowing when looking through the oculars, mount the nose pad wire arms down (example: “A to B” or “B to C”) until fixed.
4. If you see bottom shadowing when looking through the oculars, mount the nose pad wire arms up (example: “C to B” or “B to A”) until fixed.



A



B



C

3. Settings and Adjustments

1. Loosen the slide retainer screw to adjust the Vertical Position (V.P.). (See Figure 4)
2. Place the loupes at the lowest position on the frame, then slowly raise upward until you achieve a comfortable ocular height. To set the V.P., make sure the slide retainer screw is tightened. Be sure to not overtighten the screw. (See Figure 4)
3. Adjust the declination angle by moving the ocular rack until your preferred head tilt is achieved. Please note that the



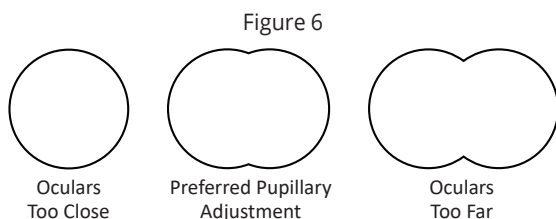
Figure 4



Figure 5

safe head tilt range is less than 20-degrees. Then adjust the ocular rack to attain your line of sight. (See Figure 11 in Section 3.3 “Adjusting Flip-Up Tension and Declination Angle”)

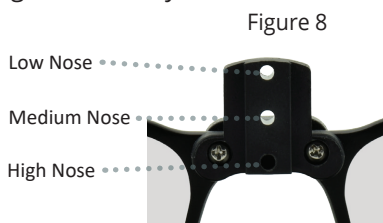
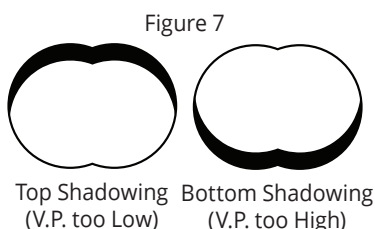
4. Tighten all hinge screws with a hex key (to add slight tension) once you have found your comfortable declination angle and alignment.
5. Position yourself into your working position and adjust the Pupillary Distance (P.D.) knob (see Figure 5) until you have one image in an oblong/oval shape. (See Figure 6)



3.1. Adjusting Vertical Position (V.P.)

If you are experiencing top or bottom shadowing (see Figure 7) follow the steps below to remedy the issue.

1. Loosen the slide retainer screw that allows the slide retainer to move up or down. (See Figure 4)
2. Position the loupes on your face/nose.
3. Adjust the oculars until oculars are aligned to the eyes.
4. If the oculars are not properly aligned, remove the loupes from your face to make adjustments. Remove the slide retainer screw and reposition the oculars as needed. For guidance on screw placement, refer to Figure 8.



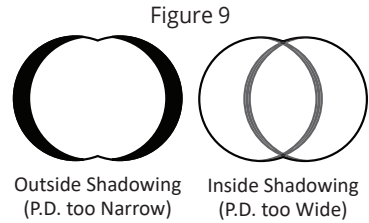
Note: If you are experiencing top shadowing, the oculars are too low. Raise the loupe using the slide retainer until the shadowing is remedied.

If you are experiencing bottom shadowing, the oculars are too high. Lower the loupe using the slide retainer until the shadowing is remedied.

3.2 Adjusting Pupillary Distance (P.D.)

Pupillary distance (P.D.) will be set to your measured specifications. If you are experiencing left or right shadowing (see Figure 9), adjust the settings as needed.

1. Position the loupes on your face and nose.
2. Using the P.D. knob (see Figure 5), spread the oculars apart to the widest distance.
3. When looking through the oculars, focus on an object in front of you (such as your thumb). If it is not in focus, move the object towards or away from you until you see it clearly.
4. With the other hand, slowly adjust the P.D. knob until you have one image in an oblong/oval shape. (See Figure 6)



Note: If you are experiencing shadowing on the outside of your field of view, your P.D. is too narrow. Widen the P.D. using the P.D. knob until the shadowing is remedied.

If you are experiencing shadowing on the inside of your field of view, your P.D. is too wide. Use the P.D. knob to narrow the distance of the oculars until the shadowing is remedied.

3.3 Adjusting Flip-Up Tension and Declination Angle

The top locking screw controls the flip-up tension. The entire loupe system can be flipped up to open your line of sight by simply rotating the link hinge upwards (see Figure 10). If you frequently flip up your loupes, keep this screw slightly loose for easier adjustment.



The bottom locking screw controls the declination angle. This screw allows for adjustment and locking of the declination angle (see Figure 11), as well as maintaining the angle whether the loupes are flipped up or down. If you use your loupes in different working postures, it is advisable to leave this screw slightly loose for easy adjustments.



Figure 11

A tip to have a wide field of view is to bring the ocular close to your eyes, ideally having the oculars touching the lens.

Note: The top and bottom screws are tightened to keep the adjustments in place.

4. Cleaning and Disinfecting

Your loupe is a precision optical instrument made from high-quality materials. To ensure its longevity and optimal performance, please follow these instructions for proper cleaning and disinfecting. Noncompliant cleaning and disinfecting methods may result in damage to the loupes and may result in a void warranty.

4.1 Cleaning

To clean your SurgiTel loupes, we advise using either eyeglass cleaner (without alcohol) or applying mild soap and water with a microfiber cloth until particles are loosened. Wipe with a microfiber cloth or air dry.

DO NOT USE

Any cleaners containing alcohol, hydrogen peroxide, ethanol, ammonia, glutaraldehyde, or iodophors. The use of these products will void the warranty.

4.2 Disinfecting

Clean loupes before disinfecting. Visit www.surgitel.com/help for the most current recommended disinfectants. To disinfect your loupes, make sure to wring out the disinfecting cloth to remove any excess moisture.






DO NOT USE

Any disinfectants containing alcohol, hydrogen peroxide, ethanol, ammonia, glutaraldehyde, iodophors, bleach, acid, phenol, or acetone

that have not been approved for use by SurgiTel. Do not immerse loupes in any liquid. Do not use an autoclave. Doing so will void the warranty.

4.3 Professional Loupe Tune Up with Detailed Cleaning

To keep your loupes working like new, we recommend that they should be sent in for a tune up at least once a year. This will ensure that your loupes are kept in great condition. To learn more about the U.S. and Canada Tune Up Program, visit www.surgitel.com/loupe-tune-up. For International customers, please contact your distributor for details.

Symbol Glossary		
Symbol	Symbol Title	Explanatory Text
	European Conformity	European conformity (CE) mark for Class I medical devices.
	UK Conformity	UK Conformity (UKCA) mark for Class I medical devices (non-sterile, no measuring function, and not reusable surgical instrument).
	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.
	Authorized Representative in the United Kingdom	Indicates the authorized representative based in United Kingdom.
	Address of Manufacturer	Indicates the medical device manufacturer.



The product complies with requirements of the EMC Directive 2014/30/EU; Medical Directive 93/42/EEC. The product was tested accordance to EMC standards EN 5501:2016/A11:2020 and IEC 60601-1-2:2020.

Tested To Comply with CE and UKCA Directives



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