PROSIDIO

PROSIDIO HiFi Rigid Endoscopes

Instructions for Use

Version: 3

Date: 19-05-2026

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PROSIDIO

READ THIS SECTION BEFORE PLACING PRODUCT INTO SERVICE

Users should carefully read the full contents of this User Manual before operating PROSIDIO endoscopes. Please be advised that serious surgical consequences, injury, or death may result if these guidelines and instructions for use are not properly followed. Adhering to the proper care and use of the endoscopes as outlined in this document will avoid possible damage to the instrument and serious risks of injury to yourself and the patient.

1 About this document

1.1 Purpose

PROSIDIO endoscopes are produced exclusively for use by certified doctors or highly trained medical professionals in medical facilities. This document provides instructions for correctly and safely using and processing the endoscope. This document is not intended for training purposes or to be singularly employed as a professional guide or reference material for endoscopic examinations or surgeries. Instructions hereby are recommended for the correct and safe handling of PROSIDIO Rigid Endoscopes by qualified medical professionals trained in the field of endoscopy to avoid potential injury to patients.

1.2 Symbols used

	Warning
	Production Date
S N	Serial Number
	Manufacturer
REF	Model Number

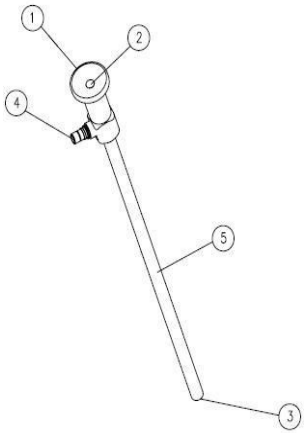
2 Description

2.1 Intended use

PROSIDIO endoscope is an unchanneled endoscope intended to provide direct visualization (through the endoscope or the video monitor) of the nasal cavity and nasopharynx. The instrument is for use in, but is not limited to, such procedures as examination of the sinus passages and cavities. PROSIDIO endoscopes are reusable and subject to cleaning, disinfection, sterilization, and proper care. To minimize patient trauma, these instruments are designed to be as small as possible and are more fragile than other instruments in the operating room or clinic setting. Handling with extreme care to prevent damage and consistently inspecting them before and after patient procedures to evaluate their condition is crucial to ensure continuing quality. Failure to properly care for the endoscopes could result in damage to the instruments and trauma or infection of the patient.

2.2 Components

1. Eyepiece / ocular funnel lens
2. Lens
3. Tip
4. Light cable adaptor
5. Jacket tube



PROSIDIO endoscopes consist of an eyepiece lens with a sapphire glass lens cover, a connection with screw-on adapters for compatible fiber optic light cables, and a jacket tube (constructed of non-corrosive 304 stainless steel), that encloses the rod lens system, and a built-in fiber optic light carrier.

2.3 Specifications

No.	Content
1	Manufacturer: PROSIDIO Address: 168b Irving Ave, Suite 302C, Port Chester, NY 10573 Contact: 914-510-2314
2	Trade Name: PROSIDIO Model: HiFi Rigid Endoscopes Endoscopic code: 59 product codes, details refer to Section 2.4
3	Outer diameter (max diameter of inserting section) and working length refer to Section 2.4
4	Minimum instrument channel inner diameter: NA
5	Field of view 2TY: 60º (standard), 90º, 110º
6	Direction of view deg: 0, 12º, 30, 45º,RP 45 70º, 90º
7	Designed optical working length: 15mm
8	Solutions refer to Section 2.6
9	Depth of field of optic lens body: 1~50mm
10	Using ISO 10526: A standard illumination spectrum 1999 CIE S 005 provided by the illumination optical path and CRI imaging system output after transmission spectra: 90% **Meaning of Ra CRI**: The Ra CRI characterizes the endoscope's ability to accurately reproduce colors. A higher Ra value indicates better color differentiation and reduction, meaning the endoscope can more accurately distinguish color differences and reproduce true colors. Energy transfer efficiency-effective luminosity ratio Dm:

	1500cd/m^2/lm
11	In the design of the optical system, the working distance (do) is set to 15mm. This distance is used to evaluate the field of view and shape characterization depending on the scene being observed. Light Efficiency of the Lighting Mirror Body: 90% Field of view: 0.39 Light Efficiency of the Integrated Lighting Mirror Body: 90% Field of view: 0.24 Integrated Edge Light Efficiency of the Lighting Mirror Body: 90% Field of view: 0.11 The amount of distortion in the shape of the unit relative to the field is controlled to -16%
12	No parts can be changed by users.
13	For sales or service contact: service@prosidio.com or call 914-510-2314
14	The endoscopes are fragile and should be handled with care.
15	The endoscopes must not be bent.

PROSIDIO endoscopes are offered in a variety of angles for different directions of view.

2.4 Endoscopes Series / Models & Specification

PROSIDIO endoscopes are available in the following designs and sizes.

Product Code	Type	Specification
P417N00	Sinuscope	0°,Φ4mm×175mm
P417N30	Sinuscope	30°,Φ4mm×175mm
P417R30	Sinuscope	Reverse-post 30°,Φ4mm×175mm
P417N45	Sinuscope	45°,Φ4mm×175mm
P417R45	Sinuscope	Reverse-post 45°,Φ4mm×175mm
P417W0090	Sinuscope	0°,Φ4mm×175mm (90°angle of field)
P417W0011	Sinuscope	0°,Φ4mm×175mm (110°angle of field)
P417N110	Sinuscope	110°,Φ4mm×175mm
P417N12	Sinuscope	12°,Φ4mm×175mm
P417W3090	Sinuscope	30°,Φ4mm×175mm (90°angle of field)
P417W3011	Sinuscope	30°,Φ4mm×175mm (110°angle of field)

P417W4590	Sinuscope	45°,Φ4mm×175mm (90°angle of field)
P417N70	Sinuscope	70°,Φ4mm×175mm
P417W7090	Sinuscope	70°,Φ4mm×175mm (90°angle of field)
P417W7011	Sinuscope	70°,Φ4mm×175mm (110°angle of field)
P417N90	Sinuscope	90°,Φ4mm×175mm
P317N0	Sinuscope	0°,Φ3mm×175mm
P317N30	Sinuscope	30°,Φ3mm×175mm
P317N70	Sinuscope	70°,Φ3mm×175mm
P217N00	Sinuscope	0°,Φ2.7mm×175mm
P217N30	Sinuscope	30°,Φ2.7mm×175mm
P217N70	Sinuscope	70°,Φ2.7mm× 175mm
P313N00	3mm Otoscopes	0°,Φ3mm×130mm
P313N30	3mm Otoscopes	30°,Φ3mm×130mm
P314R45	3mm Otoscopes	45deg, reverse post, 3mmx140
P313N70	3mm Otoscopes	70°,Φ3mm×130mm

P45N00	Otoscope	0°,Φ4mm×50mm
P49N00	Otoscope	0°,Φ4mm×90mm
P49N30	Otoscope	30°,Φ4mm×90mm
P49N70	Otoscope	70°,Φ4mm×90mm
P411N00	Otoscope	0°,Φ4mm×110mm
P411N30	Otoscope	30°,Φ4mm×110mm
P411N70	Otoscope	70°,Φ4mm×110mm
P39N00	Otoscope	0°,Φ3mm×90mm
P39N30	Otoscope	30°,Φ3mm×90mm
P311N00	Otoscope	0°,Φ3mm×110mm
P311N30	Otoscope	30°,Φ3mm×110mm
P311N70	Otoscope	70°,Φ3mm×110mm
P36N00	Otoscope	0°,Φ3mm×60mm
P29N00	Otoscope	0°,Φ2.7mm×90mm
P29N30	Otoscope	30°,Φ2.7mm×90mm
P29N70	Otoscope	70°,Φ2.7mm×90mm
P211N00	Otoscope	0°,Φ2.7mm×110mm
P211N30	Otoscope	30°,Φ2.7mm×110mm
P211N70	Otoscope	70°,Φ2.7mm×110mm
P25N00	Otoscope	0°,Φ2.7mm×50mm
P25N30	Otoscope	30°,Φ2.7mm×50mm

	Ø (mm)	Length (mm)	0°	12°	30°	45°	Reverse post 45°	70°	90°	110°
Sinuscope	2.7	175	✓		✓			✓		
	3.0	175	✓		✓			✓		
	4.0	175	✓*	✓*	✓*	✓*	✓*	✓*	✓*	✓*
Otoscope	2.7	50	✓		✓			✓		
		60	✓							
		90	✓		✓			✓		
		110	✓		✓			✓		
	3.0	60	✓							
		90	✓		✓					
		110	✓		✓			✓		
		130	✓		✓			✓		
		140				✓	✓			
	4.0	50	✓							
		90	✓		✓			✓		
		110	✓		✓			✓		
Laryngoscope	6.0	179							✓	
		180							✓†	
		184						✓		
		185						✓†		
	8.0	179						✓		
		180							✓†	
		184						✓		
	10.0	185						✓		

2.5 Endoscope Labels and Marks

Each endoscope and its related accessories and equipment have a unique model number, which is a mix of letters and numbers, and is shown on a clear spot of the product.

Endoscope	Label, Mark	Label position	Meaning
0° endoscope	Green plastic ring	Light cable adapter	Tip angle: 0°
	0°	Indicator ring	Tip angle: 0°
12° endoscope	Blue plastic ring	Light cable adapter	Tip angle: l2°
	12°	Indicator ring	Tip angle: l2°
45° endoscope	Black plastic ring	Light cable adapter	Tip angle: 45°
	45°	Indicator ring	Tip angle: 45°
30° endoscope	Red plastic ring	Light cable adapter	Tip angle: 30°
	30°	Indicator ring	Tip angle: 30°
70° endoscope	Yellow plastic ring	Light cable adapter	Tip angle: 70°
	70°	Indicator ring	Tip angle: 70°
90° endoscope	Black plastic ring	Light cable adapter	Tip angle: 90°
	90°	Indicator ring	Tip angle: 90°

3 Safety

3.1 Safety of Endoscopes

The endoscope is a very delicate, precision instrument that requires great care in handling. To ensure continuing quality, please follow the directions below.

WARNING

1. NEVER hold the tip of the endoscope. Support the instrument by holding the eyepiece end.

2. NEVER bend the stainless-steel shaft as this could cause a break or crack in the rod lens system.

3. ALWAYS handle the endoscope with the utmost care to avoid cracks which may allow liquid, steam, or other materials to enter the interior of the scope.

4. Clean, sterilize and/or disinfect the endoscope after every procedure to avoid risk of infection to patients and medical professionals.

5. ALWAYS clean, sterilize and/or disinfect separately from other instruments.

6. ALWAYS gently place the endoscope down to avoid any damage.

7. NEVER subject the endoscope to impact of any kind.

8. ALWAYS inspect the endoscope before and after use.

9. Do not bend the endoscope after inserting into the body.

10. Keep endoscopes clean and dry when not in use.

11. Bending the endoscope or using the endoscope as a lever or pry bar, may result in lens damage and may render the scope unusable.

12. Contact with a surgical laser beam may damage the endoscope surface and internal optics.

13. Transport endoscopes individually using a container to avoid any impact to the instrument.

3.2 Safety of patient

WARNING

1. Please read the instructions of the endoscope and its accessories carefully before use. Please note users are responsible for the validation of their own processes.

2. These endoscopes carry a risk of infection to patients and medical professionals.

3. Upon receipt of newly delivered endoscope, clean, disinfect, and sterilize as described in Section 4. Follow the same measures after each subsequent use of the instrument.

4. This device is for use by certified surgeons and trained physicians with experience in endoscopy. Intended only for use by medical professionals in medical facilities. Surgeons must be specifically trained and familiar with the intended anatomic site.

5. Always inspect endoscope before each use.

6. In order to avoid the injury causing from rough surfaces, sharp edges and protrusions, please check the inserting part of the endoscope and its accessories before use.

7. Make emergency preparedness before surgery in case of emergency.

8. This device carries a risk of burns to the patient and user.

Note. At the distal end of the endoscope, high-energy light is emitted by optical fibers. This can lead to an increase in body tissue temperature up to 41 degrees Celsius. If the endoscope's surface temperature surpasses 41℃, it may result in burns at the patient's contact site.

1. We advise minimizing operation time and using the lowest possible light source brightness that the procedure and circumstances allow.

2. If the endoscope becomes too hot to touch, discontinue use immediately.

3. Higher light intensity from the light source corresponds to greater heat production at the endoscope's terminal. It is crucial to avoid using the illumination before and after the endoscope procedure. Prolonged illumination may cause the temperature at the endoscope's objective tip to rise, posing a risk of burns to the patient or user.

WARNING

Risk of injury due to faulty endoscopes

1. Prior to every use, carry out the visual inspection and function check as described in this manual.

2. Do not use any endoscopes unless they are verified to be in perfect condition.

4 Cleaning and Sterilization

The endoscope is not cleaned and sterilized in the factory before distribution. Therefore, before first and each use, the operator should perform the cleaning, sterilization and/or disinfection processes described in this manual.

After each use, it is recommended that the endoscope be cleaned, sterilized and/or disinfected immediately.

Always store and transport the endoscope securely in a closed container.

Cleaning Warning

Avoid using cleaning agents such as aldehydes (e.g., formaldehyde or glutaraldehyde) or hot water (>70°C) that can cause contaminants to adhere to the endoscope surfaces, making them harder to remove. Do not clean the endoscope in an ultrasonic bath.

Pre-cleaning Warning

After withdrawal from the patient, the endoscope must be pre-cleaned at the bedside immediately. Pre-cleaning should be performed before disconnecting the endoscope from the light source. This prevents the drying of soil on the device surface prior to cleaning. Do not touch the light guide lens of the endoscope when it is disconnected from the light source.

4.1 Pre-Cleaning

Use one clean, lint-free cloth dampened with detergent to wipe the surface of the insertion section of the endoscope, removing all visible soil. Use another clean, lint-free cloth dampened with detergent to wipe the surface of other parts of the endoscope, ensuring all visible soil is removed.

Turn off the light source. Then, disconnect the light cable from the endoscope body (one hand holds the endoscope while the other hand unscrews the light connector). Use a clean, lint-free cloth dampened with detergent to wipe the outer surface and internal surface of the light connectors, as well as all the joints between the light connector and the endoscope body.

4.2 Cleaning

Fill the manual cleaning tank with sufficient detergent. Immerse the endoscope and disconnected light connectors in the detergent based on the manufacturer's recommendation. Cover the manual cleaning tank with a seal cover to reduce detergent volatilization.

Note: The endoscopes are compatible with enzymatic cleaning agents. We recommend Metrex Empower for cleaning our endoscopes.

Contact Type	Temperature	Dilution Ratio	Concentration	Manufacturer	Cleaning Detergent
Soak	20 - 40 °C	1:128	<2%	Metrex	Metrex EmPower

4.3 Rinsing

1. Fill the rinsing tank with sufficient tap water and ensure the entire endoscope can be immersed in the tap water at room temperature.

2. Immerse the endoscope and light connectors into the tap water, and use a clean, lint-free cloth to completely wipe the outer surface of the endoscope, the outer surface and internal surface of light connectors, all the joints between the light connector and endoscope body. The duration of rinsing should be not less than 5 minutes.

3. Repeat steps 4.1 and 4.2 once again.

4. Remove excess moisture from the endoscope with a clean, lint-free cloth.

4.4 Visual Inspection

The device shall undergo a 5x magnification inspection after cleaning, to determine whether there is any visible residue. The entire cleaning procedure should be repeated if there is residual soil on the device.

4.5 High-Level Disinfection

CAUTION: To avoid damage to the instruments, do not immerse the devices in disinfectant solution for longer than one hour.

1. **Preparation:** Prepare the disinfecting solution:
    - **Solution:** 0.55% ortho-Phthalaldehyde (e.g., CIDEX OPA)
2. **Immersion:** Place the instruments into a plastic container containing the HLD solution. Ensure that the instruments are fully immersed and remove any air bubbles adhered to the surfaces. Fill any lumens with the HLD solution.
3. **Disinfection Conditions:**
    - **Solution:** 0.55% ortho-Phthalaldehyde (e.g., CIDEX® OPA)
    - **Temperature:** ≥20℃
    - **Immersing Time:** 12 minutes

4. **Rinsing Instructions:**
    - After disinfection, remove the instruments from the disinfectant solution and rinse them by completely immersing them in a large volume of sterile water (e.g., two gallons). Keep the instruments immersed for at least one minute. Discard the water and repeat with fresh water for a total of three immersion rinses.
5. **Drying:** Dry the instruments with a lint-free sterile cloth or dry, oil-free compressed air (<5 PSI).

4.6 Steam Sterilization (4mm x 175mm Sinuscopes Only)

Steam sterilization is only applicable to Prosidio 4mm x 175mm sinuscopes (P417 series). Steam sterilization of other Prosidio rigid endoscopes is not validated and is not recommended. Steam sterilization may cause image quality degradation over time; this degradation is common among Hopkins rod designs and is not subject to repair or replacement under our warranty.

Please read: Prior to each steam sterilization, rigid endoscopes must be pre-cleaned according to the method noted in section 4.1. Sterilize endoscopes in suitable packaging to prevent subsequent contamination. Light connectors (adapters) should be dismounted before sterilization. When the sterilization process has ended, allow the endoscopes to cool gradually to room temperature.

The following process has been validated for steam sterilization of 4mm x 175mm sinuscopes (P417 series) only:

Temperature	135° C
Time	3 minutes
Configuration	Double packaging in sterilization pouches
Drying	16 minutes

Keep endoscopes clean and dry when they are not in use.

Note: All accessories must be cleaned, disinfected, and sterilized following the same process.

4.7 Vaporized Hydrogen Peroxide Sterilization (STERRAD)

The following STERRAD cycles have been validated by Advanced Sterilization Products (ASP) using representative Prosidio HiFi Rigid Endoscopes (P25N00 and P417N70). Applicability to other models is governed by the equivalency statement below.

- STERRAD NX Standard cycle: Sterility assurance level (SAL) of 10^-6 is achieved in a full cycle in the validated load configuration.
- STERRAD 100NX Express cycle: Sterility assurance level (SAL) of 10^-6 is achieved in a full cycle in the validated load configuration.

Procedure:

- Prior to sterilization, rigid endoscopes must be pre-cleaned according to the method noted in Section 4.1.
- place devices in an APTIMAX instrument tray with a STERRAD instrument tray mat.
- Double wrap the tray with two sheets of 1-ply Halyard Health sterilization wrap (or equivalent).
- Remove the top shelf and place the wrapped tray on the bottom shelf.

- Follow the applicable STERRAD system operator manual and facility procedures for load limits, cycle operation, biological monitoring, chemical indicators, aeration or post-cycle handling, and storage.

1. Functional compatibility: the representative devices (P25N00 and P417N70) retained functionality after 58 STERRAD NX Standard cycles (ASP report RPT04645).

Scope of validation (equivalency statement)

The STERRAD validations described above (ASP reports RPT04646, RPT04656, and RPT04645) were performed on representative test articles: the HiFi Rigid Otoscope (P/N P25N00) and the HiFi Rigid Sinuscope (P/N P417N70). These STERRAD cycle claims apply to the tested devices and to other Prosidio HiFi Rigid Endoscope models that Prosidio has determined to be equivalent to a tested representative device through a documented equivalence assessment. Equivalence is established on the basis of shared materials of construction, surface finish, device geometry and mass, joint and seal design, and the absence of internal lumens or channels. Any model not covered by such a determination is not within the validated STERRAD claim until assessed. Any subsequent design modification to a tested or equivalent device — including changes to materials, dimensions, coatings, or construction — requires re-evaluation, and where necessary re-validation, before the STERRAD claim may be extended or maintained. Prosidio will notify ASP of design modifications to the tested devices so that modified devices can be re-evaluated if necessary.

4.8 Inspection

Before each use, conduct a thorough visual inspection and functional check of the endoscope:

1. Only use endoscopes without any signs of damage or wear.

2. To check if the endoscope is functioning properly, examine the reflected light on the surfaces of the ocular and objective lenses.

3. Inspect the quality of the fiber optics by holding the light post toward a light source and observing the distal tip. If the light is evenly distributed, the fiber optics are in good condition. Darker areas could indicate broken fibers.

4. Foggy images may suggest that moisture has penetrated the seal, while partially or completely obstructed views typically indicate a damaged lens.

By consistently performing these inspections and checks, you can ensure the endoscope's optimal performance and maintain the safety of both patients and users.

5 Directions for Use

1. Always inspect the endoscope for visible damage before use.

2. Ensure the endoscope has been cleaned, disinfected, and/or sterilized.

3. Prepare for possible complications by having necessary equipment and protocols in place.

4. Check the clarity of the view by looking through the endoscope and rotating it. If the view is impaired, wipe the area and ensure a clear field of view before proceeding.

5. Set up all video and lighting equipment according to the manufacturer's instructions and connect the light cable to the endoscope's connector.

6. Refer to appropriate medical literature and surgical standardization guidelines to determine the correct entry point for the procedure.

7. Adjust the light source to the lowest intensity required for optimal illumination, whether using direct sight or connecting to a video system.

6 Limited Warranty

PROSIDIO endoscopes come with a 1-year limited warranty from the date of purchase, covering defects in materials, components, and workmanship. Contact support at service@prosidio.com for assistance. The warranty period is not extended if a warranted product or any parts are repaired or replaced.

The PROSIDIO limited hardware warranty does not cover damage caused by:

1. Handling during shipment
2. Use or maintenance not in accordance with product labeling and instructions
3. Unauthorized repair or service
4. Accidents, abuse, and misuse
5. Issues arising from accessories, parts, or components not supplied by PROSIDIO.
6. Normal wear and tear including degradation of image from steam sterilization

At PROSIDIO, we stand by our products and are committed to providing exceptional customer service. If you have any issues with your device, we will make it right.

7 Revision Control and Approval

Status: Approved final controlled document. Released under DCO-0009 on 2026-05-19 after QA/RA review and sign-off. Active controlled copies are maintained in the DMR and supplier IFU locations; superseded copies are archived per QP-0003.

7.1 Change Summary

- Added vaporized hydrogen peroxide sterilization instructions for STERRAD NX Standard and STERRAD 100NX Express cycles.
- Clarified that steam sterilization is validated for the P417 series 4 mm x 175 mm sinuscopes only.
- Added source-evidence references and approval placeholders for document-control review.
- Added a Scope of validation (equivalency statement) to Section 4.7 defining the basis on which the STERRAD claim may be extended to other models through a documented equivalence assessment.

7.2 Evidence References

Evidence	Approval basis	Source receipt
RPT04646	STERRAD NX Standard SAL 10^-6 sterilization validation for P25N00 and	ASP UID 43123; SHA f91f6b64731e...; see receipt JSON.

	P417N70.	
RPT04656	STERRAD 100NX Express SAL 10^-6 sterilization validation for P25N00 and P417N70.	ASP UID 43123; SHA e0ae393df73e...; see receipt JSON.
RPT04645	STERRAD NX Standard functional compatibility after 58 cycles for P25N00 and P417N70.	QMS DHF copy; SHA 48bed1fe9836...; see receipt JSON.

7.3 Document Control Record

Document number	C50210.2
Document title	HiFi Rigid Endoscopes — Instructions for Use
This revision	3
Supersedes revision	2
Superseded copy archived (Y/N + location)	Y - DMR/Archive and Suppliers/Archive (2026-05-19).
Effective date	2026-05-19

7.4 Approval

Role	Name	Signature/Approval	Date
Prepared by	Jonathan Simmonds, MD		05/18/2026
QA/RA review	Aniqa Shafiq		05/19/2026
Final approval	Jonathan Simmons, MD		05/19/2026